The effectiveness and cost-effectiveness of a Structured Health Intervention For Truckers (SHIFT): A cluster randomised controlled trial (RCT)

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Scientific Summary

Background

Due to the nature of their occupation, long-distance heavy goods vehicle (HGV) drivers are exposed to a multitude of health-related risk factors and have been identified as working within one of the most hazardous professions. Their working environment and job demands (long irregular hours, enforced sedentarism, poor

dietary options, high stress) constrain the enactment of healthy behaviours leaving drivers vulnerable to a myriad of physical and mental health conditions. Furthermore, long, and variable working hours, including shift work, contributes to sleep deprivation and this can lead to metabolic disturbances and further promote the uptake of unhealthy behavioural choices. As a result of their working environment and poor health behaviours, HGV drivers exhibit high rates of obesity and cardiometabolic risk factors. These factors likely culminate in HGV drivers having an increased risk of accidents, and higher rates of chronic diseases and reduced life expectancies in comparison to other occupational groups. Despite this, HGV drivers are currently underserved in terms of health promotion efforts.

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 Public and Patient Involvement (PPI) including drivers and relevant stakeholders. Initial pilot testing of our intervention delivery revealed it led to potentially favourable increases in physical activity and increases in fruit and vegetable intake. The current study extends this work by evaluating the multicomponent SHIFT programme within a cluster randomised controlled trial (RCT), with the inclusion of full process and cost-effectiveness evaluations.

Aim and objectives

The aim of this study was to evaluate the effectiveness and cost-effectiveness of the multicomponent SHIFT programme, compared to usual care, in a sample of long-distance HGV drivers at 6-months and 16-18-months follow-up.

Primary objective

To investigate the impact of the 6-month SHIFT programme, compared to usual care, on device-measured physical activity (expressed as steps/day) at 6-months follow-up.

Secondary objectives

- To investigate the impact of the SHIFT programme, compared to usual care, at 6-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)
    - cardiometabolic risk markers (glycated haemoglobin [HbA1c], total cholesterol, high-density lipoprotein cholesterol [HDL-C] and low-density lipoprotein cholesterol [LDL-C])
    - fruit and vegetable intake and dietary quality
    - blood pressure
    - psychophysiological reactivity
    - sleep duration and quality
    - functional fitness (grip strength)
    - cognitive function
    - mental wellbeing (anxiety and depression symptoms, and social isolation)
    - work-related psychosocial variables (work engagement, job performance and satisfaction, occupational fatigue, presenteeism, sickness absence, and driving related safety behaviour)
    - health-related quality of life
    - health related resource use (such as GP visits)

- To investigate the longer-term impact of the SHIFT programme, compared to usual care, at 16-18-months follow-up on:
    - steps/day
    - time spent in light physical activity and in MVPA
    - sitting time
    - fruit and vegetable intake and dietary quality
    - sleep
    - mental wellbeing (anxiety and depression symptoms, and social isolation)
    - work-related psychosocial variables (work engagement, job performance and satisfaction, occupational fatigue, presenteeism, sickness absence, and driving related safety behaviour)
    - health-related quality of life
- To conduct a mixed-methods process evaluation throughout the implementation of the intervention (using qualitative and quantitative measures) with participating drivers and site managers.
- To undertake a full economic analysis of the SHIFT programme.

Methods

Design and setting

We conducted a two-armed cluster RCT, which incorporated an internal pilot phase, and included mixed-methods process and economic evaluations. The trial took place within the worksite setting of a major international Logistics and Transport company who agreed to provide the setting and access to their drivers and sites for this research. Transport sites/depots formed individual clusters and were located across the Midlands region of the UK.

Participants

All HGV drivers within participating sites were eligible to participate, unless they met any of the following exclusion criteria: were suffering from clinically diagnosed

cardiovascular disease; had mobility limitations that prevented them from increasing their daily activity levels; the presence of haemophilia or a blood-borne virus; unable to provide written informed consent. Written informed consent was obtained from participants before baseline measurements, and before each set of follow-up measurements.

Sample size

In order to detect a difference in mean daily step counts of 1500 steps/day between the intervention and control groups (assuming a standard deviation of 2919 steps/day, 80% power, a 2-tailed significance level of 5%, an intraclass correlation coefficient of 0.05, an average cluster size of 10, and a coefficient of variation to allow for variation in cluster size of 0.51), we required 110 participants from 11 clusters per arm. This sample size was inflated by 30% to account for loss to follow-up/non-compliance to the activPAL, in addition, the number of clusters was inflated by 2 to allow for whole cluster drop out. We therefore aimed to recruit 24 clusters (transport sites) with an average of 14 participants per cluster, providing a total target sample size of 336 drivers. The internal pilot was conducted using the first six clusters (sites) recruited and examined issues surrounding worksite and participant recruitment, randomisation, compliance to the primary outcome, and retention rates at 6-months follow-up.

