Full Study Title: A cluster randomised controlled trial to investigate the effectiveness and cost-effectiveness of a Structured Health Intervention For Truckers (The SHIFT Study)

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(In cases of Multi-centre studies, this must be replicated for each site)

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1. AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1	1.1	08/11/18	Stacy Clemes	Due to 1 pilot site (a BP site) not allowing participants to wear the accelerometers during working hours for health and safety reason, thus limiting the collection of the primary outcome measure (activPAL-determined steps/day) to non-working hours only, the TSC approved the recruitment of an additional site in the main trial phase. The total number of sites recruited will now be 25 as opposed to 24.
2	1.2	05/04/19	Stacy Clemes	Due to the time needed to undertake baseline measurements in the main trial phase, sites (clusters) will be randomised into the study arms in blocks of 3 following completion of baseline measures, as opposed to randomising all sites after all baseline measures are completed.

2. SYNOPSIS

Study Title	A cluster randomised controlled trial (RCT) to investigate the effectiveness and cost-effectiveness of a Structured Health Intervention For Truckers (The SHIFT Study)
Internal ref. no.	Loughborough University Ethical Advisory Committee reference: R17-P063
Trial Design	Cluster RCT
Trial Participants	Long distance heavy goods vehicle (HGV) drivers (>18 years of age)
Planned Sample Size	25 clusters (depots) with a minimum of 20 drivers per site will be recruited. We will recruit a minimum of 14 participants per cluster, 336 participants in total.
Follow-up duration	6 and 12-months
Planned Trial Period	6 months
Primary Objective	To investigate the impact of the SHIFT programme, compared to usual care, on objectively measured physical activity (expressed as steps/day) at 12-months follow-up.
Secondary Objectives	To investigate the impact of the SHIFT programme, compared to usual care, at 12-months follow-up on; • time spent in light and moderate-to-vigorous physical activity (MVPA) • sitting time • measures of adiposity (BMI, percent body fat, waist-hip ratio, neck circumference) • blood pressure • cardiometabolic risk markers (e.g. HBA1c, total cholesterol, HDL-C and LDL-C) • fruit and vegetable intake • sleep • cognitive function and psychophysiological reactivity • psychosocial variables and mental health (e.g. anxiety and depression, work engagement, job performance and satisfaction, presenteeism, sickness absence, health-related quality of life, and driving related safety behaviour) We will also conduct a full process evaluation (secondary objective 10) and a full economic evaluation (secondary objective 11).
Primary Endpoint	End of overall study period at 36 months
Secondary Endpoints	

3. ABBREVIATIONS

AE	Adverse event
AR	Adverse reaction
BMI	Body Mass Index
CI	Chief Investigator
CILT	The Chartered Institute of Logistics and Transport
CPC	Certificate of Professional Competence
CRF	Case Report Form
CRO	Contract Research Organisation
CTU	Clinical Trials Unit
EC	Ethics Committee (see REC)
GCP	Good Clinical Practice
HBA1c	Glycosylated haemoglobin
HDL-C	High Density lipoprotein cholesterol
HGV	Heavy Good Vehicle
ICF	Informed Consent Form
LDC	Leicester Diabetes Centre
LDL-C	Low density lipoprotein cholesterol
MVPA	Moderate to vigorous physical activity
PI	Principal Investigator
PIL/S	Participant/ Patient Information Leaflet/Sheet
RCT	Randomised controlled trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SHIFT	Structure Health Intervention for Truckers
SMART	Specific, Measurable, Attainable, Relevant, and Timely principle
SOP	Standard Operating Procedure
SUSARs	Suspected Unexpected Serious Adverse Reactions
TMF	Trial Master File

4. BACKGROUND AND RATIONALE

Long-distance Heavy Goods Vehicle (HGV) driving has been identified as one of the most hazardous working professions given the exceptionally high prevalence of risk factors for chronic disease, and significantly reduced life expectancy seen in drivers, compared with the general population.[1,2] HGV drivers are exposed to a multitude of health-related risk factors associated with their occupation, including long and variable working hours, prolonged periods of sedentary behaviour, and tight schedules which contribute to psychological stress and sleep deprivation. Drivers' working environment provides limited opportunities for a healthy lifestyle and unhealthy lifestyle behaviours, such as a lack of physical activity, poor diet, smoking, high volumes of alcohol consumption, stress and irregular sleeping patterns are highly prevalent among this occupational group. Long distance drivers' exhibit higher than nationally representative rates of obesity, with our own observational data from a sample of 157 HGV drivers demonstrating that 84% were overweight or obese[3] (compared to 75% of males aged 45-54 years reported to be overweight/obese nationally[4]). Similar data have been reported from US HGV drivers.[5] The high rates of overweight and obesity in long distance drivers elevates their risk of numerous chronic diseases and conditions, including cardiovascular disease, type 2 diabetes, obstructive sleep apnoea, musculoskeletal disorders and mental ill health and well-being (stress, depression, anxiety, fatigue).[5-9] Despite this, a recent systematic review of health promotion interventions in lorry drivers concluded they are an at-risk and underserved group in terms of health promotion efforts.[1]

To compound the high-risk health profile observed in long distance drivers nationally and internationally,[5-9] within the UK Transport sector, HGV drivers (n=285,000) are also an ageing workforce (mean age: 53 years).[9] A recent report prepared by an All Party Parliamentary Group for Freight Transport has highlighted the "demographic time bomb" the logistics industry is currently facing and the health impact of an ageing, at-risk, workforce "driving a vehicle often referred to as 'a 40-tonne missile'".[10] The UK Logistics sector is also experiencing a short-fall in HGV drivers, estimated to be of the order of ~60,000, with barriers to recruitment including the lack of roadside facilities, medical concerns and long hours of work.[9] Recommendations on how to address this shortfall and attract younger employees to the sector made by the All Party Parliamentary Group for Freight Transport include increasing awareness within the industry of the need to address driver health risks and health behaviours.[10]

