

Full title of project

The effectiveness of the Older prisoner Health and Social Care Assessment and Plan (OHSCAP):

A Randomised Controlled Trial

Summary of Research

Background:

The number of older prisoners is rapidly increasing (Cooney & Braggins, 2010). Between 2000 and 2010, the percentage of older prisoners in the UK increased by a striking 128% (Prison Reform Trust, 2011). Older prisoners have complex health and social needs (Fazel et al., 2001) which are often unmet (Fazel et al., 2004). Older prisoner care is currently generally *ad hoc* and uncoordinated. In a previous study (SDO 08/1809/230), the research team developed the Older prisoner Health and Social Care Assessment and Plan (OHSCAP) to systematically identify and address the health and social care needs of older prisoners. The OHSCAP will identify health and social care needs; better meet those needs through care planning and consequent service delivery. This will result in a reduction in health and social care needs and improvements in health symptoms and social care problems.

The Intervention (OHSCAP):

The OHSCAP is a structured approach for better identification and management the health and social care needs of older prisoners. It is a paper based tool consisting of an assessment, subsequent care plan based on identified needs with reviews carried out as appropriate. It is conducted by the Older Prisoner Lead (OPL, a prison officer) or other appropriate professional. The results of the OHSCAP and care planning are shared across prison and healthcare departments via previously established computerised systems.

Treatment as Usual (TAU):

Treatment as usual includes the standard non age specific health assessment (Grubin et al., 2002). Further assessment and intervention follows local procedures at each establishment. Identification of health and social needs and care planning is generally *ad hoc* and inadequate (Shaw et al., 2009).

Research Questions:

1. Does use of the OHSCAP compared with TAU improve:
 - a. proportion of met health and social care needs
 - b. health related quality of life
 - c. depressive symptoms
 - d. functional health and wellbeing and activities of daily living
 - e. quality of health and social care planning
 - f. cost effectiveness

2. What are the facilitators and barriers to the implementation and operation of the OHSCAP?

Design:

The research programme employs mixed methods and is divided into five key parts.

Part 1: Training on the delivery of the intervention

The OPLs (prison officers) at each of the prisons will be provided with a one day training session on the delivery of the OHSCAP. The training manual developed as part of the previous study will be used. Informal supervision will be provided to the OPLs throughout the OHSCAP delivery period.

Part 2: Randomised controlled trial (RCT)

Recruitment: We will seek informed consent from approximately 504 men aged 50 and over, newly received into the identified prisons if their known release date (convicted) or likely release date (unconvicted), is at least three month after their prison entry date. Release dates for unconvicted prisoners will be predicted using an algorithm developed for a previous study (Shaw et al., 2008). Randomisation will be undertaken by the Clinical Trials Unit. Participants will be randomised to receive the OHSCAP or TAU. We require 392 participants to be recruited at three month follow-up.

Outcome Measures: The following outcome measures will be used at baseline and three months after prison entry.

Primary outcome measure:

1. The primary outcome measure is an older prisoner's mean unmet need at three month follow up. This will be measured by The Camberwell Assessment of Need – Short Forensic Version (CANFOR-S) (Thomas et al., 2003) it assesses met and unmet health and social care needs.

Secondary outcome measures:

1. The Bristol Activities of Daily Living ((Bucks, Ashworth, Wilcock, & Siegfried, 1996) to assess functional health and wellbeing and activities of daily living
2. The Geriatric Depression Scale (Sheikh & Yesavage, 1986)– Short form to assess levels of depression
3. The Secure Facilities – Service Use Schedule (SF-SUS) (Barrett & Byford, 2007) to assess appropriate health and social service usage
4. The EQ-5D (Dolan et al., 1995) to assess health related quality of life

The following tools will also be used at baseline to describe the sample.

1. Opcrit to measure mental health (Azevedo et al., 1999)
2. PrisonQuest to measure mental health (Shaw, Tomensen, & Creed, 2003)
3. Burvil Grid to measure physical health (Burvill, Mowry, & Hall, 1990)

Analysis: The primary outcome will be analysed with a Mann-Whitney U test. A sensitivity analysis will be undertaken using the data for all randomised cases by assuming no change in the number of unmet needs from baseline for cases without the three month data. A regression analysis will be used to adjust for baseline characteristics. Similar approaches will be adopted for the secondary outcomes with the details depending on the distribution of the particular outcome.

Part 3: Audit of care plans

The care plans produced by the OPLs, in conjunction with the older prisoners, will be reviewed by two members of the research team using a bespoke proforma designed to assess the quality of the care planning. Ten percent of the care plans produced will be audited. The number and type of referrals made and actions met with be detailed and descriptive statistics produced. The team have developed similar proformas for other studies (Shaw et al., 2006; Rahman et al., in preparation). Descriptive statistics will be produced.

Part 4: Qualitative interviews with prisoners and staff involved in the OHSCAP

Semi-structured interviews will take place with prisoners who received the OHSCAP at a range of follow-up periods, to gain an understanding of the barriers and facilitators to the intervention (aprox.30). A purposive sample of participants with a range of sentence length, offence type and health status will be used. In addition, semi-structured interviews with the OPLs will take place to identify the OHSCAP process. All interviews will be audio record, transcribed verbatim and analysed thematically. A number of themes will be generated and elaborated using aspects of constant comparative methods (Glaser, 1965) within the computer software NVivo (QSR International Pty Ltd., 2008).

