Health Research Authority

HRA PROTOCOL COMPLIANCE DECLARATION

This protocol has regard for the HRA guidance and order of content

FULL/LONG TITLE OF THE STUDY

Commissioning, Co-commissioning and Being Commissioned; the NHS and Third Sector Organisations. Multi-method realist study

SHORT STUDY TITLE / ACRONYM

Commissioning, Co-commissioning and Being Commissioned; the NHS and Third Sector Organisations.

PROTOCOL VERSION NUMBER AND DATE

HSDR version 2.0.

RESEARCH REFERENCE NUMBERS

IRAS Number:	270268
SPONSORS Number:	Not applicable
FUNDERS Number:	NIHR128107

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

.....

Date: ...../...../...
...

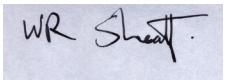
Name (please print):

.....

Position: .....
.....

Chief Investigator:

Signature:



Date: 30/1/2020

Name: (please print):

William Rodney SHEAFF

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Joint-sponsor(s)/co-sponsor(s)	Not applicable
Funder(s)	National Institute for Health Research (Health Services Delivery Research programme) Evaluation, Trials and Studies Coordinating Centre University of Southampton Alpha House, Enterprise Road Southampton SO16 7NS E: sue.pargeter@nihr.ac.uk T: +44 (0) 23 8059 5586 W: http://www.nihr.ac.uk/
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STUDY SUMMARY

Study Title	Commissioning, Co-commissioning and Being

	Commissioned; the NHS and Third Sector Organisations. Multi-method realist study.
Internal ref. no. (or short title)	Commissioning, Co-commissioning and Being Commissioned; the NHS and Third Sector Organisations.
Study Design	Multi-method realist study: Case studies of commissioning: national census of NHS-funded third sector organisations: case studies of third sector organisations: action learning set.
Study Participants	Members of third sector organisations: NHS commissioning staff.
Planned Size of Sample (if applicable)	8 study sites,approximately 120 individuals.
Follow up duration (if applicable)	Not applicable
Planned Study Period	1st December 2019 - 30th November 2022
Research Question/Aim(s)	RQ1. How do healthcare commissioners address the task of commissioning voluntary, community and social enterprises (VCSE) as service providers, and what barriers do they face? RQ2. What are the consequences for VCSEs, of the public bodies commissioning services from them? RQ3. How are VCSEs involved in CCG, local authority and other (e.g. ACS, NHS England) commissioning decisions? RQ4. What absorptive capacities do healthcare commissioners and VCSEs respectively need for enabling VSCEs to be commissioned, and for co-commissioning?

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health Research (Health Services Delivery Research programme) Evaluation, Trials and Studies Coordinating Centre University of Southampton Alpha House, Enterprise Road Southampton SO16 7NS E: sue.pargeter@nihr.ac.uk T: +44 (0) 23 8059 5586 W: http://www.nihr.ac.uk/	Grant: £800,526.40

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor's role is to ensure project is managed and undertaken in conformity with the protocol, contract with research funder, and all ethical and research governance approvals and any conditions attached to them.

The funder stipulated the overall study aims, peer-reviewed the study design and suggested revisions based on the peer reviews. It will peer-review the final report and make any recommendations for changing it based on those reviews. The funder will monitor project progress, reporting and completion, but after the peer review and decision to fund play no other part in study conduct, data analysis and interpretation, manuscript writing, and dissemination of results. The sponsor and funder do not control the final decision regarding any of these aspects of the study, nor the contents of any publications arising from the study.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

As a project oversight committee we have established a PPI Steering Committee chaired by independent person (Charlotte Augst, Chief Executive of National Voices) to oversee PPI work and participate as below in the research itself. Its members (still being recruited at the time of this application) will include:

- A majority of members from voluntary, community or social enterprises (VCSE) which represent or advocate patient interests, including a VCSE which has struggled to win contracts.
- Patient representatives recruited via the Birmingham and Plymouth research development services, and/or through care group experts for the tracer groups.
- Individual experts including Victor Adebowale, Juan Baeza.
- Researchers from the other projects working in this area of health policy.
- A care group expert for each of the focal care groups (social prescribing; people with learning disability and complex care needs; hospices).

We anticipate about 12 of the 18 or so members being patients and/or from VCSEs. We will assist them to travel to meetings (as INVOLVE recommend), provide materials in alternative formats where needed (e.g. large print). Through the Steering Committee that they can help shape the research questions, methods and sample. We will hold further meetings shortly before each main stage of work (site selection; start fieldwork; start analysis; produce outputs), inviting the members to suggest and contribute to:

1. Any necessary 'in-flight' amendments to research questions and design.
2. Identifying relevant existing instances of good practice, study sites, data, data sources and access.
3. Sense-making and analysis of the data, including reality-checks of findings and recommendations.
4. Co-producing the outputs below and dissemination activity.
5. Giving the outputs impact: testing, translation and transmission to VCSEs and networks (e.g. Guilds) likely to use them.

The PPI representatives will contribute output production and dissemination as a distinct project phase after the final report.

PROTOCOL CONTRIBUTORS

The sponsor and funder contributions to the study design, conduct, data analysis and interpretation, manuscript writing, dissemination of results and decisions about the research are described above ('Role of Sponsor and Funder').

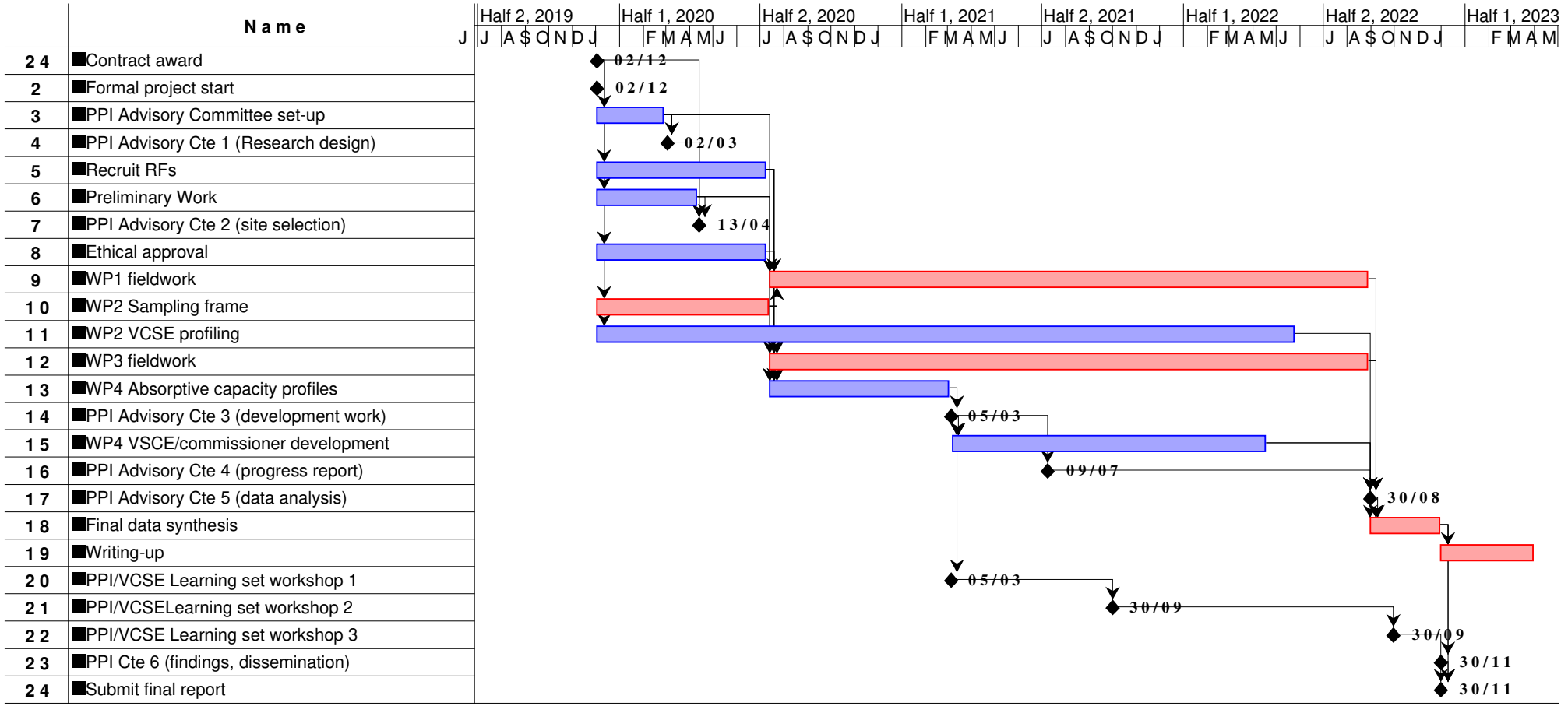
Patients, service users, and/or their carers, or members of the public contributed as follows to preparing the study protocol. PenPIG (SW Peninsula CLAHRC Patient Involvement Group), HEPE (Healthy Environment Public Engagement), the Greater Manchester Transforming Care board, National Voices (Jeremy Taylor), Dimensions, and individuals working in hospices contributed to the

