

TITLE PAGE

HRA Protocol Compliance Declaration

This protocol has regard for the HRA guidance

Full Title of Study

Reducing inequalities in exercise participation: Evaluation of the novel 'Bracknell Forest Health and Well-Being Physical Activity Service (BFHWBPAS)'.

Acronym

BFHWBPAS: Bracknell Forest Health and Well-Being Physical Activity Service

PROTOCOL VERSION NUMBER AND DATE

Version 2.0 3/5/23

RESEARCH REFERENCE NUMBERS

IRAS Number: N/A

SPONSORS Number:

FUNDERS Number: NIHR135540 as part of PHIRST NIHR131568

SIGNATURE PAGE

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


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

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

PHIRST Chief Investigator:

Signature:

Date: 3/5/23



.....
Name: (please print):

Susie Sykes
.....

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STUDY SUMMARY

Study Title	Reducing inequalities in exercise participation: Evaluation of the novel 'Bracknell <i>Forest Health and Well-Being Physical Activity Service</i> ' (BFHWBPAS)
Study Design	Mixed-methods evaluation comprising three sequential, overlapping work packages
Study Participants	<ul style="list-style-type: none"> • Stakeholders from the health sector, voluntary organisations and leisure industry, including health care professionals, social prescribing and public health teams • Local individuals referred (or self-referred) to the service who could subsequently either attend, not attend or drop-out from the service • Local community members who belong to the target groups who have never used the service
Planned Study Period (start defined as estimated date evaluation will be open for recruitment)	January 2023 – January 2024
Research Question/Aim(s)	The aim is to evaluate the new Health and Wellbeing Physical Activity Service in Bracknell Forest and the relationships and structures that support the delivery of this intervention

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
NIHR	This study forms part of a grant of £2.5 million

ROLE OF STUDY SPONSOR AND FUNDER

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

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

PHIRST South Bank Centre Executive Committee (CEC)

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

PHIRST South Bank Advisory Group

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

Project Stakeholder Group

A local stakeholder group is in place to ensure liaison between the research team, the local project leads and PPIE representatives. The group is represented by Everyone Active, Public Health team at Berkshire Local Authority and Get Berkshire Active

KEY WORDS

Health and Wellbeing, Exercise Referral, Public Health, Health Equity, Social Prescribing

STUDY PROTOCOL

1. BACKGROUND

1.1 Protocol design process

This protocol has been developed in collaboration with local stakeholders from Bracknell Forest through a series of three workshops designed to assess the evaluability of the intervention and generate an agreed set of evaluation questions and design. Our approach to assessing evaluability is informed by the five questions identified by Ogilvie et al. (2011) and the stages within the Evaluability Assessment Framework developed by What Works Scotland (Craig & Campbell, 2015): a structured engagement with stakeholders to clarify evaluation goals; agreement of an intervention logic model or theory of change; a review of existing research literature and data sources; and making design recommendations. These stages were incorporated within an introductory meeting with the Everyone Active team based in Bracknell Forest that delivers the *Bracknell Forest Health and Well-being Physical Activity Service* (BFHWBPAS). This was followed by three structured online workshops facilitated by PHIRST South Bank. Each workshop lasted three hours and was attended by: the PHIRST South Bank research team, key stakeholders from the local intervention and PPIE representatives. During these facilitated workshops we worked towards a shared understanding of:

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

Communication continued with the Bracknell Forest stakeholders after the formal workshop process to allow joint decision making around specific aspects of evaluation protocol design.

1.2 The Service

The Bracknell Forest Health and Well-being Physical Activity Service was commissioned by the public health department at Bracknell Forest Council in September 2022 and is delivered by Everyone Active. Based on an established Exercise Referral model, the service utilises physical activity to improve health outcomes and quality of life for local residents. It does however incorporate several elements that distinguish it from the traditional exercise referral programmes:

- The service is based on the principle of proportionate universalism and is available to all (with very few exclusion criteria). However, the service is made free of charge to those in receipt of benefits and targets people from socially disadvantaged communities and those with protected characteristics.
- Referrals are made from health professionals but also from social prescribers, voluntary sector and via self-referral.

- Following an initial assessment with a Health and Well-Being Physical Activity Coach, users will receive a bespoke tailored exercise programme that may not be gym based but which may include one to one or small group work and activity based in community settings.
- A programme will last 12 weeks but users will be also referred a range of options for longer term engagement.
- Health and Well-Being Coaches will also refer to other community services where needs related to health are identified and addressed, e.g., housing, debt, loneliness.

1.3 Literature review: Referral schemes to promote physical activity for health

The benefits of regular participation in physical activity (PA) for health are well known, yet globally 27.5% of adults and up to 81% of adolescents do not achieve the recommended health-enhancing levels of exercise (World Health Organisation, 2022). According to the latest Sport England's *Active Lives Adult Survey*, the prevalence of physical inactivity in England is even higher with nearly 4 out of 10 adults (38.7%) not meeting the government guidelines (150+ min PA a week) and 27.2% considered to be inactive (performing <30 min PA on average per week) (Sport England, 2022). The risk of inactivity varies across different populations, for example women (65%) are less likely to be physically active than men (70%); populations living in areas of high deprivation are less active (57% active) than those living in lesser deprived areas (73% active) (NHS Digital, 2020). Insufficient PA is a leading risk factor for global mortality and is associated with a range of non-communicable diseases that are estimated to cost the National Health Service and the UK economy £8.2 billion per year (Department of Health, 2004). The promotion of physically active lifestyles is therefore important to all those populations who are at greater risk of sedentarism.

Exercise Referral Schemes (ERS).