Part 5: Cost-effectiveness analysis

The economic analysis will estimate the incremental cost-effectiveness of the OHSCAP as compared to TAU in order to evaluate whether its implementation would likely represent a cost-effective use of resources at standard UK threshold values for health care. Resource utilisation will be collected using a combination of medical note review and patient questionnaire administered during the follow-up assessments. This patient questionnaire will be developed *de novo* from the annotated cost questionnaire (Thompson & Wordsworth, 2010). The effectiveness of the intervention will be assessed using the CANFOR and EQ-5D outcome measures. The incremental cost-effectiveness ratio per quality-adjusted life year (QALY) gained, cost-effectiveness acceptability curves (CEACs) and net benefit statistics of the OHSCAP compared to TAU will be estimated. The results of the economic analysis will inform potential further modelling of the long-term cost-effectiveness of the intervention.

Background and Rationale

The number of older prisoner is rapidly increasing (Cooney & Braggins, 2010). In June 2011, there were 8,576 prisoners aged 50 and over (11% of the prison population). Between 2000 and 2010, the percentage of older prisoners in the UK increased by a striking 128% (Prison Reform Trust, 2011). This considerable rise in the number of incarcerated older people is due to the courts

sentencing an increased number of older adults to prison for longer periods of time and an aging population. Therefore the number is likely to continue rising (Prison Reform Trust, 2011).

Older prisoners have complex health needs (Fazel et al., 2001) which are often unmet (Fazel et al., 2004). They have higher rates of illness than both younger prisoners and those of a similar age living in the community. Approximately 85% of older prisoners have one or more major illness (Fazel et al., 2001). Most commonly reported health conditions are cardiovascular diseases, arthritis and/or back problems, respiratory diseases and endocrine disorders (Loeb & Abu Dagga, 2006). Furthermore, it is estimated that more than half of older prisoners have a psychiatric diagnosis with depressive illness being the most frequently diagnosed (Fazel et al., 2001). Fazel et al. (2004) found that a high proportion of those showing signs of depression were not receiving anti-depression medication and depression was not recorded in their medical notes. Older prisoners also have considerable unmet social needs such as a lack of contact with family/friends; difficulties with activities of daily living and limited opportunities to work (HMCIP, 2008). On average, older adults cost around three to eight times as much as their younger counterparts to care for in prison (Fazel et al., 2001, 2010; Zimbardo, 1994).

Healthcare for prisoners must be equivalent in quality and range to services provided in the community (Department of Health [DH], 1999). All National Health Service (NHS) standards therefore apply to prison healthcare (ibid.). This includes The National Service Framework for Older People (DH, 2001). However, the standards outlined in this document remain largely unmet in prisons (HM Chief Inspector for Prisons [HMCIP] in England and Wales, 2008). The DH (DH, 2007) produced a toolkit for good practice for older prisoner care which provided recommendations around key issues for supporting older prisoners. The key recommendations pertinent to this proposal were for the provision of regular assessment and care planning for older prisoners and allocating a nominated person to ensure care plans are realised. Previous research showed that these recommendations are rarely currently met (Shaw et al., in preparation). For example, only 19% of prisons have a specific needs assessment for older prisoners (ibid.). There is no national strategy for older prisoners despite repeated recommendations for one to be developed (HMCIP, 2008). Consequently, health and social care service provision for older prisoners is largely uncoordinated.

Evidence Explaining Why this Research is Needed Now

The number of older prisoners is rapidly increasing (Cooney & Braggins, 2010) and is likely to continue to rise (Prison Reform Trust, 2011). This is due to an increase in older prisoners being sentenced and an aging society (Prison Reform Trust, 2011; William, 2006; Howse, 2003). Therefore, there is likely to be a continued and increasing need for, and interest in, research on the health and social care needs of older prisoners. Older prisoners have more complex health needs than their younger counterparts and those of the same age living in the community (Fazel et al., 2001). Prisons are currently generally ill-equipped to manage older prisoners' complex health and social care needs. Older prisoners' health needs are often unmet (Fazel et al., 2004). Consequently, an improved system for assessing and addressing health and social needs is required. This research will determine the extent to which OHSCAP - an intervention shown to be both feasible and acceptable to patients - is effective at reducing older prisoners' unmet health and social care needs. If proven effective, OHSCAP can be disseminated to prisons, local authorities and NHS staff to allow them to improve care planning for older prisoners across England and Wales.

The care of older people is currently a key focus of policy and research and it has been widely acknowledged that older people's health and social care in the community requires improvement. This work builds on the research being conducted on the Single

Assessment Process which involves the introduction of a single assessment for older people's health and social care needs in the community.

The introduction of the new Health and Social Care Bill (2010), particularly its emphasis on the effective integration of health and social services, provides a further impetus for conducting the proposed research now. The OHSCAP will assist multi-agency working to effectively support older prisoners by standardising assessments and care planning, and enhancing effective communication between prison services, local authorities, the NHS and voluntary services.

As part of the previous study (SDO 08/1809/230) the OHSCAP was piloted at a local prison in England. The proposed research is therefore timely as it will build on the momentum from the previous study. The OHSCAP will improve access to health and social care services, engaging with such services in prison should lead to better engagement with services when they are released into the community.

Aims and Objectives

Research questions

1. Does use of the OHSCAP compared with TAU improve:
 - a. proportion of met health and social care needs
 - b. health related quality of life
 - c. depressive symptoms
 - d. functional health and wellbeing and activities of daily living
 - e. quality of health and social care planning
 - f. cost effectiveness
2. What are the facilitators and barriers to the implementation and operation of the OHSCAP?

Objectives

- 1) To train prison staff to deliver OHSCAP.

The OPLs (prison officers) at each of the prisons will be provided with a one day training session on the delivery of the intervention. The manual developed at part of the previous study (SDO 08/1809/230) will be used. Informal supervision will be provided throughout the OHSCAP delivery period.

- 2) To implement OHSCAP in a number of prisons in England.

The proposed study will involve implementing the OHSCAP at a number of prisons in England.

- 3) To evaluate the efficacy of OHSCAP in improving i) the meeting of older male prisoners' health and social care needs (primary outcome) ii) health related quality of life iii) depressive symptoms iv) functional health and wellbeing and activities of daily living.

