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A multicomponent structured health behaviour intervention to improve physical activity in long-distance HGV drivers: the SHIFT cluster RCT

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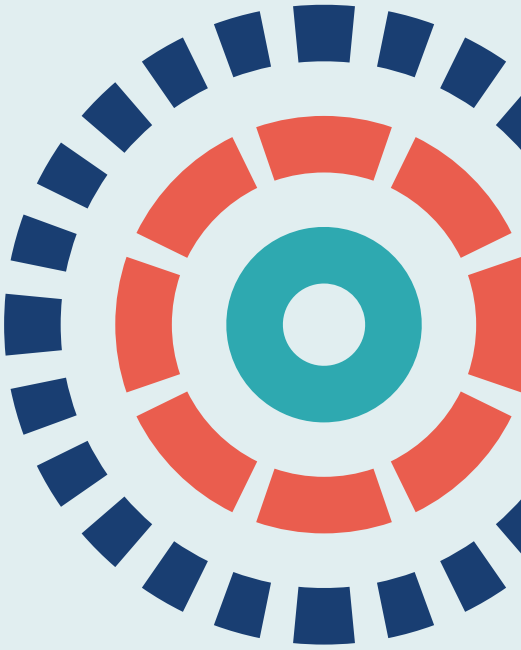

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A multicomponent structured health behaviour intervention to improve physical activity in long-distance HGV drivers: the SHIFT cluster RCT

Stacy A Clemes,[1,2*] Veronica Varela-Mato,[1,2] Danielle H Bodicoat,[3] Cassandra L Brookes,[4] Yu-Ling Chen,[1,2] Edward Cox,[5] Charlotte L Edwardson,[2,6] Laura J Gray,[7] Amber Guest,[1] Vicki Johnson,[8] Fehmidah Munir,[1,2] Nicola J Paine,[1,2] Gerry Richardson,[5] Katharina Ruettger,[1] Mohsen Sayyah,[1] Aron Sherry,[1,2] Ana Suazo Di Paola,[4] Jacqui Troughton,[8] Simon Walker,[5] Thomas Yates[2,6] and James King[1,2]

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Disclosure of interests

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research, or similar, and contains language which may offend some readers.

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Abstract

A multicomponent structured health behaviour intervention to improve physical activity in long-distance HGV drivers: the SHIFT cluster RCT

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Background: Long-distance heavy goods vehicle drivers are exposed to a multitude of risk factors associated with their occupation. The working environment of heavy goods vehicle drivers provides limited opportunities for a healthy lifestyle, and, consequently, heavy goods vehicle drivers exhibit higher than nationally representative rates of obesity and obesity-related comorbidities, and are underserved in terms of health promotion initiatives.

Objective: The aim of this trial was to test the effectiveness and cost-effectiveness of the multicomponent Structured Health Intervention For Truckers (SHIFT) programme, compared with usual care, at both 6 months and 16–18 months.

Design: A two-arm cluster randomised controlled trial, including a cost-effectiveness analysis and process evaluation.

Setting: Transport depots throughout the Midlands region of the UK.

Participants: Heavy goods vehicle drivers.

Intervention: The 6-month SHIFT programme included a group-based interactive 6-hour education session, health coach support and equipment provision [including a Fitbit® (Fitbit Inc., San Francisco, CA, US) and resistance bands/balls to facilitate a 'cab workout']. Clusters were randomised following baseline measurements to either the SHIFT arm or the control arm.

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Main outcome measures: Outcome measures were assessed at baseline, with follow-up assessments occurring at both 6 months and 16–18 months. The primary outcome was device-measured physical activity, expressed as mean steps per day, at 6-month follow-up. Secondary outcomes included device-measured sitting, standing, stepping, physical activity and sleep time (on any day, workdays and non-workdays), along with adiposity, biochemical measures, diet, blood pressure, psychophysiological reactivity, cognitive function, functional fitness, mental well-being, musculoskeletal symptoms and work-related psychosocial variables. Cost-effectiveness and process evaluation data were collected.

Results: A total of 382 participants (mean ± standard deviation age: 48.4 ± 9.4 years; mean ± standard deviation body mass index: 30.4 kg/m^2 ± 5.1 kg/m^2; 99% male) were recruited across 25 clusters. Participants were randomised (at the cluster level) to either the SHIFT arm (12 clusters, $n = 183$) or the control arm (13 clusters, $n = 199$). At 6 months, 209 (54.7%) participants provided primary outcome data. Significant differences in mean daily steps were found between arms, with participants in the SHIFT arm accumulating 1008 more steps per day than participants in the control arm (95% confidence interval 145 to 1871 steps; $p = 0.022$), which was largely driven by the maintenance of physical activity levels in the SHIFT arm and a decline in physical activity levels in the control arm. Favourable differences at 6 months were also seen in the SHIFT arm, relative to the control arm, in time spent sitting, standing and stepping, and time in moderate or vigorous activity. No differences between arms were observed at 16–18 months' follow-up. No differences were observed between arms in the other secondary outcomes at either follow-up (i.e. 6 months and 16–18 months). The process evaluation demonstrated that the intervention was well received by participants and that the intervention reportedly had a positive impact on their health behaviours. The average total cost of delivering the SHIFT programme was £369.57 per driver, and resulting quality-adjusted life-years were similar across trial arms (SHIFT arm: 1.22, 95% confidence interval 1.19 to 1.25; control arm: 1.25, 95% confidence interval 1.22 to 1.27).

Limitations: A higher (31.4%) than anticipated loss to follow-up was experienced at 6 months, with fewer (54.7%) participants providing valid primary outcome data at 6 months. The COVID-19 pandemic presents a major confounding factor, which limits our ability to draw firm conclusions regarding the sustainability of the SHIFT programme.

Conclusion: The SHIFT programme had a degree of success in positively impacting physical activity levels and reducing sitting time in heavy goods vehicle drivers at 6-months; however, these differences were not maintained at 16–18 months.

Future work: Further work involving stakeholder engagement is needed to refine the content of the programme, based on current findings, followed by the translation of the SHIFT programme into a scalable driver training resource.

Trial registration: This trial is registered as ISRCTN10483894.

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List of supplementary material

Report Supplementary Material 1 Baseline case report form

Report Supplementary Material 2 Final follow-up case report form

Report Supplementary Material 3 Trial statistical analysis plan

Report Supplementary Material 4 Trial health economics analysis plan

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/PNOY9785).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

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List of abbreviations

24/7	24 hours a day, 7 days a week
app	application
AUDIT	Alcohol Use Disorders Identification Test
BMI	body mass index
CI	confidence interval
CILT	Chartered Institute of Logistics and Transport
CONSORT	Consolidated Standards of Reporting Trials
CPC	Certificate of Professional Competence
CRF	case report form
CVD	cardiovascular disease
DESMOND	Diabetes Education and Self-Management for Ongoing and Newly Diagnosed
EQ-5D	EuroQol-5 Dimensions
EQ-5D-3L	EuroQol-5 Dimensions, three-level version
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
FFQ	Food Frequency Questionnaire
GP	general practitioner
HADS	Hospital Anxiety and Depression Scale
HbA_{1c}	glycated haemoglobin
HDL-C	high-density lipoprotein cholesterol
HGV	heavy goods vehicle
HRQoL	health-related quality of life
ICC	intraclass correlation coefficient
ICER	incremental cost-effectiveness ratio
INHB	incremental net health benefit
IQR	interquartile range
ITT	intention to treat
LDL-C	low-density lipoprotein cholesterol
MEQ	Morningness–Eveningness Questionnaire
MOVES	Model for estimating the Outcomes and Values in the Economics of Sport
MRC	Medical Research Council
MVPA	moderate or vigorous physical activity
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
OFER	Occupational Fatigue Exhaustion Recovery
PPI	public and patient involvement
QALY	quality-adjusted life-year
QRISK3	Cardiovascular Risk Score
RCT	randomised controlled trial
SAP	statistical analysis plan
SCT	social cognitive theory
SD	standard deviation
SHIFT	Structured Health Intervention For Truckers
SMART	specific, measurable, achievable, relevant, time bound
TSC	Trial Steering Committee

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Plain English summary

Long-distance heavy goods vehicle drivers are faced with many barriers when it comes to leading a healthy lifestyle. The working environment of long-distance heavy goods vehicle drivers means that they spend long periods of time sitting, have limited opportunities to be active and tend to make unhealthy food choices. Given that the well-being of heavy goods vehicle drivers can directly affect the safety of other road users, as well as their own, strategies are needed to improve their health. The Structured Health Intervention For Truckers (SHIFT) programme is designed to increase physical activity, improve diet and reduce sitting (during non-work time) in heavy goods vehicle drivers. The programme includes a 6-hour interactive education session, use of a Fitbit® (Fitbit Inc., San Francisco, CA, US) to monitor steps, health-coach support and equipment to carry out stretching exercises while in the cab.

To test whether or not the intervention worked, we recruited 382 long-distance heavy goods vehicle drivers from 25 transport sites. Drivers from 12 sites received the intervention, and drivers from 13 sites carried on as usual (forming the control group). Data were collected from both groups at the start of the study, immediately following the 6-month intervention and at 16–18 months from the beginning of the study. We measured drivers' daily step counts and sitting time using a small device worn on the thigh. We measured drivers' sleep and took several health measures. We also spoke to drivers about their thoughts on the intervention.

Following the 6-month intervention, our results revealed that participants receiving the intervention accumulated 1008 more steps daily (i.e. equivalent to $\approx$ 10 minutes of walking) than participants in the control group. This difference was largely driven by the maintenance of physical activity levels in the SHIFT group and a decline in physical activity in the control group. The intervention was well received. Drivers reported that the SHIFT programme had a positive impact on their health behaviours; however, the differences in activity levels between groups were not maintained at 16–18 months.

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Scientific summary

Background

Owing 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. The working environment of long-distance HGV drivers and their job demands (e.g. 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, contribute 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, higher rates of chronic diseases and reduced life expectancies in comparison with other occupational groups. Despite this, HGV drivers are currently underserved in terms of health promotion efforts.

We developed the Structured Health Intervention For Truckers (SHIFT) programme, which is a multicomponent theory-driven health behaviour intervention designed to promote positive lifestyle changes in relation to physical activity, diet and sitting in HGV drivers. The SHIFT intervention has been informed by extensive public and patient involvement, which has included drivers and relevant stakeholders. Initial pilot testing of our intervention delivery suggested that it led to potentially favourable increases in physical activity, as well as 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 with usual care, in a sample of long-distance HGV drivers at both 6 months and 16–18 months.

Primary objective

- To investigate the impact of the 6-month SHIFT programme, compared with 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 with usual care, at 6 months' follow-up on:
  - time spent in light physical activity and in moderate or vigorous physical activity (MVPA)
  - sitting time
  - measures of adiposity [i.e. body mass index (BMI), per cent body fat, waist–hip ratio, neck circumference]
  - cardiometabolic risk markers [i.e. glycated haemoglobin (HbA_{1c}), total cholesterol, high-density lipoprotein cholesterol (HDL-C) and low-density lipoprotein cholesterol (LDL-C)]
  - fruit and vegetable intake and dietary quality

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  - blood pressure
  - psychophysiological reactivity
  - sleep duration and quality
  - functional fitness (i.e. grip strength)
  - cognitive function
  - mental well-being (i.e. anxiety and depression symptoms, and social isolation)
  - work-related psychosocial variables (i.e. work engagement, job performance and satisfaction, occupational fatigue, presenteeism, sickness absence and driving-related safety behaviour)
  - health-related quality of life (HRQoL)
  - health-related resource use (i.e. general practitioner visits).

- To investigate the longer-term impact of the SHIFT programme, compared with usual care, at 16–18 months' follow-up on:

  - steps per day
  - time spent in light physical activity and in MVPA
  - sitting time
  - fruit and vegetable intake and dietary quality
  - sleep
  - mental well-being (i.e. anxiety and depression symptoms, and social isolation)
  - work-related psychosocial variables (i.e. work engagement, job performance and satisfaction, occupational fatigue, presenteeism, sickness absence and driving-related safety behaviour)
  - HRQoL.

- 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 [i.e. DHL Supply Chain (Milton Keynes, UK)]. DHL Supply Chain agreed to provide the setting and gave access to their drivers and sites for our 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 our exclusion criteria. Drivers were excluded from the trial if they were suffering from clinically diagnosed cardiovascular disease, had mobility limitations that prevented them from increasing their daily activity levels, were suffering from haemophilia or any blood-borne virus, or were 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

To detect a difference in mean daily step counts of 1500 steps per day between the intervention and control groups [assuming a standard deviation (SD) of 2919 steps/day, 80% power, a two-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. The sample size was inflated by 30% to account for loss to follow-up/non-compliance

to the activPAL™ (PAL Technologies Ltd, Glasgow, UK). In addition, the number of clusters was inflated by two to allow for whole-cluster drop out. Therefore, we 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 that is designed to target behaviour changes in physical activity, diet and sitting in HGV drivers. The 6-month intervention, grounded within social cognitive theory for behaviour change, consists of a group-based (4–6 participants) 6-hour structured education session, tailored for HGV drivers and 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® (Fitbit Inc., San Francisco, CA, US) (to monitor daily step counts and set goals), 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.

The 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 participants in the intervention worksites, at the same time points and received the same health feedback 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 (i.e. the SHIFT arm and the control arm). A second set of identical measurements took place at the 6-month follow-up. The 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 the 16- to 18-month follow-up. The final follow-up measures were delayed because of the COVID-19 pandemic (the measures were initially planned for a 12-month follow-up) and consisted of predominantly self-report measures because of restrictions in face-to-face data collection. Owing to the pandemic, the primary outcome was also changed from assessment at 12 months to assessment at 6 months.

Primary outcome

The primary outcome was device-measured physical activity, expressed as mean steps per 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, in prolonged sitting bouts, in light intensity physical activity and in MVPA, and the number of sit-to-stand transitions. Variables were summarised for three 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 (Activinsights, Kimbolton, UK) wrist-worn accelerometer was used to provide a measure of sleep duration and quality. The data from the accelerometer were summarised using the same time periods (i.e. daily, workdays, non-workdays) as were applied to the activPAL data. Data were collected on adiposity (i.e. BMI, fat percentage, waist circumference), and finger-prick blood samples were collected to measure HbA_{1c}, cholesterol (i.e. HDL-C, LDL-C 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 (i.e. grip strength) were also assessed. Further self-report measures

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collected at each assessment, via a questionnaire booklet, included mental well-being, 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 HRQoL 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. The costs and 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 1 month after their baseline and 6-month assessments. In addition, following completion of the trial, focus groups and semistructured interviews took place with participants and managers.

Results

Recruitment

A total of 382 participants (mean ± SD age: 48.4 ± 9.4 years; BMI: 30.4 kg/m^2 ± 5.1 kg/m^2; 99% male) were recruited across 25 clusters and randomised (at the cluster level) into either the SHIFT arm (12 clusters, $n = 183$) or the control arm (13 clusters, $n = 199$). An additional site was recruited because one internal pilot site had restrictions on when participants could wear the activPAL and GENEActiv accelerometers. The 25 transport sites operated within the transport, retail, hospitality, health-care, pharmaceutical, construction, oil and gas, and automotive industries, and the average age of our sample and our sex split match the average age of HGV drivers and the sex proportions seen nationally. Between baseline and 6-month follow-up, two sites (one intervention site and one control site) dropped out of the trial. For both sites, this was because of site closures due to the collapse of the contracting companies. At baseline, participants accumulated 8583 [interquartile range (IQR) 6922–10,696] steps per day and spent 11 hours (SD 95 minutes) per day sitting, 10 (IQR 6–19) minutes per day in MVPA and 99 (IQR 82–123) minutes per day in light physical activity. Forty-two per cent 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 (54.7%) participants for the primary outcome analysis. At 6 months, significant differences in mean daily steps were found between groups, with the SHIFT group accumulating 1008 (54.7%) more steps per day than the control group [95% confidence interval (CI) 145 to 1871 steps; $p = 0.022$]. This difference was largely driven by the maintenance of physical activity levels in the SHIFT group and a decline in physical activity in the control group. 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 minutes/day, 95% CI −43 to −6 minutes/day), standing (14 minutes/day, 95% CI 2 to 26 minutes/day) and stepping (11 minutes/day, 95% CI 2 to 21 minutes/day), and time in

MVPA (6 minutes/day, 95% CI 0.3 to 11 minutes/day). 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 (i.e. 6 months or 16–18 months).

Economic evaluation

The average total cost of delivering the SHIFT programme was £369.57 per driver, and resulting quality-adjusted life-years were similar across trial arms (SHIFT arm: 1.22, 95% CI 1.19 to 1.25; control arm: 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 of 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. Therefore, 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 to be 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 predominantly making positive behaviour changes on non-workdays.

Conclusions

The SHIFT programme may have had a degree of success in positively affecting physical activity levels and reducing sitting time in HGV drivers at 6 months; however, these differences were not maintained at 16–18 months. Owing to the nature and demands of the 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 physical activity levels 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 a sense of necessity for the SHIFT programme 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. Although the longer-term impact of the SHIFT programme is unclear, the programme (with refinement) has the potential to be incorporated into driver training courses to promote activity in this essential and underserved occupational group.

Trial registration

This trial is registered as ISRCTN10483894.

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Chapter 1 Introduction

Background and rationale

Truck driving is essential to the economy. Approximately 75% of all goods delivered in the UK are transported via road freight, with the road freight transport sector contributing over £13B to the UK economy.[1] The UK logistics sector currently employs just under 300,000 heavy goods vehicle (HGV) drivers, with a HGV being defined as having a gross vehicle weight between 3.5 and 44 tonnes.[1] Owing to the nature of their occupation, long-distance 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.[2,3] The working environment of long-distance HGV drivers and their job demands (i.e. 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.[4]

Our own systematic review-level evidence has shown that HGV drivers globally exhibit high levels of physical inactivity and accumulate large amounts of sedentary (sitting) behaviour. HGV drivers also tend to make poor dietary choices, have high alcohol intakes and have a high prevalence of smoking.[4] Furthermore, long and variable working hours, including shift work, contributes to sleep deprivation,[5,6] and this can lead to metabolic disturbances and further promote the uptake of unhealthy behavioural choices.[3,5–8] The isolated nature of driving a HGV can result in a lack of peer social support and poor mental health.[9,10] Within this occupational group, adverse mental health conditions can be exacerbated by intense job demands and low levels of perceived job control, as a result of chronic time pressures, compounded by tight delivery schedules and traffic conditions.[11] Indeed, our systematic review identified high levels of mental ill-health within HGV drivers.[4]

As a result of HGV drivers' working environment and poor health behaviours, review-level evidence has demonstrated that they nationally and internationally exhibit high rates of obesity and cardiometabolic risk factors.[4,12–14] In addition to elevating their risk of cardiovascular disease (CVD) and type 2 diabetes, the incidence of obesity-related comorbidities in HGV drivers is increasing, suggesting that the trajectory of HGV driver health is declining.[2,3,15–18] These factors likely culminate in HGV drivers having an increased risk of accidents, higher rates of chronic diseases and reduced life expectancies in comparison with other occupational groups.[2,19–24] Despite this, HGV drivers are currently underserved in terms of health promotion efforts.[25]

To compound the high-risk health profile observed in HGV drivers nationally and internationally,[4,12–14] within the UK's logistics sector, HGV drivers are an ageing workforce, with an average age of 48 years.[26] A report prepared by an All Party Parliamentary Group for Freight Transport has highlighted the challenges that the industry is facing with an ageing workforce, and the health impact of this ageing, at-risk workforce driving such large and potentially dangerous vehicles.[27]

The UK's logistics sector is also experiencing a serious shortfall in HGV drivers, which has recently been described as reaching a 'crisis point', with this shortage rising from 60,000 drivers in 2015[28] to an estimated 100,000 drivers in 2021.[29] Factors responsible for the sharp decrease in driver numbers include the uncertainties around Brexit, with a number of European drivers returning home; the COVID-19 pandemic, with the resulting national lockdowns further encouraging international drivers to return to their home countries and seeing HGV licence testing suspended; and a large number of drivers retiring.[29] Barriers to driver recruitment have been reported to include a lack of roadside facilities, medical concerns and long working hours.[27] 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

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risks and health behaviours.[27] Indeed, now more than ever, the government and sector urgently need to address working conditions and the poor health profile of this ageing workforce to attract employees to the role. Driver recruitment and a prioritisation of driver health is essential to combat the current challenges seen in maintaining critical supply chains.

A systematic review[25] of health promotion interventions in HGV drivers, including only eight studies, observed that the interventions generally led to improvements in health and health-related behaviours. However, the review[25] concluded that the strength of the evidence was limited because of poor study designs, no control groups, small samples and no or limited follow-up periods.[25] Since the publication of the systematic review,[25] studies have examined the impact of a weight loss intervention in US HGV drivers[30] and a smartphone application (app) on physical activity and diet in Australian HGV drivers.[31] Although positive findings were observed, the studies were limited by having relatively small samples and no comparison groups. It has been suggested that health and well-being programmes that focus on health education and improvements in health literacy should be implemented and prioritised across the logistics industry.[4] For example, international research has shown that HGV drivers with higher educational levels are more likely to have higher levels of physical activity[32] and lower body mass index (BMI)[33] than HGV drivers with lower levels of education. Where they exist, health and well-being programmes within the logistics industry have been considered to have the potential to have a positive impact on employee health[4,25] and, in turn, potentially benefit employers through increased employee retention and reductions in health-care costs.[4] Furthermore, health promotion initiatives targeting HGV drivers will likely have a broader public health impact through improving road safety for all users.[25] Research in the USA, for example, has shown that HGV drivers with obesity were 55% more likely to have an accident than normal-weight drivers.[34] In the UK, although only accounting for 12% of all vehicle traffic on motorways, 41% of accident-related fatalities involved HGVs in 2017,[35] highlighting the wider public safety impact of health improvement programmes in this at-risk occupational group.

Development of the SHIFT programme

We developed the Structured Health Intervention For Truckers (SHIFT) programme, which is 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 SHIFT intervention has been informed by extensive public and patient involvement (PPI), which has included drivers and relevant stakeholders, a qualitative study exploring the perceived barriers to healthy lifestyle behaviours in drivers,[7] an observational study ($n = 157$) exploring lifestyle health-related behaviours in HGV drivers and markers of health,[36] and a pre–post pilot intervention ($n = 57$)[37] with a full process evaluation.[38] Initial pilot testing of our intervention delivery, over a 3-month period, revealed potentially favourable increases in physical activity, with 81% of the sample increasing their daily step counts by an average of 1646 [standard deviation (SD) 2156] steps per day. Significant increases in fruit and vegetable intake were also observed (4.5 vs. 5.4 portions/day), along with favourable changes in markers of cardiometabolic health.[37]

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. As the intervention was administered within the worksite setting, a cluster RCT design was employed with delivery sites/depots (i.e. individual worksites) as the unit of allocation to minimise any potential contamination occurring between intervention and control participants.

Aim and objectives

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

Primary objective

- To investigate the impact of the 6-month SHIFT programme, compared with 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 with usual care, at 6 months' follow-up on:
  - time spent in light physical activity and moderate or vigorous physical activity (MVPA)
  - sitting time
  - measures of adiposity (i.e. BMI, per cent body fat, waist–hip ratio, neck circumference)
  - cardiometabolic risk markers [i.e. glycated haemoglobin (HbA_{1c}), 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 (i.e. grip strength)
  - cognitive function
  - mental well-being (i.e. anxiety and depression symptoms, and social isolation)
  - work-related psychosocial variables (i.e. work engagement, job performance and satisfaction, occupational fatigue, presenteeism, sickness absence and driving-related safety behaviour)
  - health-related quality of life (HRQoL)
  - health-related resource use [i.e. general practitioner (GP) visits].
- To investigate the longer-term impact of the SHIFT programme, compared with usual care, at 16–18 months' follow-up on:
  - steps per day
  - time spent in light physical activity and in MVPA
  - sitting time
  - fruit and vegetable intake and dietary quality
  - sleep
  - mental well-being (i.e. anxiety and depression symptoms, and social isolation)
  - work-related psychosocial variables (i.e. work engagement, job performance and satisfaction, occupational fatigue, presenteeism, sickness absence and driving-related safety behaviour)
  - HRQoL.
- 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.

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Chapter 2 Study design and methods

This chapter summarises the study protocol for this RCT as originally funded. Some of the material, including tables and figures, has already appeared in Clemes *et al.*[39] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The text below includes minor additions and formatting changes to the original text.

Study design and setting

The SHIFT trial was a two-armed cluster RCT, which incorporated an internal pilot phase and included a mixed-methods process and economic evaluations. The trial was registered with the International Standard Randomised Controlled Trial Number registry before participant recruitment commenced (URL: www.isrctn.com/ISRCTN10483894; accessed 13 July 2021). The trial protocol paper was published in November 2019,[39] and protocol revisions can be accessed via the National Institute for Health and Care Research (NIHR) Journals Library (URL: www.journalslibrary.nihr.ac.uk/programmes/phr/1519042/; accessed 13 July 2021). A summary of the amendments to the original protocol are listed in *Table 1*.

TABLE 1 A summary of the amendments made to the original protocol[39]

Amendment number	Date	Description
1	8 November 2018	Owing to one pilot site [a BP (London, UK) site] not allowing participants to wear the accelerometers during working hours for health and safety reasons and, therefore, limiting the collection of the primary outcome measure [i.e. activPAL™ (PAL Technologies Ltd, Glasgow, UK)-determined steps/day] to non-working hours only, the TSC approved the recruitment of an additional site in the main trial phase. The total site recruitment target changed from 24 to 25
2	5 April 2019	Owing to the time needed to undertake baseline measurements in the main trial phase, sites (i.e. clusters) were randomised into the study arms in blocks of three following completion of baseline measures, as opposed to randomising all sites after all baseline measures were completed
3	13 July 2020	Owing to COVID-19, face-to-face 12-month follow-up measures were no longer viable in the majority of sites. The primary outcome was assessed following completion of the 6-month intervention, with the sustainability of the intervention assessed by the self-report questionnaire-based measures at approximately 10–12 months following intervention completion The process evaluation conducted with sites within the main trial phase involved telephone interviews as opposed to face-to-face interviews and/or focus groups An additional 'COVID-19' online questionnaire was distributed to participants in May–June 2020 The trial was extended by 15 months because of delays due to COVID-19

TSC, Trial Steering Committee.

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The trial took place within the worksite setting of a major international logistics and transport company, DHL Supply Chain (Milton Keynes, UK). DHL Supply Chain agreed to provide the setting and gave access to their drivers and sites for our research. Transport sites/depots formed individual clusters. Following the completion of baseline measurements, clusters were randomised 1 : 1 to receive either the SHIFT programme or to continue with usual practice (i.e. the control condition). Outcome measurements were undertaken at baseline and at 6 months' follow-up. A third set of outcome measures were originally planned to take place 6 months following completion of the intervention (i.e. 12 months' follow-up); however, owing to the COVID-19 pandemic, these measurements were unable to be completed within this time frame for the majority of sites. As a result, the primary outcome was assessed following completion of the 6-month intervention (at 6 months' follow-up) to mitigate potential confounding factors associated with the pandemic, along with a threat of increased rates of loss to follow-up caused by drivers on furlough/isolating or drivers being re-deployed. The easing of government COVID-19 restrictions enabled a range of secondary outcome measures to be collected approximately 10–12 months following completion of the intervention (i.e. 16–18 months' follow-up), informing an assessment of the potential longer-term impact of the intervention. The study methods are reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) extension statement for cluster RCTs.[40]

Ethics approval

The trial was approved by the Loughborough University Ethics Approvals (Human Participants) Sub-Committee (reference R17-P063). Loughborough University (Loughborough, UK) sponsored the study.