The SHIFT intervention

The SHIFT programme is a multicomponent lifestyle-behaviour intervention designed to target behaviour changes in physical activity, diet and sitting in HGV drivers. The 6-month intervention, grounded within the Social Cognitive Theory for behaviour change consists of a group-based (4-6 participants) 6-hour structured education session tailored for HGV drivers, delivered by two trained educators. The education session was supplemented by health coach support (provided over a 6-month period) and equipment provision, including a Fitbit (participants were encouraged to use this to monitor their daily step counts and set goals) and resistance bands/balls

and a hand gripper (to facilitate a ‘cab workout’). Using the step count data recorded by the Fitbit, drivers were invited to participate in 6-weekly, tailored, step count challenges throughout the 6-month intervention, by the research team.

Control arm

Participants received 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 completed the same study measurements as those in the intervention worksites, at the same time points and received the same health feedback as intervention participants immediately following their measurements. Aside from receiving a generic health education leaflet and feedback from their measurements, the control group carried on with usual practice for the duration of the study.

Outcome measures

Baseline measurements took place prior to randomisation of the sites into the two study arms. A second set of identical measurements took place at 6-months follow-up. These measurements took place within the transport sites and were conducted by researchers who had undergone relevant training. A final set of measurements took place at 16-18 months follow-up. These final follow-up measures were delayed due to the COVID-19 pandemic (they were initially planned for 12-months follow-up) and consisted of predominately self-report measures due to restrictions in face-to-face data collection. Due to the pandemic, the primary outcome was also changed from assessment at 12-months to 6-months.

Primary outcome

The primary outcome was device-measured physical activity, expressed as mean steps/day using the activPAL accelerometer, at 6-months follow-up.

Secondary outcomes

Secondary outcomes measured from the activPAL included time per day spent sitting, standing, stepping, time in prolonged sitting bouts, in light intensity and moderate to vigorous intensity physical activity (MVPA), and the number of sit-to-stand transitions. Variables were summarised for 3 different time periods within each measurement period: 1) daily (i.e., across all waking hours on all valid days); 2) workdays; and 3) non-workdays. The GENEActiv wrist-worn accelerometer was used to provide a measure of sleep duration and quality. The data from this device were summarised using the same time periods (daily, workdays, non-workdays) as that applied to the activPAL data. Data were collected on adiposity (BMI, fat percentage, waist circumference), and finger prick blood samples were collected to measure glycated haemoglobin (HbA1c), cholesterol (HDL, LDL, and total), and triglycerides. Fruit and vegetable intake and dietary quality were assessed using a food frequency questionnaire. Blood pressure, cognitive function, psychophysiological reactivity and functional fitness (grip strength) were also assessed. Further self-report measures collected at each assessment, via a questionnaire booklet, included mental wellbeing, musculoskeletal symptoms, occupational fatigue, job satisfaction and performance, work engagement, sickness absence, presenteeism, perceived work ability, job demands and control, and driving-related safety behaviour.

The primary analysis was performed using a mixed effect linear regression model, using a complete case population. Sensitivity analyses were conducted including intention-to-treat, per-protocol, and the effect of a different number of valid activPAL days.

Economic evaluation

Self-reported health-related quality of life and health-related resource use data were collected at each assessment point. The economic evaluation assessed the costs and outcomes associated with the SHIFT programme when compared with usual practice. These costs/outcomes were assessed over the time period of the trial and

also over a longer time horizon to reflect the fact that short term changes in activity are associated with longer term improvements in health.

Process evaluation

A mixed-methods process evaluation was conducted to examine intervention fidelity, dose, effectiveness of implementation strategies, potential contamination, barriers, and sustainability. Participants completed feedback questionnaires one month after their baseline and 6-month assessments. In addition, following completion of the trial focus groups and semi-structured interviews took place with participants and managers.