A RCT will be conducted and older prisoners will be assigned to receive the OHSCAP or TAU.

- 4) To assess the quality of care plans produced through the OHSCAP.

The care plans produced by the OPLs, in conjunction with the older prisoners, will be reviewed by two members of the research team. The research team will develop a proforma to assess the quality of the care planning.

- 5) To explore the experiences of older prisoners receiving the OHSCAP, and staff involved in conducting the OHSCAP.

Semi-structured interviews will take place with prisoners at various time points, to gain an understanding of barriers and facilitators of the OHSCAP (aprox.30). A purposive sample of participants with a range of sentences length and offences will be

used. In addition, the four OPLs will be invited to participate in semi-structured interviews to identify their barriers and facilitators to delivery.

6) To evaluate the cost-effectiveness of the OHSCAP as compared to TAU.

The economic analysis will use health and social care utilisation, health-related quality of life (EQ-5D) (Dolan et al., 1995), and the primary outcome measures (CANFOR, Thomas, 2003) collected during the trial. The incremental cost-effectiveness ratio per Quality Adjusted Life Years (QUALY) gained, cost-effectiveness acceptability curves and net benefit statistics of the assessment intervention compared with TAU will be estimated.

Research Plan / Methods

The Intervention

The OHSCAP was developed and implemented as part of a previous study funded by the National Institute for Health Research (NIHR) Service Delivery and Organisation (SDO) programme. An Action Learning Group (including prisoners, NHS staff and prison staff) at a prison housing adult males developed the OHSCAP.

The OHSCAP is a structured approach for better identifying and managing the health and social care needs of older prisoners. The previous study showed that the OHSCAP was acceptable to prisoners and staff; could be integrated into current prison/healthcare processes; assisted effective multi-agency working; provided an opportunity for prisoners to raise their concerns that would have otherwise gone unreported; and could be successfully conducted by a prison officer.

The tool is a paper based and information derived from it is uploaded onto previously established computer systems. The first page of the OHSCAP includes instructions for completion and background information. A table for collecting basic demographic information including name, age, date of birth and National Offender Management Service (NOMS) number is also included. The OHSCAP consists of an assessment, a care plan and reviews of these.

The assessment includes a series of open questions to facilitate discussion and is divided into three key parts; namely social, well-being and discharge planning. The social assessment includes open questions around relationships, activities and mobility. The well-being assessment includes open questions around emotional well-being, physical well-being, and medications and treatment. A section for other concerns is also incorporated. The final section of the assessment includes open questions around discharge planning. A series of 'trigger' open questions are included for each of these sections. A place for signatures of those conducting the assessment and the prisoner is also incorporated.

The care plan consists of a matrix with five columns. These are: 1) Issue raised from assessment 2) Aim of the proposed action 3) Action (included by whom and when 4) Date to be reviewed and rationale 5) Status of action.

The review section includes space for a date and details of the reviewer. It also takes the form of a matrix and includes the following columns: 1) Progress since last review; 2) Action planned; and 3) Next review with rationale.

The OPL (a prison officer) at each prison conducts the assessments after specialist training. The assessment is conducted seven to 10 days after an older prisoner enters prison. This was based on discussion in the Action Learning Group around the wealth of information that is both asked for and provided to older prisoners immediately after they arrive in prison and how they are suffering from 'entry shock' and would find it difficult to cope with a further assessment during the initial entry period. In addition, it was felt that older prisoners require a period to settle into the prison in order to be able to identify their needs effectively. The OPL accesses the prisons computer system C-NOMIS on a daily basis to identify any prisoners aged 50 or over newly received into the prison, whose known release date (convicted prisoners) or likely release date (un-convicted), is at least three months after prison entry. The OPL conducts the assessment one-to-one with the older prisoner. The care plan is completed in conjunction with the older prisoner and they are provided with a copy of their OHSCAP. In addition, a summary of the OHSCAP is entered onto the prison computerised information system (C-NOMIS) and a copy of the OHSCAP is scanned onto the prison computerised clinical records system (System-one). The OPL conducts reviews of the care plans as considered appropriate and develops further action plans. Reviews of care plans will involve ensuring actions have been completed and pursuing these as necessary.

Who will deliver the intervention

The OPL, who are prison officers, at each of the four prisons will deliver the intervention. An action learning group comprising prisoners, NHS staff and prison staff decided that the OPL is the most appropriate person to conduct the OHSCAP. Findings from the previous study illustrate that prisoners are happy to discuss their health and social care issues with prison officers. The OPL will have specialised training before conducting the OHSCAP.

Treatment as Usual (TAU)

Treatment as usual includes the standard non age specific health assessment carried out at prison entry (Grubin et al. 2002). Further assessment and intervention follows local procedures at each establishment. Identification of health and social needs and care planning is generally *ad hoc* and inadequate (Shaw et al., 2009).

Design

Recruitment: The study is an RCT: individuals will be randomised to OHSCAP or TAU (TAU). We will seek informed consent from approximately 504 men aged 50 and over, newly received into one of the identified prisons if their known release date (convicted) or likely release date (unconvicted), is at least three months after their prison entry date. Release dates for unconvicted prisoners will be predicted using an algorithm developed for a previous study (Shaw et al., 2008).. We need to recruit 392 participants at follow-up in order for the study to have adequate power. Please refer to flow diagram.

Randomisation: The MAHSC Clinical Trials Unit will provide a telephone based central randomisation service for the trial. Provisionally the allocation method will be minimization with a random element over the margins of two factors: Institution (4 prisons) and baseline number of unmet needs (0, 1, 2, 3, 4+). The system is compliant with Good Clinical Practice (GCP), with a full audit trail, data entry and monitoring roles, and formal database lock functionality.

