

Study Protocol

Evaluation of the development of a behaviour change unit and its contribution to local government

Compatibility statement

This protocol has regard for the HRA guidance.

Full title of the study

Evaluation of the development of a behaviour change unit and its contribution to local government

Protocol version number and date

Version 2.1, 18th November 2021

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 publicly 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):

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Position:

.....

Chief Investigator:

Signature:

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Date:

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Name: (please print):

Jane Wills

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FUNDING AND SUPPORT IN KIND

| FUNDER(S) | FINANCIAL AND NON FINANCIAL SUPPORT GIVEN |
|------------------|---|
| NIHR | This study forms part of a grant of £1.5 million allocated to PHIRST London to undertake intervention evaluation. |

STUDY SUMMARY

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|--------------------------|---|
| Study Title | Evaluation of the development of a behaviour change unit and its contribution to local government |
| Study Design | Sequential mixed methods evaluation |
| Study Participants | Staff across Hertfordshire County Council |
| Planned Study Period | September 2021- May 2022 |
| Research Question/Aim(s) | <p>What are the short- and medium-term outcomes of the Hertfordshire BCU and how have these been achieved?</p> <p>Objectives are to investigate:</p> <ul style="list-style-type: none">• How was the BCU set up?• What political, environmental and cultural factors supported or inhibited its establishment and development?• The extent of the integration of the BCU into policy, planning and service design across the directorates of the council.• Where, and in which contexts, does a BCU add value to the organisation? |

ROLE OF STUDY SPONSOR AND FUNDER

PHIRST London is one of four UK Public Health Intervention Responsive Studies Centres funded by NIHR. It is hosted by London South Bank University (LSBU).

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

PHIRST London Centre Executive Committee (CEC)

The CEC sits within the sponsor organisation, LSBU. It has management and governance responsibility for PHIRST London and is made up of the Centre Co-Investigators, senior academic staff at LSBU and a lay representative from LSBU's People's Academy.

PHIRST London Advisory Group

The Advisory Group provides overall supervision for the Centre and each of its projects including The Hertfordshire BCU evaluation on behalf of the Project Sponsor and Project Funder and ensures that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. Membership has been approved by NIHR.

Project Stakeholder Group

A local stakeholder group is in place to ensure liaison between the research team and the local project leads. The group is represented by Hertfordshire County Council, UCL and LSBU

Keywords: Behaviour change, Behavioural science, Public health, Local government, Whole systems

Evaluation of the development of a behaviour change unit and its contribution to local government

Background

The Behaviour Change Unit (BCU) at Hertfordshire (Herts) County Council is headed by Michelle Constable and was established in August 2019. It sits within the Public Health directorate but has a Council wide remit. The unit aims to embed behavioural science across the council and support the use of insights from behavioural science across all council directorates. The BCU carries out training, provides advice and specific project support across the six directorates of the council: Children's Services, Adult Care Services, Community Protection, Environment and Infrastructure, Resources and Public Health.

Behavioural science (BS) is a science concerned with understanding behaviour and developing effective interventions to influence it. Behaviour change (BC) interventions involve activities, policies, products and services designed to make a difference to the way people act. Behaviour change frameworks include the COM-B Model for understanding individual behaviour change and the behaviour change wheel for devising intervention strategies (Michie et al., 2011). Many of the challenges and issues that face local government are influenced by people's behaviour such as environmental sustainability, crime or obesity.

The need to improve policymaking has been recognised by the Institute for Government, a think tank, which aims to improve government effectiveness. The deployment of behavioural theory as explaining the gap between policy decisions and policy outcomes was outlined by Hallsworth (2011). A Behavioural Insights Team was then established at the centre of government in the Cabinet Office in 2014 and was subsequently transferred to Public Health England (PHE). An overview (Sanders et al., 2018) outlines areas of work (e.g., tax evasion, fine recovery, consumer policy, energy conservation and charitable giving) and gives examples of changes in approach by adopting a behavioural perspective (e.g., regarding the non-payment of fines) but does suggest that implementation could be confined to "low hanging fruit" such as where compliance is desired.

Previous studies of behavioural insights applied to public policy making (Dessart et al., 2016; OECD, 2017) have shown that these lead to a more holistic analysis of problems and issues with a broader identification of policy options following a behavioural "diagnosis". This stage of analysis and design is better informed by an understanding of how people think and act and intervention scalability is better informed by understanding of social norms and networks.

Embedding behavioural science into decision making and policy is nevertheless, a challenge. A study of the factors influencing the use of behaviour change evidence (Curtis et al., 2018) concluded that a coordinated effort is needed to encourage cultural and attitudinal change together with relevant training and tools to support decision-makers and practitioners throughout the commissioning process. A strategy document by Public Health England (2018) describes how the following actions are required to embed behavioural insights in public health:

- Use evidence and theory;
- Mainstream in all organisations that commission, research, design, deliver or evaluate public health services;

- Embed skills, tools and frameworks across sectors of the workforce;
- Assist commissioners, decision makers and practitioners to understand and apply evidence and approaches from behavioural science;
- Provide a range of tools, methods and resources to support the use of approaches from the behavioural sciences;
- Develop the skills and competencies of the public health workforce so they can commission and deliver behaviour change interventions and programmes underpinned by behavioural science theory and evidence;
- Strengthen or establish vibrant networks/communities of practice.

