## FULL PROTOCOL TITLE OF THE STUDY

A prospective matched control cluster study to assess the effectiveness of health and wellbeing services (HWS) delivered by large enterprise organisations (LEOs) to small and medium sized enterprises (SME) on employees' work engagement, and exploration of SME decision makers' willingness and capacity to purchase different types of HWS from their LEO.

## SHORT STUDY TITLE and ACRONYM

Supply chain Health INitiative Evaluation (The SHINE study).


**Chief Investigator:**
Dr Vaughan Parsons



**Sponsored by:**
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## PROTOCOL VERSION NUMBER AND DATE

***Aim:*** *To track changes to the document for study conduct, review, and oversight so it is clear which is the most recent document.*

***Version control:***
*All draft versions should be numbered 0.1, 0.2 etc. Draft versions do not need to be included in the table below.*
*The final version for submission should be numbered 1.0*
*The changes made relative to the previous protocol version* ***should be listed after submission***

| Version Stage | Versions No | Version Date | Protocol updated & finalised by; | Detail the key protocol update |
|---|---|---|---|---|
| *Current* | *V2.1* | *28/10/2025* | *Brendan Dempsey, Vaughan Parsons* | *Clarified updates requested from KEC – See overview document for changes made to the protocol*<br>*Other changes included:*<br>*- Broadening the definition of an SME to include companies with 10-49 staff, as well as to increase the number of participating SMEs, if feasible.*<br>*- Include 6-month survey in WP3.*<br>*- Provide a detailed overview of the randomisation process.*<br>*- Updated the survey to include a revised version of the EQ-HWB instrument.* |

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| | | | | - *Minor changes including improved grammar, allowing champion training to take place virtually, and including updated recruitment posters for the baseline survey.* |
| *Current* | *V2.0* | *22/09/2025* | *Brendan Dempsey, Vaughan Parsons,* | *Clarified updates requested from REC – See overview document for changes made to the protocol.* |
| *Previous* | *V1.0* | *22/05/2025* | *[full name & title]* | *Briefly summarise changes made* |

## SIGNATURE PAGE

The Chief Investigator and the R&D (sponsor office) have reviewed this protocol. The investigators agree to perform the investigations and to abide by this protocol

The investigator agrees to conduct the trial in compliance with the approved protocol, EU GCP, the UK Data Protection Act (2018), the Trust Information Governance Policy (or other local equivalent), the UK policy Framework for Health and Social Care research, the Sponsor's SOPs, and other regulatory requirements as amended.

**Chief investigator**

Dr Vaughan Parsons

11/06/2025

Signature Date

**This Protocol template is intended for use with UK sites only.**

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# 1 LIST OF ABBREVIATIONS AND DEFINITIONS

| | |
|---|---|
| AE | Adverse Event |
| CI | Chief Investigator |
| CRF | Case Report Form |
| CRO | Contract Research Organisation |
| DCE | Discrete choice experiment |
| DMC | Data Monitoring Committee |
| HRA | Health Research Authority |
| HWS | Health and wellbeing service |
| ICF | Informed Consent Form |
| LEO | Large Enterprise Organisation |
| Main REC | Main Research Ethics Committee |
| NHS R&D | National Health Service Research & Development |
| PI | Principal Investigator- An individual responsible for the conduct of the research at a research site. There should be one PI for each research site. In the case of a single-site study, the chief investigator and the PI will normally be the same person. |
| Participant | An individual who takes part in a clinical trial |
| REC | Research Ethics Committee |
| SAE | Serious Adverse Event |
| SME | Small and medium sized enterprise |
| SOP | Standard Operating Procedure |
| Sponsor | The organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. |
| SSC | Study Steering Committee |

# 2 SUMMARY/SYNOPSIS

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| Protocol Short Title/Acronym | Supply chain Health INitiative Evaluation (The SHINE study) |
| IRAS Number | N/A (Non-NHS study) |
| REC Reference | HR/RGO-24/25-40064 |
| EDGE reference | |
| Study Duration | 36 months |
| Methodology | Mixed methods (prospective matched control cluster study and qualitative methods) |
| Health condition(s) or problem(s) studied | Health and wellbeing (general) |
| Purpose of clinical trial | To assess the effectiveness of health and wellbeing services (HWS) delivered by large enterprise organisations (LEOs) to small and medium sized enterprises (SMEs) in their supply chain on improving work engagement, and to explore SME decision makers' and large organisations' willingness and capacity to engage with and pay for HWS offered this way. |
| Primary objective | To:<br>1) establish what HWS can be delivered by LEOs to SMEs in their supply chain;<br>2) evaluate the effectiveness of HWS delivered by LEOs to SMEs in their supply chain and explore factors that may affect the intervention effect on outcomes when compared to control arm SMEs;<br>3) conduct an economic evaluation using cost-consequence and social return on investment (SORI) frameworks to compare the intervention benefits and costs.<br>4) conduct a process evaluation to monitor implementation and perceptions by stakeholders in SMEs and LEOs;<br>5) assess the willingness and capacity of LEOs and SMEs to engage and pay for HWS through this model. |
| Secondary objective (s) | |
| End of study definition | All data collected and database lock |
| Number of Participants | 1170-1560 participants (across the 18-24 participating SME sites) |
| Study Type | Mixed methods (prospective matched control cluster study, stated preference study, and qualitative methods) comprising three linked phases |
| Data collected/storage (if applicable) | During conduct of the study, data will be collected and stored as per each work package:<br>**Phase 1: Preparation and service evaluation activities**<br>*WP1: Preparatory work to set up the delivery and evaluation of intervention.*<br>Qualitative and quantitative data will be collected, stored and analysed by Affinity Health at Work.<br>Contact: jo.yarker@affinityhealthatwork.com |

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| | **Phase 2: Implementation (Participating x3 LEOs and x18-24 SMEs)**<br>*WP2: Study implementation with a running time of 18 months in each SME (including 12 months of intervention period and follow-up 6 months later).*<br><br>**Phase 3: Evaluation**<br>*WP3: Intervention effectiveness evaluation.*<br>*WP4: Process evaluation;*<br>Quantitative data (participant questionnaires) will be collected and held securely at Guy's and St Thomas' NHS Foundation Trust (GSTT) servers via the REDCap software, with paper records securely retained on GSTT premises. Data from champions will be collected, stored and analysed by Affinity Health at Work via shared access to One Drive (to the confirmed). The pseudonymised data files will be analysed by the research team based at GSTT, KCL, Affinity Health at Work and University of Leeds (health economic data only)<br>Contact: vaughan.parsons@gstt.nhs.uk<br><br>*WP5: Discrete Choice Experiment (DCE) to examine the willingness of SMEs to pay for activities.*<br>Anonymised, non-identifiable quantitative data will be collected by a market research company and held securely at the University of Leeds. The data files will be analysed by researchers based at the University of Leeds.<br>Contact: A.Martin1@leeds.ac.uk<br><br>At the end of the study, data will be archived following the Sponsor's archive standard operating procedure. This will include being transferred to Iron Mountain (long-term archiving facility) for a period of two years after the end of the study. |

# 3 INTRODUCTION

Health and wellbeing services (HWS) are crucial for sustaining employment, improving productivity and work engagement [1, 2]. However, only approximately 45% of UK workers have access to HWS, with most employees in small and medium-sized enterprises (SMEs) lacking such provision [3]. While 75% of SMEs provide health and safety training, more comprehensive HWS (e.g. health prevention and occupational health (OH) activities) are notably scarce and rarely evaluated [4], potentially exacerbating health inequalities between employees of large and small organisations [5]. Previous initiatives have aimed to embed HWS into SMEs in the UK, including the Workplace Wellbeing Charter, the Fit for Work Service and Business Healthy. Despite documented benefits, all had potential limitations in terms of lack of randomisation in intervention delivery and use of comparison group and comprehensive measurement of health and non-health outcomes [6-8]. The UK Government recognises the importance of workers having access to HWS and in 2024 set up an OH taskforce, which aimed to increase access and uptake of OH by all workers. Additionally, the Department of Work and Pensions is piloting a subsidy initiative for SMEs to have access to OH services [9,10]. However, fiscal concerns are not the only obstacle; SMEs often find OH legislation challenging, and informal workplace dynamics influence employee's attitudes towards health services. SMEs' decisions to purchase HWS depend on perceived need and demand with employers sometimes making discretionary choices to support or retain specific employees [4]. Our previous work has shown that SMEs see sector-specific sources of advice as trusted and relevant to their needs [11]. Our findings indicate there is value in exploring alternative channels to reach SME employees. Our preliminary study suggested that providing support through the large enterprise organisation (LEO) which already have a relationship with and understanding of the needs of supply chain SMEs which provide goods and services may be an effective model of delivering HWS to SME employees. To our knowledge, this approach has not been explored in the UK or internationally.

***Why delivering HWS through the supply chain is an appealing proposition***

There are several reasons why a supply chain approach may be compelling to LEOs, SMEs in their supply chain and government. First, with 75% of UK SMEs operating within supply chains [12], integrating HWS into these well-established channels extends their reach to this workforce segment. Second, by delivering HWS to SMEs, LEOs can bolster the resilience of their supply chains against disruptions caused by illness, injury or labour shortages. Third, LEO in-house services are typically offered in specialised environments, ensuring practicality and relevance to sector-specific job roles. This means HWS will likely be seen as relevant, acceptable, and tailored to SME employee needs. Fourth, the supply chain is an effective route to ensure compliance and regulatory adherence of SME organisations. While SMEs are aware of physical safety regulations, few are aware of their obligations regarding mental health and safety or understand what OH activities could mitigate risks. A supply chain approach to HWS provides an opportunity to remedy this and reduce risk of employee harm, fines and legal consequences. Finally, organisational reputation is often the primary driver to invest in employees' wellbeing. Collaborating in this way, LEOs and SMEs can enhance their company's reputation appealing to employees and customers.

We have recruited three diverse LEOs across manufacturing, healthcare and transport based of the high proportion of their supply chain partners are based in the UK. On this basis, we've not included retail organisations as they informed us that most of their supply chain SMEs are

abroad. We've included senior representatives from retail, energy and construction industries to our Expert Stakeholder and Patient/Public Group (ESPG), to aid generalisability of findings across business sectors.

**Incorporating preparatory work into this research design**
Our previous work informed the design and implementation of a novel way of delivering HWS in SMEs in six ways:

*i) Our study design*
Demonstrating acceptability and feasibility within Jaguar Land Rover (JLR)'s supply chain, the findings advocate for further testing in and beyond manufacturing. The three participating LEOs – JLR, Transport for London and Hampshire and Isle of Wight NHS Trust – have been recruited to provide HWS through their supply chain. These sectors were chosen due to the large numbers of UK SME suppliers. Our research with SMEs, EPSG input and consultation with the LEOs gives confidence in our intervention study design that includes intervention and control arms.

*ii) Proposed HWS intervention for SMEs in the intervention group*
We will review the existing HWS embedded within each participating LEO and map them onto bespoke HWS packages for their supply chain SMEs.

The HWS intervention will include, as a minimum, workplace health awareness, health promotion, prevention of occupational mental ill health and training managers to have work and health conversations with their teams. These HWS are proposed due to their proven benefit to employees [13] and because they can be efficiently delivered by the LEOs with minimal implications for professional liability. To support delivery of interventions, we will train 'health and wellbeing champions' (hereafter referred to as 'champions') who will develop effective communications to alert SME employees of available services and organise relevant activities. Training the champions to have work and health conversations aligns with the Government's strategy and priorities to improve work adjustments and sustainable work as outlined in the 'Get Britain Working' White paper.

