**Economic Analysis Plan – SHIFT Study**

**1. Introduction**

This document presents an analysis plan for the exploratory assessment of the 6 month Structured Health Intervention for Truckers (SHIFT) study. SHIFT is a multicomponent, theory driven, health behaviour intervention designed to promote positive lifestyle changes in relation to physical activity (PA), diet and sitting in lorry drivers.

The trial seeks to evaluate the effectiveness and cost-effectiveness of the SHIFT intervention. It is intended that the information generated will inform the development of health education resources for utilization across the transport sector, nationally and internationally. 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.

**2. Intervention**

SHIFT is a 6-month intervention, grounded within the Social Cognitive Theory for behaviour change. It consists of group-based (four to six participants) 6-hour structured education session tailored for HGV drivers, delivered by two trained educators. It includes informationabout physical activity, diet and sitting and riskfactors for type 2 diabetes and cardiovascular disease. Within the education session, participants were supported through group discussions to develop individual goals and plans, based on detailed individual feedback received during their health assessments to achieve over the 6-month intervention period. During the education session, participants were 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. ‘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’ is introduced and practised at the education session and participants are provided with resistance bands and balls, and grip strength dynamometers to take away.

**3. Study design**

This trial took place within the worksite setting of a major logistic company (DHL), all drivers within participating depots were eligible for inclusion, with the exception of those who meet the exclusion criteria. Participants were excluded if they suffered from cardiovascular disease, haemophilia, or had any blood-borne viruses or mobility limitations.

To avoid selection bias all participants were recruited and had their baseline measures collected prior to randomisation. Randomisation was stratified by depot size. An independent statistician carried out randomisation. Although blinding of the intervention participants was not possible due to the nature of the intervention, the proposed primary outcome was objectively measured using a closed-feedback system and therefore could not be influenced by observer bias. The community researchers undertaking the outcome measurements were blinded to the depot’s (and participants) allocation, as was the statistician performing the analyses. Based on power calculations, a sample of 24 clusters with an average of 14 participants per cluster were recruited.

**4. Data collection**

The outcome measurements were assessed at three time points. Baseline measures occurred prior to randomisation of the worksites into the two study arms. A second set of identical measurements were taken immediately after the 6-month intervention period (6 months after randomisation), and a final set were taken at 6-months post intervention follow-up (12 months after randomisation).

*4.1 Primary and secondary outcomes*

The primary outcome was PA, expressed as steps/day, at 12 months post-randomisation. PA was objectively measured using the activPAL micro accelerometer, worn continuously on the anterior aspect of the thigh, for 24 hours/day over 8 days during each assessment period.

Secondary outcomes included: objectively measured time in light PA and MVPA, sitting time, sleep duration, markers of adiposity, blood pressure, glycated haemoglobin, total-, HDL- and LDL cholesterol (taken from a finger prick blood sample after a ≥4 hour fast), and cognitive function. A series of self-report questionnaires examined fruit and vegetable intake, and a range of psychosocial outcomes including sickness absence. Self-report measures also examined health related quality of life and resources used (e.g. GP visits, outpatient attendances).

Health-related quality of life will be assessed during the trial using the EQ5D. In the longer-term cost-effectiveness analysis differences in the outcomes listed above (e.g. PA, sitting time etc) will be modelled to estimate differences in Quality Adjusted Life-Years (QALYs).

*4.2 Health-related resource-use*

The following resource use items were measured: health service resource use such as GPs and practice nurse appointments, occupational health visitors and counsellors. Absence from employment was also measured. This data were collected using participant questionnaires. The questionnaire was based on the Client Service Receipt Inventory and included services that the population are likely to utilise.

*4.3 Intervention costs*

Intervention costs include the wearable physical activity trackers (Fitbit Charge 2); equipment for the “cab workout” including resistance bands and balls, and grip strength dynamometers; approximate cost of covering the shifts of drivers in the intervention arm with agency staff (whilst they have time away from their normal driving duties to attend the education session). In addition, staff training costs will be assessed which includes the costs of training and mentoring the educators.

*4.4 Health related resource use costs*

All resource use will be valued in monetary terms using appropriate UK unit costs or participant valuations estimated at the time of analysis (2019-2020). 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), where available, to estimates of relevant resource use. Where up to date cost estimates are not available, costs will be inflated using the hospital and community services pay and prices index (HCHS) reported in the latest available PSSRU report (2017).

*4.5 Extrapolated resource use and costs*

Existing models will be used to project the long-term health effects of increased physical activity and corresponding changes to health costs over an expanded time horizon.

**5. Methods for analysis**

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. Secondary outcomes and 6-month data will be analysed using similar methodology.

As mentioned previously, the economic analysis will consist of a cost-consequence analysis (within-trial analysis) based on the observed results within the trial period and a cost-effectiveness analysis (extrapolated analysis) where differences between groups in the trial will be extrapolated to the longer term. Both analyses will be conducted from the NHS and personal social services (PSS) perspective as well as a wider public sector perspective. Stata version 11 or higher will be used for exploratory analysis and the main statistical analysis.

*5.1 Cost-consequence (within-trial analysis)*

Differences in the use of services between randomised groups will be described but not compared statistically. 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. Results will be presented in terms of the differences between the groups based on 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.

*5.2 Cost-effectiveness (extrapolated analysis)*

Longer term outcomes in terms of costs and QALYs associated with the intervention will be estimated via extrapolation of trial results to a more appropriate time horizon (i.e. the drivers’ lifetime). A brief literature review will be conducted to identify existing models that link short-term end points (such as PA) measured in the trial and long-term quality of life. The model will compare groups that engage in physical activity with the same group as if they had not taken part. The tool then assesses the resulting (longer term) health improvements created by the physical activity. We have previously used the MOVES model (Sport England) to extrapolate from short term physical activity to longer term HRQoL. MOVES was developed by Sport England and the University of East Anglia’s Medical School Health Economics Consulting Group.

If appropriate, an incremental cost-effectiveness ratio for the extrapolated period will be reported using the QALY. As the within-trial analysis, we will conduct analyses where productivity losses are included/excluded to assess the impact on decision-making. Costs and benefits will be discounted at a rate of 1.5% as per the NICE public health economics base-case guidance. The estimated mean QALYs and costs associated with each treatment option will be combined with a feasible range of threshold values (ʎ), to obtain the distribution of net benefits at different levels of ʎ. The primary economic analysis will use a cost-effectiveness threshold of £20,000 per QALY.

To reflect the levels of uncertainty in parameter inputs a probabilistic sensitivity analyses will be conducted; this will allow a characterisation of the uncertainty around the adoption decision, which will be depicted using cost-effectiveness acceptability curves.

*6. Missing data*

A sensitivity analysis using multiple imputation to assess the effect of missing data on the interpretation of the primary outcome will be undertaken (ITT analysis)

*7. Sensitivity analysis*

In both the cost-consequence analysis and cost-effectiveness analysis, sensitivity analyses will be performed to determine the robustness of the results to altering certain assumptions such as inclusion/exclusion of productivity losses. In particular, for the cost-effectiveness analysis (extrapolation), discount rates will be the subject of sensitivity analysis to reflect ongoing uncertainty around appropriate discount rates for public health interventions. The cost-effectiveness threshold will also be subject to sensitivity analysis to reflect threshold estimates of £30,000 per QALY and £13,000 per QALY. Finally, the hazard ratio for disease specific mortality observed during the trial is assumed to persist after the end of trial follow-up. Sensitivity analysis will assess the impact of this assumption.