Cluster recruitment and eligibility

The health and safety director of DHL Supply Chain, UK and Ireland, nominated individual DHL Supply Chain transport sites/depots for participation in this study. Sites were eligible for participation if they contained at least 20 long-distance HGV drivers and were located within a 2-hour drive of Loughborough University. Depots containing HGV drivers who made many delivery stops, for example drivers who delivered consumer goods to domestic customers throughout the day, were excluded. During enrolment into the study, transport managers were informed that their site would have a 50% chance of being randomised to the current practice control condition.

Participant recruitment

Within the nominated sites, transport managers were provided with recruitment material to promote the study. Posters advertising the study were displayed in participating sites for up to 4 weeks prior to the scheduling of baseline measurements. In addition, all drivers within participating sites received a letter and a participant information sheet informing them of the study. Following the distribution of the marketing material (e.g. posters and participant information sheets), members of the research team visited each site for at least 1 day. During these visits, the research team had stands in the lobby area with posters showcasing the study, along with example materials used in the SHIFT education session (see *The SHIFT programme*) and example devices used as part of the outcome measures (e.g. a grip strength dynamometer). Interested drivers could ask the research team any questions about the study before providing a member of the research team their name, if they were interested in taking part. On completion of these visits, the researchers provided a list of the drivers' names who had signed up to the trial to their transport manager, who then scheduled a time for participating drivers within their sites to attend the baseline (and follow-up) measurements. The baseline measurements were scheduled for at least 1 week after the site recruitment visits to enable drivers to have sufficient time to fully decide on their willingness to participate. All outcome measurements were undertaken in a private

room at each participating DHL Supply Chain site. In the UK logistics industry, 1% of HGV drivers are women.[41] At the time of participant recruitment, the proportion of female HGV drivers employed by DHL Supply Chain reflected this national average. All drivers (male and female) at participating sites were invited to participate in this study.

Participant eligibility

All HGV drivers within participating sites were eligible to participate, unless they met any of our exclusion criteria. Drivers were excluded from the trial if they were suffering from clinically diagnosed CVD, had mobility limitations that prevented them from increasing their daily activity levels, were suffering from haemophilia or any blood-borne virus, or were unable to provide written informed consent.

Informed consent

During the baseline measurement session, the study details were verbally reiterated to potential participants, including full details of the study procedures. The expectations of participating in the trial were explained, along with participants' right to withdraw. This information was provided by a member of the research team who was suitably qualified and who was authorised to do so by the principal investigator. Written informed consent was obtained prior to any measurements being taken at baseline, and at each follow-up assessment.

Trial allocation arms

The SHIFT programme

The SHIFT programme is a multicomponent lifestyle–behaviour intervention that is designed to target behaviour changes in physical activity, diet and sitting in HGV drivers. The 6-month intervention, grounded within social cognitive theory (SCT) for behaviour change,[42] consists of a group-based (4–6 participants) 6-hour structured education session, tailored for HGV drivers and delivered by two trained educators. The education session includes information about physical activity, diet and sitting, and details risk factors for type 2 diabetes and CVD. The educational component is founded on the approach used in the award-winning suite of DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed) programmes, including the PREPARE (Prediabetes Risk Education and Physical Activity Recommendation and Encouragement)[43] and Let's Prevent Diabetes programmes,[44] created by researchers at the Leicester Diabetes Centre (Leicester, UK) and used throughout the NHS,[45] while being tailored to meet the needs of HGV drivers.[7] During the education session, participants are not 'taught' in a formal way but are supported to work out knowledge through group discussions. Participants are also encouraged to develop individual goals and plans based on detailed individual feedback received during their health assessments (see *Outcome measurements*) to achieve over the 6-month intervention period. The education session is supported by specially developed resources and participant support materials for HGV drivers. The education session includes the discussion of feasible strategies for participants to increase their physical activity, improve their diet and reduce their sitting time (when not driving) during working and non-working hours. The content of the educational session is summarised in *Table 2*.

During the education session, participants were provided with a Fitbit Charge 2 (Fitbit, Inc., San Francisco, CA, USA) activity tracker. Participants were encouraged to use the Fitbit activity tracker to set goals (agreed at the session) and gradually increase their physical activity, predominantly through walking-based activity. The Fitbit activity tracker and associated smartphone app provided participants with information on their daily step counts and was used as a tool for self-monitoring and self-regulation. Physical activity tracking using step counters (traditionally pedometers) has been associated with significant reductions

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TABLE 2 Outline of the educational component of the SHIFT programme

Section name	Theoretical underpinning	Main aims and educator activities	Duration (minutes)
Welcome and introduction		Participants are introduced to the SHIFT programme and are made aware of both the content and style of the session	10
Driver story	Dual process theory[46] and common sense model[47]	Participants are asked about their beliefs about how being a HGV driver can affect health, the causes of these health problems and controllability of these problems	30
Risks and health problems	Dual process theory,[46] common sense model[47] and social learning theory[48]	The facilitator uses participant stories to help participants work out why they may be at risk of future health problems, and what to do to reduce/manage risk	55
Physical activity	Dual process theory[46] and social learning theory[48]	The facilitator supports participants to develop knowledge and skills to support confidence, to increase personal activity levels and to set personal goals, which can be self-monitored through the use of a Fitbit® (Fitbit Inc., San Francisco, CA, USA) Introduction and practical demonstration of the 'cab workout'	80
Depression, sleeping, smoking	Dual process theory[46] and social learning theory[48]	The facilitator supports participants to develop strategies to manage depression, poor sleep and smoking	30
Food choices	Dual process theory[46] and social learning theory[48]	The facilitator supports participants to develop knowledge and skills for food choices to reduce cardiovascular risk factors and to improve overall health	90
Self-management plan	Dual process theory[46] and social learning theory[48]	Participants are supported in developing personal self-management plans	15
Questions	Common sense model[47] and social learning theory[48]	The facilitator checks that all questions raised by participants throughout the programme have been answered and understood	5
What happens next	Social learning theory[48]	Follow-up care is outlined	5

in BMI and blood pressure, with interventions incorporating goal-setting being the most effective.[49] Participants were provided with instructions on how to link their Fitbit account to an online monitoring system (Fitabase, Small Steps Labs LLC, San Diego, CA, USA). Participants were encouraged to link their account to Fitabase and to regularly upload their Fitbit data from their device to their mobile phone via Bluetooth. When participants sync their Fitbit through the Fitbit app, their step count data are automatically updated on the Fitabase website. Participants' data on the Fitabase website were accessible to only two members of the research team, who used the step count data to provide participants with individually tailored step count challenges throughout the 6-month intervention period.

The education session adopted the promotion of the 'small changes' philosophy, using the specific, measurable, achievable, relevant, time bound (SMART) principle[50] to encourage participants to gradually build-up their daily activity levels, within the confines of their occupation, to meet the UK physical activity guidelines.[51] For example, participants were encouraged to establish their own personalised action plan, which may have included making dietary improvements in addition to increases in physical

activity, with SMART goals throughout the 6-month intervention. 'Step count challenges' were run every 6 weeks throughout the 6-month intervention and were facilitated by members of the research team via a text messaging service (TextMagic™, TextMagic Ltd, Cambridge, UK).

A 'cab workout' was introduced and practised at the education session, and participants were provided with resistance bands and balls, and grip strength dynamometers to take away. Participants were encouraged to undertake the cab workout during breaks when they were not permitted to leave their vehicle. Participants were able to keep the intervention tools beyond the 6-month intervention period; however, the step count challenges, as well as the supportive text messages sent by members of the research team, ended after the 6-month intervention period. A logic model detailing the underlying theory behind the intervention components is shown in *Figure 1*.

The structured education session was delivered by trained members of the research team in collaboration with trained personnel from DHL Supply Chain. Individuals from DHL Supply Chain co-delivering the education session were predominantly HGV drivers who also acted as driver trainers in each site as part of their role. The 'driver trainers' were trained by specialist educators from the Leicester Diabetes Centre and mentored by trained members of the research team. The education sessions took place within appropriate training rooms within the intervention depots. Personnel co-delivering the education sessions in each intervention depot were also trained to act as local champions, which has been shown to enhance the effectiveness of worksite physical activity interventions.[52] They provided ongoing health coach support, along with members of the research team (who provided support via the text messaging service), to intervention participants (during the 6-month intervention period).

The control arm

Sites assigned to the control arm (i.e. usual practice) were asked to continue with their usual-practice conditions. Participants in the control sites 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 participants in the intervention worksites, at the same time points, and received the same health feedback immediately following their health assessments (i.e. outcome measurements).

Outcome measurements

This section describes the outcome measurements, as explained in the original trial protocol.[39] The outcome measurements were undertaken as intended at baseline and following the completion of the 6-month intervention for all sites bar one intervention site, where these measurements had been due to take place the same week as the first national lockdown commenced. A change in protocol was required for the final set of measurements, originally intended to take place 6 months following completion of the intervention (i.e. 12 months' follow-up). The protocol for these measurements is described below.

Protocol for the outcome measurements assessed at baseline and at 6 months' follow-up

Baseline measurements took place prior to randomisation of the sites into the two study arms. A second set of identical measurements occurred at 6 months' follow-up. The two sets of measurements were undertaken in suitable rooms within participating DHL Supply Chain sites by trained researchers and lasted approximately 2 hours per participant. Participants were scheduled to attend these measurements, during their working time by their transport manager either before or following their driving shift.

Participants completed a range of self-report questionnaires and had a series of physiological health assessments taken (described below) at baseline and immediately following the completion of the 6-month intervention. Participants were also issued with two devices [an activPAL and a GENEActiv

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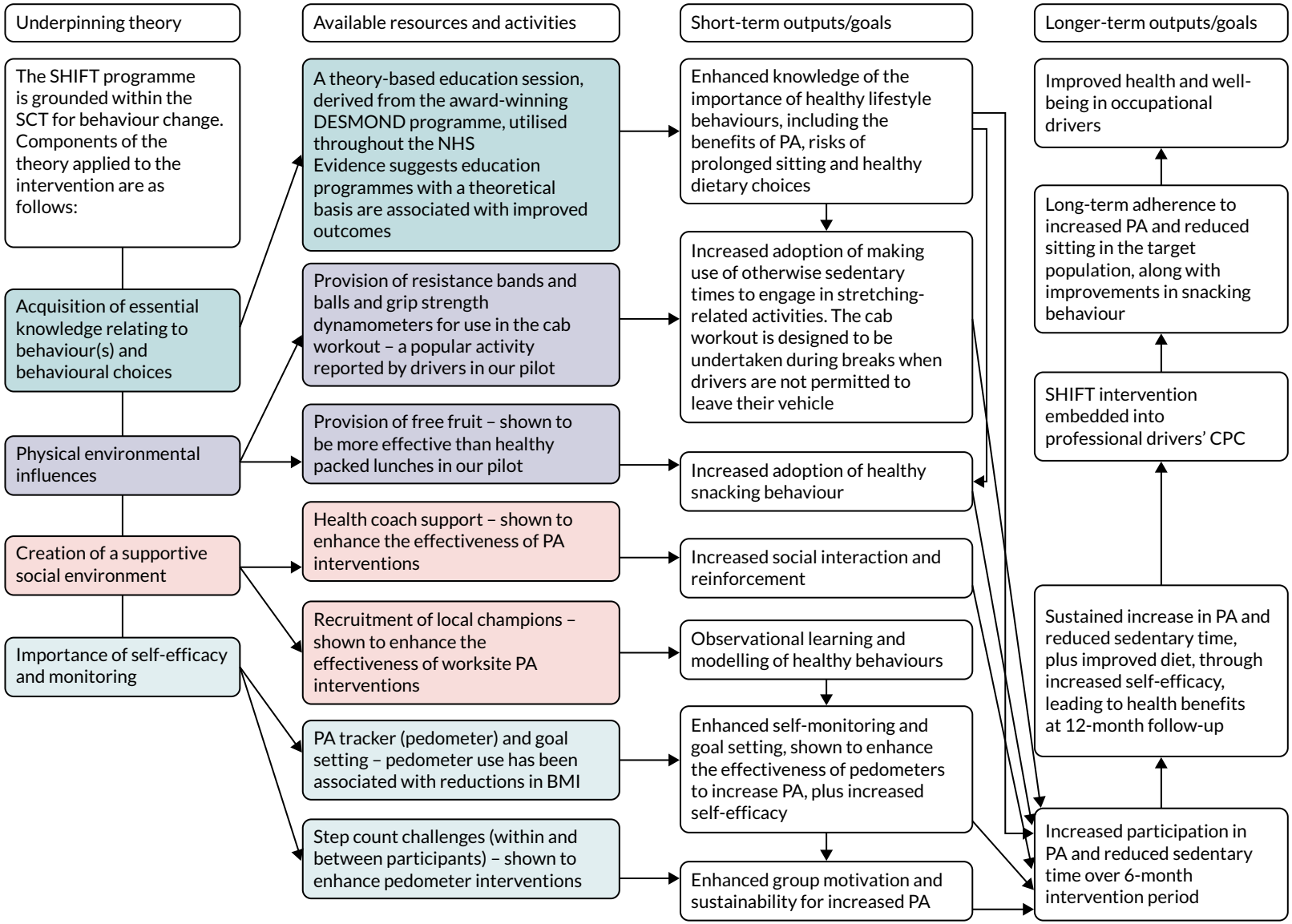

FIGURE 1 A logic model for the SHIFT programme. CPC, Certificate of Professional Competence; PA, physical activity.

(Activinsights, Kimbolton, UK) accelerometer] to wear over a period of 8 days following the measurement sessions. Participants received detailed feedback on their physiological health assessment measures during these two measurement sessions. If a potential health issue was evident during the measurements, such as undiagnosed hypertension or high cholesterol levels, then participants were advised to visit their GP for further checks. A standard referral letter was provided for participants to give to their GP, which summarised the findings from our point-of-care (i.e. blood markers) and automated (i.e. blood pressure) measures.

Protocol for the 16- to 18-month follow-up assessments (undertaken during the COVID-19 pandemic)

A third set of outcome measures were originally planned to take place 6 months following completion of the intervention (i.e. a 12-month follow-up); however, owing to the COVID-19 pandemic, these measurements were unable to be completed within this time frame. The easing of government COVID-19 restrictions enabled a range of secondary outcome measures to be collected at 16–18 months (approximately 10–12 months following completion of the intervention). Owing to restrictions on external visitors to DHL Supply Chain sites throughout the pandemic, face-to-face physiological measurements were not able to be conducted at the final follow-up phase. Instead, the case report form (CRF), which contained a series of self-report questionnaires and recording sheets for the physiological measures used during data collection at baseline and immediately following the intervention (see *Report Supplementary Material 1*), was modified into a self-administered questionnaire booklet (see *Report Supplementary Material 2*).

Individual participant packs were prepared, which contained an instruction leaflet, a questionnaire booklet, a consent form, an activPAL and logbook, and a return envelope. On prior arrangement with transport managers, a member of the research team delivered the participant packs to each site. The transport managers distributed the packs to participating drivers, who completed the relevant paperwork in their own time and, on request, wore the activPAL for a period of 8 continuous days. After this 8-day period, participants returned their activPAL and their completed logbook, questionnaire booklet and consent form in a sealed envelope to a collection point within their site. Once all packs were returned, the packs were collected from the site by a member of the research team. This protocol was also followed for the one remaining intervention site for its 6-month follow-up (which had initially been due to take place at the beginning of the first national lockdown and, therefore, was unable to be completed as intended). *Table 3* summarises all measurements collected at the three time points during the trial. All measurements are described in detail in the following sections.

Primary outcome

The primary outcome was device-measured physical activity, expressed as average steps per day, at the 6-month follow-up (originally intended to be measured at 6 months following completion of the intervention, i.e. at 12 months). Physical activity was measured using the activPAL micro accelerometer, which provides a valid measure of walking and posture (i.e. sitting and standing) in adults.[53–55] As the physical activity component of the intervention predominantly included the promotion of walking-based activity, and as participants were provided with a Fitbit, which provided information on daily step counts and promoted goal-setting to increase daily steps, steps per day was chosen as the primary physical activity-related outcome.

We have previously observed[56] that the activPAL provides a more accurate measure of physical activity and sitting in occupational drivers than waist-worn accelerometers. As a further validity check within the current trial, we attached two activPAL devices to the underneath and lateral side of a driver's seat within a HGV cab for a 24-hour period. Vehicle movement times were extracted from the vehicle's tachograph data, and the activPAL outputs were assessed during these time periods. No accelerations were detected by the activPAL, confirming that the device is not affected by vehicle accelerations, the suspension system or movement of the driver's seat during driving time.

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TABLE 3 An overview of the information collected from all participants at each time point throughout the trial

Information collected	Time point		
	Baseline	6-month follow-up	16- to 18-month follow-up
Informed consent	✗	✗	✗
Physiological measures (i.e. blood pressure, height, weight, body composition, grip strength, finger-prick blood samples, waist, hip and neck circumferences)	✗	✗	Self-reported weight only
Cognitive function and psychophysiological reactivity	✗	✗	
Health Screen Questionnaire and medication use	✗	✗	Medication use only
Demographic information	✗	✗	✗
QRISK3	✗	✗	
Short-form FFQ	✗	✗	✗
Smoking and alcohol use	✗	✗	✗
Nordic Musculoskeletal Questionnaire	✗	✗	✗
HADS	✗	✗	✗
Social Isolation Short Form	✗	✗	✗
Utrecht Work Engagement Scale	✗	✗	✗
OFER scale	✗	✗	✗
Job satisfaction	✗	✗	✗
Job performance	✗	✗	✗
Self-reported sickness absence	✗	✗	✗
Self-reported presenteeism	✗	✗	✗
Work ability scale	✗	✗	✗
Work Demands Questionnaire	✗	✗	✗
Karolinska Sleepiness Scale	✗	✗	✗
MEQ	✗	✗	✗
Driver Safety Behaviour Questionnaire (self-reported)	✗	✗	✗
EQ-5D-5L	✗	✗	✗
Health-related resource use questionnaire	✗	✗	✗
activPAL	✗	✗	✗
GENEActiv	✗	✗	

EQ-5D-5L, EuroQol-5 Dimensions, five-level version; FFQ, Food Frequency Questionnaire; HADS, Hospital Anxiety and Depression Scale; MEQ, Morningness–Eveningness Questionnaire; OFER, Occupational Fatigue Exhaustion Recovery; QRISK3, Cardiovascular Risk Score.

During each measurement session, participants were provided with an activPAL and requested to wear the device continuously (i.e. 24 hours/day) for the following 8 days. The activPALs were initialised using the default manufacturer settings and recorded data at a sampling frequency of 20 Hz. The device was waterproofed using a nitrile sleeve and attached (by the participant) to the midline anterior aspect of their non-dominant thigh using Hypafix® transparent dressing (BSN medical, Hull, UK). Participants were provided with a daily logbook in which they were requested to record the times that they got into bed,

went to sleep, woke up and got out of bed. Participants were also requested to indicate on the logbook whether each day was a workday or a non-workday, and whether or not the activPAL had been removed for any periods (and, if so, the duration), throughout the 8-day period. Following the completion of the wear period, the activPALs and logbooks were returned to the site, where they were collated by a transport manager and, subsequently, collected by a member of the research team. activPALs were downloaded and visually checked for adequate wear, if a sufficient number of valid days of data were not obtained, then participants were contacted and asked if they would be willing to re-wear the device.

Secondary outcomes

A number of secondary outcomes were assessed during each measurement time point (see below).

Secondary activPAL variables

Sitting, standing, time in light intensity physical activity and time in MVPA were assessed using the activPAL micro accelerometer. The activPAL is regarded as the most accurate method of assessing sitting behaviour in free-living settings,[55,57,58] and is recommended for use in interventions when sitting is an outcome measure.[54] From the data provided by the device, the following variables were derived by calculating the average across the number of valid days provided during each measurement period:

- average total daily sitting time (minutes/day)
- average total daily sitting time (minutes/day) accumulated in prolonged bouts lasting ≥ 30 minutes
- average total daily standing time (minutes/day)
- average total daily stepping time (minutes/day)
- average number of transitions from sitting to an upright posture
- average total daily time in MVPA (minutes/day), calculated as total stepping time at a step cadence threshold of 100 steps per minute (in bouts lasting ≥ 1 minute)
- average total daily time in light physical activity (minutes/day)
- number of valid days
- average waking wear time (minutes/day)
- average percentage of the day spent sitting
- average percentage of the day spent standing
- average percentage of the day spent stepping
- average percentage of total sitting time spent in prolonged sitting bouts (lasting ≥ 30 minutes).

The variables below were calculated and summarised for three different time periods within each measurement period: (1) daily (i.e. across all waking hours on all valid days), (2) during workdays only and (3) during non-workdays only.

Anthropometry and markers of adiposity

Height was measured at baseline only, without shoes and to the nearest millimetre, using a portable stadiometer (seca 206, seca Ltd, Birmingham, UK). Weight (kg) and body fat percentage were assessed via bio-impedance analysis using Tanita DC-360S body composition scales (Tanita Corporation, Tokyo, Japan). A clothing allowance of 1.5 kg was entered into the scales, along with participants' age, sex and height. BMI (kg/m^2) was calculated as weight (kg)/height (m^2). Waist, hip and neck circumferences (cm) were measured using standard anthropometric measuring tape (seca Ltd, Birmingham, UK), and waist-to-hip ratio was calculated.

Biochemical assessments

Capillary blood samples were collected via finger-prick blood sampling. Participants were requested to place their hand in a bowl of warm water (provided) for 5 minutes prior to the sample being collected. Participants were also requested to fast for at least 4 hours prior to attending their health assessment.

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HbA_{1c} (mmol/mol) was measured using an A1CNow®+ point-of-care analyser (PTS Diagnostics, Indianapolis, IN, USA). Triglycerides (mmol/l), HDL-C (mmol/l) and total cholesterol (mmol/l) levels were assessed using a Cardiocheck® point-of-care analyser (PTS Diagnostics, Indianapolis, IN, USA). LDL-C (mmol/l) was calculated using Friedewald's formula.[59]

Dietary quality and fruit and vegetable intake

Dietary quality and fruit and vegetable intake (g/day) were assessed using a short-form Food Frequency Questionnaire (FFQ).[60] Using this measure, a dietary quality score was derived from reported fruit, vegetable, oily fish, non-milk extrinsic sugar and fat intakes. The dietary quality score calculated using this short-form FFQ has been shown to demonstrate a significant agreement ($\kappa = 0.38$) with dietary quality determined using a 217-item FFQ.[60]

Sleep duration and quality, subjective sleepiness and chronotype

Sleep duration and quality were assessed using a GENEActiv tri-axial accelerometer (ActivInsights Ltd., Huntingdon, UK), which was worn (concurrently with the activPAL) on the non-dominant wrist continuously for 8 days. The GENEActiv has been shown to provide an accurate measure of sleep and activity behaviour patterns over a 24-hour period.[61] The device collected data at 100 Hz with a $\pm 8\,g$ dynamic range. Participants were asked to note any time they removed this device on the same logbook used for the activPAL.

Situational sleepiness was assessed using the Karolinska Sleepiness Scale, which has been shown to be a valid measure of sleepiness when validated against electroencephalography and performance outcomes.[62,63] Participants' chronotype was determined using the short version of the Morningness–Eveningness Questionnaire (MEQ).[64]

Blood pressure

Blood pressure and heart rate were measured from the left arm of the driver after a 20-minute period of quiet sitting using an automated monitor (Omron HEM-907, Omron Corporation, Kyoto, Japan), in accordance with recommendations from the European Society of Hypertension.[65] Three separate measurements of blood pressure and heart rate were taken at 5-minute intervals. The mean systolic and diastolic blood pressures, and heart rate, recorded from the second and third assessments, were calculated and used in the analyses.

Cognitive function and psychophysiological reactivity

The Stroop test was administered over a 5-minute period using a validated software package (SuperLab 5, Cedrus Corporation, San Pedro, CA, USA) to provide a measure of reaction time, sensitivity to interference and the ability to suppress an automated response (i.e. reading colour names in favour of naming the font colour).[66] The Stroop test was utilised to provide a measure of cognitive function and as part of a battery of measures to induce acute stress to support the assessment of psychophysiological reactivity.

The mirror tracing task (Campden Instruments Auto Scoring Mirror Tracer 58024E, Campden Instruments LTD, Loughborough, UK) was used as the second stress task, which has been routinely used to induce stress in field- and laboratory-based studies.[67] The mirror tracing task immediately followed the Stroop test. The mirror tracing task involved tracing an adonised star pattern using a metal-tipped stylus with the right hand continuously for 5 minutes. Participants were, however, permitted to use only the reflection of the star in an adjacent mirror for reference. The machine beeped if the metal-tipped stylus left the star pattern, and each mistake was recorded on the machine. Participants were told to aim for at least five complete stars in the time frame.[68] Measurements of blood pressure and heart rate were repeated during the mirror tracing task at 2 minutes 15 seconds, and again at 4 minutes 35 seconds, into the task to measure psychophysiological reactivity to acute stress. The mean stress-induced blood pressure and heart rate readings were calculated from these two measurements. Blood pressure and heart rate psychophysiological reactivity were calculated by subtracting the average resting systolic and diastolic blood pressures, and resting heart rate, from the average systolic and diastolic blood pressures, and heart rate, taken during the stress task.

Functional fitness

Grip strength (kg) was assessed from both hands using the Takei Hand-Grip dynamometer (Takei Scientific Instruments Co., Ltd, Niigata, Japan).

Mental well-being

Depression and anxiety symptoms were self-reported using the validated Hospital Anxiety and Depression Scale (HADS).[69] The HADS consists of two subscales containing seven questions for anxiety symptoms and seven questions for depressive symptoms. The Cronbach's alpha for HADS anxiety and HADS depression has been reported as 0.83 and 0.82, respectively.[70] Each answer is scored on a scale from 0 to 3. Therefore, total scores for each construct range from 0 to 21. For each construct, a score of ≤ 7 would be classified as 'no symptoms', whereas scores of 8–10, 11–14 and 15–21 are classified as the presence of mild, moderate and severe symptoms, respectively.[70] Social isolation was assessed using the 8-item Social Isolation Short Form from the Patient-Reported Outcomes Measurement Information System.[71,72]

Musculoskeletal symptoms

Musculoskeletal symptoms were assessed using the standardised Nordic Musculoskeletal Questionnaire, which is a self-reported measure of musculoskeletal pain covering nine body regions.[73]

Work-related psychosocial variables

A series of self-reported questionnaires assessed a range of work-related psychosocial variables. Work engagement (characterised by vigour, dedication and absorption) was measured using the Utrecht Work Engagement Scale.[74] Occupational fatigue was measured using the Occupational Fatigue Exhaustion Recovery (OFER) scale.[75] Perceived job performance[76] and job satisfaction[77] were measured using single-item 7-point Likert scales. Perceived work ability was assessed using the single-item Work Ability Index.[78] Sickness presenteeism and absenteeism were assessed using a single-item questionnaires. Participant's perceptions of their work demands and support was assessed using four subscales from the Health and Safety Executive Management Standards Indicator Tool.[79] Reported driving-related safety behaviour was assessed using a six-item measure.[80]

Health-related quality of life and resource use

Health-related quality of life was measured using the EuroQol-5 Dimensions, five-level version (EQ-5D-5L).[81,82] The EQ-5D-5L measure comprises a short descriptive questionnaire and a visual analogue scale. On the descriptive questionnaire, participants rate their current health state across five dimensions (i.e. mobility, self-care, usual activities, pain/discomfort, anxiety/depression) and across five levels of severity (ranging from 'no problem' to 'unable to/extreme problems'). The visual analogue scale (which ranges from 0 to 100) records the participant's overall current health, where the end points are labelled 'the best health you can imagine' (100) and 'the worst health you can imagine' (0).