The intervention will run for 12 months in each SME allocated to the intervention group, ensuring the interventions have sufficient time to be embedded in the SMEs [14].

Data will be collected on work engagement (primary outcome) and other (secondary) outcomes, including health (e.g. mental wellbeing), work, economic (e.g. productivity) and resource use (including employee, SME and LEOs financial investment), at baseline, 6-months, 12 months and 18 months.

*iii) Engaging control arm SMEs*
Control arm SMEs will not receive the intervention. All SMEs including those in the control arm will however receive summary data reports. To limit any contamination effects, this report will be provided after the employee survey outcome data collection at baseline and 12 months. These reports offer insights into the workforce's health and wellbeing, along with recommendations for independent, future action on employee health and wellbeing. This approach has been successfully applied in the NIHR funded IGLOo study to secure engagement from control organisations. Control SMEs will also be invited to nominate an

employee for work and health training post-intervention to transfer new knowledge and skills into the control SMEs. Together, these services would otherwise cost at least £5,000 per SME, representing an attractive financial offer to control SMEs.

*iv) Study outcomes*
The intervention seeks to deliver HWS within SMEs, aiming to foster healthier employees and workplaces, with a primary focus on evaluating work engagement. Three main reasons underpin this decision: first, evidence demonstrating correlation between work engagement and a broad range of health and work outcomes, including physical and mental health outcomes [15], performance and absenteeism [16], job commitment and satisfaction [17], and unemployment and disability pension uptake [18]; second, many companies routinely track work engagement, and have strong incentives to do so accurately, as a key performance indicator, making it a practical and accepted measure, as evidenced by the NHS [19]; third, our previous research identified its relevance, especially in SME contexts, where openness to health conversations is low and research engagement is challenging.

Secondary outcomes have been informed by workplace health evidence and following feedback from our ESPG, alongside our experience of working with SMEs in the Midlands Engine Mental Health Productivity Pilot (MHPP), a programme to support mental wellbeing in the workplace. These will include mental wellbeing, health behaviours, safety behaviours, job satisfaction, productivity, and cost.

*v) Logic model* Groundwork from the Development Award provided sufficient evidence to underpin the logic model illustrating how the intervention is expected to work, as follows:

1. Engaging employees and management are important in the successful delivery and uptake of HWS in SMEs, ensuring alignment with the specific workplace context, such as organisational policies, programmes, practices, and strategies [20]. Through participatory processes, employees engage in fostering a shared understanding of the intervention's necessity and objectives [21].

2. Multi-component interventions benefit organisations [22] but are often unattainable for SMEs due to resource and capacity constraints. Provision of multi-component interventions delivered by LEOs offer a better fit for SMEs.

3. Training an SME employee as a champion and liaison between their colleagues, managers and the HWS team of their LEO improves employee engagement and ensures sustainable impact [14].

*vi) Inclusion of a Discrete Choice Experiment (DCE)* While the implementation study of a novel HWS delivery model will provide rich data on the feasibility of the intervention, understanding the value SMEs place on HWS and their willingness to invest in them is also crucial for scalability of the approach and policy decisions. This DCE, in collaboration with the British Chambers of Commerce, will allow for the consideration of HWS delivered across diverse sectors including retail, construction, energy, telecommunications and aviation among others.

# 4 PATIENT AND PUBLIC INVOLVEMENT

As a core part of our preparatory work activities, we formed an Expert Stakeholder and Patient/Public Group (ESPG). We've interpreted ‘public and patients’ in a broad sense, reflecting the diversity of stakeholders involved in work and health research. This group reviewed the documents relevant to our preparatory research plan and provided feedback on our recruitment process and participant-facing documentation. We presented our findings and sought their advice on future research questions and methodology of this follow-up interventional study, with opportunities for them to provide written feedback too.

Additionally, findings were presented at the recent launch event of the London Centre for Work and Health through which feedback from wider stakeholders was gathered to inform the selection of outcome measures, study design, and practical considerations for implementation. At this meeting, the chief medical officer at Transport for London initiated contact with us to participate in the follow-up collaboration study.

The ESPG comprises: Employee and manager representatives from each SME; Trade Union representative; Director of Public Health, Solihull; Client Services Manager, JLR; Client Services Director, Health Partners; Director of Research, Policy Institute, King’s College, London; Chief Medical Officer, JLR ; Consultant Occupational Physician, Healthcare Partners; Chief Medical Officer, TfL; Director of Health and Wellbeing, Hampshire and Isle of Wight NHS Foundation Trust); health and wellbeing champion representatives.

In the three months prior to the proposal submission, the ESPG met twice with the research team to discuss our research questions and plan. They further reviewed the draft research proposal, provided feedback on potential challenges, and offered solutions to overcome these with regard to participant recruitment and optimal ways to engage SMEs. Their preliminary feedback on such issues will be explored further as part of our planned work. They also assisted with refining the list of potential outcomes for the study and offered important recommendations on suitable methods to use for data collection. ESPG members representing the SMEs were enthusiastic and supportive of our proposal to utilise H&W champions as a component of the intervention and our plan to develop and deliver a bespoke training programme to upskill them to take on this role.

We've scheduled four ESPG meetings per year and our ESPG activities will reflect the iterative nature of our programme of work. Accordingly, we've devised a schedule of planned ESPG activities which will be integrated across each of the WPs: WP1: The ESPG will review and provide feedback on suitable data collection tools and proposed participant-facing study documentation including the information sheet, consent form, posters and questionnaire. WP2: Review regular feedback from champions and participants regarding study engagement activity and intervention delivery challenges and propose solutions to overcome challenges where practicable. WP3: Assist the study team with reviewing and interpreting the study’s outcome data and findings; and review findings from the economic evaluations alongside the wider study results. WP4: Review and provide feedback on the proposed interview schedules to be used. We will offer 1-2 EPSG members the opportunity to co-facilitate the focus group sessions with the WP lead. WP5: Assist the study team in reviewing the Discrete Choice Experiment survey and review study findings to inform policy

and practice recommendations. Throughout the programme of work, we will collate and evaluate ESPG activities following the Evaluating Public Involvement in Research guidance.

# 5 TRIAL OBJECTIVES AND PURPOSE

**Aims and Objectives**

The study aims to assess the effectiveness of HWS delivered by LEOs to SMEs in their supply chain on improving work engagement, and to explore SME decision makers' and large organisations' willingness and capacity to engage with and pay for HWS offered this way.

The study objectives are to: 1) establish what HWS can be delivered by LEOs to SMEs in their supply chain; 2) evaluate the effectiveness of HWS delivered by LEOs to SMEs in their supply chain and explore factors that may affect the intervention effect on outcomes when compared to control arm SMEs; 3) conduct an economic evaluation using cost-consequence and social return on investment (SORI) frameworks to compare the intervention benefits and costs; 4) conduct a process evaluation to monitor implementation and perceptions by stakeholders in SMEs and LEOs; 5) assess the willingness and capacity of SMEs to engage and pay for HWS through this model.

# 6 STUDY DESIGN & FLOWCHART

## *6.1 Study Design*

A prospective matched control cluster study design involving nine intervention and nine matched control SMEs from the supply chain of three participating LEOs (JLR, Hampshire and Isle of Wight Health Integrated Care Trust and Transport for London) across diverse sectors. Collaboratively, we will tailor a multi-component HWS intervention to each SME's needs. Delivered by the LEO, it will likely include raising awareness about workplace health and wellbeing, health promotion, preventing mental ill health, and training managers in health and wellbeing (H&W) conversations. H&W champions will be recruited from each intervention SME to facilitate delivery and, supported by a qualified health and work advisor to develop effective communications to alert SME employees of available services and organise relevant activities. Effectiveness (work engagement) will be evaluated before the roll-out of the intervention (baseline), during the intervention (6-months), at the end of the intervention period (12-months) and 6 months later (18-months). An economic evaluation of the intervention will use cost-consequence and SORI frameworks. A process evaluation will identify implementation obstacles and facilitators, complemented by a discrete choice experiment (DCE) involving large numbers of SME decision makers from diverse sectors to ascertain the value they place on HWS and their willingness-to-pay for a range of potential HWS interventions.

To address the research aims and objectives, the study comprises three phases with five iterative work packages (WPs) addressing the study's research aims and objectives.

- Phase 1: Preparation and service evaluation activities
    - WP1: Preparatory work to set up the delivery and evaluation of intervention.
- Phase 2: Implementation (Participating x3 LEOs and x18-24 SMEs)
    - WP2: Study implementation with a running time of 18 months in each SME (including 12 months of intervention period and follow-up 6 months later).
- Phase 3: Evaluation
    - WP3: Intervention effectiveness evaluation; economic evaluation.
    - WP4: Process evaluation

- WP5: Discrete Choice Experiment (DCE) to examine the willingness of SMEs to pay for activities.

A detailed description of the planned methodologies is outlined in the following WPs.

# 7 Phase 1: Preparation and service evaluation activities

## *7.1 Work Package 1: Intervention co-design and preparation for the HWS intervention (Lead: JY/AS)*

### *7.1.1 Objectives:*

i) Conduct a review of the existing HWS provision within the LEOs (1)
ii) Design and plan a multi-component model of HWS implementation study (1)
iii) Recruit and train SME champions to support study implementation within their SME (2)
iv) Determine the suitable data collection tools for evaluating study outcomes (2)

### *7.1.2 Methods:*

We'll review the existing HWS provision within the LEOs. We'll co-design the HWS model with LEOs and the participating SMEs from their supply chains. Consultation meetings with each LEO will map out existing HWS and identify suitable intervention elements of the HWS services.

Work undertaken in phase 1 falls within a service evaluation as confirmed by the Health Research Authority (HRA) decision tool and confirmed by the sponsor's R&D governance department.

### *7.1.3 Review of existing HWS provisions within the LEOs*

To gain an understanding of the current health and wellbeing priorities, the operating context and the HWS available within the LEOs, we will draw on our experience of reviewing HWS in large organisations as follows:

- Conduct up to six interviews with key stakeholders within each LEO, to include those responsible for Human Resources, Health and Safety, Occupational Health, Union representatives and employee resource group representatives to ensure the complexities of wellbeing for diverse groups are understood. These interviews will provide rich information about the culture and context in which employees work, particularly with regards to staff experience, psychological and social hazards, leadership and management practices, policies and initiatives, and the governance of mental health and wellbeing. The interviews will gather information regarding how HWS are chosen, implemented and evaluated drawing on established frameworks to guide discussions (e.g. The Implementation Outcomes Framework).
- Review relevant organisational data (for instance employee survey data, psychological health claims, OH and EAP usage data and feedback received) where it is made available. This data will provide context to the services provided.
- Gather documentation and staff communications relating to the HWS

• Review the content of HWS provisions where possible, for example during an on-site guided review of the learning platform.

• Conduct two focus groups with staff from a range of roles and functions to share insights into staff engagement in the LEO's HWS, to understand how policies and practices are experienced throughout the organisation and identify learnings for the implementation of the HWS in SMEs

An initial mapping of HWS against established HWS frameworks will be developed including an examination of:

• Quality of HWS, drawing on principles of best practice intervention design, for example examining whether the HWS is underpinned by theory, evidence-informed, tailored to context through co-design, piloted among diverse staff groups.

• Accessibility of HWS, including consideration of user-centred design principles.

• Equity of HWS, including a consideration of provisions for diverse work and health needs and preferences.

• Levels of control in place (prevention, development and support)

• Levels of HWS target (Individual, Group, Leader, Organisational, Outside) to examine the extent to which a whole-system and integrated approach is in place.