Service model: OHSCAP is a structured approach for better identifying and managing the health and social care needs of older prisoners. The tool is paper based and consists of an assessment, a care plan with care plan review. The assessment includes a series of open questions to facilitate discussion on needs in those areas. It is divided into three key parts; namely social care, well-being and discharge planning. The care plan consists of a matrix with five columns. These are: 1) Issue raised from assessment 2) Aim of proposed action 3) Action (included by whom and when 4) Date to be reviewed and rationale 5) Status of action. The review section also takes the form of a matrix and includes the following columns: 1) Progress since last review; 2) Action planned; and 3) Next review with rationale.

Sampling

We have identified that on average 35 older prisoners enter the four prisons involved in the study each month (based on July 2011 – June 2012 figures) providing an ample number of older prisoners to recruitment from. Entry rates of prisoners aged 50 and over are based on personal communications with all four prison sites. Based on findings from a previous study (Shaw et al. in preparation), it is anticipated that 20% will not meet our inclusion criteria

Randomised Control Trial participants: Approximately 462 older prisoners (aged 50 or over) on entry/transfer into prison establishments (392 participants required at follow-up)

Inclusion criteria: To be eligible for inclusion, participants must:

1. be aged 50 or over,
2. be entering one of the identified prisons,
3. have a known release date (convicted) or likely release date (unconvicted) of at least three month after their prison entry date.

Qualitative sample: Semi-structured interviews will take place with prisoners who received the OHSCAP at a range of follow-up periods, to gain an understanding of the barriers and facilitators to the intervention (aprox.15). A purposive sample of participants with a range of sentences length and offences will be used. In addition, semi-structured interviews with the OPLs will take place to identify the OHSCAP process. All interviews will be audio record, transcribed verbatim and analysed thematically. A number of themes will be generated and elaborated using aspects of constant comparative methods (Glaser, 1965) within the computer software NVivo (QSR International Pty Ltd., 2008).

Setting/context

This RCT will take place in a number of prisons in England which have been selected to represent prisons which hold prisoners on short, medium and long sentences. We have selected these prisons to include local and sentenced establishments with a range of security categories within close geographical reach for the researcher, for pragmatic reasons.

Data collection

Demographic information including age, ethnicity, marital status, offence type, conviction status and sentence length will be collected for all participants. Both the primary outcome measure and secondary outcome measures will be completed within one week of prison entry and three months after receiving the intervention.

Primary outcome measure: This will be measured by The Camberwell Assessment of Need – Short Forensic Version (CANFOR-S) (Thomas et al., 2003). The CANFOR-S measures physical health, mental health and social needs across 25 domains; accommodation; food; looking after the living environment; self-care; daytime activities; physical health; psychotic; symptoms; information about condition and treatment; psychological distress; safety to self; safety to others; alcohol; drugs; company; intimate relationships; sexual expression; childcare; basic education; telephone; transport; money; benefits; treatment; sexual offending and arson. Each domain is scored either: no need, met need, or unmet need. This tool has been used previously to investigate the unmet needs of older prisoners (Hayes, 2010; Shaw et al, in preparation). The primary outcome measure will be collected at baseline and three month follow-up.

Secondary outcome measures: Secondary outcome measures will be collected at baseline and at three month follow up.

1. The Bristol Activities of Daily Living Scale (Bucks, Ashworth, Wilcock, & Siegfried, 1996)

The Bristol Activities of Daily Living measure incorporates the 20 domains of food; eating; drinks; drinking; dressing; hygiene; teeth; bath/shower; toilet/commode; transfers; mobility; orientation (time); orientation (space); communications; telephone; housework/gardening; shopping; finances; games/hobbies, and; transport. The scale was originally designed for patients with dementia but has recently been used with an older prisoner population (Hayes et al., 2013; Hayes et al., 2012). Hayes et al (2012; 2013) omitted items 18 (money) and 20 (transport) because they were not relevant to prisoners, and more relevant versions of these items were covered in the CANFOR-S (Thomas *et al*, 2003). This approach will also be adopted for the current study. Total scores will therefore not be used because this would affect the internal consistency of the measure. Items will therefore be examined separately.

- 2. The Geriatric Depression Scale short form, (GDS-15)** (Sheikh & Yesavage, 1986) will be used as a secondary outcome measure. It contains 15 questions, which are answered yes or no. Items indicative of depression carry a score of 1. A total scale score of five or more is suggestive of mild depression and scale guidelines suggest that further investigation is warranted. Total scores of ten or more according to scale guidelines, almost always indicate moderate depression. In a previous study a strong association between older prisoners' unmet needs and levels of depression were identified (Shaw et al., in preparation). Fazel et al., (2004) found that a high proportion of their sample showing signs of depression were not receiving anti-depressant medication nor was depression documented in their medical records.
- 3. The Secure Facilities – Service Use Schedule (SF-SUS)** (Barrett & Byford, 2007) records service use information from records and by asking participants. It can obtain data on the use of all individual-level services provided within a secure facility as well as external services commonly accessed by prisoners.
- 4. The Health Related Quality of Life Measure (EQ-5D)** (Dolan et al., 1995) measures mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each domain has three levels: no problems, some problems, severe problems. Prisoner EQ-5D scores will be compared with those of equivalently aged community-based patients in the UK, published by Kind (1998).

The following tools will also be used at baseline to describe the sample.

1. Opcrit to measure mental health (Azevedo et al., 1999)

Opcrit is a suite of computer programs that allow data entry and the consequent generation of diagnoses according to 12 operational diagnostic systems. It has been used internationally in Psychiatric research.

2. PrisonQuest to measure mental health (Shaw, Tomensen, & Creed, 2003)

PrisonQuest consists of seven questions each with yes or no responses. A score of three or more indicates that a further assessment for mental health is required. Prisonquest has been selected because it has been developed from other standardised assessments, is widely used in prison and is short, reducing participant burden.

