The SHIFT Study – Protocol

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

2. Background

Lorry 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] Undoubtedly, the environment, culture and job demands (long irregular hours, enforced sedentarism, high stress) within the transport industry constrain the enactment of healthy lifestyle behaviours which are responsible for high levels of obesity, metabolic syndrome and mental ill health and well-being (stress, depression, anxiety, fatigue).[1,3] Our own observational data from a sample of heavy goods vehicle (HGV) drivers has shown that 84% were overweight or obese (compared to 75% of males aged 45-54 years reported to be overweight/obese nationally[4]), 87% were physically inactive, 35% were hypertensive and 15% and 31% had borderline/abnormal scores for depression and anxiety respectively. Additionally, the driver population in the UK (n=285,000) is an ageing workforce (mean age: 53 years),[5] and collectively, these factors identify an underserved, high risk population urgently needing assistance to prevent an explosion of type 2 diabetes and cardiovascular disease.[6]

2.1. Existing research: Lorry drivers' working environments are not conducive to a healthy lifestyle. They are an underserved occupational group in terms of health promotion efforts, yet exhibit higher than nationally representative rates of obesity and related co-morbidities.[7] A recent systematic review of health promotion interventions in lorry drivers, including only 8 studies, observed that the interventions generally led to improvements in health and health behaviours.[1] However, it was concluded that the strength of the evidence was limited due to poor study designs, with no control groups, small samples and no or limited follow-up periods.[1] Only one study examined the economic impact of an intervention.[8] Since the publication of the systematic review, recent studies have examined the impacts of a weight loss intervention in US lorry drivers[9] and a smartphone application on physical activity and diet in Australian lorry drivers.[10] Whilst positive findings were observed, the studies provide limited evidence as they were again small-scale and uncontrolled. One active research trial in the US is evaluating the impact of a weight loss intervention in lorry drivers. This intervention (ref: NCT02105571) centers on a company weight loss competition with supporting platforms. The applicability of this study's findings will be limited by the financial incentives provided and lack of scalability. The proposed study will advance the current literature by examining the impact of our multicomponent health behaviour intervention (see below) using a randomized controlled trial (RCT) design, with immediate and extended follow-up. Importantly, our intervention is underpinned by sound theoretical principles and is unique in attending to both individual and environmental barriers to healthy lifestyles.

2.2. Our early-phase work: The proposed trial is supported by three years of preparatory research undertaken in partnership with a large transport company in the East Midlands, which was supported by a HEFCE funded Knowledge Transfer Partnership. 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 lorry drivers. This intervention has been informed by extensive Public and Patient Involvement (PPI) including drivers and relevant stakeholders, a qualitative study exploring the perceived barriers to healthy lifestyle behaviours in drivers,[11] an observational study (n=157) exploring lifestyle health-related behaviours in HGV drivers and markers of health, and a pre-post pilot intervention (n=57) with full process evaluation. Initial pilot testing of our intervention delivery, over a three month period, revealed potentially favourable increases in physical activity, with 81% of the sample increasing their daily step counts by an average of 1646 (SD: 2156) steps/day. Significant increases in fruit and vegetable intake were also observed (4.5 versus 5.4 portions/day). Significant reductions in waist circumference (-2.3 cm), waist-hip ratio (-0.1), fasting blood glucose (-0.5 mmol/l), LDL-cholesterol (-0.8 mmol/l), total cholesterol (-0.9 mmol/l) and diastolic blood pressure (-1.8 mmHg) were observed over the three month intervention. At baseline, 24% of the sample exhibited a >10% risk of having a cardiovascular event in the next ten years.[12] The positive changes in markers of health seen over the intervention period reduced this to 12% immediately after the intervention. Our proposed research seeks to extend this work by evaluating our multicomponent intervention within a RCT with immediate and extended follow-up. We will examine the impact of the SHIFT intervention on physical activity, sedentary behaviour, fruit and vegetable intake, adiposity, sleep quality, risk factors for cardio-metabolic disease, psychosocial outcomes and mental health. The study will include a full cost-effectiveness analysis that will provide crucial information for the transport industry

and governing bodies. It is intended that the information generated will inform the development of health education resources (delivered via drivers' compulsory Continued Professional Competence, CPC) for utilization across the transport sector, nationally and internationally.

2.3. Risks and benefits:

Participant risks: Potential risks of the intervention to participants are minimal. There is the potential that those exposed to the SHIFT intervention may suffer an injury due to starting a new physical activity regime, however as walking-based activities will be the primary type of activity promoted, this risk is minimal. Furthermore, the harms due to physical inactivity outweigh the risks of being physically active.

Societal risks: As with any health enhancing intervention, there is a risk of widening health inequalities based on which worksites agree to participate. However, the chosen setting and the target population of the proposed trial attempts to address this risk given the health inequalities seen in workers in the transport sector, particularly long distance drivers.[1,7] To limit inequalities, upon completion of all follow-up evaluation measures participants within the control worksites will receive the educational materials provided to the intervention participants. Furthermore, the intervention will be delivered by trained personnel within our partner companies (see 6.2. Intervention delivery), therefore the full intervention could be delivered to all control worksites, and the whole company, upon completion of the formal trial.

Participant benefits: There are many potential benefits to the participants of the proposed study. All participants will receive a comprehensive health check as part of the baseline and follow-up assessments. The intervention participants will receive many long term health benefits if they make, and sustain positive changes to their lifestyle health-related behaviours such as increased physical activity, improved diet and reduced sedentary time. The health benefits associated with physical activity are unequivocal, with strong evidence linking physical activity to reduced risk of all-cause mortality, coronary heart disease, hypertension, stroke, the metabolic syndrome, type 2 diabetes, breast and colon cancer, and depression.[13] Participants within our pre-post pilot exhibited many health benefits following participation in the intervention over three months, including reductions in waist circumference, waist-hip ratio, levels of fasting blood glucose, LDL-cholesterol, total cholesterol, and diastolic blood pressure.

