NIHR | Public Health Intervention Responsive Studies Teams

Project Protocol

Study title	Whole Systems Approach to Diet and Healthy Weight – Community Pilots Project
Planned study period	18 months
Study design	Mixed Methods Longitudinal Design
Research aim/s	To assess longitudinally the implementation of a Whole Systems Approach (WSA) to diet and healthy weight and to explore the range of levers (drivers) and opportunities to influence relevant local partnerships and interventions in Midlothian and West Lothian in the East of Scotland
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Co-Chief Investigator	Professor Wendy Wills, University of Hertfordshire
Co-Investigators	Dr Suzanne Bartington, University of Hertfordshire **Dr Gavin Breslin, Ulster University (Project Lead)** Dr Neil Howlett, University of Hertfordshire Professor Julia Jones, University of Hertfordshire Dr Katie Newby, University of Hertfordshire Dr David Wellsted, University of Hertfordshire Dr Adam P Wagner, University of East Anglia Mrs Amander Wellings, University of Hertfordshire
Funder	National Institute for Health Research (NIHR) Award ID: NIHR131573
Protocol version number and date	V2.0 November 2021

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1 Title and additional identifiers

1.1 Full title of the study

Whole Systems Approach to Diet and Healthy Weight - Community Pilots Project

1.2 Short title of the study

WSA Diet and Healthy Weight

1.3 Registry

[add reference and date once registered]

1.4 Funding

Funding is provided by the National Institute for Health Research (NIHR) PHIRST initiative (Public Health Research funding stream).

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2. Background information

2.1 Overview of the intervention to be evaluated and contextual information

Globally, poor diet is a leading risk factor for ill-health (Sahoo et al., 2015), while overweight and obesity is a complex problem that has been linked to a range of comorbidities including diabetes, cardiovascular disease, hypertension and certain types of cancer (Abdelaal et al., 2017). The causes of overweight and obesity are complicated and exist in the places we live and work, where defaults in the food and built environment are often those which are linked with less healthy practices (Lee, et al., 2019). In common with most of the developed world, Scotland is experiencing an obesity epidemic especially amongst children (The Scottish Government, 2010). In 2019, it was identified that 30% of children in Scotland aged 2-15 years were at risk of overweight or obesity equating to almost a quarter of a million children at risk (The Scottish Government, 2020). The comorbidities associated with obesity are also at epidemic levels and stretching the resources of health care systems around the world. Cardiovascular disease, diabetes and cancer are responsible for more than 41 million deaths annually, with a third of those occurring before 70 years of age (World Health Organisation, 2021). Thus, reductions in obesity would prevent the loss of tens of thousands of person-years of life and improve the quality of life of millions of people, by reducing the years lived with disabilities attributable to living with unhealthy weight (Murray, et al. 2012).

Obesity affects specific population groups disproportionately, including individuals in more disadvantaged communities (Loring and Robertson, 2014). This is particularly stark for children where obesity prevalence is more than twice as high for children living in the most deprived areas compared to those in the least deprived areas. Over recent years, Scotland has seen a widening gap in the prevalence of childhood obesity among those living in the least and most deprived areas of society (Obesity Action Scotland, 2020). In 2019, the prevalence of overweight or obesity in children was 23% in the least deprived areas, compared to 35% in the most deprived areas: a difference of 12% compared to 7% in 2018. This suggests that the inequalities gap in the prevalence of obesity and overweight in Scotland's children has continued to grow and is thus a cause for concern requiring targeted intervention (Obesity Action Scotland, 2020).

Obesity and its health consequences are influenced by many complex components which interact in nonlinear and unpredictable ways (McGlashan et al, 2019). There is no one solution to tackling obesity, and local action to promote healthy weight and diet across the life course requires a coordinated collaborative approach to support change (The Scottish Government, 2010). Efforts to address obesity must recognise and respond to the many socio-cultural, economic and environmental determinants of health. The disproportionate impact on individuals and families living in deprived areas means that the status quo on obesity is not acceptable (Loring and Robertson, 2014). Therefore, tackling the drivers of obesity and associated inequalities requires a Whole

Systems Approach (WSA) that shifts the focus away from individuals as points of intervention and puts an emphasis on improving the systems in which people live. Moreover, a WSA provides a strong rationale for governments and policymakers to pursue multi-sectoral partnerships to leverage the strengths and resources of a diverse range of 'actors' who have wide influence over systems.

Public health responses that adopt a WSA are becoming more prevalent, particularly in circumstances where causes and solutions to the problem are seen as manifold, interrelated, and operating at multiple levels and across settings, as is the case for obesity (Bagnall et al, 2019). A WSA can be used to describe a collection of integrated and comprehensive interventions that aim to change community systems by targeting individuals, groups and community-level environments and policies. Public Health England define a WSA as follows:

"A local Whole Systems Approach responds to complexity through an ongoing, dynamic and flexible way of working. It enables local stakeholders, including communities, to come together, share an understanding of the reality of the challenge, consider how the local system is operating and where there are the greatest opportunities for change. Stakeholders agree actions and decide as a network how to work together in an integrated way to bring about sustainable, long-term systems change." (Public Health England, 2019, p.13).

While a shared definition or model of what a WSA to healthy weight and diet should look like in practice is lacking, experts have identified a group of activities that have come to represent the approach. Garside, et al. (2010) in an evidence-based review produced for the National Institute for Health Care and Excellence (NICE) highlighted key features that a WSA to tackle health issues such as obesity should include. These elements are displayed in Table 1 below.