project foci and design. HEPE added: ‘Just to say, the group is really interested in social prescribing, so it should be a productive discussion.‘ Discussions with VCSE members during the application for funding resulted in adjustments to our research questions, a list of potential negative and positive consequences of commissioning VCSEs (which will be used to frame the data analysis), proposed sample and the possible barriers and risks. Three consultees put themselves forward for the PPI Steering Group.

KEY WORDS: Third sector: voluntary organisation; community organisation: not-for-profit organisation; commissioning: NHS

STUDY FLOW CHART

The chart shows the sequence of work-packages (WP) and the critical path for timely project completion (red).



STUDY PROTOCOL

Commissioning, Co-commissioning and Being Commissioned; the NHS and Third Sector Organisations. Multi-method realist study.

BACKGROUND

Policy Background

Recently the government's Civil Society Strategy, Innovation in Democracy and Place Based Social Action programmes have re-asserted that service providers should be 'drawn from a broad range of suppliers from the public sector and beyond' ([1] p.10) including Voluntary, Community and Social Enterprise (VCSE) organisations, often referred to as 'third sector organisations (TSO). VCSEs' intended roles include being 'citizen commissioners' 'speaking up on behalf of those they support' (p.14) and helping address 'injustices and entrenched social challenges, such as poverty, obesity, mental ill-health, youth disengagement, reoffending, homelessness, isolation, and loneliness, and the challenges of community integration' (p.18). Consequently government 'plans to reform commissioning in favour of charities and social enterprises' (p.69) through such measures as co-commissioning, 'flexible contracting' (including Innovation Partnership projects) and Social Impact Bonds. These and other policies (e.g. care integration, provider diversification, personal care budgets, the NHS Long Term Plan) involve commissioning of VCSE providers.

Many VCSEs have developed in parallel with the NHS, initially as advocates both of new kinds of healthcare and of non-healthcare activities which help maintain health and reduce demand on the NHS. Many are long-established service providers, indeed the dominant providers for some services (such as hospices) for patients whom they see as under-served by the NHS including 'hard-to-reach' care groups. They also provide adjunctive services to extend and continue NHS services (e.g. Macmillan nursing (post-acute cancer care). NHS trusts and some non-for-profit providers (e.g. Nuffield's) have volunteering schemes, fund-raising and hospital 'friends' organisations. However cuts in local government budgets have increased the financial and demand pressures on VCSEs at a time when the NHS has been increasingly looking towards them as providers. The introduction of personalised budgets for health appears to threaten some VCSEs' block contracts. Meantime some NHS trusts (providing community and/or mental health services) have been converted into 'social enterprises', which policy-makers increasingly also count as part of the 'third sector'.

NHS policy and the Sustainability and Transformation Partnerships (STP) have also increasingly supported VCSE participation in healthcare commissioning, including the Universalised Personal Care strategy, local authority and NHS joint commissioning, and the New Models of Care for cross-provider 'integration'. Health and social care systems are to 'integrate' services between NHS and local authorities, and VSCEs will provide many of the services to be integrated. The NHS Long Term Plan states 'The NHS will continue to commission, partner with and champion local charities, social enterprises and community interest companies providing services and support to vulnerable and at-risk groups.' (§2.37). Examples include stroke rehabilitation services (§3.77), mental health services (sanctuaries, crisis cafes) (§3.98), 'well-designed volunteering initiatives' (§4.54).

Accordingly this study is sponsored by the NIHR Health Services Delivery Research Programme, National Institute for Health Research and managed by their Evaluation, Trials and Studies Coordinating Centre, University of Southampton, Alpha House, Enterprise Road, Southampton SO16 7NS, UK. The sponsor called for bids then selected protocols for funding through open competition and peer review. After agreeing the details stated in this protocol with the researchers, the sponsor played no further part in study design nor had ultimate authority over collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report or materials derived from it for publication.

Existing Research

Like the call for bids, we define VCSE organisations as "formally organised; non-profit distributing; constitutionally independent from the state; self-governing and benefiting from some form of voluntarism".[2] Previous studies, including our own[3–5], suggest that VCSEs have certain distinct characteristics. They tend to be 'mission-driven'[6] rather than profit-driven[7]; to have user and/or worker representation[4] in, or even democratic control[8] over, their governance structures; to rely heavily (in some cases) on volunteers rather than employees[9]; to have distinctive patterns of innovation[10] and response to market changes[11]; and to have close (structural) ties to particular localities or care groups. VCSEs also have distinctive resource dependencies, for example their balance between help-in-kind, donations, subscriptions, commissions, sponsorship and sales; and and between voluntary and paid labour). They have distinctive ways of combining bureaucratic with democratic work-coordination, non-profit and for-profit activities.
Potential positive consequences of commissioning VCSEs as healthcare providers therefore include:

1. Responsiveness: introduction of VCSE expertise about patient activity, experience and needs, especially for (as VCSEs may see it) underserved care groups e.g. the marginalised or vulnerable groups which the call for bids lists.
2. Innovation: inventing new models of care which NHS organisations can later co-fund or adopt in place of less suitable NHS services (e.g. hospice instead of hospital in-patient care), including preventive services.
3. Participation: greater patient, carer and user participation in planning and decision-making, reaching the higher levels of Arnstein's 'ladder' of participation.[12]
4. Advocacy of specific care groups' interests at both national and commissioner levels (e.g. Lighthouse (for AIDS)).
5. Independence: Health promotion campaigns, including anti-marketing which official bodies cannot so easily undertake (e.g. against tobacco or food firms), and inter-sectoral activities (e.g. dementia-friendly airlines).
6. Complementarity: Supplementary service funding and/or provision by VCSEs themselves, possibly (e.g. by using volunteers) at lower cost than NHS or commercial providers.
7. 'Social enabling' i.e. constructing referral networks (e.g. 'social prescribing') which enable patients to access health-related services and resources, extending NHS reach and impact.