Information on health-related resource use was collected using a questionnaire designed for this study. Using this tool, participants were asked to report information on the quantity and duration of GP and nurse practitioner visits, inpatient and outpatient appointments, and visits with other relevant health professionals. The information obtained from the EQ-5D-5L and health-related resource use questionnaire was used to inform the within-trial cost-effectiveness analysis (see *Chapter 4*).

Demographics and additional lifestyle health-related behaviour and risk measures

At baseline, participants completed a brief questionnaire collecting basic demographic information, including date of birth, sex, ethnicity, highest level of education, marital status, postcode (to determine Index of Multiple Deprivation as an indicator of neighbourhood socioeconomic status), working hours, years worked as a HGV driver, shift pattern and years worked at DHL Supply Chain. At each follow-up assessment, participants were asked if there have been any changes in these variables. During each assessment, information on smoking status and typical alcohol intake [using questions 1 and 2 from the Alcohol Use Disorders Identification Test (AUDIT)[83]] was gathered. Using information collected from the

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self-report questionnaires, and data collected within the health assessments (i.e. systolic blood pressure, cholesterol/HDL-C ratio, height and weight), participants' 10-year risk of having a cardiovascular event was calculated using the Cardiovascular Risk Score (QRISK3) calculator [URL: https://qrisk.org/2017/ (accessed 16 July 2021)].

Accelerometer data processing

activPAL

activPALs were initialised and downloaded using manufacturer proprietary software (activPAL Professional v.7.2.38, PAL Technologies Ltd, Glasgow, UK). Event files were generated and processed using the freely available Processing PAL software [URL: https://github.com/UOL-COLS/ProcessingPAL (accessed 24 August 2022), version 1.3, University of Leicester, Leicester, UK]. The software provides information on valid waking wear time, sleep time, extended non-wear time and invalid data, according to a validated algorithm.[84] Once data were processed, heat maps were created, showing valid waking wear data and invalid data. The heat maps were visually checked independently by two researchers for any occasions where the algorithm had misclassified waking wear data, and vice versa. On any occasion where suspected misclassifications had occurred, the participant's self-reported logbook wake and sleep times were compared with the processed data. If a misclassification was confirmed, then the data were corrected. The logbooks were also checked for scenarios where data should be removed, for example if participants reported removing the device for any reason. Once this process was completed, summary variables were calculated (see *Secondary activPAL variables*). A valid activPAL wear-day was defined as having $\geq$ 10 hours wear time per day, $\geq$ 1000 steps per day and $<$ 95% of the day spent in any one behaviour (e.g. sitting, standing or stepping). Participants were included in the primary outcome analysis if they provided at least 1 valid wear-day at both baseline and 6 months' follow-up (i.e. immediately following completion of the 6-month intervention). One valid day was chosen to maximise our sample and is in line with previous studies.[85,86]

GENEActiv

GENEActiv devices were initialised and downloaded using manufacturer proprietary software (GENEActiv v.3.1, Activinsights Ltd, Huntingdon, UK). Accelerometer files were processed in the R package GGIR version 1.11-0 (The R Foundation for Statistical Computing, Vienna, Austria)[87] to generate sleep outcome variables, with sleep duration (i.e. minutes/24-hour period) and sleep efficiency [i.e. sleep duration/sleep window duration × 100 (%)] the variables of interest for this report. 'Sleep windows' (i.e. the time between 'lights out' and out of bed time) were detected from the accelerometer data using a validated algorithm.[88] Sleep duration within the sleep window period was calculated using a validated sleep detection algorithm, which has been shown to demonstrate high sensitivity and specificity in detecting sleep periods.[89] A device wear time of $\geq$ 16 hours per 24-hour period was required to determine a valid night of sleep data.[89] Individual nights of data with a sleep window $>$ 13 hours or $<$ 2 hours or sleep duration $>$ 12 hours or $<$ 1 hour were identified as erroneous and removed. As with the activPAL data, participants were required to have provided at least 1 valid wear-day at both baseline and follow-up (i.e. immediately following completion of the 6-month intervention) to be included in the analyses within this report.

From the data provided by the GENEActiv, the following variables were derived by calculating the average across the number of valid days provided during each measurement period:

- sleep window duration [i.e. average duration between 'lights out' and 'out of bed' time (minutes)]
- sleep duration [i.e. average time spent asleep during the sleep window (minutes)]
- sleep efficiency [i.e. sleep duration/sleep window duration × 100 (%)]
- average number of valid days (days).

The variables below were calculated and summarised for three different time periods within each measurement period: (1) daily (i.e. across all 24-hour periods on all valid days), (2) on workdays only and (3) on non-workdays only.

Cost-effectiveness evaluation

Full details of the methods for the cost-effectiveness analysis are in *Chapter 4*. In brief, the economic evaluation assessed whether or not the SHIFT programme, compared with a control arm, was likely to be cost-effective at commonly used threshold values. The economic analysis consisted of a cost–consequences analysis based on the observed results within the trial period and a cost-effectiveness analysis in which differences between groups in the trial were extrapolated to the longer term.

Within-trial analysis

Within the trial, resource use estimates were collected during each assessment point using the health-related resource use questionnaire. This questionnaire was based on a variant of the Client Service Receipt Inventory and included services that this population are likely to utilise, such as GPs and practise nurse appointments, occupational health visitors and counsellors. Costs of resources were calculated by applying published national unit cost estimates (e.g. NHS reference costs or Personal Social Services Research Unit unit costs of health and social care[90,91]), where available, to estimates of relevant resource use. A range of trial outcomes were assessed as part of this economic evaluation, including HRQoL, measured using the EQ-5D-5L.[81,82] The within-trial analysis evaluated incremental results for the primary and secondary outcomes [including EuroQol-5 Dimensions (EQ-5D)] in both intervention and control arms and compared the incremental costs mentioned above.

Longer-term analysis

Existing models linking physical activity to quality-adjusted life-years (QALYs)[92] were utilised to extrapolate costs and effects of the intervention beyond the trial period to a more appropriate time horizon. An incremental cost-effectiveness ratio (ICER) for the extrapolated period was reported using the QALY. Costs and effects were discounted at the prevailing recommended rate (currently 1.5% per annum on both costs and effects), and a sensitivity analysis was also conducted to reflect the ongoing uncertainty around appropriate discount rates for public health interventions. Sensitivity analyses were performed to determine the robustness of the results to altering certain assumptions, such as the discount rate or inclusion/exclusion of productivity losses.

Process evaluation

Full details of the methods for the process evaluation are included in *Chapter 5*. In brief, the process evaluation aimed to examine any discrepancies between expected and observed outcomes, increase our understanding of the influence of each intervention component and context on the observed outcomes, and provide insight for any further intervention development and implementation.[93] Throughout the trial, we monitored the implementation fidelity, dose, attrition, adaptation, contamination, barriers and facilitators, and sustainability, using the Medical Research Council (MRC) framework.[94] The process evaluation adopted a mixed-methods approach. Self-report questionnaires that were provided to study participants were used to evaluate the various intervention components (e.g. structured education session, Fitbit, cab workout). Interviews with participants and transport managers examined further engagement in the various components of the intervention, along with any perceived barriers to and facilitators of participating in these components.

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Sample size

Our earlier exploratory pre–post study revealed that, on average, HGV drivers accumulated 8786 steps per day across both workdays and non-workdays, with a SD of 2919 steps.[37] This trial was powered to look for a difference in step counts (i.e. the primary outcome) of 1500 steps per day (equivalent to approximately 15 minutes of moderately paced walking) between the intervention and control groups. Evidence demonstrates a linear association between step counts and a range of morbidity and mortality outcomes, as well as markers of health status, including inflammation and adiposity, insulin sensitivity and HDL-C in adults.[95–97] The linear association between step counts and health outcomes indicates 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 per day has been associated with around a 5–10% lower risk of all-cause mortality and cardiovascular morbidity and mortality in the general population and in those with a high risk of type 2 diabetes, respectively.[98,99] This proposed level of change was chosen based on findings from our exploratory pre–post intervention,[37] while also being clinically meaningful.

Based on a cluster size of 10, a conservative intraclass correlation coefficient (ICC) of 0.05 (as there were no previous data to inform this, we were guided by recommendations of Campbell *et al.*[100]), 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 information provided by DHL Supply Chain), we required 110 participants from 11 clusters per arm. From experience in conducting such studies, it was originally estimated that retention and compliance rates would be approximately 70% at 12 months' follow-up, and, therefore, the sample size was inflated by 30% to ensure that we had adequate power in the final analysis. The number of clusters was also inflated by two to allow for whole-cluster drop out. Therefore, we aimed to recruit 24 clusters (i.e. DHL Supply Chain sites), with an average of 14 participants per cluster, providing a total target sample size of 336 drivers.

Owing to one pilot site [i.e. a BP (London, UK) site] not allowing participants to wear the accelerometers during working hours for health and safety reasons and, therefore, limiting the collection of the primary outcome measure (i.e. activPAL-determined steps/day) to non-working hours only, the Trial Steering Committee (TSC) approved the recruitment of an additional site in the main trial phase (in November 2018) (see *Internal pilot*). The total number of sites recruited increased, therefore, from 24 to 25.

Internal pilot

The trial incorporated an internal pilot, which was conducted using the first six clusters (i.e. sites) recruited. The internal pilot examined issues surrounding worksite and participant recruitment, randomisation, compliance to the primary outcome and retention rates at 6 months' follow-up. The following progression criteria were reviewed by the TSC on the completion of the measurements collected from these six sites at 6 months, and the trial was considered eligible to progress to the main trial phase if it confirmed the following:

- All 24 sites required for the full sample size agreed to take part.
- A minimum of 84 drivers (based on an average of 14 participants per cluster, across the six pilot sites) had provided informed consent to participate in the internal pilot.
- An average of 75% of drivers opting into the study, randomised into the intervention arm, attended the education session across the three intervention sites in the internal pilot phase. This figure was based on the intervention uptake rate seen in our exploratory pre–post intervention study (i.e. 87%),[37] but the figure also recognises that take-up rates tend to be lower when moving from an efficacy study to a larger multicentre effectiveness trial.
- No more than 20% of participants failed to provide valid data for the primary outcome measure (i.e. activPAL-determined step counts) at baseline and at 6 months' follow-up (i.e. immediately following completion of the intervention), or had withdrew or were lost to follow-up during the 6-month intervention phase.

If the final two progression criteria were not fully met, then it was agreed that strategies to improve these metrics for the full trial would be discussed with the TSC and the TSC would have the final say on whether or not the trial progressed to the main trial phase.

Allocation to treatment groups

Clusters (i.e. individual DHL Supply Chain sites) were randomised at the worksite level into the two trial arms (i.e. intervention and control), using an allocation ratio of 1 : 1. Randomisation was conducted by a statistician from the Leicester Clinical Trials Unit using a pregenerated list. The statistician was blinded to any identifiable cluster features and all clusters were represented by a unique cluster identifier. Randomisation took place in two phases, initially as part of the internal pilot phase and then as part of the main trial phase. Within both trial phases, the research team were responsible for co-ordinating the deployment of the intervention across sites and were, therefore, unable to be blinded to allocation arm. Similarly, owing to the nature of the intervention, participants were unable to be blinded to their assigned trial arm.

Internal pilot

Within the internal pilot, the six sites were randomised into the two trial arms following the completion of baseline measurements across the sites, using simple randomisation.

Main trial

Within the main trial phase, sites/clusters were randomised in blocks of three on completion of the baseline measures in these sites. Sites were also stratified by cluster size [i.e. small (< 40 drivers) vs. large (≥ 40 drivers)].

COVID-19: impact of a temporary change in driving hour regulations on SHIFT participants

As a response to the COVID-19 pandemic, the government temporarily relaxed the driving regulations during the first national lockdown in England, extending the permitted fortnightly driving limit from 90 hours to 99 hours for HGV drivers.[101] To investigate the impact of the changes in driving regulations, along with the impact of the pandemic on SHIFT participants' mental health and health-related behaviours, participants were invited to complete an additional optional short online survey in May 2020. The online survey also asked if participants had been furloughed and if participating in the study had an impact on their lifestyle behaviours during the initial government lockdown.

Ethics approval for this additional survey was obtained from the Loughborough University Ethics Approvals (Human Participants) Sub-Committee (reference 2020-1444-1221). The online survey was created and distributed via the Jisc Online Surveys platform (Jisc, Bristol, UK), which is a General Data Protection Regulation-compliant online survey tool designed for academic research. Participants were contacted via the study's text messaging service and were invited to participate in the survey. A link to the online survey was included in the text message. In addition, a participant information sheet and a consent statement were included on the opening page of the survey.

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The following measures were included in the online survey:

- Working situation (whether participants continued to work or had been furloughed).
- Working hours, driving hours, in-cab waiting hours and between-shift resting hours before and during the pandemic.
- Sitting, standing and moving time before and during the pandemic.
- Whether or not participants had commenced any new forms of physical activity during the pandemic.
- Symptoms of anxiety and depression during the pandemic, assessed using the HADS.
- Work-related chronic and acute fatigue during the pandemic, assessed using the OFER scale.
- Whether or not participants habitually spent time in nature before the pandemic, and whether or not they were spending time in nature during the pandemic. Nature was defined as spaces such as gardens, parks, sports fields, allotments, woodland, lakes, rivers, coastline, beaches or mountains. Participants also indicated the frequency with which they spent time in nature, before and during the pandemic, using the following options: no time in nature, once per week, 2–3 times per week, almost every day and every day.[102]
- Whether or not participants had made any changes to their activity levels, diet, smoking status or alcohol intake during the pandemic.
- Sleep duration over the past 14 days.
- Whether or not participating in the SHIFT study had provided participants with the right knowledge to maintain a healthy lifestyle during the COVID-19 restrictions.

Statistical analysis

A detailed statistical analysis plan (SAP) (see *Report Supplementary Material 3*) was created and signed off before the independent statistician had access to the data. Cluster- and participant-level baseline characteristics were summarised by trial arm and for the sample as a whole. In addition, we carried out a descriptive comparison of baseline data (specifically cluster size, age, BMI, number of years as a HGV driver, number of steps/day) between completers (i.e. participants who provided valid activPAL data at baseline and at 6 months) and non-completers, within randomisation groups and overall.

Primary outcome analysis

The primary analysis was performed using a mixed-effect linear regression model, with each participant's daily average number of steps (measured using the activPAL) at 6 months' follow-up as the outcome, adjusting for the participant's daily average number of steps at baseline and for the average waking wear time at baseline and at 6 months. The model also included a categorical variable for randomisation group (control as reference) and a term for the stratification factor [i.e. cluster size: small (< 40 drivers) vs. large (≥ 40 drivers)]. Depot was included as a random effect to model driver heterogeneity within participating sites. The structure of the variance–covariance matrix for the random effect was assumed to be identity and the models were estimated using restricted maximum likelihood. The primary analysis examined the effect of the intervention using a complete-case population. All clusters randomised, and the recruited participants in these clusters, excluding participants with missing outcome data (i.e. without at least 1 valid day of activPAL data at baseline and follow-up), were included in the primary analysis, which followed the intention-to-treat (ITT) principle (i.e. participants were analysed in the arm to which they were randomised). The estimate of the difference between the SHIFT arm and the control arm for daily average number of steps at 6 months and the corresponding 95% confidence intervals (CIs) and *p*-values are presented. Statistical tests were two sided. Furthermore, the ICC was estimated to assess the strength of the clustering effect.

Sensitivity analyses

Sensitivity analyses were conducted (see *Full intention-to-treat analysis* and *Effects on the number of valid activPAL days*), using similar methodology as the primary outcome analysis. There was no formal adjustment for multiple significance testing. The sensitivity analyses were conducted for the primary outcome (i.e. average daily step counts at 6 months' follow-up). All tests and reported *p*-values were two sided. Estimates are presented with 95% CIs.

Per-protocol analysis

The effect size was also estimated using a per-protocol analysis. The per-protocol population were participants who did not exhibit any protocol deviations, and excluded participants who:

- did not provide valid activPAL data at baseline or at the 6 months' follow-up (as applied in the primary outcome analysis)
- had time window deviations for their follow-up ($> \pm 2$ months) assessment.

Full intention-to-treat analysis

Sensitivity analyses were performed to assess the impact of missing data on the primary results and to account for uncertainty associated with imputing data (full ITT analysis). To allow for analysis of the full data set, missing data from variables included in the primary analysis model (i.e. average daily steps at baseline and immediately following the intervention) were imputed using a multiple imputation procedure, which substituted predicted values from a regression equation. The following variables were used as predictors of the primary outcome in the regression equation: baseline BMI, sex, ethnicity, age, cluster size category, years worked as HGV driver and average waking wear time across baseline and 6 months. Missing values for these predictor variables were also imputed if needed. The imputation was carried out by the MI command in Stata® (StataCorp LP, College Station, TX, USA). MI replaced missing values with multiple sets of simulated values to complete the data, performed standard analysis on each completed data set and adjusted the obtained parameter estimates for missing data uncertainty using Rubin's rules to combine estimates.[103] Twenty imputations were estimated and a seed was set to allow reproducibility.

Additional worst- and best-case scenario ITT analyses using basic imputation methods were also carried out. A simple worst-case scenario ITT analysis was carried out, where missing covariate data in the final analysis model were replaced using cluster means. Where it was not possible to impute using the cluster mean, the mean for the respective arm was used instead. Missing outcome data in the final analysis model (i.e. at baseline and 6 months) were replaced using the mean for the standard care arm. Furthermore, a simple best-case scenario ITT analysis was also carried out using the same approach as above, but outcome data were replaced using the mean for the respective arm.

Effects on the number of valid activPAL days

We carried out further sensitivity analyses by assessing the effect of the number of valid activPAL days on the primary outcome analysis. This analysis was performed by including participants who provided valid activPAL data (including weekdays and weekend days) on:

- ≥ 2 valid days at both baseline and 6 months
- ≥ 3 valid days at both baseline and 6 months
- ≥ 4 valid days at both baseline and 6 months.

Secondary outcome analysis

Secondary outcomes, including those measured at 6 months and at 16–18 months, were analysed using similar methodology to the primary outcome. Owing to the volume of secondary outcomes assessed, statistical analysis of secondary outcome variables was restricted to the following key secondary outcomes: steps per day (16–18 months' follow-up), activPAL-determined time spent sitting, standing

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and stepping, and time in light intensity physical activity and MVPA daily, during workdays and during non-workdays (at both 6 months' follow-up and 16–18 months' follow-up). The models for each of these secondary outcomes were adjusted for their respective variable at baseline and for the respective average wear time period (i.e. daily, workdays or non-workdays) at baseline and follow-up.

Fruit and vegetable intake (g/day) and dietary quality score were also analysed at 6 months and at 16–18 months. The models for each of these outcomes were adjusted for their respective baseline levels. Furthermore, the following markers of cardiometabolic health were also compared statistically at 6 months' follow-up: weight, BMI, per cent body fat, waist circumference, HbA_{1c} (mmol/mol), triglycerides (mmol/l), HDL-C (mmol/l), LDL-C (mmol/l) and total cholesterol (mmol/l). The models for each of these outcomes were adjusted for their respective baseline levels.

The models above included a categorical variable for intervention group (control as reference) and the stratification factor (cluster size). No corrections for multiple testing were made. In all models, estimates of the difference between the SHIFT arm and the control arm for the variables examined are presented, along with corresponding 95% CIs and *p*-values. Statistical tests were two sided.

For the other secondary outcomes (see *Secondary outcomes*), continuous data that were approximately normally distributed were summarised in terms of the mean and SD. Skewed data are presented in terms of the medians and interquartile range (IQR). Ordinal and categorical data are summarised in terms of frequency counts and percentages. All variables are summarised by trial arm.

Statistical analysis plan deviations

Mixed-effect linear regression models were fitted, instead of analysis of covariance models, because the analysis of covariance set-up in Stata did not allow all of the options specified in the SAP. The MEQ data were added together to create a total MEQ score, which was analysed as a continuous variable. Where BMI at 6 months was missing but weight data were available, baseline height was used to calculate BMI at 6 months, and likewise for BMI at 16–18 months. Medians (IQR) were calculated for AUDIT scores and job satisfaction and performance in addition to the planned descriptive statistics in the SAP.

Analysis of the COVID-19 questionnaire

The data were downloaded from the Jisc platform and imported into Microsoft Excel® (Microsoft Corporation, Redmond, WA, USA), where all data cleaning and reduction took place. Data were then imported into SPSS v25 (SPSS Inc., Chicago, IL, USA) for analysis. Continuous data that were approximately normally distributed were summarised in terms of the mean and SD, whereas skewed data are presented in terms of the medians and IQR. Comparisons between questionnaire responses from control and SHIFT arm participants, and between participants who had been furloughed and participants who were working at the time of questionnaire completion, were conducted using between-samples tests. Baseline characteristics in terms of age, duration working as a HGV driver, duration working for DHL Supply Chain, hours worked per week, BMI, per cent body fat, waist circumference, self-reported symptoms of anxiety and depression, musculoskeletal complaints, physical activity levels, and sleep duration and efficiency were compared between participants completing the additional COVID-19 questionnaire and participants not using between-samples tests. For participants completing the online questionnaire, comparisons were made, using repeated measures tests, between participants' working, driving, in-cab waiting or rest hours reported before and during the pandemic. Similarly, comparisons were made between participants' reported time spent sitting, standing and walking/moving around on a workday before and during the pandemic, along with reported symptoms of anxiety and depression and fatigue. The impact of spending time in nature before and during the pandemic on symptoms of anxiety, depression and fatigue were explored. The impact of participating in the study on maintaining a healthy lifestyle during the pandemic, along with any lifestyle- or work-related changes experienced by participants, were explored descriptively.

Public and patient involvement

The initial development and refinement of the SHIFT intervention, and the implementation and running of this trial, have been informed by extensive PPI. The preparatory work,[7,36–38] which informed the original grant application, was the result of a 3-year partnership between the research team and a large transport and logistics company (not DHL Supply Chain) located in the East Midlands, UK. This preparatory work was instigated by the company. The company requested help in improving the lifestyle behaviours and health of their long-distance drivers, who were proving difficult to engage. As part of the preparatory work, the SHIFT programme was developed in collaboration with long-distance HGV drivers and health and safety personnel working within the logistics sector. Following pilot testing,[37] and input from drivers and associated stakeholders,[38] the intervention and outcome measures were refined. Specifically, the duration of the intervention increased from 3 months to 6 months, as it was felt that a longer intervention duration would lead to more sustainable changes in health behaviours. The provision of free fruit at the participating DHL Supply Chain sites was removed as an intervention component, as senior health and safety personnel at DHL Supply Chain felt that this would not be feasible to implement across the wide range of sites across their business. Assessments of lung function were removed from the collection of outcome measures, as the relevance of this particular measure was questioned.

As part of the implementation planning for the trial, an initial meeting was held with transport managers from a range of DHL Supply Chain sites. The feedback obtained during this meeting informed our driver recruitment plans and highlighted effective strategies for informing and engaging office staff and drivers about the study across the individual sites. Extensive input and feedback were obtained from DHL Supply Chain health and safety personnel and human resources staff on our study marketing materials and on our health assessment feedback booklet produced for drivers.

There was extensive PPI regarding the creation and refinement of the project CRFs. We sought opinions and feedback from HGV drivers (independent from DHL Supply Chain), DHL Supply Chain transport managers and DHL Supply Chain health and safety personnel regarding the development of the drivers' health-related resource use questionnaire to inform part of our economic evaluation. We also asked independent HGV drivers, via research team contacts, to complete draft versions of our CRFs. Initial concerns were raised over the length of time taken to complete the CRFs, and this led to subtle changes being made to reduce the overall length of the included self-report questionnaires (e.g. a shorter version of the Nordic Musculoskeletal Questionnaire was used).

To inform the best practice procedures for undertaking the health assessments (i.e. outcome measurements), independent HGV drivers (i.e. contacts of the research team) were invited to undertake health assessments at Loughborough University. The HGV drivers provided further feedback on the length of the CRF and on the general procedures adopted for the physiological health assessments. Based on feedback, the order in which a number of the physiological measures were conducted as part of the health assessments was revised. In addition, we piloted the updated SHIFT education session on two independent HGV drivers, prior to running these sessions in the trial. A half-day workshop was arranged for senior DHL Supply Chain health and safety personnel at Loughborough University, where the personnel experienced our health assessments and a shortened version of the education session. This workshop was organised to enable colleagues to experience aspects of the health assessments and intervention that would be undertaken by their participating drivers, and to obtain feedback on these components from senior staff.

Throughout the study, members of the research team have presented the project at the DHL Supply Chain Transport Safety Conference (2017 and 2020), which is attended by transport managers, health and safety personnel, and drivers. The conferences have enabled the team to update a wider audience of DHL Supply Chain staff about the project and to initiate discussions about the sustainability of the intervention throughout the company. We have also attended a range of events throughout this project with industry stakeholders [e.g. attending events organised by the Chartered Institute of Logistics and Transport (CILT) (Corby, UK), the East Midlands Chamber of Commerce (Chesterfield, UK) and Women

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in Logistics (Corby, UK)], which have enabled us to provide updates to stakeholders and gain feedback on the project as it has progressed. We have had regular engagement with colleagues from CILT, and we have kept CILT informed with the project progress.

In addition, throughout the project, we organised workshops and events at Loughborough University, with a wide range of stakeholders invited. An initial workshop was organised in 2018, the purpose of which was to increase awareness of the project within the logistics sector and to gain feedback from personnel working in the sector. Attendees included representatives from 3t Logistics Ltd (Leicester, UK), Foster Logistics Consulting Ltd (Ashby-de-la-Zouch, UK), Tarmac Ltd (Solihull, UK), the Road Haulage Association Ltd (Weybridge, UK), Keltruck Scania (West Bromwich, UK), CILT and UK-Aggregates (Nottingham, UK), a local haulage company, and a member of the public interested in the project. We gained valuable feedback from participants attending this workshop with regard to both the project and how the SHIFT intervention could potentially be rolled out to all HGV drivers in the future.

In December 2019, we hosted a 1-day conference entitled 'A healthier workforce for a healthier UK', which focused on health within the logistics and transport sector. The conference included presentations from a variety of speakers [including the SHIFT team, a HGV driver, a local council representative, Unite the Union (London, UK) and Public Health England (London, UK)]. The varied audience included representatives from companies with logistics and transport/delivery departments [e.g. DHL Supply Chain, John Lewis & Partners (London, UK), Forterra plc (Northampton, UK), Wincanton plc (Chippenham, UK), Wren Kitchens (Barton-upon-Humber, UK), Bibby Distribution (Edinburgh, UK), PepsiCo, Inc. (London, UK) and Tower Transit (London, UK)], along with other stakeholders, policy-makers (including the Health and Safety Executive, the Department for Work and Pensions, Institution of Occupational Safety and Health, County Councils, CILT, the Road Haulage Association) and academics. The day concluded with all delegates agreeing that driver health should be considered a priority, and there was resounding support for policy change within the sector to promote drivers' health and well-being.

An independent HGV driver and a manager working within the logistics sector were members of our TSC (note that the manager was a member of the TSC for the first 18 months of the project only), and both members provided invaluable insight into the design, set-up, conduct and dissemination of this research as it progressed. The inclusion of the COVID-19 questionnaire within the trial was the result of discussions with our health and safety colleagues at DHL Supply Chain, who expressed concerns about drivers' physical and mental health following the government's relaxation in driving hours for HGV drivers during the height of the first wave of the pandemic. The questionnaire content was designed in partnership with DHL Supply Chain colleagues. Draft versions of the questionnaire were piloted with four HGV drivers who were independent to the study, and this was facilitated through our public member of the TSC (a HGV driver). The questionnaire, and its appearance and formatting on the online platform, was modified following feedback obtained from these drivers, prior to it being finalised and issued to SHIFT participants.