Another conceptualisation of a WSA is as a complex map of interconnecting factors, called the 'obesity systems map' as identified in the Foresight report (Vandenbroeck et al., 2007). This 'map' is a causal loop diagram that represents an increasingly obesogenic environment which facilitates weight gain. It was developed through consultations with stakeholders and experts in the United Kingdom (UK) and consists of 108 variables and approximately 304 causal linkages (Vandenbroeck et al., 2007). Since its publication in 2007, the map has helped shape discourse about causality and individual responsibility among policymakers and public health researchers and has popularised the concept of WSA for policymakers (Jebb, 2017) leading to certain actions – for example, Public Health England commissioned Leeds Beckett University to design an obesity prevention strategy informed directly by the Foresight map. It was suggested that core elements of the WSA include: 1) recognition of obesity's complexity and the need for a cross-sector approach; 2) strong partnership and active engagement, commitment and action from a wide range of stakeholders that have a role to play in the obesity system; and 3) employing systems science methods to identify causal factors and changing dynamics (Public Health England, 2019).

A long-term ambition in Scotland is to see widespread adoption of a WSA to reduce health inequalities and improve life expectancy, to support Scotland's Public Health Priorities, one of which is diet and healthy weight. A WSA is currently being piloted across five local authority areas, Midlothian, West Lothian, East Lothian, Fife and Scottish Borders within the East Region of Scotland. A total of £60,000 is being awarded to each of these five local authority areas to help them test a WSA through the design of a local pilot project. The aim is to put a WSA in place to address diet and healthy weight in each of the five areas, with a focus on children and health inequalities. Local Authorities will receive the funds, conditional on collaborative and partnership working within each area encompassing Local Authorities, Health Boards, Community Planning Partnerships (CPP), and Integration Joint Boards, to test the WSA. Two council areas in the East Region have been selected to participate in the current PHIRST evaluation: Midlothian and West Lothian. The rationale for these areas being selected is due in part to an ongoing national evaluation of WSA taking place in the other areas in the East Region and not wanting to duplicate efforts, and the desire to compare potentially different WSAs through a comparison of West Lothian and Midlothian who share similar

demographic profiles yet different WSAs to diet and healthy weight (see section 4.1 for a description of the demographics).

Table 1: Ten key elements of a Whole Systems Approach to obesity (Garside, et al. 2010).

No.	Element	Goals/objectives
1	Identification of a system and its boundaries	Explicit recognition of the public health system with the interacting, self-regulating and evolving elements of a complex adaptive system in relation to obesity.
2	Capacity building	An explicit goal to support communities and organisations within the system, e.g. increasing understanding about obesity in the community and by potential partner organisations or training for those in posts directly or indirectly related to obesity.
3	Creativity and innovation	Mechanisms to support and encourage local creativity and/or innovation to address obesity, e.g. allowing the local community to design locally relevant activities and solutions.
4	Establishing relationships	Methods of working and specific activities to develop and maintain effective relationships within and between organisations.
5	Engagement	Clear methods to enhance the ability of people, organisations and sectors to engage community members in programme development and delivery, e.g. ensuring community involvement in planning and assessing services.
6	Establishing strong methods for communication across the system	Mechanisms to support communication between stakeholders and organisations within the system.
7	Embedding action and policies within organisations	Practices explicitly set out for obesity prevention within organisations within the system, e.g. local strategic commitments to obesity, aligning with wider policies and drivers (i.e. planning or transport policy) and ensuring obesity is an explicit concern for organisations without a health remit.
8	Developing leadership throughout the system	Strong strategic support and appropriate resourcing developed at all levels, e.g. specific methods to facilitate and encourage bottom-up solutions and activities.
9	Robust and sustainable	Clear strategies to resource existing and new projects and staff, e.g. contingency planning to manage risks.
10	Monitoring and evaluation	Well-articulated methods to provide ongoing feedback into the system, to drive change to enhance effectiveness and acceptability e.g. developing a continuous improvement model for service delivery.

2.2 The public health problem to be addressed and why this research is needed now

Childhood obesity has become a major global epidemic in developed countries despite the implementation of a plethora of person-centred interventions and policies to reverse this trend, as noted above. This suggests that innovative approaches are needed to combat this epidemic and prevent and control obesity. Parts of the UK, including Scotland, have a high prevalence rate for obesity among children (see section 2.1); this is a significant public health issue as it has been linked to a range of medical conditions that contribute to increased morbidity and premature death. Moreover, children at risk of obesity are likely to experience negative psychological effects such as lower wellbeing and reduced self-esteem during their childhood years (Sahoo, et al. 2015). To target obesity, there is broad consensus that decisions around supporting healthy eating, healthy weight, and being physically active are important factors that Scotland as a nation must focus on to improve population health. Despite the persistent health inequalities related to healthy eating, weight and physical activity, the Scottish Government has set an ambition to halve childhood obesity by 2030. As drivers of obesity are complex, a local WSA is being adopted, where councils and community planning partners can consider the drivers and barriers in their local system, and how they can be galvanised to deliver their vision of a healthier generation of children in their local community.