Societal benefits: The health and wellbeing of professional drivers is of public concern given their health impacts the safety of all road users.[1] Of concern, obese lorry drivers are 55% more likely to have an accident than normal weight drivers.[14] Our proposed intervention will target health-related behaviours of this at-risk and underserved occupational group, with the goal of making a positive long-term impact on long distance lorry drivers' health. The Chartered Institute of Logistics and Transport (CILT) fully support our work given the absence of resources available to tackle health inequalities within the transport sector. Once evaluated, it is anticipated that our intervention could be scalable as a CPC resource for lorry drivers nationally and internationally and could be modified for use across other workers within the logistics and transport industry. This could have a long-term impact on professional drivers' health, and ultimately impact road safety for all road users.

2.4. Rationale for the current study: Long distance lorry 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. Similar data have been reported from US HGV drivers.[7,15] 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 and musculoskeletal disorders.[3,7,15-17] Indeed, UK and US data suggest that lorry drivers are among those with the lowest life expectancies compared to other occupational groups.[2,3] 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,[3,7,15-17] within the UK Transport sector, HGV drivers are also an ageing workforce.[5] 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'".[6] 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.[5] 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.[6] The proposed research directly addresses this recommendation.

The All Party Parliamentary Group for Freight Transport report[6] highlights an expressed need to raise awareness of the importance of HGV drivers' health within the transport industry. Currently, no national-level health education resources exist for professional drivers. While HGV drivers undertake compulsory CPC, this does not cover lifestyle health behaviours. The 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.[1,9,10] 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 lorry drivers evaluated using a robust RCT design.

3. Research aims and objectives

The aim of the proposed research is to evaluate the effectiveness and cost-effectiveness of the SHIFT programme using a cluster RCT.

3.1. Primary objective: To investigate whether the SHIFT programme leads to increases in objectively measured physical activity (expressed as steps/day) compared to usual care at 12 months follow-up.

3.2 Secondary objectives: To investigate whether the SHIFT programme at 12 months follow-up, compared to usual care, leads to;

1. Increases in time spent in light and moderate-to-vigorous physical activity (MVPA)
2. Reductions in sitting time
3. Reductions in measures of adiposity (BMI, percent body fat, waist-hip ratio, neck circumference)
4. Reductions in blood pressure
5. Improvements in blood markers (e.g. HBA1c, total cholesterol, HDL-C and LDL-C)
6. Improvements in dietary intake (i.e. increases in fruit and vegetable intake)
7. Improvements in sleep quality
8. Improvements in cognitive function
9. Improvements in 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).

4. Research design

4.1. Design: This is a workplace two-armed 12-month cluster RCT, which will incorporate an internal pilot. Clusters (different worksites/depots within the same company) will be randomised to receive either the 6-month 'SHIFT programme' or usual care. The impact of the intervention will be assessed immediately following intervention delivery, 6-months after randomisation, and 12-months after randomisation. Appendix 1 shows the overall trial design.

4.2. Setting, socioeconomic position and inequalities: This research will take place within the worksite setting of partner organisations from the logistics industry. 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.[6] In 2014 there were approximately 285,000 HGV drivers in employment.[5] Partner companies (including DHL) who have multiple depots and employ their own long distance HGV drivers, have agreed to participate. Our partner companies have a sufficient number of depots and drivers for us to reach our recruitment target (see Section 9, Sample Size).

Due to the nature of their employment, long distance lorry drivers are exposed to a multitude of risk factors which elevate their risk of many chronic diseases and premature mortality.[1] Our own data and published reviews,[1,3] show that unhealthy lifestyle behaviours are highly prevalent among this

occupational group. 84% of lorry drivers participating in our observational study were overweight or obese, higher than the 77% classified as overweight or obese in a 2004 survey of lorry drivers from the North of England.[18] As a consequence of unfavourable working conditions and unhealthy lifestyle choices, US data show that lorry drivers have a life expectancy ~15 years less than the average population.[3] Similarly, UK data suggest that lorry drivers are among those with the lowest life expectancies compared to other professions.[2] Lorry drivers are an at-risk and underserved population in terms of health promotion.[1] Given that the well-being of lorry drivers can directly affect the safety of other road users, intervention research targeting lorry drivers is considered a priority.[1]

4.3. Allocation to treatment groups: Clusters will be randomised at the worksite level. Randomisation into the study arms will take place in two batches, initially the first 6 clusters involved in the internal pilot will be randomised, and in the second batch all of the remaining clusters will be randomised stratified by company and size. In both batches randomisation will take place upon completion of baseline measurements and will be done by an independent statistician at the Leicester Clinical Trials Unit (CTU).

4.4. Confounding/bias: A cluster RCT design will minimise possible contamination between arms. To avoid selection bias all participants will be recruited and have their baseline measures collected prior to randomisation. Randomisation will be stratified by company and size ensuring an even distribution across arms of these factors. Although blinding of the intervention participants is not possible due to the nature of the intervention, the proposed primary outcome (see section 8) is objectively measured using a closed-feedback system and therefore cannot be influenced by observer bias. The community researchers who will be undertaking the outcome measurements will be blinded to the depot's (and participants) allocation, as will the statistician performing the analyses.

4.5. Internal Pilot: We intend to conduct an internal pilot study using the first 6 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 only if the following 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.
- A minimum of 84 drivers agree to participate in the internal pilot. This figure is based on the necessary minimum of 14 participants per cluster (see Section 9).
- 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%), whilst also recognising that take-up rates tend to be lower when moving from an efficacy to 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).

A figure of six depots was chosen as this will give data on around 84 participants (~25% of the total participant sample, see Section 9). This will enable us to estimate the recruitment rate to within a 95% confidence interval of +/- 8%, and a valid data rate to within a 95% confidence interval of +/- 9%.