• Implementation factors (e.g. reach, acceptability, fidelity, maintenance)

• Evaluation processes in place (e.g. reaction, learning, behaviour change, impact on work and health outcomes)

#### *7.1.4 Outputs (1):*

This information will be used to:

i) Develop a logic model for HWS within each of the three LEOs to outline the anticipated pathway of effect and inform the selection of study outcomes.

ii) Provide a comprehensive overview of HWS provision within each of the LEOs to share with the SMEs in their supply chain to support the identification of suitable HWS. The H&W Advisor and SME senior leaders will refer to the overview to identify which HWS could best meet their needs (e.g. filling resource gaps, addressing priority outcomes). Should any HWS be found to lack rigour in design, implementation or effectiveness we will caution against its use in the SMEs.

iii) Provide the LEOs with an insight report providing an overview of their existing HWS as mapped against best practice approaches. LEOs will be provided with a feedback report and where appropriate a presentation of findings. Where possible, LEOs will be provided with early feedback to ensure that this data could be used to inform adjustments to their HSW prior to offering services to the SMEs where time and resource allow. This report will include:

   a. a quantitative evaluation of effectiveness and resources used in service delivery, if such data exist and where access to data allows.

   b. gather learnings for implementation, identifying obstacles and facilitators experienced by the LEOs to ensure that these are considered in the roll-out of HWS within the SMEs.

iv) To inform the implementation of the HWS in the SMEs (WP2) and to inform the process evaluation (WP4).

v) Compare the acceptability, uptake and implementation of HWS in LEOs versus SMEs (WP3 and WP4).
vi) Provide a list of factors related to HWS provision which can be used as candidate attributes for the DCE (WP5).

vii) Where appropriate, with permissions and in collaboration with the LEOs, learnings for good practice or caution will be shared among the work and health community through dissemination activities.

### *7.1.5 Recruiting participating SMEs and randomisation of sites to control or intervention group*

The three participating LEOs will each help us to recruit between six and eight SMEs seeking to improve their HWS provision in their supply chain to participate in the study. We will aim for eight SMEs per LEO, but acknowledge we may have difficulty recruiting the full complement across all supply chains. If it not deemed feasible to recruit eight SMEs in an LEO, we will accept a minimum of six SMEs, which should still allow for adequate power for our study (see Section 8.1.6 – Power calculation). A maximum four-month window period will be used to identify and recruit the 18-24 SMEs (six to eight SMEs from each of LEO supply chain) into the study during the pre-randomisation stage. Those who are interested will be told to contact the research team. We will set up a meeting with each interested SME to ensure that they are eligible for the study, to explain the study to them and answer any questions they may have, and to share a provisional version of the study contracts with them. If all are satisfactory and the SME consents to participate in the study, the study team will collect data about the workforce demography and size of each SME.

In late November/early December 2025, randomisation will occur (assigning SMEs to intervention or control arm). We would ideally randomise all eight SMEs per LEO together, however, we will conduct the first randomisation in each LEO at this time if a minimum of four SMEs have been recruited. We will then begin to roll-out the study in these randomised SMEs, and continue to recruit additional companies in background, which we can then randomise at a later point and who would have a slightly delayed beginning for the study/HWS intervention. Therefore, randomisation may occur at six separate time periods (twice for each LEO), ensuring there are no delays in the randomisation and delivery of the intervention from each LEO. There will be no more than a month or two between the staggered beginning of the study roll-out in SMEs within each LEO. We will endeavour to recruit even numbers of SMEs for each LEO to ensure that half of all participating sites are in the intervention arm and half are in the control arm. Randomisation will be undertaken by a co-investigator who is not involved in recruiting or working directly with the SMEs (likely Dr Adam Martin - University of Leeds).

Prior to randomisation, and if possible, we will match SMEs within each LEO by workforce size (i.e., the companies with the two highest workforce sizes will be matched, then SMEs with the 3$^{rd}$ and 4$^{th}$ highest workforce size will be matched, and so on). SMEs will then be randomised within each of these pairings. This will help us to ensure that our intervention and control arms are balanced for size, considering some SMEs may have 200+ employees while others may have 10-20. As above, we will aim to randomise all SMEs per LEO at the same time, however, to avoid potential delays, we will conduct the first randomisation with a minimum of four SMEs if appropriate. In this event, we will pair and randomise the SMEs that we have already recruited, continue working to recruit new SMEs, and then we will pair the new SMEs in the same manner and then randomise them within their pairings, via a second randomisation.

Each organisation will be assigned an ID and paired by LEO and workforce size by Affinity, and the IDs will be provided on an excel sheet to Adam so he is blind to organisation name. Dr Martin will then randomly allocate the paired organisations into either the control or intervention group. He will put the outcome of the randomisation process for each organisation on the excel sheet and send it back to Affinity. These will result in 3/4 SMEs in the intervention group and 3/4 in the control group for each LEO (9-12 in intervention and 9-12 in control overall). Affinity will notify the SMEs of the outcome of the randomisation process. Each envelope will be opened in a recorded Teams meeting with others present from Affinity and GST to ensure transparency, and the recording will be stored in GST files.

Once intervention and control SMEs are identified, inception meetings will be held for each SME we which we will include the LEO, the SME's management team and the research team to establish the implementation and research requirements. Following SME director/owner commitment, arrangements will be made with intervention and control arm SMEs to set up the study.

Intervention SMEs will establish a working group to work with the research team to simplify the HWS package for implementation, determine delivery methods, and plan evaluation procedures.

The control SMEs will also make arrangements for data collection (administration of surveys) and mechanism for seeking feedback.

#### *7.1.6 Recruitment of health champions*

Within each intervention SME, at least two volunteer champions will be recruited internally via an expression of interest process. Role specifications for champions will be provided by the research team drawing on insights from the MHPP project for their role specification. Specifically, we will ask a senior HR/management team member at each intervention SME to share information about the champion role with employees that they feel would be suitable. Those who are interested will then be able to contact the research team to express their interest. Should more than two people in any SME express an interest in the role, we will work with the SME management to decide on which two people should be chosen for the role. Supported by a senior HR/management member, champions will dedicate work hours to fulfil the dual role of acting as natural helpers in intervention delivery and liaising with the research team to capture implementation insights.

Champions will receive training in principles of health and work including health promotion, return to work, behaviour change and communication skills. Delivered by a Health and Wellbeing Advisor (hereafter referred to as 'advisor') who specialises in workplace interventions, this training will equip champions to facilitate health-promoting activities. Champions will be invited to join a monthly "Community of Practice" meeting [23] alongside peers from other SMEs, facilitated by the advisor. Additionally, to safeguard the champions' own health and wellbeing, champions will have the opportunity to contact the advisor throughout the study for support and advice regarding the implementation of the HWS intervention. Records of these interactions will inform the process evaluation.

Informed by research with SMEs, proposed measures will undergo assessment by SME employees and employers from the ESPG. The questionnaires, tailored to preferences, will

be either paper based or on-line. We'll ask SMEs if we can access and use routinely collected data relevant to employee engagement, health and productivity. While this may not be consistently available, gathered data may be used in cost-effectiveness assessments.

### *7.1.7 Output (2):*

i) Finalise the study intervention characteristics and mode of delivery
ii) Prepare SMEs for intervention implementation including training SME 'health and wellbeing champions'
iii) Finalise data collection tools and draft study questionnaire.

The study activities described above and undertaken within WP 1 fall within the definition of a 'service evaluation'.

### *7.1.8 DATA*

**Data to be collected**

***Qualitative data***

1. An interview guide will be used to facilitate the qualitative data collection. Interviews will be conducted either in-person or virtual based on local preferences. Interviews will be recorded with permission. Audio data will be transcribed verbatim and automatically generated using Microsoft Teams. As part of data cleaning, the transcripts will be compared with the audio files to ensure data quality assurance. Interviewers will also type notes during/after interview.

***Organisational data, policies and HWS material for LEOs and organisational data from SMEs***

2. Organisational policies, data exports, existing reports, employee communications and field notes on use and evaluation of HWS will be requested from participating LEOs and used to collate organisational data for review and analyses. This information will be used to inform which components of HWS are offered to SMEs and how these HWS are communicated to SME employees.

A range of documents, reports and data will be requested from LEOs as part of the review exercise including:

- documents outlining the LEO's priorities and operations around health and wellbeing (e.g. health and wellbeing strategy, risk assessments, health/wellbeing department structure chart)
- policies on health and wellbeing (e.g. sickness absence policy, flexible working policy)
- documents outlining the development, design and delivery of HWS, including how they are communicated and accessed by staff (e.g. map of services, theoretical underpinnings, referral systems, promotion posters/emails)
- evaluation reports and/or data on the reach, impact and implementation of HWS
- contextual anonymised organisational data on staff health and wellbeing (e.g. employee mental wellbeing, no. near misses/accidents, on sickness absence).

LEO contacts will also be asked to complete an onboarding excel spreadsheet asking for organisational demographics (e.g. size, type of work, main hazards, whether policy and practice documents listed above are in place, type of services run by their OH/wellbeing department).

SMEs that consent to take part in the study will be asked to complete a short onboarding document on the size of their organisation, length of operation, length of contracting with LEO, sector, type of work, main hazards in place and use of OH services. Where available they will also be asked to provide policies on health and wellbeing (e.g. sickness absence policy) and organisational data or reports on staff health and wellbeing (e.g. employee mental wellbeing, sickness absence rate).

## 2. Data handling and record keeping

***Qualitative data***

1. The study team will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Host or its designee will be obtained for the disclosure of any said confidential information to other parties.

Digital recordings of interviews will be made using a Dictaphone device (for telephone and in-person interviews) or Microsoft Teams (for online interviews) and transcribed within Microsoft Teams. Files will be downloaded and securely stored at Affinity Health at Work only on a password protected shared drive, with limited access by the authorised study staff only. Recordings and transcriptions made on Teams will be immediately deleted from the Microsoft Cloud once they have been securely downloaded. The saved transcripts will be pseudonymised and identified by unique participant IDs and a member of the Affinity research team will check the transcript for clarity and accuracy. The recorded interview will then be deleted soon after transcription has been checked. Audio files created on an encrypted Dictaphone will be sent via upload to a cloud-based depository portal and processed by Accuro, an external transcription service approved by the Guy's and St Thomas NHS Foundation Trust. Recordings will be immediately deleted after the transcription has been completed.

Data storage procedures will follow Affinity Health at Work standard operating procedures for research.

All the information/data collected for this study from participants will be securely stored in folders on the Affinity Health at Work secure servers, folders will be password protected and can only be accessed by the research team. The recording equipment used to record the interviews will be erased after each interview has been uploaded to the secure folder on the Affinity Health at Work server. The pseudonymised interview recording, pseudonymised transcripts, and the consent form with identifiable personal information, will be stored in separate locked and protected folders on Affinity Health at Work secure servers in line with GDPR requirements for the duration of the study. Each file will have the unique study ID for each participant, and it will only be possible to identify the participant by looking at the consent form and linking this study ID to the other documents. Data will remain pseudonymised to allow participants to withdraw their data from the study, should they desire. The protocol for withdrawing data will be explained to participants in the PIS.

All qualitative data collected will not be stored with any identifying information. A code number will be allocated to each qualitative participant and will be stored securely, to ensure that participants cannot be identified from their response.

Affinity Health at Work will be the data processor for this qualitative work, working on behalf of Guy's and St Thomas' NHS Foundation Trust as the data controller, and responsible for looking after the information and using it properly.

Data will only be held where there is a legitimate need to do so. Once the stage of the study which involves inviting participants to take part in research and asking for their express consent is complete the contact details will be securely destroyed.

All data will be retained for two years after the end of the research study as per GSTT guidance before being destroyed (deleted electronically).