The Herts BCU is one of a handful of units or services to attempt to embed behavioural insights within local government in England. As such, this evaluation will focus on those actions outlined in the PHE strategy document above, namely the extent to which: BS is mainstreamed, is understood and applied. This includes how BS evidence, its tools and resources are used and the extent to which the workforce is confident and competent in BS theory and evidence and the ways in which communities of practice and BC champions are being used.

Co-design of the BCU evaluation

This protocol has been developed in collaboration with local stakeholders from Hertfordshire County Council through a series of workshops designed to assess the evaluability of the intervention and generate an agreed set of evaluation questions and design. The PHIRST London PPIE co-investigator attended two of the workshops and discussed the evaluation design. Our approach to assess evaluability is informed by the five questions identified by Ogilvie et al. (2011) and the stages within the Evaluability Assessment Framework developed by What Works Scotland (Craig & Campbell, 2015). These stages include a structured engagement with stakeholders to clarify evaluation goals; agreement of an intervention logic model or theory of change; a review of existing research literature and data sources; and making design recommendations. The stages were incorporated within an introductory meeting with the Herts BCU team followed by three structured online workshops facilitated by LSBU. Each workshop lasted three hours and was attended by: the PHIRST London research team, key stakeholders from the local intervention and PPIE representation. During these facilitated workshops we worked towards a shared understanding of:

- The aims and processes of the intervention;
- The logic model and theory of change underpinning the intervention, see Figure 1;
- The existing evidence and gaps in knowledge;
- An evaluation question that is feasible and useful to both the local intervention and the wider public health community;
- And an appropriate evaluation design plan.

Communication continued with the Hertfordshire team after the formal workshop process to allow joint decision making around specific aspects of protocol design.

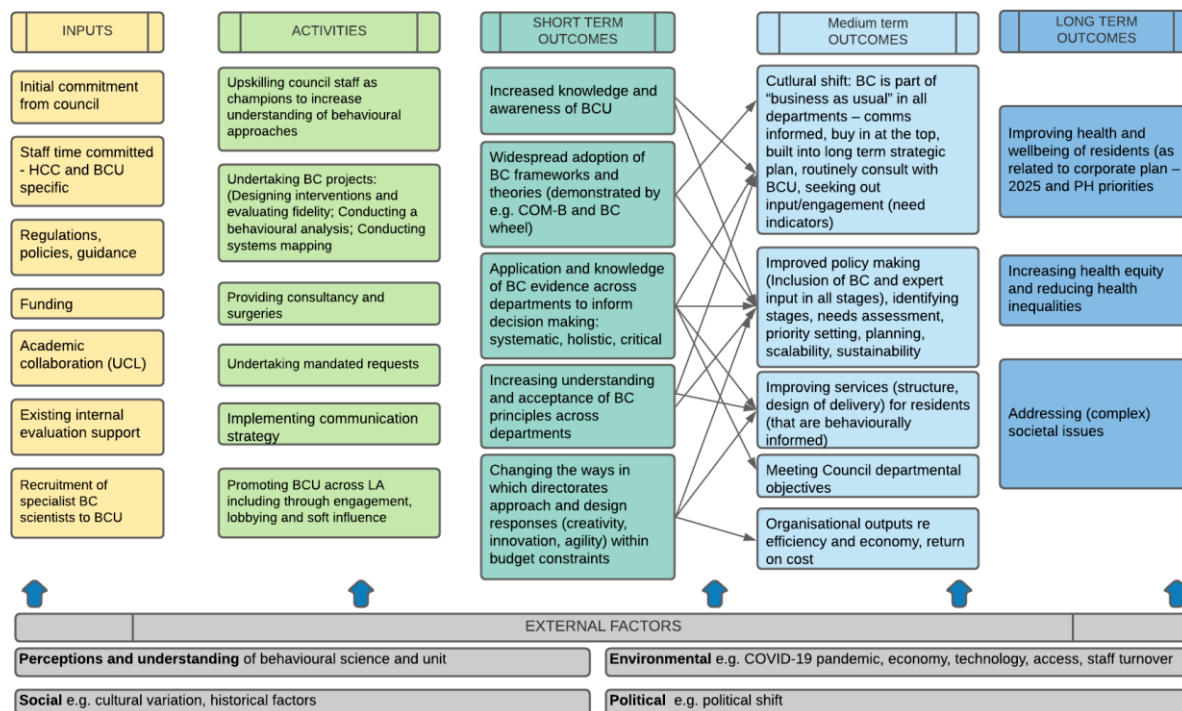


Figure 1: Co-designed Logic Model for the Hertfordshire Behaviour Change Unit

Rationale

Our purpose is for this evaluation not to focus on causal relationships and whether local government decision making is improved by behavioural insights as the BCU is in an early stage of development but rather to illuminate the process in which it was put forward and whether it is perceived as “adoptable”. As more local public health departments seek to find ways to formally integrate behavioural sciences into their departments and the work of their councils, learning from the establishment of the Hertfordshire unit will be important in informing decisions about whether to establish a dedicated unit and how this can best be achieved.