4.6. Trial monitoring: We will monitor study uptake by recording the number of partner worksites/depots approached and the number agreeing to participate. We plan to recruit 24 clusters, and anticipate acceptance rates >80%, based on PPI with our partner companies. If rates are lower, we will modify our recruitment strategy, for example, by seeking opportunities to attend meetings with senior management and health and safety advisors within our partner companies. An independent Trial Steering Committee (TSC) (see Section 13, Research Governance) will oversee worksite and participant recruitment rates. Continuation criteria for the full trial will be the same as that described above for the internal pilot.

5. Study population and recruitment

5.1. Worksite/Depot recruitment: We will work with our logistics industry partners to recruit depots into this study. Depots will be included in the study if they contain long distance HGV drivers. 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 logistics reasons, we will target depots within a 1.5 hour drive of Loughborough. Data provided from DHL has shown that sites within this radius (40 sites, with 1695 drivers) have a similar size and variation in size to their national-level data.

5.2. Participant inclusion criteria: All drivers within participating depots will be eligible to participate, with the exception of those who meet the exclusion criteria.

***5.3. Participant exclusion criteria*:** Participants will be excluded if they currently suffer from cardiovascular disease, haemophilia, or have any blood-borne viruses or mobility limitations.

5.4. Participant recruitment: Within each depot, the study will be advertised to HGV drivers using the communication methods deemed most effective by an Internal Steering Group for each organisation. A facilitator for each site will be nominated who will provide assistance with employee communication and any logistical and security issues related to delivering the intervention and conducting the research methods. Worksites/depots will be made aware that they may be randomised to a current practice control condition where they will maintain their usual care conditions, although the intervention will be offered to all trial participants at the end of the trial.

6. Planned intervention

6.1. Experimental intervention: The SHIFT intervention is a multicomponent programme promoting positive changes in physical activity, diet and sitting in HGV drivers. A recent systematic review has shown that multicomponent interventions are effective in promoting favourable health outcomes (i.e. reductions in adiposity) and health behaviours (i.e. physical activity/nutrition) in drivers over the short term.[1] The proposed intervention has been developed over 3 years following a qualitative study exploring the barriers to healthy lifestyle behaviours in drivers,[11] and has received extensive PPI input from drivers and logistics industry Health and Safety personnel. The intervention delivery and outcome measures have been successfully piloted (in a 3-month pre-post study, see Section 2.2) and the intervention led to increases in physical activity and fruit and vegetable intake, reductions in fasting blood glucose, LDL-cholesterol, total cholesterol, diastolic blood pressure, waist circumference and waist-hip ratio. A full process evaluation has further refined and informed the proposed study.

The 6-month intervention, grounded within the Social Cognitive Theory for behaviour change[19] (see logic model, Appendix 2), consists of a group-based interactive 6-hour education session tailored for HGV drivers, delivered by 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 derived from the award winning DESMOND programme, created by educators at the Leicester Diabetes Centre (LDC) and used throughout the NHS.[20] 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 drivers 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 wearable physical 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 physical activity tracker will provide drivers with information on their daily step counts and will be used as a tool for self-monitoring and self-regulation. Physical activity tracking using pedometers has been associated with significant reductions in BMI and blood pressure, with interventions incorporating goal setting being the most effective.[21] The education session will adopt the promotion of the "small changes" philosophy using the Specific, Measurable, Attainable, Relevant, and Timely (SMART) principle [22] to encourage drivers to build-up their daily activity levels, within the confines of their occupation, to meet the current UK Physical Activity guidelines.[23] For example, drivers will be encouraged to establish their own action plan with SMART goals for the duration of the 6-month intervention. 'Step count challenges' (1-week competitions between and within intervention depots) will run on a monthly basis throughout the intervention which will be facilitated by local worksite champions (see Section 6.2, Intervention delivery). A "cab workout" will be introduced and practised at the education session and drivers will be provided with resistance bands and balls, and grip strength dynamometers to take away. Drivers will be encouraged to undertake the cab workout during breaks when not permitted to leave their vehicle. Drivers will be able to keep the intervention tools and encouraged to continue with their use beyond the 6-month intervention period. Our partner companies will provide drivers with free fruit to encourage healthier snacking; this was more successful in our exploratory pre-post intervention than the provision of healthy pack lunches.

6.2. Intervention delivery: The structured education session will be delivered by trained personnel from within DHL. These individuals will be trained and mentored by educators from the LDC. The LDC Team successfully developed, evaluated and disseminated to the NHS the DESMOND programme for type 2 diabetes,[20] and the Let's Prevent Diabetes Programme.[24] The educational component of the proposed study has been derived from these programmes and tailored to HGV drivers. The educational session can be delivered in either a one 6-hour session, or as two 3-hour sessions. Our PPI with transport

managers revealed companies would welcome such flexibility in session length. The educational sessions will take place within appropriate training rooms within our partner companies. Within the education session participants will not be 'taught' in a formal way, but supported to work out knowledge and develop individual goals and plans to achieve over the 6-month intervention period. We will assess the cost of training and delivery of the education session using a simple questionnaire completed at the end of each session. Within each intervention depot we will recruit an employee to act as a local champion, shown to enhance the effectiveness of worksite physical activity interventions.[25] They will receive training on how to provide ongoing health coach support to intervention participants (during and after the 6-month intervention period) and be responsible for facilitating the monthly step count challenges. Participants will also be able to contact the trained educators within their company throughout the intervention for one-to-one support in person, or via the telephone.

6.3. Control treatment (comparator): 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 companies, the companies may choose to provide the full intervention (including the education session and health coach support) to control participants upon completion of the formal trial.

6.4. Funding providers: The LDC will cover the costs of training the nominated personnel within our logistics partners to become health educators and worksite champions; our partner companies will cover the costs of intervention tools and costs associated with participants attending the education sessions.

