NIHR PHIRST Elevate

Southwark Council's Integrated Healthy Lifestyle Service for weight management

Evaluation Protocol V9.0 02/10/24

Funder	NIHR PHIRST
Chief Investigator	Dr Paul Kelly, Co-Principal Investigator PHIRST Elevate, University of Edinburgh
PHIRST Team	Prof Marie Murphy (Co-Principal Investigator) Dr Andrew Williams (Co-Investigator) Dr Anna Boath (Research Fellow) Sarah Janac (Knowledge Broker) Dr Jillian Manner (Research Fellow)
Southwark Team	Maria Bujor (Public Health Programme Manager – Southwark Council) Jennifer Elliot (Public Health Project Officer – Southwark Council, Embedded Team Member)
Timeline	May 2024 - April 2025

This project has been funded by the National Institute for Health and Care Research (NIHR) Public Health Research Programme (NIHR160288).

1 BACKGROUND

Integrated health and wellbeing services

Integrated health and wellbeing services have their root in acknowledging the multiple factors that contribute to an individual's sense of wellbeing and quality of life (Dahlgren & Whitehead, 1991). Integrated community-delivered health services, based around a "hub" model, have been commissioned by many UK local authorities in order to move from a siloed approach to delivery of healthcare service, to a more efficient and tailored service delivery (NHS Confederation, 2011). Implementing health hubs, at a local government level, may allow for improved service capacity management and allow local governments to address specific health inequalities (NHS England, 2014; Marmot, 2013).

These hub models are frequently referred to as integrated healthy lifestyle services and offer a streamlined process for residents to access tailored support and interventions, and for healthcare professionals to refer patients to interventions. This model focuses on providing an initial assessment of an individual's needs to facilitate onward referral to a service, or range of services. Services typically include weight management, smoking cessation, mental health services and diabetes care. Addressing individuals' health needs via a hub, has been shown to positively impact sense of wellbeing, and reduce hospital visits; reducing pressure at a systems level (Friedli et al., 2012; Dayson & Bashir, 2014).

A mixed-methods evaluation of this service model in the northeast of England reported that integrated service provision allowed for multiple health and social concerns to be addressed compared to a single issue (Cheetham et al., 2018). Findings from semi-structured interviews with service users identified that alongside directly addressing health issues, the community-delivered programmes allowed users to engage with other members of the community which promoted an improved self-confidence, reduced social isolation and fostered a sense of community.

Southwark Council's Integrated Healthy Lifestyle Service

Southwark, a borough in central London, has an obesity prevalence of 41.8% in children and 51.1% in adults, with 68.9% of adults engaging in regular physical activity (Southwark Council, 2022). Southwark Council's Integrated Healthy Lifestyle Service (IHLS) offers a holistic approach to tackling obesity and physical inactivity through providing weight management and physical activity support services (among other services), while addressing key health inequalities by creating a single point of access for residents.

Referrals to health services are managed through the Healthy Lifestyle Hub (HLH), a triage service delivered by telephone. The service provides an initial consultation followed by 9 points of contact; 5

days after the initial call and once per week for up to 30 minutes for a 4-week period, followed by 4 further points of contact. Service users are also contacted 6 and 12-months after programme completion (post-intervention) to identify goals, further programmes and prevent relapse. Services that residents can be referred on to include Exercise on Referral, Alive 'n' Kicking, the National Diabetes Prevention Programme, Walking for Health, Southwark Stop Smoking Service, Weight loss support (either WeightWatchers® or online exercise and healthy eating classes delivered by Guy's and St Thomas' NHS Foundation Trust) and Talking Therapies.

The IHLS, the HLH, and its associated services are commissioned by Southwark Council and run by a third-party community health company called Everyone Health. In addition, the HLH acts as a single point of contact to refer to other programmes not commissioned by Southwark Council (e.g., national programmes, Weight Watchers, Ramblers programmes). A key component of the IHLS service offering are their weight management services, which are available for both adults and children. The main services the HLH refers into are:

(1) Alive 'n' Kicking (AnK); a 12-week nutrition, physical activity and behaviour change service for children aged 4-17 years and their families, and;
(2) Exercise on Referral (EoR); a 12-week structured physical activity programme for adults with three different support levels (depending on participant needs).

AnK is a child weight management programme for children aged 4-17 years, delivered in the community, focussing on both diet and physical activity. The service is delivered over 12-weeks at local leisure centres and involves aged-appropriate physical activity, nutrition workshops for the wider family unit (e.g., preparation of snacks), and SMART goal setting.

EoR is a 12-week supervised gym-based programme for adults >18 years old, focussing on building confidence around physical activity. Within EoR there are three sub-programmes: Active Boost, Kickstart, and Cardiactive. Active Boost provides the lowest level of support and is recommended for those who are confident to exercise safely. Kickstart provides increased support, for example demonstrating exercises. The highest level of support is Cardiactive which requires specific referral as only those who have history of a cardiac event are eligible for this programme. Upon completion of EoR individuals are then eligible for discounted leisure centre memberships for 12 months, and other free activities such as led walks. Ank and EoR are offered across multiple Southwark Council leisure centres across the borough.

The HLH, AnK and EoR are currently funded by Southwark Council (Recurrent Public Health Grant) until 31st March 2025. This evaluation will inform recommissioning decisions for 2025/26 and beyond.

2 RATIONALE

Weight management programmes

The prevalence of overweight and obesity in England is estimated to be 64% in adults 32.3% in children aged 4-5 years and 37.7% children aged 10-11 years (UK Government, 2024). These figures demonstrate a clear need for weight management programmes. Delivery of weight management programmes within the community setting, referred to as tier 2 weight management, is beneficial as investment into locally-delivered services assist in reducing inequalities relating to service access (Hazlehurst et al., 2020). In 2021/22 the UK government provided a one-off increase of funding (£100 million) towards tier 2 weight management programmes; of this £30.5 million was distributed between local governments to support expansion of tier 2 adult weight management services (UK Government, 2023).