2.3 Review of relevant existing evidence

Whole Systems Approaches (WSAs) have been used to address diet and healthy weight nationally and internationally, yet evidence for their effectiveness remains in its infancy (Bagnall et al, 2019). A recent systematic review of 33 studies that included some elements of a WSA showed improved health outcomes: reductions in body mass index (BMI), increased parental and community awareness, community capacity building, nutrition and physical activity environment changes, and improved safety and wellbeing of community members (Bagnall et al, 2019). The success of a WSA was attributed to the full engagement of stakeholders and community, good governance, trust and capacity, sufficient time to build real relationships, finance, and the embedding of the WSA within broader policy. Although initial findings are promising, a cautionary approach is advised as many studies that were included in the review do not report what they set out to implement or do not fully evaluate the implementation of a WSA. Also, methodologies, descriptions of what constitute a WSA and outcomes reported in some studies were limited, or lacked longitudinal follow-up. Furthermore, consistency in definition, application and evaluation of WSAs is lacking in the available literature. To address some of these shortcomings Public Heath England (2019) provided a six-phase framework, referred to as the 'Leeds Beckett Model'. This operationalises the process of how to apply a Whole Systems Approach to diet and healthy weight.

The Leeds Beckett Model six phases include: 1. Set-up; 2. Building the local picture; 3. Mapping the local picture; 4. Action; 5. Managing the system network; and 6. Reflect and refresh. To date, the model has been expanded to nine points by Public Health Reform (2019), but a comparison between applying this framework against service as usual or no framework has not been conducted in Scotland or elsewhere. The WSA pilot projects in the East Region offer an opportunity to investigate how WSAs are being implemented and how these change over time.

3. Study Information

3.1 Aim

To assess the implementation of a Whole Systems Approach to diet and healthy weight and to explore longitudinally the range of levers and opportunities to influence relevant local partnerships and interventions in East Scotland.

3.2 Research questions

1. What elements of a WSA model existed within Midlothian and West Lothian prior to the Public Health Scotland pilot project and what did this entail?
2. What is the current practice and how has it changed to either include the Leeds Beckett WSA, continuing usual practice or incorporating an alternative WSA?
3. Which elements of the Leeds Beckett WSA have been implemented locally and what were the reasons for this?
4. How do different Whole Systems Approaches across Midlothian and West Lothian compare?
5. What impact did the implementation of a WSA have on: a) local stakeholders' knowledge and understanding of how best to address diet and healthy weight issues; and b) local stakeholders' service planning and delivery ethos, policy and practice?
6. What was the process of implementing the WSA and how was it experienced by local stakeholders?
7. To what extent did the WSA meet the needs of local stakeholders and the community?
8. What were the barriers and enablers to implementing a WSA?
9. To what extent was any implementation of a WSA sustained over time?
10. What factors enabled the sustainability of the WSA?
11. Has adopting a WSA benefitted any other areas of working beyond healthy diet and weight?
12. What are the implications in terms of the resources used, and associated costs, for sustainability of the WSA? What are the:
    a) most resource intensive activities resulting from the WSA?
    b) associated costs of these resources, and who bears them?
13. Using Systems Dynamic Theory, determine what casual link diagrams emerge and interact in a whole system approach to diet and healthy weight.

4. Research design

Four research Workstreams have been developed to address the above questions, these are described below.

4.3.1 Workstream 1 (WS1): Literature review

A review of reviews will be conducted to synthesise ways that whole systems approaches (WSA) to diet and healthy weight have been implemented and evaluated nationally and internationally. The review will assess the various theoretical approaches or models used to implement the WSA. The following research questions will be addressed:

1) What models or theories have been used to implement whole systems approaches?
2) How have whole systems approaches been evaluated to date?
3) What evidence is there of the effectiveness of whole systems approaches?
4) What has been the contribution of the public and/or service users in the development of whole systems approaches?

Systematic searches will be carried out using Scopus, PsycINFO (ProQuest), the Cochrane Library, and MEDLINE. Key search terms will include: 'whole system approach' and related terms such as systems-based approach; multi-agency approach; system approach; systems modelling; integrated approach; community-wide approach; collaborative OR joined up approach; or multi-disciplinary OR inter disciplinary approach. Databases will be searched from 1995 to 2022 using a combination of text and Medical Subject Headings (MeSH terms). Additionally, the reference section in identified articles will be searched for relevant articles. Review papers will be included if they satisfy all the following eligibility criteria:

- A review of any type;
- Available in English language;
- Focus of the review is on the application of a whole systems approach to diet and healthy weight;
- Reported the approach, theory or model used to implement a whole systems approach.

The Covidence software (www.covidence.org) will be used to support title and abstract screening, to import full-text papers, resolve conflicts and extract data. Data to be extracted is expected to include the following domains: 1. Identification of the study (article title; authors; full reference; study title; publication year; country of study), 2. Implementation process of WSA (theory or model used to implement or underpinning WSA), and 3. Main findings (outcomes identified). The Public Involvement in Research Group (PIRG; see Section 5) and WSA Project Advisory Group are involved in refining the review questions, eligibility criteria, data synthesis and dissemination.

4.3.2 Workstream 2 (WS2): Qualitative Longitudinal study

A two groups by three time point qualitative, longitudinal design. To assess implementation and the effectiveness of a WSA to diet and healthy weight, focus groups and/or interviews will be conducted at three phases: approximately 6, 12 and 18 months after initiation of a WSA with members of the WSA Core Working Groups (CWG) in West Lothian and Midlothian and the Wider Stakeholder Network (WSN; addressing research questions 1-11). The CWG are responsible for leading/facilitating the local WSA and WSN are the wider group of stakeholders who participate in workshops and in the implementation of the WSA. Two council areas have been selected for evaluation: Mayfield and Easthouses in Midlothian, and Whitburn in West Lothian. This selection is driven by their contrasting choice of methodology in implementing the Leeds Beckett Model of a WSA. In addition, it was important to ensure there was limited overlap with an ongoing National Evaluation of the Whole Systems Approach pilots across Scotland, which involves the other three areas within the East Region.