For commissioners to take advantage of these possibilities requires capacity[13–15] to acquire, assimilate, adapt and apply knowledge from many sources, both knowledge about VSCEs and knowledge provided by them. However commissioners often lack this capacity.[16] They often have limited understanding of the VCSE sector and how best to engage with it. Often they see VSCEs as able to provide low level services but not necessarily clinical care. Conversely, VCSEs also face specific barriers (see below) to using research[2] and need to develop their own capacity to bid for commissions and then supply the commissioned services. That implies correspondingly adapted forms of volunteering, VCSE management, 'performance', culture and (employed) workforce.[17] In sum, VCSEs still lack embeddedness in the NHS and much of the health system more widely.
Previous studies also describe how, in certain circumstances, VCSEs' mission-driven character, their original mission itself, or their democratic or participatory governance may 'degenerate'.[18] For VCSEs, being commissioned by public bodies may involve restrictions on their advocacy and autonomy and being made 'governable'.[17] It may create pressure to develop structures and managerial practices more like those of for-profit corporations.[19] So there are also risks in commissioning VCSEs, not least to VSCEs themselves. Resource dependency theory[20] implies that heavy dependence on NHS income also risks making VCSE providers become more like NHS providers because:

1. Commissioners' demand specific 'innovations' (e.g. service models). VCSEs then have to accumulate profits to finance them, making VCSEs in that sense more 'corporate' [21].
2. External payments enable, and their contracts compel, VCSEs to use paid rather than volunteer labour[22], accentuating the gap[23] between patient and professional discourses.

3. Competition for commissions motivates 'commercial-in-confidence' secrecy about VCSEs' distinctive inventions or working methods, and more generally the 'commercialisation' of VCSEs' internal managerial practices and regimes.[19]
4. VCSEs become more accountable to healthcare commissioners than to their members, volunteers, care group or community. That inhibits their campaigning about what they see as policy or service shortcomings.[17,19]
5. VCSEs experience managerial 'capture'[24], immersion in an 'audit culture' [25,25] or 'cultural take-over by stealth'[26], which 'block' their original institutional logic.[27] They become more bureaucratic and the transaction costs of commissioning them increase. Charities with multiple income streams may become large enough to sustain teams who specialise in seeking funding, but smaller charities who cannot may struggle to survive.
6. VCSEs become so dependent on healthcare commissions that they respond to budget cuts much as public bodies do, for instance by defending their vested interests or block contracts against, say, more personalised forms of contracting. Conversely, large VCSEs, or those mainly funded from non-NHS sources, may be in a stronger bargaining position than local healthcare commissioners.
7. Commissioners' focus on cost-savings results in VCSEs receiving less income or resources than they need to sustain both themselves, their workers and informal carers.

At worst, unsuitable modes of commissioning would then undermine the very characteristics which made VCSEs valuable to the health system in the first place.[28]

RATIONALE

VSCE contributions to healthcare commissioning currently include:

1. Advocating inclusion and service 'co-design' for specific care groups. VCSE activities range from outside campaigner or pressure group to consultee or advocate (e.g. National Osteoporosis Society) to actively participating within healthcare commissioning.
2. Acting as 'social enablers' of 'social prescribing'.
3. Co-funding services in parallel with public commissioners (as do e.g. Alzheimers Society, British Heart Foundation), whether at care group level through large contracts or at individual level through personal budgets or grants.
4. Funding research, including making their own independent evaluations of service accessibility and quality. (This research is often linked to their advocacy.)

The term 'co-commissioning' covers any of the above. Indeed the above list is an initial typology of co-commissioning variants. As noted, the NHS Long Term Plan continues these policies. Scotland, Wales and NI have similar policies. Yet as the call for bids notes, policy makers consider VCSE input to the health system as 'too often restricted in scope and in funding and that they [VCSEs] face difficulties of expertise and funding to evidence their impact and value'; and so do the practitioners whom this research is intended to support.

The rationale for the present research is therefore to discover which commissioning methods can harness for the NHS these positive characteristics of VCSEs whilst preventing the potential adverse consequences noted above. That is, to discover what:

1. Benefits that healthcare commissioners currently gain, and in future might reasonably seek, by commissioning VCSEs as providers and by co-commissioning with them.
2. Commissioning methods (including co-design[29]) appear best adapted for these purposes, and best able to avoid the potential adverse consequences noted above.
3. Practical capacities VCSEs and healthcare commissioners currently need (both in their own perceptions and according to research evidence) so that VCSEs can bid credibly for healthcare commissions and so that once they are commissioned, both parties can sustain mutually beneficial roles.

4. Methods can be devised for developing these practical, absorptive capacities, especially for VCSEs.

THEORETICAL FRAMEWORK

Our previous studies[5,30] developed a typology of commissioning models. To exercise power or control over providers, healthcare commissioner use a range of methods: managerial techniques (planning, evaluation), persuasion, financial incentives, provider competition, relationship-building, and contracts or regulation. Commissioners tend to find different combinations of methods (i.e. different 'modes of commissioning') effective in influencing different kinds of providers (NHS-owned, corporate, VCSE etc.). However it is not yet well understood how the effective combinations of methods might differ for different kinds of VCSE. Neither is it known which combinations of methods are more likely to produce the positive, or the negative, consequences listed above. It is not known, either, whether these combinations methods work differently when VSCEs participate in commissioning (i.e. in co-commissioning). It also remains to be seen how how VSCEs will respond, both as service providers and as co-commissioners, to the new strategic environment of STPs, integrated care and public health. We will use this framework, which builds on the existing research outlined above, to frame the data analysis.

RESEARCH QUESTION/AIM(S)

The reason (aim) for this study is to produce knowledge which will help strengthen collaboration between healthcare commissioners and VSCEs in commissioning all kinds of healthcare providers, and make commissioning relationships between the NHS and VCSEs more productive for both. Such changes may be expected to make NHS-funded services more responsive to patients' and carers' needs. Our research aims are therefore to:

1. Strengthen the evidence-base for guidance to commissioners on how:
   (a) VSCE contributions can strengthen healthcare commissioning
   (b) VCSEs should use research to inform their activities, to encourage and enable them to produce evidence in their own cause.
   (c) Commissioners and VCSEs can gain knowledge of each other's needs.
2. Produce evidence about how, and under what conditions, healthcare commissioning of VCSEs and co-commissioning with them tends to produce the potential positive or the potential negative consequences listed above.
3. Develop the typology of commissioning methods[30] relevant commissioning VCSE providers and to co-commissioning with VCSEs,

Additional study aims are to develop:

4. Commissioners' capacity for co-commissioning with VCSEs, and the training and knowledge mobilisation methods required.
5. Practice guides for VCSEs about service commissioning at the scale of CCGs (including merged CCG), local authorities, and local communities.

Lack of published administrative data (see below) prevent this study being a cost-effectiveness, cost-efficiency or cost-utility analysis of the <u>costs and outcomes</u> of commissioning VCSEs.

<u>Objectives</u>

The two explanatory frameworks outlined above (potential positive and negative consequences of commissioning VCSEs; distinctive commissioning methods) both suggest a making VCSE-commissioner interactions the focus of this research and (as explained below) the route to mobilising the resulting knowledge with evidence users. We therefore propose to address four over-arching research questions (objectives). One of them (RQ1) therefore concerns what the organisations commissioning VCSEs bring to, and take from, those interactions; RQ2 addresses the same issues for the VCSEs who are commissioned; and RQ3 addresses them in regard to co-commissioning.

RQ1. How do healthcare commissioners address the task of commissioning voluntary, community and social enterprises (VCSE) as service providers, and what barriers do they face?
RQ2. What are the consequences for VCSEs, of the public bodies commissioning services from them?
RQ3. How are VCSEs involved in CCG, local authority and other (e.g. ACS, NHS England) commissioning decisions?
RQ4. What absorptive capacities do healthcare commissioners and VCSEs respectively need for enabling VSCEs to be commissioned, and for co-commissioning?

Here, 'healthcare commissioners' are defined as all forms of publicly-funded healthcare commissioning organisations (i.e. CCGs, local government etc.).

Outcome

The broad outcome of this study will be to inform and strengthen VCSE and NHS capacity in the commissioning of third sector organisations as providers of NHS-funded services.