Tier 2 weight management programmes are important in the context of overweight and obesity as they are the "first line" of treatment option and are delivered within communities. Successful tier 2 weight management supports reductions in adiposity and long-term behaviour change. In turn, this should reduce the need for tier 3 (multi-disciplinary team care at a tertiary hospital) or tier 4 (bariatric surgery) intervention, as well as overweight/obesity related co-morbidities such as type 2 diabetes mellitus and cardiovascular disease (UK Government, 2023). However, tier 2 weight management services have a high level of drop-out. Within England in 2021/22 only 35% of adults completed the programme they were referred to (UK Government, 2023). To this end, a key area of focus of this evaluation is to understand reasons why individuals may not initiate programmes they are referred on to and to analyse reasons for drop-out from the programmes.

A recent scoping survey investigating provision and delivery of these programmes was conducted across local governments in England (Fong et al., 2024). Key recommendations from this survey included the need for a straight-forward referral systems and an ability to manage surplus referrals (Fong et al., 2024). These recommendations support the use of hub-models, such as HLH, in making the referral pathway a single-point of contact for supporting access and managing capacity.

Consultation with Local Authority and stakeholders

Southwark Council, Everyone Health and Leisure Centre staff

An evaluability assessment, consisting of three online workshops was conducted between June and July 2024 with key stakeholders (including Southwark Council, Everyone Health and Leisure Centre staff). This allowed for a shared understanding of evaluation priorities and questions, development of a flowchart of the referral process incorporating the relationship between HLH, AnK and EoR, a logic model (Appendix 1), existing data sources, and preferred evaluation outputs. Through the evaluability assessment with stakeholders and extensive consultation with Southwark staff overseeing the intervention, the aims, objectives and research questions to be addressed by the evaluation were developed and agreed. A key part of the evaluability assessment process is to ensure evaluation

feasibility, the workshops helped clarify what could be done with the existing data and time. On the basis of this assessment, we deemed this to be a feasible evaluation.

Public involvement

A two-hour public involvement workshop held on 5th August 2024 helped identify any gaps in our evaluation proposal and gather feedback to inform our research questions and proposed methods. We also used the opportunity to consider preferred outputs and channels for knowledge mobilisation. Five public contributors – a mixture of current and past service users across HLH, AnK, and EoR – joined the workshop. As no formal processes for public involvement exist within the Integrated Healthy Lifestyle Service, the public contributors were recruited on a one-off basis through the service provider Everyone Health using email and/or phone calls.

Work Package development

Collectively, the consultations with Southwark Council, Everyone Health, Leisure Centre staff and service users informed the development of three Work Packages for the evaluation. Work Package 1 (WP1) involves secondary analysis of existing data which will allow for answers to a number of the agreed upon research questions. Work Packages 2 and 3 involve collecting new data to answer research questions that cannot be addressed by existing data. Work Package 2 (WP2) involves collecting survey data to understand why significant numbers of service users who are referred on to AnK or EoR via the HLH do not initiate these programmes. Work Package 3 (WP3) involves collecting qualitative data to understand themes such as barriers and enablers to accessing services, perceptions and experiences of accessing services via the HLH, and broader impacts upon health not captured by objective measures. Stakeholders were also interested in the research team collecting qualitative data more broadly as they do not currently have this type of data in relation to the IHLS.

The consultations also helped to shape our participant recruitment, data collection (e.g., setting, topic guides), dissemination and knowledge mobilisation plans. For example, service users and Southwark Council preferred that Everyone Health be responsible for recruitment, that focus groups and interviews be offered both in-person (at several leisure centres across the borough) and online, and suggested we offer vouchers for research participation to incentivise participants and as a token of appreciation for their time.

3 THEORETICAL FRAMEWORK

This evaluation will be guided by the Utilisation Focussed Evaluation approach (Patton, 2003). This approach prioritises that the findings generated by the evaluation are useful to the intended user(s). Specifically, in this case Southwark Council, who have already stated that the evaluation findings will be used in service recommissioning decisions. Our evaluation questions, methods, and knowledge mobilisation strategy will therefore be framed to be useful to Southwark Council in terms of making their recommissioning decisions.

4 RESEARCH QUESTION/AIM(S)

The aim of this evaluation is to understand how Southwark Council's Healthy Lifestyle Hub (HLH) influences referral to and engagement in health improvement services, including two local weight management services Alive'n'Kicking (AnK) and Exercise on Referral (EoR)).

4.1 Objectives

Specifically, our evaluation will help Southwark Council to:

1. Assess whether the HLH facilitates appropriate and equitable access to health improvement services (primarily AnK and EoR);
2. Assess whether referral from the HLH to AnK and EoR improves health behaviours and outcomes.

Research Questions

Evaluation research questions are listed below based on the study objective they correspond to.

Objective 1: Assess whether the HLH facilitates appropriate and equitable access to health improvement services (primarily AnK and EoR)

- Why have individuals who have been referred not initiated the programme?
- How did the referrals (to EoR and AnK) from the HLH compare to those from other sources? Have the quality of referrals increased since the HLH was introduced? (Overall and by demographic groups e.g., age, postcode ethnicity, gender)
- Who was referred compared to who took up the programmes? Have initiation and completion (adherence) rates increased since the HLH was introduced? (Overall and by demographic groups e.g., age, postcode ethnicity, gender)
- How do HLH staff decide which services to refer people on to? Are there certain groups the HLH is targeting (e.g., certain demographics)?
- How do services users/Everyone Health staff perceive that the triage service supports their/service users readiness to change their behaviour?
- Does the referral recommendation from HLH on which services to join influence people's decisions?
- Does the length of time between referral to a programme and programme start date impact completion?
- How does the HLH support inappropriate referrals? E.g., do they refer on/link into to external services (wider impact)?

- What are service users experience of referral to EoR and AnK via HLH?
- How has the HLH facilitated access to services?
- What services or support do participants access post-programme?

Objective 2: To assess whether referral from the HLH to AnK and EoR improves health behaviours and outcomes

- Do programmes lead to changes in physical activity, sedentary behaviour and mental health at 3, 6 and 12 months?
- Do the follow-ups help support behaviour change?
- Does EoR and AnK objectively change health markers (12-weeks)?
- Do service users report improved health?
- Why do people choose to take up memberships (or not) post-completion?
- Do people feel an increased sense of community following participating in a HLH programme?

