

Delivering primary health care to homeless people: an evaluation of the integration, effectiveness and costs of different models

1 Summary of research

Many homeless people have poor health yet experience difficulties in accessing primary care services. Since the 1980s the NHS has funded primary health care services for homeless people to encourage service-use, including special health centres, mobile teams in hostels, and special services within GP practices. Some areas with a homeless population have no specialist service, and generic GPs attend to their health problems. There is no evidence about which schemes are more effective in addressing homeless people's health needs. This study aims to address this knowledge gap by evaluating the different models of primary health care services for homeless people. It will provide much needed evidence for local NHS and Health and Well-being Board commissioners and primary health care workers about the best ways to deliver health care to homeless people, in terms of effectiveness and good value for money.

Firstly, a mapping exercise will be undertaken across England to identify the location of the specialist homeless health services and the services they provide, and areas with a homeless population but no specialist health service. Eight schemes that represent the distinct models (health centres, mobile teams, special services in GP practices and generic GP practices treating homeless people) will then be evaluated. Information will be collected about how each service works and its integration with other agencies, and its effectiveness in engaging homeless people in health care, in responding to their health, social care and welfare needs, and in providing continuity of care over 12 months for health problems. The impact over time of the different models on service-users' health and well-being, and the resource implications and costs to deliver the service, will also be examined.

This type of investigation is unprecedented in the UK. It brings together a strong multi-disciplinary team of experts in homelessness research, in the delivery of health care and dental services to homeless people, and in health economics. It will also directly involve homeless people in advisory and interviewing roles. The longitudinal design of the study means that the fieldwork will be challenging, but members of the research team (Crane, Joly and Coward) have extensive successful experience of tracking and retaining homeless and formerly homeless people in longitudinal studies.

2 Background and rationale

Homelessness has increased substantially in England over the last five years. The number of households who presented as homeless to local authorities increased from 62,420 in 2009/10 to 81,750 in 2012/13 (Communities and Local Government, 2013). There are just over 39,600 beds in hostels, which accommodate an estimated 100,000 individuals each year (DH Office of the Chief Analyst, 2010; Homeless Link, 2013). Many others stay in bed-and-breakfast hotels, 'sofa-surf', or sleep on the streets. The number of rough sleepers in London rose from 3,673 in 2009/10 to 6,437 in 2012/13 (Broadway, 2013).

Homelessness has a devastating impact on health and well-being. The health needs of homeless people are greater than those of the general population, including a higher prevalence of problematic drug and alcohol use, mental illness, physical illnesses and infectious diseases (Bines, 1994; Wright, 2002). They have higher rates of serious and multiple morbidity, and die earlier (Wright 2003). There are numerous difficulties in meeting their health needs. Many neglect their health, and their unsettled lifestyle and sometimes challenging behaviour reduce their likelihood of completing treatment programmes. They are less likely than the general population to be registered with a GP, and more likely to use walk-in centres or A&E, which offer no continuity of care. Our 2011 study of homeless people in South Yorkshire found that just 38% per cent were permanently registered with a local GP, while 39% had used A&E in the last six months (Crane and Warnes, 2011a).

Primary health care services for homeless people have been unevenly developed, and therefore homeless people's access to health care is highly variable (Crane and Warnes, 2011a). Many also face barriers in using health services, including the inflexibility of services, staff attitudes, and the difficulties that services have in treating people with complex and multiple needs (Crane and Warnes, 2001a). As described by the Chief Executive of a large homelessness organisation, 'we straddle intersections between primary care, public health and health inequalities – and it is the fact that we do not "fit" neatly anywhere which compounds and exacerbates our residents' ill-health' (Public Health Action Support Team, 2008:3).

The HS&DR programme has issued a call for studies on the effectiveness and cost-effectiveness of innovative and integrated homeless health and care services. This study addresses this call in the

context of the delivery of primary health care to homeless people. In 2010, the DH attempted to categorise specialist homeless primary care provision, but was 'unable to demonstrate how far the provision is fully meeting the needs of [the homeless] population' (DH Office of the Chief Analyst, 2010: 20). It identified four specialist homeless health care models: (i) mainstream GP practice that provides special services for homeless people; (ii) outreach team of specialist homelessness nurses; (iii) full primary care specialist homelessness team; and (iv) a fully coordinated primary and secondary care service (based on services provided in Boston, Massachusetts, but unavailable in England). The study found that one-third of PCTs provided no specialist primary care services for homeless people, and another one-third had a specialist service but did not provide permanent registration. It also reported a lack of systematic data on homeless people's use of health services and the costs, and a lack of research evidence on the potential for improved primary care to reduce secondary care costs and improve health outcomes (p.21).

Our study will address the knowledge gap identified in the DH study, by mapping and categorising models of specialist health provision for homeless people in England, recording key factors about their services and integration, and identifying areas with unmet needs. The various models will then be evaluated to provide evidence of their effectiveness in addressing homeless people's health and other needs, and the resources and costs involved. At present, there is a lack of evidence about what models work best, in which context, for which groups of homeless people, and at what cost. The study will provide much needed evidence for NHS commissioners and providers about the organisation and delivery of primary health care to homeless people, and the models or service components that work best and provide value-for-money. This in turn will help to improve the health status and well-being of homeless people, and reduce their need for costly emergency and unscheduled secondary health care. Drawing on the DH findings and our previous work (Crane and Warnes, 2011a; DH Office of the Chief Analyst, 2010), we propose to evaluate four broad models in England for delivering primary health care to homeless people:

1. Health centres specifically for homeless people – comparable to the DH's full primary care specialist homelessness team but located at a fixed site.
2. Mobile teams that run sessions in homeless services such as hostels – comparable to the DH's outreach team of specialist homelessness nurses but also including GPs.
3. GP practices with specialist services for homeless people and other disadvantaged groups as identified by DH.
4. Generic GP practices located close to a hostel that provide 'usual care' to the local population including the hostel residents. This type of provision is not included in the DH models but is a means by which homeless people access primary care if there are no specialist homeless health services in the locality.

There are many variations within these models and hybrid services, *e.g.* health centres that also provide outreach. There is a marked variation in the provision of services beyond primary health care (*e.g.* drug and alcohol counselling), links with secondary care, and the extent of integration between community health, housing and social care services. The concentration or profile of homeless people in an area is also likely to have affected what services have developed and been commissioned.

3 Why the research is needed now

Since the 1980s the NHS has funded initiatives to improve homeless people's access to health care, including Personal Medical Services for 'hard-to-reach' groups and National Enhanced Services for Homeless People. In 2002, the Royal College of General Practitioners (RCGP) recommended that homeless people should be registered permanently with a GP and integrated into the practice's prevention and promotion activities. Rule changes in 2005 made this much more difficult as patients registering needed proof of address. It is well-documented that the health needs of many homeless people are not met, and that they make unusually high demands on emergency services such as A&E and on hospital in-patient services (Crane and Warnes, 2011a). The 2010 DH study estimated that this client group consumes around four times more acute hospital services than the general population, costing at least £85m per year. When admitted to hospital, they tend to stay on average three times longer than the general population due to the severity of their health conditions (DH Office of the Chief Analyst, 2010).

The number of people with long-term conditions and multiple health problems is growing, and several recent reports stress the importance of addressing health inequalities (*e.g.* Hutt and Gilmour, 2010; Marmot, 2010). This is now a requirement under the Health and Social Care Act 2012. Clinical Commissioning Groups have a duty to provide health services to their local population, and local authorities to commission public health services. Standards have been produced for commissioners

and service providers regarding health service delivery for homeless people (Hewett, 2013). Yet there is insufficient evidence as to whether these standards are being met, and whether and how care for homeless people is integrated within primary care services. There have been several calls over recent years for better understanding of the effectiveness of the primary health care models serving homeless people (Wright and Tompkins, 2006; DH Office of the Chief Analyst, 2010). In June 2013, the Department of Health's National Inclusion Health Board meeting reiterated the need for thorough evaluation of the models of primary care initiatives for vulnerable groups.

4 The study's aims and objectives

The overall aim of our study is to evaluate the effectiveness and cost-effectiveness of different models of delivering primary health care to homeless people, with special reference to their integration with other services and how this impacts on a range of health, social and economic outcomes.