7. Proposed methods

The SHIFT programme will be evaluated and reported using a cluster RCT following CONSORT guidelines and Medical Research Council guidance.[26] A cluster design was deemed appropriate as the intervention is delivered on a worksite basis and many of the characteristics will be common amongst participants within each cluster (depot). The evaluation methods proposed in Section 8 are commonly used within workplace intervention research.[27] The objective measurement of physical activity and sedentary behaviour using accelerometry is seen as the preferred method of assessing these behaviours in adults,[28] and will allow comparison with other trials of activity-promoting interventions. The anthropometric measurements, assessment of body composition and blood pressure, and collection of blood samples are routinely undertaken in adults as part of the Health Survey for England.[29]

7.1. Loss to follow-up/attrition: It is acknowledged that individual participants may be lost to follow-up due to changing employment during the study and there may be missing data from some participants at follow-up visits. Multiple imputation will be used to replace any missing data (see Section 10, Statistical analysis). Based on our exploratory pre-post intervention study, we expect ~70% of the sample to provide valid activPAL data across the baseline and follow-up assessments. We have built in these losses into the sample size calculation (see Section 9, Sample size).

7.2. Assessment and follow-up - assessment of efficacy/effectiveness: The outcome measurements (see section 8) will be assessed at 3 time points. Baseline measures will occur prior to randomisation of the worksites into the 2 study arms (control and intervention conditions, 12 depots [clusters] in each, see Section 9, Sample Size). A second set of identical measurements will take place 6-months post randomisation (i.e. just after the completion of the 6-month intervention), and a final set will be taken at 12-months post randomisation to assess the sustainability of the intervention (i.e. 6 months after completion of the intervention, as recommended by the National Obesity Observatory[30]).

The measurements will be undertaken in suitable rooms within our partner organisations, by trained researchers. During each assessment period, drivers will attend the measurement visits which will last between 1.5 and 2 hours. During each visit, participants will complete a range of self-report questionnaires and have a series of physiological health assessments taken (see Section 8). 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 (see Section 8) to assess their free-living physical activity, sedentary behaviour and sleep, which they will be instructed to wear for seven days following each assessment visit. After seven days, participants will be requested to return these monitors to their depot where they will be collected by a member of the research team. Our exploratory pre-post intervention study has demonstrated the feasibility of conducting the measurement visits and outcome measures described below.

8. Proposed outcome measures

8.1 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 (weighing 9 grams), worn continuously on the anterior aspect of the thigh, for 24 hours/day over 7 days during each assessment period. The activPAL provides a valid measure of walking and posture (i.e. sitting and standing) in adults,[31-33] and provides a superior measure of physical activity and sitting in occupational drivers in comparison to waist-worn accelerometers.[34] As the physical activity component of the intervention predominantly includes the promotion of walking based-activity, and as participants will be provided with a wearable physical activity tracker 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. Interventions promoting walking have been shown to produce gains in fitness, lead to reductions in blood pressure, improvements in blood lipid profiles, increases in bone density and enhanced mood state, with the greatest gains being observed in older adults, and in sedentary and obese individuals.[35] Evidence has highlighted a linear association between total daily steps and a range of health outcomes (including markers of inflammation, BMI, insulin sensitivity and HDL-cholesterol) in adults.[36-38]

The process evaluation conducted as part of our exploratory pre-post intervention revealed improved compliance in those participants using the new, smaller, activPAL micro accelerometers. These devices will be used in the proposed study as opposed to the larger activPAL monitors (used in our observational study, and used by some in our exploratory pre-post intervention). Compliance in our exploratory pre-post intervention was also impacted by the use of an additional waist-worn accelerometer, which will not be included in the proposed study due to observed inaccuracies of these devices in the assessment of physical activity in HGV drivers.

8.2 Secondary outcomes**:** A number of secondary outcomes will be assessed at all measurement time points. The secondary outcomes (mapped to the secondary objectives highlighted in section 3.2) are described below:

- *Light and moderate-to-vigorous physical activity (MVPA) (secondary objective 1)*: Participants will be asked to wear the wrist worn GENEActiv accelerometer continuously for 7 days. This lightweight device, resembling a sports watch, can be worn 24 hours/day as it is waterproof and has been found to be a valid and reliable objective measure of physical activity.[39] The GENEActiv was selected for these advantages and based on our previous experience, these factors help maximise compliance and reduce missing data. Wrist worn accelerometry, as opposed to waist worn, is now being used in national surveys such as the national health survey in the US (NHANES) and in the UK Biobank (https://www.ukbiobank.ac.uk/). 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 to investigate when activity change occurs.
- *Sitting time (secondary objective 2)*: Sedentary behaviour (sitting) is a key health-related outcome within our target population. Our observational data revealed that HGV drivers spend 13 hours/day sitting on a workday. High volumes of sedentary behaviour have been shown to independently impact health, increasing the risk of cardiovascular disease incidence and mortality, type 2 diabetes, cancer incidence and mortality, and all-cause mortality.[40,41] Sitting will also be measured for 7 consecutive days during each assessment period using the activPAL3 micro. The activPAL has been successfully used as an outcome measure in our exploratory pre-post intervention, and in other workplace intervention research.[42,43] The activPAL is regarded as the most accurate method of assessing sitting behaviour in free-living settings,[33] and is recommended for use in interventions when sitting is an outcome measure.[32] 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.