4.2 Outcome

Outcomes will be reported for each of the research questions above (as data availability and completeness allows). Broadly, this will include:

- Characteristics of HLH referrals (over time, by demographic group, by referral route, pre-HLH compared to implementation of the HLH) and reasons for not initiating programmes after referral
- Number of programme initiators and completers
- How HLH staff decide which services to refer people on to
- How the triage process supports behaviour change
- How the HLH supports inappropriate referrals
- Service users experience of referral to EoR/AnK via HLH
- How the HLH facilitates access to services
- Leisure centre access post-programme (and reasons for this)
- Changes in health outcomes (BMI/waist circumference, self-reported etc.) and behaviours (physical activity, sedentary behaviour and mental health) at 3, 6 and 12 months for EoR completers
- If/how follow-ups support behaviour change

5 STUDY DESIGN, METHODS OF DATA COLLECTION, AND DATA ANALYSIS

Study design and overview

Many of the evaluation questions identified in the evaluability assessment and in discussions with Southwark Council were process focused, however stakeholders also indicated the importance of

assessing changes in health behaviour and outcomes. Based on the evaluability assessment and ongoing consultation with Southwark Council both process and outcome evaluation components will be included.

The evaluation will be comprised of three distinct Work Packages, using a mixed method approach.

1) Work Package 1 (WP1): Secondary data analysis of existing data
2) Work Package 2 (WP2): Online survey of HLH service users
3) Work Package 3 (WP3): Focus groups and interviews with service users, Everyone Health staff and non-initiators

WP1 will focus on secondary analysis of existing data collected by Southwark Council (Leisure Centre usage data) and Everyone Health. This will include (anonymised) data related to service user demographics, referrals, programme attendance, leisure centre usage, objective health markers (e.g., BMI, blood pressure) and mental wellbeing (Edinburgh Warwick Mental Wellbeing Scale). To supplement the existing data a short online survey **(WP2)** will be sent to all individuals who contacted the HLH up until 31/10/24. Emails will be sent to prospective participants from Everyone Health, who have contact details and permission to contact (consent from) service users. The short survey will aim to gather information on which services people were referred to and demographic characteristics. The main purpose of the study is to gather information on individuals who were referred AnK or EoR and do not intend on starting the programme and what their reason for this is. Those who indicate that they will not initiate AnK/EoR will also be invited to take part in a short interview as part of WP3. Given the lack of progression from the HLH to any of the services on offer, we anticipate low response rates from these individuals. To address this challenge survey invitations will be sent from Everyone Health (rather than the research team or Southwark council) to ALL residents who have been in recent contact with the HLH. In addition, the survey will be short (<5mins) with completion incentivised. The qualitative element **(WP3)** will involve focus groups and interviews with service users and Everyone Health staff as well as any non-initiators who are willing to take part.

Data collection

WP1: Secondary data analysis

These data are already collected by Everyone Health and Southwark Council (Leisure Centre usage data) and will be shared with the PHIRST Elevate Evaluation team once a Data Sharing Agreement is in place.

WP2: Survey of HLH service users

The online survey will (administered using Qualtrics) will take <5minutes to complete. Survey questions developed and refined in consultation with key stakeholders (public involvement group and Southwark Council staff) will capture non-identifiable information on the service that respondents were referred to, if they initiated / intended to initiate programmes (and if not, a reason for this), and how long it has been since they were in contact with the HLH. Participant demographics will also be collected (Appendix 2). Ethnicity, sex, gender, sexual orientation, and marital status will be determined using census categories. Year of birth will be requested to determine age. Participants will also be asked if they have caring responsibilities and how many dependants they have and their employment status (census categories). Postcode will be requested to allow for calculation of indices of deprivation. As a token of appreciation for completing the survey, respondents will be offered an opportunity to enter into a prize draw and asked to provide their email address solely for this purpose. In addition, following survey completion participants will have the opportunity to provide their email address and consent to be contacted by the research team and invited for an online interview (as part of WP3).

WP3: Focus groups and interviews

Focus groups and interviews will be conducted using semi-structured topic guides (one for each of the **three participant groups**) based on research questions identified in the evaluability assessment. This will be a combination of online and in-person according to preference and convenience of participants, as informed by evaluability assessment and public involvement workshops. ***Focus groups and interviews with service users*** will last approximately 90 minutes and 60 minutes respectively. Participants will be asked about their experiences of engaging with the Healthy Lifestyle Hub and/or weight management services. This will include elements such as the referral process, and (if applicable to them) changes to health (such as mental health) and changes to health behaviours (such as physical activity). ***Focus groups with Everyone Health staff*** will last approximately 90 minutes, and participants will be asked about their experiences in running/supporting the Healthy Lifestyle Hub or weight management services. This will include elements such as the referral process (to the extent in which it relates to their role), and (if applicable to their service users) changes to health (such as mental health) and changes to health behaviours (such as physical activity). ***Interviews with non-initiators*** will last approximately 30 minutes, and participants will be asked about their experiences with the Healthy Lifestyle Hub and why they chose not to initiate any of the services offered. In-person and Zoom focus groups/interviews will be recorded using an encrypted audio recorder and Microsoft Teams focus groups will be recorded directly on Microsoft Teams, as per University of Edinburgh Policy.

We will also ask for demographic data via an anonymous survey (same questions as the survey; e, sex, gender, sexual orientation, marital status, year of birth, caring responsibilities and dependants and employment status). We will ask participants to fill this out before their focus group or interview (online or on paper).

We will reimburse research participants for any costs they incur as a result of participating in the research (e.g., travel, childcare costs, carer costs or personal assistant costs). Participants will be given an email to get in contact with our administrator, who will provide the University's non-staff expenses form and arrange for payment via bank transfer as per University policy. These forms and contact details will be kept separately from the research data. Informed by discussions with services users and Southwark Council, we will provide participants with shopping vouchers after taking part in focus groups or interviews as a token of appreciation for their time. This will be in the form of a voucher, with amounts proportional to time commitment to be determined.