Due to patient contact, primary care presents a key setting for health promotion, and has traditionally involved a health professional, usually a GP either (1) prescribing exercise or providing exercise advice to an individual, or (2) referring them to a third-party service. In the latter case, these Exercise Referral Schemes (ERS) involve a number of health professionals who assess the needs of the individual, develop of a tailored PA programme, monitor progress and provide follow-up (Campbell et al., 2015). They often require the individual to go to an exercise facility such as a leisure centre for participation in a structured exercise programme usually lasting 10-12 weeks.

There has been a sustained growth of ERS since they were first formally introduced in the 1990s and today around 600 ERS exist across the UK (Morgan et al., 2020). ERS have been described as low/moderate-risk provision aligned with the prevention model (Rowley, 2019). Many studies have reported outcomes such as increased amount of moderate/vigorous PA, decreases in blood pressure and body composition (Crichton & Bowtell, 2010; Rowley et al., 2018), reduced anxiety and depression (Rowley et al., 2018).

Despite this, following a review of the effectiveness of ERS by the *NICE Public Health Intervention* programme, due to insufficient monitoring and reporting it was recommended that ERS should only be employed as part of a research study to ensure rigorous evaluation of their impact on health (NICE, 2006). Later, Pavey et al., (2011) found

limited evidence to support the use of ERS as an intervention to promote PA and improve health outcomes and questioned their worth for sedentary individuals without existing medical conditions. In 2014, NICE recommended that ERS should be provided only to individuals who are inactive and have existing health conditions or risk factors and not for those who are otherwise healthy (Campbell et al., 2015).

Community-based PA programmes (CBP).

With the increasing trend of physical inactivity within the UK population (UK Government, 2022) and given its association with poor-health, the need for life-course approaches to PA interventions as a form of preventative healthcare across the general communities became apparent. This prompted the development of community-based PA programmes (CBP). These interventions target and engage a defined population at-risk of physical inactivity such as children, older adults, and those living in social deprivation. Generally, unlike ERS, CBP provide opportunities to be physically active through self-referral regardless of health status and therefore have greater reach across the community. CBP varies widely in practice and can include a range of activities such as group-based interventions or mass media campaigns to environmental, structural or policy changes that are adapted to, set in, and ideally delivered by the community for that community (Abrahams et al., 2021).

CBP has been shown to improve cardiovascular disease risk factors, including reduced blood pressure, improved blood lipid profiles and obesity indices (Soltani et al., 2021). A CBP for overweight and obese children was reported to have high attendance and retention rates and produced positive changes in physical, behavioural and psychological outcomes similar to those achieved by controlled trials (Smith et al., 2013). Efficacious interventions for children and adolescents focus on enjoyment, socialisation, are unstructured, informal, involve partnership working with families, free taster sessions, can be combined with peer-to-peer groups, use convenient timings and location, positive role models and incentive vouchers (PHE, 2021). The importance of effective messaging was highlighted as essential to promote physical activity to females by the participants in the 'This Girl Can Lambeth' project (Hull et al., 2021). In older adults, improvements in physical strength, aerobic endurance, mobility, exercise self-efficacy, and balance were found in those participating in CBP (Levy et al., 2018).

The main factors that heighten engagement with PA in older adults include embedding social support facilitators, training instructors in effective and supportive communication, the use of incentives/rewards (particularly for 'new starters'), accessible locations and affordable prices (Szekeres, 2021). In socially deprived communities, provision of free or subsidised classes incorporating individualised assessment, follow-up and support is reported to facilitate engagement in socioeconomically deprived populations (Garner-Purkis et al., 2020). In general, factors that can impact implementation and maintenance of CBP include instructor training, the structure of the programme, reporting requirements, organisational support and infrastructure for programme delivery (Petrescu-Prahova et al., 2016). In addition to behavioural and social factors, increasing PA is linked to physical and social environmental correlates that are often satisfied by CBP and therefore such CBP may play a critical role in the overall strategy to increase physical activity (Kahn et al., 2002). They have been endorsed by the World Health Organisation as a 'cost-effective, feasible and a 'best buy' in the prevention and management of non-communicable diseases (WHO, 2017).

Contemporary hybrid PA referral schemes

Whilst ERS are still being implemented across the UK, the underwhelming evidence of their effectiveness has led to concerns over their commissioning in an increasingly resource-constrained public-sector environment. With the growth of CBP, new approaches to exercise referral that combine both evidence-informed models and contemporary practices have emerged and present a range of innovative interventions that may prove more cost-effective for increasing PA at the community level. For example, when referring to a CBP, a signposting pathway produced similar increases in activity level to motivational interviewing-based PA interventions but less resources were required (Wade et al., 2020). As a result, there has been movement away from the traditional ERS model and towards CBP through incorporation of local strategies for PA referral. Indeed, over time, ERS have been increasingly referred to in the literature under various labels (for example, a scoping search at the time of protocol writing identified terms such as Healthy Life-, Physical Activity-, GP Exercise-, Fitness for Health-, Active- and Wellness Schemes), which are highly heterogeneous in nature (Shore et al., 2021). Recently, Shore et al., (2021) found evidence to suggest contemporary ERS were not fit for purpose and no longer provided a 'disease centred' approach to exercise prescription, instead the focus is on promoting participant independence and autonomy.