The All Party Parliamentary Group for Freight Transport report highlights an expressed need to raise awareness of the importance of HGV drivers' health within the transport industry.[10] Currently, no national-level health education resources exist for professional drivers. While HGV drivers undertake compulsory Certificate of Professional Competence (CPC) training, this does not cover lifestyle health behaviours. We have developed a Structured Health Intervention For Truckers (the SHIFT programme), a multicomponent, theory driven, health behaviour intervention designed to promote positive lifestyle changes in relation to physical activity, diet, and sitting in HGV drivers. This intervention has been informed by extensive stakeholder engagement, including a qualitative study exploring the perceived barriers to healthy lifestyle behaviours in HGV drivers,[11] an observational study exploring lifestyle health-related behaviours in HGV drivers and markers of health,[3] and a pre-post pilot intervention[12] with full process evaluation.[13] Initial pre-post testing of the intervention revealed the SHIFT programme lead to favourable changes in physical activity and some markers of health.[12] The Chartered Institute of Logistics and Transport (CILT) support the view that if successful, the SHIFT programme could be embedded within driver CPC on a national level. Given the focus of the programme on health-related behaviours in relation to a driving occupation, the programme will likely be generalizable to all professional drivers (i.e. bus, taxi drivers) both nationally and internationally.

Whilst limited international studies have examined the impact of health behaviour interventions on markers of adiposity, physical activity and nutrition in lorry drivers, poor study quality limits the available evidence to date.[1,14,15] The proposed study will build on our preparatory work and generate new knowledge on the effectiveness and cost-effectiveness of a multicomponent health behaviour intervention for HGV drivers evaluated using a robust RCT design.

5. OBJECTIVES

5.1 **Primary aim**

To investigate the impact of the SHIFT programme, compared to usual care, on objectively measured physical activity (expressed as steps/day) at 12-months follow-up.

5.2 **Secondary objectives:**

To investigate the impact of the SHIFT programme, compared to usual care, at 12-months follow-up on;

1. time spent in light and moderate-to-vigorous physical activity (MVPA)
2. sitting time
3. measures of adiposity (BMI, percent body fat, waist-hip ratio, neck circumference)
4. blood pressure
5. cardiometabolic risk markers (e.g. HBA1c, total cholesterol, HDL-C and LDL-C)
6. fruit and vegetable intake
7. sleep
8. cognitive function and psychophysiological reactivity
9. psychosocial variables and mental health (e.g. anxiety and depression, work engagement, job performance and satisfaction, presenteeism, sickness absence, health-related quality of life, and driving related safety behaviour)

We will also conduct a full process evaluation (secondary objective 10) and a full economic evaluation (secondary objective 11).

6. STUDY DESIGN

6.1 Summary of Trial Design

This is a workplace two-armed 12-month cluster RCT, which will incorporate an internal pilot, and include both economic and process evaluations. Clusters (different worksites/depots within the same company) will be randomised, following the completion of baseline measurements, to receive either the 'SHIFT programme' or usual care condition. The impact of the intervention will be assessed at 6 and 12-months after randomisation. Figure 1 shows the overall trial design.

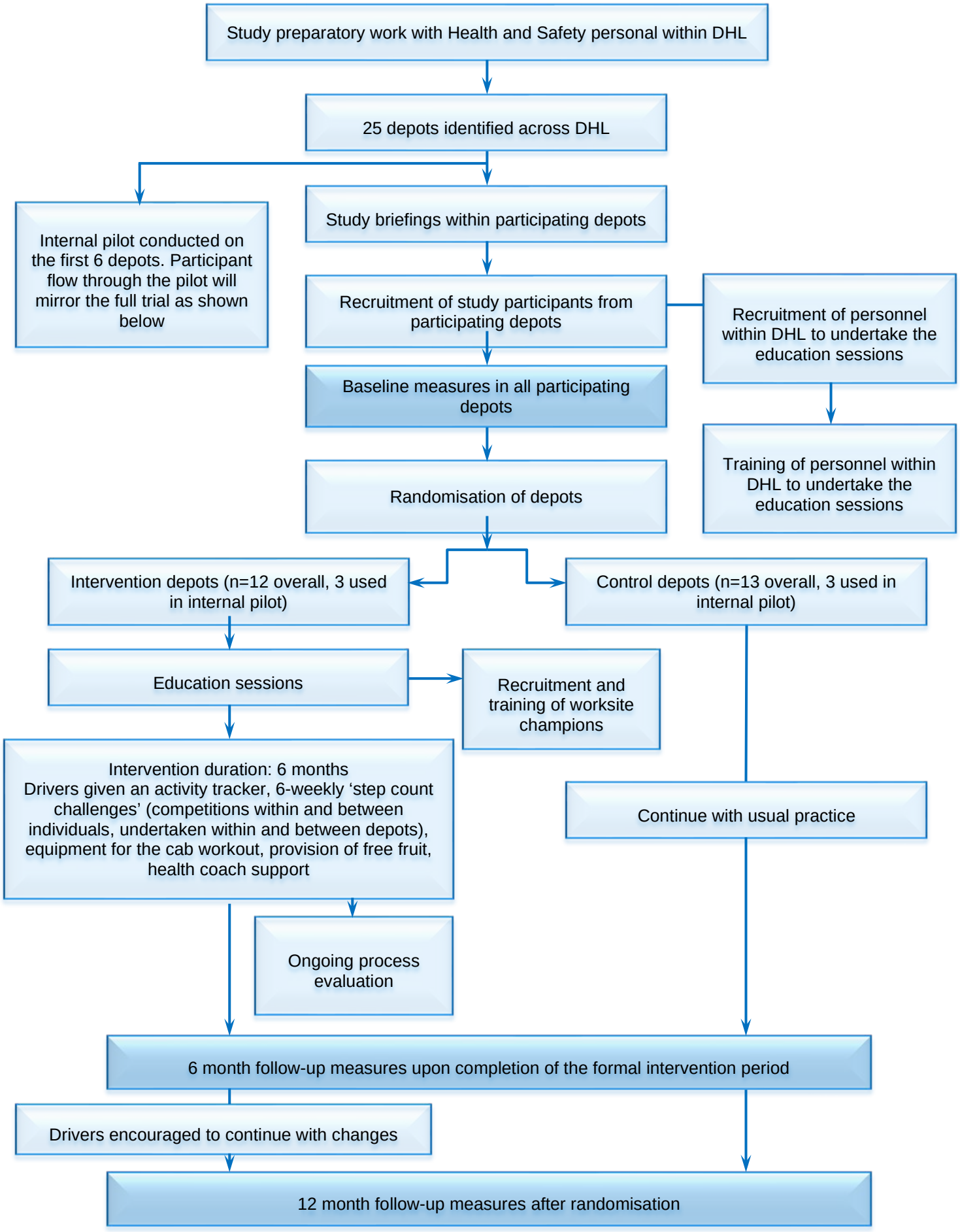

Figure 1. Study design

7. TRIAL PARTICIPANTS

7.1 Setting

This research will take place within the worksite setting of a major international Logistics and Transport company. The Logistics and Posts Sector is worth approximately £55 billion to the UK economy and currently employs approximately 1.7 million people. Driving is a fundamental occupation within this industry, and drivers and warehouse workers make up the majority of the workforce within the industry.[10]