Data analysis

WP1: Secondary data analysis

This work package will involve secondary analysis of data collected by Everyone Health and Southwark Council (Leisure Centre usage data). Anonymous data (those who contact/use services will be represented by client ID number) will be transferred to the University of Edinburgh via the DataSync platform and stored securely using the DataStore platform. Pre-agreed analysis will be conducted, as per the data sharing agreement. Data will be dated, so that the impact of COVID-19 can be accounted for. If the available data permits, we will analyse this across three distinct time points: 1) pre-HLH data (pre-COVID); 2) HLH data during COVID, and; 3) HLH data post-COVID. Dates of Southwark COVID-19 restrictions will be confirmed at the outset based on a knowledge of the restrictions in place at a local level.

Prior to analysis data checking, cleaning and coding will be conducted using Stata (Version 18). Missing data will be summarised at this stage. Continuous variables will be assessed for normality; with overall distribution being assessed by generating histograms. Differences in binary variables will be presented as or frequency (%), continuous/categorical variables will be depicted as mean (+SD) and median, and mode for categorical variables. If the data allows, comparison between timepoints or participant groups will be made using two-tailed t-tests, (for continuous characteristics), or chi-squared tests (for categorical characteristics) to detect any significant differences (e.g., pre/post HLH, or health variables Pre/post intervention). Significance levels will be defined as strong ($p<0.01$), moderate ($p<0.05$), and weak ($p<0.1$). Descriptive statistics will be used to explore the above research questions.

WP2: Survey of HLH service users

Prior to analysis any required data checking, cleaning and coding will be conducted using Stata (version 18.0). Data coding will be required for binary/categorical (e.g., question outcomes with numbers denoted to answer options, year of birth converted to age). Continuous variables will be assessed for normality; overall distribution will be assessed by generating histograms. Binary/categorical variables

will be presented as mean (SD) or frequency (%) for categorical variables. Appropriate analysis and testing will be conducted to address each research question (above).

WP3: Focus groups and interviews

The recordings will be uploaded by the research team to 1st Class Secretarial through their secure online platform. Interviews and focus groups will be transcribed anonymously (completely and verbatim) by a third-party company (1st Class Secretarial) specialising in transcription. Data will be analysed using a codebook thematic analysis approach (as defined by Braun and Clarke, 2021) (Braun and Clarke, 2021). Transcripts will be coded inductively and deductively to develop themes using NVivo 12 data analysis software (QSR International). Multiple coders will be used to code the first set of transcripts (one to two from each participant group) to seek "interpretative depth" (Braun and Clarke, 2022), rather than as a means of increasing coding reliability or establishing consensus between coders. These initial coded transcripts will be used to develop iterative codebooks with key themes and sub-themes for each data set (participant group). The remaining transcripts will be single-coded using the codebooks, which will evolve as relevant codes and themes are added, to capture the main codes and themes of the full dataset.

Equity, diversity and inclusion requirements

As detailed in section 2, we have consulted with Southwark Council, Everyone Health, Leisure Centre staff and service users. This, in addition to consulting EDI experts within our research team and following best practice, will ensure our we are inclusive in our plans for activities such as: recruitment (e.g., offering compensation for travel, childcare, etc.); data collection (e.g., offering in-person options for focus groups and interviews to avoid digital exclusion, choosing accessible venues) and dissemination and knowledge mobilisation plans (e.g., translation of outputs into different languages). Outputs will be translated to Spanish, as this is the second most common language spoken in Southwark. Translation of outputs will be carried out within the PHIRST Elevate team as we have the required capabilities.

6 STUDY SETTING

WP1: Secondary data analysis

Not applicable.

WP2: Survey of HLH service users

A link to the online survey will be distributed via email by a staff member at Everyone Health to all individuals who contacted the HLH (and provided an email address) from the establishment of the hub until 31/10/24. The survey will remain live for three months (01/11/24 – 31/01/25). The wider study will also be advertised through various local communication channels. See below for more information on recruitment.

WP3: Focus groups and interviews

The qualitative component will cover three participant groups: 1) Service users from AnK (parents) and EoR, 2) Everyone Health staff (from HLH, AnK and EoR), and 3) non-initiators.

1) **Service users** will be offered in-person focus groups at one of Southwark Council leisure centres (either the one they attended as part of their programme or in a nearby area). If they cannot make an in-person session, they will be offered an online session on Zoom. They will also be able to opt for an interview (online or in-person) if that is their preference;
2) **Everyone Health staff** will be offered online focus groups conducted on Microsoft Teams;
3) **Non-initiators** will be offered an interview conducted on Zoom.

In-person and Zoom focus groups/interviews will be recorded using an encrypted audio recorder and Microsoft Teams focus groups will be recorded directly on Microsoft Teams, as per University of Edinburgh Policy.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

WP2: Survey of HLH service users

Any individual who contacted the HLH between from its inception until 31/10/24 will be invited to complete the online survey. At the end of this survey, they will have an opportunity to consent to be contacted by the research team to take part in WP3.

WP3: Focus groups and interviews

Service users: Any current and previous participants of both AnK (parents), and EoR (from 2022 onwards). ***Everyone Health Staff:*** All staff members from HLH, AnK and EoR. ***Non-initiators:*** participants from WP2 who indicated on the survey that they contacted/were referred to the HLH but did not initiate services and provided their email to be contacted for an online interview. All participants must be at least 18 years of age.

7.2 Sampling

WP1: Secondary data analysis (criterion sampling)

The sampling frame will be all service users in contact with the Hub. As the data has not been transferred at time of protocol submission, we cannot confirm the sample size available however approximately 4926 Southwark residents are referred to the Hub annually, with 160 and 1439 initiating AnK and EoR respectively. The final dataset number will be determined by data availability and completeness, with the final number used for analysis determined during transfer and preparation of the dataset.

WP2: Survey of HLH service users (criterion sampling)

The sampling frame will be all service users in contact with the Hub. The survey will be distributed to all individuals who were in contact with the HLH (and provided an email address) and advertised through various local communication channels to maximise potential sample size. As mentioned above, we do not know the specific sample we will be emailing, however we do have approximate numbers of annual referrals and AnK and EoR initiators.

WP3: Focus groups and interviews (stratification sampling)

For focus groups and interviews a purposive sampling approach will be used. The sampling framework shown in Table 1 summarises the number of people we aim to recruit for each participant group. The total number of participants for WP3 will be approximately 40-56.