***2. Organisational data and documentation***

Affinity Health at Work will be the data processor for the organisational data and documentation, working on behalf of Guy's and St Thomas' NHS Foundation Trust as the data controller, and is responsible for looking after the information and using it properly. Data storage procedures will follow Affinity Health at Work standard operating procedures for research. All data will be retained for two years after the end of the research study as per GSTT guidance before being destroyed (deleted electronically).

### *7.5 Data Sharing*

The data generated by this work package will be created and stored at Affinity Health at Work, as they are operating as a Data Processor on behalf of GSTT.

The only components of the work package that will be stored within GSTT will be the finalised analysis report of the qualitative interview data. The completed consent forms will be transferred from Affinity Health at Work to GSTT for the purposes of archiving, and the analysis report will contain only pseudonymized data about the participants who completed interviews. Other outputs from the qualitative interview analysis other than the analysis report (i.e. annotated transcripts, etc) will be retained at Affinity Health at Work.

At the end of the study and with consent from participants, the final anonymised dataset will be uploaded to OSF (a publicly accessible) data repository for future ethically approved research. This has been highlighted on the PIS and the ICF, and participants will have the option to with-hold their anonymised data if they desire.

A full description of the data flow is provided in the study's Data Protection Impact Assessment document.

# 8 Phase 2: Implementation

## *8.1 Work Package 2: Implementation of the HWS intervention in SMEs within supply chains (Leads: JY/VP/AS)*

### *8.1.1 Objectives:*

i) To implement the multi-component model of HWS in SMEs within the supply chain of LEOs. (WP2)

### *8.1.2* Description of the intervention

Each supply chain SME will receive a bespoke HWS intervention which has been specially designed and tailored to their specific needs and requirements. This HWS intervention will be a package of individual components which will include as a minimum: workplace health awareness, health promotion, prevention of mental ill health and training managers to have work and health conversations with their teams. The individual components included in the HWS intervention for each supply chain SME will be developed based on: (1) a review of the existing HWS within each participating LEO to ensure that the individual components are designed and delivered in accordance to good practice and can be delivered safely and with fidelity in an SME context and (2) the needs of each supply chain SME, appreciating that each SME may have some existing HWS in place. The exact Health and Wellbeing Support (HWS) offered to each SME will depend on the HWS available at the Local Enterprise Organisation (LEO) they work with, and will be advertised to staff locally in the workplace before and throughout the intervention. As the protocol was submitted for ethical review prior to finalising the HWS with participating LEOs and SMEs, the specific interventions to be implemented are not described in detail here. However, any new HWS interventions not currently described in this protocol will be submitted for ethical approval as an amendment prior to implementation.

The development of each HWS intervention will be also consider coverage of i) levels of control [22] (Lecours et al., 2024); ii) levels of intervention target (including individual, group, leader, organisation; Yarker et al., 2024); and iii) guided by the Society of Occupational Medicine's buyers guide for health and wellbeing products and services (Yarker et al., 2024).

It is likely that several delivery channels will be incorporated including:

- access to self-guided resources, accessed via web, intranets or in hard copy
- all staff webinars with question and answer opportunities
- tailored expert-led training sessions facilitated by work and health experts, delivered to all staff or specific staff groups (eg. Hand arm vibration for estates workers, male mental health for men, leaders)

To promote intervention delivery, 'health and wellbeing champions' from each SME in the intervention group will be trained and supported to develop bespoke communication material to raise awareness of available HWS services on offer from the LEO to their SME workforce and will coordinate targeted engagement activities for the HWS intervention as a whole package and the specific individual components. This will also include champions facilitating work and health conversations with individuals in the workplace.

In the intervention group, the duration of the intervention delivery will be 12 months.

### *8.1.3 Control arm (Comparator)*

Control arm SMEs will not receive the intervention. However, in order to provide some form of compensation and incentive to take part in the study, control arm SMEs will receive the same summary data reports following data collection, and champion training post-study evaluations, that are also provided to the intervention group SMEs. These reports offer insights into the workforce's health and wellbeing, along with recommendations for independent, future action on employee health and wellbeing. To limit the risk that employee outcome survey responses are influenced by these summary data reports (contamination

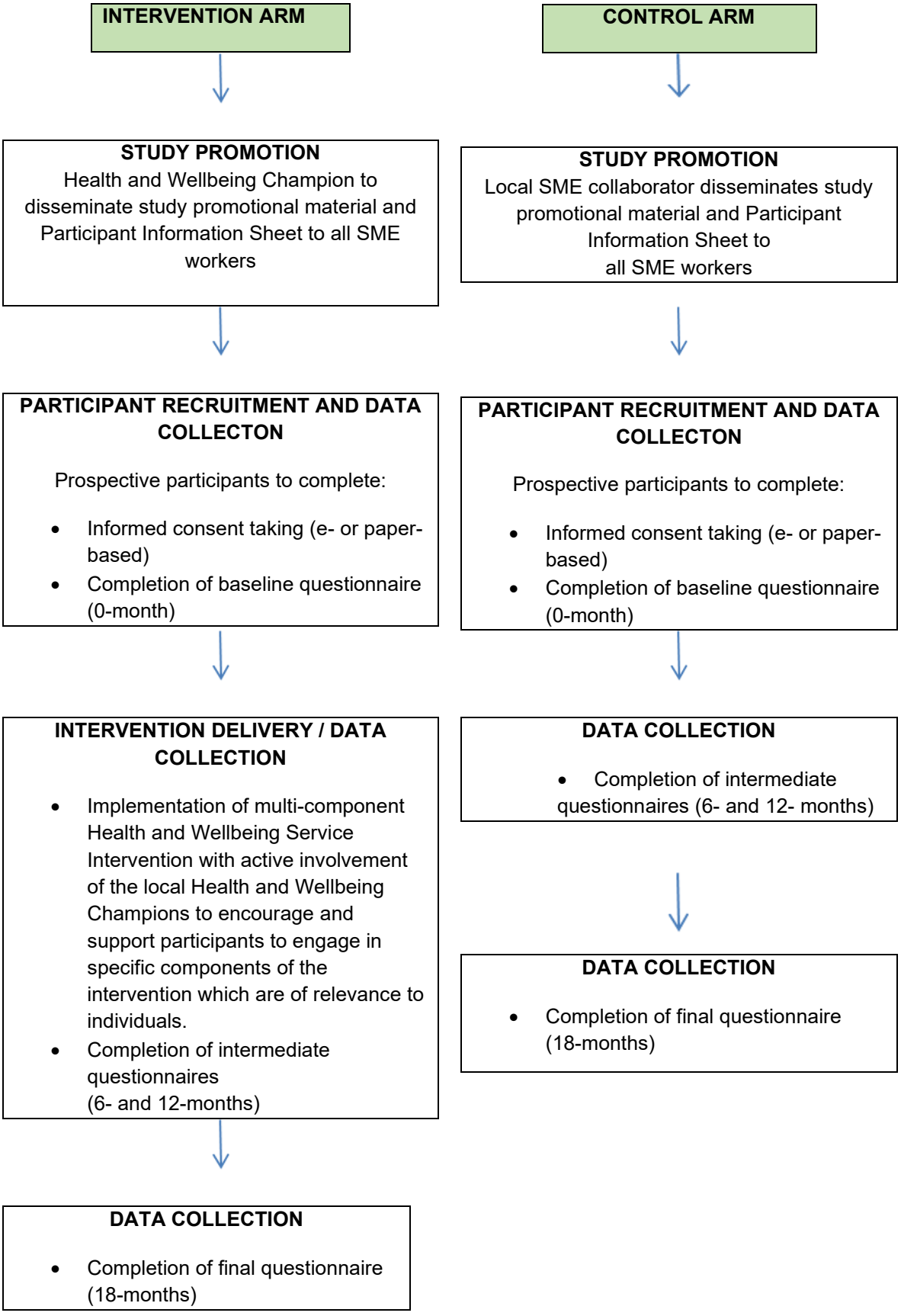
effects), they will be provided to control arm SMEs after the employee survey has been conducted at each time point (baseline, 6, 12 and 18 months). This approach has been successfully applied in the NIHR-funded IGLOO study to secure engagement from control organisations.  Additionally, once all study data has been gathered, control SMEs will also be invited to nominate an employee for work and health training to transfer new knowledge and skills into the control SMEs.

Together, these services would otherwise cost at least £5,000 per SME, representing an attractive financial offer to control SMEs.

### *8.1.4 Masking & other measures taken to avoid bias*

As referred to above, upon consenting into the study, SMEs will be randomly allocated to intervention or control arms by a member of the research team who has had no prior interaction with the employees at any SME. Prior to randomisation, we will match SMEs within each LEO by workforce size (i.e., the companies with the two highest workforce sizes will be matched, then with the 3rd and 4th highest workforce size will be matched, and so on). SMEs within each of these pairings will then be randomised. This will help us to ensure that our intervention and control arms are balanced for size, considering some SMEs may have 200+ employees while others may have 10-20.Due to the nature of the intervention, it is not possible to blind participants in the LEOs and SMEs to their group allocation. Companies will be informed of the allocation soon after consenting for their involvement in the study prior to consent.

### *8.1.5 STUDY FLOW DIAGRAM (INTERVENTION and CONTROL ARM)*



### *8.1.6 Participant Selection*

Participants recruited into the study will be drawn from the 18-24 SMEs recruited to take part in the study and we will work with the local collaborator at each SME to develop an acceptable method to invite participants to take part. We will monitor recruitment from each participating centre and will relay information back to the local sites, so they are aware of the recruitment uptake.

**Sample size calculation and justification**

A previous study of a workplace intervention to build and sustain work engagement [27] suggests a mean (SD) work engagement score of 5.08 (1.40) in the control and 5.76 (0.86) in the intervention group. As the proposed intervention is SME-based, sample size calculations must account for clustering effects. With the rho of 0.1 and the above values for expected change in work engagement scores, seven SMEs per intervention arm ensure 90% power at a 5% significance level (2-sided) to detect differences in the primary outcome. To account for participant attrition, we plan to over-sample with nine to twelve SMEs per arm, depending on the availability of interested SMEs, and to maximise the recruited employee sample per SME.

Given the workforce size of SMEs (between 10 and 249 employees), and assuming a uniform response rate across the recruited SMEs no greater than 50%, the anticipated number of participating employees per SME will range from 5 to 125, equivalent to an average of 65 employees per SME. Put together, the anticipated sample size across the minimum of 18 recruited SMEs would be 1170 employees, rising to 1560 employees if we can recruit the full complement of 24 SMEs. This ensures robustness in detecting meaningful changes in work engagement attributable to the proposed intervention.

### *8.1.7 Participant inclusion criteria*

This study will be implemented at an organisational-level and so all employees at participating SMEs will be eligible to take part in the study. We anticipate this will include salaried employees and others that SMEs deem appropriate to involve, e.g. those undertaking apprenticeships. All participants will be of working age, i.e. 16+ years).

### *8.1.8 Participant exclusion criteria*

Persons aged under 16 years.

### *8.1.9 Study Procedures:*

**Screening procedure**

On behalf of the research team, the local collaborator and champions (intervention sites) at each of the participating SME organisations will disseminate study promotional material (invitation letter) and participant information sheet (PIS) in either an email or in paper format (depending on their preference) to all employees at least 7 days before the participant recruitment period commenced. The invitation letter and PIS will be co-designed and co-signed by our ESPG, which we anticipate will assist in optimising the participant recruitment rates. The PIS will include an overview of the study, with the contact information for the research team should individuals have any questions or require further clarifying information. Additionally, a study poster or other promotional material (flyer) will also be displayed within the workplace setting to promote the study locally.