7.2 Depot recruitment and exclusion criteria

Depots will be included in the study if they contain at least 20 long-distance HGV drivers (see sample size). Depots containing HGV drivers who make many delivery stops, for example, drivers who deliver consumer goods to domestic customers throughout the day will be excluded. For logistical reasons, depots located within the Midlands region of the UK will be recruited. Our partner company has approximately 40 sites, containing approximately 1700 HGV drivers within this region. These sites are a similar size, and have a similar variation in size, to the company's national-level data. During recruitment, depots will be informed that they will have a 50% chance of being randomised to a current practice control condition.

7.3 Participant recruitment and exclusion criteria

All HGV drivers within participating depots will be eligible to participate, unless they meet the following exclusion criteria:

- suffering from clinically diagnosed cardiovascular disease
- mobility limitations that prevent them from increasing their daily activity levels
- haemophilia, or have any blood-borne viruses.

Posters advertising the study will be placed in participating depots for up to four weeks prior to the scheduling of baseline measurements. In addition, all drivers within participating depots will receive a letter and participant information sheet informing them of the study. Following the distribution of the study marketing material, researchers will visit participating depots for one to two days to enable interested drivers to ask any questions about the study before signing up. Upon completion of these visits the researchers will provide a list of drivers' names who have agreed to participate to their Transport Managers who will then schedule time for participating drivers to attend the baseline (and follow-up) measurements.

Within the UK logistics industry, 1% of HGV drivers are women,[10] and the proportion of female HGV drivers employed by our partner company reflects this national average. Whilst females will be included in the study, due to the small proportion of the workforce they represent, the included sample of females may not enable statistically meaningful comparisons to examine any influences of sex on the intervention. However, the sample recruited, will likely reflect the gender disparities seen in the Logistics and Transport industry nationally and internationally.

7.4 Sample size

Our earlier exploratory pre-post study revealed that on average HGV drivers achieve 8786 steps/day across both workdays and non-workdays with a standard deviation of 2919 steps.[12] We have powered this study to look for a difference in step counts (the primary outcome) of 1500 steps/day (equivalent to approximately 15 minutes of moderately paced walking) between the intervention group and control group. Evidence demonstrates a linear association between step counts and a range of morbidity and mortality outcomes, as well as with markers of health status including inflammation and adiposity, insulin sensitivity and HDL cholesterol in adults.[16-18] The linear association between step counts and health outcomes indicate that regardless of an individual's baseline value, even modest increases in daily step counts can yield clinically meaningful health benefits. For example, a difference in daily steps of 1500 steps/day has been

associated with around a 5-10% lower risk of all-cause mortality and cardiovascular morbidity and mortality in the general population and in those with a high risk of type 2 diabetes respectively.[19,20] The proposed level of change has been chosen based on findings from our exploratory pre-post intervention,[12] whilst also being clinically meaningful.

Based on a cluster size of 10, a conservative ICC of 0.05 (as there is no previous data to inform this, we have been informed by recommendations of Campbell et al.[21]), an alpha of 0.05, power of 80% and a coefficient of variation to allow for variation in cluster size of 0.51 (based on partner company data) we will require 110 participants from 11 clusters per arm. From experience in conducting such studies, it is estimated that retention and compliance rates will be approximately 70% at 12-months follow-up; therefore, the sample size will be inflated by 30% to ensure we have adequate power in our final analysis. We will also inflate the number of clusters by 2 to allow for whole cluster drop out. We will recruit 24 clusters with an average of 14 participants per cluster.

Due to 1 pilot site (a BP site) not allowing participants to wear the accelerometers during working hours for health and safety reason, thus limiting the collection of the primary outcome measure (activPAL-determined steps/day) to non-working hours only, the TSC approved the recruitment of an additional site in the main trial phase. The total number of sites recruited will now be 25 as opposed to 24.

8. STUDY PROCEDURES

8.1 Informed Consent

Participants will be provided with a written consent form that they will be requested to sign prior to participating in the study. An informed consent form will be provided at every new stage of the data collection including baseline, 6-month and 12-month health assessments and during the participation of any one-to-one interviews or focus group.

8.2 Screening and Eligibility Assessment

All long-distance HGV drivers (>18 years of age) within participating depots will be eligible to participate, except for those who meet the exclusion criteria described in section 7.3

8.3 Measurements

The outcome measurements will be assessed at 3 time points. Baseline measures will occur prior to randomisation of the depots into the 2 study arms. A second set of identical measurements will take place following completion of the 6-month intervention, and a final set will be taken 6 months after completion of the formal intervention period, as recommended by the National Obesity Observatory.[22] At the baseline assessment, the study will be explained to the participant and written informed consent will be obtained. The measurements will be undertaken in suitable rooms within participating depots by trained researchers and will last between 1.5 and 2 hours per participant. Participants will complete a range of self-report questionnaires and have a series of physiological health assessments taken. All participants will receive detailed feedback on their physiological health assessment measures during each measurement session. In the event that a potential health issue is evident during the health assessments, such as undiagnosed hypertension or high cholesterol levels, participants will be advised to visit their GP for further checks. We will provide participants with a letter to give to their GP which summarises the findings from our point-of-care (blood markers) and automated (blood pressure) measures. Participants will be requested to inform the researchers about the use of any prescribed medications that they commence throughout the study duration which may impact the proposed outcome measures. Participants will be issued with objective monitoring devices to assess their free-living physical activity, sedentary behaviour and sleep, which they will be instructed to wear for eight days following each measurement visit. After eight days, participants will be requested to return these monitors to their depot where they will be collected by a member of the research team.