In terms of demographics, Midlothian has a population size of approximately 95,000 (Midlothian a Place to Grow, 2019) and the area of focus will be Mayfield/Easthouses (≈14,000) as this area is in the top 20% most deprived areas in Scotland. Statistics highlight that within Mayfield/Easthouses, there are, compared with other areas within Scotland:

- Poorer levels of employment
- Lower wage rates
- Higher proportion of families with lower incomes
- Lower average life expectancy
- Greater concentrations of people who are elderly or disabled
- Poorer access to physical amenities such as shops, health care, public spaces and play facilities
- Lower than average educational qualifications and
- Higher levels of crime

Additionally, other statistics show that Mayfield/Easthouses has a higher free school meal entitlement compared to other areas of Midlothian. Mayfield/Easthouses also has a higher proportion of fast-food outlets in comparison to other neighbourhoods in Midlothian. Thus, it is likely that fewer children in these areas have a healthy weight and therefore a higher likelihood of developing type 2 diabetes.

West Lothian has a population size of 183,000 (2019) and the area of focus will be Whitburn (10,670) as it is one of the most deprived parts of West Lothian. Similar to Mayfield/Easthouses, Whitburn is

in the top 20% of the most deprived areas in Scotland. Whitburn is characterised by underlying poverty and income deprivation and an older population than the West Lothian average. There is also a higher incidence of poor health in Whitburn than in West Lothian in general. The most deprived 'intermediate' area in Whitburn, Whitburn Central, compares as lower than the Scottish average and the West Lothian average for the following associated indicators:

- Maternal obesity (2nd worst in West Lothian)
- Babies exclusively breastfed at 6-8 weeks (3rd worst in West Lothian)
- Child healthy weight in Primary 1 ('p1'; first year of primary school)
- Child dental health in p1 (3rd worst in West Lothian)
- Child dental health in p7 (2nd worst in West Lothian)
- Population income deprived (worst in West Lothian)
- Working population employment deprived (worst in West Lothian)
- Children in low-income families (worst in West Lothian)
- Young people living in the most income deprived quintile, aged 0-25 years (4th worst in West Lothian)

Participants

Participants will be recruited from two groups: 1. WSA Core Working Group (West Lothian n=6; Midlothian n=6), and 2. the WSA Wider Stakeholder Network who attended training during WSA workshops (West Lothian n=25; Midlothian n=25).

Participants will be emailed with an invitation to participate by completing the Participant Information Sheet and Consent Form via REDCap (Vanderbilt University 2021), a secure online platform.

Data Analysis

Focus group and interview data will be analysed using Framework Analysis (Ritchie and Spencer, 2004), a type of data analysis that offers a structured, systematic approach to summarising and analysing qualitative data. It has particular utility where multiple researchers are involved in analysing qualitative data, where large qualitative datasets need to be summarised (Gale et al., 2013). It provides a summary of the qualitative dataset that can then be explored to generate themes, and its suitability for use with non-specialists means it supports PIRg and service user involvement in the analytic process.

4.3.3 Workstream 3 (WS3): Momentary Analysis

A sample of participants from the *WSA Core Working Group* and the *WSA Wider Stakeholder Network* will in addition to focus groups and/or interviews be invited to complete monthly momentary analysis (MA) surveys throughout the duration of the project to log activity and capture changes in the system as they occur (addressing mainly research question 12, but also capturing changes/evolution of the system).

Most MA questions record levels of agreement to a series of statements either on Likert scales (which will be coded one to five) or scale of agreement (giving a value of 0-100). Specific statistical analysis of this quantitative data will depend on the quantity of data collected but will likely utilise descriptive statistic summaries by time point, visual plots of changes over time (given monthly responses) and qualitative comparisons of these between sites.

Questions logging activities of relevance to the WSA and time spent delivering these activities will be analysed to understand the resources and associated costs of delivering a WSA (RQ12). Descriptive statistics will be used to summarise the range of activities and the time devoted to them. An

indicative cost of delivering these activities will be determined by multiplying time estimates by a suitable hourly rate of employment[1] (to be determined in discussion with stakeholders and advisory group). Depending on data collected, we will consider comparing sites to explore indications of differences in resource use between WSA approaches. We will augment these health economic considerations additionally with explorations of how the two sites have utilised funding given to each to establish and deliver WSA.

4.3.4 Workstream 4 (WS4): System Dynamics Modelling

Systems Dynamics Modelling (SDM) will be used to help understand how social and economic forces impact levers of change. A key element of (SDM) is mapping out the structure of the problem/area to be explored, for example through a process of 'group model building' (GMB) that involves stakeholders working together to build a group understanding of the multiple components influencing a complex problem and the dynamic relationships between them. Here, by following the principles of GMB, mapping and model building will be used to understand what key stakeholders consider to be the best way of incorporating a WSA into practice (informing RQs: 6, 8, 10). We will develop casual loop diagrams (CLDs) based on the understandings produced from the focus groups and interviews (conducted for WS2), publicly available documentation, and the analysis of other mapping work conducted by stakeholders during workshops. Where required, additional interviews, may be conducted specifically to inform our SDM work (for example, to supplement our understanding of cause-effect relationships between components).