Data management and research governance

Data were entered in an anonymised format into the Clinical Data Management System (InferMed Macro v4, Elsevier Ltd, Oxford, UK) provided by the Leicester Clinical Trials Unit. The validated system included a number of quality control mechanisms to ensure that the data entered were complete and accurate. This trial was sponsored by Loughborough University. Two groups were created to oversee the trial, including an independent TSC and a Project Committee. As applied elsewhere,[104] and because the study was regarded as low risk, the TSC took on the role of a Data Monitoring Committee to monitor progress with data collection and to review any serious adverse events should they have arisen. The TSC met every 6 months and included the principal investigator (SAC), an independent chairperson (a medical statistician), two independent academics, including a health economist, an independent delivery driver and a logistics industry manager. The Project Committee comprised the principal investigator, all co-investigator and those concerned with the day-to-day running of the study. The Project Committee provided update reports for the TSC.[104]

Chapter 3 Results

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Internal pilot

Site recruitment for the internal pilot phase, which involved six sites, commenced in August 2017, with participant recruitment across these sites commencing in October 2017. Participants consented into the study and baseline measurements were undertaken between January and August 2018. A delay in recruitment was experienced in one site. Baseline measurements were undertaken in five sites between January and April 2018 and between July and August 2018 in one site.

Data regarding worksite and participant recruitment, randomisation, compliance to the primary outcome and retention rates at 6 months' follow-up were examined to determine whether or not the trial should progress to the main trial phase. The study's TSC agreed to base the progression criteria review on the baseline data collected from all six sites, which included site and participant recruitment numbers and activPAL compliance data, and to base the follow-up progression criteria (in terms of retention rates and activPAL compliance at follow-up) on the data collected from the five sites that had completed the 6-month follow-up measures by November 2018. This enabled the progression criteria to be reviewed by the end of 2018, as opposed to waiting until March 2019, when the follow-up measures were due to be completed in the final site, thereby minimising further delays to the trial.

Recruitment, compliance and retention outcomes

Table 4 summarises the recruitment, compliance and retention outcomes observed from the internal pilot sites. Outcomes were reviewed by the TSC on the 11 December 2018; on the basis of the data reviewed, the TSC recommended continuation of the trial.

TABLE 4 Progression criteria results from the internal pilot

Progression criterion	Observed outcome
All 24 sites required for the full sample size agree to take part in the study	Twenty-four sites were identified and agreed to participate in the trial by November 2018. Following agreement by the TSC, an additional site was recruited into the main trial phase because of participants in one pilot site (a BP site) not being able to wear the activPAL during working hours for health and safety reasons
A minimum of 84 drivers agree to participate in the internal pilot	Ninety-eight drivers across the six internal pilot sites provided informed consent and participated in the baseline measures, of which 84% provided valid activPAL data at baseline
An average of 75% of drivers, randomised into the intervention arm, attended the education session across three intervention depots	Seventy-four per cent of drivers in the intervention sites attended the education workshop
No more than 20% of participants fail to provide valid data for the primary outcome measure (i.e. activPAL-determined step counts) at baseline and at 6 months' follow-up, or withdraw or are lost to follow-up during the 6-month intervention phase	Across the five sites completing the 6-month follow-up assessments by November 2018, 57% of participants provided valid activPAL data at baseline and follow-up Strategies were discussed with, and approved by, the TSC for how activPAL compliance could be improved for the main trial phase

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Main trial

Participant recruitment

Participant recruitment across the remaining 19 sites commenced in January 2019, and baseline measurements for participants consented into the study were undertaken across these sites between February and July 2019.

As experienced in the internal pilot, a number of delays were encountered during the main trial phase. The delays were predominantly associated with challenges across sites in scheduling drivers for their measurement sessions, which required drivers to be released from their duties for 2 hours. The challenges were further exacerbated in the sites randomised to the SHIFT arm, which required drivers to attend the 6-hour structured education session, which was scheduled during work time. As a consequence, delays in the 6-month follow-up measures were experienced across the majority of sites.

Overall cluster and participant numbers

Figure 2 shows the flow of all participants through the study, combining data from the internal pilot and main trial phases. Overall, 386 participants across 25 clusters (i.e. sites) were recruited and consented into the study. The 25 sites were located across the Midlands region of the UK (1502 drivers were employed across these sites), and the sites operated within the transport, retail, hospitality, health-care, pharmaceutical, construction, oil and gas, and automotive industries. Of the 386 participants recruited, 382 participants were randomised into the two trial arms and four participants withdrew prior to randomisation. Thirteen sites ($n = 199$ participants) were randomised to the control arm and 12 sites ($n = 183$ participants) were randomised to the SHIFT arm. Between baseline and 6-month follow-up measures, two sites (i.e. one intervention site and one control site) dropped out of the trial. For both sites, this was because of site closures due to the collapse of the contracting companies.

Baseline characteristics

Characteristics of the clusters and baseline demographic characteristics of participants within each trial arm, and overall, are shown in *Table 5*. *Table 6* displays the biometric measurements collected from the sample overall, and according to trial arm, at baseline. *Table 7* displays the accelerometer-derived measures (i.e. physical activity, sitting time and sleep) collected at baseline. Descriptive comparisons between baseline characteristics of participants completing the trial and non-completers are shown in *Appendix 1*, *Table 42*. There were no noticeable differences between completers (i.e. participants who provided valid activPAL data at baseline and at 6 months) and non-completers in terms of cluster size, age, BMI, number of years as a HGV driver and number of steps per day at baseline.

Primary outcome analysis

A mixed-effect linear regression model revealed a statistically significant difference in mean daily step counts at 6 months' follow-up, in favour of the SHIFT group [SHIFT group mean change: 32 (SD 2939) steps/day; control group mean change: −716 (SD 2109) steps/day], in the complete-case analysis (1008 steps/day, 95% CI 145 to 1871 steps/day; $p = 0.022$) (*Table 8*). The ICC for the model was 0.112. Mixed results were seen in the ITT and per-protocol analyses (see *Table 8*).

Sensitivity analyses

Sensitivity analyses showed similar results to the primary analysis, with significant differences observed between groups in terms of daily step counts measured at 6 months' follow-up, when including participants with ≥ 2, ≥ 3 and ≥ 4 valid days of activPAL data (see *Table 8*).

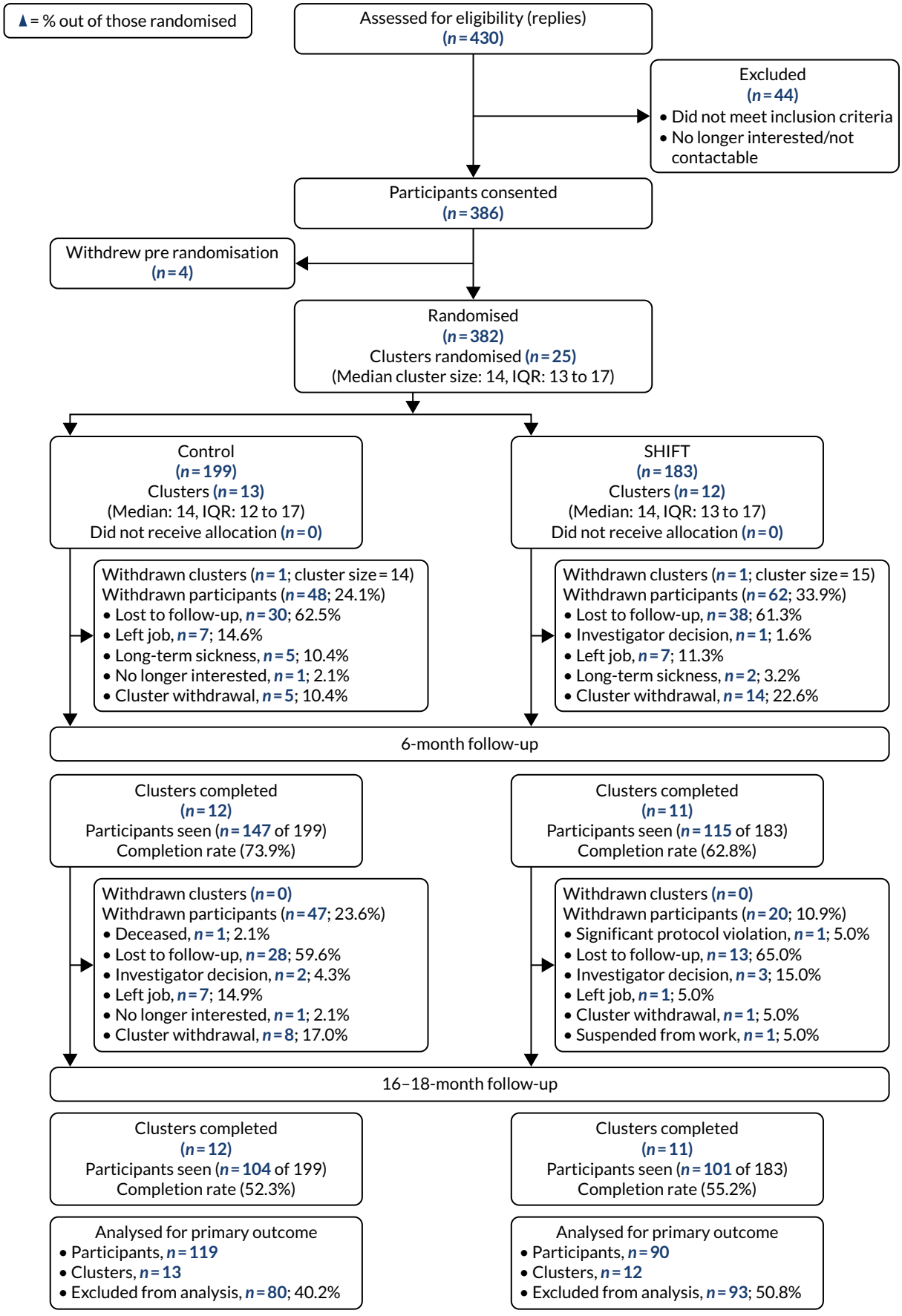

FIGURE 2 A CONSORT diagram of participant flow through the study.

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TABLE 5 Cluster characteristics and demographic characteristics of participants per trial arm and overall at baseline

Characteristic	Trial arm		Overall (clusters, *n* = 25; participants, *n* = 382)
	Control (clusters, *n* = 13; participants, *n* = 199)	SHIFT intervention (clusters, *n* = 12; participants, *n* = 183)	
Cluster level			
Cluster size category, *n* (%)			
Small (< 40 drivers)	81 (40.7)	93 (50.8)	174 (45.6)
Large (≥ 40 drivers)	118 (59.3)	90 (49.2)	208 (54.4)
Participant level			
Cluster size			
Median (IQR)	14 (12–17)	14 (13–17)	14 (13–17)
Minimum, maximum	9, 24	11, 25	9, 25
Age (years), mean (SD)	48.3 (9.7)	48.6 (9.1)	48.4 (9.4)
Sex, *n* (%)			
Male	196 (98.5)	182 (99.5)	378 (99.0)
Female	3 (1.5)	1 (0.5)	4 (1.0)
Ethnicity, *n* (%)			
White British	154 (77.4)	152 (83.1)	306 (80.1)
Other ethnicity	45 (22.6)	30 (16.4)	75 (19.6)
Shift pattern, *n* (%)			
Morning	146 (73.4)	124 (67.8)	270 (70.7)
Afternoon	29 (14.6)	31 (16.9)	60 (15.7)
Night	35 (17.6)	45 (24.6)	80 (20.9)
Duration working at DHL Supply Chain (years), median (IQR)	6.17 (3.67–11.50)	9.30 (4.06–14.27)	7.75 (3.88–13.42)
Duration working as a HGV driver (years), median (IQR)	15.00 (6.00–26.00)	17.00 (10.00–25.02)	16.00 (9.00–25.17)
Average hours worked per week, median (IQR)	48 (45–50)	48 (45–50)	48 (45–50)
IMD rank, median (IQR)	16,779.0 (8499.5–22,903.5)	16,040.0 (7934.0–22,171.0)	16,591.0 (8165.0–22,544.0)
Marital status, *n* (%)			
Married	133 (66.8)	113 (61.8)	246 (64.4)
Living with partner	34 (17.1)	31 (16.9)	65 (17.0)
Separated/divorced	9 (4.5)	13 (7.1)	22 (5.8)
Single	22 (11.1)	25 (13.7)	47 (12.3)
Widowed	1 (0.5)	1 (0.6)	2 (0.5)
Level of education: degree or above, *n* (%)	16 (8.0)	10 (5.5)	26 (6.8)
Diabetes history: yes, *n* (%)[a]	15 (7.5)	9 (4.9)	24 (6.3)

TABLE 5 Cluster characteristics and demographic characteristics of participants per trial arm and overall at baseline (*continued*)

Characteristic	Trial arm		Overall (clusters, *n* = 25; participants, *n* = 382)
	Control (clusters, *n* = 13; participants, *n* = 199)	SHIFT intervention (clusters, *n* = 12; participants, *n* = 183)	
Smoking status, *n* (%)			
Never smoked	73 (36.7)	77 (42.1)	150 (39.3)
Ex-smoker	84 (42.2)	73 (39.9)	157 (41.1)
Current smoker	42 (21.1)	32 (17.5)	74 (19.4)

IMD, Index of Multiple Deprivation.

a In the control arm, 14 of 15 participants had type 2 diabetes and one participant did not report type. Eleven of 15 participants controlled their diabetes with medical treatment, three participants controlled their diabetes with lifestyle only and one participant did not report control type. In the SHIFT arm, all nine participants had type 2 diabetes. Seven participants controlled their diabetes with medical treatment and two participants controlled their diabetes with diet only.

TABLE 6 Biometric measurements collected from the sample overall and per trial arm at baseline

Biometric measurement	Missing values (*n*)	Trial arm		Overall (clusters, *n* = 25; participants, *n* = 382)
		Control (clusters, *n* = 13; participants, *n* = 199)	SHIFT intervention (clusters, *n* = 12; participants, *n* = 183)	
Anthropometric measures and markers of adiposity				
Weight (kg), median (IQR)	2	94.0 (84.2–106.9)	95.7 (84.0–106.4)	94.8 (84.1–106.5)
Body fat (%), mean (SD)	11	26.8 (5.8)	27.3 (6.0)	27.0 (5.9)
Fat mass (kg), median (IQR)	11	25.3 (19.6–32.3)	25.6 (19.9–32.7)	25.5 (19.6–32.4)
Fat-free mass (kg), mean (SD)	12	69.3 (8.6)	69.6 (7.8)	69.5 (8.2)
BMI (kg/m^2), median (IQR)	2	29.6 (27.0–32.8)	29.9 (26.9–33.7)	29.8 (26.9–33.2)
Waist circumference (cm), median (IQR)	2	104.4 (94.6–113.1)	103.0 (95.0–113.5)	103.7 (95.0–113.4)
Hip circumference (cm), median (IQR)	2	106.5 (101.0–111.8)	107.5 (103.0–114.0)	107.0 (102.0–112.5)
Waist–hip ratio (cm), mean (SD)	2	0.97 (0.07)	0.97 (0.07)	0.97 (0.07)
Neck circumference (cm), median (IQR)	2	40.2 (38.9–42.5)	41.0 (38.3–42.5)	40.5 (38.4–42.5)
Resting blood pressure and heart rate				
Systolic blood pressure (mmHg), median (IQR)	2	130 (122–140)	130 (122–138)	130 (122–139)
Diastolic blood pressure (mmHg), median (IQR)	2	82 (76–90)	81 (76–88)	82 (76–88)
Heart rate (b.p.m.), mean (SD)	4	68 (10)	68 (10)	68 (10)
Biochemical assessments, median (IQR)				
HbA_{1c} (mmol/mol)	14	35 (32–38)	34 (31–38)	35 (31–38)
HbA_{1c} (%)	14	5.4 (5.1–5.6)	5.3 (5.0–5.6)	5.4 (5.0–5.6)
Triglycerides (mmol/l)	5	1.3 (1.0–2.1)	1.3 (0.9–2.1)	1.3 (0.9–2.1)
HDL-C (mmol/l)	5	1.1 (1.0–1.4)	1.1 (1.0–1.4)	1.1 (1.0–1.4)
LDL-C (mmol/l)	6	2.8 (2.3–3.5)	2.8 (2.4–3.5)	2.8 (2.3–3.5)
Total cholesterol (mmol/l)	5	4.4 (3.8–5.1)	4.4 (3.8–5.1)	4.4 (3.8–5.1)

b.p.m., beats per minute.

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TABLE 7 Accelerometer-derived measurements collected from the sample overall and per trial arm at baseline

Accelerometer measurement	Missing values (*n*)	Trial arm		Overall (clusters, *n* = 25; participants, *n* = 382)
		Control (clusters, *n* = 13; participants, *n* = 199)	SHIFT intervention (clusters, *n* = 12; participants, *n* = 183)	
Physical activity and sitting time				
Steps/day, median (IQR)	41	8471 (6774–10,160)	8725 (7033–11,298)	8583 (6922–10,696)
Sitting (minutes/day), mean (SD)	41	678 (91)	651 (97)	665 (95)
Prolonged (i.e. ≥ 30 minutes) sitting (minutes/day), mean (SD)	41	428 (118)	389 (128)	409 (124)
Standing (minutes/day), median (IQR)	41	195 (165–238)	213 (180–244)	203 (169–243)
Stepping (minutes/day), median (IQR)	41	112 (90–134)	116 (93–149)	114 (92–139)
Number of sit-to-stand transitions (transitions/day), median (IQR)	41	49 (38–59)	47 (39–58)	48 (39–58)
MVPA (minutes/day), median (IQR)	41	10 (6–18)	11 (6–21)	10 (6–19)
Light physical activity (minutes/day), median (IQR)	41	97 (81–114)	102 (83–129)	99 (82–123)
Number of valid days, median (IQR)	41	8 (6–8)	7 (5–8)	7 (6–8)
Waking wear time (minutes/day), median (IQR)	41	993 (955–1033)	989 (950–1022)	990 (953–1032)
Sitting (%/day), median (IQR)	41	69 (64–73)	67 (61–72)	68 (62–72)
Prolonged (≥ 30 minutes) sitting (%/day), median (IQR)	41	63 (56–70)	62 (51–69)	63 (54–70)
Standing (%/day), median (IQR)	41	20 (16–24)	22 (18–25)	21 (17–24)
Stepping (%/day), median (IQR)	41	11 (9–13)	11 (10–15)	11 (9–14)
Sleep, median (IQR)				
Sleep window duration (minutes/day)	36	426 (393–465)	424 (387–459)	425 (390–460)
Sleep duration (minutes/day)	36	371 (336–405)	371 (340–407)	371 (337–406)
Sleep efficiency (%)	36	88.5 (84.2–91.3)	88.9 (84.6–92.0)	88.6 (84.3–91.5)
Number of valid nights	36	6 (6–6)	6 (5–6)	6 (6–6)

Secondary outcomes: statistical analyses

activPAL-assessed secondary outcomes

Steps per day, time spent sitting, standing and stepping, and time in light physical activity and MVPA across all monitored days

In complete-case analyses, at 6 months' follow-up, a series of mixed-effect linear regression models revealed statistically significant differences in favour of the SHIFT group in time spent sitting, standing and stepping, and time in MVPA. At 6 months, daily sitting time was significantly shorter in the SHIFT arm (–24 minutes/day, 95% CI –43 to –6 minutes/day), whereas times spent standing (14 minutes/day, 95% CI 2 to 26 minutes/day) and stepping (11 minutes/day, 95% CI 2 to 21 minutes/day) and time in MVPA (6 minutes/day, 95% CI 0.3 to 11 minutes/day) were greater, than in the control arm.

TABLE 8 Summary of primary outcome results from the mixed-effect linear regression models

Analysis	Number of clusters		Number of participants		Baseline, mean (SD)		6-month follow-up, mean (SD)		Mean (SD) change from baseline to 6 months[a]		SHIFT intervention vs. control at 6 months	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Adjusted mean difference (95% CI)[b]	*p*-value
Primary analysis (complete case)[c]	13	12	119	90	8932 (2922)	9355 (3305)	8216 (2767)	9387 (3455)	−716 (2109)	32 (2939)	1008 (145 to 1871)	0.022
Per protocol[c]	12	2	98	2[d]	8887 (2856)	9531 (263)	8175 (2758)	9613 (1231)	−711 (2002)	82 (1494)	929 (−1705 to 3563)	0.489
ITT[c]												
Multiple imputation[e]	13	12	199	183							335 (−471 to 1141)	0.414
Worst-case scenario	13	12	199	183	8788 (2843)	9394 (3134)	8244 (2270)	8846 (2527)	−544 (2499)	−548 (3056)	399 (−129 to 927)	0.139
Best-case scenario	13	12	199	183	8788 (2843)	9464 (3127)	8244 (2270)	9344 (2466)	−543 (2499)	−120 (2985)	868 (398 to 1338)	< 0.001
Sensitivity analyses: effect of number of valid activPAL days (complete case)												
≥ 2 days	13	12	118	88	8960 (2919)	9427 (3291)	8238 (2768)	9411 (3488)	−722 (2117)	−16 (2949)	981 (102 to 1860)	0.029
≥ 3 days	13	12	116	87	8925 (2921)	9459 (3296)	8278 (2770)	9456 (3484)	−647 (2015)	−4 (2963)	906 (27 to 1784)	0.043
≥ 4 days	13	12	113	79	8832 (2877)	9385 (3290)	8179 (2710)	9480.69 (3509)	−653 (2020)	96 (3028)	973 (76 to 1870)	0.034

a Additional analyses not described in the SAP.
b Adjusted for steps per day at baseline, average waking wear time across baseline and 6 months, and cluster size category [i.e. small (< 40 drivers) vs. large (≥ 40 drivers)], with a random effect for cluster (depot).
c One or more valid days at baseline and at 6 months. Exclusion reasons from per-protocol analysis: control – steps missing at baseline ($n = 7$, 3.5%), steps missing at 6 months ($n = 14$, 7.0%), time window deviation for follow-up visit ($n = 80$, 40.2%); intervention – steps missing at baseline ($n = 0$, 0.0%), steps missing at 6 months ($n = 1$, 0.6%), time window deviation for follow-up visit ($n = 180$, 98.4%).
d A large proportion of intervention participants did not have their follow-up visit within the 2-month window. One participant had their visit too early, whereas 179 participants had their visit too late. Twenty-three of these participants had their visit within 2 weeks of the window, and a further 14 participants within 4 weeks of the window.
e Means (SDs) cannot be calculated for ITT population because multiple imputation methodology was used.

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There were no statistically significant differences between groups at 6 months' follow-up in time spent in light physical activity (*Table 9*). There were no statistically significant differences observed between groups in activPAL variables at 16–18 months' follow-up (see *Table 9*).

Steps per day, time spent sitting, standing and stepping, and time in light physical activity and MVPA on workdays

There were no statistically significant differences observed between groups in any activPAL variables measured on workdays at 6 months' follow-up or at 16–18 months' follow-up (*Table 10*).

Steps per day, time spent sitting, standing and stepping, and time in light physical activity and MVPA on non-workdays

In complete-case analyses, at 6 months' follow-up, mixed-effect linear regression models revealed statistically significant differences in favour of the SHIFT group in daily step counts, time spent sitting and stepping, and time in light physical activity and MVPA on non-workdays. At 6 months, on non-workdays, daily step counts were larger in the SHIFT group than in the control group (2012 steps/day, 95% CI 480 to 3545 steps/day). In the SHIFT group, non-workday sitting time was shorter (–40 minutes/day, 95% CI –65 to –14 minutes/day), whereas time spent stepping was greater (21, 95% CI 6 to 37 minutes/day), as was time in light physical activity (10 minutes/day, 95% CI 2 to 17 minutes/day) and time in MVPA (11 minutes/day, 95% CI 1 to 20 minutes/day), than in the control group. There were no statistically significant differences observed between groups in activPAL variables measured at 16–18 months' follow-up (*Table 11*).

Anthropometry and markers of adiposity

There were no statistically significant differences observed between groups in anthropometric measures or markers of adiposity at 6 months' follow-up, although differences in weight and BMI were marginal, with these differences being in favour of the SHIFT group (weight: –1.2 kg, 95% CI –2.6 kg to 0.1 kg; BMI: –0.35 kg/m^2, 95% CI –0.75 kg/m^2 to 0.05 kg/m^2) (*Table 12*).

Biochemical assessments

There were no statistically significant differences observed between groups in any biochemical measures at 6 months' follow-up (*Table 13*).

Dietary quality and fruit and vegetable intake

There were no statistically significant differences observed between groups in reported fruit and vegetable intake or overall dietary quality at 6 months' follow-up or at 16–18 months' follow-up (*Table 14*).

Secondary outcomes: descriptive analyses

Further activPAL variables

Across all monitored days and workdays, for the SHIFT group, there were no noticeable differences in time spent sitting in prolonged bouts (> 30 minutes), the number of transitions from sitting to standing and the proportions of time spent sitting, standing and stepping, and the proportion of sitting spent in prolonged bouts, between baseline and 6 months' follow-up. Similar findings were observed for the control group, except for the time spent sitting in prolonged bouts, which tended to increase at 6 months' follow-up (*Table 15*). On non-workdays, the control group exhibited increases in the time spent sitting (and the proportion of sitting) in prolonged bouts at 6 months' follow-up, relative to baseline. The control group also exhibited an increase in the overall proportion of time spent sitting and a decrease in the proportion of time spent standing on non-workdays at 6 months' follow-up. For the SHIFT group, no noticeable differences were observed for any variables on non-workdays between baseline and 6 months (see *Table 15*).

TABLE 9 Summary of key daily activPAL secondary outcome results from mixed-effect linear regression models

	Number of clusters		Number of participants		Baseline, mean (SD)		Follow-up, mean (SD)		Mean (SD) change from baseline to follow-up[a]		SHIFT intervention vs. control	
Daily variable	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Adjusted mean difference (95% CI)[b]	*p*-value
Steps/day[c]												
16–18 months	12	10	90	74	8978 (3226)	9663 (3122)	8789 (3148)	9259 (3105)	−189 (2169)	−404 (2688)	94 (−878 to 1066)	0.849
Time (minutes/day) spent sitting[c]												
6 months	13	12	119	90	675 (92)	664 (92)	696 (87)	655 (93)	21 (79)	−9 (77)	−24 (−43 to −6)	0.011
16–18 months	12	10	90	74	676 (97)	651 (87)	679 (98)	647 (77)	4 (82)	−4 (90)	−12 (−34 to 9)	0.268
Time (minutes/day) spent standing[c]												
6 months	13	12	119	90	204 (55)	209 (53)	194 (56)	210 (61)	−10 (37)	1 (48)	14 (2 to 26)	0.024
16–18 months	12	10	90	74	200 (54)	216 (61)	197 (58)	211 (64)	−3 (45)	−5 (77)	11 (−5 to 27)	0.183
Time (minutes/day) spent stepping[c]												
6 months	13	12	119	90	116 (34)	122 (40)	107 (32)	122 (40)	−8 (23)	−0.4 (32)	11 (1 to 21)	0.024
16–18 months	12	10	90	74	117 (36)	125 (38)	114 (37)	120 (36)	−2 (22)	−5 (31)	1 (−9 to 11)	0.818
Time (minutes/day) in LPA[c]												
6 months	13	12	119	90	101 (29)	107 (34)	94 (28)	104 (33)	−6 (19)	−3 (25)	5 (−2 to 12)	0.152
16–18 months	12	10	90	74	102 (29)	109 (34)	100 (32)	104 (32)	−2 (18)	−5 (26)	−1 (−8 to 7)	0.863
Time (minutes/day) in MVPA[c]												
6 months	13	12	119	90	15 (15)	15 (14)	13 (10)	18 (18)	−2 (14)	3 (19)	6 (0.3 to 11)	0.038
16–18 months	12	10	90	74	14 (15)	16 (14)	14 (13)	16 (16)	−1 (15)	−0.1 (16)	2 (−3 to 7)	0.539

LPA, light physical activity.

a Additional analyses not described in the SAP.

b Adjusted for variable at baseline, average waking wear time across baseline and 6 (or 12) months and cluster size category [i.e. small (< 40 drivers) vs. large (≥ 40 drivers)], with a random effect for cluster (i.e. depot).

c One or more valid days at baseline and at 6 (or 16–18) months.