8.3.1 Primary outcome

The primary outcome will be physical activity, expressed as steps/day, at 12 months post randomisation. Physical activity will be objectively measured using the activPAL micro accelerometer, worn continuously on the anterior aspect of the thigh, for 24 hours/day over eight days during each assessment period. The activPAL provides a valid measure of walking and posture (i.e. sitting and standing) in adults,[23-25] and provides a more accurate measure of physical activity and sitting in occupational drivers in comparison to waist-worn accelerometers.[26] As the physical activity component of the intervention predominantly includes the promotion of walking based-activity, and as participants will be provided with a Fitbit providing information on daily step counts to set goals to increase their physical activity, steps/day was chosen as the primary physical activity related outcome.

8.3.2 Secondary outcomes

A number of secondary outcomes will be assessed at all measurement time points. The secondary outcomes are described below:

Physical activity and sedentary behaviour

Light and moderate-to-vigorous physical activity (MVPA) will be assessed using the activPAL and the wrist-worn GENEActiv accelerometer, both worn continuously for eight days. The GENEActiv is a lightweight waterproof device, resembling a sports watch, which has been found to be a valid and reliable objective measure of physical activity.[27] Outcomes calculated from the GENEActiv include minutes spent in MVPA, proportion of participants meeting the MVPA guidelines of 150 minutes per/week, total volume of physical activity regardless of intensity, and sleep duration. The accelerometer provides time stamped data so activity at specific times of the day (e.g., during work, after work) will also be extracted.

Sedentary behaviour will also be measured for 8 consecutive days during each assessment period using the activPAL3 micro. The activPAL is regarded as the most accurate method of assessing sitting behaviour in free-living settings,[25,28,29] and is recommended for use in interventions when sitting is an outcome measure.[24] From the data provided, we will extract total daily sitting time, work-time and leisure-time sitting, sitting bout durations, and number of transitions between sitting and standing.

Sleep duration, subjective sleepiness and chronotype

Sleep duration and efficiency will be measured objectively using the GENEActiv which has been shown to be an accurate measure of sleep, in addition to physical activity.[30] Subjective sleepiness will be assessed using the Karolinska Sleepiness Scale, shown to be a valid measure of sleepiness when validated against electroencephalography (EEG) and performance outcomes.[31,32] Participants' chronotype will be determined using the short version of the Morningness-Eveningness questionnaire.[33]

Anthropometry, adiposity and blood pressure

Stature (measured at baseline only) and body mass (both assessed without shoes), along with waist and hip circumferences, will be measured using standardised anthropometric techniques by trained research staff. BMI will be calculated as weight (kg)/height (m^2). Body composition (percentage body fat and fat mass) will be assessed via bio-impedance analysis, using Tanita DC-360S body composition scales. We will also measure neck circumference which is a novel marker which links strongly to obstructive sleep apnoea, insulin resistance and cardiovascular disease risk.[34] Blood pressure will be measured from the left arm after a twenty minute period of quiet sitting using an automated recorder (Omron HEM-907), in accordance with current recommendations.[35]

Biochemical assessments

Finger-prick blood samples will be collected from participants, with participants being requested to fast for ≥4 hours prior to attending each health assessment. The 'A1CNow®+ point-of-care analyser will be used to measure glycated haemoglobin which is a marker of long-term glucose regulation used in clinical care. Additionally, we will use the Cardiochek® point-of-care analyser to measure circulating cholesterol (total, HDL, LDL). Both of these systems are manufactured by PTS Diagnostics and possess analyte validation certificates from the International Federation of Clinical Chemistry and Laboratory Medicine.

Functional fitness

Grip strength will be assessed from both hands using the Takei Hand-Grip dynamometer (Takei Scientific Instruments Co., Ltd; Japan). Reduced muscular strength, as measured by grip strength, is associated with an increased risk of cardiovascular disease, and all-cause and cardiovascular mortality.[36]

Cognitive function and psychophysiological reactivity

The Stroop test will be administered over a five minute period using a validated software package to provide a measure of reaction time, sensitivity to interference and the ability to suppress an automated response - reading colour names in favour of naming the font colour.[37] To examine psychophysiological reactivity, acute stress will be induced using a five-minute mirror-tracing task (Campden Instruments Ltd.), during which measures of blood pressure and heart rate will be taken.[38]

Work-related psychosocial variables and mental health

A series of self-report measures will be employed to characterise work-related health and mental health: musculoskeletal symptoms will be assessed using the Standardised Nordic Questionnaire;[39] work engagement (characterized by vigour, dedication, and absorption) will be measured using the Utrecht Work Engagement Scale (UWES);[40] occupational fatigue will be measured using the Occupational Fatigue Exhaustion Recovery (OFER 15) scale;[41] job performance[42] and job satisfaction[43] will be measured using single-item 7-point Likert scales; sickness presenteeism will be assessed using a single-item questionnaire; participant's perceptions of work demand and support will be assessed using four subscales from the Health and Safety Executive Management Standards Indicator Tool (HSE MSIT),[44] and driving-related safety behaviour will be assessed using a 6-item measure.[45] Anxiety and depression will be measured using the Hospital Anxiety and Depression Scale (HADS),[46] and Social Isolation will be assessed using the 8-item Social Isolation short form from the Patient-Reported Outcomes Measurement Information System.[47,48] Data on sickness absence will be collected via self-report and will include frequency and duration of self-certified and certified sickness.

Health-related quality of life and health-related resource use

The self-reported EQ5D[49] will be completed by participants during each assessment period to inform the within-trial cost-effectiveness analysis (see cost-effectiveness). Participants will also complete a questionnaire, developed for this study, assessing health-related resource use at the same time points.

Demographics and additional lifestyle health-related behaviour measures

At baseline we will collect basic demographic information for each participant including their date of birth, sex, ethnicity, highest level of education, marital status, postcode (to determine Index of Multiple Deprivation as an indicator of neighbourhood socio-economic status), working hours, years worked as a HGV driver, and years worked at our partner company. At each follow-up assessment, participants will be asked if there have been any changes in these variables. During each assessment, information on smoking status and typical alcohol intake will be gathered by self-report measures. Dietary quality, including fruit and vegetable intake, will be assessed using a short-form food frequency questionnaire.[50]

8.4 **Internal pilot**

We intend to conduct an internal pilot study using the first six clusters (depots). The internal pilot will examine issues surrounding worksite and participant recruitment, randomisation, compliance to the primary outcome, and retention rates at 6-months following randomisation. After this period, we will continue to the full trial if the following progression criteria are met:

- All 24 depots required for the full sample size agree to take part in the study. Six depots will be selected to take part in the internal pilot (three will be randomised to the intervention arm and three to the control arm). This will demonstrate that depot recruitment and intervention delivery is on-track.