Table 1 Sampling framework

Participant group	Sub-groups	Target recruitment number
Service users (n = 28-40)	AnK service users 1. Current 2. Past (completer) EoR service users 1. Current 2. Past (completer) 3. Active Boost 4. Kickstart 5. Cardiactive	4 focus groups • 2x AnK (n = 6-8 participants per focus group with a mix of AnK subgroups) • 2x EoR (n = 6-8 participants per focus group with a mix of EoR subgroups) Interviews* • AnK (n = 2-4) • EoR (n = 2-4) *This could be more or less depending on personal preference for interview or focus group

Staff from Everyone Health (n = 9-12)	1) HLH (2 staff) 2) AnK (4 staff) 3) EoR (6 staff)	3 focus groups • 1x HLH (n = 2) • 1x AnK (n = 3-4) • 1x EoR (n = 4-6)
Non-initiators (n = 3-4)	NA	3-4 if recruitment permits

7.3 Recruitment

WP2: Survey of HLH service users

All individuals who were in contact with the HLH (and provided an email address) from its inception until 31/10/24 will be sent an email inviting them to participate in the survey and provided with a survey link. Two follow-up emails will be sent approximately two weeks apart to maximise response rates and reduce non-responder bias (Prince, 2012). The survey will remain live for three months (01/11/24 – 31/01/25). To protect the contact details of participants, and further maximise response rates, a staff member from Everyone Health will send these emails. If the participant indicates on the survey that they contacted/were referred to the HLH but did not initiate services, they will be invited to provide their email address if they are willing to be contacted for an online interview by one of the researchers at the University of Edinburgh. The email addresses of individuals who have consented to be contacted will be used to recruit for WP3 (see below section). To incentivise completion all participants will be given the option to provide their email address to be entered into a prize draw to win one of four £25 vouchers after completion of the survey.

WP3: Focus groups and interviews (stratification sampling)

To recruit service users, a recruitment poster will be sent out via email to all current and previous service users of both AnK (parents), and EoR (we will aim to recruit individuals from all three strands of EoR to participate in focus groups; Active Boost, Kickstart and Cardiactive). Emails will contain a one-liner from Everyone Health (e.g., "Please see attached for opportunity to participate in a study on the Integrated Healthy Lifestyle Service"). If responses are low, emails will be followed up with a phone call (if a phone number has been provided) approximately one to two weeks after the email. To protect the contact details of participants, and to maximise response rates, a staff member from Everyone Health will be responsible for sending these initial recruitment emails and phone calls. Participants will be directed to email our Embedded Team Member at Southwark Council. The Embedded Team Member will then send a participant information sheet tailored to their participant group via email. The email will ask that the participant to read through the information sheet and email the Embedded Team Member with any questions. It will advise them to let the Embedded Team member know when they have done this and if they would like to proceed. Once the service user has had an opportunity to read through the information sheet and ask any questions, the Embedded Team Member will provide a number of dates, times and locations (of Southwark Council leisure centres) for a focus group (or interview if that is their preference). If the participant is unable to make it to an in-person

session they will be offered an online focus group or interview conducted on Zoom at a convenient time.

To recruit staff from Everyone Health a separate recruitment poster will be sent out via email to all staff from the HLH, AnK and EoR. A staff member from Everyone Health (not one of the eligible participants) will be responsible for sending this initial email. Staff will be directed to contact our Embedded Team Member. The Embedded Team Member will then send a participant information sheet tailored to their participant group. via email. The email will ask that the participant to read through the information sheet and email the Embedded Team Member with any questions. It will advise them to let the Embedded Team member know when they have done this and if they would like to proceed. Once the staff member has had an opportunity to read through the information sheet and ask any questions, the researcher will schedule an online focus group on Microsoft Teams at a time that suits their group.

To recruit non-initiators our research team will email participants from WP2 who provided their email to be contacted for an online interview. The email will and include a reminder of them providing their email at the end of the survey, and a participant information sheet tailored to their participant group. The email will also ask that the participant to read through the information sheet and email the Embedded Team Member or Research Fellow with any questions. It will advise them to let the Embedded Team member or Research Fellow know when they have done this and if they would like to proceed. Once they have had an opportunity to read through the information sheet and ask any questions, the researcher will schedule an online interview on Zoom at a time that suits them.

Additionally, the study (and opportunities to participate in both WP2 and WP3) will be advertised through various local communication channels, such as Southwark Council's monthly online resident's newsletter. Those who are interested in participating will be advised to get in contact with the Embedded Team Member who will 'triage' prospective participants to WP2 and/or WP3 activities based on their appropriateness.

7.3.2 Consent

WP1: Secondary data analysis

We are working with Southwark Council and partners to establish what consent has already been provided for use of the existing data. Once this is known we will take appropriate steps for the transfer of anonymised data to the Evaluation team.

WP2: Survey of HLH service users

Information on the study and a consent form will be included at the beginning of the HLH service user survey, and participants will be asked to tick a box indicating their consent before proceeding to the survey. Only by indicating consent in this way will participants be able to continue to the survey.

WP3: Focus groups and interviews

For focus groups and interviews, participants will be emailed a participant information sheet (PDF) and consent form (Qualtrics) from the Embedded Team Member or a Research Fellow at least 48 hours prior to their research activity. They will be asked to fill out a consent form prior to their session, with the option of receiving a hard copy of both the consent for and information sheet if they prefer.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

The ethics application will ensure that assessment of risk and safeguarding are appropriately addressed across all aspects of the research process. As part of this process, we will have a risk management plan for both study participants and others, with safeguarding mechanisms as required.

Considering likelihood and potential impact of severity, there are no substantive risks for WP1 and WP2. Plausible risks include transfer of inappropriate data or variables (WP1) or outside access of confidential data (WP2). These and any other identified risks will be considered, and mitigation implemented in our data protection and storage processes.

For WP3 (service users component), although psychological stress or discomfort is unlikely, there is a very small chance that discussing personal experiences of participating in weight management services could be upsetting. As such we have offered participants the choice of an interview if they feel uncomfortable discussing such topics in a group setting, and our focus group and interview facilitators are experienced at managing this in a sympathetic and appropriate manner. Breaks and withdrawal at any time will be supported.