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TABLE 10 Summary of key workday activPAL secondary outcome results from mixed-effect linear regression models

	Number of clusters		Number of participants		Baseline, mean (SD)		Follow-up, mean (SD)		Mean (SD) change from baseline to follow-up[a]		SHIFT intervention vs. control	
Daily variable	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Adjusted mean difference (95% CI)[b]	*p*-value
Steps/day[c]												
6 months	13	12	111	84	9308 (3154)	9547 (3458)	8890 (3041)	9357 (3241)	−418 (2046)	−190 (2649)	541 (−269 to 1351)	0.190
16–18 months	12	10	88	66	9394 (3177)	9881 (3472)	9491 (3388)	9456 (3390)	97 (2817)	−425 (3067)	−325 (−1578 to 928)	0.611
Time (minutes/day) spent sitting[c]												
6 months	13	12	111	84	720 (95)	713 (118)	740 (94)	700 (96)	20 (83.41)	−13 (101)	−14 (−36 to 8)	0.215
16–18 months	12	10	88	66	718 (98)	701 (122)	726 (117)	707 (91)	8 (97)	6 (115)	0.1 (−22 to 22)	0.995
Time (minutes/day) spent standing[c]												
6 months	13	12	111	84	191 (58)	195 (61)	186 (52)	194 (59)	−5 (52)	−2 (60)	10 (−3 to 23)	0.129
16–18 months	12	10	88	66	191 (57)	201 (68)	190 (60)	195 (48)	−2 (55)	−6 (64)	3 (−12 to 18)	0.708
Time (minutes/day) spent stepping[c]												
6 months	13	12	111	84	120 (37)	124 (43)	115 (37)	123 (42)	−5 (24)	−2 (30)	7 (−3 to 16)	0.162
16–18 months	12	10	88	66	122 (37)	128 (43)	122 (40)	122 (42)	0.05 (32)	−5 (31)	−3 (−17 to 10)	0.621
Time (minutes/day) in LPA[c]												
6 months	13	12	111	84	105 (35)	110 (38)	102 (34)	109 (40)	−3 (22)	−1 (26)	4 (−5 to 13)	0.343
16–18 months	12	10	88	66	109 (33)	112 (39)	108 (36)	108 (39)	−1 (27)	−4 (24)	−2 (−13 to 8)	0.692
Time (minutes/day) in MVPA[c]												
6 months	13	12	111	84	14 (13)	14 (13)	13 (10)	14 (11)	−2 (10)	−0.1 (14)	2 (−2 to 6)	0.357
16–18 months	12	10	88	66	13 (11)	16 (13)	14 (11)	15 (16)	1 (10)	−1 (19)	−0.4 (−5 to 5)	0.875

LPA, light physical activity.

a Additional analyses not described in the SAP.

b Adjusted for variable at baseline, average waking wear time across baseline and 6 (or 12) months and cluster size category [i.e. small (< 40 drivers) vs. large (≥ 40 drivers)], with a random effect for cluster (i.e. depot).

c One or more valid days at baseline and at 6 (or 16–18) months.

TABLE 11 Summary of key non-workday activPAL secondary outcome results from mixed-effect linear regression models

	Number of clusters		Number of participants		Baseline, mean (SD)		Follow-up, mean (SD)		Mean (SD) change from baseline to follow-up[a]		SHIFT intervention vs. control	
Daily variable	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Adjusted mean difference (95% CI)[b]	*p*-value
Steps/day[c]												
6 months	13	12	102	77	8467 (5248)	8733 (3894)	6897 (3331)	9077 (4895)	−1570 (4754)	344 (4150)	2012 (480 to 3545)	0.010
16–18 months	12	9	81	65	8348 (5935)	9252 (3994)	7397 (4116)	9096 (4167)	−951 (5561)	−156 (4031)	1392 (−277 to 3060)	0.102
Time (minutes/day) spent sitting[c]												
6 months	13	12	102	77	577 (118)	587 (121)	610 (131)	584 (132)	33 (110)	−4 (123)	−40 (−65 to −14)	0.003
16–18 months	12	9	81	65	585 (122)	568 (105)	595 (140)	563 (114)	11 (116)	−5 (112)	−20 (−62 to 23)	0.360
Time (minutes/day) spent standing[c]												
6 months	13	12	102	77	233 (75)	234 (73)	214 (88)	240 (88)	−18 (67)	6 (82)	20 (−1 to 41)	0.059
16–18 months	12	9	81	65	222 (75)	243 (69)	213 (84)	230 (74)	−9 (68)	−12 (81)	7 (−22 to 36)	0.630
Time (minutes/day) spent stepping[c]												
6 months	13	12	102	77	110 (54)	114 (42)	93 (40)	117 (51)	−17 (48)	3 (44)	21 (6 to 37)	0.008
16–18 months	12	9	81	65	109 (62)	120 (42)	100 (47)	117 (47)	−9 (54)	−3 (47)	14 (−5 to 32)	0.155
Time (minutes/day) in LPA[c]												
6 months	13	12	102	77	93 (36)	96 (31)	81 (33)	94 (35)	−12 (31)	−2 (31)	9 (2 to 17)	0.017
16–18 months	12	9	81	65	92 (42)	101 (32)	87 (39)	97 (40)	−5 (27)	−3 (40)	5.28 (−7 to 17)	0.381
Time (minutes/day) in MVPA[c]												
6 months	13	12	102	77	17 (37)	18 (21)	12 (14)	23 (29)	−6 (37)	4 (29)	11 (1 to 20)	0.027
16–18 months	12	9	81	65	17 (42)	19 (22)	13 (21)	20 (21)	−4 (45)	0.5 (18)	6 (−2 to 14)	0.123

LPA, light physical activity.

a Additional analyses not described in the SAP.

b Adjusted for variable at baseline, average waking wear time across baseline and 6 (or 12) months and cluster size category [i.e. small (< 40 drivers) vs. large (≥ 40 drivers)], with a random effect for cluster (i.e. depot).

c One or more valid days at baseline and at 6 (or 16–18) months.

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TABLE 12 Summary of adiposity-related secondary outcome results from mixed-effect linear regression models

Anthropometric measure	Number of clusters		Number of participants		Baseline, mean (SD)		Follow-up, mean (SD)		Mean (SD) change from baseline to follow-up[a]		SHIFT intervention vs. control	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Adjusted mean difference (95% CI)[b]	*p*-value
Weight (kg)												
6 months	13	12	143	112	94.9 (17.5)	96.9 (16.0)	94.8 (17.4)	95.5 (16.2)	−0.1 (4.48)	−1.4 (5.2)	−1.2 (−2.6 to 0.1)	0.078
BMI (kg/m^2)												
6 months	13	12	143	112	29.9 (5.2)	30.7 (5.0)	29.9 (5.1)	30.3 (5.1)	−0.0 (1.4)	−0.4 (1.6)	−0.4 (−0.8 to 0.1)	0.086
Per cent body fat												
6 months	13	10	141	96	26.3 (5.9)	27.3 (5.9)	26.4 (6.0)	27.1 (5.8)	0.1 (1.7)	−0.2 (2.0)	−0.2 (−0.7 to 0.3)	0.435
Waist circumference (cm)												
6 months	13	11	143	103	103.7 (13.7)	104.9 (12.7)	103.8 (13.9)	103.6 (12.7)	0.1 (5.1)	−1.3 (6.7)	−1.1 (−2.7 to 0.5)	0.195

a Additional analyses not described in the SAP.
b Adjusted for variable at baseline.

TABLE 13 Summary of biochemical secondary outcome results from mixed-effect linear regression models

Biochemical measure	Number of clusters		Number of participants		Baseline, mean (SD)		Follow-up, mean (SD)		Mean (SD) change from baseline to follow-up[a]		SHIFT intervention vs. control	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Adjusted mean difference (95% CI)[b]	*p*-value
HbA_{1c} (mmol/mol)												
6 months	13	10	139	89	36.8 (9.4)	35.6 (10.3)	37.1 (10.4)	35.0 (9.0)	0.2 (6.0)	−0.6 (6.9)	−1.9 (−4.9 to 1.2)	0.229
Triglycerides (mmol/l)												
6 months	13	10	143	98	1.7 (1.1)	1.6 (0.9)	1.7 (1.1)	1.7 (1.1)	0.1 (1.0)	0.04 (0.9)	−0.08 (−0.3 to 0.2)	0.530
HDL-C (mmol/l)												
6 months	13	10	143	98	1.2 (0.4)	1.2 (0.3)	1.3 (0.3)	1.3 (0.3)	0.02 (0.2)	0.1 (0.2)	0.04 (−0.02 to 0.1)	0.241
LDL-C (mmol/l)												
6 months	13	10	143	98	2.9 (0.8)	2.8 (0.8)	2.9 (0.9)	2.8 (0.9)	−0.01 (0.9)	−0.03 (0.8)	0.0 (−0.2 to 0.2)	0.973
Total cholesterol (mmol/l)												
6 months	13	10	143	98	4.4 (0.9)	4.4 (0.9)	4.5 (1.0)	4.4 (1.0)	0.02 (0.9)	0.1 (0.9)	0.02 (−0.2 to 0.2)	0.868

a Additional analyses not described in the SAP.
b Adjusted for variable at baseline.

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TABLE 14 Summary of fruit and vegetable intake and dietary quality secondary outcome results from mixed-effect linear regression models

Fruit and vegetable intake and dietary quality	Number of clusters		Number of participants		Baseline, mean (SD)		Follow-up, mean (SD)		Mean (SD) change from baseline to Follow-up[a]		SHIFT intervention vs. control	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Adjusted mean difference (95% CI)[b]	*p*-value
Fruit (g/day)												
6 months	13	12	147	124	100.8 (122.2)	135.4 (158.1)	123.9 (142.3)	120.6 (153.6)	23.1 (128.1)	−14.8 (159.5)	−20.6 (−64.5 to 23.3)	0.359
16–18 months	12	10	112	102	92.2 (109.4)	127.4 (152.7)	89.6 (111.8)	112.1 (148.0)	−2.7 (105.3)	−15.2 (162.8)	7.4 (−30.3 to 45.2)	0.700
Vegetables (g/day)												
6 months	13	12	147	124	110.5 (135.3)	127.7 (165.8)	106.1 (142.1)	131.9 (184.6)	−4.4 (167.3)	4.1 (207.0)	27.3 (−24.8 to 79.4)	0.305
16–18 months	12	10	112	102	95.1 (98.1)	127.3 (167.8)	100.2 (145)	90.0 (101.0)	5.1 (148.5)	−37.2 (157.4)	−25.3 (−68.5 to 17.9)	0.251
Dietary quality score[c]												
6 months	13	12	147	124	11.1 (2.0)	11.1 (2.1)	11.4 (1.7)	11.1 (2.0)	0.3 (2.2)	−0.01 (2.4)	−0.2 (−0.7 to 0.2)	0.241
16–18 months	12	11	112	102	11.1 (1.8)	11.0 (2.0)	11.3 (1.6)	11.3 (1.8)	0.1 (2.0)	0.3 (2.3)	0.07 (−0.4 to 0.5)	0.778

a Additional analyses not described in the SAP.
b Adjusted for variable at baseline.
c Dietary quality score ranges from 5 to 15, with higher scores indicating higher dietary quality based on consumption of fruit, vegetables, oily fish, fats and non-milk extrinsic sugars.

TABLE 15 Further activPAL outcomes measured at baseline and at 6 months' follow-up, along with changes calculated from baseline

Variable	Number of participants		Baseline, mean (SD)		6-month follow-up, mean (SD)		Mean (SD) change from baseline to 6-month follow-up	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
All days[a]								
Valid days (*n*)	119	92	7 (2)	6 (3)	7 (1)	7 (1)	1 (3)	1 (3)
Waking wear time (minutes/day)	119	92	995 (66)	997 (56)	997 (64)	987 (67)	2 (67)	−10 (60)
Sitting time (minutes/day) in prolonged bouts (i.e. > 30 minutes)	119	92	430 (116)	396 (127)	456 (115)	395 (113)	26 (92)	−1 (90)
Number of transitions	119	92	50 (16)	53 (18)	49 (18)	52 (19)	−1 (12)	−1 (14)
Per cent of day sitting	119	92	68 (8)	67 (8)	70 (7)	67 (8)	2 (5)	0 (6)
Per cent of day standing	119	92	21 (6)	21 (5)	19 (5)	21 (6)	−2 (4)	0 (5)
Per cent of day stepping	119	92	12 (3)	12 (4)	11 (3)	12 (4)	−1 (2)	0 (3)
Per cent of day sitting in prolonged bouts (i.e. > 30 minutes)	119	92	63 (11)	58 (13)	65 (12)	59 (11)	2 (8)	1 (9)
Workdays[a]								
Valid days (*n*)	114	87	4 (2)	4 (2)	5 (1)	5 (2)	1 (2)	1 (3)
Waking wear time (minutes/day)	114	87	1033 (75)	1037 (96)	1032 (126)	1017 (86)	−1 (133)	−20 (94)
Sitting time (minutes/day) in prolonged bouts (i.e. > 30 minutes)	114	87	481 (128)	452 (171)	494 (140)	433 (139)	13 (118)	−19 (142)
Number of transitions	114	87	51 (21)	54 (23)	49 (21)	54 (26)	−2 (14)	0 (21)
Per cent of day sitting	114	87	70 (7)	69 (9)	70 (10)	69 (8)	0 (9)	0 (8)
Per cent of day standing	114	87	19 (6)	19 (7)	18 (5)	19 (5)	−1 (5)	0 (7)
Per cent of day stepping	114	87	12 (4)	12 (4)	11 (4)	12 (4)	−1 (3)	0 (3)
Per cent of day sitting in prolonged bouts (i.e. > 30 minutes)	114	87	66 (13)	61 (16)	66 (15)	61 (14)	0 (12)	0 (13)

continued

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TABLE 15 Further activPAL outcomes measured at baseline and at 6 months' follow-up, along with changes calculated from baseline (*continued*)

Variable	Number of participants		Baseline, mean (SD)		6-month follow-up, mean (SD)		Mean (SD) change from baseline to 6-month follow-up	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
Non-workdays[a]								
Valid days (*n*)	102	80	2 (1)	2 (1)	3 (1)	3 (1)	1 (2)	1 (2)
Waking wear time (minutes/day)	102	80	920 (78)	937 (86)	917 (107)	937 (103)	−3 (107)	0 (107)
Sitting time (minutes/day) in prolonged bouts (i.e. > 30 minutes)	102	80	325 (139)	329 (137)	375 (156)	325 (140)	50 (137)	−4 (124)
Number of transitions	102	80	48 (21)	47 (14)	46 (18)	47 (15)	−2 (16)	0 (14)
Per cent of day sitting	102	80	63 (11)	63 (11)	66 (12)	62 (12)	3 (10)	−1 (11)
Per cent of day standing	102	80	25 (8)	25 (8)	23 (9)	26 (9)	−2 (7)	1 (9)
Per cent of day stepping	102	80	12 (6)	12 (5)	10 (4)	12 (5)	−2 (5)	0 (5)
Per cent of day sitting in prolonged bouts (i.e. > 30 minutes)	102	80	55 (16)	54 (13)	60 (16)	54 (14)	5 (15)	0 (12)

a One or more valid days at baseline and at 6 months.

Across all monitored days, workdays and non-workdays, for both groups, there were no noticeable differences in time spent sitting in prolonged bouts (> 30 minutes), the number of transitions from sitting to standing, the proportions of time spent sitting, standing and stepping, and the proportion of sitting spent in prolonged bouts, between baseline and 16–18 months' follow-up (*Table 16*).

Sleep duration and quality, subjective situational sleepiness and chronotype

Across all monitored days, between baseline and 6 months' follow-up, both groups exhibited a decrease in their sleep window duration (defined as the time between 'lights out' and out of bed time) and a decrease in their overall sleep duration. These changes appeared to be driven by large reductions in sleep window duration and sleep duration on workdays at 6 months' follow-up. In contrast, on non-workdays, increases in sleep window duration and sleep duration were observed for both groups at 6 months. There were no noticeable changes in sleep efficiency across any types of day between baseline and 6 months' follow-up for either group (*Table 17*). There were no changes in ratings of situational sleepiness or chronotype score between baseline and either follow-up period for both groups (*Table 18*).

Blood pressure and psychophysiological reactivity

Small reductions in resting systolic and diastolic blood pressure were observed for both groups between the baseline and 6-month follow-up measures, but no noticeable changes were observed in resting heart rate for either group (*Table 19*). Mean blood pressure and heart rate measures increased during the mirror tracing task; however, the differences between resting values and values recorded during the task tended to be smaller for both groups during the 6-month follow-up measures (see *Table 19*). There were no differences in perceived stress ratings during this task between baseline and follow-up for either group. The control group tended to have fewer errors while undertaking this task at 6-months follow-up, whereas no evidence of a change in performance was observed for the SHIFT group (see *Table 19*).

Cognitive function

There were no noticeable differences in reaction times, measured using the Stroop test, between baseline and 6 months' follow-up for both groups. No noticeable differences were observed between groups at baseline and 6 months (*Table 20*).

Functional fitness

No noticeable changes in grip strength were observed between baseline and 6 months' follow-up in the control group, whereas modest improvements in grip strength for both hands were observed following completion of the intervention in the SHIFT group (*Table 21*).

Mental well-being

There were no noticeable differences in self-reported scores for symptoms of anxiety, depression or social isolation between baseline and 6 months' follow-up for both groups, and similar findings were also observed for symptoms of anxiety and depression at 16–18 months' follow-up. There was a tendency in both groups for perceived social isolation scores to increase marginally at 16–18 months' follow-up (*Table 22*). No noticeable differences were observed between groups at any assessment point.

Musculoskeletal symptoms

Table 23 provides a summary of the prevalence of musculoskeletal discomfort reported in the past month for each body site, along with discomfort scores by body region, reported over the three time points. There was a tendency for the prevalence of musculoskeletal discomfort across the majority of body sites to decrease at the two follow-up assessments in both groups, with similar changes in prevalence occurring between groups. Similarly, there were no noticeable differences in discomfort scores (i.e. upper extremity, lower extremity and overall) between baseline and 6 months' follow-up, and between baseline and 16–18 months' follow-up, for both groups. No noticeable differences in discomfort scores were observed between groups at any assessment point.

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TABLE 16 Further activPAL outcomes measured at baseline and at 16–18 months' follow-up, along with changes calculated from baseline

Variable	Number of participants		Baseline, mean (SD)		16- to 18-month follow-up, mean (SD)		Mean (SD) change from baseline to 16- to 18-month follow-up	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
All days[a]								
Valid days (*n*)	90	74	7 (2)	6 (2)	7 (1)	7 (1)	0 (2)	1 (3)
Waking wear time (minutes/day)	90	74	993 (67)	992 (54)	991 (59)	978 (65)	−2 (62)	−14 (78)
Sitting time (minutes/day) in prolonged bouts (i.e. > 30 minutes)	90	74	434 (124)	380 (121)	434 (134)	383 (114)	0 (107)	3 (115)
Number of transitions	90	74	49 (18)	54 (17)	51 (21)	53 (19)	2 (15)	−1 (19)
Per cent of day sitting	90	74	68 (8)	66 (8)	69 (8)	66 (7)	1 (6)	0 (9)
Per cent of day standing	90	74	20 (6)	22 (6)	20 (6)	21 (5)	0 (5)	−1 (7)
Per cent of day stepping	90	74	12 (4)	13 (4)	12 (4)	12 (4)	0 (2)	−1 (3)
Per cent of day sitting in prolonged bouts (i.e. > 30 minutes)	90	74	63 (12)	58 (14)	63 (14)	58 (14)	0 (11)	0 (12)
Workdays[a]								
Valid days (*n*)	89	68	5 (2)	4 (2)	5 (2)	5 (2)	0 (2)	1 (3)
Waking wear time (minutes/day)	89	68	1031 (78)	1028 (84)	1026 (141)	994 (192)	−5 (137)	−34 (189)
Sitting time (minutes/day) in prolonged bouts (i.e. > 30 minutes)	89	68	480 (132)	429 (163)	478 (161)	419 (163)	−2 (131)	−10 (163)
Number of transitions	89	68	51 (23)	55 (22)	51 (25)	55 (24)	0 (20)	0 (21)
Per cent of day sitting	89	68	70 (7)	68 (10)	69 (11)	67 (14)	−1 (10)	−1 (15)
Per cent of day standing	89	68	19 (5)	20 (8)	18 (6)	18 (6)	−1 (6)	−2 (8)
Per cent of day stepping	89	68	12 (4)	12 (4)	12 (4)	12 (5)	0 (4)	0 (4)
Per cent of day sitting in prolonged bouts (i.e. > 30 minutes)	89	68	66 (13)	60 (17)	65 (16)	60 (17)	−1 (12)	0 (15)

Variable	Number of participants		Baseline, mean (SD)		16- to 18-month follow-up, mean (SD)		Mean (SD) change from baseline to 16- to 18-month follow-up	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
Non-workdays[a]								
Valid days (*n*)	83	69	2 (1)	2 (1)	2 (1)	3 (2)	0 (2)	1 (2)
Waking wear time (minutes/day)	83	69	915 (76)	928 (75)	886 (163)	858 (230)	−29 (164)	−70 (221)
Sitting time (minutes/day) in prolonged bouts (i.e. > 30 minutes)	83	69	342 (149)	305 (115)	344 (174)	286 (145)	2 (146)	−19 (143)
Number of transitions	83	69	45 (21)	48 (15)	47 (25)	46 (20)	2 (21)	−2 (21)
Per cent of day sitting	83	69	64 (12)	61 (10)	64 (17)	58 (18)	0 (15)	−3 (19)
Per cent of day standing	83	69	24 (8)	26 (8)	23 (10)	24 (10)	−1 (8)	−2 (10)
Per cent of day stepping	83	69	12 (6)	13 (4)	11 (6)	12 (6)	−1 (6)	−1 (5)
Per cent of day sitting in prolonged bouts (i.e. > 30 minutes)	83	69	57 (16)	53 (14)	57 (17)	52 (16)	0 (16)	−1 (16)

a One or more valid days at baseline and at final follow-up.

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TABLE 17 Device-based measures of sleep outcomes from the GENEActiv at baseline and at 6 months' follow-up, along with changes calculated from baseline

Variable	Number of participants		Baseline, mean (SD)		6-month follow-up, mean (SD)		Mean (SD) change from baseline to 6-month follow-up	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
All days								
Number of valid nights	118	89	6 (1)	5 (2)	5 (1)	5 (1)	−1 (1)	0 (2)
Sleep window[a] duration (minutes)	118	89	425 (54)	419 (54)	410 (62)	405 (65)	−15 (70)	−14 (58)
Sleep duration (minutes)	118	89	370 (54)	368 (55)	355 (57)	357 (59)	−15 (57)	−11 (51)
Sleep efficiency[b] (%)	118	89	87 (7)	88 (6)	87 (6)	89 (6)	0 (4)	1 (5)
Workdays								
Number of valid nights	100	67	3 (1)	3 (1)	3 (1)	3 (1)	0 (1)	0 (2)
Sleep window[a] duration (minutes)	100	67	420 (61)	402 (67)	363 (74)	369 (79)	−57 (80)	−33 (70)
Sleep duration (minutes)	100	67	366 (56)	354 (65)	317 (68)	329 (72)	−49 (69)	−25 (64)
Sleep efficiency[b] (%)	100	67	87 (8)	88 (7)	88 (7)	89 (6)	1 (6)	1 (5)
Non-workdays								
Number of valid nights	96	60	2 (1)	2 (1)	2 (1)	2 (1)	0 (1)	0 (1)
Sleep window[a] duration (minutes)	96	60	422 (79)	429 (78)	482 (92)	462 (103)	60 (107)	33 (123)
Sleep duration (minutes)	96	60	367 (74)	377 (78)	416 (78)	406 (95)	49 (90)	29 (111)
Sleep efficiency[b] (%)	96	60	87 (7)	88 (7)	87 (7)	88 (8)	0 (6)	0 (5)

a Sleep window was defined as the time between 'lights out' and out of bed time.
b Sleep efficiency ranges from 0% to 100%, with higher values indicating better sleep efficiency.

TABLE 18 Situational sleepiness and chronotype score measured at baseline and at 6 months and 16–18 months' follow-up, along with changes calculated from baseline

	Number of participants		Baseline, median (IQR)		Follow-up, median (IQR)		Median (IQR) change from baseline to follow-up	
Variable	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
Karolinska Sleepiness Scale rating[a]								
6 months	144	113	3 (2–5)	3 (2–5)	3 (2–5)	3 (2–5)	0 (–1 to 1)	0 (–1 to 1)
16–18 months	99	90	3 (2–5)	3 (2–5)	3 (3–6)	3 (2–5)	0 (–1 to 1)	0 (0–2)
MEQ score[b]								
6 months	144	113	19 (15–21)	17 (14–20)	18 (16–21)	17 (14–20)	0 (–1 to 1)	0 (–1 to 1)
16–18 months	99	90	18 (15–21)	16 (13–20)	19 (16–21)	17 (14–20)	0 (–1 to 2)	0 (–1 to 1)

a The Karolinska Sleepiness Scale ranges from 1 'extremely alert' to 9 'extremely sleepy – fighting sleep'.
b MEQ scores range from 16 to 86. Scores of ≤ 41 indicate 'evening types', scores of ≥ 59 indicate 'morning types' scores between 42 and 58 indicate 'intermediate types'.