The objectives are:

1. To identify the extent of provision of specialist primary health care services for homeless people in England, the types of models that are found in different NHS Area Teams and in areas with different population sizes, and areas with a homeless population but no specialist health care service.
2. To examine the characteristics and integration of the primary health care services with other local providers, particularly primary dental care, mental health, secondary health, substance misuse, homelessness sector, housing and social care services.
3. To examine the effectiveness of the different models in engaging homeless people in health screening, in responding to their physical health, mental health and social care needs, and in providing continuity of care for health problems including long-term and complex conditions.
4. To evaluate over time the impact of the different models on service-users' health and well-being, and their utilisation of other health and social care services including dental, emergency and secondary care.
5. To investigate the resource implications and costs of delivering services for the various models.
6. To compare the various models across a range of outcomes, reflecting service-user and NHS perspectives, using a cost-consequences framework.
7. To provide evidence for local commissioners of NHS services and service providers regarding cost-effective organisation and delivery of primary health care to homeless people.

The particular **research questions** that this study will address are:

- i. Which models or particular service elements are more effective in engaging homeless people in health screening and health care?
- ii. Which models are more effective in providing continuity of care for long-term or complex health conditions?
- iii. What are the associations between the integration of the models with other services and health outcomes for homeless people?
- iv. How satisfied are service-users, primary health care staff and other agencies with the services provided by the various models?

5 Research plan / methods

5.1 Literature reviews

Two literature reviews will be undertaken during the first six months of the study. The first, **Primary Health Care for Homeless People: Evidence-based Practice**, will build on the synthesis by co-investigator Joly (2009) of the effectiveness of models of interagency working in health care provision to homeless people in the UK up to 2004. It will also review the international literature. In the US, for example, the Health Care for the Homeless programme has been operating since 1985, and now delivers services in 208 sites nationwide. The review will include the academic and the grey literature. Medical and social care databases will be searched including: Allied and Complementary Medicine (AMED), British Nursing Index (BNI), Cochrane Database of Systematic Reviews (CDSR), Cochrane Central Register of Controlled Trials (CCRCT), Cumulative General Practice Research Database (GPRD), Index to Nursing and Allied Health Literature (CINAHL), Intute (Social Sciences and Medicine), MEDLINE, NHS EED, PsycINFO, SCOPUS, and Web of Knowledge. The US National Health Care for the Homeless Council website and similar will also be searched.

A **Policy and Service Review** will examine the changing policy context in which primary health care services for homeless people in England have been developed, dating back to 1990 when major government-funded programmes for rough sleepers and single homeless people were initiated. The review will examine national strategies, policies and standards for health, welfare, social care and housing and how these have had an influence on the development of health services for homeless people and other underserved groups. This will be updated in months 31-32.

5.2 Design and theoretical / conceptual framework

It has long been recognised that those who are in most need of health care are least able to access services, a phenomenon termed the 'inverse care law' (Tudor Hart 1971). In terms of homeless people, the belief was that their complex needs could not be met by generic GP services, and therefore specialist primary health care services for the group were established. Some theorists associate the social exclusion of vulnerable people with issues of discrimination and the 'bureaucracy' and regimes of formal services, which result in people being inadvertently or deliberately excluded from services. In contrast, Merton (1968) associates homeless people's exclusion from mainstream society with 'retreatist' behaviours, and an inability or unwillingness to comply with society's norms and values.

Our study will challenge or confirm the theory that homeless people's health care needs are best met by specialist, targeted services, and establish the reasons why this is or is not the case. It will build on the 2010 DH study by examining whether certain models or their service configurations are more effective in engaging with homeless people and addressing their health and other needs. Emmi Poteliakhoff, Senior Policy Officer at the NHS Policy & Strategy Unit was the lead on the DH study and has agreed to be a member of the study's Advisory Group.

A case study design based on the principles of 'realist evaluation' (context + mechanism = outcome) will be used to examine the effectiveness of the different models in terms of 'what works, for whom, how and in what circumstances?' (Marchal et al., 2012). Realism's 'key feature is its stress on the mechanics of explanation ... programs work (have successful 'outcomes') only in so far as they introduce the appropriate ideas and opportunities ('mechanisms') to groups in the appropriate social and cultural conditions ('contexts')' (Pawson and Tilley, 1997: 55 and 57). Mechanisms explain what it is about the system that makes things happen. A case study approach allows researchers to investigate a contemporary phenomenon within its real-life context, when the boundaries between phenomenon and context are not clearly evident.

In our study, the role of contextual factors and mechanisms in the delivery of health care to homeless people and how these influence outcomes will be examined. Table 1 identifies many factors relating to 'context' and 'mechanisms' that will be examined in each case study site. We also expect others to emerge as the study progresses. In relation to context, for example, we will examine the wider health and care system including commissioning, type of provision (NHS / voluntary sector), financing, staff and physical resources, and the availability and accessibility of complementary services such as for substance misuse problems.

Local housing and homelessness policies are important contextual factors affecting health care for homeless people. For example, the length of time that homeless people remain in a hostel and in a locality may affect continuity of health care. Over the last 2-3 years, the length of stay of homeless people in hostels has been reduced substantially in many areas due to the contract and funding arrangements imposed by local authority service commissioners. This could have implications for the delivery of health care if homeless people are moved to another area. We will examine how this is managed at each case study site (CSS), and arrangements that are in place to facilitate the transfer of such people to other primary health care teams.

In terms of 'mechanisms' we will examine strategies used by CSS staff to engage with homeless people and encourage them to accept health care, the types of assessments that are undertaken to identify health and other needs, the ways in which the staff manage difficult or challenging behaviour, and their knowledge of and integration with other services required by homeless people.

In the analyses, we will examine the interactions of the 'context conditions', the 'underlying mechanisms' and 'outcomes' of the different models of primary health care services. The theoretical framework for the analyses of why homeless people do / do not use mainstream health care services will be informed by the Behavioral Model for Vulnerable Populations which was developed by Andersen (1995), and tested and refined in a study by Gelberg *et al.* (2000) of homeless people's health services utilisation and physical health outcomes. This model has three domains: (i) predisposing characteristics, personal and family resources, community and health services resources, and perceived health needs; (ii) health behaviour, such as self-care and use of health

services; and (iii) outcomes, such as general satisfaction with care, and the availability, accessibility and convenience of health services.

Table 1 Framework to be used for the evaluation of the primary health care Case Study Sites

Context	Mechanisms	Outcomes (objectives 3-6)
<p>The size and geographical spread of the local homeless population</p> <p>Availability of resources (funding and staff) to enable CSS to respond to local homeless people's health needs</p> <p>Availability of competing primary health care services</p> <p>Availability of local health and social care agencies, and their knowledge of the CSS and referral procedures</p> <p>Availability of resources for other local health and social care agencies to provide services to CSS referrals</p> <p>Local commissioning influences, e.g. catchment area, population to be served by CSS, exclusion groups</p> <p>National policy influences relating to who is eligible / not eligible for NHS care</p> <p>Local authority influences, e.g. length of time homeless people can remain in a hostel in the locality</p>	<p>Staff's understanding of homelessness and their attitude towards working with homeless people</p> <p>Composition of team and their clinical expertise in assessing and treating health problems of homeless people or referring to appropriate services</p> <p>Staff's knowledge of the local homeless population and of services to which homeless people can be referred</p> <p>Flexibility and accessibility of the service</p> <p>An environment that is welcoming and acceptable to homeless people</p> <p>Person-centred approach to health care that encourages engagement and continuity of care</p> <p>Holistic approach that also identifies and responds to housing, social and welfare needs</p> <p>Champions health promotion and health screening</p> <p>Availability of protocols and ability of staff to manage difficult or challenging behaviour</p> <p>Integration with mental health, dental, substance misuse, social care services, homelessness and other services required by homeless people</p>	<p>Primary outcome</p> <p>6 indicators of engagement in health screening (Table 2):</p> <ul style="list-style-type: none"> • Weight / BMI • Smoking • Hepatitis A • Mental health • Alcohol • TB <p>Secondary outcomes</p> <p>Continuity of care and outcomes for five Specific Health Conditions (SHCs) (Table 3):</p> <ul style="list-style-type: none"> • Hypertension • Chronic chest disease • Depression • Alcohol related problems • Drug related problems <p>Oral health status and receipt of dental care</p> <p>Self-ratings of health status and well-being over time</p> <p>Health-related behaviours over time</p> <p>Service-users' satisfaction with the CSS</p> <p>Utilisation of other health and social care services, including substitute primary care services (walk in, A&E) and unplanned hospitalisations</p> <p>CSS staff and local service-providers' satisfaction with the CSS</p> <p>Addressing the unmet needs of local homeless people</p>

Integration

The overall health and wellbeing of homeless people depends, to some extent, on factors beyond their access to primary health care services. For each CSS, we will examine (i) the extent, scope and depth of integration with other services, and (ii) the types of integration.