3. Burvil Grid to measure physical health (Burvill, Mowry, & Hall, 1990)

The Burvill Grid will be used to obtain data on the physical health of participants. The Burvill Grid categorises physical disorders into different body systems. Each system is rated according to severity of disorder (coded 0=absent, 1=mild, 2=moderate, 3=severe) and disability as a consequent of the disorder (coded 0=none, 1=little,

2=some, 3=great deal). Physical problems are also defined as acute or chronic. A chronic diagnosis is given if it has been present for at least the previous three months. The Burvil Grid has been used in previous studies regarding older prisoners (Fazel, Hope, O'Donnell, et al., 2001; Hayes et al., 2013).

Qualitative data collection

Semi-structured interviews will take place with prisoners who received the OHSCAP at a range of follow-up periods, to gain an understanding of the barriers and facilitators to the intervention (aprox. 15). A purposive sample of participants with a range of sentences length, offences and health status will be used. In addition, semi-structured interviews with the OPLs will take place to identify the OHSCAP process. All interviews will be audio record, transcribed verbatim and analysed thematically. A number of themes will be generated and elaborated using aspects of constant comparative methods (Glaser, 1965) within the computer software NVivo (QSR International Pty Ltd., 2008).

Data analysis

The proposed study will identify whether the OHSCAP is effective in reducing older prisoners' unmet health and social care needs compared to TAU. From our previous work (a cross-sectional study assessing the unmet needs of 100 older prisoners at baseline) the mean number of unmet needs was 2.71 (sd=2.65). The distribution which has integer support 0-25 was unsurprisingly positively skewed with a median number of unmet needs of 2. Whilst we do not have supporting data we assume that this distribution will be broadly similar at three months follow up in the TAU group. The purpose of the current study proposal is to see if the average number of unmet needs can be reduced with the OHSCAP intervention. For the study to be practice changing we believe that at least a 30% reduction to a mean of 1.90 will be required and so have powered the study proposal accordingly.

The primary outcome (number of unmet needs at three months) will be analysed with a Mann-Whitney U test. A sensitivity analysis will be undertaken using the data for all randomised cases by assuming no change in the number of unmet needs from baseline for cases without the three month data i.e. imputing the three month value with the baseline value for such cases (anticipated to be < 10%). A regression analysis will also be used to adjust for baseline characteristics e.g. age, number of unmet needs at baseline etc. The details will be specified in an analysis plan prior to the locking of the database. As the response is a skewed ordinal variable it is likely that an ordinal regression approach (proportional odds) with a moderate number of categories will be adopted after grouping of the right tail e.g. 0, 1, 2, 3, 4+ unmet needs. Similar approaches will be adopted for the secondary outcomes with the details depending on the distribution of the particular outcome.

Cost effective analysis - The effectiveness of the intervention will be assessed using the CANFOR and EQ-5D outcome measures. Analysis will be performed according to the intention to treat principle. The incremental cost-effectiveness ratio per quality-adjusted life year (QALY) gained, cost-effectiveness acceptability curves (CEACs) and net benefit statistics of the OHSCAP compared to TAU will be estimated. Given that cost data are frequently skewed, which can cause a violation of the assumptions of standard significance tests, bootstrapped estimates will be used. All analysis will be performed using STATA version 11.

Audit of care plans: Data on the number and type of referrals made and actions completed will be obtained and descriptive statistics will be produced.

Qualitative Analysis: All interviews will be transcribed verbatim and analysed thematically. A number of themes will be generated and elaborated using aspects of constant comparative methods (Glaser, 1965). NVivo 9 software will be used to facilitate data management and analysis.

Dissemination and Projected Outputs

A comprehensive strategy will be implemented to ensure that the findings are appropriately disseminated to a wide range of relevant professionals and service users.

This will include publications in peer-reviewed journals such as the British Medical Journal, the British Journal of Psychiatry, Age and Ageing, the Journal of Social Work and The Prison Service Journal.

Best practice booklets will also be developed for prison staff and staff working in partner agencies such as housing organisations, job centres, social services, Age UK, medical centres, probation, hostels, homeless services and other voluntary organisations. The report and an executive summary will also be distributed to these organisations.

The report, best practice booklets, copies of the OHSCAP and examples of good practice would be uploaded on to the 'NHS Evidence' and OHRN websites. The NHS website allows health and social workers to access information to help them deliver quality care for service users. The chief investigator is the academic lead for the OHRN which is funded by the DH and is a multi-disciplinary and multi agency network with 1,800 members.

The research team will work alongside prisoners completing National Vocational Qualifications in business administration at the prisons involved to develop newsletter style reports to ensure they are appropriate and accessible to prisoners. The prison advisory groups will inform the research team on how best to disseminate these. Our key findings will be summarised and disseminated using the Centre for Mental Health and Risk Facebook and Twitter accounts.

In addition, the team will present at a number of conferences attended by a wide range of service representatives including: The International Association of Forensic Mental Health Services Conference, The Agenda for Later Life Conference (Age UK) and any other available timely relevant conferences. Additionally, we will have specific discussion with charity providers such as Age UK to ensure the needs of this group are considered as part of their campaigning/provider work.

Presentations will also be held at each of the establishments involved to ensure participants (prisoners and staff) are informed of the findings.

A workshop will also be held to disseminate the findings of this research to prison staff, health staff, probation and social service staff and policy makers at the DH. There will be ongoing involvement of the DH through existing OHRN reporting mechanisms. We will develop an OHSCAP interests group, including staff and prisoners to champion OHSCAP's adoption across the prison estate. This will facilitate the introduction of the OHSCAP at prisons across England, where appropriate.

As part of the dissemination strategy, a publicly accessible/open access webpage on the OHRN website will be developed as part of the OHRN website. It will include a downloadable version of the OHSCAP tool; training materials; and good practice examples of how to use OHSCAP. The website would be promoted at each of the presentations and workshops mentioned above.