STUDY DESIGN, METHODS OF DATA COLLECTION AND ANALYSIS

Design and theoretical/conceptual framework

To answer the above research questions we propose a mixed methods research design applying realist methodology (the applicants have published several such studies[5,30,31]) but in a two-sided way: a methodological innovation. From the commissioners' standpoint, commissioning VCSEs can be understood as a means of achieving the positive outcomes noted above (responsiveness, innovation etc.). As the mechanism for achieving them, the commissioners will use some selection of the commissioning methods listed above. From the VCSEs' standpoint, making these contracts is implicitly a mechanism for achieving the outcomes that *they* seek. (What specific outcomes those are, will be one finding from this study.) As the mechanisms for doing so, VCSEs will rely on their own distinctive governance structures, external and network relationships, and working practices. We therefore require a study design that will identify the respective intended outcomes, the mechanisms which either party thinks will achieve them, their actual effects and what contexts these effects depend upon, the most important context being (we assume) what the other party to the commissioning relationship does. Similar reasoning applies to co-commissioning.

This reasoning suggests making the *relationship* and interactions between VCSE and commissioner, rather than organisational structures, the research focus and the unit of analysis or 'case'. In practice this unit of analysis may vary considerably in size between local health economies ('commissioning networks'), a factor which may itself impact upon commissioning and co-commissioning relationships. Accordingly we propose four work-packages (WP) and, to get them started, some preliminary work. Two WPs (WP1, WP3 below) use predominantly qualitative methods, supplemented with a quantitative study (WP2) of England-wide patterns of VCSE commissioning by the NHS. WP2 will also help us assess the likely generalisability of the findings from WP1 and WP3. WP4 uses surveys of absorptive capacity to ground action learning methods which (as explained below) are also a means of mobilising knowledge more widely.

Preliminary Work

The preliminary work will be to make a more specific preliminary classification of the kinds of VCSE commissioning and co-commissioning relationships likely to be found. The findings will be used to specify more exactly the sampling criteria for the following work packages and contribute to

developing the project's analytic frameworks (see below). This preliminary work will draw on advice from the PPI Steering Committee (see below), large VCSEs and approximately 10 individual key informants from VCSEs, an initial review of the provider lists in published CCG accounts, existing research studies[32], other published sources (e.g. Carers Support Centre, NHS Choices provider lists, NCVO Almanac), national and professional press rapportage, VCSE networks and national bodies.

VSCE-commissioner relationships (WP1)

WP1 addresses **RQ1** (how the NHS currently commissions VCSEs) and **RQ2** (consequences for VCSE by systematically comparing case studies of the commissioning relationships between commissioners and VCSEs providers. We will observe and analyse these relationships from both the commissioner and VCSE sides. Involving service users and (where applicable) volunteers, these case studies will trace down to service delivery level the consequences of commissioning VCSEs; and examine user involvement in VCSE governance (about which little research yet exists). Outputs from WP1 include the pithy evidence-based guidance for the use of VCSEs and the corresponding social marketing materials (see 'Outputs' below).

WP1 Sample

At study site level WP1 will use a purposive maximum-variety qualitative sample of local health economies (commissioning 'patches'), the variety being in terms of patterns of commissioning relationship with VCSEs. Details are below.

Inclusion: WP1 will focus on commissioning of VCSEs serving three tracer care groups and their corresponding communities (social prescribing: hospices; People with a learning disability and complex behavioural needs). Fuller details are below

1. Social prescribing for older people, for which NHSE has recently funded 23 projects and about which some outcome data already exist at CCG level. VCSEs are main providers of such 'integration' activities, which appear to improve patients' quality of life and reduce unnecessary demands on hospitals.[16] VCSEs providing social prescribing are mostly quite newly commissioned, indeed quite new organisations, hence probably less accomplished than older, larger VCSEs in monitoring, evaluation and research. Given the policy context and research call priorities we will seek study sites with social prescribing projects serving more deprived and/or excluded communities.
2. Hospices, whose models of care the NHS subsequently adopted and who provide end-of-life services which the NHS traditionally delivered in very different ways.
3. People with a learning disability and complex behavioural needs, sampling sites where healthcare commissioners have worked with the VSCEs, both large and small, to develop more individualised packages of support, and building on previous studies.[36,37]

These tracer groups provide opportunities to contrast VSCEs of different sizes, ages, health system function (prevention, self-management, formal care); and different mixes of contracts and funding sources, hence different degrees of dependence on commissioners. Some organisations and services (e.g. for LD) which cater for children and young people *among others* are likely to be included, but not children or young people as a separate care group. Commissioning for all these groups raises questions, which cut across many care groups, of equal access to care.
In each study site we will study at least two of these tracer groups. Hence the setting for WP1 is VCSEs concerned with these three tracer groups. Since our proposed unit of analysis is the commissioner-VCSE relationship, the set of these relationships is (so to speak) our 'target population'. To avoid overlapping other studies the exclusions will be VCSEs concerned predominantly with gender identity[34], mental health crisis care, child mental health, the on-going evaluations of personal budgets (e.g. for people with learning disabilities).

WP1: Data collection

Data for WP1 will be collected by key informant interview, content-analysis of documents (including unpublished managerial documents) and the observation of commissioning and/or monitoring meetings. Whilst COVID19 pandemic restrictions apply we will undertake most interviews by 'phone or internet video-conference (e.g. Zoom or similar) rather than face to face. In the on-line and 'phone cases we will obtain informant consent by e-mail, sending our approved consent form and participant information before we first meet them. Then they will still receive exactly the same prior information as for a face-to-face interview, allowing informants the same time to consider their participation and ask further questions. For informants who then consent we will start our first direct meeting by seeking and addressing any further queries or observations they may have, then orally confirm (and record) their consent to take part. We will recruit key informants by 'snowballing' from an initial contact (either indicated by the PPI group, already known to the researchers, or the CEO or equivalent) to those responsible for commissioning. We will collect data from commissioners who negotiate, monitor and revise contracts; from VCSE employees and/or volunteers working in publicly-commissioned services; and members of patient fora (or the equivalent) who can report how patients are involved commissioning and the implications for services of provision by VCSEs. We will be guided by all these informants as to which meetings to observe and which managerial documents to content-analyse. The interview schedule will be developed from the two main frameworks outlined above (Background), seeking Oversight Committee advice. With interviewees' consent the interviews will be audio-recorded and professionally transcribed. When we clean these data, we will pseudonymise (de-identify) all named individuals and organisations. The data recordings will be securely stored in password-protected computers in locked offices and on secure, password-protected university servers which are not exposed to public access. Data will be transferred and archived in password-protected encrypted files only. We do not anticipate software-assisted analysis of these data, but if we undertake it we will use only open-source software since its security is, in effect, multiply peer-reviewed.

From these sources we will collect data on:

- What outcomes commissioners sought; what mechanisms, including commissioning methods, they assumed would produce these outcomes; and what contexts they took into account.
- Conversely, what outcomes the VCSEs sought to produce; through what commissioning or contract mechanisms; and what contexts they took into account.
- What commissioning methods commissioners used in relation to VSCE providers.
- What kinds of evidence commissioners expected from VCSEs when deciding whether to commission them as providers, and what kinds of evidence the commissioners in fact got.
- Barriers to VCSE involvement and development.
- Whether any of the aforementioned potential positive and/or negative consequences of commissioning VCSEs materialised, and if so under what conditions.
- How VCSEs relate to their patients in terms of advocacy, accountability, representation etc.
- Whether VCSE services appeared more acceptable to users, produced different service outcomes for them, and had different innovation patterns and lower long-term overall costs for commissioners than non-VCSE services.
- Contracting, payment, monitoring and dispute-resolution; how trust and working relationships; associated transaction costs; any differences between the different types of VCSE mentioned above.
- How commissioning changes (e.g. CCG re-alignment with ICSs, budget cuts) affected the commissioned VCSEs.

These data will cover the range of VCSE providers, including those on contracts valued below £25000.