**Participant recruitment**

Participants who are interested in taking part in the study will be directed to complete informed consent via REDCap (database form 1). For those who choose to complete an online survey, we will enable a setting in REDCap that will send participants an email reminding them about the survey and providing a link to it if they have not completed it within a set period of time after completing the consent form. We will send participants a maximum of two follow-ups; the first 48 hours after they completed the consent form and the second one week after they completed the consent form. A paper study pack containing the consent form and questionnaire will also be made available upon request.

#### *8.1.10 Delivery of the intervention and follow-up*

The champions will raise awareness of the HWS intervention throughout the study duration through a communication plan developed with the support of the advisor and LEO's OH team.

As described in section X above, all study participants in the intervention SMEs will receive the full intervention, while control SMEs will receive a health and wellbeing status report followed by a work and health training post intervention for individuals nominated by the SME.

At intervention sites, once participants are consented into the study the champion will support the intervention roll-out ensuring all employees within their participating SME are aware of, supported and encouraged to access the HWS offered by the LEO. Participants within SMEs who have not consented into the study will still be able to engage with the intervention, and will be invited to consent into the follow-up surveys (at 6 and 12 months) instead. To optimise the value of the study and uptake of components of the intervention, practical actions to overcome challenges will be taken where appropriate.

# 9 Phase 3: Evaluation

## *9.1 Work Package 3: Quantitative evaluation and social return on investment analysis (Leads: AM/EW)*

### *9.1.1 Objective*

i) To compare the acceptability, uptake and implementation of HWS in LEOs versus SMEs. (WP3)

ii) To evaluate the effectiveness, costs and value for money of the HWS intervention from the perspectives of employees, employers, the healthcare system and wider economy (WP3)

### *9.1.2 METHOD and DATA*

## Quantitative data to be collected (Participant-level data)

**Participant questionnaires**

In addition to the collection of screening and consent data, immediately following consent, all participants (both in the intervention and control SMEs) will be invited to complete a baseline study questionnaire (database form 3) using the same REDCap link enquiring into work engagement (primary outcome) and secondary outcomes (as per WP1 above).

Our data collection methodology and design will consider survey fatigue and time constraints on SME employees, aiming for completion within 15 minutes. Data collection tools will capture information on work engagement (primary study outcome) and various secondary outcomes (encompassing health and occupational measures, and resource use-/cost-related measures) along with other co-variates (e.g. demographic characteristics and organisational factors). These could include:

Demographics

- Age
- Sex
- Job role

Health outcomes

- Primary outcome: Work Engagement (UWES)
- Secondary outcomes:
    - Health-related quality of life (e.g. EQ-5D-5L)
    - Mental wellbeing (WHO-5)
    - Health behaviours (7-Day Physical Activity Recall Question)
    - Safety behaviours (Work Safety Scale (WSS))

    Occupational outcomes

        - "Employees' perspective" (single item job satisfaction)
        - "Employers' perspective" (productivity (WPAI scale)) Resource use measures
        - SMEs and LEOs: Financial investment and time investment (of management and paid time of employees) in HWS scheme and specific resources used in the delivery of the intervention
        - Employees: Financial investment (purchasing additional materials to support their involvement in the intervention and changes in their lives outside of the workplace, e.g. signing up to the gym) and time investment outside of paid work time.
        - Wider economy: DOH (e.g. GP appointments, hospital visit) and DWP (e.g. social security expenditures)

In the middle of the 12-month intervention period (6-months), participants will be invited to complete a short survey, which will ask about the primary outcome (work engagement) and, if they are in the intervention arm, will also ask if they are aware of all available HWS offers, if they have engaged with any of the offers, and their interim thoughts on these offers. At the end of the 12-month intervention period, and at 18 months, all study participants will complete a follow-up questionnaire (database form 4 & form 5) like that at baseline, with

further questions about engagement with specific components of the HWS for those in the intervention group (supplementary Fig 2).

**Implementation of Organisational Engagement Activity Log**

Throughout the HWS intervention implementation period, intervention fidelity and participants' engagement related activities will be monitored and documented using an online engagement activity log. The activity log will serve three purposes:

i) To act as a central repository for all SHINE activity within each SME. Recognising that each SME is likely to have different ways of working and communication channels, and each H&W Champion is likely to have multiple demands on their time, the activity log will allow information to be gathered in a consistent way across organisations, and act as a live 'to do' list and activity log for both the H&W Champion and their Advisor to keep track of progress.

ii) It is envisaged that the H&W Champions and the Advisor will use the activity log as a platform for discussion during monthly meetings, optimising the value of the study through the early identification of implementation issues and facilitating identification of practical actions to be taken to overcome challenges.

iii) It will provide an opportunity to monitor the HWS intervention implementation, intervention fidelity and participants' engagement in related activities, and will be analysed in the process evaluation and triangulated with qualitative and quantitative data gathering (WP4).

NOTE: To ensure participant confidentiality, NO personal identifiable information will be recorded in this activity log.

**Data handling and recording keeping**

***SURVEY DATA***

During conduct of this study, the research team will not disclose or make use of any information other than for its intended purpose. All survey data will be collected and initially stored using sponsor approved REDCap (electronic software database) and access to the source data within the software portal will be password protected, and only accessible by authorised persons i.e. central study team only. A back-up paper-based survey will be available upon request and on their return to the study team using a business reply envelope, data will be entered by the research team into the REDCap database and paper records will be securely stored by the research team in a locked cupboard in the Occupational Health, Safety and Wellbeing Service at Guy's and St Thomas NHS Foundation Trust) prior to long-term storage.

Personal identifiable data will be stored on the REDCap software for the duration of the study and personal identifiable data will only be accessible for members of the study team based at Guy's and St Thomas NHS Foundation Trust. However, all downloaded data files from REDCap will have personal identifiable data removed at the point of data extraction and at this point the data file will then become fully pseudonymised and kept in a secure, password file, and only accessible by the study team responsible for conducting the study. Additionally, the separate personal data extracted at the time of download will be removed

from the main data file, along with information on the specific reasons why they provided their contact information (i.e. to be entered into the prize draw, to hear about the study results). Included in this contact information data file will be each participant's unique study ID, and this will be used to link participants' contact information back to their response. This will mean that the survey will be pseudonymized for the duration of data analysis and storage. If it is necessary to email data files among research team members, this will be done by sending securely via email in encrypted and password protected data files. Passwords will be sent to the recipient in a separate email.

Paper-based questionnaires returned to the central study team will be manually entered into the database (REDCap software) by the study team member. To securely return completed questionnaires, participants who choose to complete a paper survey will be provided with a pre-paid business reply envelope marked 'Confidential'. Upon receipt by the research team, paper-questionnaires will be processed in a timely manner.

Participants will be informed in the PIS that they can withdraw from the study at any point during the study period (up to 31 March 2027) without giving a reason. For participants completing the survey online, they can close the browser before submitting their answers at any point, if they wish to discontinue. Those completing a paper survey will be able to destroy the survey themselves or submit the incomplete survey to the research team. Incomplete surveys which are returned to the research team, either via secured post for paper surveys or submitted on REDCap for online surveys, will be included in the analysis.

As the data collected by the survey will be pseudonymized, we can allow participants to withdraw their data after they have submitted the survey, should they desire. Participants will be made aware that they should contact the research team if they would like to withdraw their data. If this occurs, we will use their contact information to identify responses. If an individual did not provide their contact information but would like to withdraw their data, we will use their date of birth and demographic information to identify their record. Participants who did not provide sufficient data required to undoubtedly identify their response will be told that it is not possible to withdraw their data. Participants will be informed in the PIS that they will not be able to amend their data once their survey has been submitted.

***ENGAGEMENT ACTIVITIY LOG***

Engagement activity logs will take the form of an excel spreadsheet, word document or paper version, depending on H&W champion preference. To optimise buy-in to maintaining the activity log, the activity log will be co-developed with the H&W champions during training led by the H&W advisor. The log's format will ensure it meets study aims and engages champions optimally. Held by the H&W champion, the activity log will likely include key metrics regarding:

i) Activities offered to SME employees, including eligibility and uptake

ii) Communications shared within the SME, including key content components, channel and date

iii) Actions devised with the H&W advisor to help track actions to promote H&W offers within the organisation

iv) Questions or concerns raised by employees, including a place to log questions to discuss at monthly meetings with the advisor or in peer-conversations.

v) Reflections, including an open section for champions to reflect on what works, what doesn't, obstacles and opportunities.

The H&W advisor, supported by the Affinity research team members, will work with the H&W champions to identify the most acceptable format of hosting and managing the activity log. Ideally, we will work with electronic versions of the activity log, stored on a shared MS Teams site to which the H&W champion and the H&W advisor both have access. However, recognising that not all SME organisations will use Teams/ MS and some may have limited access to computers/ phones during working hours, hard copy activity logs may also need to be made available. In this eventuality, as hard copies can be lost, hard copies will be gathered quarterly with learnings captured during meetings to ensure there is a backup of information. Once the format and process for maintaining the activity log has been agreed, detailed instructions on monitoring and documenting will be shared to ensure consistency; and the importance of accurate maintenance of the activity log will be raised during monthly meetings between the champions and advisor. Where necessary, adaptations will be made to enhance usability to optimise the information gathered.

After site closure, each participating site will archive their research data in accordance with instructions from the Sponsor for a period of 2 years. The process of destroying documents will be in accordance with the standard procedures of the Sponsor.

A full description of the data flow is provided in the study's Data Protection Impact Assessment document. The chief investigator will be acting as data custodian during the conduct of the study.

**Data sharing**

Pseudonymised questionnaire data collected in the survey will be transferred out from Guy's and St Thomas NHS Foundation Trust (as sponsor) to our research partners based at Affinity Health at Work and at the University of Leeds for the analyses. This will not include any of the participants' identifiable data. The pseudonymised data files will be encrypted and password protected and shared securely via email. Passwords will be sent to the recipients in a separate email.

At the end of the study, data collected in the engagement activity log will be transferred from Affinity Health at Work to Guy's and St Thomas NHS Foundation Trust (as sponsor).

All data transferred to Guy's and St Thomas NHS Foundation Trust will be archived as per the study's long-term archiving requirements.

### *9.1.3 Outputs:*

i) Study implementation and collected data at three time points (WP2)
ii) Study engagement activity log (WP2)
iii) List of study implementation challenges and changes made (WP2)
iv) Resources used by SMEs and LEOs in intervention delivery (WP2)
v) Effectiveness analysis results (WP3)
vi) List of factors that moderate impact of intervention (WP3)
vii) Economic evaluation including Social Return on Investment (SROI)(WP3)

## *9.2 Work Package 4: Process evaluation and feedback (Lead: JY)*

### *9.2.1 Objectives:*

i) To explore perceived obstacles and facilitators by champions to deliver the study intervention to employees in their organisational settings

ii) To explore champions' perceived level of upskilling, and sustainability of skill proficiency

iii) To gather feedback from stakeholders regarding the intervention

iv) To explore transferability of a supply chain approach with cross-sector OH and wellbeing leads

### *9.2.2 Participant inclusion criteria*

We'll conduct focus groups with champions in all intervention SMEs to explore their training experience, resulting acquisition and maintenance of skills over the study period, and confidence in delivering the study intervention. Questions will further examine sustainability of skills acquired and level of supplementary training required to achieve established competency goals and maintain skill proficiency.

We will also conduct semi-structured interviews with key stakeholders in SMEs and LEOs to explore engagement in the study, implementation factors and potential considerations of sustainability of model delivery service. Individuals who supported set-up and implementation of the study or are responsible for or have sound knowledge of important considerations will be eligible to take part.