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

All study documents will be reviewed by the College of Arts, Humanities and Social Sciences (CAHSS) at University of Edinburgh for governance review and study sponsorship. Ethics approval will then be sought from the Moray House School for Education and Sport (MHSES) Ethics Committee (University of Edinburgh). The ethics application will ensure that issues of confidentiality, consent, anonymity,

assessment of risk, safeguarding and data management are appropriately addressed across all aspects of the research process including recruitment, data collection, analysis and dissemination.

Regulatory Review & Compliance

Southwark Council will review and indicate approval for the protocol. They will also approve any public facing documents (including recruitment materials, participant information sheets, and all evaluation outputs).

Amendments

Proposed amendments to the protocol will be documented, and approval sought from NIHR. Where required, approvals will be sought from CAHSS Governance (Sponsor) and MHSES Ethics for proposed protocol changes - for example changes to the protocol that alter study methods (e.g., participant recruitment).

8.3 Peer review

As discussed in section 8.2, all study documents will be reviewed by CAHSS Governance (University of Edinburgh) for study sponsorship. Ethics approval will then be sought from the MHSES Ethics Committee (University of Edinburgh).

8.4 Patient, Policy & Public Involvement

Patient Involvement

This research does not include clinical work and no patients will be involved.

Policy involvement

Our aim is to work closely with Southwark Council and the multiple teams (e.g., public health team, leisure team) who are involved in planning and running the health improvement services. We want to make our evaluation as relevant and useful as possible, and align with aims and objectives of the Council. Thus, we have embedded two main processes into our evaluation to facilitate close collaboration with the local authority: conducting an evaluability assessment (as detailed in section 2) and working with an Embedded Team Member (a Project Officers within Southwark Council who has joined our research team for two days a week). The Embedded Team Member will be part of team meetings and help with recruitment,

data collection and analysis, public involvement and knowledge mobilisation. The Embedded Team Member has already been helpful in providing practical and logistical details for this evaluation.

In addition to the activities above, we will embed other policy involvement and engagement opportunities throughout the evaluation. Preliminary ideas include a half-way presentation and Q&A session for key stakeholders within the council, as well as creating Action Learning Sets after the evaluation to reflect on key findings and discuss opportunities to implement any recommendations arising from the evaluation report to improve service delivery.

Public involvement

Our aim is to work closely with members of the public to shape and conduct this research. This approach is strongly supported by the local authority. As discussed in section 2, we have already run one public involvement workshop with a mixture of active service users, which helped to share our participant recruitment, data collection, dissemination and knowledge mobilisation plans. We will continue to involve public contributors throughout the evaluation, focusing mainly on co-production of research outputs (e.g., lay summaries, infographics, newsletter pieces) and dissemination. Depending on people's availability, skills and preferences, we aim to work with some or all of the following public contributors:

- Individuals who joined for the public involvement workshops on 5th August;
- Additional local public contributors recruited through our contact at Everyone Health;
- Local Public Health Ambassadors associated with Southwark Council;
- A public involvement panel which we are currently setting up to accompany us on this five-year research grant.

As per NIHR guidance, no ethical approval is needed for public involvement. We will maintain high ethical standards for our public contributors and embed the UK Standards for Public Involvement throughout our work. Moreover, we will create a payment policy (informed by the NIHR payment policy) and data protection policy (informed by the University of Edinburgh data policy) to have a unified approach to public involvement and ensure we handle data and expenses in an informed, ethical and fair way.

8.5 Protocol compliance

Any deviations, non-compliances, or breaches to the evaluation protocol will be documented and reported to NIHR and CAHSS Sponsorship. Such issues will be reported to the PHIRST Elevate Oversight Group, with discussions held as needed and appropriate actions taken.

8.6 Data protection and patient confidentiality

To attain secondary data for WP1, separate data sharing agreements will be generated between the University of Edinburgh and data controllers (1) Southwark Council 2) Everyone Health). Data shared is for pre-specified analysis agreed between the data controller and University of Edinburgh, with all data received anonymised (via DataSync) and held securely using DataStore. Secondary data will not be made available for further use due to the conditions under which it was originally collected. Data collected as part of the survey (WP2) will contain no identifiable information. If participants opt-in to be contacted for participation in WP3, contact information will be stored separately to avoid any personal data breaches. Focus group and interview data (WP3) will be transcribed anonymously, with consent forms and survey responses stored separately.

General electronic project documents will be stored online in a shared SharePoint folder, accessible only to members of the research team at the University of Edinburgh, plus controlled access for other project team members (the Embedded Team Member at Southwark Council). Paper documents will be stored in cabinets in the research offices which are locked and secure. All sensitive data will be stored in password protected folders on the University of Edinburgh's DataSync server. This includes secondary data from Southwark Council, and Everyone Health data we collect such as contact information for participants, audio recordings, original transcripts and survey responses.

Public involvement

We will follow GDPR guidance and the University of Edinburgh data policy. Any contact that is made with residents of Southwark or IHLS service users for the purposes of public involvement activities will be directly through Southwark Council or Everyone Health – depending on who has permissions to contact them in the individual instances. The residents or service users will be asked whether they are happy for their name, email address and details of their involvement (which programme, whether they are active or have completed) to be shared with PHIRST Elevate. Only if they agree, will a meeting be set up between members of PHIRST Elevate and the public contributors. For online focus groups with residents or service users we will use Zoom to minimise visibility of email addresses between meeting attendees.

For the purposes of compensation for their time, public contributors will be asked to share their email address with the research team, so that we can send them an electronic gift card. Emails and contact details will not be used for any other purpose.

There are two exceptions to the immediate deletion of personal details after receiving a gift voucher. These are:

- If a public contributor has asked for ongoing involvement in the evaluation, e.g., through coproduction of research outputs or through attending another public involvement workshop;
- If a public contributor has asked to be kept updated with the research progress and would like to receive research outputs once they are available.

In these instances, we will save their details so we can contact them at appropriate points during and after the evaluation. Similar to research participant's data, we will delete the data of public contributors who have expressed an ongoing interest to be involved 1 year after closing the evaluation.