WP1: Analysis

Since we will use framework analysis[38] to analyse data from WP1 and simultaneously synthesise them with the data from WP2, WP3 and WP4, we outline it below after describing them.

Profile of healthcare commissioning of VCSEs (WP2)

WP2 also addresses **RQ1** (how the NHS currently commissions VCSEs) and **RQ2** (the consequences for VCSEs). WP2 will analyse routine administrative data about the commissioning of VCSEs. Since 2014 CCG accounts have published all expenditures of £25k or more, sub-classifying 'Clinical & Medical' providers as 'Commercial', 'Independent' or 'Other Public' & 'Voluntary Sector', assigning each item of expenditure to an 'expense area' (e.g. 'Hospices' or 'Learning Difficulties') and to a particular organisation (e.g. a named hospice). These data provide a census of CCG contracts valued above £25k.

WP2 will be a cross-sectional and longitudinal analysis of the extent (proportion of contracts and of contract value) and profile (variety of VCSEs) of CCG commissioning of VCSEs as providers. We will use established automated 'web scraping' methods to establish the geographic and temporal spread of >£25k contracts in the years since 2014 in terms of proportion of contracts, contract value, types of VCSEs involved and expense types. The first use of these findings will be as a sampling frame for study sites. Patterns of CCG commissioning of VCSEs as providers will be tested against various CCG characteristics to identify correlates with the commissioning of VCSE providers. This is a stand-alone objective, but will also help place the study sites in a broader context vis-à-vis the use made of VCSEs to provide services.

Whilst providing an important overview on patterns of VCSE commissioning, this analysis has unavoidable evidential limitations. Our preliminary investigation of the data reveals some variation in the classification of organisations as VCSEs (so WP2 will involve cleaning these data), the accounts do not include VSCEs that are subcontracted via another provider, and do not always cover contracts valued <£25k. The automated web-scrapers will detect those contracts <£25k whose details are published online, although those data will probably not be exhaustive because CCGs themselves vary in how much they publish on-line about contracts <£25k..We will also use Charity Commission and further sources of published data on contracts <£25k. As noted, WP1 and WP3 would cover contracts of all values, including <£25k. Taking care not to over-interpret the data, we will include a profile of those contracts <£25k for which data are available for the most recent financial year in the analysis. Even combined, however, these sources are less comprehensive and uniform than data on the larger contracts and there appears to be no realistic means of obtaining complete national-level data on contracts <£25k short of making multiple FOI requests which would be a huge dataset and entail large FOI costs, time and labour for data-cleaning. Given the size and timescale of this project we cannot feasibly extend the primary data collection required to fill these gaps beyond the case study sites to the rest of England.

In the WP1 and WP3 sites we will also investigate through the case studies what biases the omissions and mis-classifications of data mentioned above might introduce. In these ways we will review the availability, usefulness and limitations of currently published data for supporting VCSE self-evaluation, VCSE bidding for commissions, and identify ways in which the routine data might be made more valid and reliable.

WP2 Sample

WP2 will be a census of CCGs.

WP2 Data Collection

Data will be extracted from CCG websites, NHS Digital, NCVO and others describing what kinds, numbers and sizes of VCSEs are being commissioned (including co-commissioned), where, and with what spending. Data held by CCGs are suitable for automated web scraping, with additional use of Tabula to extract data from PDF files. Personally-identifiable or pseudonymised personal data are not involved or required.

WP2 Analysis

The data collected for WP2 will be analysed cross-sectionally, longitudinally with a view to providing (mostly descriptive) statistics detailing the geographical distribution and penetration of different kinds of VCSE, including the extent to which they are concentrated in economically deprived areas and areas with large ethnic minority populations. Because CCGs are currently undergoing extensive mergers, the longitudinal analyses are likely to be on the basis of post-merger CCG configurations. We will compare the study site sample with other English CCGs in respect of those characteristics of VCSE commissioning which the routine data cover, thereby adding to our understanding of the extent to which the findings of WP1, WP3 and WP4 may be generalisable. We will also make any necessary recommendations for making the routinely collected data more consistently coded and reliable, and more useful for commissioning VCSEs. For analysis we will use open-source software (Julia, R) for security.

Co-commissioning (WP3)

This WP addresses **RQ3** (about VCSE involvement in co-commissioning). It will systematically compare case studies of co-commissioning with VCSEs, contrasting different types of co-commissioning relationship, again with the VCSE-commissioner relationship as the unit of analysis. In doing so, we will investigate what research evidence VCSEs use, and how, in designing and evaluating services; their capacity to use the evidence, and that of their NHS and local government commissioning partners. WP3 will be the main source of the pithy evidence-based guidance, for VCSE and commissioner use, on co-commissioning; and of the corresponding social marketing materials.

WP3 Sample

WP3 study sites will be sampled in the same way as for WP1, except that if co-commissioning is absent in any of the WP1 sites, we will for WP3 replace that site with one where co-commissioning does occur (otherwise maintaining as similar a pattern of VCSEs as possible) where co-commissioning does occur. We would prefer, however, to sample the same sites as for WP1 because that will enable us to investigate any interactions between the consequences of being a commissioned VCSE and those of being a co-commissioning VCSE (and simplify fieldwork).

WP3 Data Collection

Data collection methods will be as for WP1 but different data will be collected i.e:

- How VCSEs participate in CCG, local authority and other (e.g. ACS, NHSE) commissioning decisions; ways in which this involves co-*design* of services.
- Acceptability to service users, overall costs for commissioners of co-commissioned services compared with other services.
- What distinctive mode(s) of commissioning commissioners use when co-commissioning with VSCEs
- Barriers to VCSE involvement and development.

As for WP1 these data will cover the range of VCSE providers, including those on contracts valued below £25000.

WP3: Analysis

The same framework analysis as for WP1 will also synthesise data from WP3 with data from the other work packages and is therefore described below.

Absorptive capacity and action learning (WP4)

WP4 will seek to generate insights on how the commissioning process with VSCEs can be practically improved, addressing **RQ4** (practical methods for improving VCSE and healthcare commissioners' capacity to use evidence for commissioning purposes[16] and improving VCSE ability to bid credibly for healthcare commissions). Using action learning methods[39,40], the VCSE and NHS participants in WP4 will develop, apply and refine through practice a set of learning opportunities and resources tailored to the requirements of commissioning VCSEs as providers, and co-commissioning with them. In addition we will directly help some of the study VCSEs build their capacity in these areas. We will recruit VCSE members to the project work (details below), giving them practical organisational research experience and mentoring whilst they contribute to project design and implementation. In this way WP4 will provide an extended case method[41] for WP1 and WP3. Interim outputs from this WP will be

1. A profile of the values, skills and behaviours that enhance commissioners and VSCEs' absorptive capacity, including capacity to use, or produce, the kinds of evidence relevant to bidding, commissioning and co-commissioning.
2. Co-designed work-based learning opportunities to develop and consolidate these competences.

Its eventual outputs will be a cohort of VCSE members with enhanced capacities for engaging in commissioning and co-commissioning; a tested suite of developmental activities for strengthening those capacities; and formal, published outputs about how to achieve these things. To that extent WP4 itself provides a route to knowledge mobilisation by certain key evidence users.

WP4 Sample

WP4 will take place in the same study sites as WP1 and WP3. Subject to the self-assessment findings, we anticipate that the WP4 participants will include key informants from WP1 and WP3. A maximum variety sample gives scope for evaluating different models (e.g. training, evaluation of pilot innovations, social marketing, knowledge mobilisation) for developing the practical skills that WP4 focuses on.