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TABLE 19 Blood pressure measured at rest and during the mirror tracing task, along with further outcomes from the mirror tracing task at baseline and at 6 months' follow-up (changes calculated from baseline are also presented)

Variable	Number of participants		Baseline, median (IQR)		6-month follow-up, median (IQR)		Median (IQR) change from baseline to 6-month follow-up	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
Resting blood pressure and heart rate[a]								
Systolic blood pressure (mmHg)	145	104	130 (120–139)	130 (122–138)	127 (118–135)	127 (118–136)	−2 (−9 to 4)	−3 (−10 to 5)
Diastolic blood pressure (mmHg)	145	104	82 (76–88)	82 (78–88)	80 (74–86)	80 (75–87)	−2 (−6 to 4)	−1 (−6 to 4)
Heart rate (b.p.m.)	143	104	67 (60–74)	68 (60–74)	66 (60–73)	66 (58–72)	0 (−5 to 5)	−1 (−6 to 3)
Blood pressure and heart rate during the mirror tracing task[b]								
Systolic blood pressure (mmHg)	138	100	146 (134–159)	145 (137–158)	142 (132–156)	143 (131–153)	−3 (−12 to 5)	−4 (−10 to 4)
Diastolic blood pressure (mmHg)	138	100	91 (85–98)	92 (85–103)	89 (81–95)	89 (84–96)	−2 (−9 to 3)	−3 (−9 to 1)
Heart rate (b.p.m.)	136	100	74 (67–80)	72 (66–82)	72 (66–78)	72 (65–78)	−1 (−7 to 4)	−2 (−7 to 3)
Psychophysiological reactivity[c]								
ΔSystolic blood pressure (mmHg)	138	100	17 (10–22)	16 (9–26)	16 (9–24)	15 (8–22)	−1 (−8 to 8)	−3 (−9 to 6)
ΔDiastolic B blood pressure (mmHg)	138	100	10 (6–14)	10 (7–14)	8 (4–12)	8 (4–14)	−2 (−6 to 4)	−1 (−6 to 3)
ΔHeart rate (b.p.m.)	136	100	7 (2–10)	6 (3–10)	5 (2–8)	6 (4–10)	−1 (−6 to 2)	0 (−4 to 5)
Number of errors and feelings of stress								
Number of errors	132	100	28 (12–48)	32 (17–54)	23 (8–52)	34 (14–56)	−5 (−15 to 11)	−1 (−17 to 11)
Perceived stress[d]	136	100	3 (2–4)	3 (2–4)	2 (1–3)	3 (2–4)	0 (−1 to 0)	0 (−1 to 0)

b.p.m., beats per minute.

a Three measures of resting blood pressure and heart rate were taken after a 20-minute rest period, and the average of the second and third measures were calculated for each participant.

b Two measures of blood pressure and heart rate were taken during the mirror tracing task, and the average of these measures was calculated for each participant.

c To calculate reactivity to stress, the mean systolic and diastolic blood pressure and heart rate values recorded at rest were subtracted from the corresponding mean values recorded during the mirror tracing task for each participant.

d Perceived stress during the task was recorded on a Likert scale, ranging from 1 'not stressed at all' to 5 'very stressed'.

TABLE 20 Reaction time from the Stroop test measured at baseline and at 6 months' follow-up, along with changes calculated from baseline

Reaction time (ms)	Number of participants		Baseline, median (IQR)		6-month follow-up, median (IQR)		Median (IQR) change from baseline to 6-month follow-up	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
Congruent condition[a]	111	68	988 (880 to 1112)	998 (888 to 1110)	959 (895 to 1058)	976 (878 to 1058)	−17 (−104 to 68)	4 (−102 to 59)
Incongruent condition[b]	111	68	1121 (992 to 1325)	1125 (994 to 1420)	1078 (977 to 1247)	1095 (968 to 1268)	−41 (−145 to 36)	−44 (−135 to 43)

a Naming colour of font of random words.
b Naming colour of font of colour names that are written in a different font colour.

TABLE 21 Grip strength measured at baseline and at 6 months' follow-up, along with changes calculated from baseline

Grip strength	Number of participants		Baseline, mean (SD)		6-month follow-up, mean (SD)		Mean (SD) change from baseline to 6-month follow-up	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
Right hand (kg)	144	104	52.0 (9.6)	51.9 (8.5)	52.2 (10.2)	52.7 (8.9)	0.2 (6.9)	0.8 (6.2)
Left hand (kg)	144	104	50.0 (9.2)	49.1 (7.5)	50.0 (9.8)	50.6 (8.0)	0.02 (6.6)	1.5 (5.1)
Average (kg)	143	104	51.0 (9.0)	50.5 (7.6)	51.0 (9.5)	51.6 (7.9)	0.09 (5.7)	1.1 (4.9)

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TABLE 22 Anxiety, depression and social isolation scores measured at baseline and at 6 months and 16–18 months' follow-up, along with changes calculated from baseline

	Number of participants		Baseline, median (IQR)		Follow-up, median (IQR)		Median (IQR) change from baseline to follow-up	
Variable	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
HADS anxiety[a]								
6 months	145	113	5 (3–7)	4 (2–7)	4 (2–6)	4 (2–7)	−1 (−3 to 1)	0 (−2 to 1)
16–18 months	100	88	5 (3–7)	4 (2–7)	4 (2–7)	4 (2–7)	−1 (−2 to 1)	0 (−1 to 1)
HADS depression[a]								
6 months	145	113	3 (2–7)	3 (1–5)	3 (1–6)	3 (1–5)	−1 (−2 to 1)	0 (−1 to 1)
16–18 months	100	88	3 (2–6)	3 (1–4)	3 (1–6)	3 (1–5)	0 (−2 to 1)	0 (−1 to 1)
Social isolation[b]								
6 months	145	113	44 (39–51)	41 (34–49)	44 (34–49)	43 (34–50)	0 (−5 to 2)	0 (0 to 5)
16–18 months	101	88	44 (39–51)	41 (34–49)	47 (39–52)	44 (34–51)	0 (−2 to 4)	0 (0 to 5)

a HADS anxiety and depression scores range from 0 to 21, with higher scores indicating a greater degree of anxiety/depression. A score of ≤ 7 is classified as 'no symptoms'.
b Social Isolation Scale scores range from 33.9 to 76.9, with higher scores indicating a greater perception of social isolation.

TABLE 23 The prevalence of musculoskeletal discomfort reported in the past month for each body site, along with pain scores by body region, at baseline and at 6 months and 16–18 months' follow-up (changes calculated from baseline are also presented)

Prevalence of musculoskeletal discomfort in the past month per body area[a]	Number of participants		Baseline, proportion (%)		Follow-up, proportion (%)		Change in proportion (%)	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
Neck								
6 months	145	112	39	34	36	34	−3	0
16–18 months	101	91	42	31	38	37	−4	7
Shoulder								
6 months	145	112	40	44	41	43	1	−1
16–18 months	101	91	44	42	49	43	5	1
Upper back								
6 months	145	112	21	27	17	20	−4	−7
16–18 months	101	91	22	29	25	26	3	−2
Elbow								
6 months	145	112	21	19	19	24	−2	5
16–18 months	101	91	23	15	29	18	6	2
Wrist/hand								
6 months	145	112	26	33	29	31	3	−2
16–18 months	101	91	30	34	38	33	8	−1
Lower back								
6 months	145	112	57	56	50	49	−7	−7
16–18 months	101	91	59	57	53	47	−6	−10
Hip/thigh								
6 months	145	112	26	24	14	13	−12	−11
16–18 months	101	91	24	25	22	22	−2	−3
Knee								
6 months	145	112	45	44	41	40	−3	−4
16–18 months	101	91	47	48	42	42	−5	−7

continued

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TABLE 23 The prevalence of musculoskeletal discomfort reported in the past month for each body site, along with pain scores by body region, at baseline and at 6 months and 16–18 months' follow-up (changes calculated from baseline are also presented) (*continued*)

Prevalence of musculoskeletal discomfort in the past month per body area[a]	Number of participants		Baseline, proportion (%)		Follow-up, proportion (%)		Change in proportion (%)	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
Ankle/feet								
6 months	145	112	28	27	21	21	−8	−5
16–18 months	101	91	32	26	29	29	−3	2
Discomfort scores			**Median (IQR)**		**Median (IQR)**		**Median (IQR) change from baseline to follow-up**	
Upper extremity discomfort[b]								
6 months	145	112	0.5 (0.0–1.5)	1.0 (0.0–2.0)	0.5 (0.0–1.8)	0.8 (0.0–2.0)	0.0 (−0.5 to 0.5)	0.0 (−0.5 to 0.5)
16–18 months	101	91	0.5 (0.0–1.5)	0.8 (0.0–1.9)	1.0 (0.0–2.5)	0.8 (0.0–2.0)	0.0 (−0.3 to 1.0)	0.0 (−0.5 to 0.6)
Lower extremity discomfort[c]								
6 months	145	112	0.7 (0.0–2.0)	0.3 (0.0–1.7)	0.3 (0.0–1.7)	0.3 (0.0–1.7)	0.0 (−1.0 to 0.3)	0.0 (−0.3 to 0.3)
16–18 months	101	91	1.0 (0.0–2.0)	0.7 (0.0–2.0)	0.3 (0.0–1.7)	0.3 (0.0–2.0)	0.0 (−0.7 to 0.3)	0.0 (−0.3 to 0.7)
Overall discomfort[d]								
6 months	145	112	1.0 (0.3–1.8)	1.0 (0.3–1.9)	0.9 (0.2–1.8)	0.9 (0.3–1.7)	0.0 (−0.7 to 0.4)	0.0 (−0.6 to 0.3)
16–18 months	101	91	1.1 (0.4–1.7)	1.0 (0.4–1.9)	1.3 (0.3–2.2)	1.0 (0.2–2.1)	0.0 (−0.3 to 0.8)	0.0 (−0.4 to 0.6)

a Standardised Nordic Musculoskeletal Questionnaire. Participants reported trouble (e.g. aches, pain, discomfort, numbness) occurring in the past month in nine body areas on a 11-point Likert scale, ranging from 0 'no trouble' to 10 'severe trouble'.
b Upper extremity discomfort was calculated by averaging discomfort ratings from the shoulder, upper back, elbow and wrist/hand.
c Lower extremity discomfort was calculated by averaging discomfort ratings from the hip, knee and ankle/feet.
d Overall discomfort was calculated by averaging discomfort ratings from all nine areas.

Work-related psychosocial variables

Table 24 provides a descriptive summary of a range of work-related psychosocial variables assessed across the three time points. There were no noticeable differences in any of the outcome measures (i.e. work engagement, occupational fatigue, perceived job satisfaction and performance, sickness absence, presenteeism, perceived work ability and perceived job demands) between baseline and 6 months' follow-up, and between baseline and 16–18 months' follow-up, for both groups. No noticeable differences in any measure were observed between groups at any assessment point.

Driving-related safety behaviour

There were no noticeable differences in self-reported driving-related safety behaviour between baseline and 6 months' follow-up, and between baseline and 16–18 months' follow-up, for both groups (*Table 25*). No noticeable differences were observed between groups at any assessment point.

Health-related quality of life

There were no noticeable differences in perceived markers of HRQoL between baseline and 6 months' follow-up, and between baseline and 16–18 months' follow-up, for both groups (*Table 26*). No noticeable differences were observed between groups at any assessment point.

Lifestyle health-related behaviours and risk measures

There were no noticeable differences in reported alcohol intake between baseline and 6 months' follow-up, and between baseline and the final follow-up, for both groups (*Table 27*). No noticeable differences were observed between groups at any assessment point.

There were no differences in QRISK3 scores between baseline and 6 months' follow-up for both groups (see *Table 27*). Likewise, there were no noticeable differences in QRISK3 scores between the control group and the SHIFT group at any assessment point. When examining the proportion of participants with an estimated CVD risk of $\geq$ 10% over the next 10 years, 23.6% of control participants fell into this category at baseline, with this proportion increasing to 26.4% at 6 months. In contrast, 24.3% of participants in the SHIFT group exhibited a $\geq$ 10% risk of CVD over the next 10 years at baseline, but this fell slightly to 23.4% at 6 months.

Table 27 also provides a summary of the smoking prevalence reported by participants at each time point. There was a tendency for a higher smoking prevalence to be seen in the control group, than in the SHIFT group, across all assessment points. Between baseline and 6 months, two participants in the control group and one participant in the SHIFT group reported changing from a past smoker to a current smoker (i.e. re-starting smoking), and four participants in the SHIFT group reported stopping smoking. No control participants reported stopping smoking between baseline and 6 months. The average number of cigarettes smoked per day by current smokers in the SHIFT group (baseline, $n = 16$; 6 months, $n = 13$) was 14 (SD 5) cigarettes per day at both baseline and 6 months' follow-up. The average number of cigarettes smoked per day by current smokers in the control group (baseline, $n = 27$; 6 months, $n = 29$) was 14 (SD 6) cigarettes per day at baseline and 13 (SD 7) cigarettes per day at 6 months.

Between baseline and 16–18 months' follow-up, one participant in the SHIFT group reported re-starting smoking at and three participants (control group, $n = 1$; SHIFT group, $n = 3$) reported stopping smoking. The average number of cigarettes smoked per day by current smokers in the SHIFT group (baseline, $n = 14$; 16–18 months, $n = 13$) was 15 (SD 5) cigarettes per day at both baseline and 16–18 months. The average number of cigarettes smoked per day by current smokers in the control group (baseline, $n = 21$; 16–18 months, $n = 20$) was 14 (SD 6) cigarettes per day at both baseline and 16–18 months.

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TABLE 24 Work-related psychosocial variables measured at baseline and at 6 months and 16–18 months' follow-up, along with changes calculated from baseline

Variable	Number of participants		Baseline, median (IQR)		Follow-up, median (IQR)		Median (IQR) change from baseline to follow-up	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
Utrecht Work Engagement Scale[a]								
Vigour								
6 months	144	113	4.0 (3.3–5.0)	4.0 (3.0–4.7)	4.0 (3.0–5.0)	4.0 (2.7–5.0)	0.0 (–0.7 to 0.3)	0.0 (–0.7 to 0.3)
16–18 months	100	89	4.0 (3.3–5.0)	3.7 (3.0–4.7)	4.3 (3.3–4.7)	3.7 (2.3–4.7)	0.0 (–0.7 to 0.7)	–0.3 (–0.7 to 0.0)
Dedication								
6 months	144	113	4.3 (3.3–5.3)	4.0 (3.0–5.0)	4.3 (3.3–5.0)	4.3 (3.0–5.0)	0.0 (–0.7 to 0.3)	0.0 (–0.3 to 0.7)
16–18 months	100	89	3.7 (4.7–6.0)	4.0 (3.0–5.0)	4.3 (3.6–5.0)	3.7 (2.7–5.0)	–0.2 (–0.7 to 0.3)	0.0 (–0.7 to 0.3)
Absorption								
6 months	144	113	4.0 (3.0–5.0)	3.7 (2.7–4.7)	3.7 (2.7–4.7)	4.0 (2.7–4.7)	0.0 (–0.7 to 0.3)	0.0 (–0.7 to 0.7)
16–18 months	100	89	3.3 (3.7–5.0)	3.7 (2.3–4.7)	4.0 (3.3–5.0)	3.7 (2.3–4.7)	0.0 (–1.0 to 0.7)	0.0 (–0.7 to 0.3)
Overall summary score								
6 months	144	113	4.3 (3.2–5.0)	3.9 (3.0–4.9)	4.1 (3.0–4.8)	3.9 (2.8–4.8)	–0.1 (–0.7 to 0.3)	0.0 (–0.4 to 0.4)
16–18 months	100	89	3.7 (4.4–5.2)	3.8 (2.9–4.9)	4.2 (3.4–4.8)	3.7 (2.7–4.6)	–0.1 (–0.7 to 0.6)	–0.1 (–0.7 to 0.3)
OFER scale[b]								
Chronic fatigue								
6 months	144	113	33.3 (16.7–60.8)	33.3 (16.7–53.3)	36.7 (16.7–56.7)	36.7 (16.7–56.7)	0.0 (–6.7 to 10.8)	0.0 (–10.0 to 13.3)
16–18 months	100	90	31.7 (16.7–53.3)	31.7 (16.7–53.3)	36.7 (20.0–57.5)	33.3 (20.0–53.3)	3.3 (–3.3 to 13.3)	1.7 (–13.3 to 16.7)

Variable	Number of participants		Baseline, median (IQR)		Follow-up, median (IQR)		Median (IQR) change from baseline to follow-up	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
Acute fatigue								
6 months	144	113	46.7 (32.5–60.0)	50.0 (30.0–63.3)	43.3 (26.7–63.3)	46.7 (30.0–66.7)	0.0 (−10.8 to 10.0)	0.0 (−13.3 to 6.7)
16–18 months	100	90	50.0 (33.3–60.8)	48.3 (26.7–63.3)	50.0 (30.0–63.3)	50.0 (30.8–66.7)	−3.3 (−14.2 to 13.3)	3.3 (−6.7 to 13.3)
Intershift recovery								
6 months	144	113	55.0 (40.0–80.0)	60.0 (43.3–76.7)	60.0 (43.3–76.7)	56.7 (43.3–76.7)	0.0 (−13.3 to 10.0)	0.0 (−10.0 to 6.7)
16–18 months	100	90	53.3 (42.5–80.0)	60.0 (43.3–80.0)	56.7 (40.0–77.5)	53.3 (40.8–80.0)	0.0 (−10.0 to 10.0)	0.0 (−10.0 to 12.5)
Job satisfaction rating[c]								
6 months	144	113	5.0 (4.0–6.0)	5.0 (4.0–6.0)	5.0 (4.0–6.0)	5.0 (4.0–6.0)	0.0 (−1.0 to 0.0)	0.0 (−1.0 to 0.0)
16–18 months	100	90	6.0 (4.0–6.0)	5.0 (4.0–6.0)	5.0 (4.0–6.0)	5.0 (4.0–6.0)	0.0 (−1.0 to 0.0)	0.0 (−1.0 to 1.0)
Job performance rating[c]								
6 months	144	113	6.0 (5.0–7.0)	6.0 (6.0–7.0)	6.0 (6.0–7.0)	6.0 (6.0–7.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)
16–18 months	100	90	6.0 (5.0–6.3)	6.0 (6.0–7.0)	6.0 (5.0–7.0)	6.0 (6.0–7.0)	0.0 (−1.0 to 1.0)	0.0 (0.0–0.0)
Sickness absence (days)[d]								
6 months	142	113	0.0 (0.0–2.0)	0.0 (0.0–1.0)	0.0 (0.0–3.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)
16–18 months	100	90	0.0 (0.0–2.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (−1.3 to 0.0)	0.0 (0.0–0.0)
Presenteeism (days)[d]								
6 months	141	113	2.0 (0.0–5.0)	2.0 (0.0–5.0)	1.0 (0.0–5.0)	1.0 (0.0–5.0)	0.0 (−2.0 to 1.0)	0.0 (−1.3 to 3.0)
16–18 months	98	89	2.0 (0.0–5.0)	2.0 (0.0–5.0)	0.0 (0.0–2.0)	0.0 (0.0–5.0)	0.0 (−4.0 to 0.0)	0.0 (−2.0 to 2.0)
Work ability rating[e]								
6 months	144	113	9.0 (8.0–10.0)	8.5 (8.0–10.0)	8.0 (7.0–9.0)	9.0 (8.0–9.0)	0.0 (−1.0 to 1.0)	0.0 (−1.0 to 1.0)
16–18 months	96	87	9.0 (8.0–9.0)	9.0 (8.0–10.0)	8.0 (8.0–9.0)	9.0 (8.0–10.0)	0.0 (−1.0 to 0.0)	0.0 (−1.0 to 1.0)

continued

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TABLE 24 Work-related psychosocial variables measured at baseline and at 6 months and 16–18 months' follow-up, along with changes calculated from baseline (*continued*)

Variable	Number of participants		Baseline, median (IQR)		Follow-up, median (IQR)		Median (IQR) change from baseline to follow-up	
	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
Work demands (Health and Safety Executive Management Standards Indicator Tool)[f]								
Demand summary score								
6 months	144	113	2.1 (1.8–2.5)	2.1 (1.6–2.9)	2.1 (1.8–2.6)	2.1 (1.6–2.6)	0.1 (–0.3 to 0.4)	0.0 (–0.4 to 0.3)
16–18 months	100	90	2.1 (1.8–2.7)	2.2 (1.6–2.9)	2.2 (1.6–2.8)	2.3 (1.6–2.8)	0.1 (–0.4 to 0.5)	0.0 (–0.5 to 0.4)
Control summary score								
6 months	144	113	3.3 (2.7–3.8)	3.3 (2.8–3.8)	3.3 (2.7–3.8)	3.2 (2.8–3.8)	0.0 (–0.3 to 0.5)	0.0 (–0.5 to 0.3)
16–18 months	100	90	3.2 (2.6–3.8)	3.2 (2.8–3.8)	3.3 (2.7–3.9)	3.2 (2.8–4.0)	0.0 (–0.5 to 0.7)	0.0 (–0.3 to 0.5)
Support summary score								
6 months	144	113	3.3 (2.8–3.8)	3.3 (2.7–3.9)	3.2 (2.6–3.8)	3.2 (2.7–3.9)	–0.1 (–0.4 to 0.3)	–0.1 (–0.4 to 0.4)
16–18 months	100	90	3.4 (2.9–4.0)	3.3 (2.7–4.0)	3.2 (2.8–3.9)	3.3 (2.8–3.9)	0.0 (–0.4 to 0.3)	0.1 (–0.3 to 0.4)

a For each construct (i.e. vigour, dedication and absorption), responses are scored on a 7-point Likert scale, ranging from 0 'never' to 6 'always (every day)'. Higher scores indicate greater work engagement.
b For each subscale (i.e. chronic fatigue, acute fatigue and intershift recovery), responses are scored on a 7-point Likert scale, ranging from 0 'strongly disagree' to 6 'strongly agree'. A score for each subscale is calculated, which ranges from 0 to 100, with a higher score indicating a higher degree of the subscale construct.
c Job satisfaction and performance were rated on 7-point Likert scales, ranging from 1 'dissatisfied/very poorly' to 7 'extremely satisfied/extremely well'.
d The total number of days participants reported being absent from work due to sickness over the last 6 months and the total number of days participants reported attending work despite not feeling well over the past 6 months.
e Current work ability rating, reported on a 11-point Likert scale, ranging from 0 'worst' to 10 'best'.
f Perceived work demands, scored using a 5-point Likert scale, ranging from 1 'never' to 5 'always'. Higher calculated scores for each construct (i.e. demand, control and support) represent a higher degree of that construct.

TABLE 25 Markers of driving-related safety behaviour measured at baseline and at 6 months and 16–18 months' follow-up, along with changes calculated from baseline

	Number of participants		Baseline, median (IQR)		Follow-up, median (IQR)		Median (IQR) change from baseline to follow-up	
Variable	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
Occasionally jump to get out of lorry quickly								
6 months	144	113	2 (1–3)	2 (1–3)	2 (1–3)	2 (1–2)	0 (–1 to 0)	0 (–1 to 0)
16–18 months	100	89	2 (1–3)	2 (1–3)	1 (1–3)	1 (1–2)	0 (–1 to 0)	0 (–1 to 0)
Compliance with posted speed limits								
6 months	144	113	4 (4–5)	4 (4–5)	4 (3–5)	4 (4–5)	0 (–1 to 0)	0 (0–0)
16–18 months	100	89	4 (4–5)	4 (4–5)	4 (4–5)	5 (4–5)	0 (0–1)	0 (0–1)
Occasionally drive without getting enough sleep								
6 months	144	113	3 (2–4)	3 (2–4)	3 (2–4)	3 (2–4)	0 (0–0)	0 (0–1)
16–18 months	100	89	3 (2–4)	3 (2–4)	3 (2–4)	3 (2–4)	0 (–1 to 0)	0 (0–1)
Always use logbook legally								
6 months	144	113	5 (4–5)	5 (4–5)	5 (4–5)	5 (4–5)	0 (0–0)	0 (0–0)
16–18 months	100	89	5 (4–5)	5 (4–5)	5 (4–5)	5 (4–5)	0 (0–0)	0 (0–0)
Skip the daily vehicle inspection when tired or rushed								
6 months	144	113	1 (1–2)	1 (1–2)	1 (1–2)	1 (1–2)	0 (0–0)	0 (0–0)
16–18 months	100	89	1 (1–2)	1 (1–2)	1 (1–1)	1 (1–1)	0 (0–0)	0 (0–0)
Sometimes get in a difficult situation without having a way out								
6 months	144	113	2 (1–3)	2 (1–3)	2 (1–3)	2 (1–2)	0 (–1 to 0)	0 (0–0)
16–18 months	100	89	2 (1–3)	2 (1–3)	2 (1–3)	1 (1–2)	0 (–1 to 1)	0 (–1 to 0)

Responses to each statement were scored using a 5-point Likert scale, ranging from 1 'strongly disagree' to 5 'strongly agree'.

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TABLE 26 Markers of HRQoL assessed via the EQ-5D-5L at baseline and at 6 months and 16–18 months' follow-up, along with changes calculated from baseline

	Number of participants		Baseline, median (IQR)		Follow-up, median (IQR)		Median (IQR) change from baseline to follow-up	
Variable	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
Mobility								
6 months	144	113	1 (1–1)	1 (1–1)	1 (1–1)	1 (1–1)	0 (0–0)	0 (0–0)
16–18 months	100	90	1 (1–1)	1 (1–1)	1 (1–1)	1 (1–1)	0 (0–0)	0 (0–0)
Self-care								
6 months	144	113	1 (1–1)	1 (1–1)	1 (1–1)	1 (1–1)	0 (0–0)	0 (0–0)
16–18 months	100	90	1 (1–1)	1 (1–1)	1 (1–1)	1 (1–1)	0 (0–0)	0 (0–0)
Usual activities								
6 months	144	113	1 (1–1)	1 (1–1)	1 (1–1)	1 (1–1)	0 (0–0)	0 (0–0)
16–18 months	100	90	1 (1–1)	1 (1–1)	1 (1–1)	1 (1–1)	0 (0–0)	0 (0–0)
Pain/discomfort								
6 months	144	113	2 (1–2)	2 (1–2)	2 (1–2)	2 (1–2)	0 (–1–0)	0 (0–0)
16–18 months	100	90	2 (1–2)	2 (1–2)	2 (1–2)	2 (1–3)	0 (0–1)	0 (0–1)
Anxiety/depression								
6 months	144	113	1 (1–2)	1 (1–1)	1 (1–1)	1 (1–1)	0 (0–0)	0 (0–0)
16–18 months	100	90	1 (1–2)	1 (1–1)	1 (1–2)	1 (1–2)	0 (0–0)	0 (0–0)
Overall health today								
6 months	144	113	80 (70–90)	80 (75–90)	80 (74–90)	80 (75–90)	0 (–5 to 5)	0 (–9 to 9)
16–18 months	100	90	80 (70–89)	82 (75–90)	80 (70–85)	85 (71–90)	0 (–5 to 10)	0 (–5 to 8)

Mobility, self-care, usual activities, pain/discomfort and anxiety/depression are assessed across five levels of severity (ranging from 1 'no problem' to 5 'unable to/extreme problems'). 'Overall health today' is assessed using a visual analogue scale (which ranges from 0 to 100), where the end points are labelled 'the best health you can imagine' (100) and 'the worst health you can imagine' (0).

TABLE 27 Alcohol Use Disorders Identification Test scores, QRISK3 scores and smoking prevalence at baseline and at 6 months and 16–18 months' follow-up, along with changes calculated from baseline

	Number of participants		Baseline, median (IQR)		Follow-up, median (IQR)		Median (IQR) change from baseline to follow-up	
Variable	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention	Control	SHIFT intervention
AUDIT score[a]								
6 months	144	113	4 (2–5)	4 (3–6)	3 (2–5)	4 (2–5)	0 (0–0)	0 (0–0)
16–18 months	101	91	3 (2–5)	4 (3–6)	3 (2–5)	4 (2–6)	0 (–5 to 10)	0 (–5 to 8)
QRISK3 score[b]								
6 months	144	111	5.6 (2.4–9.6)	5.3 (2.5–9.7)	5.3 (2.3–10.6)	5.7 (2.2–9.3)	0.2 (–0.6 to1.2)	0.0 (–0.9 to 0.7)
			Proportion (%)		Proportion (%)		Change in proportion (%)	
Smoking prevalence[c]								
6 months	145	113	19	14	20	12	1	–2
16–18 months	101	91	21	15	20	14	0	–1

a The first two items from the AUDIT were assessed: 'How often do you have a drink containing alcohol?' [answers range from 'never' (0) to '4 or more times a week (4)] and 'How many units of alcohol do you have on a typical day when you are drinking?' [answers range from '1 or 2′ (0) to '10 or more' (4)]. The scores from the two items are summed, giving a range in scores from 0 to 8.
b Calculated from URL: https://qrisk.org/three/ (accessed 26 August 2022).
c Reported prevalence of smokers.