A blend of ERS and CBP elements may offer unique benefits for promoting PA; the evidence suggests that rather than a single defined approach, a wide range of approaches are needed for encouraging physically active lifestyles, each facilitating small increments in behaviour change (Pavey et al., 2011). There is evidence to suggest that individuals who value the social and psychological benefits of ERS are more likely to be high attenders (Pentecost & Taket, 2011) and therefore CBP may be better suited to PA promotion. With CBP, the provision of choice in terms of the intensity and variety of activity may promote uptake of and adherence to exercise; 16 studies in a review suggested that interventions to increase PA were more efficacious when personalised (Ghanvatkar, 2019). Further, referral to CBP may also provide more accessible options as intimidating environments, inadequate supervision and inconvenient access hours have been identified as scheme specific barriers to traditional ERS (Williams et al., 2007).

To differentiate from ERS, such interventions have been termed '*PA referral schemes*' (Hanson et al., 2020) and encompass all schemes that (1) have the primary aim of increasing PA; (2) have a formalised referral process; and (3) are provided for individuals who are inactive/sedentary, and/or have or are at risk of a health condition. Specific examples include entry routes via self-referral or from other professionals (e.g., health trainers) and group-based needs assessments (Hanson et al., 2020). Both self-referred and NHS-referred individuals have benefited from sport-led community programmes (Garner-Purkis et al., 2020). The value of such schemes appears promising, however, unlike the traditional ERS model, the effectiveness of these newly formatted PA referral schemes for reducing inactivity has not been evaluated. Elements that are effective for engaging some populations with exercise may be less effective for other populations, especially for different age groups (Craike et al., 2018). Understanding which elements of the PA referral scheme are successful for different populations and the impact on health outcomes is important for developing strategies for the management and prevention of chronic health conditions.

The whole-system approach to increasing PA

In evaluating the effectiveness of PA interventions, the wider landscape and multiple levels of influence on health-related behaviour e.g., social and environmental factors (Speake et al., 2016) should be considered (Hull et al., 2018; Hull et al., 2021). The five quality statements set by NICE (2019) for encouraging PA in the community involves embedding senior level PA champions within local authorities and healthcare commissioning groups; prioritisation of sustainable active travel; community member co-design and management of public open spaces; workplace and school programmes. Achieving these objectives requires working with a range of partners (for example, the voluntary sector, community groups, faith groups, education sector, businesses, and disability groups) and ensuring that the setting of priorities is jointly agreed. Co-production between communities, user groups and deliverers in the development of PA interventions is recommended (Copeland et al., 2012).

Whole systems thinking in public health has grown rapidly in the last decade (Nau et al., 2022) and is increasingly being applied to complex issues such as physical inactivity (Cavill et al., 2020; Rutter, 2019; Murphy, 2021). A systems approach focuses on the contexts within which an intervention/programme/service takes place, the relations between the multiple factors at play and the actors and agencies, and the ways in which systems can adapt. It disaggregates key factors in a system and can help local authorities to prioritise where to intervene in the local system, leverage the greatest impact, align effort, and drive change. For example, a process evaluation underpinned by realist philosophy was employed to understand the development and implementation of a programme and the mechanisms influencing PA for children and young people (Hull et al., 2021). In evaluating health interventions, engaging stakeholders can provide insights to supporting programme implementation and delivery, as well as the scalability and sustainability in real world practice (Teychenne et al., 2021). However, such approaches to intervention evaluation are less prominent within PA research and more advanced forms of practice and analysis using mixed-methods evaluation approaches are needed (Nau et al., 2022) to progress the understanding on contemporary PA referral schemes and their value for improving population health.

2. RATIONALE

The literature highlights the importance of considering numerous individual intrinsic factors when setting up a local ERS, including personalisation of exercise according to needs, abilities and preferences. (Morgan et al., 2016). Equally important are the nature and quality of the partnerships that facilitate referral and how to join up health, community and sport/leisure activity sectors. The use of social prescribing, a community-based approach which focuses on a person's strengths and encourages self-management to improve wellbeing, has expanded rapidly in the United Kingdom and prescribing to physical activity is one of its main activities but little is known about how this can be most effectively achieved (Polley and Sabey, 2022). Our review of the literature also found that not enough is known about: (i) the type of service/offer that is acceptable to those with long term conditions AND those least likely to be active; (ii) the enablers and barriers to

taking up a service; (iii) how best to recruit and retain participants into pathways of referral.

Therefore, this evaluation will address the knowledge gap relating to:

- a) *How best to set up ERS.* BFHWBPAS aims to incorporate those factors identified in previous reviews of ERS to facilitate recruitment and retention of participants, namely good support and supervision from staff (the Health and Wellbeing coaches) and greater accessibility including low cost.
- b) *How to reduce inequalities in physical activity.* BFHWBPAS seeks also to address the wider drivers of behaviour and social inequity barriers by engaging directly with those who would not normally access the scheme.
- c) *How to build a sustainable wider system for physical activity.* BFHWBPAS intends to actively engage the local structures for social prescribing alongside the traditional GP referrals.

3. THEORETICAL FRAMEWORK

The coproduction workshops attended by the evaluation team, local stakeholders and PPIE representatives resulted in the development of a logic model of the BFHWBPAS project evaluation (see Figure 1) underpinned by *The Theory of Change*. The model assumes that the design of the scheme will increase its acceptability and accessibility and improve service users' health outcomes and establish a sustainable and coherent system partnership.

This model encompasses a series of '*if...then...*' statements and assumptions (see Downey & Golder, 2022):

- a) If service users are given a 1-1 appointment with a coach during which a co-created plan is created, then there is a greater chance of a sustained change in PA because the service is tailored to them, so, they are more likely to commit.
- b) If service users can choose from a variety of forms of exercise and are offered flexibility, including the option for social interaction, then adherence will improve because they have more personal choice and enjoyment.
- c) If service users in deprived areas are directly offered the scheme, then they are more likely to participate because it has no cost and there will be fewer barriers to access
- d) If all referrers (primary care, social prescribing and voluntary sector) have a clear understanding of the nature and aims of the scheme, have some training, have clear, accessible guidance and there are processes to support referral, then they will participate more and refer more appropriately.
- e) If all practitioners involved with a potential service user have a clear understanding of the scheme and other partners continuity will improve and people referred will be suitable, and inter-professional/inter-sectoral cooperation and mutual value will improve.