CLD development will be conducted through a collaborative process involving ongoing consultation with stakeholders to verify our understandings and interpretations. In particular, CLDs will be used to describe the components needed to deliver a WSA to diet and healthy weight and provide a description of how these interact and the relative importance of each. By mapping relationships between the elements, a more explicit understanding of how things change over time may be revealed and highlight the interdependent variables and levers that may accommodate greater and sustained behaviour change (Lounsbury et al, 2015).

The produced CLDs will be explored to understand how the identified components interact with each other and implications for improving the delivery of WSAs. We will reflect on the feasibility of developing a full SDM for future use, considering: data requirements and their availability; levels of expertise and resourcing required to deliver modelling; and the potential benefit to WSAs of such a model.

Objective: To develop causal link diagrams that demonstrate the elements needed to deliver a whole system approach to diet and healthy weight and an understanding of how these elements interact

Research questions:

1. What is the most appropriate context/boundary to consider in the SD mapping?
2. What do causal link diagram(s) of implementing a WSA to diet and health weight look like?
3. What are the components that enable the implementation of a local WSA to diet and healthy weight and how do these interact with each other?
4. Is it feasible to develop a more substantial system dynamics model for future use?
    a. What information and data would be required?
    b. What information and data are available?
    c. What level of expertise and resourcing would be needed to deliver this model?

[1] Given the pragmatic approach necessary to maximise data collection, we do not consider a finer granular costing approach appropriate.

d. What value would an expanded system dynamic model add to implementing and evaluating a WSA?

4.5 Co-production and PPI

4.5.1 Co-production

Co-production is a central tenet of the Central PHIRST initiative and our evaluation plans. This evaluation will be co-produced by the Central PHIRST with Public Health Scotland/ East Region team and other local partners and stakeholders, including recipients of the service or programmes, all working together to plan, design, deliver, and disseminate the evaluation. We will routinely communicate and consult with these partner organisations and stakeholders, and in addition present proposals and updates to our Independent PHIRST Advisory Board (composed of relevant stakeholders in the field of public health and evaluations, which includes academics, third sector, governmental and public expertise) and our Scottish specific Advisory Group (similarly composed of key stakeholders but with membership more closely reflecting the subject and area of the evaluation). The feedback they provide will continue to shape key decisions within the research process including design, ethics and dissemination.

4.5.2 Patient and public involvement

The PHIRST and its research partners are committed to involving the public in all stages of its research and the University of Hertfordshire has an existing Public Involvement in Research group (PIRg) composed of members of the public, service users and carers. PPI (patient and public involvement) involvement is key to the Central PHIRST and will be integral at all stages. All PPI activities will be co-ordinated by the PPI co-investigator (Amander Wellings), the academic PPI co-investigator Professor Julia Jones and members of the PHIRST team.

Central PHIRST Public Involvement in Research group (PIRg), hosted by the University of Hertfordshire, will collaborate with the research team across all projects. The Central PHIRST PIRg will provide public, service user and carer perspectives to all the public health evaluation projects conducted by the team. The eleven members of the PIRg meet monthly to discuss key aspects of Central PHIRST evaluation work (for example, research questions, methodology, literature review, research tools, and dissemination), and between meetings work closely with the PHIRST to co-produce evaluations.

Stakeholder involvement: In consultation with Public Health Scotland and the East Region team, the project leads in Midlothian and West Lothian and the project's Advisory Group, we will convene with a public stakeholder group or consult with existing public stakeholder groups, whichever will best meet the needs of the evaluation. The focus will be on engaging children, young people and families in the Lothians.

4.6 Capacity building

We are able to offer capacity building opportunities to partners in Scotland. This will be discussed further in due course.

4.7 Dissemination and outputs

Dissemination will initially be through academic peer-reviewed publications for each of the workstreams: 1) a review of reviews of WSAs to diet and healthy weight; 2) a protocol article for a longitudinal study of WSA to diet and healthy weight in Scotland; 3) An article reporting the findings of the process evaluation of a WSA to diet and healthy weight in Scotland; 4) A Systems Dynamic Modelling case study article presenting the system map, feedback loops and how local health authorities can effectively implement a WSA to diet and healthy weight; and 5) a reflective article on

the extent of the application of PPI throughout the development of a WSA. These articles will be alongside other outputs to be developed and shared with non-academic policy, professional, and public audiences, including local authorities, service users and community organisations.

4.8 Plain English Summary

Overview of the project being evaluated

Tackling the causes of obesity and promoting healthy weight and diet throughout life requires joint effort from the government, service deliverers and people in the community. Using a method called a 'Whole Systems Approach' (WSA) allows different people and communities to work together to:

- find a shared understanding of tackling diet and healthy weight issues
- consider how well the local system is working to support diet and healthy weight
- find out what can be changed quickly and over time to encourage diet and healthy weight
- find out how well the WSA is working

Once the various elements of the 'system' is better understood, partners can agree on actions and decide how to work together to create changes that last.

Public Health Scotland are providing funding to try-out the WSA to tackle diet and healthy weight. The East Region of Scotland have asked the Central PHIRST to evaluate their WSAs, to determine whether a WSA works; what can be done to make it more effective; how funding was used, and what the findings mean for what should be done in the future.

Why is this study needed and what are we aiming to do?

Scotland, like other parts of the UK, is experiencing an obesity problem which particularly affects certain groups of people, such as those living in poverty and more ''deprived'' communities. There is an increase in childhood obesity among those living in the most ''deprived'' areas of Scotland compared to those living in wealthier areas. Childhood obesity continues to be a major public health issue, despite the introduction and use of programmes and policies to reverse the trend. Obesity is linked with health and wellbeing issues for children and adults throughout their life.