Extent, scope and depth of integration

The extent and scope of integration between each CSS and relevant local services will be measured drawing on Browne *et al.*'s (2004) 'Integration of Human Services Measure' (see also Ye *et al.* 2012 and Joly *et al.* 2011 taxonomy of interagency working). Information will be collected about all relevant local services and whether they are integrated with the CSS. Distinctions will be made between types of services, *i.e.* health, housing, social care and welfare agencies, and between NHS, local authority or voluntary sector agencies. Distinctions will also be made between organisations involved at different stages of care such as hospital services (vertical integration), and those that are providing complementary services (horizontal integration).

The 'depth' of integration between the CSS and *each* service will be scored along a continuum of involvement. During interviews with CSS staff, they will be asked: (i) to what extent *are you* involved with the service? and (ii) to what extent *should you* be involved with the service? Participants will be asked to rate actual and expected levels of integration by selecting one of the following choices.

0 = no awareness: no awareness of the existence of the other service;

1 = some awareness: awareness of the service but no direct communication or shared working with them.

2 = formal brief communication: brief formal communication with the service for example receiving information by post or email.

3 regular communication: regular communication with the service perhaps at meetings or other events.

4 = High level of joint working with a focus on the individual:

5. =High level of joint working with the service but this is specific to work around specific clients or referrals between services. Does not continue if no client in common. Collaborative approach with a focus on the community or population: Have a collaborative approach to working with the service and have carried out shared projects, perhaps involving informal agreements or formal written agreements. Not solely based around individuals but takes a broader community based or population based approach.

To obtain reciprocal data on actual and expected integration, local stakeholders and other health and social care agencies will also be asked to rate their actual and expected level of integration with the CSS, using the above method.

In the interviews with CSS staff and other agencies, we will also explore the reasons for their integration score ratings, explanations for differences in actual and expected integration scores if applicable, changes in levels of integration over time, and any future plans for integration.

Information will also be collected from the service-users about their views and experiences of service integration (using a modified version of The GP Patient Survey).

Types of integration

Drawing on the work of Sara Shaw and Rebecca Rosen (2013), the 'types' of integration within each CSS and between the CSS and other agencies will be examined. This will include:

- a. Systemic, *e.g.* coherence of policies, rules and regulatory frameworks at all organisational levels.
- b. Normative, *e.g.* shared values in coordinating work; collaboration in delivering health care.
- c. Organisational, *e.g.* mergers, contracts between different parties, pooled budgets.
- d. Functional, *e.g.* merging different functions such as non-clinical support and back-office functions.
- e. Informational, *e.g.* different services are integrated at an organisational level, such as use of clinical information systems, joint training.
- f. Clinical, *e.g.* coordinating patient care across clinical teams and organisations, shared clinical records.

Information about types of integration will be collected through interviews with the CSS manager and staff, and with local stakeholders and agencies, including commissioners, and through our review of documentary evidence. Both Sara Shaw and Rebecca Rosen have agreed to be members of our Advisory Group and will advise on the design of relevant instruments.

Key phases of the study

There will be two key phases of the study:

Phase 1: (Objectives 1 and 2) A systematic 'mapping exercise' across England of the availability of primary health care services for homeless people, their integration with other health and social services, and how they fit into the four broad models described above (specialist health centres, mobile teams, GP practices with homeless services, generic GP practices).

Phase 2: (Objectives 3-7) An evaluation of case study sites (CSS) within the four different models of primary health care provision to homeless people. The framework for the evaluation is detailed in Table 1.

5.3 Phase 1: National survey of specialist primary health care services for homeless people

A systematic 'mapping exercise' will be carried out across England of specialist primary health services for homeless people. Using Homeless UK (a national directory of homeless services www.homelessuk.org) provided to us in a database by Homeless Link, managers of homelessness services (numbering 1116 hostels and 211 day / drop-in centres in 2013; some managers will be responsible for more than one project) will be contacted by phone or email to find out their arrangements for accessing primary health care for their service-users, and the contact details of any local specialist primary health care services for homeless people. The managers of the specialist health services will then be contacted by telephone or email, provided with information about the study, and asked to complete a semi-structured questionnaire about the key factors of their service, e.g. origins of the service and organisational changes over time; opening hours and type of registration; composition of the team and client groups served; homeless patient numbers; types of services provided and where; integration with other services; resources and funding sources; and the perceived strengths and limitations of their scheme. In areas that are identified as having a homeless population but no specialist homeless health service, homelessness service managers will be contacted and asked to complete a semi-structured questionnaire about how primary health care is accessed by their clients, and their views of the effectiveness of these arrangements. This will assist in identifying unmet needs.

To increase response rates, follow-up contacts and telephone interviews will be undertaken where necessary. The team has experience in working with and accessing homelessness services, and good response rates (81-94%) have been achieved in our other mapping exercises of homeless service provision (Crane and Warnes, 2001b; Crane and Warnes, 2011a; Warnes *et al.*, 2005).

Data from the mapping exercise will be entered into an SPSS database, categorised by NHS Area Teams and county, and distinguished according to broad population sizes from the rural-urban classification for England (major urban areas 100,000+; other urban areas >10,000-99,999; and small towns / rural areas 10,000 or less) (Department for Environment, Food and Rural Affairs, 2013). Health schemes will be categorised according to whether they are a mobile team only or facilities-based (health centre for homeless people or GP practice), and by key characteristics of their services, including integration with other health and social care services. The analyses will examine the prevalence and types of specialist primary health care services for homeless people in relation to the size of the homeless population in the area. Associations will be explored between different models and service characteristics (e.g. opening hours, types of registration), ways of working (e.g. outreach services), resources, composition and level of staff, homeless patient numbers, and integration with other agencies.

5.4 Phase 2: Evaluation of different models of primary health care provision

An evaluation will be undertaken of different models of providing primary health care to homeless people. Eight primary health care services that reflect the different models will be selected as case study sites (CSSs). The mapping exercise will inform their final selection, but at this stage we anticipate the CSSs will be:

1. Two health centres specifically for homeless people;
2. Two mobile teams that run sessions in homeless services such as hostels and drop-in centres;
3. Two GP practices with special services for homeless people;
4. Two generic GP practices that provide 'usual care' to the local population, including to homeless people, in localities that do not have a specialist homeless health service.

We expect that population sizes and concentrations of homeless people will influence the model(s) found in different areas and that this categorisation will result in the selection of CSS which are integrated with other local health and social care service providers to varying extents. At least two CSS will likely be in Nottinghamshire / South Yorkshire, and at least two within daily commuting distance of London (see justification of costs). One health centre for homeless people and two GP practices that provide specialist services to homeless people have so far been contacted and have provisionally agreed to participate.

In each model we will use mixed methods to evaluate how the context and mechanisms of care delivery affect outcomes. Data will be collected through interviews with CSS managers and staff, and representatives of local health, social care and welfare agencies. The work of the CSS will be observed and documentary evidence reviewed. To assess the effectiveness of each model, we will recruit homeless people who use each CSS and collect information (from CSS records and by interview with the participants) about the services they receive, their health and well-being and satisfaction with care over a 12 month period. Costs of service provision will also be collected.

5.4.1 Outcomes

Several outcome measures will be used to determine the relative effectiveness of each model in meeting the health needs of homeless people.

Primary outcome: The engagement of homeless people in health screening

Six 'Health Screening Indicators' (HSIs) have been selected to measure the effectiveness of the CSSs in engaging homeless people in health screening (Table 2). Screening of homeless people for a variety of health problems is considered a priority, and various international and national guidelines and recommendations have been issued recently. The six screening indicators selected for this study are derived from existing guidelines, and from the expert opinion of Dr Ford (research team member), who has also consulted with 2 generic GPs, 2 GPs specialising in homelessness, and a hospital physician. While we acknowledge there is debate on the usefulness of some screening measures used for the general population, expert opinion suggests screening for blood pressure and drug problems, for example, is particularly important for the homeless population.

The six indicators selected for the primary outcome are a set of minimum standards or 'markers' from a clinical perspective. They extend beyond screening alone, as evidence of an intervention is also sought if a problem has been identified. While it is not possible to distinguish between a score of 3 or a score of 4 in absolute terms, the combination of screening *and* intervention gives a clear indication of the quality of clinical care provided by a particular model. Furthermore, the primary outcome measure is one of a number of aspects that will be analysed to determine the effectiveness of each model. The secondary outcomes will also be important factors in understanding how each model works, for whom, and its effectiveness.