The logic model guided the design of the three work packages.

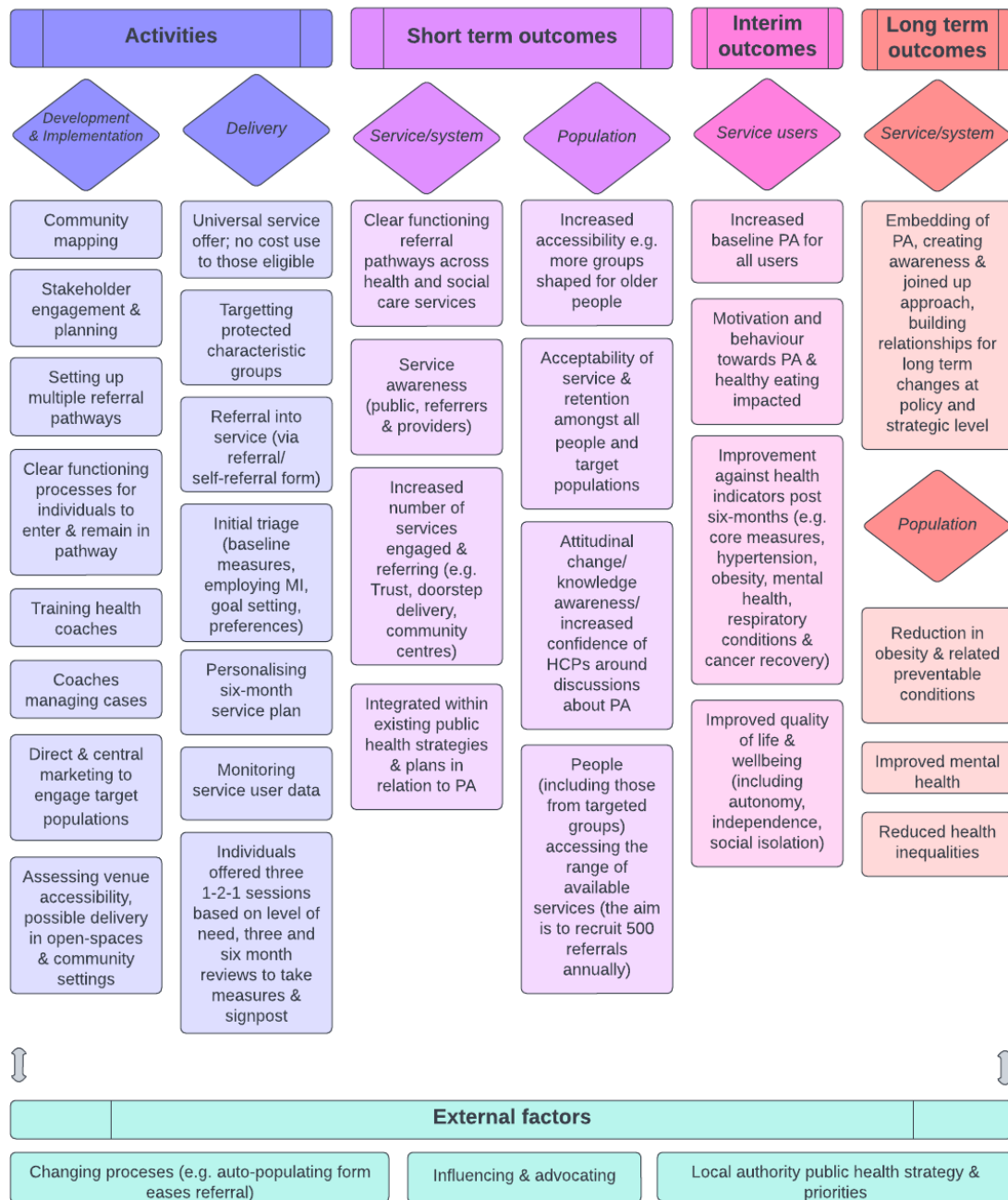


Figure 1: Logic model for evaluation of the HWBS intervention

4. RESEARCH QUESTION/AIM(S)

4.1 Aim:

The aim is to evaluate the new Health and Wellbeing Physical Activity Service in Bracknell Forest and the relationships and structures that support the delivery of this intervention.

4.2 Questions:

- What is the level and process of engagement of agencies and structures in the local health and social care system with the BFHWBPAS?
- How do the specific characteristics of the BFHWBPAS (e.g., cost, length, referral routes, personalised program) influence uptake, engagement, acceptability and impact on users and target populations?

4.3 Objectives Aligned to Work Packages (WP)

- To identify the elements of the health and social care system that have the potential to support and promote engagement in PA via exercise referrals. **(WP1)**
- To explore the views, experiences, interactions and perceived impact of agents across the health and social care system of the HWS and establish the implications for uptake, engagement, impact and delivery. **(WP1)**
- To explore the experience, acceptability and health impact on different categories of participants in the BFHWBPAS- referred and attended; referred and did not attend; referred, attended and subsequently dropped out. **(WP2)**
- To understand the factors that act as perceived barriers and enablers to uptake in the BFHWBPAS amongst members of the target groups from the socially disadvantaged areas not currently accessing the service. **(WP3)**
- To identify the cost of delivering the service **(WP4)**

4.4 Outcomes of the Evaluation

- A refined logic model.
- An empirically informed systems' map for physical activity in Bracknell Forest.
- A narrative capturing referral and non-service user experience and engagement with the service.
- Recommendations for improvements of the BFHWBPAS going forward.
- Best practice guidance for councils aiming to employ the service model.