This evaluation will add to the case that has been made about the benefits of a behaviour change approach in decision making by investigating: i) how best to integrate behaviour science across local government and ii) what is its potential scope across service areas.

Theoretical Framework

The participatory workshops with stakeholders from the BCU produced a logic model describing the inputs into the intervention and the activities alongside short, interim and long-term outcomes (see Figure 1). Through an understanding of BC and use of its frameworks and theories and evidence, the BCU expect there to be a change in the ways in which directorates design services.

Local government addresses a whole range of “wicked” problems which have multiple stakeholders e.g., tackling climate change and complex causality for which there may be many options. Developing policies and services that reflect how people behave may be key to improving services. For a local council to adopt the perspective of behavioural science, there will be multi-level influences.

Systems thinking seeks to understand the complex and dynamic nature of an organisation and ‘what and where are the influences on the organisation?’. Describing the system is necessary to understand where the potential leverage points are to influence the willingness and ability to adopt BS.

Figure 2 illustrates some of the actors (people in the organisation) and the structures of the local government system in which the BCU operates. It identifies possible influences that may affect whether BS will inform directorate’s and staff perspective and their approach to planning. The BCU itself is at the centre of Figure 2 and its relationship to individual, social, organisational and governmental systems is depicted through the concentric arches.

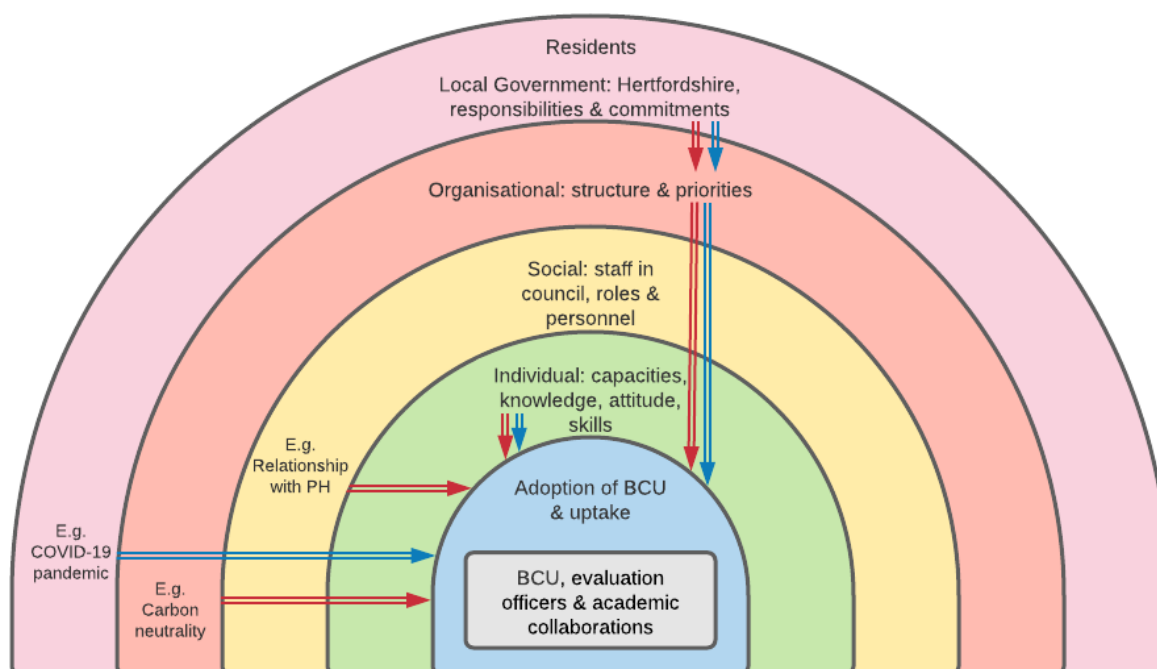


Figure 2: Influences and potential leverages of the adoption of behavioural science. Red and blue arrows indicate positive and negative influences, respectively.

Through the participatory workshops with the BCU, examples of such enabling and inhibiting influences were identified and include:

- Regulatory constraints and expectations for cost effectiveness, value for money, equity, improvements for residents;
- Organisational environment, collaborations and relationship to public health;
- Actors in the council;
- Broader environmental pressures such as the culture of directorates, personnel, priorities (e.g., COVID-19 responses) and relationship with Public Health;
- Priorities within the work environment;
- Personal factors such as attitudes, skills, knowledge, awareness and morale.

The cultural shift of embedding BS across the council can be regarded as an innovation or a new way of thinking for a service based and policy making organisation. Understanding how it can become embedded and integrated, often called *assimilation*, will be determined by those factors identified in studies of the determinants of organisational innovation (Greenhalgh et al., 2004). These are identified as:

- The nature of the innovation (a BCU) and its perceived advantage and linkage to existing priorities. Innovations that are compatible with the organisation's values, norms and perceived needs are more readily adopted and are perceived to be simple to implement and supported by demonstration and trialability;
- The context for its introduction and the size, function, resources and specialisation/devolution of the organisation alongside factors such as the prevailing culture, climate and social relations;
- The role of individuals as champions and those who lead the innovation and the ways in which they present the innovation;
- The motivation, knowledge, skills, attitudes of those who might adopt BS.