Table 2 Health Screening Indicators for the primary outcome

Indicator	Measure		Sources / screening recommendations
Weight / BMI	1	Documented in last 6 months and action for underweight (BMI <18.5) / overweight (BMI ≥25.0)	WHO BMI classification. Coufopoulos and Mooney, 2012; Bonin <i>et al.</i> , 2010.
	0	Not documented in last 6 months or no action if underweight / overweight	
Smoking	1	Smoking status recorded in preceding 24 months and intervention if a smoker	QoF indicator. Hewett, 2013.
	0	Smoking status not recorded or no intervention if a smoker	
Hepatitis A	1	Record of having received 2 vaccinations for Hep. A in last 10 years or vaccination programme in progress	Salisbury and Ramsay, 2013; Wright, 2014.
	0	No record of 2 vaccinations for Hep. A in last 10 years and no vaccination programme in progress	
Mental health	1	Record of screening for mental health problems in last 12 months, and intervention if required	Bonin <i>et al.</i> , 2010; Hewett, 2013; Wright,

	0	No record of screening for mental health problems in last 12 months, or no intervention if a problem	2014.
Alcohol	1	Record of screening for alcohol problems in last 12 months, and intervention if required	Bonin <i>et al.</i> , 2010; Hewett, 2013; Wright, 2014.
	0	No record of screening for alcohol problems in last 12 months, or no intervention if required	
TB	1	Record of TB screening within last 12 months or screening offered	Hewett, 2013; NICE, 2012; World Health Organization, 2013.
	0	No record of TB screening within last 12 months and no screening offered	

There is no mandatory requirement in the UK for primary health care services to undertake screening indicated by available guidelines, although some incentive exists where recommendations coincide with the NHS Quality and Outcomes Framework (QOF) for GPs. Models will be evaluated on the primary outcome over a 12 month follow up period. The CSS records of each participant recruited will be accessed at the end of the follow-up period and whether or not (score 1 or 0) the participant has been screened on each of the six indicators will be noted (giving a total score range of 0 - 6).

Secondary outcomes:

- 1 ***Continuity of care and outcomes over 12 months for Specific Health Conditions (SHCs).***
Five health conditions, which may be difficult to manage because of homeless people's lifestyle or may require integration with other agencies, have been selected to study in detail in order to assess how the CSS responds to the illness or problem and how effective it is in providing care and treatment to the homeless person. The five 'Specific Health Conditions' (SHCs) are:
 - hypertension;
 - chronic chest disease, including chronic obstructive pulmonary disease and asthma;
 - depression;
 - alcohol related problems;
 - drug related problems

The reasons for their selection are summarised in Table 3. It is not feasible to study all common health problems experienced by homeless people, e.g. foot conditions.

Given the prevalence of ill-health in the homeless population and the relatively common nature among the group of the conditions selected (Crane and Warnes, 2011a; Wright, 2014), it is likely that most of the people recruited to the study will have at least one of these conditions. Among homeless people, the following prevalences are reported in studies: (i) chronic chest problems, 17-29%; (ii) depression, 30-43%; (iii) hypertension, 17-33%; (iv) alcohol problems, 27-50%; and drug problems, 39-54% (Crane and Warnes, 2011a; Homeless Link, 2014; Kinchen and Wright, 1991; Lee *et al.* 2005; Mares and Rosenheck, 2011; Snyder and Eisner, 2004; Szerlip and Szerlip, 2002; Wagner *et al.*, 2013; Zlotnick and Zerger, 2008). It is expected that the distribution of the SHCs will be similar between the CSSs, and this will be checked during the baseline statistical analysis.

Table 3 Specific Health Conditions, reasons for selection and instruments

Condition	Reason for selection	Instruments to measure change in health status of SHC
Hypertension	Long-term condition likely to be managed by CSS.	QoF indicator of BP control / improvement in BP.
Chronic chest disease	Common. Long-term condition likely to be managed by CSS.	Instrument to measure change in symptoms and respiratory well-being. COPD assessment test http://www.catestonline.org/ Whether participant has received influenza vaccine and / or pneumococcal vaccine

Depression	Common. May be managed by CSS or involve integration with mental health services.	Instrument to measure change in level of depression. – PHQ-9
Alcohol related problems	Common. May involve integration with alcohol services, and CSS to manage related physical health problems.	Instrument to measure change in alcohol intake (Audit-C) and some questions from FAST
Drug related problems	Common. May involve integration with drug services, and CSS to manage related physical health problems.	Some questions from the drug screening questionnaire DAST to measure change http://www.sbirtoregon.org/resources/SBIRT%20-%20DAST.pdf .

The following five outcomes will be used to monitor the effectiveness of the CSS in providing health care for the five SHCs. SHC outcomes 1 and 2 assess processes of care by the CSS; SHC outcomes 3 and 4 measure client perceptions of the quality of care; SHA outcome 5 assesses effect on health.

SHC Outcome 1: Whether or not there is evidence in the CSS records at the end of follow up that the CSS **started treatment / offered advice / made a referral** (collectively a treatment plan) to a person who they identified as having a SHC. (score 1 or 0)

SHC Outcome 2: Whether or not there is evidence in the CSS records at the end of follow up that the CSS **provided continuity of care / follow up as required** for a person who they identified as having a SHC and who started a treatment plan. (score 1 or 0)

SHC Outcome 3: Whether the person believed that they had **received sufficient information / explanation from the CSS** to enable them to understand their SHC and how they could help manage or overcome it (asked at final interview with participant). (score 1 or 0)

SHC Outcome 4: Whether the person was **satisfied with the treatment plan that the CSS arranged or provided** for their SHC (asked at final interview with participant). (score 1 or 0)

SHC Outcome 5: **Change in health status of SHC** from baseline to final follow up (score 1 for improvement or 0 for no change or deterioration), using validated instruments specific to the SHC that are administered at baseline and 8 months.

The instruments that are likely to be used are summarised in Table 3, but they will be discussed and agreed with the Advisory Group, PPI Group, and other experts. Decisions will also be made, with expert input, about what might be reasonably expected to be an improvement for each SHC.

- 2 Oral health status and receipt of dental care** Poor oral health and dental problems are common among homeless people and have an adverse effect on quality of life. Access to dental care is believed to have a beneficial impact on oral health outcomes (self-reported dental problems e.g. pain, felt need), and on global and oral health related quality of life (OHRQoL), dental anxiety, satisfaction with dental care, and positive health behaviours (oral hygiene practices, sugar consumption patterns and smoking). The impact over time of the CSS on homeless people's receipt of dental care and oral health status will be assessed. Factors predicting dental access will be analysed by extent of integration using a modification of Gelberg *et al.*'s (2000) model of access for vulnerable populations as the theoretical framework (described earlier). The CSSs which have greater integration with primary care dental services are hypothesised to have higher rates of access to dental care and more positive impacts on oral health outcomes. Instruments to measure the impact of the CSS on dental service use, dental anxiety, and changes in self-reported oral health status and oral health quality of life will be administered to all participants at baseline and 8 months. Measures will be used from the Adult Dental Health Survey, the Household Survey and The GP Patient Survey, and will also include the Oral Health Impact Profile (OHIP-14), and the Global self-rating of oral health and change, which is used to anchor data for cross sectional and longitudinal analyses of oral health related quality of life outcomes (Locker *et al*, 2004; O'Sullivan *et al*, 2011; Steele and O'Sullivan, 2011). The self-reported and oral health related quality of life measures have been validated for use in homeless populations by this study's co-investigator (Daly *et al.*, 2010).

3. Self-ratings of health status and well-being over time. Using the SF-8 (<http://www.sf-36.org/tools/sf8.shtml>) (a widely used and well validated measure of health-related quality of life), and Short Warwick Edinburgh Mental Well-being Scale (SWEMWS), homeless people will be asked to rate their health status and well-being at baseline and 8 months so that changes over time can be ascertained. The SF-8 captures how people perceive their health, and whether health problems affect their activities and social functioning. The SWEMWS collects details of how people have been feeling during the previous two weeks. Both instruments are short, which is ideal for homeless people, and have been used in the UK's Household Longitudinal Study.

4. Health-related behaviours over time Information on dietary, exercise, and smoking behaviour and advice given by the CSS will be collected at baseline and 8 months to assess the impact over time of the CSS in improving homeless people's health-related behaviour. Alcohol and drugs will be studied as SHCs. The questions to be used have been discussed and agreed with the Study Steering Committee

5. Service-users' satisfaction with the CSS. A modified version of The GP Patient Survey will be used to collect homeless people's views about and satisfaction with the CSS (www.gp-patient.co.uk). The GP Patient Survey includes questions about accessing the service, making appointments, waiting times, satisfaction with opening hours, and quality of care. Some questions have also been included from the General Practice Assessment Questionnaire (<http://www.phpc.cam.ac.uk/gpaq/>)

6. Utilisation of other health and social care services, and service use cost. A modified version of the Client Service Receipt Inventory (CSRI) (Chisholm *et al.*, 2000) will be used to collect data on service use over the 12 month study period. Utilisation of all primary, community (including dental) and hospital services, social services and support from voluntary sector will be included. Use of substitute primary care services (walk in, A&E) and unplanned hospital admissions will be taken as indicators of the effectiveness of the CSS in providing an accessible service for homeless people and preventing avoidable hospital admissions or re-admissions. Self-reported information on service use collected by interview will be checked and supplemented with data extracted from primary care records at the end of the study. Overall costs of service utilisation will be calculated.