5. STUDY DESIGN AND SETTING

To address the complexity of the four **research** objectives, this evaluation will adopt a mixed-methods research design and comprise of three work packages operating sequentially with overlapping phases.

Work package 1 – Systems mapping

Through Actor mapping, the initial phase of this evaluation will identify the key organisations, individuals and factors influencing PA in the local area, operating across multiple levels in accordance with the Whole Systems Mapping Approach (PHE 2019 and 2021). This map will be used to explore the existing PA system and how and where this service sits within the local system. There will be an initial mapping workshop with stakeholders involved with funding, promoting and referring service users with a follow up workshop after two months. Online/Telephone interviews with the identified key stakeholders representing various roles e.g., policy makers, practitioners, service delivery managers across multiple levels of the service delivery will explore their experiences of the service design, implementation, and referral pathways. They will also review the Actor map and offer feedback for its refinement. The workshops, COVID-19 guidance permitting, will take place onsite at a location of the partner's choosing.

Work package 2 – Service evaluation from referral perspective

This work will follow a prospective approach comprising longitudinal qualitative case study interviews with BFHWBPAS participants supplemented by Everyone Active's survey data (recording reasons for service discontinuation) and a statistical analysis of service data (routine outcome data collected by the partner). The latter will allow an understanding of whether the BFHWBPAS achieves an impact in line with other researched ERS. Interviews will take place via Microsoft Teams audio/video call or telephone call, depending on participant access and preference.

Work package 3 – Service evaluation from targeted non-users' perspective

The study design is descriptive and quantitative. The approach is a cross-sectional street intercept face to face survey in the location of the target groups, advised by Everyone Active. The timing, late in the research process, allows for any type of communications affecting awareness of BFHWBPAS to diffuse across the population. To identify sample elements, participants will be screened as (1) resident in a target ward, (2) inactive as defined by IPAC score (3) >18 (4) and a non-user of the BFHWBPAS. The survey will explore awareness of BFHWBPAS and recommendations and understanding of the benefits from physical activity, knowledge of local opportunities for exercising in principle, and for engagement with the BFHWBPAS specifically. Informed consent will be obtained from participants and logged in the app to be used for data collection at the beginning of every survey.

Work package 4 – cost analysis.

A small-scale work package that will include a descriptive cost analysis of the program delivery. It is not possible to conduct a full economic evaluation given the limitations of the data collected locally and the timing of the evaluation against the service delivery. However, it is possible to undertake a rigorous assessment of the costs associated with delivering the intervention.

6. SAMPLING AND RECRUITMENT (including consent processes)

Work package 1 – Systems mapping and perspectives

Stakeholders (n<20) representing key organisations across multiple levels of the service delivery will be identified through desk-based mapping work and workshops in conjunction with the partner. Key stakeholder representatives will be purposefully selected and invited by e-mail to participate in online/telephone interviews, surveys and workshops; they will be provided with a participant information sheet and consent form. Participation will be on a voluntary basis and written consent will be sought prior to the workshop, interview and survey participation. Recorded verbal consent will also be obtained during the interview.

Work package 2 – Service evaluation from referral perspective

Purposive sampling will be used for the qualitative data component. The researchers will aim to recruit 20 participants who are 18 years of age or over, have provided consent for data to be shared with the evaluation team and have been recently referred to the service. We will follow the journey of those who are i) referred and will go on to attend the service ii) referred but will not go on to attend the service and iii) referred, do attend but later drop out. This sample size could result in up to 60 interviews in total across three time points. The literature indicates that attrition for ERS may be up to fifty percent, in which case, around 10 participants from the proposed sample would be expected to fall into group one, perhaps less when also accounting for evaluation attrition. Written or recorded verbal consent will be sought prior to participation in longitudinal qualitative interviews. In the perhaps unlikely eventuality of all 20 participants continuing to attend the service, we will actively recruit individuals referred to the service who do not become service users.

For the quantitative data component, all enrolled participants will be included in the sample population following informed written consent which will be sought during the enrolment process by the partner. The sample population will be stratified in accordance with demographics and characteristics such as health status, ethnicity, and age. There will likely be two referral pathways, one for GPs using existing referral systems and one on the 'JOY' Application which will be used by the social prescribers and the voluntary sector. The partner has submitted a request for a permissions box to be added to both to enable details of potential participants to be shared with the evaluation team. If appropriate, the partner gatekeeper managing this system will then securely transfer this data to the appropriate researcher(s) in line with the data sharing agreement.

To compensate participants for their time, we will explore the use of a voucher incentive (approximately £15 for each 30-minute interview, £25 an hour). The proposed voucher value will be discussed amongst our PPIE representatives and the evaluation team to confirm that this is perceived as reasonable.

Work package 3 – Service evaluation from targeted non-users' perspective

The population of interest for this work package accounts for around 20% of residents in the wards identified by Everyone Active as being the most socioeconomically deprived in Bracknell Forest, but the further defining criteria (inactive non-users of the new BFHWBPAS) make them a particularly hard-to-reach group. Street intercept survey is a feasible alternative to more usual methods (Miller et al., 1997) particularly for harder to reach populations (Singh, 2020) and generates moderate to high participation (Graham et al., 2014) and completion rates when a small incentive is offered (Rotheram-Boras, 2001). The study in WP3 sets out to collect categorical variables from a single sample from a

population of known size (Omair, 2014). As such, the required sample size can be estimated using freely available open-source software such as *openepi.com*. To obtain a sample that gives a 5% margin of error and a 95% confidence interval, a total of 366 participants are required for the study.