- According to our criteria, 84 drivers will need to agree to participate in the internal pilot, based on an average of 14 participants per cluster.
- An average of 75% of drivers opting into the study, randomised into the intervention arm, attend the education session across the 3 intervention depots. This figure is based on the intervention uptake rate seen in our exploratory pre-post intervention study (87%),[12] whilst also recognising that take-up rates tend to be lower when moving from an efficacy to a larger multi-centre effectiveness trial.
- No more than 20% of participants fail to provide valid data for the primary outcome measure (activPAL-determined step counts) at baseline and at 6 months post randomisation or withdraw/are lost to follow-up during the six-month intervention phase. This threshold is necessary as study power requires total withdrawal or loss to follow-up of no higher than 30% during the six-month intervention and six-month follow-up (12 months post randomisation).

If the final two progression criteria are not fully met, strategies to improve these metrics for the full trial will be discussed with the Trial Steering Committee and the study will progress based upon recommendations from this committee.

8.5 **Process evaluation**

The process evaluation will be used to help explain any discrepancies between expected and observed outcomes, to understand the influence of intervention components and context on the observed outcomes, and to provide insight for any further intervention development and implementation.[51] Throughout the intervention, we will monitor the reach, efficacy, adoption, implementation, and maintenance of the intervention using the RE-AIM framework.[52] We will employ a variety of techniques (e.g., logbooks, questionnaires, interviews and focus groups) to inform our process evaluation. For example, Transport Managers (or their nominated facilitators) and educators/worksite champions from each site will report on a monthly basis if there were any organisational changes (e.g. job changes) or events which may affect participation. Self-report questionnaires provided to study participants will evaluate the various intervention components (e.g. education session, physical activity monitoring tool, cab workout). Interviews and focus groups with study participants will further examine engagement in the various components of the intervention, along with any perceived barriers or facilitators to participating in these components. Interviews and focus groups with worksite champions, HR staff, health and safety personnel and logistics timetabling and planning staff will further examine the intervention implementation. We will also document any environmental factors (e.g. movement of personnel between worksites/depots, potential contamination of the intervention through drivers in different groups meeting at service stations/customer distribution centres) that may have an influence on intervention effectiveness. Details of the process evaluation components are included in Appendix 1.

8.6 **Randomisation and Codebreaking (if applicable)**

Clusters (depots within the same company) will be randomised at the worksite level into the two study arms (intervention and control). Randomisation into the study arms will take place in two phases; initially the first 6 clusters (depots) involved in the internal pilot will be randomised, and in the second phase the remaining clusters will be randomised in blocks of three upon completion of the baseline measures in these sites. In both phases randomisation will be done by an independent statistician at the Leicester Clinical Trials Unit (CTU).

8.7 **Definition of End of Trial**

The end of trial is the date of the last follow up assessment of the last participant.

8.8 **Discontinuation/Withdrawal of Participants from Study Treatment**

Each participant and/or depot has the right to withdraw from the study at any time. In addition, the investigator may discontinue a participant from the study at any time if the investigator considers it necessary for any reason including:

- Significant protocol deviation
- Significant non-compliance with the outcome measurements
- An adverse event which requires discontinuation of the study or results in inability to continue to comply with study procedures
- Consent withdrawn
- Lost to follow up

Withdrawal from the study will result in exclusion of the data for that participant from analysis if the results of the study have not been processed, at which point it will not be possible to withdraw individual data from the research.

The reason for withdrawal will be recorded in the CRF.

If the participant is withdrawn due to an adverse event, the investigator will arrange for follow-up visits or telephone calls until the adverse event has resolved.

8.9 **Source Data**

Source documents are original documents, data, and records from which participants' CRF data are obtained. These include, but are not limited to, demographic information, anthropometric measurements (height, weight, BMI, % body fat, neck, waist and hip circumference), physiological measurements (blood pressure, blood markers obtained from the finger prick test). CRF entries will be considered source data if the CRF is the site of the original recording (e.g., there is no other written or electronic record of data). All documents will be stored safely in confidential conditions. On all study-specific documents, other than the signed consent, the participant will be referred to by the study participant number/code, not by name.

9. TREATMENT OF TRIAL PARTICIPANTS

9.1 Description of Study Treatment

The SHIFT programme is a multicomponent lifestyle-behaviour intervention designed to target behaviour changes in physical activity, diet and sitting in HGV drivers. This 6-month intervention, grounded within the Social Cognitive Theory for behaviour change[53] consists of a group-based (4-6 participants) 6-hour structured education session tailored for HGV drivers, delivered by two trained educators. It includes information about physical activity, diet and sitting and risk factors for type 2 diabetes and cardiovascular disease. The educational component is founded on the approach used in the award winning suite of DESMOND programmes, including the PREPARE[54] and Let's Prevent Diabetes programmes,[55] created by researchers at the Leicester Diabetes Centre and used throughout the NHS,[56] whilst being tailored to meet the needs of HGV drivers.[11] Within the education session participants will not be 'taught' in a formal way, but supported to work out knowledge through group discussions and to develop individual goals and plans, based on detailed individual feedback received during their health assessments (see Measurements) to achieve over the 6-month intervention period. The education session is supported by specially developed resources for HGV drivers and participant support materials. The session will include the discussion of feasible strategies for participants to increase their physical activity, improve their diet and reduce their sitting time (when not driving) during working and non-working hours.