7. CSS staff and local service-providers' satisfaction with the CSS. Perspectives of, and satisfaction with, the CSS will be sought during interviews with CSS staff and other agencies.

8. Addressing the unmet health needs of local homeless people. Information will be collected through interviews with homeless people, CSS staff, and local agencies including staff at A&E departments, about whether the CSS is addressing the unmet health needs of the local homeless population.

5.4.2 Data collection and methods

At each CSS, there will be three phases of data collection spread over 10 months (see separate flowchart), and mixed methods will be used to collect data on the context, mechanisms and outcomes from each CSS (Table 1). Throughout the study, interviews will only be conducted with homeless people and workers who give informed and written consent.

Interviews with CSS manager and CSS staff about service delivery to homeless people

Using an interview schedule and building on the information collected during the mapping exercise, more detailed operational and performance data will be collected from the CSS manager about: (i) the origins of the CSS and its development and changes over time; (ii) its current operation, including staffing and skills-mix, client groups served, facilities, opening hours, registration, types of services provided and where; (iii) extent and intensity of integration with local homelessness services and with health, dental, welfare and social care services; (iv) funding and changes over time; (v) homeless patient numbers, including number removed from practice list or refused registration in last 12 months and reasons; and (vi) involvement of the CSS in local strategy and service development, e.g. CCGs, Joint Strategic Needs Assessment, and the Joint Health and Wellbeing Strategy.

Using an interview schedule, CSS staff members (average 8) will be interviewed and information gathered about: (i) length of time with the CSS, working hours, qualifications, role within the team, and experiences of working with homeless people and other underserved groups; (ii) types of services they provide to homeless people; (iii) methods of encouraging homeless people to engage with the CSS, attend consultations, and follow health care and treatment programmes; (iv) strategies for working with homeless people who have multiple needs or challenging or reticent behaviour; (v) ways in which they address health related behaviours such as smoking, oral hygiene, and dental attendance with homeless people; (vi) awareness of other local services and their eligibility criteria; (vii) collaboration and integration with other local agencies, including primary dental care and

substance misuse services, and their effectiveness; (viii) perspectives of the CSS's strengths, weaknesses and limitations in addressing homeless people's unmet health needs; and (ix) recommendations for improvements or changes to the CSS. With permission, these interviews will be recorded.

Towards the end of the third phase of data collection, a focus group will be held with the CSS staff to gather their reflections on their work as a team, collective strategies to engage with homeless people, the processes of integration with other services, and service elements of the CSS that work well and not so well and their suitability for replication in other areas with homeless people and other underserved groups.

Transcriptions from the staff interviews and focus groups will be entered into NVivo. A coding frame incorporating issues and themes revealed by the open-ended data will be developed by the research team through an iterative process.

Longitudinal case studies of homeless people's health, service use and outcomes

At each CSS, longitudinal case studies will be undertaken with homeless people who use the service to find out about the help that they have received from the CSS and other services over 12 months, and changes in their health status and needs over time. They will be interviewed at baseline and after 4 and 8 months. On each occasion, information will be gathered about their circumstances, health problems and service use for the last four months, resulting in 12 months' data overall.

Inclusion criteria: (i) aged 18+ years; (ii) currently homeless or have been homeless at some time during the last 12 months; (iii) have been a patient with the CSS for at least four months; and (iv) at least one previous consultation with a CSS doctor or nurse during the last four months.

Homeless people are defined as: rough sleepers; squatters; residents of hostels, bed-and-breakfast hotels, or other temporary accommodation; and 'sofa surfers' who are staying temporarily (<3 months) with friends or relatives in makeshift arrangements. By focusing on those who have been homeless at *some time* during the last 12 months, this will capture people who frequently move in and out of homelessness. A longer registration with the CSS cannot be considered due to the mobility of this particular client group.

Sample size and attrition: 96 homeless people from each of the four models will be recruited (total $N = 384$). They will be divided evenly, as far as possible, between the two CSSs in each model. We estimate the attrition rate (through loss of contact or transfer to another GP service) will be 33%. Hence, we expect to interview at least 80 people in each of the four models at 4 months and 64 people at 8 months (final total $N = 256$).

Sample size requirement: The primary outcome variable is the 6 item Health Screening Indicators tool, with a minimum score of 0 and a maximum score of 6. Given the innovative nature of this tool, there are no previous data on its level of variation. Extensive simulations exhibit a maximum standard deviation (SD) of 2.0. An outcome variable with a SD of no more than 2.0 would necessitate a minimum required sample size of 64 in each of the four models in order to detect a difference of 1 point on the 6 item tool between any 2 types of model, with size = 5% and power = 80%.

The possibility of small percentages of homeless people with a particular SHC means that we might only be able to detect relatively large differences in continuity of care for that SHC between the four models. For example, if only approximately 30% of homeless people in any group have a particular condition, it would be difficult to identify a difference between groups in continuity of care for that condition of less than 40%. This will therefore be managed by considering continuity of care across all the conditions combined, as well as assessing each SHC separately if numbers permit.

The estimated attrition rate is based on our previous success in retaining homeless people in longitudinal research. In the FOR-HOME study, which followed up 400 homeless people who were rehoused for 18 months, the attrition rate was 19% (Crane *et al.*, 2011b). In the subsequent Rebuilding Lives study, which followed up 297 of these participants after five years, the attrition rate was 22% including deaths and imprisonment (www.kcl.ac.uk/scwru/res/hrp/index.aspx). Although the follow-up time in the proposed study is considerably less, the higher attrition rate takes into account that the participants are still homeless and more likely to move around.

Recruitment: For the specialist homeless health services, the case study participants will be recruited at the CSS with help from the CSS staff (costed as research costs). Over a two-week period (or until the required number is achieved), consecutive service-users who fit the study criteria will be invited to participate. The study will be explained briefly to service-users by the CSS staff, and those who are interested will be introduced to the research team (who will be on site or easily available during this period). The research team will carry out a short 'screening exercise' based on inclusion criteria to

check eligibility, and explain the study in more detail to those who are eligible. They will be given a study information sheet and details will be collected of how they can be contacted in the next two days to find out if they are willing to participate.

For the generic GP practices, the case study participants will be recruited at the hostel where they are staying. The hostel staff will explain the study to all residents they believe may be eligible and give them an Information Sheet about the study. The staff will then pass on to the research team the names of those who consented for their names to be forwarded. The research team will arrange to see them, determine their eligibility. Although some potential participants will be able to give details of their use of the health practice, this will not apply to all. If needed we will therefore obtain the potential participants' written consent to request the information needed to check their eligibility to participate with the practice (date registered with the CSS and date last seen a doctor or nurse from the CSS). The practice will then be given a copy of the consent form and an information request form to complete. Once the practice has provided this information and the participant's eligibility is confirmed, the research team will explain the study again in more detail, and gain their written consent to participate.

Attempts will be made to recruit as many women as possible into the study, although it is well-recognised that their numbers are smaller and they tend to be more difficult to engage.

Interviews and data collection: The case study participants will be interviewed three times – at baseline, and at 4 and 8 months. A semi-structured questionnaire will be used to collect information at each interview. Details of the information to be collected are summarised in Table 4.

Background demographic details, and history of engagement with the CSS, will be collected from participants at baseline. Information on current living situation, employment, income, health problems and informal support will be collected at baseline and updated at subsequent interviews. Outcomes will be collected at baseline and follow up, according to the schedule in Table 4.

Continuity of care and outcomes over 12 months for Specific Health Conditions: At baseline, all participants will be asked whether they are experiencing each of the five Specific Health Conditions (SHCs; Table 3). For those who report a condition, the relevant instrument will be administered to assess their health status related to that condition. At 8 months, the same instruments will be administered again, and they will also be asked (i) whether they have received sufficient information or explanation from the CSS to enable them to understand their SHC and how they can help manage or overcome it; and (ii) whether they are satisfied with the treatment plan arranged or provided by the CSS for their SHC.