To conduct the street intercept and reduce researcher selection bias, the following process will be followed. Each interviewer stands in the pedestrian flow and imagines a line between two fixed points over which the pedestrian traffic is passing. It is then a simple matter of attempting to intercept the *n*th pedestrian for interview. If unsuccessful, the count starts again. Successful intercepts will be informed of the purpose of the survey, and the screening questions administered. Once a qualified respondent is identified, they will be offered an incentive of £15.00 to complete the survey. On any one day at any location a team of three or four researchers will be needed to cover different available traffic flows identified in advance of the operation. It is envisaged that the data can be collected over five days.

7. METHODS OF DATA COLLECTION

Work package 1 – Systems mapping and perspectives

This WP will be in three stages. In stage 1, a draft actor map will be produced based on the existing literature on determinants and enablers of PA based on the work of Rutter (2019). This draft map will be presented to stakeholders at a half day workshop in which it can be amended to reflect any specific characteristics of the local context. System intervention entry points including primary care, education, transport and infrastructure, leisure and recreation, workplaces will then be mapped using the local knowledge of stakeholders.

In stage two, a conceptual map will then be produced of the local system for PA showing the relationships between the different components. The map will be fed back to stakeholders for further comment in a second workshop at which a graphic recorder will record the relationships and feedbacks suggested by participants.

The third stage will comprise online/telephone interviews with stakeholders who currently act or could act as referrers to the HWBS to gather their views and perspectives on their part in the system: their awareness and understanding of the scheme, their awareness and understanding of PA for health conditions, their access to digital platforms for service users, their relationship with others in the scheme. At this stage, the stakeholder representatives will be given the opportunity to provide feedback on the actor map for its final refinement.

Work package 2 – Service evaluation from referral perspective

We will aim for all groups to participate in three interviews to facilitate case to case comparison and demonstration of change over time. However, a pragmatic approach will be employed if required, with consideration to timepoint of recruitment and levels of engagement with the evaluation e.g., referrals choosing to not attend the service may only be able/willing to participate in one or two interviews.

Participants will be invited to three interviews over the course of six months (i.e., around month 1, 3.5 & 6). Interviews will be transcribed verbatim by a University approved service. The semi-structured topic guide will be devised by the research team, in

collaboration with the partner and PPIE representatives to explore, for example, perceptions of specific characteristics of the service (such as cost, length, referral routes and the personalised programme), facilitators and barriers to use of the service, attitudes towards PA, effects on lifestyle and intentions for engagement with the service and PA in the future. Questions will be designed to be open-ended to ensure that researchers do not impose their views on the narrative.

It should be noted that Interpretive Phenomenological Analysis (IPA; Smith et al., 2009; see data analysis section) typically endorses deep level analysis of one dimension within one group and at beginner level this may involve recruiting between three and six participants. Making case to case comparisons and longitudinal study requires a larger sample (Hefferon & Gil-Rodriguez, 2014). Accordingly, the work package will be conducted by three researchers, overseen by a researcher with post-doctoral level experience in conducting and teaching advanced qualitative methods.

Quantitative data, to supplement the qualitative interviews, will be transferred by the local authority partner to the research team, this will be cleaned as required ahead of statistical analysis.

Work package 3 – Service evaluation from targeted non-users' perspective

Survey data will be collected from the eligible participants by trained researchers, following a questionnaire loaded into the Qualtrics offline surveys app for mobile phones. The researchers will read each question as written to participants and record responses directly into the app. At the end of each completed survey, data is either stored securely in the app or (if wi-fi is available or data roaming enabled) transferred to the central password protected database. The app allows visual stimuli to be shown if prompted awareness questions are required. Quality control metrics including geo-location, time and date stamps for each completed questionnaire are incorporated into the system.

Work package 4 – Cost analysis

The cost analysis work package will be undertaken in a collaborative way with the service providers in the following stages:

- Workshop 1: - Exploring unit costs associated with delivering BFHWBPAS, identifying which data is already held and which will need to be collected.
- Local stakeholders begin retrieving data
- Workshop 2: Building cost picture, identifying data limitations.
- Local stakeholders continue data retrieval
- Workshop 3: Final review of unit cost data
- PHIST South Bank undertake analysis and report writing.

The local stakeholders will collect associated unit cost data with support from PHIRST South Bank. The exact nature of these costs will be identified through the workshopping process but are likely to include staff time (i.e. all staff involved, their hourly rates and total number of hours involved in the project), the total budget allocated to the programme and the cost of the actual intervention (disaggregated and described separately to the overall budgetary costs), any additional training costs, any additional building rental, office space or equipment cost as well as additional IT and travel costs.

8. DATA ANALYSIS

Work package 1 – Systems mapping a

The initial and follow up workshops will produce a conceptual 'map' of the multiple factors that constitute the system and the cross-sectoral nature of the influences on physical activity illustrating the breadth of opportunities to influence the system. The initial map will be based on existing literature and the work of Rutter et al, (2019). Qualitative systems mapping will be used to develop the map based on feedback from the core working team and wider stakeholder groups which will be captured via graphic recording and through the process of facilitation. Interviews will be analysed using Framework Analysis.