During the education session, participants will be provided with a Fitbit® Charge 2 activity tracker and encouraged to use this to set goals (agreed at the session) to gradually increase their physical activity predominately through walking-based activity. The Fitbit® activity tracker will provide participants with information on their daily step counts and will be used as a tool for self-monitoring and self-regulation. Physical activity tracking using step counters (traditionally pedometers) has been associated with significant reductions in BMI and blood pressure, with interventions incorporating goal setting being the most effective.[57]

The education session will adopt the promotion of the "small changes" philosophy using the Specific, Measurable, Attainable, Relevant, and Timely (SMART) principle[58] to encourage participants to gradually build-up their daily activity levels, within the confines of their occupation, to meet the current UK Physical Activity guidelines.[59] For example, participants will be encouraged to establish their own personalised action plan, which may also include making dietary improvements in addition to increases in physical activity, with SMART goals throughout the 6-month intervention. 'Step count challenges' (1-week competitions within intervention depots) will run every 6-weeks throughout the 6-month intervention which will be facilitated by local worksite champions. A "cab workout" will be introduced and practised at the education session and participants will be provided with resistance bands and balls, and grip strength dynamometers to take away. Participants will be encouraged to undertake the cab workout during breaks when not permitted to leave their vehicle. Participants will be able to keep the intervention tools beyond the 6-month intervention period, however the company will choose whether to sustain the worksite champion support and step count challenges beyond the 6-month intervention period. A Logic Model detailing the underlying theory behind the intervention components is shown in Appendix 2.

The structured education session will be delivered by trained personnel from our partner company and by trained members of the research team. These individuals will be trained and mentored by trainers from the Leicester Diabetes Centre. The education sessions will take place within appropriate training rooms within the intervention depots. Personnel delivering the education sessions within each intervention depot will also be trained to act as a local champion, shown to enhance the effectiveness of worksite physical activity interventions.[60] They will provide ongoing health coach support to intervention participants (during the 6-month intervention period) and be responsible for facilitating the step count challenges.

9.2 **Control Condition**

Depots assigned to the usual practice control arm will be asked to continue with their usual care conditions. Participants in the control depots will receive an educational leaflet at the outset detailing the importance of healthy lifestyle behaviours (i.e., undertaking regular physical activity, breaking up periods of prolonged sitting, and consuming a healthy diet) for the promotion of health and well-being. Control participants will be requested to complete the same study measurements as those in the intervention worksites, at the same time points. Upon completion of the study, control depots will be provided with all of the educational material provided to the intervention participants as part of the SHIFT programme. As the intervention will be delivered by trained personnel within our partner company, the company may choose to provide the full intervention (including the education session and health coach support) to control depots upon completion of the formal trial.

10. SAFETY REPORTING

10.1 Definitions

10.1.1 Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation participant, which does not necessarily have to have a causal relationship with the treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the study, whether or not considered related to the study.

10.1.2 Adverse Reaction (AR)

All untoward and unintended responses related to the study.
All cases judged by either the reporting medically qualified professional or the sponsor as having a reasonable suspected causal relationship to the study qualify as adverse reactions.

10.1.3 Severe Adverse Events

To ensure no confusion or misunderstanding of the difference between the terms "serious" and "severe", which are not synonymous, the following note of clarification is provided:
The term "severe" is often used to describe the intensity (severity) of a specific event (as in mild, moderate, or severe myocardial infarction); the event itself, however, may be of relatively minor medical significance (such as severe headache). This is not the same as "serious," which is based on patient/event outcome or action criteria usually associated with events that pose a threat to a participant's life or functioning. Seriousness (not severity) serves as a guide for defining regulatory reporting obligations.

10.1.4 Serious Adverse Event or Serious Adverse Reaction

A serious adverse event or reaction is any untoward medical occurrence that at any dose:

- Results in death,
- Is life-threatening,

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

- Requires inpatient hospitalisation or prolongation of existing hospitalisation,
- Results in persistent or significant disability/incapacity, or
- Is a congenital anomaly/birth defect.
- Other important medical events*

*Other events that may not result in death, are not life threatening, or do not require hospitalisation, may be considered a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the patient and may require medical or surgical intervention to prevent one of the outcomes listed above.

10.1.5 Expected Serious Adverse Events/Reactions

No serious Adverse Events/Reactions are expected to occur within the present study.

10.1.6 Suspected Unexpected Serious Adverse Reactions

A serious adverse reaction, the nature or severity of which is not consistent with the applicable product information

10.2 Reporting Procedures for All Adverse Events

Due to the nature of this study we do not anticipate any adverse events to occur; however, should any arise, we will follow Loughborough University guidelines for managing and reporting adverse events, serious adverse events and suspected, unexpected serious adverse reactions which follow those outlined in good clinical practice guidance. If a participant has an adverse event relating either to the study measurements or the intervention the researcher will record this on a report form. Report forms relating to the intervention will be collected at the end of the intervention, unless the adverse event requires further NHS treatment. In this case, the person in charge of the specific depot will be asked to contact the research project manager immediately and fax/email the completed report form to immediately.

10.3 Reporting Procedures for Serious Adverse Events

All SAEs must be reported to the Sponsor within one working day of discovery or notification of the event. The Sponsor will perform an initial check of the information and ensure that it is reviewed at the next R&D Management meeting. All SAE information must be recorded on an SAE form and sent to the Sponsor using the appropriate reporting form and the contact details on there. Additional information received for a case (follow-up or corrections to the original case) needs to be detailed on a new SAE form which must be sent to the Sponsor using the appropriate reporting form and the contact details on there.

The Sponsor will report all SUSARs to the Research Ethics Committee concerned. Fatal or life-threatening SUSARs must be reported within 7 days and all other SUSARs within 15 days. The CI will inform all investigators concerned of relevant information about SUSARs that could adversely affect the safety of participants.

In addition to the expedited reporting above, the CI shall submit once a year throughout the study or on request an Annual Report to the Ethics Committee which lists all SAEs / SUSARs that have occurred during the preceding 12 months.

11. STATISTICS

A statistical analysis plan will be written prior to database lock for the internal pilot and full cluster RCT.

11.1 Internal pilot

The average recruitment rate across depots, proportion of participants providing valid data, and attendance rate at the education sessions will be reported with 95% CI. The point estimates and 95% CIs will be compared to the progression criteria outlined in section 8.4.