The medical record obtained for each participant will be examined for strategies used to engage participants in their health care, strategies that worked well, difficulties or challenges in providing care and reasons, and whether and how the difficulties were overcome. We will also draw on fieldwork notes regarding the tracking of each participant for follow up interviews as this contains relevant information about the person's whereabouts, and degree of contact with the CSS. This analysis will then be used to inform a discussion of engagement during the focus group with staff at each CSS.

Health related behaviours, quality of life, wellbeing and satisfaction with the CSS will be assessed at baseline and 8 month follow up.

Table 4 Summary of data to be collected from case study participants and intervals

Type of data	Secondary outcome	Months		
		0	4	8
Personal & background details, e.g. age, gender, ethnicity, homeless history	N/A	✓		
Past use of primary care services: GP registration; length of time used CSS and how initial contact made; registration with dentist and when last seen	N/A	✓		
Current circumstances, e.g. living situation, employment and income status, informal support from family and friends, physical and mental health problems	N/A	✓	✓	✓
SHC outcomes 3 and 4 – understanding of illness and satisfaction with treatment plan	1			✓
SHC outcome 5 – assessment of health status using validated instrument	1	✓		✓

Oral health and dental measures	2	✓	✓	✓
Rating of health status and well-being	3	✓		✓
Health-related behaviours: diet, exercise, smoking	4	✓		✓
Perspectives of and overall satisfaction with CSS	5	✓		✓
Service utilisation (CSS, other health, social care and welfare) in last 4 months	6	✓	✓	✓

Conducting the interviews: Interviews will be conducted at times and places convenient to participants. Wherever possible they will take place within a service or in a public place. If it is necessary to conduct them elsewhere, then two researchers will be present. Each interview will last about 60 minutes, and if necessary information will be gathered over more than one interview. Wherever possible, the same researcher will conduct all three interviews with a participant to enable continuity. Participants will be offered £10 for each interview as appreciation of their time and input. Repeated attempts will be made to arrange interviews in cases of missed appointments.

Maintaining contact over time: Retaining homeless people in longitudinal research is difficult and time-consuming. In our previous studies, multi-faceted and effective tracking systems have been implemented, and persistence, patience, flexibility and use of multiple contact methods have resulted in high retention rates (Crane *et al.*, 2011b; Crane and Warnes, 2002; also section on attrition). Several tracking methods will be used to maintain contact. At each interview, details will be collected from the participants about how they can be contacted, relatives and friends that we could approach if necessary, and services and locations where they could be found. We will also seek their permission to contact the CSS staff, hostel and day centre workers in the area, and other staff and agencies to find out their whereabouts. Other strategies that have proved effective include freepost 'contact cards' that they can return, and Internet searches and social networking sites.

Data collection from medical and other records of homeless participants

After the 8 month interview, information about care received by each case study participant will be collected from their records held by the CSS. CSS administrative staff will be requested to extract the data with facilitation from the research team (Joly, co-investigator, has experience of this). Information will be extracted by the CSS for:

- Service use for the health economic analysis, including CSS consultations and use of other health services over last 12 months, e.g. secondary care, hospital admissions, and use of A&E and walk-in facilities.

The CSS staff will be requested to provide print outs of the records for the relevant twelve months for each participant. This will include all consultations, and copies of letters, reports, results and referrals made by or received by the CSS during this time. The research team will then use these to extract relevant data for:

- Engagement in health screening for the six selected Health Screening Indicators for the primary outcome (Table 2).
- Treatment and continuity of care for the five Specific Health Conditions (SHC outcomes 1 and 2, Table 3), including advice about lifestyle, referrals and care provided by other agencies, and take up;

Observations and review of documentary evidence

Up to five days' observation of selected aspects of the work of the CSS will be carried out during the second and third phases of data collection to add to the information collected about processes and behaviours. With permission, this will involve observations of: (i) ways in which CSS staff engage with homeless people, particularly those who are reticent or have challenging behaviour; and (ii) interactions and collaborative ways of working between CSS staff and other agencies. Observations will be undertaken, in staff meetings, and by shadowing staff where appropriate. Field notes of these activities will also be made throughout the data collection phases at each CSS.

We will review documentary evidence about the operation and performance of the CSS, including internal reports, Care Quality Commission reports, results of patient satisfaction surveys, QoF returns and contributions to local Joint Strategic Needs Assessment and Joint Health and Wellbeing Strategy. Broader contextual data about the location served by the CSS will also be gathered from documents and reports: (i) population size and index of deprivation; (ii) local homelessness services and their operation (e.g. hostels, drop-in centres, street outreach, soup runs); (iii) number of homeless people

in the area (rough sleepers, hostel residents, B&B dwellers, numbers presenting as homeless to the local authority); (iv) local health and homelessness strategies; and (v) availability and accessibility of local health, welfare and social care services.

Interviews with local health, social care and welfare agencies and other stakeholders

To provide information on the wider context in which the CSS delivers care to homeless people, semi-structured interviews will be conducted with: local health services, including primary dental care; homelessness sector services (street outreach workers, drop-in centre and hostel staff); and social care and welfare agencies that work with homeless people. Information will be gathered about: (i) their work with homeless people; (ii) their awareness of the CSS and their referral / contact procedures; (iii) use of the CSS by their clients or reasons for non-use; (iv) collaboration and integration with the CSS and its effectiveness; (v) perspectives of the CSS's strengths, weaknesses and limitations in addressing homeless people's unmet health needs; and (vi) recommendations for improvements or changes to the CSS. With their permission, these interviews will be digitally recorded. Each person will be asked to complete a short structured questionnaire to rate their satisfaction with the CSS.

Interviews will also be conducted with local stakeholders, including a member of the CCG, the Local Authority Public Health Board, the local Health and Wellbeing Board, and the Local Authority homelessness department. Information will be gathered about the local context of homelessness and the health care needs of homeless people, local strategies and plans for health care delivery to homeless people and other underserved groups, the role of the CSS in local health provision, and their perspectives of the effectiveness of the CSS in addressing homeless people's unmet health needs.

Interviews with homeless people not using the CSS

In each CSS area, short semi-structured interviews will be conducted with up to 30 homeless people who are not using the CSS to find out about their awareness of the CSS, reasons for not using it, their health needs and whether and where these are being met. The purpose of these interviews is to find out how well the CSS is known and accessed in the area. The participants will be recruited opportunistically on the streets and at homeless settings, e.g. drop-in centres, and interviewed once by one of the PPI group. They will be offered £5 for the interview.

5.4.3 Data analysis

The first step in the data analysis will be to build a descriptive picture of the context and mechanisms of each CSS from interviews with staff, stakeholders and documentary evidence (Table 1). Similarities and differences between and within models will be examined, including staff skill mix, types of services provided, the flexibility and accessibility of the CSS (e.g. eligibility criteria, opening hours, type of registration), and its degree of integration with various other health, social care and welfare agencies. Associations will be explored between types of models, contexts and mechanisms, and perspectives of and satisfaction with the service by CSS staff and other agencies.

The second step will be to assemble a service user level database containing background demographic and other information about the case study participants, their health and service use profiles, and data relating to the quantitative outcomes collected from them at each assessment point. The information collected from the review of CSS records will also be entered into this database.

Summary statistics for the whole database, relating to both background characteristics of participants and quantitative outcomes, will be produced, along with histograms to enable assessment of normality so that appropriate statistical tests are employed. The data will be checked for missing items, although we do not expect this to be a serious problem as information will be collected from participants in face-to-face interviews, or by researchers from medical records.,

Retention rates at 4 and 8 month follow up will be checked and reported, and characteristics of participants who were lost to follow up will be compared with those of the people who were retained in the study to the final 8 month end point using appropriate statistical tests.

A range of indicators will be used to measure the relative effectiveness of the four models of service delivery, and each indicator will be analysed separately. Firstly, the four models will be compared with respect to the primary outcome variable (the 6 item Health Screening Indicator, score 0-6) using ANOVA (assuming a normal distribution). An in-depth comparison will then be performed using appropriate regression techniques to explore the associations between the Health Screening Indicator and the demographic, background and health profiles of service users. The model type will be entered as a dummy variable.

The four models will then be compared for each of the secondary outcomes. The prevalence of each of the five SHCs will be compared across the models using the chi square test. The analysis of each SHC will then proceed using just the subgroup of homeless people having the relevant condition. Each of the five dichotomous SHC outcomes within each SHC will be compared across the four models using the chi square test.

Comparisons will be made between oral health status, receipt of dental care and the four models, including their mechanisms of care, and their extent of integration with primary dental care services. Comparisons will also be made between access to dental care and impact on self-reported oral health status and oral health quality of life, dental anxiety and satisfaction.