Work package 2 – Service evaluation from referral perspective

With a view to addressing the question, "how do referrals think about the service in terms of affect, acceptability and perceived impact?", IPA will be used to explore referrals' experiences and perceptions. Data will be stored and coded using the qualitative software NVivo. No prior assumptions about the data will be made. The qualitative methodology will capture idiographic experience of service involvement, allow cross-case analysis and illustrate processes of change. It may be supplemented by descriptive statistics from the partner survey capturing reasons for service discontinuation.

For the quantitative component, data collected by the partner will be descriptively analysed e.g., service uptake by deprivation level, age, ethnicity, health status. Population data will be statistically analysed for changes in health indices e.g., blood pressure, body mass index, mental wellbeing, personal wellbeing. Health indices at baseline will be compared to those at 12 weeks, and stratified according to different individual characteristics e.g., health status at baseline, activity level at baseline, programme adherence. Descriptive and statistical analysis will be accomplished using Microsoft Excel and SPSS Statistics software packages.

Work package 3 – Service evaluation from targeted non-users' perspective

The final dataset will be downloaded from the Qualtrics database into the *SPSS Statistics* software package, cleaned and analysed for main patterns and associations in the distributions of its categorical variables. Responses to open-ended questions will be re-coded for quantitative analysis. There are no pre-existing hypotheses; the aim is to develop insight from the data itself, which, when aligned with prior knowledge, will lead to actionable recommendations.

Work package 4 – Cost analysis

A descriptive analysis of costs will be undertaken with a distinction between commissioned costs and actual costs. A breakdown of income generated will also be captured. Data will be analysed alongside service user patient monitoring data collected as part of work package 2 and where data allows basic cost impact assessments made. Where data quality permits the analysis team will also work with BF colleagues to explore the combination of;

- a) Resource use collected
- b) Unit cost data associated with the above

And

- c) Any suitable and/or appropriate outcome data (such as Quality of Life, Life Expectancy or change in diastolic and/or systolic blood pressure) – where quality and completeness criteria are met.

9. ETHICAL AND REGULATORY CONSIDERATIONS

Informed consent will be sought from all participants who wish to be interviewed or take part in workshops. Additionally, as part of the work on WP2, permission will be sought from all individuals referred to the BFHWBPAS to allow sharing of their personal data with the LSBU research team, collected as part of the BFHWBPAS. Residents from the targeted areas in Bracknell and Forest will be informed that by accepting to complete the survey as part of the WP3 work they provide an implied consent for use of their data. Participant information sheets (PIS) will be provided to inform participants of the studies' aims, methods and risks, etc. Contact details will also be provided for participants to ask questions prior to taking part. Once participants have read this, they will give written or recorded verbal consent to participate in the study and for use of the data.

Participant facing documents will undergo automated readability checks, will be based on LSBU ethics panel approved templates and approved by LSBU University Ethics Panel (UEP). We will involve our PPIE representatives in the development of these documents.

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

The research will receive ethical oversight from LSBU UEP as required. This oversight will include the study protocol and all participant facing documentation. A favourable opinion will be secured before any data collection takes place. Any adverse events will be reported to the above bodies.

All research will be conducted in line with LSBU ethics panel code of conduct for research involving human participants and the British Psychological Society's ethical guidelines. These guidelines include principles of holding participants rights and dignity, anonymity, and freedom to choose to participate or not.

Research will also be conducted and reviewed in compliance with General Data Protection Regulation (GDPR) or replacement legislation and all data will be managed in line with the PHIRST South Bank Data Management plan. A data sharing agreement will be put in place between LSBU and Everyone Active and permission secured from service users before any user data is shared. Each work package presents ethical risks, outlined in the table below with strategies to mitigate the risks.

9.2 Assessment and Management of risks

Table 1: Risk register

Key risk	Likelihood	Impact on participants	Impact on project	Mitigation
WP1	Low	Some participants may find the complexity of mapping challenging	Low levels of participation will make the mapping less rich	Working with the commissioner to recruit across the system
WP2 qualitative Participant discomfort discussing personal barriers to exercise	Low/ Moderate	Some participants find space to reflect helpful and cathartic, for others this may be a source of short-term psychological distress	This could increase likelihood of evaluation attrition and ability to meet target sample size	Researchers will follow guidance on how to keep participants and themselves well-supported (Silverio et al., 2022). Participants will be debriefed, and appropriate resources will be signposted.
WP2 Quantitative Participants will not agree to share their health data with LSBU researchers	Moderate	Participants may feel intimidated to share personal health data, especially in case of failing to complete the full program and achieve good progress	Missing data and failing to reach the required sample size will impact the power of the study to formulate conclusive recommendations	Data collection will start as early as possible after the launch of the BFHWBPAS. Researchers will work closely with the Health and Well-Being coaches to ensure completeness of the data base.
WP3 Permissions to intercept in BF settings No appropriate public venues for interviews	Low Low / Moderate	N/A Participants may not feel relaxed enough to elaborate on their personal experiences and perspectives	Not reaching the target quota for the sampled population Lack of sufficiently rich evidence to fill in the targeted gaps in knowledge	LSBU research team will work closely with engaged local stakeholders to secure the permissions in advance. The potential venues for the street interception and the follow-up interviews will be chosen based on advice will be sought from the local collaborators and the PPIE representatives
COVID-19 interferes with staff availability (research team and stakeholders)	Moderate	N/A	Moderate	Clear project planning to facilitate handover, lines of alternative communication established, agreement to support the evaluation through a Data Sharing Agreement

				between LSBU and BF
Failure to recruit participants across work packages	Moderate	N/A	High	Guidance from PPIE and partner in planning stage Exploring use of incentives where appropriate
Data not available from partners	Low	N/A	Moderate	Agreement with partners on data, ongoing stakeholder involvement Agreement in place to support the evaluation through a Data Sharing agreement between LSBU and BF

9.3 Amendments

Amendments to the protocol will be directed to the PHIRST South Bank CEC for approval and where necessary to the LSBU UEP/Institute of Health and Social Care (HSC) research ethics committee. All revisions will be submitted to the NIHR for approval.