Research Question/Aim(s)

What are the short- and medium-term outcomes of the Hertfordshire BCU and how have these been achieved?

The project aims to evaluate the BCU addressing the following:

- How was the BCU set up?
- What political, environmental and cultural factors supported or inhibited its establishment and development?
- The extent of the integration of the BCU and BS principles into policy, service design and delivery across the directorates of the council.
- Where, and in which contexts, does a BCU add value to the organisation?

Study Design and Methods of Data Collection and Data Analysis

The evaluation will be a sequential mixed methods design (Creswell & Plano Clark, 2017) with three separate work packages (WP), see Figure 3. Each WP is of equal status and they are sequential and informed by the findings of the preceding WP. The BCU has an academic collaboration with University College London (UCL) and two Master's students have undertaken dissertations about the BCU, these are identified as data sources in the study design.

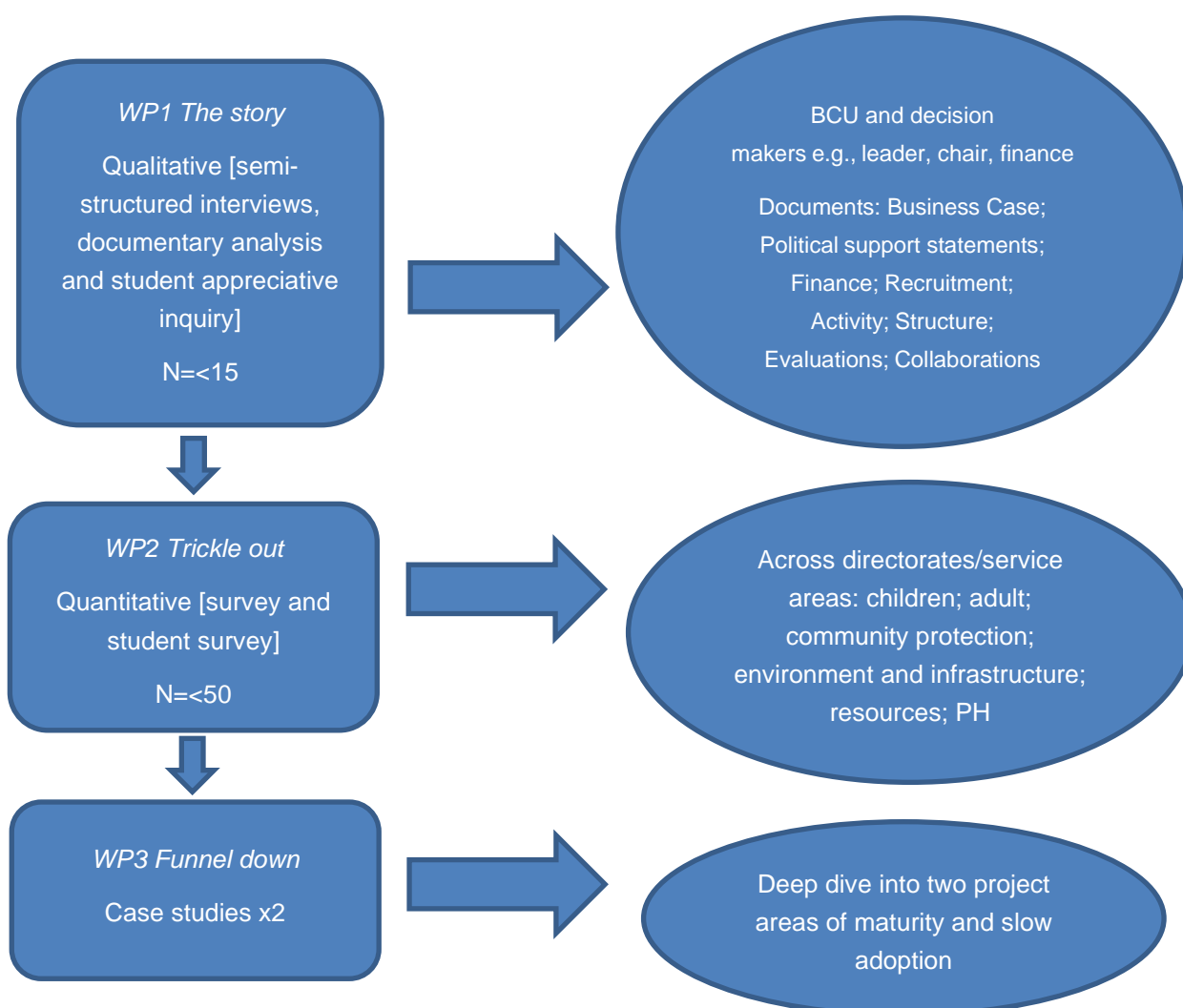


Figure 3: Evaluation design using sequential mixed methods

As part of the academic collaboration that the BCU has with UCL Centre for Behaviour Change, two concurrent studies conducted by students will inform the triangulation of the data sets from the work packages designed for this evaluation. The student studies include an appreciative inquiry with individuals involved in setting up the BCU and a descriptive analysis of the activities and actions of the BCU.