WP4 Data Collection

In year 1 of the study we will use an established knowledge mobilisation tool[16] to profile VCSEs' and the commissioners' current ability to gather and deploy information regarding the services concerned. This will ground self-assessment by the commissioners and the VCSEs, gaining the perspectives of both. The commissioners and VSCEs will reflect upon the findings for their site to identify the key enablers and barriers to gaining and understanding of the knowledge relevant to commissioning, focusing in particular on the values, skills and behaviours that commissioners and the VSCEs need to adopt. The participants and the researchers will co-design work-based learning opportunities to develop and consolidate these competences. WP4, and to some extent WP1 and WP3, will also identify the routes to mobilising the knowledge so produced with evidence users.
By these methods WP4 will collect data on:

- What capacities commissioners require for constructive collaboration with VCSE providers and, reciprocally, what capacities VCSEs require.

- What kinds of evidence and competences co-commissioning requires.
- What competences, capacities and other support VCSEs have to acquire, in order to bid for NHS-funded care, then evidence their contributions to it.
- How VCSEs use research evidence in designing, delivering and evaluating services.
- The practical consequences of WP4 participants trying to apply their existing absorptive capacities, and those developed through this action learning work package.

Insofar as subsequent data collection involves interviewing or meeting informants, the same arrangements as for WP1 above will apply whilst the COVID19 pandemic restrictions obtain.

WP4 Analysis

Within WP4, commissioners' competences in commissioning VCSEs and in co-commissioning with VCSEs first will be evaluated normatively against a framework derived from the concepts of absorptive capacity mentioned above, Anheier's theory of VCSE management[42], and current health policy objectives. Then, following practical application of the co-designed learning activities, the participants will (applying action learning methods[39,40]) again reflect on their learning needs, adapting or extending the learning activities as needed.

Data Analysis (all work packages)

Combining the findings

To combine the findings from WP1, WP3 and WP4 we will make a systematic comparison of the case studies, comparing them through a framework analysis based on the explanatory frameworks noted above. We will explore any cross-site patterns or differences in terms of:

1. Which commissioning methods the commissioners used, including:
   (a) whether they used different methods with different kinds of VCSEs (helping to answer **RQ1,RQ3**).
   (b) Whether the possible positive and negative observed consequences noted above were associated with any specific commissioning methods (helping answer **RQ1, RQ2**).
2. Which of the aforementioned potential benefits and/or disbenefits materialised, and if so under what conditions (helping answer **RQ2**).
3. Whether, and if so through what mechanisms and in what contexts did:
   (a) commissioning VCSEs as providers yielded the policy and services outcomes that the commissioners had initially sought (helping to answer **RQ1, RQ4**).
   (b) Obtaining healthcare commissions led to the outcomes that VCSEs had initially sought. (helping to answer **RQ2, RQ4**).

We will also consider whether the outcomes that VCSEs and commissioners each sought, the mechanisms that each used, and the contexts required, were mutually compatible (addressing **all four RQs**).

We will analyse any data which do not fit into the above frameworks inductively to reveal any additional patterns with which to supplement or revise those frameworks. As noted, WP2 will compare the study sample with other English CCGs in respect of the characteristics of VCSE commissioning which the routine data cover. On that basis we will assess how far the findings from the systematic comparisons may be generalisable.

Insofar as our sample includes examples of good practice in VCSE-commissioning relationships, it will yield evidence above when, why and in what contexts, any of the potential benefits of VCSE commissioning and co-commissioning occur. That will identify mechanisms and contexts for

commissioning VCSEs as providers and for co-commissioning with VCSEs successfully, in terms of current policy and VCSEs' own aims.

By combining the framework and the inductive analyses across the policy outcomes mentioned above, we will formulate thematic findings in ways that are generalisable, both empirically (with due caution) and practically, across other sites. That is, we will use the methods of qualitative generalisation.[43]

Critical distance

WP1 and WP3 would involve VCSE co-researchers and outpost research team members to VCSEs. As precautions against lacking or losing critical distance from the commissioning relationships that we study we propose that:

1. For each study site the WP leads will review and triangulate the co-researcher and out-posted researchers' initial findings (in effect, a 'clean room' review).
2. Similarly we will invite co-researchers from other VCSEs to check the emerging findings from each site for face-validity in respect of objectivity and critical distance.
3. We will as far as practicable rotate the RF out-postings. Each RF will spend a period in each of several organisations to reduce the likelihood of 'going native' in just one.
4. In mentoring co-researchers we will include falsificationist methods[44] (including explicitly re-checking data for evidence *against* their initial interpretations and conclusions); fieldwork techniques such as probe questioning; and explanations of cognitive biases known[45] to affect analysis (e.g. availability, confirmation and reporting biases).

STUDY SETTING

Since the research questions concern VCSEs and NHS commissioners, those are the study settings. The study sample is described above. We will identify participants by snowballing from an initial contact (chief executive or equivalent) in the study organisation. We will access participants directly, preferably be e-mail in the first instance, to make it easy for them to consider participation and reply in their own time and on their own terms. This is a multicentre in that three institutions are involved and will collect data largely independently, but the data will be pooled and analysed in common, as for a single centre study. Apart from eligibility to be included there are no site specific requirements to run the study. The same types of activity are being undertaken at each site.

SAMPLE AND RECRUITMENT

<u>WP1, WP3 and WP4: Sample of organisations for case-study</u>

At study site level WP1 will use a purposive maximum-variety qualitative sample of local health economies (commissioning 'patches'), the variety being in terms of patterns of commissioning relationship with VCSEs. The preliminary work findings will differentiate the types of commissioning relationship more concretely, but as a first approximation we expect them to vary in terms of :

1. The size of VCSEs involved, ranging through (for example) national VCSEs with local branches (e.g. Macmillan); local VCSEs which already have contracts with healthcare commissioners (e.g. a single free-standing hospice); and VCSEs which struggle to win contracts at all. One would expect all these VCSEs to differ in bargaining power and resources, especially access to specialised bidding expertise, and absorptive capacity.

2. How large a proportion of services VCSEs provide in each CCG, which is likely be an proxy for the extent, complexity and variety of commissioning relationships between healthcare commissioners and VCSEs.
3. How long-standing the commissioning relationships are, because mutual trust and working relationships, and the concomitant skills, on either side take time to develop.

Elaborating the preliminary work findings, we will assemble a list of publicly-commissioned VCSE providers (a method we used in an earlier study[5]). It will be the sampling frame for the maximum-variety sample. We will sample one site (CCG) in each quartile for proportion of services provided by VCSEs. This sampling strategy will guarantee at least two sites in the middle quartiles, i.e. which are middle-range in terms of the proportion of VCSE-provided services. It is also likely to include sites which approximately cover the variety of local commissioning relationships with VCSEs, on the assumption (explained above) that the development of commissioning relationships with VCSEs partly reflects the proportion of commissioning that involves VCSEs. In addition the preparatory work (see above) will identify between two and four further sites which have comparatively well-developed commissioning relationships with VCSEs. From these 'positively deviant'[33] sites will select (if available) one for each of the above quartiles. This sampling strategy is also likely to maximise the social diversity of sites studied. It is likely to include inner-city, suburban and rural[34] VCSEs, and populations that differ in socio-economic terms, because a locality's population size affects the availability and size of its VCSEs, and its socio-economic profile their range and character[35]. Similarly we anticipate that such a sample will include sites with high and low percentages of volunteers in the resident population. As explained below (see 'Analysis'), WP1 will use systematic qualitative comparisons, not statistical generalisation, to detect patterns and differences across VCSE-commissioner relationships.

WP3 study sites will be sampled in the same way as for WP1, except that if co-commissioning is absent in any of the WP1 sites, we will for WP3 replace that site with one where co-commissioning does occur (otherwise maintaining as similar a pattern of VCSEs as possible) where co-commissioning does occur. The study sites for WP1 will be also used for WP4.

Within each study organisation, our criteria for sampling key individual informants will be:
1. Recent, preferably current, first-hand knowledge of the VCSE-commissioner interface(s).
2. Balanced inclusion of VCSE and commissioner informants
3. Informants whose work includes the three tracer groups listed below.