Expected Output of Research / Impact

Outputs from the proposed research will include:

- 1) Publication in Journals such as the British Medical Journal, the British Journal of Psychiatry, Age and Ageing, the Journal of Social Work and the Prison Service Journal.
- 2) Best practice booklets for prison staff and staff working in partner agencies such as housing organisations, job centres, social services, Age UK, medical centres, probation, hostels, homeless services and other voluntary organisations
- 3) Report for practitioners, managers, policy leads and academics
- 4) Newsletter style report for prisoners
- 5) Conference presentations (these will be conducted at The International Association of Forensic Mental Health Services Conference, The Agenda for Later Life Conference (Age UK) and any other available timely relevant conferences)
- 6) Presentations to NHS staff members, prison staff members and older prisoners at the four prisons involved in the study
- 7) Workshop for prison staff, NHS staff, local authority practitioners and managers as well as policy leads at the DH to disseminate the findings of the research and to assist the implementation of the OHSCAP across prisons in England and Wales
- 8) As part of the study, staff will be trained on how to effectively use OHSCAP
- 9) A webpage will be developed by the research team (as part of the OHRN website) which will include a downloadable version of the OHSCAP tool; training materials; and good practice examples of how to use OHSCAP.

Plan of Investigation and Timetable

Research Timetable

Months 1 - 5: Preparation and approval - Permission will have already been obtained from an NHS ethics committee with specialist interest/expertise in prison based studies. Formal governance permission will also be obtained from the appropriate Trust Research and Development Departments and through the central National Offender Management research ethics and governance committee. The web page will be developed.

Months 6 - 32: Part 1 Training on delivery of intervention and informal supervision. A one day training session with four prison officers across the four prisons (**month 6**) and informal supervision will be provided (**months 7 – 32**).

Months 7 - 32: Part 2 Randomised Controlled Trial - Participants will be randomised to receive OHSCAP or TAU. Primary and secondary outcome measure tools will be administered up to one week before receiving the OHSCAP and three months after receiving the intervention. Demographic information will be collected.

Month 12 - 33: Part 4 Qualitative interviews - Semi-structured interviews will take place with prisoners (approx.30) at a range of follow-up periods and OPLs (4). Qualitative data analysis will be conducted throughout this period.

Month 26 - 29: Part 3 Audit care plans - The care plans will be reviewed by two members of the research team. The research team will develop a proforma to assess the quality of the care planning.

Months 32- 35: Part 5 Cost-effectiveness analysis - The incremental cost-effectiveness ratio per Quality Adjusted Life Years gained, cost-effectiveness acceptability curves and net benefit statistics of the assessment intervention compared with TAU will be estimated.

Months 33 - 42: Data analysis, report writing and dissemination - Quantitative and qualitative analysis completed. Web page further developed; report, newsletter style report and best practice booklet written; papers written and submitted for publication; presentation at conferences and prisons conducted; and workshop held.

Project Management

The project will be overseen by Professor Jenny Shaw. Jenny Shaw is a Professor of Forensic Psychiatry, Consultant Forensic Psychiatrist and academic lead for the OHRN. Jenny Shaw has successfully managed a multitude of prison healthcare studies. Jenny Shaw will chair the Steering Group and will ensure project milestones are met. The Steering Group meetings will be scheduled to best inform the different stages of the research and will meet at least twice a year. In addition, Steering Group members can be approached in between committee meetings to offer *ad hoc* advice specific to their expertise. On a day-to-day basis, the researchers (Katrina Forsyth & Laura Archer-Power) will be supervised by Jenny Shaw. The work will be located within the offices of the OHRN which will give the researcher the opportunity of receiving peer support from a number of other researchers who have developed particular expertise in specific aspects of research, for example ethics applications, statistical analysis etc. Dr Jane Senior will manage the project budget and receive quarterly statements of accounts. She will also supervise KF & LAP on a day-to-day basis.

The RCT design and statistical aspect of the bid will be supervised by Dr Roger Webb, Dr David While and the CTU. The MAHSC-CTU will also provide trial (project) manager support activities to the study researchers on behalf of the study sponsor, to ensure compliance with national and international regulations such as DH Research Governance and Good Clinical Practice.

Dawn Edge will supervise the qualitative parts of the research.

Project Management Group

All co-applicants will sit on the over arching Steering Group tasked to ensure that project milestones are met and expenditure is appropriate within available funds. The Steering Group meetings will be scheduled so as to best inform the different stages of the research and provide the researchers with timely guidance. It is envisaged that the Steering Group will meet at least twice a year.

Prison Advisory Groups

Prison Advisory Groups will be set up in each of the prisons involved. Prisoners, prison officers and healthcare members of staff will all be invited to join the groups. As the proposed study progresses, the Prison Advisory Groups will guide and inform the research. They will contribute to the development of the participant information sheets and interview guides. Furthermore, the researchers will work alongside the Prison Advisory Groups to develop newsletter style reports to disseminate the findings of the proposed research to other prisoners and ex-prisoners in an accessible and appropriate format. Prisoners completing National Vocational Qualifications (NVQ) will be given the opportunity to design and produce the newsletter style reports. In line with INVOLVE's guidance, Steering Group and Prison Advisory Group members will be asked about their training and development needs throughout the process, and training and support will be tailored accordingly and in consultation with INVOLVE workers.

Trial Steering Committee (TSC)

A trial steering committee (TSC) will be created to provide overall supervision for the trial. In line with the Medical Research Council Guidelines, it will focus upon the progress of the trial, adherence to the protocol, patient safety and will consider any new information relevant to the research question. The membership of the TSC will include an independent chair. We will aim to recruit someone with prison and experience of conducting RCTs. In addition, at least two other independent members, one or two principal investigators and at least one ex-older prisoner will be recruited. Representatives from the trial sponsor and the trial funder will also be invited to all TSC meetings. The TSC will meet at least annually but will meet more frequently if required.