The continuous outcome variables (PCS and MCS of SF-12, SWEMWS (wellbeing) and service user satisfaction with the CSS will each be compared between the four models at baseline, and change from baseline to 8 months will be calculated and assessed by model type. Stepwise linear regression modelling will then be performed in order to adjust for other factors (such as personal characteristics, length of time using CSS, service features of the CSS, and the CSS's response to health and other problems) whilst comparing the four models. This will be carried out initially at baseline, in order to include as many service users as possible, but also at 8 months if changes have been observed. The four models will be compared with respect to health related behaviours using a similar approach.

Differences in outcomes between models will be investigated in relation to the particular contexts and mechanisms of care to seek understanding of reasons underlying the patterns observed. The quantitative information will be triangulated with data from the qualitative interviews with case study participants and staff about accessing health, dental care, and other services, including the flexibility and timeliness of services, their eligibility criteria and the attitudes of staff. Comparisons will be made between the health status and well-being of the case study participants and of the general population in similar age groups (using data from the UK's Household Longitudinal Study). The satisfaction of the participants with the CSS will be compared to that of the satisfaction of the general population with their GP service, using data from The GP Patient Survey. Receipt of dental care by the four models will be compared with local and national population's access to primary dental care, using area based and national NHS statistics.

Economic analysis

The resource implications and costs of providing health care services for homeless people will be explored at two levels. First, information on the staff, facilities and services provided by each CSS will be assembled from the interviews with service managers and documentary evidence that is gathered. The health economist will ensure that appropriate questions are asked in interviews to capture information, skill-mix and time dedicated to the care of homeless patients in the CSSs. Costs will be assigned to the resources that are used so that a total cost of service provision, and an average cost (per homeless person treated) can be determined over the 12 month study period. Human resource costs will be based on staff time inputs (covering medical, nursing, allied and administrative) and valued using national tariffs, inclusive of all estates and indirect overhead costs (Curtis, 2013). Costs of materials and equipment (e.g. mobile units) will be obtained from local financial managers. Data will be assembled first by CSS, and then by model and compared.

Second, a micro costing exercise at the level of homeless participants will be performed. Data on service utilisation will be collected from homeless people by self-report at the three interview points (baseline, and 4 and 8 months follow-up, each requesting 4 month recall) to provide information over a 12 month period. In conjunction with representatives from the PPI group, the Client Service Receipt Inventory (Chisholm *et al.*, 2000) will be customised to reflect the pattern of services used by homeless people, and piloted. It will incorporate use of primary (GP and walk in), community (nursing, allied therapies, psychological and dental), hospital (A&E, outpatient, in-patient stays), social (housing, substance misuse services), and voluntary services. Details of all contacts, treatments, tests and medications will be requested. Self-reported service use will be triangulated with information collected from CSS patient records of each homeless participant at the end of the data collection period to provide as complete an account as possible of their utilisation of health and other services.

Service use will be valued using national tariffs (Curtis, 2013) at the individual participant level to provide a total cost over the 12 month period. Associations between service use costs (dependent variable) and participant characteristics (age, gender, homelessness history, health status, long term conditions) and model will be explored through regression analysis.

Collection of service use data is part of the main analysis of study outcomes, including measures of health screening and continuity of care for SHCs by the CSS. Use of substitute primary care services (walk in, A&E), and unplanned hospitalisations are indicators of the effectiveness of the CSS in providing accessible services and preventing avoidable hospital admission or readmissions, particular attention will be paid to these aspects during analysis.

A cost-consequences framework will be used to evaluate service use outcomes, as well as other outcomes reflecting the health, wellbeing and satisfaction with CSS of participants in relation to the staff resources, characteristics and average costs of the different models of primary health care for homeless people.

6 Projected outputs and dissemination

There will be five principal outputs from the study:

- 1 An **'Inventory of Specialist Primary Health Care Services in England for Homeless People'**, organised by NHS Commissioning Regions and NHS Area Teams. It will summarise the key characteristics of services and their integration with other agencies. It will serve as a resource tool for service commissioners and practitioners, and will identify those areas with a homeless population but no specialist homeless health service. It will be completed in month 10.
- 2 A synthesis of national and international literature on **'Primary Health Care for Homeless People: Evidence-based Practice'** from literature review A. Completed in month 16.
- 3 **Delivering Primary Health Care to Homeless People: A Guide**, will summarise the study's findings, and identify the services provided by the different models, their effectiveness in engaging with homeless people and providing continuity of care, their integration with other services and impact over time on homeless people's health and well-being, and the resource implications and costs to deliver the service. Examples will be given of interventions and ways of working and their effectiveness, and conclude with our policy and practice recommendations. It will be targeted at NHS commissioners, managers and practitioners, and will enable them to review current arrangements and practices, and develop more effective and cost-effective primary health care services for homeless people. It will be launched at the end of the study.
- 4 **A Policy and Service Review** of the context in which primary health care services for homeless people and other underserved groups in England have developed since 1990. It will identify national strategies, policies and standards for health care and be a resource for health and social care service commissioners, managers and practitioners. It will summarise evidence from literature review B and be launched at the end of the study.
- 5 **A Final Report** for the NIHR which gives a full account of the study and its findings, with particular attention to the methodology and lessons learned from conducting this type of research with a mobile and hard-to-engage population.

Academic papers will be written for health care, health service delivery, dentistry, social care, homelessness and research methods journals. With help from the PPI group, a short 'findings' paper will be produced and distributed to homeless people through service contacts.

Every opportunity will be taken by the research team to disseminate the study's findings and to impact on policy and practice. Where permissible, all outputs will be available for downloading from the study partners' web sites. The final report will be launched at a dissemination event, targeted at health and social care service commissioners and practitioners. Short 'findings' papers will be written for journals such as Health Services Journal, and Community Care. The Final Report will also be distributed to relevant agencies in other countries, including FEANTSA (the European Federation of Organisations Working with the Homeless), the American Public Health Association's Caucus on Homelessness, and the US National Health Care for the Homeless Council.

Briefing Papers will be tailored for and distributed to different professional groups, e.g. Clinical Commissioning Groups, the Royal College of General Practitioners (RCGP), the Royal College of Nursing (RCN), Faculty of Public Health, The College of Social Work, the British Dental Association, the British Association for the Study of Community Dentistry, and the British Society for Disability and Oral Health Special Care Dentistry Association. SITRA and Homeless Link (through Helen Mathie, member of Advisory Group) are both membership organisations and will assist with dissemination.

Presentations will be made to groups, such as the DH National Inclusion Health Board and the Ministerial Working Group on Preventing and Tackling Homelessness, and at conferences and seminars, including the Primary Care & Public Health Conference, the RCN Annual International Nursing Research Conference, and the RCGP Annual Conference. A presentation will also be made at the US National Health Care for the Homeless Conference.

7 Plan of investigation and timetable

The study will last 36 months. Crane and Joly will spend the first three months designing instruments and other documents for submission to NRES and local R&D. The literature reviews and mapping exercise will be undertaken during the first six months. At each CSS, there will be three phases of data collection spread over 10 months. Data collection will commence at: CSS 1 & 2 in month 7; CSS 3 & 4 in month 9; at CSS 5 & 6 in month 19; and at CSS 7 & 8 in month 21. All data collection will be completed by month 30. Data analysis (of the first 4 CSSs) will begin month 25. The final six months will be spent completing analyses, preparing reports and other outputs, and disseminating the findings. Full details are in Table 5.

8 Project management

Crane will be responsible for the overall management of the project, and Manthorpe will oversee the project budgeting and financial management. The research team will meet every six months throughout the study, and more frequently as required, *e.g.* in the first six months when the instruments are being developed and the CSSs selected, and in the latter six months when the analyses, reporting and dissemination plans are in progress. Email and phone contact will be maintained throughout the study. Most of the research team have worked together on other studies. Joly, assisted by Borysik (SITRA), will co-ordinate PPI member inputs and provide them with training and support.

Responsibility for data collection at the CSSs will be divided between Joly and Crane, and they will co-ordinate and supervise the work of Coward and the RA. Fieldwork will be a team process with two researchers working alongside each other in each CSS for the majority of the time. This will provide the flexibility and expertise required to achieve successful recruitment and retention of participants, and to manage safety issues.

Crane is accustomed to managing homelessness studies involving data collection at several case study sites across England, and Joly and Coward are accustomed to working across multiple sites. Crane also directed a three-nation study of older homeless people, with partners in Boston (Massachusetts) and Melbourne (Australia).