8.7 Indemnity

The University of Edinburgh provides indemnity arrangements for staff conducting research or fieldwork. The University's Insurance Office manages a range of insurance coverages, including employer's liability, public liability, and professional indemnity. These policies ensure that university staff, students, and third parties acting on behalf of the University are protected against claims arising from negligence and other liabilities during research activities.

8.8 Access to the final study dataset

Data collected as part of WP2 and WP3 will be the intellectual property of the University of Edinburgh, data will be stored in DataVault (secure, closed access database). Any final datasets resulting from WP1 the evaluation will be stored or destroyed as per the request of the Data Controller (Southwark Council/Everyone Health). Any stored data requested to be stored beyond project completion will be transferred to DataShare (open access) or DataVault (secured database), depending on the instruction from data controller.

9 DISSEMINATION POLICY

9.1 Dissemination policy

Our approach to knowledge sharing is aligned with the School for Public Health Research Knowledge Sharing Principles: 1. Clarify your purpose and knowledge sharing goals, 2. Identify knowledge users, 3. Design the research to incorporate the expertise of the knowledge users, 4. Agree expectations, 5. Monitor, reflect and be responsive in sharing knowledge, 6. Leave a legacy

Using insights from the evaluability assessment workshops, public involvement workshop and regular knowledge mobilisation workshops with key stakeholders from Southwark Council and Everyone Health, a Knowledge Mobilisation Plan was created. The plan outlines knowledge sharing goals, knowledge users and possible outputs and communication channels. It is a living document and will be continuously updated throughout the evaluation based on feedback received from key stakeholders and public contributors and dissemination opportunities that are identified.

The main knowledge users are on local authority level (e.g., parties delivering the IHLS, decision-makers, practitioners, members of the public) and beyond local authority (e.g., other councils in the region or nationally, national bodies, academic community, other PHIRST Teams). As well as targeted communication and updates, we will produce key knowledge mobilisation outputs including a final evaluation report (which will include comprehensive data analysis and tabulation), a slide deck, an infographic and potentially an animation and/or summary postcards for the public in different languages. This will be made available through the NIHR PHIRST website, and any local websites or national websites identified in knowledge mobilisation planning. The funder will be acknowledged on any of the outputs.

The Embedded Team Member will be key in helping identify and deliver key dissemination activities to appropriate audiences following the most established and targeted communication channels. Where possible, we will also involve members of the public in dissemination and co-production of outputs (see section on public involvement).

A key part of the knowledge mobilisation plan is to leave a legacy after the evaluation, i.e., ensuring that we create the right outputs, engagement and/or infrastructure the for the evaluation to have an impact beyond the PHIRST Elevate – Southwark collaboration timeframe. Ideas for this include creating Action Learning Sets specific to this evaluation or trainings or handbooks on topics such as public involvement or evaluating complex public health interventions.

We will develop a framework to track and evaluate any knowledge mobilisation activities. This may include a knowledge mobilisation log with reach indicators, feedback received from key stakeholders and knowledge users, as well as how different outputs are used internally and externally by the Council.

In terms of academic knowledge exchange and dissemination, we will publish and academic output in either an open-access peer reviewed journal, an NIHR journal (NIHR Journals Library) or the NIHR Open Access Publishing Platform.

Research participants who have joined any of the research components (interviews, focus groups, survey), as well as any members of the public who have contributed in public involvement workshops, will be given the opportunity to opt-in to receive research updates and final outputs. This will be managed through a mailing list. Moreover, anyone will be able to specifically request information on the progress of the study and any publicly facing outputs by emailing our research team specific email address (phirst@ed.ac.uk). This email is accessed by multiple members of the research team.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Dr Anna Boath will be first author on for the Final Study Report, and any resulting scientific outputs. Other PHIRST Elevate Team Members (including the Embedded Team Member) will have the opportunity be co-authors or acknowledged as appropriate based on guidelines on the role of authors and contributors (e.g., ICMJE).

10 TIMELINES

Timing of data collection was informed through consultation with stakeholders according to how they will use findings and will depend on when we receive ethics approval and receipt of quantitative data.

Milestone	**Date**
Ethics approval	w/c 7 October 2024
Work Package 1: Receipt of data Data preparation/analysis Preliminary results for recommissioning	 October 2024 October 2024 - Jan 2025 December 2024*
Work Package 2: Data collection (survey distribution) Data analysis	 October 2024 – January 2025 December 2024 - February 2025
Work Package 3: Recruitment Data collection Data analysis	 October 2024 – December 2024 November 2024 - February 2025 January 2025 – March 2025
Final reporting to Southwark/NIHR	Up to May 2025
Post-evaluation knowledge mobilisation and dissemination activities	Up to May 2025

*****Southwark Council will require preliminary results by December 2024 to add to their recommissioning paperwork. Although we will not be near completion of our analysis, we had advised them that we will provide what we can (from WP1 only) at that time.

11 REFERENCES

Braun, V., & Clarke, V. (2021). Can I use TA? Should I use TA? Should I not use TA? Comparing reflexive thematic analysis and other pattern-based qualitative analytic approaches. Counselling and Psychotherapy Research, 21(1), 37-47. https://doi.org/10.1002/capr.12360

Braun, V., & Clarke, V. (2022). Thematic analysis: a practical guide. SAGE.

Cheetham, M., Van der Graaf, P., Khazaeli, B. et al. "It was the whole picture" a mixed methods study of successful components in an integrated wellness service in North East England. BMC Health Serv Res 18, 200 (2018). https://doi.org/10.1186/s12913-018-3007-z

Dahlgren, G., & Whitehead, M. (1991). Policies and strategies to promote social equity in health. Background document to WHO – Strategy paper for Europe. https://core.ac.uk/download/pdf/6472456.pdf

Dayson, C., & Bashir, N. (2014). Evaluation of the Rotherham social prescribing pilot. https://www.shu.ac.uk/centre-regional-economic-social-research/projects/all-projects/evaluation-of-the-rotherham-social-prescribing-pilot

Fong, M., McSweeney, L., Adamson, A., Mathews, C., Lloyd, S., & Rothwell, C. (2024). A cross-sectional survey study exploring provision and delivery of expanded community tier 2 behavioural weight management services in England. Clinical Obesity, 14(2), e12629. https://doi.org/10.1111/cob.12629

Friedli, L., Themessl-Huber, M., & Butchart, M. (2012). Evaluation of Dundee equally well sources of support: social prescribing in Maryfield. Evaluation report four.