9.4 Peer review

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

9.5 Patient & Public Involvement

The workshops that informed this design were attended by two service users from Everyone Active, Bracknell Forest. They have reviewed the research questions and commented on aspects of the design. We plan to appoint a further 3-4 service users to create a PPIE Advisory Panel and we are currently working with Everyone Active to recruit a panel that reflects the diversity of the HWBS target populations. The first introductory meeting with the full PPIE Advisory Panel will introduce the project, research design and recruitment methods and possible improvements will be discussed.

Future involvement may include:

- Reviewing and providing feedback on participant information sheets to ensure content and language is appropriate.
- Discussing the content and wording of surveys and interviews
- Consider and discuss recruitment strategies
- Discussing the best way of collecting qualitative data for WP3
- Discussing emergent findings
- Review and feedback on lay summaries to ensure content and language is appropriate
- Assist with the development of the dissemination plan and possibly engage with dissemination if available/willing

9.6 Data protection and patient confidentiality

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

Where data is offered to online repositories (see *Dissemination*, below), it will be rendered fully anonymous prior to upload. Data may be stored indefinitely with participant consent. All information which is collected during the course of the research will be kept confidential by using password protected computerised records. All written transcripts will be kept in a secured locked filing cabinet, when not in use. Any information regarding participants that is shared with others (for instance in reports, publications or shared with a supervisor) will also have pseudonyms used, which will prevent the identification of people involved in the study. All data will be secured in a locked filing cabinet for as long as required for the duration of the study and will then be destroyed 18 months after the completion of the project.

9.7 Indemnity

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

10 DISSEMINATION POLICY

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

Key research outputs will include:

- 1) Interim report of findings, if useful to partner
- 2) A final report for the BF team, also lodged on the Open Science Framework (OSF)
- 3) Peer review journal articles, also lodged on the OSF
- 4) Briefing and dissemination to relevant stakeholders in physical activity for population health

We will offer a workshop event in which the study findings will be presented to the BF team, and other meetings on an ad-hoc basis as required. We may also present findings to the wider Public Health professional community at conferences and through briefings.

Where possible and depending on partner agreement, final quantitative dataset(s) will be lodged (in fully anonymous form) on the OSF, which will also host study documentation, analysis files (any syntax, coding frames, etc.) and research outputs associated with the project.

Qualitative datasets such as transcripts will not be lodged on the OSF due to the nature of the data, it may not be possible to fully anonymise these data. In this case, in compliance with the GDPR, data will be kept for 10 years from study completion and will then be destroyed.

11 MILESTONES

Table 2: Evaluation milestones

Stage	Activity	Completion Date
Evaluation Inception	Introductory meetings	Apr 2022
	Identification of project team	Oct 2022
	Identification of local stakeholder group	
	Workshop 1 - understanding the intervention	5 th Jul 2022
	Workshop 2 - understanding the theory of change	27 th Jul 2022
	Workshop 3 - agreeing a design	13 th Sep 2022
	Workshop evaluation survey for partners to complete	
	Evidence scoping	Jul 2022 onwards
	Design and protocol development	End of Oct 2022
	Ethics application	Aiming for regulatory approvals by Dec 2022- Jan 2023
	Research Governance Approval (if local authority requires)	Aiming for regulatory approvals by end of Dec 2022
	Research Registration	
	Local PPIE recruitment	
	Local collaboration agreement	End of Dec 2022
WP1: Systems' mapping	Material preparation/desktop research	Jan 2023
	Recruitment and identification of participants	Jan-Feb 2023
	Data collection	March 2023
	Workshop 1	April –May 2023
	Workshop 2	May- June 2023
	Interviews	
	Data analysis	June 2023
	Data archiving	Jan 2024
WP2: Service evaluation from referral perspective (Qualitative data)	Material preparation (participant consent form, information sheets, topic guide, debrief sheet, resources for researchers etc.)	Nov 2022
	Participant recruitment	Jan-Feb 2023
	Data collection (three longitudinal interviews across six months)	Feb-July 2023
	Data cleaning and preparation (including transcription and anonymisation)	Feb-Aug 2023
	Data analysis (to occur alongside collection to aid subsequent interview preparation)	Mar-Sep 2023
	Data checks	Sep-Oct 2023
	Data archiving	Jan 2024
	Content production	Dec 2023
WP2: Service evaluation from	Gaining access to partner survey and routine outcome data	Aug 2023
	Data cleaning and preparation	Sept 2023

referral perspective (Quantitative data)	Data analysis	Oct-Nov 2023
	Data checks	Dec 2023
	Data archiving	Jan 2024
WP3: Service evaluation from targeted non-users' perspective	Material preparation and research assistants' training	Jun-Jul 2023
	Data collection (street intercept survey)	Jul -Aug 2023
	Recruitment and data collection (interviews)	Sept 2023
	Interview records transcription	Oct-Nov 2023
	Data analysis	Nov 2023-Jan 2024
	Data archiving	Jan 2024
WP4: cost analysis	Workshop 1	April 2023
	Workshop 2	June 2023
	Workshop 3	September 2023
	Data analysis	September - November 2023
Project Management and Reporting	Reporting to stakeholder group	Ongoing
	PPIE meetings	Ongoing
	Project management meetings	Every six weeks
	Interim reporting	Aug 2023 (TBC)
	Final reporting (slide deck & executive summary)	Jan 2024

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