We want to investigate whether a Whole Systems Approach to addressing diet and healthy weight is useful for the longer-term management and prevention of obesity among children and young people. We will find out whether local councils, community planning partners and other organisations can work together to identify ways to address diet and healthy weight. We have selected Midlothian and West Lothian for this evaluation because they are relatively similar in terms of location and resident type but are setting-up a WSA in different ways. We will study and compare how well the approach works in each area.

Overall aim

The overall aim of the study is to evaluate how the Whole Systems Approach to diet and healthy weight is put into practice over time. This will include exploring the drivers and barriers to achieving a Whole Systems Approach within Midlothian and West Lothian.

Research questions

This evaluation aims to answer the following, broad research questions:

- What aspects of a WSA were already being used in each area before the Public Health Scotland funding was available?
- What is currently being done in terms of a WSA, how has this changed, and has a particular way of implementing a WSA been used?
- How do the WSAs used in each area compare?

- How did a WSA affect knowledge and understanding of how to address diet and healthy weight issues?
- To what extent did a WSA meet the needs of local stakeholders and the community?
- What helped or held back the development of a WSA?
- How did local community members, groups, and others experience the WSA?
- What is the impact of WSAs in terms of costs and resources (for example, people's time)?
- What are the different elements that are important for a successful WSA?

Research design

1. A review of published articles will take place to see how Whole Systems Approaches have been used to tackle diet and healthy weight in the UK or internationally, and how well the process went.
2. Focus groups and interviews will be carried out with key stakeholders from Midlothian and West Lothian at different points over 18 months. We will ask people to take part who contributed to the Whole Systems Approach design, development, and implementation in Midlothian and West Lothian.
3. Participants will be asked to complete short surveys as part of a 'momentary analysis' throughout the duration of the study - this record of activities means we can identify any changes over time.
4. Systems Dynamics Modelling is an approach used to understand the different components that influence a complex issue. Our data will be used, alongside discussions with stakeholders, to understand the components that are important in putting in place an effective WSA.

Local stakeholders and the Central PHIRST Public Involvement in Research group will be involved throughout the design of this project, adding their insight to help the researchers answer questions that are important to them. They will also help with understanding the results of this evaluation and with sharing them.

Evaluation timescales

Start of evaluation work: March 2021

Draft final report completed: February 2023

Key dissemination activities completed: TBD

The value of the findings

The understanding produced will guide public health policy. Whole Systems Approaches are increasingly popular within public health, so this study will generate important evidence on the usefulness of the implementation of the approach. It will also provide a better understanding of best practice when implementing a WSA and how to ensure that key stakeholders are involved so that any changes made can be maintained.

5. Research governance and project management

5.1 Central PHIRST governance and project management

Appendix 1 presents an organogram of the Central PHIRST showing the team structure and roles.

Project Leads

The project is led by the two PHIRST Chief Investigators, Professor Katherine Brown and Professor Wendy Wills. Dr Gavin Breslin, co-applicant, is overall lead for the day-to-day management of this project.

Management Group

The Central PHIRST Management Group meets on a weekly basis to provide oversight and guidance to the Central PHIRST. The Management Group comprises the Chief Investigators and the eight PHIRST Co-Investigators listed in section 1.5.

Central PHIRST Patient Involvement in Research group (PIRg)

The University of Hertfordshire is committed to involving the pubic in all stages of its research and has an existing Public Involvement in Research group (PIRg) comprised of members of the public, service users and carers. In collaboration with our PPI Co-Investigator Amander Wellings, we have set up a dedicated Central PHIRST PIRg, which is chaired by Amander and supported by Professor Julia Jones and members of the research team.

The PIRg work closely with the Central PHIRST team and provide public, service user and carer perspective to all the public health evaluation projects conducted by the team. The eleven members of the PIRg meet as a whole on a monthly basis to discuss various aspects of Central PHIRST evaluation work (for example, research questions, methodology, reviews of literature, research tools, and dissemination), and between meetings work closely with the PHIRST to co-produce the evaluation.

5.2 PHIRST advisory and consultative groups

Central PHIRST Independent Advisory Board

An Independent Advisory Board (Central PHIRST Independent Advisory Board) has been convened to provide independent, external and policy-orientated advice to the Central PHIRST. The Board provides specific advice and support in relation to the strategic direction of the Central PHIRST and its allocated projects. It comments on the ongoing work plan and progress in line with study protocols, acts as a sounding board for new ideas and developments, and advises on opportunities for wider dissemination and for translating research into policy and practice. It is an advisory only body and does not make decisions in its own right or report to any other group or committee.

The Board will meet up to three times per year and is comprised of experts in the fields of public health and evaluation from academic, third sector, governmental and public sector backgrounds. It is comprised of the following members:

Table 2. List of Independent Advisory Board Members

Name	Job title	Organisation
Mrs Helen King Varah (**Chair**)	Former Deputy Director of Public Health / currently Independent Public Health Consultant	Solihull Public Health Department
Dr Nicola Armstrong	Programme Manager, HSC & R&D Division	Northern Ireland Public Health Agency
Professor Katherine Brown	Professor of Behaviour Change in Health	University of Hertfordshire (non-independent)
Mr Geoff Brown	CEO	Healthwatch Hertfordshire
Dr Tim Chadborn	Head of Behavioural Insights and Evaluation Lead	Public Health England
Dr Suzanne Connolly (Please note Dr Connolly is seconded	Senior Health Improvement Manager	Public Health Scotland

to the project advisory group for the duration of the evaluation)		
Mrs Marion Cowe	PPI Expert by Experience on Central PHIRST Public Involvement In Research Group (PIRg)	Independent member
Professor Steve Cummins	Co-Director of the Population Health Innovation Lab	The London School of Hygiene and Tropical Medicine
Ms Charlotte Grey	Public Health Evaluation lead	Public Health Wales
Dr Sarah Hotham	Senior Research Fellow & NIHR RDS SE Research Adviser	University of Kent
Professor Margaret Maxwell	Director of MHANP Research Unit	University of Stirling
Professor Toby Prevost	Director, Nightingale-Saunders Clinical Trials & Epidemiology Unit at King's CTU	Kings College London
Mrs Genevieve Riley	Senior Researcher	Public Health Wales
Professor Richard Smith	Professor of Health Economics	University of Exeter
Professor Sarah Stewart-Brown	Professor of Public Health	University of Warwick
Ms Ruth Tennant	Director of Public Health	Solihull Metropolitan Borough Council
Mrs Amander Wellings	PPI Expert by Experience; Chair of Central PHIRST PIRg	University of Hertfordshire (non-independent)
Professor Wendy Wills	Director of the Centre for Research in Public Health and Community Care	University of Hertfordshire (non-independent)

Central PHIRST WSA Diet and Healthy Weight Evaluation Advisory Group

A project-specific Advisory Group has been convened to offer specific advice and support in relation to the WSA Diet and Healthy Weight evaluation. The Advisory Group will meet up to six times per year for the duration of the evaluation. It is comprised of the following external members:

Table 3. List of WSA Advisory Group Members

Name	Job title	Organisation
Mark McAllister (Chair)	Public Health Policy	COSLA
Irene Beautyman	Planning for Place Programme Manager	Improvement Service/PHS
Suzanne Connolly	Senior Health Improvement Manager	Public Health Scotland
Brian Couzens	Partnership Programme Lead	NHS Scotland
Fiona Doig	ADP Strategic Coordinator	NHS Borders
Scott Findlay	Project Coordinator	Youth 1st

Ashley Goodfellow	Public Health Consultant, chair of the CPP's Health and Wellbeing Partnership	NHS Lothian
Shona Hilton	Professor of Public Health Policy	MRC/CSO Social and Public Health Sciences Unit, University of Glasgow
Lucy Shardalow	Communications Manager	NHS Lothian
Niamh Smith	National Coordinator WSA Diet and Healthy Weight	Obesity Action Scotland
Yvonne Traynor	Development Coordinator	Public Health Scotland
Amander Wellings	Public Involvement co-applicant	University of Hertfordshire

Local PPI and service-user involvement

A local PPI group will be convened to advise on, and assist with, key aspects of our methodology, data collection, and implementation/impact work. This group will meet on a minimum of three occasions (to be confirmed), which coincide with particular points in the WSA Diet and Healthy Weight evaluation workplan, to provide invaluable input into the evaluation and provide an additional route through which PPI can be realised.

6. Ethical considerations and approvals

This project approaches ethics as an ongoing reflexive exercise relevant to all aspects of data collection, analysis and publication. While this protocol provides a description of the ethical issues identified, it is possible that unexpected ethical issues will arise during the course of the research. The research team will monitor and document ethical concerns that arise and these will be captured in the study's 'issue log'. When necessary, these will be discussed with partner organisations (in accordance with the above provisions regarding confidentiality). PPI input will be sought in any discussion about ethical matters at all stages of research, both routinely during approval of different forms and data collection instruments, and when particular issues arise.

Informed Consent and withdrawal

All potential participants will be provided with a detailed Participant Information Sheet, which will convey comprehensive information about the project to allow them to provide written consent. They will be requested to record this consent in an electronic Consent Form. Participants will be informed about their right to withdraw from the study at any time.

Participant information will be written in a style of language that is accessible to participants. To ensure this, we will seek input/review from the Central PHIRST PIRg and the local PPI group that has been convened for the evaluation. A dedicated telephone number and email address will be set up for participants to contact the research team with queries.

Data protection

All data will be stored and processed in line with GDPR and our Data Protection Impact Assessment (DPIA). Data will be stored on our project-specific R drive (on UH server) and only accessible to those within the research team who require this. The R drive will be used to store details of those participating in focus groups/interviews, audio recordings, transcripts of focus groups/interviews, and other qualitative data collected for the evaluation. Also see section 7 below (data protection and management).

Confidentiality

With the exception of where participants identify themselves or others as being in danger or at

imminent risk, or where potential criminal activity is indicated, all personal information will be considered as confidential. Data will be stored and processed in line with GDPR and a Data Protection Impact Assessment (DPIA) will be developed.

This project will seek to maintain full participant confidentiality. Participants' contributions to the research will not be shared with service providers or stakeholder organisations and will be anonymised in publications, and focus group participants will be encouraged to consider their discussions confidential.

Risks, safeguarding and referrals

It is not expected that the nature of the project will give rise to safeguarding concerns beyond those of any other project. A PHIRST safeguarding protocol has been developed which will be used to guide decision-making/actions as and when necessary. A copy of the safeguarding protocol is available on request from the Chief Investigators.

Where necessary, risk assessments will be conducted, and further safeguarding protocols developed in collaboration with the partner organisations. We will seek to ensure that partner organisations' standard safeguarding and referral pathways are available to all research participants.