Eligibility Criteria

The study population of organisations and individuals, and the sample, are described above.

Inclusion criteria

WP1, WP3 and WP4: Inclusion of organisations for case-study
At organisational level, WP1 will focus on commissioning of VCSEs serving three tracer care groups and their corresponding communities (social prescribing: hospices; People with a learning disability and complex behavioural needs). Fuller details are below

1. Social prescribing for older people, for which NHSE has recently funded 23 projects and about which some outcome data already exist at CCG level. VCSEs are main providers of such 'integration' activities, which appear to improve patients' quality of life and reduce unnecessary demands on hospitals.[16] VCSEs providing social prescribing are mostly quite newly commissioned, indeed quite new organisations, hence probably less accomplished than older, larger VCSEs in monitoring, evaluation and research. Given the policy context and research

call priorities we will seek study sites with social prescribing projects serving more deprived and/or excluded communities.
2. Hospices, whose models of care the NHS subsequently adopted and who provide end-of-life services which the NHS traditionally delivered in very different ways.
3. People with a learning disability and complex behavioural needs, sampling sites where healthcare commissioners have worked with the VSCEs, both large and small, to develop more individualised packages of support, and building on previous studies.[36,37]

These tracer groups provide opportunities to contrast VSCEs of different sizes, ages, health system function (prevention, self-management, formal care); and different mixes of contracts and funding sources, hence different degrees of dependence on commissioners. Some organisations and services (e.g. for LD) which cater for children and young people *among others* are likely to be included, but not children or young people as a separate care group. Commissioning for all these groups raises questions, which cut across many care groups, of equal access to care.
In each study site we will study at least two of these tracer groups. Hence the setting for WP1 is VCSEs concerned with these three tracer groups. Since our proposed unit of analysis is the commissioner-VCSE relationship, the set of these relationships is (so to speak) our 'target population'.

For individuals, the inclusion criteria are current first-hand knowledge of, and participation in at least one of:

1. service provision through a voluntary, charitable to social enterprise (VCSE) organisation.
2. co-commissioning with an NHS or local authority commissioner on behalf of a VCSE organisation.
3. commissioning a VCSE organisation for the NHS or a local authority.

WP2 is a census of CCGs, so all CCGs will be included in the sampling frame.

Exclusion criteria

The exclusion criteria for case study sites (WP1, WP3, WP4) are to avoid overlapping other studies. So the exclusions will be VCSEs concerned predominantly with gender identity[34], mental health crisis care, child mental health, the on-going evaluations of personal budgets (e.g. for people with learning disabilities).

Exclusion criteria for individual informants are:
1. Aged below 18.
2. Lack mental capacity to give informed consent
3. Lack mental capacity to participate in action learning and/or as co-researcher.

Because WP2 is a census of CCGs, no CCG will be excluded.

Sampling

Size of sample

At organisational level, the sample size will be eight sites, as described above.

At individual level, we will start from a lead informant (usually chief executive or equivalent in each site and snowball from them, continuing sampling until we reach saturation. This method makes is difficult to state in advance an exact number of individual informants in each study site but in our experience

of conducting similar studies saturation is often reached in the range 10-15 informants per site (so 80-120 in total for this study).

Sampling technique

Sampling methods are described more fully above. In brief, the sampling technique for the case-study based work (WP1 and WP3) is a purposive qualitative sample of local health economies (CCGs) with maximum variety in the scale, hence complexity and development, of NHS commissioning of VCSE organisations. nd in terms of volume and technique. WP2 is a census of local health economies. WP4 will take a sample individuals from among the key informants in each study site, the individuals being selected for willingness, ability and opportunity to participate in action learning.

Recruitment

In each study site (sample described above) we will recruit individual informants by starting from a lead informant (usually chief executive or equivalent in each site and snowball from them, seeking individuals who meet the above inclusion criteria. Applying these criteria will serve as the equivalent of a participant eligibility screening process for the project.

Sample identification

The researchers will identify a lead informant for each study site on the basis of published information about which person holds the role of chief executive, or equivalent (e.g. coordinator of a voluntary organisation). That lead informant will then identify further participants, on the basis of her local knowledge of which individuals are likely to satisfy the study inclusion criteria. This will require no resources other than local knowledge. Participants will therefore not be recruited through Patient Identification Centres (PICs) nor by means of publicity (posters, leaflets, adverts or websites). The lead informant will be the sources of identifiable personal information that will be used to identify potential participant, and that information will normally be limited to the potential participant's name, organisational role(s) and contact details. Access to patient records is not required, nor researcher access to referral details, patient or disease registers.

We will pay non-salaried participants honoraria costed nationally at the rates recommended by INVOLVE (https://www.invo.org.uk/) and meet reasonable expenses for any travel and accommodation arising from project participation.

Consent

We will obtained informed consent before collecting data from any study participant. In the first instance we will send the participant a Participant Information Sheet (as approved by an REC) and allow them at least a week to consider it before seeking consent. The information sheet will state how the potential participant can gain further information, including by asking questions and by talking to a researcher. The inclusion criteria (above) stipulate capacity to consent, but in addition the researchers undertaking fieldwork will be instructed to satisfy themselves that each participant from whom they seek data has at that time capacity (i.e. understand the purpose and nature of the research, what it involves, its benefits), risks and burdens; the alternatives to taking part; can retain the information

long enough to make an effective decision; can choose freely) and that consent comes direct from the participant themselves (not a proxy).

ETHICAL AND REGULATORY COMPLIANCE

The Participant Information Sheet explains that a participant can at any time withdraw from the research, and what its risk and benefits to them are. The data collection methods uphold the dignity of the participants by treating the latter as informants with privileged knowledge of NHS commissioning of VCSEs. The research methods, study management arrangements, and researchers' fieldwork all conform to the relevant legislation (e.g. for data protection) and regulatory requirements for obtaining approval (e.g. via the NHS CRN network, IRAS and local research governance leads) to conduct the study at the proposed sites.

Assessment and management of risk

Being non-clinical research, and not involving vulnerable informants or informants lacking capacity to consent, the risks of participants are small. Nevertheless the Patient Information Sheet explains 'We do not expect our interviews to make you feel uncomfortable in any way. If they did, the researcher would end the interview as soon as he or she became aware of the fact'. Should the researcher discover any potential risk or harm to the participant, or to others, the researchers will share that information with agencies who can respond to mitigate or prevent harm. Which agencies that would be would depend on the case but might for example include an occupational health department, third-party counselling, healthcare professional or social worker.

Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of those part of the study that involve fieldwork, a favourable opinion will be sought from a REC and from a University Research Ethics Committee for the study protocol, informed consent forms and other relevant documents e.g. advertisements.

Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site. The CI will retain all correspondence with the REC, report annually as required, otify the REC of the end of the study, notify the REC of any premature termination of the study and the reasons for that, and submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

Before enrolling participants into the study, the CI will ensure that the participating organisations approve. For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

The process for amending this protocol will be that the CI will first agree any proposed amendments with the funder. Then, any substantial amendment (as defined by the sponsor) to the REC application or the supporting documents will be submitted for REC approval following REC requirements and procedures, and to the HRA and to the participating organisations' R&D offices and local research teams, for them to confirm whether NHS permission for that site is unaffecte. No other specialist review body approvals apply to the present study. Version numbers will be used to document the amendment history of the protocol and identify the most recent protocol version.

Peer review

This protocol was anonymously peer-reviewed by the NIHR HS&DR programme, by their methods and too their standards, and the protocol adjusted to meet the peer-reviewers' recommendation before funding was offered. The peer review included scientific and PPI reviews.

Patient & public involvement

As the most relevant public and patient constituency, PPI in this proposal focuses on VCSEs that represent and consult patients, and/or provide NHS-funded services. All those taking part in the PPI activities described below will however do so as members of the public who belong to a specific care group and/or are members of relevant organisations, not in any capacity as patients undergoing treatments arising from this research.