A Study Steering Committee of experts in public health, health inequalities, and primary health care delivery has been formed and approved by the NIHR. The following are the members:

- Liddy Goyder, Professor of Public Health, Univ. of Sheffield. Lead for CLAHRC for South Yorkshire Inequalities Team;
- Rebecca Rosen, GP, Clinical Commissioner and Senior Fellow in Health Policy at Nuffield Trust
- Sara Shaw, Senior Lecturer at Centre for Primary Care and Public Health, Queen Mary University of London.
- Jeremy Porteus, Director, Housing Learning and Improvement Network;
- Helen Mathie, Head of Policy, Homeless Link
- Gill Leng, Housing and Health Lead; Health Equity and Place, Public Health England.
- Rosemary Main, Statistician / Social Care, Department of Health.
- Andrew Casey, Director of Health, St Mungo's Broadway
- Jennifer Beecham, Professor of Health and Social Care Economics, PSSRU, University of Kent
- Mohamed Ismail, Statistician / Director, Analytical Research Ltd.

9 Ethical issues and approval by ethics committee

Approval will be obtained from a National Research Ethics Committee before fieldwork and data collection begin. Instruments and other documents will be designed and submitted for ethical review by the end of month 3. NHS R&D approval will be obtained for each CSS to participate in the study. Throughout the study, interviews will only be conducted with homeless people and workers who give informed and written consent, and medical data will only be requested about homeless people who consent. Information collected from all participants will be kept confidential.

Many homeless people have mental health or substance misuse problems, their behaviour can be difficult or challenging, and homeless sites such as hostels and drop-in centres can be volatile settings. A 'Safety Procedures Code' for interviewing homeless people has been used effectively in our previous studies. It draws on the 'Code of Practice for the Safety of Social Researchers' developed by the Social Research Association. All interviewers will inform a member of the research team when starting and completing an interview, the location of the interview, and details of the participant. The researcher's mobile phone will be switched on throughout an interview. If there are any safety issues or cause for concern, two researchers will attend an interview.

10 Patient and Public Involvement (PPI)

A PPI Group of three homeless and formerly homeless people was formed to work with the research team in preparing this proposal and bring their unique perspectives on the problems that homeless people face to the study. Two more people will be recruited to the group if the study is funded to ensure that women and young people are represented.

The existing PPI Group confirmed the importance of the study, and throughout the preparation of this proposal, has made valuable contributions about the questions that should be addressed, and the ways in which information should be collected. They suggested we should talk to homeless people on the streets who are not using the specialist health schemes to find out the reasons. They believed it is important to explore the attitudes of health care staff, and whether and how they identify patients who are homeless and in housing need. They said that we should consider the layout of the health scheme, particularly whether the reception desk affords privacy. We have incorporated all their suggestions into the study design.

PPI members will be integral throughout the study. Their continuing input and expertise will help to steer and strengthen the study's design and implementation. They will be asked to comment on draft questionnaires and interview schedules, and will be actively involved in the development of participation information sheets to ensure they are easy to read and understand. They will be involved in interviewing homeless people who are not accessing specialist homeless health schemes to find out the reasons, and will also co-facilitate focus groups in some hostels to find out the residents' perspectives of the CSS. In the later stages of the study, a workshop will be held with PPI members to discuss preliminary findings and their interpretation of these. They will also attend research team meetings.

11 Expertise and justification of support required

The proposed research is ambitious and challenging, in that it will be conducted at eight sites across England, and involves collecting longitudinal data from a hard-to-engage and mobile population, *i.e.* homeless people. This type of study is unprecedented in the UK, requiring a high level of methodological rigour, and even in the US the difficulties of undertaking evaluations of the Health Care for the Homeless projects are well documented (Post *et al.*, 2005: 12). This study brings together a strong and highly skilled multi-disciplinary team of experts in homelessness research, in the delivery of primary health and dental care to homeless people, and in health economics. Crane, Joly and Coward have extensive experience of conducting this type of longitudinal research, having successfully tracked and maintained contact with homeless and formerly homeless people for five years in the FOR-HOME and Rebuilding Lives studies. They have also undertaken evaluations of services for homeless people, including wet day centres for street drinkers, homeless sector day centres, and hostels (Crane and Joly, 2011c; Crane *et al.* 2005; Crane and Warnes, 2004). The research team members and their experiences and contributions are:

Maureen Crane (60%): qualified general and mental nurse, specialising in homelessness research for 20+ years, including longitudinal studies, international comparative research, and service evaluations. Advises governmental policy makers and service providers. Member of the American Caucus on Homelessness. Conference presentations to the Caucus at annual meetings of the American Public Health Association and conference presentations to FEANTSA (European Federation of National Organisations Working with the Homeless). Invited participant at OECD workshop on 'Integrated Services and Housing' in Paris (2012). Responsible for the study's overall design, management, analysis and reporting, and for data collection at four CSSs.

Louise Joly (100%): qualified general and district nurse who practised as a nurse in a homeless health team for six years, before completing PhD on health and homelessness. Extensive experience of tracking and interviewing homeless people, and interviewing health and social care staff. Conducted research in primary care settings, including facilitating data extraction from medical records, data management, and supervision of coding and data entry. To lead on data collection at four CSSs, and responsible for co-ordinating the work of the PPI and their training. Substantial role in study design, analysis and reporting.

Heather Gage (4%): health economist and health services researcher with extensive experience in evaluative studies and outcome measurement, including social care. Will supervise all economic aspects of study, including questions about funding of homeless health services in national survey and case studies, and the collection and analysis of service use data in case studies. Will be assisted by a health economics researcher who will undertake data analysis and calculation of costs.

Jill Manthorpe (5%): NIHR Senior Investigator Emeritus and Director of SCWRU in which the study will be based. 20+ years' experience in social care and applied health research focusing on their interfaces, interprofessional activity, and vulnerable populations. Will contribute to study design and management, support for research team, and oversee project budgeting and financial management.

Blánaid Daly (0.5%): Senior Clinical Lecturer and discipline lead for Special Care Dentistry at KCL Dental Institute. Provided dental services to homeless people for 12 years and set up two dental services for homeless people. Completed PhD on oral health needs of homeless people. Member of Chief Dental Officer's dental task group looking at access for vulnerable people (2013). Will advise and analyse questions on dental health and use of dentists.

Vic Rayner and Burcu Borysik (15 days): Rayner is CEO of SITRA, a voluntary membership organisation specialising in housing with care, support and health. Has worked in housing sector for 15+ years and well connected to providers and commissioners of homelessness and housing support services. Provides information and policy advice to government departments. With Borysik (research/policy officer at SITRA) will assist with liaising with organisations, mapping, PPI and dissemination.

Chris Ford (10 days): GP for 30+ years (retired 2012), with special interest in drug and alcohol misusers with multiple health needs. Founder of Substance Misuse Management in General Practice, and Clinical Director, and founder of International Doctors for Healthier Drug Policies. To advise on health and substance misuse, outcome measures and recommendations, including consulting with other experts in the field.

Peter Williams (6%): Medical statistician for 25+ years, undertaking planning and analysis in over 400 projects, from randomised controlled clinical trials to large scale observational and epidemiological studies. Will provide statistical advice at all stages and conduct statistical analysis.

Sarah Coward (150 days): 15+ years' experience of social, housing, homelessness and urban regeneration research. Worked on several studies with Crane and Joly, and responsible for tracking and interviewing the FOR-HOME and Rebuilding Lives participants in Nottinghamshire and South Yorkshire. To assist with tracking and interviewing at CSSs in north England.

The costs cover staff salaries, staff and PPI travel and overnight accommodation when collecting data at sites distant from London. To minimise travel and overnight accommodation costs, at least 2 CSS will be in Nottinghamshire / Yorkshire (close to where Coward lives) and at least 2 will be within daily commuting distance of London. In appreciation of their time and to encourage them to keep in contact, we are including small incentive payments for interviews with the case study participants. From our experience, this greatly assists recruitment and follow up. We are also including costs for the participating health schemes, for staff time in interviews, and for them to assist with recruitment and to extract data from patient records. We have also included costs for interpreters.

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Table 5 Plan of investigation and study timetable

Tasks		Months																	
		1	3	5	7	9	11	13	15	17	19	21	23	25	27	29	31	33	35
		2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Advisory Group meetings																			
Design instruments and prepare ethics submission																			
Mapping of primary health services for homeless people and selection of CSSs																			
Literature review A: Evidence-based practice																			
Literature review B: Policy and service review																			
Data collection	CSS 1 and 2																		
	CSS 3 and 4																		
	CSS 5 and 6																		
	CSS 7 and 8																		
Data coding and data entry																			
Data analyses and reporting																			
Output 1: Inventory of Specialist Health Services																			
Output 2: Synthesis of Evidence-based Practice																			
Output 3: Primary Health Care – A Guide																			
Output 4: Policy and Service Review																			
Output 5: Final report for the NIHR																			
Dissemination event																			