Potential benefits for study participants

The project focuses on evaluating the Whole Systems Approaches to diet and healthy weight adopted within Midlothian and West Lothian. This will include exploring the nature of the WSAs taken, the process of implementing them, facilitators and barriers to implementation, stakeholders' experiences, and the outcomes of these pilot projects for stakeholder groups. Study participants will be representatives from stakeholder group involved in the local implementation of WSAs. The evaluation will provide valuable learning about the implementation of the WSA at a local and regional level that stakeholders will be able to utilise to enhance the coordination and delivery of their future diet and healthy weight intervention work. The knowledge gained about effective practice in WSA implementation has the potential to contribute to the development of more effective policy responses, modification of service provision, and better outcomes for recipients of services. Project outputs will be planned in collaboration with stakeholders to help ensure they are impactful.

Approvals

Ethics approval will be sought through the University of Hertfordshire Health, Science, Engineering & Technology Ethics Committee with Delegated Authority.

7. Data protection and management

The PHIRST is an NIHR funded initiative and the University of Hertfordshire is leading a consortium involving Ulster University, the University of Birmingham and the University of East Anglia. Staff at the University of Hertfordshire will take full responsibility for organising data collection and the safe management and storage of data.

A study Data Protection Impact Assessment (DPIA) has been developed for review and approval by the University of Hertfordshire Data Compliance Officer. As this evaluation does not involve the transfer of data from the local authority partners, the Data Compliance Officer has agreed that the DPIA is not essential and only needs updating should the evaluation require data to be transferred from other partners.

A Data Management Plan (DMP) will be produced specifying the types of data that will be generated by the study, how this data will be preserved, and how it will be shared. The DMP will reflect the University of Hertfordshire's commitment to open access science.

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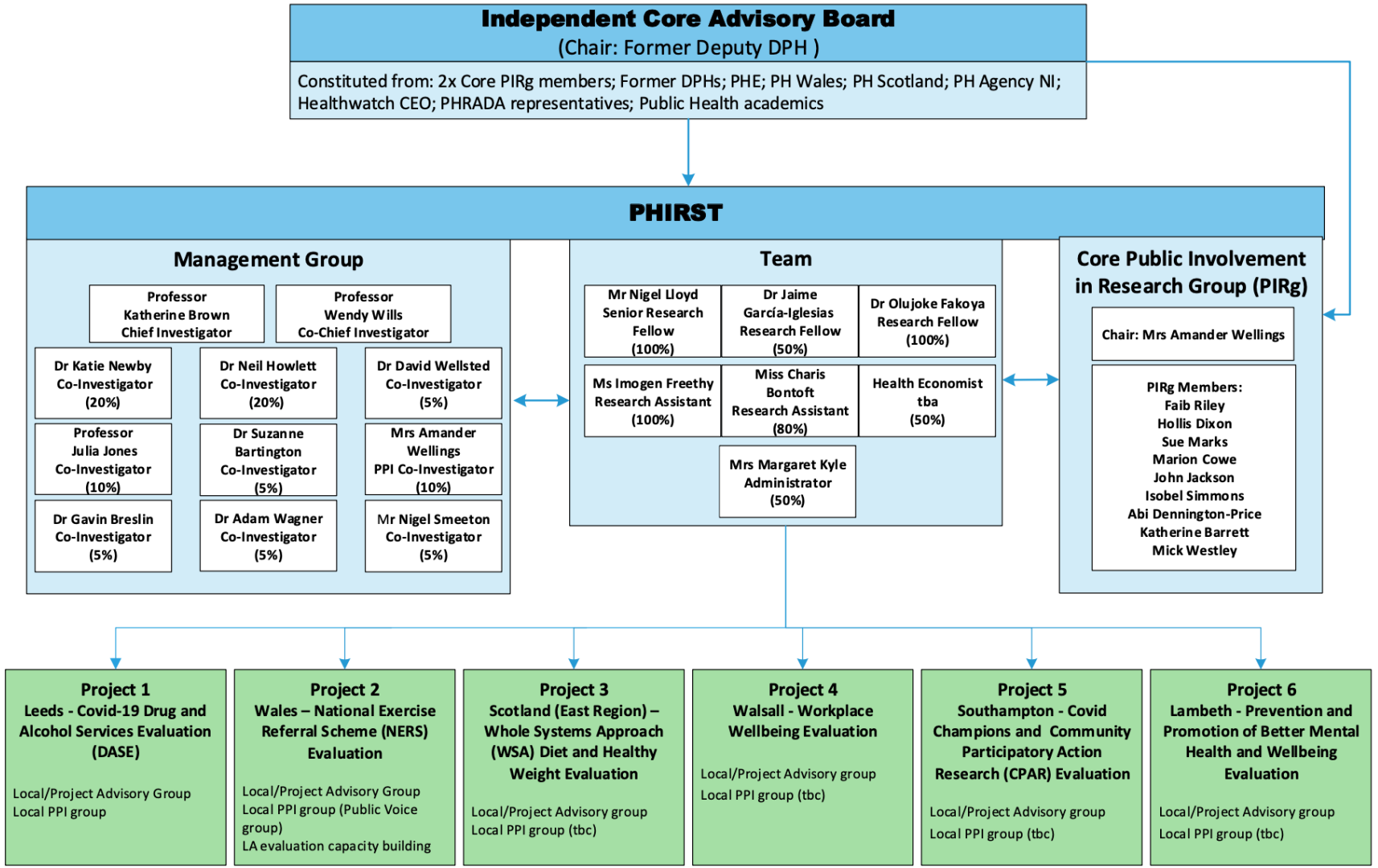
Appendix 1: Central PHIRST team organogram



Appendix 2: Project timescale / GANTT chart