Work package 1:

Aims

This qualitative work package will investigate the establishment and development of the BCU through interviews with those involved in shaping and approving the initial set-up of the BCU. A documentary analysis will also be undertaken, for which documents pertaining to the establishment and activities of the BCU will be compiled. It will provide an in-depth exploration of the rationale and the business case for the BCU, expectations for its outcomes and any challenges encountered. Table 1 shows the basis for chosen methods for WP1.

Table 1: Basis for chosen methods for WP1

| Relevant study objectives | Broad topic | Specific areas of inquiry | Reasoning and key references | Method(s) for collecting this information |
|--|--------------------------------|--|--|--|
| How the BCU was set up and the political, environmental and cultural factors which supported or inhibited its establishment and development. | <i>Exploration / inception</i> | Exploring the inception of the unit, influencing factors, decision makers and decision-making process, early beliefs, expectations, key considerations and stakeholder involvement (including citizens). | <p>Need to investigate the context for BCU introduction (function, resources etc.) alongside factors such as culture, climate and social relations (Greenhalgh et al., 2004). Studies on BS do not take into account 'cultural, historical, political and structural factors' so investigation of these is also essential to understanding the BCU (IJzerman et al., 2020).</p> <p>Behavioural scientists are seen as 'doing to' rather than 'doing with' the public therefore it is key to check the involvement of the public in BCU inception.</p> <p>Understanding the decision-making context, culture and priorities of the council that influence the adoption or otherwise of behavioural science and the extent to which it is seen as according with priorities.</p> | Interviews and documentary analysis |

| Relevant study objectives | Broad topic | Specific areas of inquiry | Reasoning and key references | Method(s) for collecting this information |
|---|--------------------------|---|---|---|
| The extent of integration of BC into policy and service design and decisions across directorates. | <i>Embeddedness/ use</i> | The extent to which the BCU /BS is embedded and used across the council directorates, experiences of it, beliefs and knowledge about it, examples of areas of work. | It is argued that BS needs to be seen as feasible and acceptable by those in leadership/politics otherwise it will not work or be adopted (John, 2015). Innovations that are compatible with the Organisation's values, norms and perceived needs are more readily adopted and are perceived to be simple to implement and supported by demonstration and trialability (Greenhalgh et al., 2004). Incorporates understanding domains of 'beliefs', 'reinforcement' and 'influences' in adopting BS interventions (Curtis et al., 2018). | Interviews |
| The perceived added value of a BCU to local government. | <i>Benefit/ value</i> | Expected or experienced impact and value of the BCU/BS approach and potential/existing benefits to the public and within the council. | Exploring the narrative of key stakeholders, motivations and attitudes in relation to the potential impact of the BCU (Greenhalgh et al., 2004). | Interviews and documentary analysis |

Data analysis methods

This work package will use qualitative phenomenological methodology, by means of interviews with key stakeholders about experiences, perceptions, opinions, awareness and knowledge. The questions will focus on the setting up of the BCU, its embeddedness across the organisation and its anticipated value and benefit to the organisation.

The interviews will be audio recorded and transcribed using an LSBU approved transcription service. Framework analysis (Gale et al., 2013) will be used to identify, analyse and report themes in the data and NVivo software will be used to code themes from the transcribed digital recordings. All data will be anonymised.

In order to establish the factors which supported the development of a BCU, there will also be an analysis of any documentary evidence which supported the formation of the BCU.

Study Setting

The interviews will be held over phone or online via Microsoft Teams.

Sample and recruitment

Purposive sampling will be used to identify key individuals who a) set up the BCU, b) allocated funded and/or senior support, c) key figures whose teams can be expected to use, benefit from, collaborate or receive input from the service (key stakeholders).

It is not yet known how many individuals will be regarded as key stakeholders in total, but indicative numbers are: Public Health (n=3); Academic collaborator (n=1); Assistant directors of directorates (n=6); Head of PH Programme Management and Resources (n=1); Chief executive of council (n=1); Portfolio lead of councillors (n=1); Total N = 13.

Documentary evidence will be collected for the establishment and implementation of the BCU that outline their principles and the case for change, the business case, the implementation plan and expected outcomes, yearly reports and minutes. This evidence will support the development of the 'pathway' which led to the BCU being formed and identification of key factors supporting its formation as well as any challenges.

Participant recruitment will only commence once the LSBU ethics approval is in place. The participants will be invited to take part in the interviews via email addresses, obtained via the BCU lead.

Work package 2:

Aims

This quantitative work package will investigate the extent to which the BCU principles and approach are embedded across the council and how they are being used. It will explore how staff perceive the BCU and its value for service design and delivery. This will be examined in relation to primary outcome measures as shown in Table 2 below. The Theoretical Domains Framework (TDF, Cane et al., 2012) is an integrated framework developed from an expert consensus process that synthesised 128 constructs from 33 behaviour change theories into 14 domains. It provides a well-established and validated tool to identify influences on implementation behaviour, including that of public health interventions (Curtis et al., 2018).