11.2 Main trial

11.2.1 Statistical analyses

Average daily steps at 12-months will be compared by group using generalised estimating equation models adjusted for baseline values and waking wear time with an exchangeable correlation structure, which adjusts for clustering. For the primary analysis missing data will not be replaced (complete case analysis) but participants will be included in the intervention group in which their depots were randomised irrespective of the intervention actually received (modified intention-to-treat analysis). We have inflated our sample size by 30% to account for potential loss to follow-up and non-compliance with the primary outcome measure. We will compare the baseline characteristics of those who have complete primary outcome data and those who do not. A sensitivity analysis using multiple imputation will be performed to assess the impact of missing outcome data on the results found and to account for uncertainty associated with imputing data (full intention to treat analysis). The imputation will be carried out using the command MI in Stata. MI replaces missing values with multiple sets of simulated values to complete the data, performs standard analysis on each completed dataset, and adjusts the obtained parameter estimates for missing-data uncertainty using Rubin's rules to combine estimates. The effect size will also be assessed by attendance excluding those who did not attend the full intervention (per-protocol analysis). Secondary outcomes and 6-month data will be analysed using similar methodology.

11.2.2 Qualitative analyses

Audio-recordings of interviews and focus groups with drivers, worksite champions, HR staff, health and safety personnel and logistics timetabling and planning staff will be transcribed verbatim and analysed using framework analysis,[61,62] using the RE-AIM framework[52] as the overarching framework.

11.2.3 Cost-effectiveness

The economic analysis will consist of a cost-consequence analysis based on the observed results within the trial period and a cost-effectiveness analysis where differences between groups in the trial will be extrapolated to the longer term. For both analyses, costs in both arms will be estimated from a NHS and Personal Social Services (PSS) perspective (consistent with that used by NICE) as well as a wider public sector perspective. In each analysis, the cost of the SHIFT arm will include an estimate of the cost of the intervention (including the cost of training the educators), generated through a staff questionnaire completed at the end of each education session.

Within-trial analysis

Within the trial, resource use estimates will be collected from participant questionnaires and will include health related resource use as well as absence from employment. The health-related resource use will be based on a variant of the Client Service Receipt Inventory and will include services that this population are likely to utilise such as GPs and Practise nurse appointments,

occupational health visitors and counsellors. Costs of resources will be calculated by applying published national unit cost estimates (e.g. NHS reference costs or PSSRU Unit costs of health and social care[63,64]), where available, to estimates of relevant resource use.

A range of outcomes will be assessed in the trial including health related quality of life, measured using the EQ5D.[49] The within trial analysis will present incremental results for the primary and secondary outcomes (including EQ5D) in both intervention and control arms and will be compared with the incremental costs measured above. We will also present the results in terms of the differences between the groups in time absent from work. Two analyses will be conducted, one including these productivity losses, the other excluding them. This will allow decision makers to assess the importance of inclusion of these costs in the adoption decision.

Longer-term analysis

It is acknowledged that although there may be short term health benefits from the intervention, the longer-term effects of, for example, increased physical activity on diabetic status and number of cardiovascular events may be more important. We will therefore conduct a brief literature review to identify existing models that link short term endpoints (including physical activity) measured in the trial and longer-term quality of life. We have identified and utilised existing models[65] linking physical activity to Quality Adjusted Life Years (QALYs) previously. These models will be utilised to extrapolate costs and effects of the intervention beyond the trial period to a more appropriate time horizon. If appropriate an Incremental Cost-effectiveness Ratio for the extrapolated period will be reported using the QALY. As with the within-trial analysis, we will conduct analyses where productivity losses are included/excluded to assess the impact on decision making. Costs and effects will be discounted at the prevailing recommended rate (currently 1.5% per annum on both costs and effects), but will be the subject of sensitivity analysis to reflect the ongoing uncertainty around appropriate discount rates for public health interventions. To reflect the levels of uncertainty in parameter inputs we will conduct probabilistic sensitivity analyses; this will allow a characterisation of the uncertainty around the adoption decision which we will depict using cost-effectiveness acceptability curves. Sensitivity analyses will be performed to determine the robustness of the results to altering certain assumptions such as the discount rate or inclusion/exclusion of productivity losses.

12. DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

Direct access will be granted to authorised representatives from the sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections.

13. QUALITY CONTROL AND QUALITY ASSURANCE PROCEDURES

The study will be conducted in accordance with the current approved protocol, ICH GCP, relevant regulations and standard operating procedures.

Regular monitoring will be performed according to ICH GCP. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents. The standard operating procedures will be followed for all assessments and documented and reported in compliance with the protocol, GCP and the applicable regulatory requirements.

14. CODES OF PRACTICE AND REGULATIONS

14.1 Ethics

Ethical consideration has been given to the study design in relation to participant exposure and participant burden as well as to the collection of meaningful data.

14.2 Sponsor Standard Operating Procedures

All relevant Sponsor SOPs will be followed to ensure that this study complies with all relevant legislation and guidelines

14.3 Declaration of Helsinki

The Investigator will ensure that this study is conducted in full conformity with the current revision of the Declaration of Helsinki (last amended October 2000, with additional footnotes added 2002 and 2004).

14.4 ICH Guidelines for Good Clinical Practice

The Investigators will ensure that this study is conducted in full conformity with relevant regulations and with the ICH Guidelines for Good Clinical Practice (CPMP/ICH/135/95) July 1996.

14.5 Approvals

Once Sponsor authorisation has been confirmed, the protocol, informed consent form, participant/parent/teacher/school information sheets and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), regulatory authorities and host institution(s) for written approval.

Once Sponsor authorisation has been confirmed, the Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

14.6 Participant Confidentiality

The trial staff will ensure that the participants' anonymity is maintained. The participants will be identified only by initials and a participant's ID number on the CRF and any electronic database. All documents will be stored securely and only accessible by trial staff and authorised personnel. The study will comply with the Data Protection Act which requires data to be anonymised as soon as it is practical to do so.

15. DATA HANDLING AND RECORD KEEPING

The Leicester CTU use an 'off the shelf' commercial Clinical Data Management System (CDMS) called InferMed MACRO v4 (Macro) to implement compliant database solutions. Macro is an integrated electronic data collection system developed for running multi-centre clinical research studies and trials. It is intuitive to use, has interactive tools for study definition, and supports on-line data entry and remote study monitoring.

All study data will be entered into the database and checked visually and verbally at entry. The participants will be identified by a study specific number and/or code in the database. The name and any other identifying detail will NOT be included in the study data electronic file. A separate secure database will be used to record participant information and contact details, in addition to their follow up dates.