- *Measures of adiposity (secondary objective 3)*: Elevated adiposity, particularly when stored centrally, is a potent yet common risk factor for impaired metabolic heath and chronic disease in men. Data from our exploratory research demonstrates that UK lorry drivers' body weight and composition contributes significantly to their heightened risk of chronic metabolic disease, with elevated BMI, percentage body fat and waist circumference all being apparent. These important variables will be measured using standardised anthropometric techniques. Notably, body fat percentage will be measured using the portable Tanita 418 bioelectrical impedance analyser which is a validated instrument that enables total and segmental body composition analysis.[44] We will also measure neck circumference which is a novel marker which links strongly to obstructive sleep apnoea, insulin resistance and cardiovascular disease risk.
- *Blood pressure (secondary objective 4)*: high blood pressure is the leading risk factor for coronary heart disease and stroke and is inversely related to habitual levels of physical activity and dietary quality. In our observational and pre-post pilot research we found that the median blood pressure for our sample of UK lorry drivers (129/82 mmHg) categorised the group as 'pre-hypertensive' which highlights the relevance of this clinical outcome within this population. Using an established best practice protocol, we will measure systolic and diastolic blood pressure at each assessment point using automated blood pressure analysers (M6 Comfort, Omron Healthcare), validated and certified by The European Society for Hypertension.
- *Blood markers (secondary objective 5)*: low levels of physical activity and poor diet are intimately tied to impaired glucose regulation and dyslipidaemia which in turn are primary risk factors for chronic metabolic disease. Our pilot research shows that impaired glucose control and dyslipidaemia are more prevalent in UK lorry drivers than the general population which identifies these parameters as key targets for therapeutic intervention. In this project we will obtain finger-prick blood samples with participants having fasted for ≥4 hours. We will use the 'A1c Now' point-of-care analyser to measure glycated haemoglobin which is a marker of long-term glucose regulation used in clinical care. Additionally, we will use the Cardiocheck 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.
- *Fruit and vegetable intake (secondary objective 6)*: regular consumption of fruit and vegetables, in line with Public Health England recommendations, is associated with reduced risk of obesity, coronary heart disease, type 2 diabetes and certain cancers. Our qualitative data highlights a lack of awareness and understanding of the importance of a healthy diet amongst drivers which is compounded by restrictions on food choices at truck stops.[11] A central component of our structured education platform therefore focuses on dietary quality, particularly the consumption of fruit and vegetables, fats and sugar. Dietary quality, including fruit and vegetable intake, will be assessed using a short-form food frequency questionnaire.[45]
- *Sleep duration and quality (secondary objective 7)*: sleep duration will be measured objectively using the GENEActiv for 7 days, shown to be an effective measure of sleep.[46] Sleep quality will be assessed using the Pittsburgh Sleep Quality Index (PSQI).[47]
- *Cognitive function (secondary objective 8)*: the Stroop test[48] will be administered over a 5 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. Cardiovascular measures (blood pressure and heart rate) will be recorded during the test to provide a measure of psychophysiological reactivity.[49]
- *Work-related psychosocial variables and mental health (secondary objective 9)*: various self-report measures will be employed to characterise work-related health: musculoskeletal symptoms will be assessed using the Standardised Nordic Questionnaire;[50] work engagement (characterized by vigour, dedication, and absorption) will be measured using the Utretcht Work Engagement Scale (UWES);[51] occupational fatigue will be measured using the Need for Recovery Scale;[52] job performance[53] and job satisfaction[54] will be measured using single-item 7-point likert scales; general quality of life will be assessed using the WHO QOL-BREF;[55] presenteeism will be assessed using the Work Limitations Questionnaire[56] and the Work Productivity and Activity Impairment Questionnaire (WPAI-GH 2.0);[57] 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),[58] and driving-related safety behaviour will be assessed using a 6-item measure.[59] Anxiety and depression will be measured using the Hospital Anxiety and Depression Scale (HADS).[60] Data on sickness absence will be collected via self-report and employer records and will include frequency and duration of self-certified and certified sickness. Reasons for sickness absence will also be recorded. Data on sickness

absence will be collected from organisational records for 12 months prior to the intervention and for the 6 month intervention and follow-up periods.

- *Cost-effectiveness (secondary objective 11):* the self-reported EQ5D[61] will be completed by participants during each assessment period to inform the within-trial cost-effectiveness analysis. Participants will also complete a questionnaire assessing health-related resource use at the same time points (see Section 8.4). In addition, we will assess the impact of inclusion/exclusion of productivity losses (including those from objective 9 above) on the assessment of cost-effectiveness and the likely influence of longer term costs and outcomes likely to occur outside the period of the trial.
- *Demographics and other self-report measures:* we will also collect basic demographic information for each participant including their date of birth, ethnicity, highest level of education and postcode (to determine IMD as an indicator of neighbourhood socio-economic status). Information on smoking status and typical alcohol intake will also be gathered by self-report measures.

8.3. Process evaluation (secondary objective 10): Due to the multicomponent nature of the intervention, the process evaluation will be particularly important. 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, to understand any differential effects of the intervention on male and female drivers (subject to females enrolling in the study, see Section 10), and to provide insight for any further intervention development and implementation.[26] Throughout the intervention, within each intervention depot, we will monitor the fidelity of the intervention implementation using the Normalisation Process Theory framework,[62] in line with guidance from the National Institutes of Health Behaviour Change Consortium and the DESMOND collaborative. We will employ a variety of techniques (e.g., log books, questionnaires, interviews and focus groups) to inform our process evaluation. For example, facilitators and intervention 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 3.

8.4. Estimates of cost-effectiveness (secondary objective 11): 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, 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[60,61]), 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.[61] 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 measured in the trial and longer term quality of life. 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 Quality Adjusted Life Year (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.

9. Proposed sample size

Our exploratory pre-post intervention revealed that on average lorry drivers achieve 8786 steps/day across both workdays and non-workdays with a standard deviation of 2919 steps. We have powered our study to look for an increase in step counts of 1500 steps/day (equivalent to approximately 15 minutes of moderately paced walking) in the intervention group relative to the 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.[36-38] 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 to 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.[63,64] An increase of 1500 steps/day has also been associated with a reduction in BMI of 0.12 kg/m^2, a reduction in waist-hip ratio of 0.23, and an increase in HOMA insulin sensitivity score of 2.1 units.[38] Research in older adults has shown that a sustained increase in daily steps of 1500 steps/day over a 12 month period leads to reductions in systolic blood pressure, increases in HDL-cholesterol and reductions in overall risk of cardiovascular disease.[65] The proposed level of change has thus been chosen based on our exploratory pre-post intervention whilst also being clinically meaningful.