While the TDF provides a comprehensive tool to examine facilitators and barriers to implementation via qualitative interviews, a TDF-based generic questionnaire has been developed to discriminately measure 11 of 14 domains (Huijg et al., 2014). These are domains of: 'Knowledge', 'Skills', 'Social/professional role and identity', 'Beliefs about capabilities', 'Optimism', 'Beliefs about consequences', 'Intentions', 'Memory, attention and decision processes', 'Environmental context and resources', 'Social influences', and 'Emotion'. The TDF can be mapped against the COM-B system of "capability", "opportunity" and "motivation" to examine implementation behaviour. It will be used to identify those factors that influence staff use of behaviour change knowledge and principles for the behavioural/systems mapping, commissioning, design, delivery and evaluation of services and projects.

Table 2: Indicative outcome measures for WP2

| Factor | Operationalisation | Source of data |
|--|--|---|
| Capability: Knowledge of BC frameworks e.g., COM-B, and skills | Knowledge and skills | Study generated test questions based on constructs in TDF domain of knowledge and skills. |
| Opportunities: Social influences and resources | Social and environmental context | Study generated test questions based on constructs in TDF domain of social influences, and environmental context and resources. |
| Motivation | Intentions, Confidence and Emotion | Study generated test questions based on constructs in TDF domain of beliefs about consequences, beliefs about capabilities, optimism, intentions, professional role and identity, memory, attention and decision processes, and emotions. |
| Behaviour | Made changes following training/advice | Study generated test questions adapted from BCU practitioner training materials. |

Data analysis

This will be exploratory in nature. Descriptive statistics will be used to examine engagement with the BCU and BC principles and TDF domains. T-tests and repeated-measures ANOVAs will be used to examine differences for key factors (e.g., staff role) and engagement behaviour. We will test how engagement with the BCU relates to perceived knowledge, understanding and willingness to apply the principles of BC. These analyses will provide a quantitative evaluation of the extent to which the intervention has met and could meet its aim to ‘inform’, ‘assist’ and ‘improve’ services and planning. Table 3 shows the basis for chosen methods for WP2.

Study setting

Data collection will be via an online survey, on the platform Qualtrics.

Sample and recruitment

A total population sampling strategy will be used to purposively sample all staff who have used the BCU. The 43 trained “champions” across the organisation will be invited to complete the survey and disseminate it to five members of their immediate teams (n= 215) with the following inclusion criteria:

- Familiarity with behavioural science principles either as an expected part of their role or introduced to it by a champion;
- Involved in at least one of the following: Behavioural/systems mapping, commissioning, design, delivery and/or evaluation of services or projects.

Table 3: Basis for chosen methods for WP2

| Relevant study objectives | Broad topic | Specific areas of inquiry | Reasoning and key references | Method(s) for collecting this information |
|---|---------------------------------|--|--|---|
| The extent of the integration of the BCU into policy, service design and delivery across the directorates of the council. | <i>Embeddedness/application</i> | Engagement with BCU support and incorporation of the BS approach used across the council directorates. The extent to which the target behaviours of the BCU training (e.g., accessing BCU advice/surgeries/resources, literature searching, identification of behaviour change techniques) are engaged within practice. | Understanding the knowledge, skills and motivation towards an innovation such as the BCU is important to understanding its adoption (Greenhalgh et al., 2004). | Online survey |
| The extent to which BCU principles and approach are embedded in practice. | <i>Knowledge, skills</i> | Perceived physical and mental skills to incorporate BC in practice. Understanding of BC principles and approach. | Theoretical Domains Framework | Online survey |
| The extent to which BCU principles and approach are embedded in practice. | <i>Opportunity</i> | Perceptions of the physical (e.g., time and cost) and social (e.g., social cues and cultural norms) resources necessary to apply BC. | Theoretical Domains Framework | Online survey |
| The extent to which BCU principles and approach are embedded in practice. | <i>Motivation/Disposition</i> | Perceived understanding of the benefits of engagement with BCU support and the incorporation of the BS approach in practice. | Theoretical Domains Framework | Online survey |

Work package 3:

Aims

The adoption and incorporation of behaviour change techniques and principles is relatively new across government and new to local government in England. This work package will therefore examine what features account for the success of the BCU in this context and the relative lack of success in a different context (directorate or project area) using an exploratory multiple holistic case study approach (Yin, 2018). An exploratory case study nested within a mixed methods approach allows for the 'how' and the 'why' of issues raised in the previous work packages to be explored in greater detail within a real-world exemplar, in the Hertfordshire setting.

Based on the findings of Greenhalgh et al. (2004), this work package will examine the innovation and the inner (organisational) context. This will include both antecedents for innovation in general, readiness for particular innovations and the outer (interorganisational) context, for example, the impact of environmental variables, policy incentives and mandates, and interorganisational norms and networking that allowed for the ready adoption or otherwise of the BCU.