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COVID-19: impact of a temporary change in driving hour regulations on SHIFT participants

Participants

Of the 220 participants who were still enrolled in the study in May 2020, 91 (41.4%; control group, $n = 48$; SHIFT group, $n = 43$; 99% male) participants completed an additional online questionnaire that captured data on the effect of the pandemic on their working hours, mental well-being and health-related behaviours. The questionnaire was completed during the UK's first national lockdown. At the time of completing the questionnaire, 20 (22%) participants [control group, $n = 15$ (31%); SHIFT group, $n = 5$ (12%)] were on furlough, and 44 (48%) participants [control group, $n = 32$ (67%); SHIFT group, $n = 12$ (28%)] reported being on furlough at some point during the pandemic.

There were no statistically significant differences in questionnaire responses between intervention or control participants, or between participants who were/had been furloughed and participants not furloughed. As a result, the responses received for the COVID-19 questionnaire are presented for the group as a whole. The only measure where a difference was reported was 'sleep duration in the past 14 days'. Participants who had been or who were still on furlough reported a longer sleep duration [median 7.0 (IQR 5.5–8.5) hours/night] than participants who were not furloughed [median 6.5 (IQR 5.5–7.5) hours/night].

Baseline characteristics and measures of the 91 participants completing the COVID-19 questionnaire did not differ significantly from the remainder of the participants within the SHIFT study, and this suggests that the subsample of 91 participants are largely representative of the wider sample. Specifically, there were no differences at baseline between participants completing the COVID-19 questionnaire and the wider sample in terms of age, duration working as a HGV driver, duration working for DHL Supply Chain, hours worked per week, BMI, per cent body fat, waist circumference, self-reported symptoms of anxiety and depression, musculoskeletal complaints, physical activity levels, and sleep duration and efficiency.

Working hours and activity levels before and during the pandemic

Participants reported no changes to their working, driving, in-cab waiting or rest hours during the pandemic. Similarly, participants reported no changes in the time spent sitting, standing and walking/moving around on a workday during the pandemic (*Table 28*).

TABLE 28 Working-related variables and activity-related behaviours reported within the online questionnaire in May to June 2020

Variable	Number[a]	Before COVID-19, median (IQR)	During COVID-19, median (IQR)	Difference (*p*-value)[b]
Working hours (hours/week)	46	48.0 (44.0–50.0)	47.5 (43.0–51.0)	0.46
Driving hours (hours/day)	46	7.0 (6.0–7.8)	7.0 (6.0–8.0)	0.75
In-cab waiting hours (hours/shift)	46	1.5 (1.0–2.0)	1.5 (1.0–2.9)	0.15
Rest hours between shifts (hours)	46	12.0 (11.0–14.0)	12.0 (11.0–14.0)	0.70
Sitting time (hours/day)	86	7.0 (6.0–8.6)	7.0 (5.0–9.0)	0.81
Standing time (hours/day)	86	1.0 (1.0–2.0)	1.0 (1.0–2.0)	0.78
Walking/moving time (hours/day)	86	3.0 (2.0–4.0)	3.0 (2.0–4.0)	0.56

a Data on working-related outcomes were provided by participants who had not been furloughed during the pandemic. Data on activity-related variables were provided by all participants.
b Results of the Wilcoxon signed-rank tests, comparing responses before and during COVID-19, reported within the online questionnaire.

Anxiety, depression and fatigue before and during the pandemic

In comparison with baseline, there was a tendency for participants who completed the additional COVID-19 questionnaire to report lower levels of symptoms of anxiety during the pandemic (*Table 29*). There were no differences observed in symptoms of depression, levels of acute and chronic fatigue or intershift recovery during the pandemic, compared with baseline, for this subsample (see *Table 29*).

The impact of exposure to green space on anxiety, depression and fatigue before and during the pandemic

Within the online questionnaire, 72% ($n = 65$) of participants reported that they regularly spent time in nature (e.g. spending time in their garden/allotment, in parks and woodland, at the coast and in open green spaces) prior to the onset of the pandemic. Data collected at baseline revealed that participants who reported spending time in nature also reported significantly lower amounts of chronic fatigue associated with their work than participants who reported that they did not spend time in nature ($n = 25$) [median chronic fatigue score: 23.3 (IQR 10.0–40.0) vs. 43.3 (IQR 26.7–66.7); $p = 0.008$]. There were no other differences between groups in terms of other markers of fatigue and symptoms of anxiety and depression at baseline.

During the pandemic, 78% ($n = 70$) of participants reported spending time in nature. Examining data from participants working at the time of completing the online questionnaire revealed that participants who reported spending time in nature ($n = 51$) also reported significantly lower amounts of chronic and acute fatigue associated with their work than participants who reported that they did not spend time in nature ($n = 17$) [median chronic fatigue score: 20.0 (IQR 3.3–41.7) vs. 51.7 (IQR 35.8–65.0), $p = 0.002$; median acute fatigue score: 40.0 (IQR 16.7–56.7) vs. 55.0 (IQR 47.5–79.2), $p = 0.009$]. The differences between groups for intershift recovery were marginal, but in favour of the group spending time in nature [median intershift recovery score: 63.3 (IQR 50.0–83.3) vs. 50.0 (IQR 36.7–66.7); $p = 0.06$]. There were no differences between groups in symptoms of anxiety and depression reported during the pandemic.

TABLE 29 Anxiety, depression and fatigue scores reported within the online questionnaire in May to June 2020 (pre-COVID data were derived from the baseline measurements collected from this subsample)

Variable	Number[a]	Before COVID-19, median (IQR)[b]	During COVID-19, median (IQR)	Difference (*p*-value)[c]
HADS anxiety[d]	90	3.0 (1.0–5.0)	3.0 (1.0–6.0)	0.01
HADS depression[d]	90	4.0 (3.0–7.0)	1.0 (0.3–5.0)	0.27
Chronic fatigue[e]	69	26.7 (16.7–43.3)	30.0 (8.3–51.7)	0.98
Acute fatigue[e]	69	46.7 (30.0–63.3)	46.7 (21.7–63.3)	0.77
Intershift recovery[e]	69	63.3 (46.7–83.3)	56.7 (45.0–83.3)	0.12

a The HADS questionnaire was completed by all participants undertaking the online survey, whereas the OFER scale was completed by participants who were working at the time of completing the questionnaire.
b Data derived from the baseline measures collected from participants completing the COVID-19 questionnaire.
c Results of the Wilcoxon signed-rank tests, comparing variables before and during COVID-19.
d HADS anxiety and depression scores range from 0 to 21, with higher scores indicating a greater degree of anxiety/depression. A score of ≤ 7 is classified as 'no symptoms'.
e For each subscale (i.e. chronic fatigue, acute fatigue, intershift recovery) on the OFER scale, responses are scored on a 7-point Likert scale, ranging from 0 'strongly disagree' to 6 'strongly agree'. A score for each subscale is calculated, which ranges from 0 to 100, with a higher score indicating a higher degree of the subscale construct.

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The impact of the pandemic on drivers' lifestyle health-related behaviours

Twenty-three (25%) participants reported engaging in a new form of physical activity since the COVID-19 outbreak. New activities reported by participants included cycling ($n = 10$), walking ($n = 5$), gardening ($n = 3$), running ($n = 2$), weights at home ($n = 2$), boxing (punchbag training) ($n = 1$), exercises at home ($n = 1$), home workouts with a personal trainer ($n = 1$) and DIY ('do it yourself') ($n = 1$) (note that some participants reported more than one new activity). Seven of 47 (15%) participants who had not been furloughed reported engaging in a new activity, compared 16 of 44 (36%) participants who had been furloughed during the pandemic.

Twenty per cent of participants reported that their consumption of snacks (e.g. cakes, biscuits, crisps, chocolate and sweets) had decreased during the pandemic, whereas 19% reported an increase. Twenty-three per cent of participants reported that their consumption of fresh fruit and vegetables had increased during the pandemic, whereas 7% reported a decrease. Thirty-four per cent of participants reported not being able to access healthy food while at work during the pandemic, whereas 45% reported accessing healthy food, all stating that they brought their own from home.

Five per cent of participants reported a change to their smoking status during the pandemic. One participant reported starting smoking, two participants reported smoking less and two participants reported stopping smoking. Five per cent of participants reported a decrease in their alcohol intake during the pandemic, whereas 26% reported an increase.

Twenty-seven per cent of participants reported that their sleep duration had increased during the pandemic, whereas 13% reported a decrease. Of the participants reporting an increase in sleep duration, 23 of 25 participants had been furloughed. Participants currently furloughed at the time of completing the questionnaire ($n = 20$) reported a median sleep duration over the past 14 days of 8 (IQR 6–10) hours per day. Participants currently working ($n = 70$) reported a median sleep duration over the past 14 days of 7 (IQR 6–8) hours per day.

The impact of involvement in the SHIFT study on health behaviours during the pandemic, and lifestyle changes experienced

Participants were asked within the online questionnaire whether or not they felt that participating in the SHIFT study had given them the right knowledge to maintain a healthy lifestyle during the COVID-19 restrictions. A total of 63% of both intervention and control participants answered 'yes' to this question. Overall, 63% of both intervention and control participants answered 'yes'. A range of qualitative quotes were provided by respondents on how the study had helped them maintain a healthy lifestyle during the pandemic. The responses received were similar between intervention and control participants, and largely centred around an increased understanding of the importance of activity and a better diet. The quotes are shown in *Appendix 2*, *Box 1*.

When asked within the questionnaire whether or not they had experienced any changes in lifestyle and/or work that had either a positive or negative impact on health, 40 (44%) participants answered 'yes'. Of them, 20 (22%) participants reported that these changes had a positive impact and 20 (22%) reported that these changes had a negative impact. A range of qualitative quotes were provided from respondents regarding changes in lifestyle experienced (see *Appendix 2*, *Box 2*). Participants reporting positive changes tended to refer to having time off work as a result of being furloughed and, therefore, having more time to be physically active. Participants reporting negative changes tended to refer to a lack of access to facilities (e.g. gyms, swimming pools) to enable them to be active, increased snacking behaviours due to being at home and reductions in the overall quality of their diets due to limited food choices.

Adverse events

No serious adverse events were reported during the trial.

Chapter 4 Economic evaluation

Methodology overview

The economic evaluation considers the resource use, costs and cost-effectiveness of the SHIFT intervention compared with usual practice, using evidence from the SHIFT RCT and other sources. Costs were measured in GBP (2019–20) from a public sector perspective (i.e. NHS and Personal Social Services). A private sector perspective (haulage firm) was also considered for secondary analyses.[106,107] Health outcomes were primarily measured in QALYs and based on the EQ-5D-5L questionnaire.[81,108] Other measures, including productivity, employee well-being and absenteeism, were also considered. Missing data were populated using multiple imputation by chained equations.[109] Within-trial costs and QALYs were estimated using multilevel econometric modelling to control for participant co-variables and cross-cluster variation.[110] Decision-analytic models were used to extrapolate the results over a longer time horizon, based on any observed differences in physical activity between trial arms.[111] In line with UK guidelines,[106] costs and QALYs were discounted at 3.5% per annum. Cost-effectiveness was measured using ICERs and incremental net health benefits (INHBs) at cost-effectiveness thresholds of £15,000, £20,000 and £30,000 per QALY.[106,112]

Probabilistic sensitivity analysis was used to characterise the uncertainty, and decision uncertainty was assessed across alternate cost-effectiveness thresholds. Scenario, sensitivity and threshold analyses were also conducted to consider the implications of alternate methods and modelling assumptions on study findings.[106] Further details are available in the health economic analysis plan (see *Report Supplementary Material 4*).

Resource use and costs

Health-related resource use was collected from participants using a service use questionnaire at baseline and at 6 months and 16–18 months. Responses at each time point related to participants' resource use in the 6 months prior. Health-care costs were calculated for each trial participant by resource use category and at each follow-up period by applying unit costs to any resources used. It was assumed that the 16- to 18-month follow-up occurred at 18 months, and resource use between 6 and 12 months was equal to resource use between 12 and 18 months. Health-related resources and costs were categorised into primary care, secondary care, mental health care and occupational services. Unit costs were measured in GBP (2019–20) and were sourced from published UK sources (see *Appendix 3*, *Table 43*).[91,113] Unit costs were inflated to 2019–20 prices using inflation indices where necessary.[91] Costs of absenteeism were calculated based on firm-reported full-day driver-replacement costs.

The resource use and associated intervention costs for the SHIFT intervention comprised (1) exercise-related devices, equipment and materials [e.g. wearable device (i.e. a Fitbit Charge 2), THERABAND® bands (Akron, OH, USA), intervention booklet] and (2) a 6-hour education session that required driver time, course materials and staff training. It was assumed that the education session would require a full worker day for each attendee and that the session was delivered by existing facilitators and, therefore, incurred no additional costs. The average SHIFT intervention cost per driver was treated as an up-front cost (i.e. with no follow-up costs) and calculated on an ITT basis. Usual practice was assumed to incur no intervention-related costs. Intervention unit costs were based directly on those incurred during the trial.

Outcomes

The primary outcome used in the cost-effectiveness analysis was QALYs, which is a generic measure of health that combines both length of life and HRQoL (1 QALY is equal to 1 year in perfect health).[108] Participants' HRQoL was assessed using the EQ-5D-5L questionnaire, collected at baseline and at 6 months and 16–18 months. The EQ-5D-5L is a descriptive HRQoL instrument that comprises five

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levels of severity across the following five health dimensions: (1) mobility, (2) self-care, (3) usual activity, (4) pain/discomfort and (5) anxiety/depression.[81] In accordance with National Institute for Health and Care Excellence (NICE) recommendations, HRQoL weights were calculated from a published mapping of EQ-5D-5L responses onto HRQoL values calculated for the EuroQol-5 Dimensions, three-level version (EQ-5D-3L) instrument from a survey of the UK general public.[106,114] Trial QALYs were estimated through an area under the curve approach, with linear interpolation between observations.[108] It was assumed at the 16- to 18-month follow-up occurred at 18 months to allow for a common time horizon for estimation of QALYs. Longer-term cost-effectiveness analyses calculated QALYs using decision-analytic models (see *Decision-analytic model and longer-term cost-effectiveness*), which combined estimated within-trial QALY differences (i.e. within-trial analysis) with QALYs estimated over a longer time horizon, based on any observed impacts on levels of physical activity. It was assumed that the HRQoL of drivers beyond the trial were equal between arms (i.e. any within-trial differences did not persist beyond the trial period) and equivalent to age-specific values observed in the trial. The removal of estimated within-trial differences in outcomes and the use of HRQoL weights from the EQ-5D-5L value set were explored in scenario analyses.

Secondary outcomes included productivity, employee well-being and absenteeism. Productivity considered employee-assessed job performance and work ability on Likert scales that ranged from 0 to 7 and 0 to 10, respectively (with higher scores denoting more favourable outcomes). Participants' work-related well-being considered employee-assessed job satisfaction on a Likert scale that ranged from 0 to 7 (with higher scores denoting greater satisfaction) and presenteeism according to the number of days drivers have worked despite feeling unwell.

Methods for analysis

Analysis

A health economics analysis plan (see *Report Supplementary Material 4*) was created before the health economics analysts had access to the data. From a public sector perspective, the cost-effectiveness of the SHIFT intervention (compared with usual practice) was assessed according to (1) the estimated differences in the QALYs gained by drivers and (2) the incremental costs to public services incurring over a 16- to 18-month time horizon (i.e. within trial) and over the longer term. Secondary analyses considered cost-effectiveness from a private sector perspective by assessing the differences in changes to measures of productivity and employee well-being at 6 months and 16–18 months from baseline, as well as the incremental costs. From a public perspective, intervention costs and all costs relating to health resource usage were considered. Only intervention and absenteeism costs were considered from the private sector perspective. Both public and private sector perspectives included SHIFT intervention costs, as these could feasibly be financed by either source.

For the public sector analysis, estimated costs and outcomes in each arm, and their differentials, are presented alongside ICERs and INHBs. ICERs represented the cost per additional unit of outcome for the SHIFT intervention compared with usual practice. The INHBs for the SHIFT intervention measured the intervention's health gain less the health that would have otherwise been generated elsewhere had the additional resources (compared with usual practice) been allocated for alternative purposes (i.e. the opportunity cost estimated using a given cost-effectiveness threshold). Three cost-effectiveness thresholds (i.e. measures of health opportunity cost) were considered in the analysis: (1) £15,000 per QALY [i.e. the Department of Health and Social Care's usual threshold (based on recent empirical estimates)],[112,115] (2) £20,000 per QALY and (3) £30,000 per QALY. The thresholds (i.e. £15,000, £20,000 and £30,000) are used by NICE to assess cost-effectiveness of health-care interventions.[106] At a given threshold, the SHIFT intervention is considered cost-effective, compared with usual practice, when its ICER is below the chosen cost-effectiveness threshold and it has positive INHB. For the private sector perspective, ICERs are presented, showing the cost per unit change in the measure of productivity or well-being.

Within-trial analysis

Estimated within-trial costs and QALYs in each treatment arm were obtained using multilevel linear regression models on multiply imputed data that controlled for a set of relevant participant co-variables and accounted for cross-cluster variation (i.e. variation between sites). Regression analyses controlled for age (i.e. 40–49 years, 50–59 years and ≥ 60 years vs. < 40 years), sex (i.e. female vs. male), ethnicity (i.e. white vs. other), BMI category (i.e. overweight, morbidly obese and obese vs. healthy), presence of diabetes, smoking status (i.e. ex-smoker and current smoker vs. never smoked) and cluster size. QALY regression analyses also controlled for baseline EQ-5D scores to account for differences in baseline HRQoL.[116] Scenarios considered the following alternative approaches: (1) a generalised linear model using a log-link transformation and gamma family form to account for the positive and right-skewed nature of the cost data; (2) excluding the costs from inpatient-related services, given the potential for random imbalances in hospital procedures to affect cost differentials between arms; and (3) an analysis that considers only participants with complete data (i.e. complete-case analysis).

Missing data

Missing cost and outcome data were populated via multiple imputation using chained equations, with predictive mean matching used to match predicted missing values with the closest observed value.[116] The imputation model controlled for all the covariates considered in the within-trial regression models, including clusters. Using Rubin's rules, overall imputed mean estimates and standard errors were calculated from 20 imputed data sets to reflect the variability within and across imputations.[116,117]

Decision-analytic model and longer-term cost-effectiveness

The longer-term cost-effectiveness of the SHIFT intervention was assessed using decision-analytic models that sought to capture the longer-term benefits of physical activity for HGV drivers. Given the uncertainties associated with modelling the impact of physical activity on public health,[118] alternative measures of physical activity and modelling approaches were considered to estimate outcomes.

The first decision-analytic model was a two-state Markov model, where the cohort starts in an alive state and will either remain in that state or transition into an absorbing dead state. Beyond the first year, the model captured QALYs using the age-specific HRQoL observed in the trial and did not consider additional costs. For usual practice, transitions to the death state were based on age- and sex-adjusted English general population mortality rates.[119] Mortality rates for the SHIFT arm were then adjusted according to estimated changes in one of two alternative measures of physical activity: (1) time spent in MVPA (i.e. the MVPA-based model) and (2) time spent sedentary (i.e. the sedentary-based model) (see *Chapter 2*). The dose–response relationship between changes in accelerometer-measured physical activity (specifically MVPA and sedentary time) and all-cause mortality was based on hazard estimates reported in Ekelund *et al.*'s meta-analysis.[120] Polynomial functions were used to interpolate between all-cause mortality hazard ratios, relative risks and 95% CI point estimates (see *Appendix 3*, *Figures 4* and *5*). Physical activity in the usual-practice arm was assumed to follow baseline values (across arms) and to remain constant over time (see *Table 7*). In the SHIFT arm, the average change in physical activity relative to usual practice in the first year was assumed to be equal to estimated differences at the yearly mid-point (i.e. 6 months) (see *Table 9*). After the first year, SHIFT-associated differentials in physical activity were reduced exponentially at a 50% decay rate per annum from estimated differences at final follow-up, although the decay rate was varied in sensitivity analyses. The model was run using average participant characteristics over a lifetime horizon.

An alternative decision-analytic model considered was the Model for estimating the Outcomes and Values in the Economics of Sport (MOVES) tool, version 2.0, which was developed for Sport England.[92,121] The MOVES tool estimates risk reductions across seven completing diseases (i.e. dementia, depression, colon cancer, type 2 diabetes, breast cancer, ischaemic heart disease and stroke) from changes in physical activity measured by metabolic-equivalent hours per week. The model was modified to have the same treatment effect schedule as the first decision-analytic model, with first year exercise differences equal to those estimated at 6 months, second year differences equal to those estimated at 16–18 months, and

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differences thereafter reduced exponentially from 16–18 months at a 50% decay rate per annum. The underlying HRQoL of the cohort over time was aligned with the age-specific HRQoL observed in the trial. Minutes in MVPA were translated into metabolic-equivalent hours per week by assuming the intensity of activity within MVPA follows a uniform distribution between 3 (i.e. light moderate exercise) and 6 (i.e. vigorous exercise). Metabolic-equivalent hours per week in each arm were defined according to baseline MVPA minutes (pooled across arms), estimated treatment differentials in MVPA minutes and presumed metabolic intensity (drawn from identical uniform distributions) (see *Table 9*). Exercise differentials were bounded such that no individual could undertake a negative number of minutes exercise. The model was run using average participant characteristics over a 25-year time horizon.

In all models, treatment-associated changes in physical activity were applied as common effects (i.e. irrespective of participant characteristics). Estimated within-trial cost and QALY treatment differences were incorporated in the first year, but were not extrapolated thereafter. In accordance with NICE guidance,[106] costs and QALYs were discounted at a 3.5% discount rate. Scenario analyses considered removing all estimated trial-specific treatment differentials in QALYs and non-intervention costs, as well as an annual discount rate of 1.5%.[122]

Uncertainty

Monte Carlo simulation was used to propagate the uncertainty in the analyses to estimate overall decision uncertainty surrounding the adoption of the SHIFT intervention. It was assumed that (1) event probabilities followed beta distributions (MOVES[92,121]), (2) baseline physical activity (i.e. usual practice), treatment effects and all-cause mortality hazard ratios (Ekelund *et al.*[120]) were normally distributed and (3) regression coefficients (i.e. within-trial non-intervention costs and outcomes) followed multivariate normality.[111] Regression parameter correlations were accounted for using Cholesky transformations of the variance–covariance matrix.[111]

Uncertainty was reported at 95% credible intervals around mean cost, QALY and INHB values, alongside the probabilities of the SHIFT intervention/usual practice being the most costly, clinically effective and cost-effective alternative. INHB and the probability of being cost-effective are presented for cost-effectiveness thresholds of £15,000, £20,000, and £30,000 (i.e. the health that would have been generated elsewhere using the same resources). Cost-effectiveness acceptability curves illustrated the probability of the SHIFT intervention or usual practice being cost-effective up to a threshold of £50,000 per QALY.

Key uncertainties were explored in a range of scenario analyses involving alternative methodological approaches (see above) and the removal of all estimated within-trial differences in non-intervention costs and QALYs between trial arms. Sensitivity and threshold analyses explored the impacts of two alternative degrees of treatment maintenance on study findings: (1) the annual rate of decay in the treatment effect on physical activity beyond the first year (i.e. a 50% decay rate used in the base case) and (2) the continuation of the treatment effect on physical activity observed at 6 months.

Results

The SHIFT trial involved 382 participants (SHIFT intervention, $n = 183$; usual practice, $n = 199$). Health-care resource use forms were fully completed by approximately 93.5%, 63.9% and 46.9% of participants at baseline, 6 months and 16–18 months, respectively. Complete-case resource use was achieved by 40.8% of participants. EQ-5D-5L questionnaires were complete for 98.2% of participants at baseline, and for 66.8% and 49.2% of participants at 6 months and 16–18 months, respectively. Complete-case EQ-5D-5L responses amounted to 44.5% of participants. Secondary outcome data (i.e. productivity, employee work-related well-being and absenteeism) had a comparable degree of missingness, ranging between 98.7% and 99.5% at baseline, between 67.0% and 67.3% at 6 months and between 48.4% and 50.5% at 16–18 months. Participant characteristics are reported in *Table 5*.

Treatment effect

Baseline physical activity (i.e. usual practice) was modelled at 15.36 minutes per day in MVPA and 670.31 minutes of sedentary time per day. In the first year, the SHIFT intervention was associated with an additional 5.84 minutes per day in MVPA and a reduction in sedentary time of 24.37 minutes per day (see *Table 9*). In the second year, the SHIFT intervention was associated with an additional 1.6 minutes per day in MVPA and a reduction in sedentary time of 12.16 minutes per day. In the subsequent years, the treatment effect was extrapolated from second year differentials (i.e. a 1.6-minute/day increase in MVPA and a 12.16-minute/day reduction in sedentary time).

Resource use and costs

Intervention-level costs

Table 30 provides the average per driver costs of delivering each element of the SHIFT intervention. The average total cost of delivering the SHIFT intervention was £369.57 per driver. The equipment (£182.49) and education (£187.08) elements of the SHIFT intervention had comparable costs. Education costs mostly comprised driver replacement costs.

Health-care resource use and non-intervention costs

Resource use and associated costs were broadly balanced between the SHIFT intervention and usual practice over the course of the trial (*Table 31*). Differences within and across resource categories were small in magnitude and inconsistent in direction of effect (see *Appendix 3*, *Tables 44–53*). The total imputed costs were lower for usual practice (£637.66) than for the SHIFT intervention (£1,162.50). When controlling for participant covariates, the SHIFT intervention was associated with an additional £181.50 in non-intervention costs compared with usual care (see *Appendix 3*, *Table 57*). *Appendix 3*, *Tables 44–47*, present available- and complete-case breakdowns of resource use for each comparator by resource category and follow-up period. *Appendix 3*, *Tables 48–51*, describe available-case, complete-case and imputed costs by resource category and follow-up period for each trial arm.

TABLE 30 SHIFT intervention costs

SHIFT intervention component	Cost (£) per driver
Equipment and materials	182.49
THERABAND bands	12.17
Exercise balls	3.80
Fitbit Charge 2	90.99
Fitabase software	65.53
Duffel bag	2.20
Text messaging service	2.80
Intervention booklet	5.00
6-hour education session	187.07
Individual driver's time	180.00
Printing of curriculum and laminates	1.21
Creation of resources	0.74
Training staff facilitators	5.12
Total cost per participant	369.56

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TABLE 31 Average imputed total costs by treatment arm

	SHIFT intervention			Usual practice		
Imputed cost	*n*	Mean (SD)	95% CI	*n*	Mean (SD)	95% CI
SHIFT intervention	185	369.57 (0)	0 to 0	201	–	–
Primary care						
GP: surgery visit	185	52.37 (104.03)	37 to 68	201	57.72 (115.81)	41 to 74
GP: home visit	185	5.29 (62.01)	−4 to 14	201	3.46 (183.48)	−22 to 29
GP: telephone call	185	11.85 (44.81)	5 to 18	201	13.66 (40.7)	8 to 19
General practice nurse: surgery visit	185	3.08 (9.63)	2 to 4	201	3.13 (9.06)	2 to 4
General practice nurse: home visit	185	2.74 (26.9)	−1 to 7	201	1.76 (23.3)	−2 to 5
General practice nurse: telephone call	185	1.14 (7.65)	0 to 2	201	1.17 (7.82)	0 to 2
Secondary care						
Inpatient days	185	440.24 (3405.4)	−63 to 943	201	306.95 (2740.31)	−80 to 694
Outpatient visits	185	102.67 (331.89)	54 to 151	201	112.97 (348.93)	64 to 162
Accident and emergency visits	185	37.88 (137.35)	18 to 58	201	33.32 (133.51)	14 to 52
NHS walk-in centre visit	185	3.86 (24.99)	0 to 8	201	4.17 (23.75)	1 to 7
NHS urgent care centre visit	185	2.01 (20.01)	−1 to 5	201	3.42 (23.05)	0 to 7
Other hospital-based services	185	7.68 (64.73)	−2 to 17	201	3.75 (48.38)	−3 to 11
Mental health care						
Mental health nurse	185	3.80 (44.29)	−3 to 10	201	8.02 (53.42)	1 to 15
Occupational services						
Occupational health nurse	185	3.93 (25.71)	0 to 8	201	1.93 (20.61)	−1 to 5
Physiotherapist	185	114.4 (408.15)	55 to 174	201	82.24 (462.83)	17 to 147
Total costs						
Overall total observed costs	185	1162.50 (3976.2)	576 to 1749	201	637.66 (3251.62)	179 to 1096
Total costs, excluding inpatient-related services	185	722.26 (873.19)	595 to 850	201	330.71 (809.67)	217 to 444

Outcomes

Quality-adjusted life-years and HRQoL scores were similar between the arms, albeit with modest differences in baseline values and changes at 6 months' follow-up (*Table 32*). In the SHIFT arm, EQ-5D-5L and mapped EQ-5D-3L scores fell over the trial period. In the usual-practice arm, scores rose between baseline and 6 months, before declining to levels below baseline (see *Appendix 3*, *Table 54*). Adjusted QALY estimates (i.e. QALY estimates estimated using imputed data while controlling for participant covariates) found −0.028 and −0.015 QALY decrements associated with the SHIFT intervention compared with usual practice over the trial horizon when using mapped EQ-5D-3L and EQ-5D-5L preference weights, respectively (see *Appendix 3*, *Tables 61* and *62*). Secondary outcomes are reported in *Table 33*. There were small and largely inconsistent changes within and between arms for each outcome considered.