Additionally, we will invite OH and wellbeing leaders from diverse sectors to participate in an interactive knowledge mobilisation day. Study findings will be shared and round table discussions held to explore opportunities and obstacles in delivering HWS through the supply chains in other industry sectors.

### *9.2.3 Participant recruitment*

All champions in intervention SMEs will be invited to take part in focus groups. A purposive sampling method will be used to identify and invite individuals to take part in the stakeholder interviews. The purposive sampling will be a collective effort by the research team, champions at each of the intervention SMEs, and leaders in each SME and LEO to identify those who would be knowledgeable about the topic of the interview and likely to take part. We will then send a participant information sheet to those people who we purposively identify and will be able to answer any questions they may have and consent them into the study if they are willing to participate..

### *9.2.4 Study Procedures:*

Organisations' preference for offering face-to-face, telephone or video conferencing options will be accommodated. Interviews and focus groups will be recorded and transcribed to aid analyses.

### *9.2.5 DATA*

**Qualitative data to be collected (Champions and stakeholder level data)**

We'll record contact between champions and advisors, and will conduct focus groups with the former to explore their training experience, resulting acquisition and maintenance of skills over the study period, and confidence in delivering the study intervention. Questions will further examine sustainability of skills acquired and level of supplementary training required to achieve established competency goals and maintain skill proficiency.

See the Interview topic guide appendix for an example topic guide that will be used to interview participants. Broadly, the qualitative work will explore champions and advisors training experience, resulting acquisition and maintenance of skills over the study period, and confidence in delivering the study intervention. Questions will further examine sustainability of skills acquired and level of supplementary training required to achieve established competency goals and maintain skill proficiency. The topic guide will be further developed to take account of earlier work packages and then iteratively modified as data generation and analysis progresses.

We anticipate interview (1-2-1 and focus group) sessions will be held online (with in-person sessions available if required). Interviews will be recorded using Microsoft Teams with back-up encrypted Dictaphone device; audio data will be transcribed verbatim. Transcription will be conducted by Microsoft Teams or by an external contracted provider i.e. audio files created on an encrypted Dictaphone will be sent via upload to a cloud-based depository portal and processed by Accuro, an external transcription service approved by the Guy's and St Thomas NHS Foundation Trust. Recordings will be immediately deleted after the transcription has been completed.

#### *Data handling and record keeping*

The study team will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Host or its designee will be obtained for the disclosure of any said confidential information to other parties.

Digital recordings of interviews will be made using a Dictaphone device (for telephone and in-person interviews) and Microsoft Teams (for online interviews) and transcribed using Microsoft Teams or through Accuro, an external transcription service approved by the Guy's and St Thomas NHS Foundation Trust. Files will be downloaded and securely stored at Affinity Health at Work only on a password protected shared drive, with limited access by the authorised study staff only. Recordings and transcriptions made on Teams will be immediately deleted from the Microsoft Cloud once they have been securely downloaded. The saved transcripts will be pseudonymised and identified by unique participant IDs and a member of the Affinity research team will check the transcript for clarity and accuracy. The recorded interview will then be deleted soon after transcription has been checked.

Data storage procedures will follow Affinity Health at Work standard operating procedures for research.

All the information/data collected for this study from participants will be securely stored in folders on the Affinity Health at Work secure servers, folders will be password protected and can only be accessed by the research team. The recording equipment used to record the

interviews will be erased after each interview has been uploaded to the secure folder on the Affinity Health at Work server.

The pseudonymised interview recording, pseudonymised transcripts, and the consent form with identifiable personal information, will be stored in separate locked and protected folders on Affinity Health at Work secure servers in line with GDPR requirements for the duration of the study. Each file will have the unique study ID for each participant, and it will only be possible to identify the participant by looking at the consent form and linking this study ID to the other documents. Data will remain pseudonymised to allow participants to withdraw their data from the study, should they desire. The protocol for withdrawing data will be explained to participants in the PIS.

All qualitative data collected will not be stored with any identifying information. A code number will be allocated to each qualitative participant and will be stored securely, to ensure that participants cannot be identified from your response.

Affinity Health at Work will be the data processor for this qualitative study, working on behalf of Guy's and St Thomas' NHS Foundation Trust as the data controller, and is responsible for looking after the information and using it properly.

Data will only be held where there is a legitimate need to do so. Once the stage of the study which involves inviting participants to take part in research and asking for their express consent is complete the contact details will be securely destroyed.

All data will be retained for two years after the end of the research study as per GSTT guidance before being destroyed (deleted electronically).

A full description of the data flow is provided in the study's Data Protection Impact Assessment document.

### *Data Sharing*

The data generated by this work package will be created and stored at Affinity Health at Work, as they are operating as a Data Processor on behalf of GSTT. The only components of this work package that will be stored within GSTT will be the finalised analysis report of the qualitative interview data. The completed consent forms will be transferred from Affinity Health at Work to GSTT for the purposes of archiving, and the analysis report will contain only anonymized data about the participants who completed interviews. Other outputs from the qualitative interview analysis other than the analysis report (i.e. annotated transcripts, etc) will be retained at Affinity Health at Work.

Audio files created on an encrypted Dictaphone will be sent via upload to a cloud-based depository portal and processed by Accuro, an external transcription service approved by the Guy's and St Thomas NHS Foundation Trust.

At the end of the study and with consent from participants, the final anonymised dataset will be uploaded to OSF (a publicly accessible) data repository for future ethnically approved research. This has been highlighted on the PIS and the ICF, and participants will have the option to with-hold their anonymised data if they desire.

## *9.3 Analysis (WP2-4):*

### Quantitative data and economic analysis
### Participant questionnaire

Questionnaire responses will be converted into relevant outcome metrics (e.g. work engagement score, health economic utility scores). Employee-level outcome data collected at baseline, 6 months, 12 month and 18 months will be analysed using two-level multilevel regression models, with employee participants nested within SMEs. Analyses will include an interaction term between the intervention group and time period, to assess differences in change in work engagement (and then separately for each of the secondary outcome measures) between baseline, 6-months (work engagement only) and 12 months (i.e. short-term intervention effect), and between baseline and 18 months (long-term intervention effect) between the intervention and the control SMEs.

Further analyses will assess effect modification by organisational (information collected at the recruitment process like workforce size, sector, relative size of customer, and length of business operation) and intervention delivery factors (dependent on the variation in the recruited SMEs), including a multiplicative interaction between intervention group and each of the factor under consideration. If there is evidence of significant effect modification, we will stratify our analyses accordingly to determine the strength and the direction of the effect by levels of the modification factor.

Economic evaluation will take the form of a cost-consequence analysis (whereby disaggregated non-monetised changes in outcomes are presented alongside costs to inform decision making) and a Social Return on Investment (SROI) [24,25], whereby benefits observed after 12 and 18 months are monetised using published sources, and potential longer-term impacts are explored using different assumptions about the sustainability of changes in behaviour and health. Resources used in intervention delivery will be assessed using data collected in WP2 and costed using a micro-costing approach [26]. Resources used by companies and employees will be assessed using questionnaire data (example measures listed above in WP1), and costs incurred will be calculated using relevant unit cost data. Differences in the results will also be presented in terms of the person- and SME-level moderators defined above and the perspective of the analysis, which will include the employer, employee and wider economy perspectives.

### Engagement activity log

Information recorded in the activity log will be used to inform the process evaluation (WP4). Specifically, analysis will include:

i) Collation of the HWS implemented in the SMEs. The activities offered (as identified in the activity log and triangulated by LEO service use), can then be compared with data on uptake and evaluation (as identified in the follow-up employee survey) within each SME organisation.

ii) Review of the communications cascaded. This data will be collated and cross-referenced to explore variations in the volume or nature of communications within each SME.

iii) Thematic analysis of reflections on obstacles and opportunities as recorded by the H&W champions and advisor throughout the study duration. This data will provide valuable information on how the HWS were implemented within the SME organisations, and how the SMEs worked with their LEO throughout the implementation contributing to the process evaluation. Learnings from the implementation of this 'activity log' process will be captured by the research team and shared through our project reporting and dissemination activities.

**Qualitative data**

Data will be analysed using inductive and deductive thematic analysis. We will draw on the Implementation Outcome Framework [28] as applied by Yarker and colleagues in a recent meta-synthesis of the barriers and facilitators to workplace mental health interventions to inform our approach [29].

OH and wellbeing leaders from diverse sectors will be invited to the interactive knowledge mobilisation day. For this dissemination event, we will invite a wide range of important parties through our existing professional networks. These will include the wider research team, as well as our stakeholders, including NIHR/DHSC staff, those leading HWS in the participating SMEs and LEOs (OH, Human Resources and Wellbeing reps), their Financial Directors and the Head of Procurement from the LEOs. We will also invite members of the EPSG, wider colleagues working in the area of work and health research, and representatives from other LEOs across diverse sectors, with whom we will explore the possibility of implementing this model in their companies and their supply chain. Study findings will be shared and round table discussions held to explore opportunities and obstacles in delivering HWS through the supply chains in other industry sectors.

### *9.3.1 Outputs:*

i) Study experience of champions and views of the acquired skills during the study period and beyond

ii) A list of perceived benefits and obstacles of implementation of HWS intervention for LEOs and SMEs

iii) Production of a detailed logic model to inform research and practice

iv) A list of organisations willing to explore a supply chain approach to HWS delivery and sector-specific considerations to inform policy decisions

## *9.4 Work Package 5: Discrete choice experiment (DCE) (Leads: AM/EW)*

### *9.4.1 Objectives:*

We will use an online survey to

i) Quantify SMEs' willingness-to-pay (WTP) for a range of potential HWS interventions

ii) Identify the intervention components that SMEs value most

Iii) Identify the greatest barriers to implementation

(iv) Estimate the predicted uptake for an HWS intervention with given components at a given level of subsidy

(v) Explore how the results above vary across SMEs with different characteristics.

### *9.4.2 Methods:*

We anticipate using ACCENT, a UK-based company accredited by the Market Research Society which whom we have collaborated on several previous research projects. However, the final decision on which company to use will be made after survey development.

In a DCE, participants make a series of choices between two or more alternatives, in this case HWS interventions. The alternatives are described using 6-8 key features termed attributes. For example, attributes could be line manager training and/or cost. The levels the attributes vary from question to question, and statistical analysis of how participants' choices change as the levels change reveals how much they value each attribute. In particular, as we will include (post-subsidy) cost as an attribute, we will measure participants' WTP for each of the other attributes.

Limited prior research exists in this area. Burge et al. [30] conducted a DCE on governmental schemes, which was not based on the attributes of a specific intervention that could be adapted to numerous SMEs, while it also lacked the context of partnership with a LEO with which they have an established relationship. Finally, it did not include cost as an attribute, so SMEs' WTP for interventions was not possible to calculate.

In developing a DCE survey, we will create a suitable set of attributes, leveraging recommendations [31] and insights from our Development Award and the intervention co-design work in WP1, and finalise a list of intervention components and implementation barriers, including costs and non-monetary factors (eg. staff time). We anticipate identifying more potential attributes than can be incorporated into the final study. We will invite key stakeholders including ESPG representatives and champions to complete a ranking exercise to advise on the most important ones. We will then finalise a list of attributes based on the ranking exercise and the overall project's aims. We will create a draft survey, including a statistical design, i.e. what levels the attributes take in each question. The statistical design will aim to maximise D-efficiency, a measure of how much information it is possible to obtain from a survey design [32].

In line with good practice [33], we will iteratively refine the survey by pre-testing with up to 10 participants from the target population. Pre-testing involves one-on-one interviews with participants as they go through the survey and speak their thought process aloud. Feedback will be incorporated after each interview.