Theoretical propositions will be developed through the analysis of work packages 1 and 2 and will be used to guide the data collection and analysis. Data will include case study held documents reflecting involvement with, or impact of work with, the BCU and a focus group with key staff ($n = > 4$) from each case study site to explore the relevance of each proposition and the nature and strength of the system influencing factors elaborated from Figure 2. Anticipated participants in each focus group include directorate staff, workforce panel representative(s) and planning officers. Table 4 shows the basis for chosen methods for WP3.

Data analysis

The analytic strategy will be driven by the theoretical propositions and will adopt Yin's analytic principles of explanation building (2016). Each case will be analysed individually which will be followed by a cross case synthesis. A framework approach (Gale et al., 2013) will assist with comparing and contrasting data *within* and *across* cases to facilitate pattern matching and explanation building. This allows for a combination of deductive and inductive analysis, building upon preceding work packages.

Study Setting

The study settings for WP3 will be two project or service areas with which the BCU has engaged.

Sample and recruitment

A case will be defined and bounded as a Directorate led initiative to work in partnership with the BCU. Two case studies of project areas will be identified. They will be selected based on theoretical replication; they will produce different results but for reasons that can be anticipated (Yin, 2016). The case studies will represent contrasting positions in relation to their level of engagement with the BCU i.e., one that is mature and where the directorate

adopted the BC approach and one which expressed interest but has been slower in adopting BCU support.

Table 4: Basis for chosen methods for WP3 forming the case study approach

| Relevant study objectives | Broad topic | Specific areas of inquiry | Reasoning and key references | Method(s) for collecting this information |
|--|------------------------------|--|--|--|
| The extent of integration of BC into policy, service design and decisions across directorates. | <i>Barriers/facilitators</i> | Perceived and experienced barriers, challenges, uses and enablers to BCU/BS within directorates as well as intended and unintended consequences. | <p>BS intervention outcomes are often context specific and cannot be generalised or drawn directly from the wider literature therefore in-depth understanding of this example is needed (IJerman et al., 2020).</p> <p>Studies on BS do not take into account 'cultural, historical, political and structural factors' so investigation of these is also essential to understanding the BCU (IJerman et al., 2020).</p> <p>The role of individuals who champion the BCU and the ways in which they present it need to be explored in terms of enablers/facilitators within the system, as well as the motivations and attitudes of those who might adopt BS (Greenhalgh et al., 2004).</p> <p>Investigates the role of environmental context and resources in adopting BS (Curtis et al., 2018).</p> | Documentary analysis |
| Where, and in which contexts, does a BCU add value to the organisation? | <i>Features for success</i> | Relevance of each proposition and the nature and strength of the system influencing factors. | BS interventions are often difficult to scale, so investigation into local value and impact is required but this needs to be understood in relation to context and not a generalisable finding (Sanders et al., 2018; IJerman et al., 2020). | Focus groups |

Ethical and Regulatory Considerations

Ethical oversight

The research will receive ethical oversight from the LSBU University Ethics Panel (UEP) and also Hertfordshire County Council as required. This oversight will include the study protocol and all participant facing documentation, and a favourable opinion will be secured before any data collection takes place. Any adverse events will be reported to the above bodies.

All research will be conducted in line with LSBU ethics panel code of conduct for research involving human participants and the British Psychological Society's ethical guidelines. These guidelines include principles of upholding participants rights and dignity, anonymity, and freedom to choose to participate or not. Research will also be conducted and reviewed in a way which makes it compliant with GDPR (or replacement legislation). Each strand of the research presents a number of particular ethical risks.

Informed consent will be sought from all participants who wish to be interviewed or surveyed. A participant information sheet (PIS) will be provided to all participants giving them full information on the studies' aims, methods and risks, etc. Contact details will be provided for participants to ask questions prior to taking part. Once participants have read this, they will give written consent to participate in the study and for use of the data. This PIS and consent form has undergone automated readability checks and are based on LSBU ethics panel approved templates and have been approved by LSBU UEP.

Assessment and management of risk

Table 5: Risk register

| Key risk | Likelihood | Impact on participants | Impact on project | Mitigation |
|---|-------------------|-------------------------------|--------------------------|--|
| COVID19 interferes with staff availability (research team + stakeholders) | Moderate | N/A | Moderate | Depth of team, clear project planning to facilitate handover, lines of alternative communication established, agreement to support the evaluation through a Memorandum of Collaborations between LSBU and HCC. |
| Access to key stakeholders | Low | N/A | Moderate | Collaboration with the BCU. |
| Data not available from partners | Low | N/A | Moderate | Agreement with partners on data and ongoing stakeholder involvement, agreement in place to support the evaluation through a Memorandum of Collaborations between LSBU and HCC. |

Amendments

Significant amendments to the protocol will be discussed in advance with the PHIRST London Central Executive Committee and Hertfordshire DPH and BCU Management. Should these discussions suggest a need for consultation with the NIHR, this will be co-ordinated by PHIRST London.

Peer review

This protocol will receive a proportionate review by PHIRST London and the NIHR.