The database management system which stores the databases underlying the MACRO application is Microsoft SQL Server. SQL Server and its supporting hardware infrastructure is provided by the University of Leicester's IT Services (ITS).

The database solutions implemented by the CTU using MACRO are validated.

The CTU has procedures in place to manage the Study Definition Life Cycle, covering the Design, Build, Verification, Routine Use, Maintenance (including change management) and Archiving of trial databases.

16. STUDY GOVERNANCE

Two groups will be created to oversee the study; a TSC and a Project Committee. As the study is regarded as low risk, we request not to have a separate Data Monitoring Committee, rather the TSC will take on the role of a Data Monitoring Committee and review any serious adverse events which are thought to be intervention related and monitor progress with data collection. The TSC will meet every 6 months and include the principle investigator (Dr Clemes), an independent chair, two independent external academic members, the trial statistician(s), and two industry/public members. The TSC will act as an independent strategic oversight body to ensure transparency and that relevant milestones are being met and will report back to the NIHR PHR Programme. The TSC will provide advice and updates to the Project Committee which will comprise the PI, all co-investigators, a financial representative and those concerned with the day to day running of the study (research associates, administrator, etc.). The Project Committee will meet bi-monthly and provide an update report for the TSC. The TSC and the study investigators will be responsible for the strategic direction and performance monitoring of the research including study delivery, risk management, public and stakeholder engagement, dissemination of results, communications, and strategic planning. The study will comply with 'The Medicines for Human Use (Clinical Trials) Regulations 2004' and all study documentation and data will be retained for the set number of years specified by the study sponsor.

17. FINANCING AND INSURANCE

Funder: This research will be funded by a research grant awarded by the NIHR Public Health Research programme (80% - £706,197)

Sponsorship and indemnity for the study will be provided by Loughborough University.

18. PUBLICATION POLICY

Publications from this study will be co-authored and internally reviewed by Dr Stacy Clemes, Dr James King, Dr Veronica Varela Mato, Dr Yu-Ling Chen, Dr Charlotte Edwardson, Dr Fehmidah Munir, Prof Mark Hamer, Dr Thomas Yates, Dr Laura Gray, Prof Gerry Richardson, Miss Vicki Johnson and Jacqui Troughton. All study publications will acknowledge the funder (the NIHR PHR stream).

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20. APPENDIX 1 - PROCESS EVALUATION PLAN

Key elements of process evaluation: Based on Hasson et al (2010)

Areas to measure	General process questions	Data source and data collection method	Total numbers and sampling strategy/timescales
Recruitment	Number of depots/worksites invited to participate, and number agreeing Number of possible participants at each depot, number invited/recommended for participation, number opting in to the intervention Number of participants opting-out, dropping out and non-compliance to the primary outcome measure	Project records, including the number of drivers within each depot approached Depot logs of staff numbers, project records, attendance records at measurements Participant attendance records, short questionnaires to explore reasons for non-participation, dropping out and non-compliance	On-going throughout the project
Acceptability of randomisation and measurement tools	How depots feel about being randomised to intervention / control arms Did participants find outcome assessments acceptable How did participants and logistics timetabling staff experience recruitment and timetabling of outcome assessments	Focus groups with participants Interviews with local depot health and safety advisors/HR/timetabling staff	~8 focus groups, or until data saturation is reached, with participants ~1 month following completion of baseline measures ~8 interviews, or until data saturation is reached, with local depot health and safety advisors/HR/timetabling staff ~1 month after completion of baseline measures in their depots
Intervention acceptability and fidelity - implementation	Was the intervention implemented as planned How did participants and logistics timetabling staff experience scheduling the education sessions	Interviews with personnel within our logistics partners who are trained as educators and implemented the education sessions Interviews with local worksite champions and timetabling staff within intervention depots Participant questionnaires	Interviews with educators, the number of which will depend on the number of educators trained, and timetabling staff immediately following delivery of the education sessions Interviews with local champions 3 months into the intervention, immediately following the intervention (6 months), and at 9 and 12 months Questionnaires administered after education sessions to participants
Intervention acceptability and fidelity - participation	What proportion of the target group participated in the intervention, and what components of the intervention were preferred, did this differ between males and females What strategies were put in place by intervention participants to facilitate behaviour change	Focus groups with intervention participants Attendance logs at education sessions and measurement visits Questionnaires and focus groups	~8 focus groups, or until data saturation is reached, with participants immediately following completion of the intervention (6 months) Brief questionnaires administered to all intervention participants at 6 months during health assessments

Areas to measure	General process questions	Data source and data collection method	Total numbers and sampling strategy/timescales
Intervention sustainability	What proportion of the target group maintained any changes in their health behaviours following the 6 month intervention period Were there any differences in sustainability between males and females Are the company going to continue with the intervention in some way	Focus groups with intervention participants Questionnaires Interviews with health and safety personnel	~8 focus groups, or until data saturation is reached, with participants at 10 months follow-up (4 months after completion of the intervention. Brief questionnaires administered to all intervention participants at 12 months during health assessments Interviews at 12 months
Intervention contamination	Did movement of staff (e.g. participants, health and safety personnel) occur from intervention to control depots Did intervention drivers interact with control drivers at customer warehouses/distribution centres etc.	Control depots to keep a log of any staff changes Focus groups with intervention and control participants	Logs collected upon completion of the 12 month follow-up assessments 8 focus groups, or until data saturation is reached, with intervention and control participants immediately following completion of the intervention (6 months) and at 10 months follow-up
Unexpected events arising from the study	Did intervention and control participants modify their behaviours based on information provided at the baseline health assessments? Did the health assessments prompt GP visits Did increased self-awareness of health status and constraints within the job lead to cognitive dissonance Did intervention participants change an existing activity-related behaviour for another as a result of participating in the study	Focus groups, interviews and questionnaires delivered to intervention and control participants	Questionnaires delivered to intervention and control participants 1 month after completion of the baseline health assessments 8 focus groups, or until data saturation is reached, with intervention and control participants immediately following completion of the intervention (6 months) and at 10 months follow-up One-to one interviews based on questionnaire and focus group responses at 1 and 10 months

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21. APPENDIX 2: LOGIC MODEL FOR THE SHIFT INTERVENTION