Preparing this protocol

PenPIG (SW Peninsula CLAHRC Patient Involvement Group), HEPE (Healthy Environment Public Engagement), the Greater Manchester Transforming Care board, National Voices (Jeremy Taylor), Dimensions, and individuals working in hospices contributed to the project foci and design. HEPE added: 'Just to say, the group is really interested in social prescribing, so it should be a productive discussion.' Discussions with VCSE members resulted in adjustments to our research questions, the list of potential negative and positive consequences of commissioning VCSEs, proposed sample and the possible barriers and risks. Three consultees have put themselves forward for the PPI Steering Group. Our costings include the PPI activities below.

Patient and Public Participation in the Research

As an oversight committee for the project we have established a Committee chaired by independent person (Charlotte Augst of National Voices) to oversee PPI work and participate as below in the research itself. As we recruit sites we will invite further Committee members so that the Committee will include:

- A majority of members from VCSEs which represent or advocate patient interests, including a VCSE which has struggled to win contracts.
- Patient representatives recruited via the Birmingham and Plymouth research development services, and/or through care group experts for the tracer groups.
- Individual experts including Victor Adebowale, Stewart Hetherington (NCVO), Juan Baeza.
- Researchers from the other projects with whom we will liaise (see above).
- A care group expert from each of the focal care groups.

We anticipate about 12 of the 18 or so members being patients and/or from VCSEs. We will assist them to travel to meetings (as INVOLVE recommend), provide materials in alternative formats where

needed (e.g. large print). We are establishing the Committee early (see flowchart) so that they can help shape the research questions, methods and sample. We will hold further meetings shortly before each main stage of work (site selection; start fieldwork; start analysis; produce outputs), inviting the members to suggest and contribute to:

1. Any necessary 'in-flight' amendments to research questions and design.
2. Identifying relevant existing instances of good practice, study sites, data, data sources and access.
3. Sense-making and analysis of the data, including reality-checks of findings and recommendations.
4. Co-producing the outputs below and dissemination activity.
5. Giving the outputs impact: testing, translation and transmission to VCSEs and networks (e.g. Guilds) likely to use them.

The PPI representatives will contribute output production and dissemination as a distinct project phase after the final report.

We will recruit an individual VCSE member from each case study site as a co-researcher, starting from Steering Committee nominations. This use of 'research intermediaries', similar to 'researchers in residence'[46], is intended to address the reported problem that lack of time, skills and resources, and the acontextual nature of some research, are in many VCSEs barriers to research use.[2,47] We aim to move away from a 'linear' towards a 'relationship' or (preferably) 'systems model'[48] that engages with VCSEs' own motivations for exploiting research.

These co-researchers would participate as equals in the research, so that they and their VCSEs can 'learn by doing' evidence-basing and research with career researchers. We will select the co-researchers for their ability to do so which, subject to the initial findings from WP4, we anticipate may include experience in providing VCSE services and dealing with commissioners; willingness to participate in action learning sets and the tasks that follow; and ability to deal with commissioning documents (specifications, application forms etc.). Nevertheless, individuals with these abilities may also require support to participate as co-researchers. Again subject to the first year findings from WP4, we anticipate offering them training and mentorship in:

1. Good data-collection practice (open vs. closed questioning; non-leading questions; checking for counter-evidence; awareness of sources of bias etc.).
2. Finding out from potential commissioners (and elsewhere e.g. other VCSEs) what information a credible bid has to contain, obtaining it and assembling it into a bid.
3. What monitoring data commissioners are likely to require, and how to gather, interpret and present it.

Mentoring will be one-to-one on a 'buddy' basis to give informal besides meeting-based contact. We will also run three (annual) cross-site action learning workshops which will provide further peer-to-peer mentoring. JC, ME, RMa, RMi and RS are experienced health-worker developers.

Protocol Compliance

The researchers recognise that protocol deviations, non-compliances, or breaches are departures from an approved protocol. Should any serious or repeated breaches occur, the researcher(s) involved will document them on the relevant forms (insofar as applicable to non-clinical research of this kind) for reporting to the CI and sponsor, who will decide what further action to take and who to inform.

Data Protection And Patient Confidentiality

All investigators and study site staff will comply with the requirements of the Data Protection Act 1998 concerning the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Personal information collected for the project will be kept secure, and maintained firstly at the initial data cleaning, during which coded, depersonalised pseudonyms will replace all information identifying individual participants, organisations and any other (e.g. geographical) description which might real such identities. The data and the codes linking the data to identifiable individuals, organisations and places will be kept in separate locations using encrypted digital files within password protected folders and storage media. Only the CI and the University of Birmingham research lead (Professor Exworthy) will have access to the linking codes. Insofar as data are transmitted to sponsors, and when they are transmitted to co-investigators, that will be in encrypted password-protected files, and only in pseudonomised form. To enable maximum exploitation of the data, the data will be stored for three years after the end of the project. The CI is data custodian.

Indemnity

Given the nature of this research, and that no equipment will be provided to sites for the purposes of the study, the likelihood and extent of any harm to participants is small. Nevertheless:

1. The University of Plymouth holds insurance enabling it to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research. The insurance certificate is among the REC application documents.
2. The same applies to meeting the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research.
3. The same also applies to meeting the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research.
4. The sponsor has standing arrangements for compensating harm to the research participants where no legal liability arises.

Access To The Final Study Dataset

All the researchers named on the IRAS form, plus one research fellow to be appointed at the University of Birmingham, will have access to the final study dataset, but restricted to the pseudonymised form. The dataset will not be included in or appended to the full final research report, nor any resulting publications. The study will only allow site co-researchers to access the full dataset if the Project Oversight Group approve a formal request describing their plans. The dataset will not be used for secondary analysis.

DISSEMINATION POLICY

The data arising from the study are jointly owned by the research team. On completion of the study, the data will be analysed and tabulated and a Final Study Report prepared. Subject to peer review, the full study report will be made available as an HSDR Journal paper, freely publicly accessible at <https://www.journalslibrary.nihr.ac.uk/HSDR/#/> , without any time limit. The funder has no further review and publication rights for the data from the study. It is a condition of funding that the funding

body be acknowledged within any arising publications. The researchers plan to notify the participants of the outcome of the study by provision of the publication and by face-to-face feedback presentations at the study sites. Findings for each site will be made available on request to the participants there, and will be provided after the Final Study Report has been compiled. The study protocol, full study report and statistical codes for generating the results will be made publicly available, the latter within the final report, and the report itself and the study protocol on the HIHR/HSDR website <https://www.journalslibrary.nihr.ac.uk/programmes/hsdr/view-health-services-and-delivery-research-projects.htm> . Access to the anonymised participant level dataset is described above.

Authorship Eligibility Guidelines And Any Intended Use Of Professional Writers

All the researchers will be named as authors of the final study report, provided that they satisfy the International Committee of Medical Journal Editors authorship criteria. No professional writers will be involved. The same will apply to all publications arising from this study.

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APPENDICES

Appendix 1- Required documentation

No specifically local documentation is required before initiating a participating site. All relevant documentation (Patient Information Sheet on headed paper, consent form etc.) are generic to all study sites and included in the documentation for REC approval.

Appendix 2 – Schedule of Procedures

Procedures	**Visits (number)**						
	Month 3	**Month 9**	**Month 15**	**Month 21**	**Month 27**	**Month 33**	**Month 39**
Interview		80-120		Update interviews, if required			
Learning set		1		1		1	
Project Oversight	1	1	1	1	1	1	1

No screening, diagnostic, clinical, or therapeutic procedures are involved. This is non-clinical research.

Appendix 3 – Amendment History

Details of all protocol amendments will be listed here should (a) new version(s) of the protocol be produced.

Amendment No.	**Protocol version no.**	**Date issued**	**Author(s) of changes**	**Details of changes made**