Public Involvement

The PHIRST London PPIE Co-investigator has contributed to the co-production and design of this evaluation by supporting the planning of, and attending two of the co-production events and providing feedback on the development of the logic model. The evaluation aims to understand the internal processes of the Unit and illuminate whether it is perceived as “adoptable”. It will add to the case that has been made about the benefits of a behaviour change approach in decision making. It does not focus on causal relationships relating to outcomes nor the impact to the citizens. This makes it a unique case in terms of how PPIE is understood where PPIE seeks to involve lay audiences/ the public under the premise that research is done *with* the public and not *to* the public.

The benefits of having end-user involvement is to ensure that appropriate questions are asked and that there is relevant knowledge mobilization from the evaluation. Since the intervention is aimed at the employees of six HCC Directorates, these employees are considered to be the end user. Following discussions with the PPIE Co-I and subsequent communications with the LA the evaluation has taken the decision to adopt an engagement strategy through the “end-user” perspective that pertain to the internal organizational culture. To ensure user representation, the evaluation will seek to establish a workforce panel comprising five members that will collaborate with the project team to refine the design of WP3. PHIRST London will create a flyer inviting employees to self-nominate and the BCU will circulate widely within the six Directorates.

Data protection and patient confidentiality

Where data is collected on third party data collection platforms outside of LSBU (e.g., Qualtrics) data will be anonymised at the point of download, and the third-party copy of the data deleted. All data will be kept in an anonymous or pseudo anonymous format and stored on LSBU secure servers. Any key files will be kept on a secure server, encrypted and passwords shared separately from files.

Quantitative data may be stored indefinitely with participant consent. Where data is offered to online repositories (see *Dissemination*, below), it will be rendered fully anonymous prior to upload.

For qualitative data, in compliance with the General Data Protection Regulation, digital data will be kept for 10 years from study completion and will then be destroyed. Audio files will, however, be deleted following transcription.

When audio files are transcribed, transcripts will be pseudo-anonymised. All information which is collected during the course of the research will be kept confidential by using password protected computerised records. All written transcripts will be kept in a secured locked filing cabinet, when not in use. All data will be secured in a locked filing cabinet for as long as required for the duration of the study and will then be destroyed 18 months after the completion of the project.

Any information regarding participants that is shared with others (for instance in reports, publications or shared with a supervisor) will also have pseudonyms used, which will prevent the identification of people involved in the study.

Indemnity

Indemnity will be provided by LSBU for the research activity undertaken by its staff.

Dissemination and output plans

LSBU will own foreground IP arising from the project, including the final dataset(s) and transcripts. Data will be made available as a 'public good' for secondary analysis (see below). Details of IP ownership and usage rights will be finalised in the collaboration agreement between LSBU and HCC.

Key research outputs will include:

1. Interim report of findings
2. A final report for the HCC team (also lodged on OSF)
3. Peer review journal articles (also lodged on OSF)
4. A briefing for local government

We will also offer a workshop event in which the study findings are presented to HCC, and other meetings on an ad-hoc basis as required. We may present findings to the wider Public Health professional community including the Behavioural Science and Public Health Network (BSPHN) at conferences and through briefings.

The final quantitative dataset(s) will be lodged (in fully anonymous form) on an Open Science Framework site which will also host study documentation, analysis files (coding frames, etc.) and research outputs associated with the project.

Milestones

| Stage | Activity | Completion Date |
|----------------------------------|---|-----------------------------|
| Inception | Introductory meetings | 23 March 2021 |
| | Identification of project team | April 2021 |
| | Identification of local stakeholder group | April 2021 |
| | Sandpit workshop 1 - understanding the intervention | 14 th April 2021 |
| | Sandpit workshop 2 - understanding the theory of change | 5 th May 2021 |
| | Sandpit workshop 3 - agreeing a design | 20 th May 2021 |
| | Sandpit evaluation survey | End June 2021 |
| | Evidence scoping | May-June 2021 |
| | Design and protocol development | June 2021 |
| | Ethics application | July 2021 |
| | Research Governance Approval | July 2021 |
| | Research Registration | End June 2021 |
| | Local collaboration agreement | July 2021 |
| Implementation: WP1 | Documentary data harvesting | Jan 2022 |
| | Invitation and PIS sent | Feb 2022 |
| | Interviews arranged | Feb 2022 |
| | Data collection | Feb-March 2022 |
| | Transcription (outsourced) | March 2022 |
| | Data analysis, application of framework and synthesis | April 2022 |
| | Write up WP1 first draft | May 2022 |
| Implementation: WP2 | Survey design and creation of survey on Qualtrics | April 2022 |
| | Survey data collection including reminders after two weeks | May 2022 |
| | Data analysis | June 2022 |
| | Write up WP2 first draft | July 2022 |
| Implementation: WP3 | Study document consolidation and recruitment | March 2021 |
| | Data collection (focus groups) | May 2022 |
| | Data transcription, document harvesting and data management | June 2022 |
| | Main data analysis, application of framework and synthesis | July 2022 |
| | Output production | August 2022 |
| Project Management and Reporting | Reporting to stakeholder group | Ongoing - TBC |
| | | |
| | Project management meetings | Occur every six weeks |
| | WP1 interim reporting | Feb 2021 |
| | WP2 interim reporting | May 2022 |
| | WP3 interim reporting | June 2022 |
| | Final reporting | August 2022 |

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