Approval by Ethics Committees

The process of obtaining ethical approval commence as soon as confirmation has been received that funding has been secured. The process would therefore commence in December 2012 and ethical approval would be obtained before the end of May 2013. As the research team have already piloted the OHSCAP, and have experiencing of obtaining ethical approval for similar studies, it is anticipated that ethical approval will be obtained quickly and smoothly.

The chief investigator is Assistant Director for The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness and has experience of ensuring data is held in accordance with strict data protection policies. Data obtained from this study will be held in line with the University of Manchester's data protection and NHS policy.

All participants will be appropriately informed about the study in writing and will have the study explained to them verbally. The research team is experienced in explaining studies to prisoners, who may have lower literacy rate levels and may be experiencing mental health problems. Consent will be obtained in line with the Mental Health Capacity Act 2005 Code of Practice (Lord Chancellor, 2007). Confidentiality will be maintained unless there is a risk to the participants or others.

The department has a protocol for researcher safety which the team is experienced in following in similar projects (SDO 08/1809/230; Shaw et al., 2009). Appropriate Research and Development approval, research passports and letters of access will be obtained.

Patient and Public Involvement

The current proposal is informed by a previous NIHR funded study (SDO 08/1809/230). As part of the previous study, older prisoners at a prison housing adult males designed the OHSCAP as active members of an Action Learning Group. The OHSCAP will be piloted as part of the proposed research. Prisoners successfully participated in the Action Learning Group and have since reported that they valued the opportunity to be involved in shaping future services. The information the prisoners provided was extremely valuable, and informed the content and format of the OHSCAP, including the inclusion of open questions to facilitate discussion. These discussions have also informed the development of this research proposal. Furthermore, Dr Stuart Ware, is a Steering Group member. Dr Ware is an older ex-prisoner and founder member of the group Restore (a support network for older prisoners). His involvement has been highly valuable and an important mechanism for ensuring we have considered the needs of older prisoners throughout the development of this proposal. He has contributed to the development of this application.

Prison Advisory Groups will be set up in each of the prisons involved. Prisoners, prison officers and healthcare staff will be invited to join the groups. As the proposed study progresses, the Prison Advisory Groups will inform the research. They will contribute to the development of the participant information sheets and interview guides to ensure they are appropriate to the needs of prisoners. Furthermore, the researchers will work alongside the Prison Advisory Groups to develop newsletter style reports to disseminate the findings of the proposed research to other prisoners in an accessible format. Prisoners completing National Vocational Qualifications (NVQ) will be given the opportunity to produce the newsletter style reports. The Steering Group and Prison Advisory Group members will be asked about their training and development needs throughout the process, and support will be tailored accordingly in consultation with INVOLVE workers. As a member of the Steering Group Dr Stuart Ware will provide his expertise on matters as they arise. This will ensure the perspectives of older prisoners are considered throughout the research process including dissemination of findings

Expertise and Justification of Support Required

Research Team

Jenny Shaw is Professor of Forensic Psychiatry, Head of the Mental Health and Neurodegeneration Research Group and Assistant Director of the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness. She is also Consultant Forensic Psychiatrist and Director of Research and Development at Lancashire Care NHS Foundation Trust. Professor Shaw and Dr Jane Senior head the National Offender Health Research Network at the University of Manchester, acting as academic lead and network manager respectively. Both have extensive experience as researchers and clinicians, providing expertise and leadership across the network's portfolio of ongoing research projects. Dr Senior acts in a consultative capacity to prisons and NHS organisations undertaking evaluations of current methods of service delivery. Dr Roger Webb and Dr David While will provide input on study design and statistical analysis. Dr While is a statistician at the Centre for Suicide Prevention. Dr Webb is an experienced quantitative researcher with knowledge of health services research, epidemiology and biostatistics. They will be supported by senior statisticians at the CTU. Ms Katrina Forsyth and Kate O'Hara worked on a previous study examining older prisoners' health and social care needs. They have gained valuable insight into older prisoners' needs by conducting a range of quantitative and qualitative assessments and interviews.

Dr Dawn Edge specialises in qualitative research methods and will advise the team on these matters. Dr Elisabeth Walsh is a Senior Lecturer in Offender Health at the University of Leeds has successfully facilitated action learning groups to develop prison healthcare including the group which developed and implemented the OHSCAP. She will act as a consultant during this proposed study and provide training and ongoing informal supervision on the OHSCAP to prison officers. Stuart Ware is an older ex-prisoner and formed the group Restore (a support network for older prisoners) he will provide a valuable insight into issues affecting older prisoners which will be fed into all aspects of the research. Dr Adrian Hayes carried out his PhD older prisoners' health and social care need and will provide expertise on this topic. Dr Elaine Crawley is the director of the Salford University Centre for Prison studies and has published numerous papers regarding older prisoners. She will provide valuable criminological knowledge to the research team. David Challis is a Professor of Community Care and Director of the Personal Social Services Research Unit. He has conducted a number of studies on assessment of older people ranging from development of tools to the evaluation of national initiatives in assessment. Alistair Burns is a Professor of Old Age Psychiatry and an Honorary Consultant Old Age Psychiatrist. His areas of expertise include Dementia and Alzheimer's disease. Professor Challis and Professor Burns will provide expert expertise on the mental health and social care respectively. All co-applicants will attend the over-arching steering committee at least bi-annually. Dr Nat Wright is currently the clinical director for substance misuse at

HMP Leeds and a GP advisor to the UK DH Prison Policy Unit having formally been GP advisor to the National Treatment Agency for Substance Misuse. He is an Honorary Research Fellow at Leeds University and will contribute clinical and research expertise to the project, especially in terms of service design and delivery.