The following outlines our planned methods for conducting the DCE although further refinement and development of the planned DCE survey will be finalised during conduct of the interventional study (Phase 2), with an amendment submitted to REC for approval.

### *9.4.3 Participant Recruitment*

i) Ranking exercise

The ranking exercise will be conducted online using Jisc Online Surveys. ESPG representatives and champions already taking part in the study will be emailed a link to complete the ranking survey.

ii) Pre-testing interviews

Here we will recruit around 10 people from the target population. The participants will be sent a link to a draft version of the DCE survey and will go through it during a Zoom/Teams call interview with a member of the research team. The participants will talk aloud about their decision-making process as they go through the survey, and suggest potential improvements that may be appropriate or highlight areas that they do not understand. We will iteratively incorporate participants' feedback into the survey until we are confident that the final survey works as intended.

iii) Discrete choice experiment

Data will be collected online, with the survey programmed by a market research company (as said, we anticipate using ACCENT though this may change). The target population is decision-makers around HWS in SMEs. We have set the below inclusion and exclusion criteria for people who are eligible to take part in this DCE survey.

**Inclusion criteria**

- Work in an SME in the supply chain of an LEO
- Self-identify as being involved in some way in decision-making around HWS provision
- Able to understand English sufficiently well to meaningfully engage with the survey

- Aged 18 years or older.

**Exclusion criteria**

- Aged under 18

Recruitment will be done by email. An email request will be sent to each of the SMEs in our LEOs' supply chains (N~2400) with the request to forward it to staff. Additionally, the British Chamber of Commerce will also forward invitations to around N~1,500 SMEs who are part of the supply chain of non-partner LEOs. The email will explain the study and invite people to take part in the survey by clicking a link. The link will take them to an online participant information sheet and consent form. After consenting, participants will complete a survey that should take around 10-15 minutes.

### *9.4.4 Analysis*

We will use advanced choice modelling techniques such as mixed logit, nested logit and/or latent class models. This will quantify SMEs' WTP for HWS intervention components, and the trade-offs they make between providing each HWS component and non-monetary barriers such as staff time. The large sample size we are planning to recruit will facilitate examining heterogeneity in SMEs' preferences and could for example reveal whether SMEs in different sectors prioritise different components. We will combine findings on SMEs' WTP

with findings on intervention costs from WP3, to predict what levels of subsidy would be required (and optimal from the perspective of taxpayers) to ensure the widespread uptake of a wide range of potential interventions.

#### *9.4.5 Outputs:*

i) SMEs' WTP for different components of HWS interventions;

ii) A model to predict the uptake of a given HWS intervention at a given level of subsidy across different sectors.

### *9. DATA*

## Data to be collected

A market research company appointed by the research team will collected data on people's preferences for different aspects of HWS interventions using a DCE survey. The survey will also record demographic information (age, gender, ethnicity, etc.). Data will be anonymous and non-identifiable.

### *Data handling and record keeping*

Anonymous data will be collected by a market research company which will adhere to all relevant data-handling legislation and industry standards. The data will be transferred to the University of Leeds where it will be stored electronically in a secure, encrypted environment.

A full description of the data flow is provided in the study's Data Protection Impact Assessment document.

## Data sharing

Data will be transferred immediately after collection from the market research company to the University of Leeds, where it will be stored in a secure, encrypted environment. Raw data will not be shared with the other participating organisations.

# 10 END OF STUDY DEFINITION

The end of study definition will be the end of data collection (i.e., once the participant questionnaire data and the last interview has been conducted) and the completion of data analysis. We will then produce the final study report within the 12 months after this study has ended.

# 11 ASSESSMENT OF SAFETY

This study is deemed low risk in terms of the potential for serious adverse events to arise. As such, we do not envisage participants, either in intervention or control arm, will be at an increased risk of harm from taking part in this study. Moreover, participants in the intervention arm will be offered access to a package of health and wellbeing services and support which are already routinely made available to others i.e. employees (non-research participants) who are employed at one of the participating large enterprise organisations.

There is a low risk that participants may experience distress when reflecting on their health and wellbeing during completion of the study questionnaires or when taking part in the qualitative work. Participants will be informed in the participant information sheet that they

are free to skip any questions which they would prefer not to answer. If a participant becomes distressed or upset during the qualitative meeting, then the qualitative researcher will pause the interview/focus group and allow participant's an opportunity to stop the interview/leave the focus group altogether if they prefer. Where necessary, the qualitative research will also follow-up with individual's post-interview/focus group to check on their wellbeing. Additionally, the study questionnaires have been intentionally designed to be kept to minimal without compromising the collection of rigorous study data.

### *11.1 Ethics Safety Reporting*

In the unlikely event an unexpected SAE arises during the conduct of this study, the study team will adhere to the reporting requirement as outlined in the SAE reporting appendix i.e. the chief investigators of the study will report incidents to the Research Ethics Committee within 15 days of becoming aware of the event. We will use the NRES template and will sign the document.

### *11.2 Ethics & Regulatory Approvals*

The study documentation relating to phases 2 and 3 of the study will be submitted to the Research Ethics Committee at King's College London for ethical opinion. The scope of work outlined in phase 1 meets the criteria for a service evaluation activity and as such is exempt from the requirement for ethical review to conduct.
For any amendments to the study in phase 2 and 3, the Chief Investigator, in agreement with the Sponsor, will submit information to REC at KCL for them to issue approval for the amendment.
All correspondence with the Sponsor and REC will be retained and the Chief Investigator will notify the Sponsor and REC of the end of the study.

## 12 COMPLIANCE AND WITHDRAWAL

### *12.1 Participant compliance*

Throughout the HWS intervention implementation, intervention fidelity and participants' engagement in related activities will be monitored using an online engagement activity log, a series of study questionnaires and focus group or 1-2-1 interviews.
A series of reminders will be used to encourage completion of the online engagement activity log and study questionnaires although no active follow-up of non-engagement with components of the intervention will be undertaken.

### *12.2 Withdrawal / dropout of participants*

Throughout the study period, personal identifiable data will be stored on the REDCap software for the duration of the study. However, all downloaded data files from REDCap will have personal identifiable data removed at the point of data extraction and at this point the data file will then become fully pseudonymised and kept in a secure, password file, and only accessible by the study team responsible for conducting the study. This will mean that the survey will be pseudonymized for the duration of data analysis and storage. In light of this, participants will be able to withdraw from the study at any time during the study period (up to approximately 31 March 2027). Their data will be retained and used in the study unless they express the wish that their responses should be destroyed. They can either make this request when they

withdraw or by emailing the research team later. If participants ask to withdraw their data after they have completed and submitted the survey or the interview, we will first use contact information to identify their record for deletion. If they did not provide their contact information, we will identify records using date of birth and demographic information. Participants who did not provide sufficient data required to undoubtedly identify their response will be told that it is not possible to withdraw their data This will have previously been clarified for participants in the PIS. After the data analyses has been completed, it will not be possible to withdraw a participant's data from the study.

## *12.3 Protocol Compliance*

During conduct of the project, the research team will meet weekly to discuss and monitor the conduct of the study. These meetings will include Prof Jo Yarker (CI), Dr Vaughan Parsons (co-CI), the study manager and other members of the central research team as required. Additionally, monthly meetings involving all co-investigators will take place. These meetings will discuss and monitor the set-up, conduct and progress of the study, and will provide an opportunity to monitor the progression of individual work packages in the specified time periods. We will prepare meeting agendas and share minutes with the group following the meeting so that we can monitor actions arising. The CI, being familiar with the content of this protocol, will record any unintended deviations from the protocol and list them in a deviation log. A study steering committee will also monitor the study conduct throughout.

## *12.4 Data Protection and Personal Data Breaches*

The CI and study team will comply with the requirements of the UK's data protection law and all data collected as part of this study will strictly be within the terms of the UK GDPR and Data Protection Act 2018. The CI and study team will also adhere, where appropriate, to the current version of the NHS England Code of Practice (Confidentiality). Access to collated participant data will be restricted to the CI and appropriate members of the study team. Computers used to collate the data will have limited access measures via usernames and passwords. Recorded consent will be stored as a datafile on a Guy's and St Thomas NHS Foundation Trust or Affinity Health at Work secured shared drive, separate from study data.

At the end of the study, data will be archived following the Sponsor's archive standard operating procedure. Research data will be stored securely in the Occupational Health Service at Guy's and St Thomas NHS Foundation Trust or at our partner organisations (i.e. Affinity Health at Work or University of Leeds) during the study before being transferred to Iron Mountain (Sponsor's contracted long-term archiving facility) for a period of two year after the end of the study.

Data records relating to the interview/focus group will be retained for a period of two year in a secure location at Affinity Health at Work.

To facilitate the long-term storage of electronic data, data files will be converted to 'read only' before being downloaded onto two encrypted USB sticks. These will be retained in a sealed archive box along with other study documents.

All personal data will be handled and securely stored during the study as outlined above. If there is a data breach/breach of confidentiality (as per GDPR definitions), GSTT Trust

incidence reporting mechanisms will be followed. The data subject(s) would also be informed promptly. GSTT Information Governance team will also be immediately informed.
The CI will determine whether the breach meets the definition of a serious breach and warrants reporting to the regulators including the ICO https://ico.org.uk/for-organisations/report-a-breach/personal-data-breach-assessment/.

# 13 MONITORING AND AUDITING

The Chief Investigator will be responsible for the ongoing management of the study. Conduct of the study will be monitored at monthly operational management group meetings involving all investigators. The CI will oversee the study with regular input and day-to-day coordination and conduct of the study undertaken by the study manager overseen by members of the wider study team. A study steering group (comprising independent members) will also be established to overseeing the set-up and conduct of the study and will meet twice yearly.

The study team will permit study-related monitoring, audits and ethics committee review. The Sponsor will monitor and conduct audits on a selection of studies in its clinical research portfolio. Monitoring and auditing will be conducted in accordance with the UK Policy Framework for Health and Social Care and in accordance with the Sponsor's monitoring and audit procedures.

# 14 STATISTICAL CONSIDERATIONS

Details relating to the sample size calculations are outlined in WP3 and WP5

# 15 PEER REVIEW

The research proposal has been scrutinised by the NIHR funding committee following external peer review by independent reviewers appointed by NIHR. All the points raised by the independent expert reviewers and the NIHR board have been addressed. These included providing further clarification in terms of the use and the proposed development, management and use of engagement activity log, incorporate additional work into the research plan (i.e. conducting a review of health and wellbeing services within LEOs and development of a logic model and insight report, and appointing a member from our Expert Stakeholder and Public/Patient Group to join the study team as a co-investigator).

The final study protocol was developed and refined based on the grant proposal. The study will be further reviewed by GSTT R&D, prior to submission, along with the study documents, to the King's College Research Ethics Committee for their review and approval.

# 16 FINANCING

The NIHR has fund the study on a Work and Health: Collaboration Award (ref: NIHR208251). This award will run for 36 months, beginning the 1 December 2024 and ending the 31 November 2027.

# 17 INSURANCE AND INDEMNITY

This study is sponsored by Guy's and St Thomas' NHS Foundation Trust and indemnity is provided through NHS Resolution's Clinical Negligence Scheme for Trusts (CNST) which provides indemnity for clinical negligence. In the case of negligent harm, health care

professionals undertaking clinical trials or studies on volunteers, whether healthy or patients, during their NHS employment are covered by NHS Resolution. In the case of non-negligent harm, legal liability does not arise where a person is harmed but no one has acted negligently. In exceptional circumstances NHS bodies may consider whether an ex-gratia payment could be offered.
Other insurance or indemnity arrangements will apply for other non-NHS protocol authors.