Results

Recruitment

382 participants (mean±SD age: 48.4±9.4 years, BMI: 30.4±5.1 kg/m^2, 99% male) were recruited across 25 clusters, and randomized (at the cluster level) into either the SHIFT (12 clusters, n=183) or control (13 clusters, n=199) arms. An additional site was recruited due to one internal pilot site having restrictions on when participants could wear the activPAL and GENEActiv accelerometers. The 25 transport sites operated within the transport, retail, hospitality, healthcare, pharmaceutical, construction, oil and gas, and automotive industries, and the average age of our sample and gender split matches the average age of HGV drivers and gender proportion seen nationally. Between baseline and 6-months follow-up, 2 sites dropped out of the trial (1 intervention, 1 control). For both, this was due to site closures because of the collapse of the contracting companies. At baseline, participants accumulated 8583 steps/day (IQR 6922-10696) and spent 11 hours/day sitting (SD 95 mins), 10 minutes/day (IQR 6-19) in MVPA and 99 minutes/day (IQR 82-123) in light physical activity. 42% of the sample were classified as overweight, and 46% were classified as having obesity at baseline.

Primary outcome

Valid accelerometer data were available from 209 participants (54.7%) for the primary outcome analysis. At 6-months, significant differences in mean daily steps were found between groups, with the SHIFT group accumulating 1008 steps/day more than the control group (95% confidence interval (CI) 145 to 1871, p=0.022). These differences were largely driven by the maintenance of physical activity levels in the SHIFT arm and a decline in the control arm. Sensitivity analyses showed similar results to the primary analysis, with significant differences observed between groups when including participants with ≥2, 3 and 4 valid days of activPAL data.

Secondary outcomes

Favourable changes at 6-months were also seen in the SHIFT group, relative to the control group, in time spent sitting (-24 mins/day, 95% CI: -43 to -6), standing (14 mins/day, 95% CI: 2 to 26), stepping (11 mins/day, 95% CI: 2 to 21), and time in MVPA (6 mins/day, 95% CI: 0.3 to 11). These differences were largely driven by changes in behaviours on non-workdays. No differences between groups were observed when these variables were assessed at 16-18-months follow-up. No differences were observed between groups in the other secondary outcomes at either follow-up.

Economic evaluation

The average total cost of delivering the SHIFT programme was £369.57 per driver, resulting quality-adjusted life-years were similar across trial arms (SHIFT: 1.22 (95% CI: 1.19 to 1.25); control: 1.25 (95% CI: 1.22 to 1.27)). Analyses revealed that the probability of the SHIFT programme being cost-effective in the within trial period was low, with a probability between 0.009 and 0.011 for the range of cost-effectiveness thresholds considered. Overall, the SHIFT programme was associated with higher costs than usual practice with little impact on other outcomes. It was concluded that the SHIFT programme is not likely to be cost-effective in its current delivery format and this result was robust to a range of alternative assumptions and additional analyses.

Process evaluation

Questionnaire and interview data indicated favourable attitudes towards the SHIFT programme from both drivers and managers. The Fitbit was the most favoured component of the intervention, whereas the cab workout appeared the least favoured. The education session was deemed useful for facilitating improvements in knowledge and behaviour change, however only dietary knowledge changes from the education session were predominantly recalled. Receiving feedback about their current health status from the physiological outcome measurements assessed at baseline and 6-months motivated participants to change aspects of their lifestyle (proportion agreeing: intervention = 91.1%, control = 67.5%). Barriers to a healthy lifestyle at work were still apparent and affected drivers throughout the study, with participants predominately making positive behaviour changes on non-workdays.

Conclusions

The SHIFT programme may have had a degree of success in positively impacting physical activity levels and reducing sitting time in HGV drivers at 6-months, however these differences were not maintained at 16-18-months. Due to the nature and demands of their occupation, the statistically significant differences observed between groups in these behaviours were largely driven by changes occurring on non-workdays, and largely attributable to the maintenance of physical activity levels in the SHIFT arm, and a decline in the control arm. The process evaluation revealed favourable attitudes towards the SHIFT programme from both drivers and managers, with drivers highlighting that the education session, Fitbit and step count challenges were particularly effective for facilitating behavioural changes. Managers and participants reported enthusiasm and necessity for SHIFT to be included in future Certificate of Professional Competence Training for professional drivers in the UK.

The high prevalence of drivers with obesity, along with the poor cardiometabolic health profile and sleep deprivation seen in our sample highlight substantial health issues in this at-risk and hard to reach occupational group. While the longer-term

impact of the SHIFT programme is unclear, the programme (with refinement) offers potential to be incorporated into driver training courses to promote activity in this at-risk, underserved, and hard-to-reach essential occupational group.

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