Within our partners, DHL for example have 283 sites across the UK with around 7,000 drivers. Of these sites we have decided to concentrate on those with 20 or more drivers. Based on our exploratory pre-post intervention, around 50% of drivers will be willing to take part giving a minimum of 10 per site. There are 92 sites meeting these criteria with a total of 3642 drivers, on average 34 per site. 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.[66]), 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 DHL data) we will require 110 participants from 11 clusters per arm. From our experience in conducting such studies and our pre-post pilot data, we believe final valid steps/day data will be available from 70% of participants; therefore we will inflate this sample size by 30% to ensure we have adequate power in our final analysis. We will also inflate our cluster size by 2 to allow for whole cluster drop out. We will therefore recruit 14 participants per cluster, 336 participants in total. For logistical reasons we will concentrate the recruitment of clusters within a 1.5 hour drive of the lead researchers (Loughborough), the sites within this radius have a similar size and variation in size to the national data. Within this radius there are 40 sites, with a total of 1695 drivers.

10. Statistical analysis

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

10.1. 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 stopping rules outlined in Section 4.5.

10.2. Main trial: Average daily steps at 12 months will be compared by group using generalised estimating equation models adjusted for baseline value 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. 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 ITT 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.

Within the logistics industry, currently 1% of HGV drivers are women.[6] The proportion of female HGV drivers employed by our largest partner, DHL, reflects this national average. Whilst females will be included in the study, due to the small proportion of the workforce that they represent, the included sample of females may not enable statistically meaningful comparisons to examine any influences of sex on the intervention. Where possible, any differences in the effects of the intervention on males and females will be explored qualitatively through our process evaluation.

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,[67,68] using the Normalisation Process Theory[62] as the overarching framework.

11. Assessment of harms

We do not foresee any adverse events arising from the intervention. Loughborough University's guidelines for managing and reporting any serious adverse events (SAE) will be followed, which reflect those outlined in Good Clinical Practice (GCP) guidance for non-CTiMP trials and are based upon Medicines and Healthcare Products Regulatory Agency feedback. Adverse events which do not fall into the GCP categories of an SAE are defined as non-serious. All SAEs will be reported internally and to the sponsor (Loughborough University) using appropriate reporting forms within 24 hours of the study team becoming aware of an event. The immediate report of an event may be made orally or in writing and will be followed by a detailed written report. If requested, additional information can be provided to the sponsor and the main Research Ethics Committee. The principal investigator will be responsible for the review and signing of the SAE, or in their absence, another member of the team (in order to avoid a delay). The investigator site file will contain documentation for SAE reports and evidence of submission of SAEs to the sponsor within 24 hours of the team becoming aware of an event.

12. Ethical arrangements

Ethical approval will be obtained from Loughborough University's Ethical Advisory Committee (Non-NHS) prior to commencement and will comply with the ESRC Research Ethics Framework. For ethical approval, we will be required to provide details of the research purpose and proposed methods, a risk assessment, a full protocol, participant information sheets, a consent form, and any advertising/recruitment materials. The SHIFT intervention is low risk and we have received ethical approval for previous work of this nature so we do not anticipate ethical concerns.

An independent Trial Steering Committee (TSC) will be established to ensure the safe and effective conduct of the study and to recommend conclusion of the trial if/when significant benefits or risks have developed or the trial is unlikely to be concluded successfully. The Committee will meet on a 6 monthly basis. Any issues raised will be addressed with the principle investigator and reports and recommendations will be provided.

13. Research governance

The study will be sponsored by Loughborough University. 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, three independent external members, two logistics company representatives and a statistician. 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 review the recruitment, compliance and retention data collected during the internal pilot, and if satisfactory, will recommend continuation to the full trial. The TSC will provide advice

and updates to the Project Committee which will comprise the PI's, 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 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. The project will be managed to the standards required by GCP and the Research Governance Framework.

The Leicester CTU is one of the UKCRC fully Registered CTUs and has been involved in this application from the outset and will be involved throughout the project. We have had face-to-face meetings with the CTU (Operations Director, Principal Statistician IT Manager, Senior Trial Manager) to discuss the design of the research, the data collection logistics, costs, staffing that will be required to conduct the research and the database and data management requirements. The CTU has a well-established IT infrastructure and will be providing a GCP-compliant database solution using a Clinical Data Management System (CDMS) called InferMed Macro v4. This is a secure and validated database solution with quality control mechanisms to ensure that the data collected are complete and accurate. The CTU works within a Quality Management System framework and will ensure that the relevant staff utilising CTU services are adequately trained and supported, and adhere to the required standards of GCP, Research Governance and sponsor SOPs.

14. Expertise

- Stacy Clemes will contribute expertise in the design and evaluation of the intervention while also providing academic leadership of the project and direct supervision of the research staff. She will provide a link to the Prevention theme of the East Midlands CLAHRC who will support dissemination.
- James King will assist Dr Clemes in the leadership of the project including the day-to-day conduct of the research; he will also contribute expertise in the physiological health assessments, and contribute to the analyses and dissemination.
- Charlotte Edwardson will contribute expertise in the measurement of physical activity and sedentary behaviour. She will be responsible for the processing of the objectively measured physical activity and sedentary behaviour data and will also form a direct link with the Leicester CTU (she is an affiliated CTU project manager).
- Fehmidah Munir will contribute expertise in occupational health psychology, intervention process evaluation and qualitative research. She will oversee the psychosocial and health behaviour outcome measures, along with the intervention process evaluation.
- Mark Hamer will contribute expertise in the assessment of cardio-metabolic risk factors and oversee biomedical data collection in addition to the psychophysiological testing.
- Thomas Yates will contribute expertise in the use of physical activity for the promotion of health and wellbeing. He is an academic lead for commissioned prevention programmes that have informed this grant and will ensure the grant is supported by the wider infrastructure for lifestyle research in the East Midlands.
- Heather Daly has expertise in developing and delivering behavioural interventions within clinical and community settings and led the development of the education component of the SHIFT intervention, she will oversee the educator training of logistics personnel and delivery of the education sessions.
- Laura Gray will contribute expertise in medical statistics and the design and analysis of cluster RCTs; she will lead the analysis strategy with support from the Leicester CTU.
- Gerry Richardson will provide expertise in health economics and will be responsible for the cost-effectiveness analysis.
- Veronica Varela-Mato (Research Associate) will provide expertise in logistics-industry research and contribute to the day to day management of the project and participant recruitment. She will supervise data collection staff, contribute towards data collection and the process evaluation.
- Alison Stanley (Project Manager and PPI officer) will contribute expertise in logistics-industry research and be responsible for the day to day management of the project and PPI.
- Lorraine Martin Stacey (Research Associate) will contribute expertise in the delivery of health interventions in community settings and will oversee the process evaluation and assessments of intervention fidelity.
- The Leicester CTU will provide IT support, database development and data management, a trial statistician as well as senior statistical experience (costs have been factored in for this).