## 18 DATA CONTROLLER

Guy's and St Thomas' NHS Foundation Trust is the Data Controller as defined by UK GDPR for this study and as such agrees to comply with the obligations placed on a Data Controller by the UK GDPR. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to Processing of Personal Data (Article 5 UK GDPR).

## 19 INTELLECTUAL PROPERTY (IP)

All foreground IP and research data arising from this study will reside with the Contractor (Guy's and St Thomas NHS Foundation Trust).

The following table outlines specific background IP aspects in relation to the study.

| **Description of Background IP** | **Owner of relevant Background IP** | **Nature of restriction** | **Risk to research and outcomes (low, medium, high)** |
|---|---|---|---|
| Policy review Tool: assessment framework and reporting mechanism | Affinity Health at Work | None; available for duration of project | Low |
| Working Well Assessment Tool: assessment framework and reporting mechanism | Affinity Health at Work | None; available for duration of project | Low |
| Absence Management Framework Tool: assessment framework and reporting mechanism | Affinity Health at Work | None; available for duration of project | Low |
| Working Well Assessment Tool: assessment framework and reporting mechanism | Affinity Health at Work | None; available for duration of project | Low |
| Existing health and wellbeing products / services offered by the research sites (Large Enterprise Organisations) (LEOs) listed.<br><br>In addition to the Background IP held by the research partners, there will be IP considerations related to the health and wellbeing | Jaguar Land Rover<br>Transport for London (TfL)<br>Hampshire and Isle of Wright NHS) | Unknown at this stage (will be determined by month 7 of the project) | We will minimise risk to research and outcomes by ensuring that IP matters are discussed during the selection of |

| | | | |
|---|---|---|---|
| services provided by the LEOs to the SMEs that are evaluated during the project. The first phase of the study will determine what services will be included and therefore these services, and the IP related to them are currently unknown. | | | the services to be delivered by the LEOs and selecting services where background IP is clear and uncontentious, and where foreground IP is able to be retained by GGST. An updated (table?) will be provided documenting IP matters related to the services selected for evaluation in month 7 |
| Discrete choice experience (DCE) tools and resources | Uni of Leeds | Using tools and resources for the purposes of research; and data gathered and outcomes would reside with Guy's and St Thomas NHS Foundation as the Contractor. | Low |

# 20 REPORTING AND DISSEMINATION

We will collaborate with our ESPG and industry partners to develop a comprehensive knowledge mobilisation and dissemination strategy. We will share our research study findings through various channels, reaching audiences at local, national, and international levels. As a collaboration, communications at each University (KCL, Leeds), the London Centre for Work and Health, British Chambers of Commerce and Affinity's Research Consortium will play a key role when it comes to dissemination and media and policy reach.

To optimise knowledge mobilisation and our dissemination strategy we will:

• Continue to share our findings, as they emerge, with the cross-government Work and Health Unit as we have done with the Development Award learnings. As required, we will discuss how our study findings can inform emerging Government policy on increasing the provision of HWS to SMEs.
• Work with the British Chamber of Commerce to produce materials to share with their members as they develop their SME employer community of practice in health and wellbeing.
• Hold an interactive knowledge mobilisation day to present our findings and facilitate implementation of our findings with our stakeholders, including NIHR/DHSC staff, those leading HWS (OH, Human Resources and Wellbeing), their Financial Directors and Head of Procurement from LEOs across diverse sectors. During this event we will explore ways to sustain the champion communities of practice and EPSG collaboration developed during the study and extend knowledge mobilisation beyond the Collaboration Award.
• Create a training package to upskill SME employees to achieve established competency goals and sustainable skill proficiency in promoting health and wellbeing activities among their colleagues.
• Derive a logic model aiming to explain how HWS delivered in this way can increase work engagement to inform future research and practice.
• Provide a lay summary of findings to the study participants and managers in the participating SMEs, LEOs and DCE study, reaching over 3000 SME decision makers. Beyond this, our ESPG will assist in identifying appropriate distribution channels.
• Present at industry conferences alongside our LEO and SME to share learnings across sectors and regions.
• Present our findings to the scientific community i) at national and international conferences, ii) through peer-reviewed publications in open-access journals, iii) through the report with study findings for NIHR.
• Seek funding opportunities to extend our collaborations within and beyond our multi-disciplinary team and industry partners to provide early career researchers an opportunity to leverage the learnings and connections post-Collaboration Award.

We have connected with other Collaboration Award submissions, including the National Centre for Working Age Health (of which members of our team are also applicants). If successful, we will collaborate on knowledge exchange, leverage PPIE input and employer engagement, and provide development and networking opportunities for early career researchers.

We will also work with NIHR and stakeholders to identify opportunities to share new knowledge and practice at research events. The main scientific papers will describe the: i) study protocol, ii) results on effectiveness and cost-effectiveness of the intervention, iii) process evaluation findings and from both employees and employers' perspectives and iv) findings from the DCE on SMEs' WTP for interventions and individual components.

# 21 End date

The study end date is 30 November 2027

# 22 REFERENCES

1. Improving lives: the future of work, health and disability. Available from:

https://www.gov.uk/government/publications/improving-lives-the-future-of-work-health-and disability
2. Taimela S, Malmivaara A, Justen S, Läärä E, Sintonen H, Tiekso J, Aro T. The effectiveness of two occupational health intervention programmes in reducing sickness absence among employees at risk. Two randomised controlled trials. Occupational and environmental medicine. 2008;65(4):236-41.
3. Employee research Phase 1: Sickness absence, reasonable adjustments and Occupational Health. Available from: https://www.gov.uk/government/publications/employeeresearch-phase-1-and-2/employee-research-phase-1-sickness-absence-reasonableadjustments-and-occupational-health
4. Sickness absence and health in the workplace: understanding employer behaviour and practice. Available from: https://www.gov.uk/government/publications/sickness-absence-and health-in-the-workplace-understanding-employer-behaviour-and-practice/sickness-absence-and health-in-the-workplace-understanding-employer-behaviour-and-practice-report#executive summary
5. DWP, 2019. Health in the workplace: patterns of sickness absence, employer support and employment retention. Health in the workplace: patterns of sickness absence, employer support and employment retention - GOV.UK
6. Hofman J, Garrod B, Stewart K, Stepanek M, Van Belle J. Workplace Wellbeing Charter: Analysis of take-up and impact. Rand Health Quarterly. 2018;7(2).
7. Fit for Work: Evidence Review. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/362480/fit-for-work.pdf
8. Business Healthy. Available from: https://www.businesshealthy.org/about/
9. New Occupational Health Taskforce to tackle in-work sickness and drive down inactivity. Available from: https://www.gov.uk/government/news/new-occupational-health-taskforce-to tackle-in-work-sickness-and-drive-down-inactivity
10. HM Treasury. Chancellor of the Exchequer. Spring Budget 2023. Available from: https://www.gov.uk/government/publications/spring-budget-2023/spring-budget-2023-html
11. Yarker J, Peters R, Lewis R, Donaldson-Feilder E, Blackburn R, Munir F. Return to work toolkit: post-implementation learning review. 2018.
12. Chain Reaction: Improving the Supply Chain Experience for Smaller Firms. Available from: https://www.fsb.org.uk/resources/policy-reports/chain-reaction-MCCVYCUGFCLFDIFN3KEHPVJLBMGE
13. Lecours A, Major MÈ, Lederer V, Vincent C, Lamontagne MÈ, Drolet AA. Integrative Prevention at Work: A Concept Analysis and Meta-Narrative.
14. Russell S, Ghose, C. MHPP (Mental Health and Productivity Programme) final Report Executive Summary. 2024. Available from: https://midlandsengineintelligencehub.org/wpcontent/uploads/2024/04/Exec-summary-MHPP-final-310324.pdf
15. Garg N, Singh P. Work engagement as a mediator between subjective well-being and work-and-health outcomes. Management Research Review. 2020;43(6):735-52.
16. Neuber L, Englitz C, Schulte N, Forthmann B, Holling H. How work engagement relates to performance and absenteeism: a meta-analysis. European Journal of Work and Organizational Psychology. 2022;31(2):292-315.

17. Mazzetti G, Robledo E, Vignoli M, Topa G, Guglielmi D, Schaufeli WB. Work engagement: A meta-analysis using the job demands-resources model. Psychological reports. 2023;126(3):1069-107.
18. Hakanen JJ, Rouvinen P, Ylhäinen I. The impact of work engagement on future occupational rankings, wages, unemployment, and disability pensions—a register-based study of a representative sample of Finnish employees. Sustainability. 2021;13(4):1626.
19. Moscelli G, Sayli M, Mello M. Staff engagement, coworkers' complementarity and employee retention: evidence from English NHS hospitals. 2022.
20. Peters SE, Nielsen KM, Nagler EM, Revette AC, Madden J, Sorensen G. Ensuring organization-intervention fit for a participatory organizational intervention to improve food service
workers' health and wellbeing: Workplace organizational health study. Journal of Occupational and Environmental Medicine. 2020;62(2):e33-e45.
21. Roodbari H, Nielsen K, Axtell C, editors. An integrated realist evaluation model to evaluate organisational interventions. Academy of Management Proceedings; 2021: Academy of Management.
22. Lecours A, Major M-È, Lederer V, Vincent C, Lamontagne M-È, Drolet A-A. Integrative prevention at work: a concept analysis and Meta-narrative review. Journal of Occupational Rehabilitation. 2023;33(2):301-15.
23. Pyrko I, Dörfler V, Eden C. Thinking together: What makes Communities of Practice work? Human relations. 2017;70(4):389-409.
24. Nicholls J, Lawlor E, Neitzert E, Goodspeed T. A guide to Social Return on Investment. Cabinet Office, Office of the Third Sector. 2009.
25. Edwards RT, Lawrence CL. 'What You See is All There is': the importance of heuristics in cost-benefit analysis (CBA) and social return on investment (SROI) in the evaluation of public health interventions. Applied Health Economics and Health Policy. 2021;19(5):653-64.
26. Jones C, Charles JM, Edwards RT. Identification, measurement, and valuation of resource use in economic evaluations of public health interventions. Applied Health Economics for Public
Health Practice and Research. 2019:107-30.
27. Knight C, Patterson M, Dawson J, Brown J. Building and sustaining work engagement–a participatory action intervention to increase work engagement in nursing staff. European Journal
of Work and Organizational Psychology. 2017;26(5):634-49.
28. Peters DH, Adam T, Alonge O, Agyepong IA, Tran N. Implementation research: what it is and how to do it. Bmj. 2013;347.
29. Yarker J, Lewis R, Sinclair A, Michlig G, Munir F. Meta-synthesis of qualitative research on the barriers and facilitators to implementing workplace mental health interventions. SSM-Mental Health. 2022;2:100148.
30. Burge P. Lu H SP, Koch N. Incentivising SME uptake of health and wellbeing support schemes. In: Department for Work and Pensions, editor. 2023.
31. Coast J, Al-Janabi H, Sutton EJ, Horrocks SA, Vosper AJ, Swancutt DR, Flynn TN. Using qualitative methods for attribute development for discrete choice experiments: issues and recommendations. Health economics. 2012;21(6):730-41.
32. Kessels R, Jones B, Goos P, Vandebroek M. The usefulness of Bayesian optimal designs for discrete choice experiments. Applied Stochastic Models in Business and Industry. 2011;27(3):173-88.
33. Campoamor NB, Guerrini CJ, Brooks WB, Bridges JF, Crossnohere NL. Pretesting

Discrete-Choice Experiments: A Guide for Researchers. The Patient-Patient-Centered Outcomes Research. 2024:1-12.
34. Kok M, Gibson A, Evans D. Guidance document: evaluating public involvement in research. People in the Health West of England, UWE Bristol. 2018.