Clinical Trials Unit

The CTU currently has 15 managed trials on their portfolio including major national and international multi-centre trials covering over 120 clinical research sites.

Health Economics Team

Dr Mark Harrison in the health economics team has over 10 years experience as an epidemiologist and health economist and will support Ms Rachel Meacock to conduct the cost-effectiveness analysis, she has completed similar cost-effectiveness studies.

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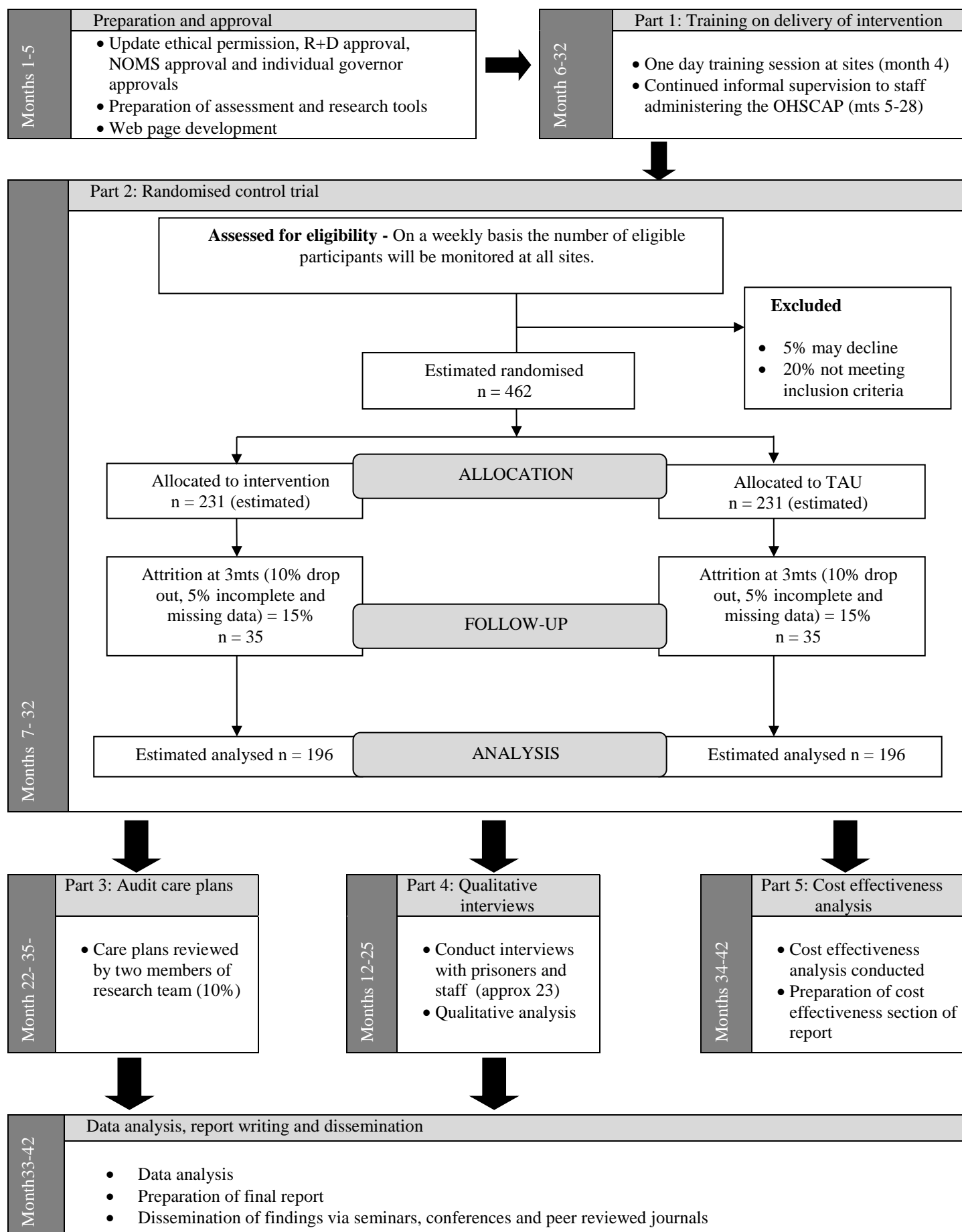
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Flow diagram/Project Plan



GANNT Chart

Research Activities	May 13'	Jun 13'	Jul 13'	Aug 13'	Sep 13'	Oct 13'	Nov 13'	Dec 13'	Jan 14'	Feb 14'	Mar 14'	Apr 14'	May 14'	Jun 14'	Jul 14'	Aug 14'	Sep 14'	Oct 14'	Nov 14'	Dec 14'	Jan 15'
Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Update ethical permission																					
Obtain R+D approval																					
Obtain NOMS approval																					
Obtain Governor approvals																					
Prepare research tools																					
Training on use of OHSCAP																					
Supervise staff using OHSCAP																					
RCT recruitment baseline																					
Conduct qualitative interviews																					
RCT 3 month follow up																					
Research Activities	Feb 15'	Mar 15'	Apr 15'	May 15'	Jun 15'	Jul 15'	Aug 15'	Sep 15'	Oct 15'	Nov 15'	Dec 15'	Jan 16'	Feb 16'	Mar 16'	Apr 16'	May 16'	Jun 16'	Jul 16'	Aug 16'	Sep 16'	Oct 16'
Month	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42
CONT. supervise staff using OHSCAP																					
CONT. recruitment baseline																					
CONT. qualitative interviews																					
CONT. RCT 3 follow up																					
Audit care plans																					
Cost effectiveness analysis																					
Cost effectiveness report																					
Data entry																					
Data analysis																					
Preparation of final report																					
Dissemination of findings																					