15. Partner collaborations

There are a number of NIHR networks associated with the research team that we will draw on for support and dissemination. The University Hospitals of Leicester, University of Leicester and Loughborough University host one of two NIHR Lifestyle Biomedical Research Units (BRU) in the UK; the Leicester-Loughborough Lifestyle BRU. MH is the nominated lifestyle theme lead for our Leicester-Loughborough BRC 2016 application. This research will be linked with our current BRU (TY, MH, SC, CE, JK) and any future BRC. We will use this infrastructure to support the research by providing expertise in lifestyle research, additional equipment (activPALs and GENEActiv accelerometers), PPI engagement as well as dissemination pathways. One of the key research priorities of the East Midlands CLAHRC (TY, CE, SC, LG) is the development of lifestyle interventions and initiatives aimed at the promotion of metabolic health and prevention of chronic disease in high risk target groups. One of the key research priorities of the Yorkshire and Humber CLAHRC (GR) is to increase the understanding of health economics and outcome measurement in all aspects of healthcare. A further priority is in the generation of evidence on interventions which aim to address inequalities in risk and outcomes for chronic disease. The proposed research is in line with priorities of both the East Midlands and Yorkshire and Humber CLAHRC's. The East Midlands and Yorkshire and Humber CLAHRCs will offer a route for dissemination of the research findings to health practitioners and health researchers, and provide links with regional commissioners. We will also utilise links with the East Midlands Academic Health Science Network (TY, HD) to enhance dissemination with commissioners in the area. The Leicester CTU will provide IT support, database development and management, a trial statistician as well as senior statistical experience.

AS, JK, SC and VVM have established links with the Chartered Institute of Logistics and Transport (CILT), and a number of logistics companies. We will work closely with CILT to facilitate research dissemination (articles, conferences, workshops) across the logistics and transport sector nationally and internationally. The Loughborough researchers (SC, JK, MH, FM) are based within the National Centre for Sport & Exercise Medicine (East Midlands). They will utilise the Centre's extensive dissemination channels and links with Public Health England to aid in the dissemination of the study. The British Heart Foundation National Centre for Physical Activity and Health is a partner organisation and Centre staff will join the projects steering group and support the dissemination of the findings.

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Logic model references (Appendix 2)