Hazlehurst, J.M., Logue, J., Parretti, H.M. et al. (2020) Developing Integrated Clinical Pathways for the Management of Clinically Severe Adult Obesity: a Critique of NHS England Policy. Curr Obes Rep 9, 530–543. https://doi.org/10.1007/s13679-020-00416-8

Marmot, M. Goldblatt, P. Allen, J. et al. (2010). Fair society, healthy lives (The Marmot Review). Institute of Health Equity. https://www.instituteofhealthequity.org/resources-reports/fair-society-healthy-lives-the-marmot-review

NHS Confederation. (2011). From Illness to Wellness: Achieving efficiencies and improving outcomes. NHS Confederation. London, NHS Confederation, (224).

NHS England. (2014). Five year forward view. Community Practitioner, 87(12)4.

Patton, M.Q. (2003). Utilization-Focused Evaluation. In: Kellaghan, T., Stufflebeam, D.L. (eds) International Handbook of Educational Evaluation. Kluwer International Handbooks of Education, vol 9. Springer, Dordrecht. https://doi.org/10.1007/978-94-010-0309-4_15

Prince, M. (2012). Epidemiology. In P. Wright, J. Stern, & M. Phelan (Eds.), Core Psychiatry (3rd ed., pp. 115-129). W.B. Saunders. https://doi.org/10.1016/B978-0-7020-3397-1.00009-4

Southwark Council. (2022). Southwark Council Healthy Weight Strategy 2022-27. https://www.southwark.gov.uk › assets › attach

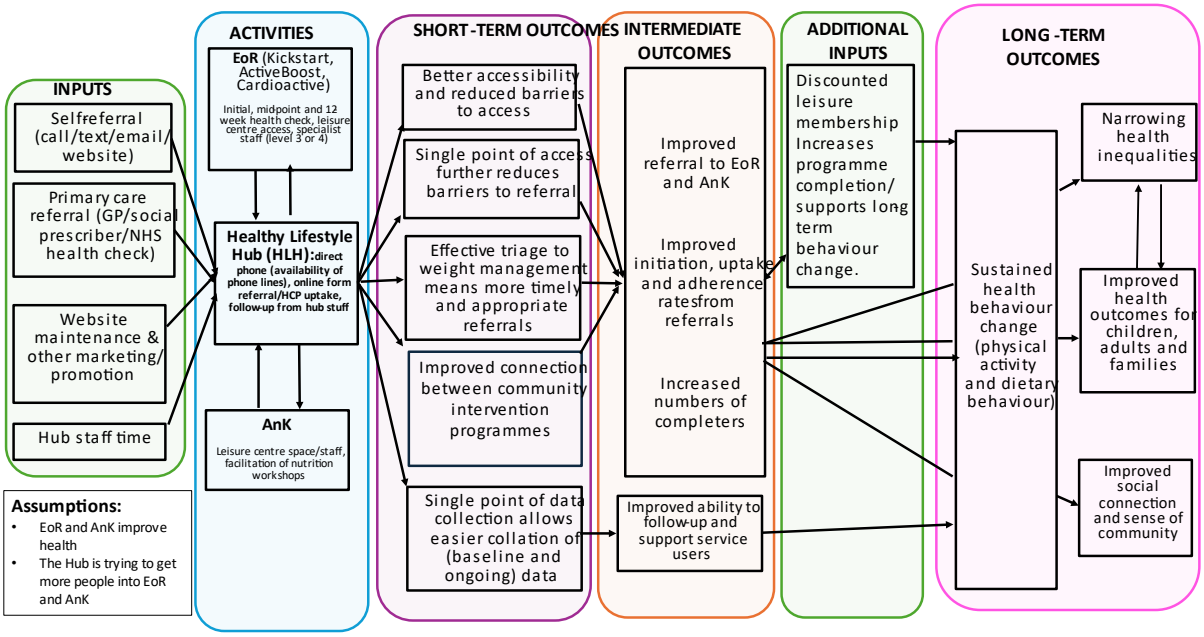
UK Government. (2023). Adult tier 2 weight management services: Short statistical commentary. GOV.UK. https://www.gov.uk/government/statistics/adult-tier-2-weight-management-services-provisional-data-for-april-2021-to-december-2022-experimental-statistics/adult-tier-2-weight-

management-services-short-statistical-commentary-april-2023#summary-figures-and-outcome-measures

UK Government. (2024). Obesity profile: Short statistical commentary. GOV.UK. https://www.gov.uk/government/statistics/update-to-the-obesity-profile-on-fingertips/obesity-profile-short-statistical-commentary-may-2024

12 APPENDICES

Appendix 1: IHLS Logic Model



Appendix 2: HLH service user survey demographic questions

Demographic Characteristic	Question	Description and coding
Age	What is your year of birth?	Year of birth. Transformed in Excel to provide Age.
Ethnicity	What is your ethnic group?	Census overarching categories: (1) Asian/Asian British (2) Black/Black British/Caribbean/African (3) Mixed or multiple ethnic groups (4) White (5) Other ethnic groups
Indices of deprivation	What is your full postcode?	Postcode
Sex	What is your sex?	Census categories: (1) Male (2) female
Gender identity	What is your gender identity?	Census categories: (1) Gender identity the same as sex registered at birth (2) Gender identity different from sex registered at birth but no specific identity given (3) Trans woman (4) Trans man (5) Nonbinary (6) All other gender identities.
Sexual orientation	Which of the following best describes your sexual orientation?	Census categories: (1) Straight/heterosexual (2) Gay or lesbian (3) Bisexual (4) Other sexual orientation
Marital status	On [date] what was your legal marital or registered civil partnership status?	Census categories: (1) Never married and never registered in a civil partnership (2) Married (3) In a registered civil partnership (4) Separated, but still legally married (5) Separated, but still legally in a civil partnership (6) Divorced (7) Formerly in a civil partnership which is now legally dissolved (8) Widowed (9) Surviving partner from civil partnership