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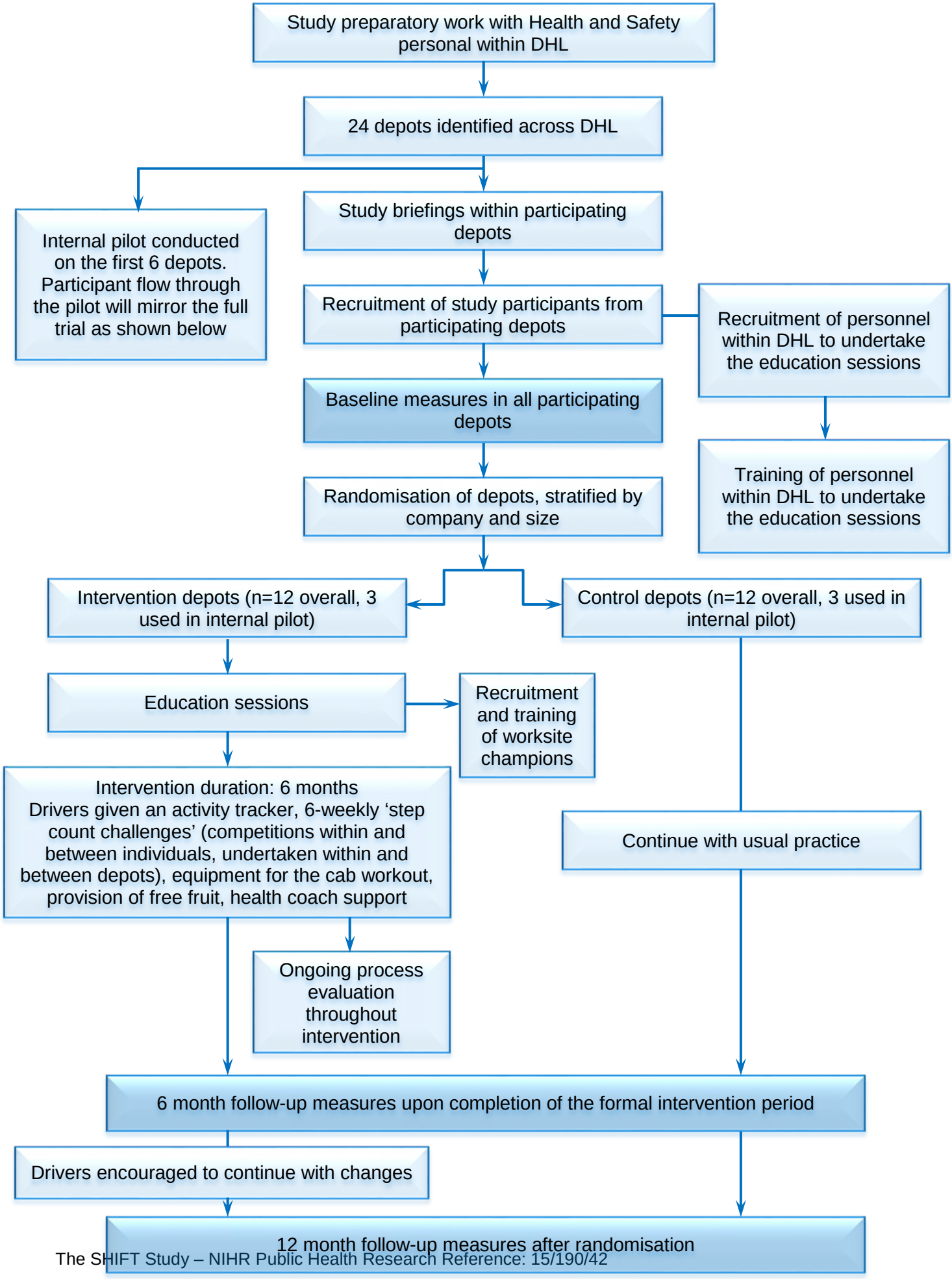
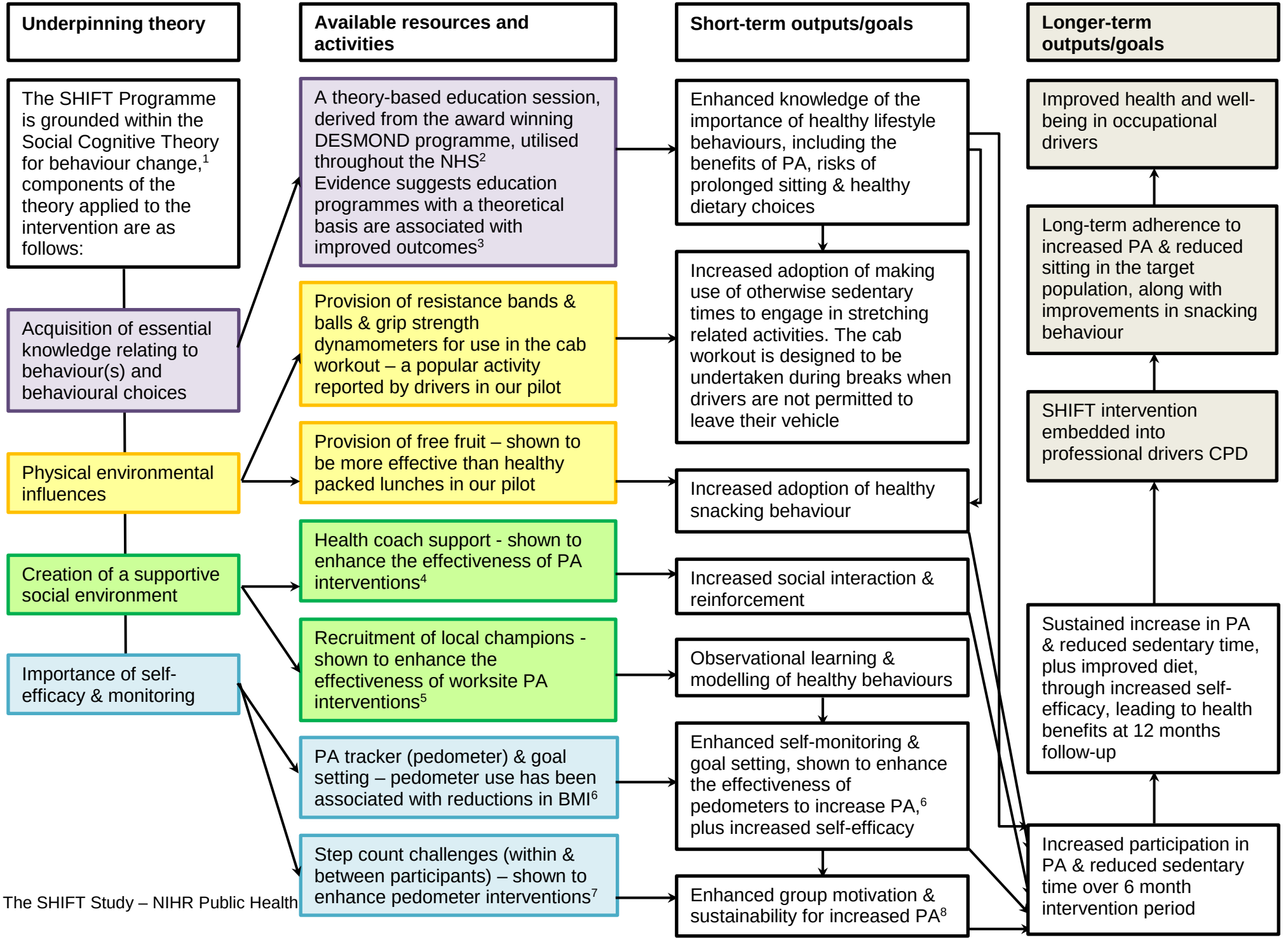
Appendix 1 - Trial design and participant flow through the study



Appendix 2 - Logic Model for the SHIFT Intervention



Appendix 3 - 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	Focus groups with intervention participants Attendance logs at education sessions and measurement visits	~8 focus groups, or until data saturation is reached, with participants immediately following completion of the intervention (6 months) Brief questionnaires administered to all

Areas to measure	General process questions	Data source and data collection method	Total numbers and sampling strategy/timescales
	intervention participants to facilitate behaviour change	Questionnaires and focus groups	intervention participants at 6 months during health assessments
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

Reference

Hasson H. (2010). Systematic evaluation of implementation fidelity of complex interventions in health and social care. Implementation Science, 5: 67