TABLE 32 Primary imputed outcomes by treatment arm and follow-up

Outcome	SHIFT intervention, mean (SD)	Control, mean (SD)	Differential, mean (95% CI)
Preference scores *EQ-5D-3L (base case)*			
Baseline	0.852 (0.146)	0.839 (0.141)	0.013 (−0.016 to 0.042)
6 months	0.838 (0.155)	0.864 (0.147)	−0.026 (−0.056 to 0.003)
16–18 months	0.797 (0.188)	0.795 (0.197)	0.002 (−0.039 to 0.042)
EQ-5D-5L (scenario)			
Baseline	0.909 (0.113)	0.902 (0.108)	−0.016 (−0.039 to 0.007)
6 months	0.905 (0.121)	0.922 (0.103)	−0.016 (−0.016 to 0.029)
16–18 months	0.875 (0.153)	0.869 (0.166)	0.006 (−0.027 to 0.040)
QALYs *EQ-5D-3L (base case)*			
0–6 months	0.422 (0.063)	0.426 (0.061)	−0.003 (−0.016 to 0.009)
16–18 months	0.817 (0.146)	0.830 (0.145)	−0.012 (−0.042 to 0.017)
Total	1.240 (0.198)	1.256 (0.194)	−0.016 (−0.054 to 0.023)
EQ-5D-5L (scenario)			
0–6 months	0.454 (0.051)	0.456 (0.045)	−0.002 (−0.012 to 0.007)
16–18 months	0.890 (0.115)	0.895 (0.114)	−0.005 (−0.028 to 0.018)
Total	1.344 (0.157)	1.351 (0.148)	−0.007 (−0.038 to 0.023)

Cost-effectiveness analysis

The within-trial and longer-term base-case mean cost, QALY and cost-effectiveness estimates for each arm and modelling approach are reported in *Table 34*.

The within-trial analysis found the SHIFT intervention to be more costly and less effective than usual practice, resulting in it being dominated. The probability of the SHIFT intervention being cost-effective in the within-trial period was low, with a probability of between 0.009 and 0.011 for the range of cost-effectiveness thresholds considered.

For the MVPA-based model, when using Ekelund *et al.*[120] all-cause mortality estimates with changes to MVPA minutes per day, the SHIFT intervention was found to be more costly and less effective than usual practice and, thereby, dominated. Incremental costs (£555) were the same as the within-trial analysis (the model did not extrapolate costs); however, QALY decrements were reduced to −0.022 per driver because of the increased physical activity in the SHIFT group reducing mortality. Similar results were found when using the sedentary-based model, with costs aligned to within-trial results and QALY decrements of −0.021.

The SHIFT intervention was also found to be more costly and less effective when using the MOVES tool. The inclusion of lifetime costs in the MOVES model increased overall cost estimates, but resulted in a small reduction in the incremental costs for the SHIFT group (£507). QALY decrements were reduced to −0.016 in the SHIFT group, relative to usual practice.

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TABLE 33 Secondary imputed outcomes by treatment arm and follow-up

	Baseline			Month 6			Months 16–18[a]		
Secondary outcome: imputed	SHIFT intervention, mean (SD)	Usual practice	Differential (95% CI)	SHIFT intervention, mean (SD)	Usual practice	Differential (95% CI)	SHIFT intervention, mean (SD)	Usual practice	Differential (95% CI)
Absenteeism									
Number of sick days	3.492 (15.405)	3.814 (12.866)	−0.322 (−3.154 to 2.51)	1.776 (6.796)	3.039 (8.241)	−1.263 (−2.745 to 0.218)	6.388 (24.251)	5.015 (22.726)	1.372 (−3.028 to 5.773)
Productivity									
Employee-assessed job performance[b]	6.019 (0.907)	5.974 (0.859)	0.045 (−0.132 to 0.222)	6.026 (1.076)	5.981 (1.004)	0.045 (−0.148 to 0.238)	6.059 (1.253)	5.933 (1.236)	0.126 (−0.112 to 0.364)
Employee-assessed work ability[c]	8.349 (1.385)	8.275 (1.512)	0.074 (−0.218 to 0.365)	8.342 (1.989)	8.12 (1.714)	0.222 (−0.15 to 0.595)	8.363 (1.731)	8.134 (2.045)	0.228 (−0.145 to 0.602)
Employee work-related well-being									
Presenteeism	4.846 (11.993)	3.944 (7.786)	0.902 (−1.104 to 2.909)	7.521 (25.216)	4.262 (12.841)	3.259 (−0.707 to 7.224)	5.851 (21.833)	6.138 (26.285)	−0.287 (−4.482 to 3.908)
Job satisfaction	4.798 (1.422)	4.997 (1.337)	−0.199 (−0.475 to 0.077)	4.692 (1.827)	4.855 (1.539)	−0.163 (−0.523 to 0.197)	4.845 (1.927)	4.893 (1.598)	−0.048 (−0.39 to 0.294)

a Outcomes corresponding to participant responses in reference to the past 6 months (approximately 12–18 months' follow-up).
b Employee-assessed job performance was assessed on a scale from 0 to 7 [with 7 indicating 'at its best (extremely well)' and 0 indicating 'at its worst (very poorly)'].
c Employee-assessed work ability was assessed on a scale from 0 to 10 (with 10 indicating 'at its best' and 0 indicating 'at its worst').

TABLE 34 Base-case (imputed) cost-effectiveness results

Analysis	Costs (£) (95% CI) [*p* (most costly)]	QALYs (95% CI) [*p* (most effective)]	ΔCost (95% CI)	ΔQALYs (95% CI)	ICER	INHB (95% CI) [*p* (cost-effective)]		
						£15,000	£20,000	£30,000
Within-trial cost-effectiveness								
Usual practice	403.76 (−215.63 to 1045.02) [0.049]	1.24624 (1.21873 to 1.27376) [0.96]				[0.989]	[0.99]	[1]
SHIFT intervention	958.51 (299.02 to 1639.83) [0.951]	1.21818 (1.1888 to 1.2466) [0.04]	554.75 (−119.64 to 1228.65)	−0.02806 (−0.059 to 0.002)	Dominated	−0.065 (−0.118 to −0.013) [0.011]	−0.056 (−0.099 to −0.013) [0.01]	−0.047 (−0.081 to −0.011) [0.009]
Cost-effectiveness analysis: Ekelund *et al.*[120] MVPA minutes/day (1)								
Usual practice	403.76 (−215.63 to 1045.02) [0.049]	16.15429 (16.15429 to 16.15429) [0.931]				[0.978]	[0.982]	[0.983]
SHIFT intervention	958.51 (299.02 to 1639.83) [0.951]	16.13240 (16.10182 to 16.16267) [0.069]	554.75 (−119.64 to 1228.65)	−0.02190 (−0.052 to 0.008)	Dominated	−0.059 (−0.113 to −0.004) [0.022]	−0.050 (−0.094 to −0.003) [0.018]	−0.040 (−0.078 to −0.002) [0.017]
Cost-effectiveness analysis: Ekelund *et al.*[120] sedentary minutes/day (2)								
Usual practice	403.76 (−215.63 to 1045.02) [0.049]	16.15429 (16.15429 to 16.15429) [0.908]				[0.981]	[0.982]	[0.983]
SHIFT intervention	958.51 (299.02 to 1639.83) [0.951]	16.13350 (16.10327 to 16.16419) [0.092]	554.75 (−119.64 to 1228.65)	−0.02079 (−0.051 to 0.01)	Dominated	−0.058 (−0.114 to −0.004) [0.019]	−0.049 (−0.095 to −0.004) [0.018]	−0.039 (−0.076 to −0.002) [0.017]
Cost-effectiveness analysis: MOVES MVPA minutes translated into metabolic equivalents (3)								
Usual practice	13,336.41 (7657.31 to 19,927.97) [0.066]	14.16817 (13.78574 to 14.56869) [0.833]				[0.956]	[0.952]	[0.946]
SHIFT intervention	13,843.20 (8049.98 to 20,393.84) [0.934]	14.15197 (13.7727 to 14.54723) [0.167]	506.79 (−145.31 to 1180.41)	−0.0162 (−0.049 to 0.019)	Dominated	−0.050 (−0.103 to 0.009) [0.044]	−0.042 (−0.088 to 0.008) [0.048]	−0.033 (−0.071 to 0.008) [0.054]

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In all base-case analyses, the SHIFT intervention was found to be dominated by usual practice. The 95% credible intervals around incremental QALYs overlapped zero in the MOVES model, suggesting a significant level of uncertainty in the QALY differentials of the SHIFT intervention compared with usual practice. *Appendix 3*, *Tables 57–63*, present each regression analysis used to inform the cost-effectiveness analysis. *Appendix 3*, *Figure 8*, shows the cost-effectiveness acceptability curves for each modelling approach.

Scenario analyses

Table 35 presents the incremental cost, incremental QALY and associated ICER estimates for the scenario analyses considered for the long-term analyses, based on the three decision-analytic models. Base-case estimates are also provided for reference. A more detailed breakdown of each scenario can be found in *Appendix 3*, *Tables 64–69*.

In each modelling approach, removing estimated trial-specific differentials in non-intervention costs and QALYs between arms resulted in smaller incremental costs for the SHIFT intervention and positive incremental QALYs, compared with usual practice. For the MVPA- and sedentary-based models, the resulting ICERs were £65,072 and £51,174 per QALY, respectively, which are above the cost-effectiveness thresholds considered. For the MOVES model, SHIFT was associated with an ICER of £29,287 per QALY, thereby falling below the highest cost-effectiveness threshold considered. Under this scenario, for the MOVES model, the SHIFT intervention had a 12.4%, 26.1% and 46.6% probability of being cost-effective at the cost-effectiveness thresholds £15,000, £20,000 and £30,000 per QALY, respectively (see *Appendix 3*, *Table 64*).

Scenarios concerning the application of EQ-5D-5L preference weights, a 1.5% discount rate, generalised linear models to estimate costs, participant costs omitting inpatient-related resource utilisation and a complete-case analysis framework did not have marked impacts on results and, therefore, did not change base-case findings (i.e. the SHIFT intervention dominated by usual services).

Sensitivity and threshold analyses

Study findings were largely insensitive to changes in the decay rate of the treatment effect on physical activity. At base-case settings, the INHB of the SHIFT intervention remained negative for each threshold considered across the range of decay rates examined (i.e. 10–100%) in all models considered (*Figure 3*). When removing estimated trial-specific differentials in non-intervention costs and QALYs between arms, the INHB for the SHIFT intervention was positive at a decay rate of approximately 20% at a £30,000 per QALY threshold for the sedentary-based model. Likewise, for MVPA-based model, the SHIFT intervention was positive at a decay rate of approximately 15% at a £30,000 per QALY threshold (see *Appendix 3*, *Figure 6*). For the MOVES model, when within-trial differences were removed, the SHIFT intervention was cost-effective at all cost-effectiveness threshold values considered at a decay rate at, or below, approximately 20%.

The base-case cost-effectiveness results were also largely insensitive to extensions in the duration of treatment effect on physical activity observed at 6 months. A comparison of SHIFT intervention ICERs (relative to usual practice) for alternative additional intervention costs and extension periods in treatment benefit are displayed in *Table 36*. With all other things remaining equal, the SHIFT intervention remained dominated for extensions up to and including 7 years for the MVPA- and sedentary-based models. For the MOVES model, ICERs only fell below £30,000 at a 6-year extension (see *Table 36*). Cost-effectiveness results were more sensitive to extensions in treatment effect when removing estimated trial-specific differentials in non-intervention costs and QALYs between arms. For the MVPA-based model, ICERs fell below £30,000 per QALY at 3 years, below £20,000 per QALY at 5 years and below £15,000 per QALY at 7 years. For the sedentary-based model, ICERs fell below £30,000 per QALY at 3 years, below £20,000 per QALY at 5 years and below £15,000 per QALY at 6 years. For the MOVES model, ICERs fell below £20,000 per QALY at a 1-year extension and below £15,000 per QALY for a 2-year extension (see *Appendix 3*, *Table 72*).

TABLE 35 Scenario analyses

Scenario analysis	Ekelund *et al.*:[120] MVPA minutes/day[a]			Ekelund *et al.*:[120] sedentary minutes/day[b]			MOVES model[c]		
	Incremental cost (£)	Incremental QALY	ICER (£)	Incremental cost (£)	Incremental QALY	ICER (£)	Incremental cost (£)	Incremental QALY	ICER (£)
Base case	555	−0.02190	Dominated	555	−0.02079	Dominated	507	−0.01620	Dominated
No within-trial differences in costs and QALYs	364	0.00559	65,072	364	0.00711	51,173	340	0.01161	29,287
EQ-5D-5L preference values	555	−0.00918	Dominated	555	−0.00737	Dominated	507	−0.00215	Dominated
1.5% discount rate (costs and QALYs)	555	−0.02037	Dominated	555	−0.01827	Dominated	424	−0.01343	Dominated
Costs estimated using generalised linear models	548	−0.02190	Dominated	548	−0.02079	Dominated	518	−0.01620	Dominated
Inpatient-related costs removed	383	−0.02190	Dominated	383	−0.02079	Dominated	353	−0.01620	Dominated
Complete-case analysis	751	−0.01975	Dominated	751	−0.02018	Dominated	721	−0.01581	Dominated

a Ekelund *et al.*[120] all-cause mortality estimates: MVPA minutes/day.
b Ekelund *et al.*[120] all-cause mortality estimates: sedentary minutes/day.
c MOVES model extrapolation: MVPA minutes translated into metabolic equivalents.

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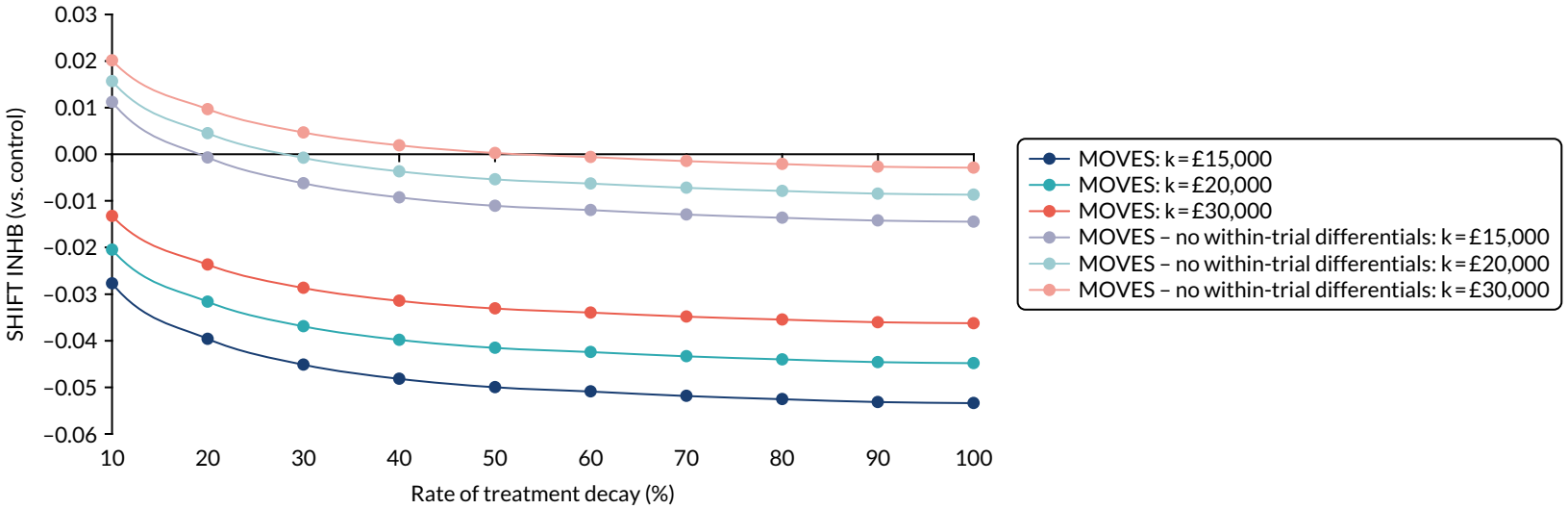

FIGURE 3 Incremental net health benefit of the SHIFT intervention relative to usual practice for alternative rates of treatment decay: MOVES model.

TABLE 36 Two-way sensitivity analysis: continuation in treatment benefit and additional cost ICER matrix (Δcost)

	Continuation of SHIFT treatment benefit and additional cost profiles: ICER (£)																	
	(1): Ekelund *et al.*[120] MVPA						(2): Ekelund *et al.*[120] sedentary						(3): MOVES model					
ΔCost (£)	1 year	2 years	3 years	4 years	5 years	6 years	1 year	2 years	3 years	4 years	5 years	6 years	1 year	2 years	3 years	4 years	5 years	6 years
−370	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	69,399	Dominated	Dominated	28,422	8480	4742	2309
−200	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	133,256	Dominated	Dominated	85,269	29,189	19,027	12,303
−100	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	170,819	Dominated	Dominated	118,709	41,370	27,430	18,181
Base case	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	208,382	Dominated	Dominated	152,148	53,551	35,833	24,060
100	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	245,945	Dominated	Dominated	185,588	65,733	44,236	29,938
200	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	283,508	Dominated	Dominated	219,028	77,914	52,640	35,817
370	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	347,204	Dominated	Dominated	275,732	98,570	66,889	45,785
500	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	396,197	Dominated	Dominated	319,347	114,459	77,849	53,452
1000	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	Dominated	584,012	Dominated	Dominated	486,545	175,366	119,865	82,845

Notes
Light purple shading indicates that the ICER is < £15,000 per QALY.
Blue shading indicates that the ICER is between £15,000 and £20,000 per QALY.
Dark purple shading indicates that the ICER is between £20,000 and £30,000 per QALY.

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Secondary cost-effectiveness analysis from a private sector perspective

Absenteeism-related cost differentials between the SHIFT intervention and usual practice at baseline equated to a cost saving of £57.98 between the two arms (SHIFT intervention, £628.50; usual practice, £686.46). At the 6-month follow-up, larger reductions in absenteeism in the SHIFT arm (see *Table 33*) resulted in a cost saving equivalent to £169.43, compared with baseline differences. At the 16- to 18-month follow-up, an increase in absenteeism amounted to an additional £552.05, compared with baseline differences. Over the course of the trial, changes in absenteeism costs were £324.64 higher in the SHIFT group than in the usual-practice group, relative to baseline values. Incremental private costs per driver equated to £200.16 at 6 months and amounted to £694.23 at final follow-up (see *Appendix 3*, *Table 72*).

Employee-assessed job performance and presenteeism at 6 months were less favourable in the SHIFT arm, relative to the differences in changes from baseline. At 6 months, differences in employee-assessed work ability and satisfaction rose relative to baseline differences by approximately 0.148 and 0.036, respectively, in favour of the SHIFT arm, equating to a £1353 and £5560 cost per unit increase on each respective Likert scale. At the final follow-up, relative to baseline differences, differences in employee-assessed job performance, work ability, presenteeism and satisfaction changed in favour of the SHIFT intervention by approximately 0.081, 0.154, 1.19 and 0.151 less days worked while sick, respectively, equating to a £6816, £3585, £465 and £3656 cost per unit increase on each respective Likert scale. Average difference in results over the trial equated to the SHIFT intervention being dominated in presenteeism (compared with usual service), while having ICERs of £17,142, £4598 and £7425 with respect to one unit increases in employee-assessed job performance, work ability and job satisfaction, respectively (see *Appendix 3*, *Table 72*). Given the modest changes over time and largely inconsistent differences between arms, caution must be taken when interpreting the differences in costs, outcomes and associated ICERs.

Given the additional productivity costs (i.e. lost driver days), QALY decrements and higher public costs associated with the SHIFT intervention, relative to usual practice, a broader perspective that considers public costs and productivity would fail to alter base-case study findings.

Chapter 5 Process evaluation

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Overview

Process evaluations provide a contextual understanding of how a particular intervention or programme was delivered, how participants reacted to it and why it was successful/unsuccessful in influencing behaviour change. In the context of complex and multicomponent interventions, such as the SHIFT intervention, which was delivered across multiple heterogeneous working environments throughout the UK, process evaluations provide useful information relating to all aspects of programme delivery and potential success, helping to inform which intervention components contributed the most and least to overall effectiveness. Therefore, process evaluations allow potential modification of the intervention, if required, and can inform the future implementation of the intervention (e.g. the SHIFT intervention as a training resource to HGV drivers across the logistics sector).[94]

The purpose of this process evaluation, therefore, was to investigate the application of the SHIFT intervention to understand the context within which the intervention was applied and the key elements of its implementation, including fidelity (i.e. components of the intervention), adaptations, contamination, sustainability, barriers and facilitators. To determine the implementation fidelity (which is the extent to which the programme adhered to the protocol model initially developed[124]), we aimed to understand whether or not components were used as intended (e.g. dosage, attrition rates) and if any adaptations were made to the intervention. A further aim was to describe and understand the contextual factors that may have influenced the intervention's implementation and/or effectiveness. In addition, the process evaluation will recommend refinement of the intervention for future sustainability to ensure that the intervention can be optimally embedded into the stakeholders' routine policies. Finally, this process evaluation will also help to support the development of further effective RCTs that are evaluating lifestyle health-related behaviours in HGV drivers (and employees with similar enforced sedentary occupations).

Methods

The MRC guidance for process evaluation of complex interventions was the most suitable framework for this process evaluation.[94] The MRC guidance offers key comprehensive direction to describe the intervention, implementation and mechanisms of change, while understanding the contextual factors throughout. This integrated process evaluation proceeded in a series of steps and took place alongside the RCT. Mixed methods were used to deepen analytic understanding of a specific issue and, in turn, triangulate results. Fidelity and dose were measured both quantitatively and qualitatively. Qualitative research techniques were used to identify how context affects implementation, barriers, mechanisms of impact and future sustainability. Using a feedback questionnaire, we aimed to collect data on key aspects from both control and intervention participants, and combined these data with information gained from in-depth interviews and focus groups with drivers and managers who were purposively sampled from each depot. Feedback questionnaires were given to every participant 1 month after baseline measures and 1 month after 6-month follow-up measures. Interviews were conducted with one participant and one manager from each site after the 16- to 18-month follow-up measures.

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Table 37 summarises each of the evaluation outcomes examined, how the evaluation outcomes were defined and how the evaluation outcomes were measured. *Table 38* provides a detailed overview of the process evaluation data collected through each method. The process evaluation results are presented according to the key outcomes examined (see *Table 37*).

Quantitative data collection

To inform attrition rates, records were gathered from all participants, including participation uptake per site (i.e. the number of participants who completed the baseline health assessment per site), dropout rate per site (i.e. the number of participants who failed to complete each follow-up), engagement with text messaging service (i.e. the number of responses) and compliance with activity monitor wear.

Feedback questionnaires

All participants were asked to fill out feedback questionnaires 1 month after the baseline health assessment and 1 month after the 6-month follow-up health assessment. The questionnaires included a mix of multiple-choice, open-ended and Likert scale questions. At baseline, the questionnaires sought

TABLE 37 Process evaluation outcomes examined, along with how each outcome was defined and assessed

Implementation outcome	Definition	Data source	Time point
Context of the intervention	Contextual factors that affected the implementation, intervention mechanisms and outcomes	Initial discussions with site managers prior to intervention implementation	Pre study
		Interviews with participants and managers	16–18 months
		First-hand experience of data collection	Continuous
Fidelity	The extent to which the intervention was delivered as planned	Project records	Post-study
		Interviews with participants and managers	16–18 months
Dose	How frequently participants engaged with intervention components	6-month follow-up questionnaires	6 months
		TextMagic statistical reporting	Continuous
Adaptations	Changes made to improve the delivery of the intervention	Interviews with the drivers and managers	16–18 months
		Fortnightly research team meetings	Continuous
Sustainability	Were changes in health behaviours following the 6-month intervention period maintained?	Interviews with the drivers and managers	16–18 months
	The extent to which participants and managers can envisage the SHIFT intervention becoming sustainable in the future		
Mechanisms of impact	What strategies were put in place by intervention participants to facilitate behaviour change	Interviews with the participants and managers	16–18 months
		6-month follow-up questionnaires	6 months
Contamination	Did intervention and control participants/managers interact with one another?	Interviews with the participants and managers	16–18 months

TABLE 38 Process evaluation data collected

Component	SHIFT intervention group				Control group			
	Baseline questionnaire	6-month questionnaire	Driver interviews/ focus groups	Interview with managers	Baseline questionnaire	6-month questionnaire	Driver interviews/ focus groups	Interview with managers
Heath assessment								
Did the health assessment encourage participation?	✓	✓			✓	✓	✓	
Did the health assessment meet expectations?	✓		✓		✓		✓	
Did the health assessment increase awareness of health?	✓		✓		✓		✓	
Was the health assessment understandable?	✓		✓		✓		✓	
What was the most useful measurement?	✓		✓		✓		✓	
Did the health assessment motivate lifestyle change?		✓	✓			✓	✓	
Intervention component								
Education session								
Was the education session understandable?		✓	✓					
Was the education session engaging?		✓	✓					
Was the booklet informative?		✓						
Did the education session increase awareness of health?		✓	✓					
Did the education session motivate lifestyle change?		✓	✓					
Did participants create action plans?		✓						
What were the key messages?		✓						

continued

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TABLE 38 Process evaluation data collected (*continued*)

Component	SHIFT intervention group				Control group			
	Baseline questionnaire	6-month questionnaire	Driver interviews/ focus groups	Interview with managers	Baseline questionnaire	6-month questionnaire	Driver interviews/ focus groups	Interview with managers
Did the booklets increase awareness?		✓						
Cab workout								
Regularity of use?		✓	✓					
What was the most common equipment?		✓	✓					
Where was the most common location?		✓	✓					
Barriers to the cab workout?		✓	✓					
Fitbit								
Was the Fitbit understandable?		✓	✓					
Did the Fitbit increase awareness of health?		✓	✓					
Did the Fitbit motivate changes to lifestyle?		✓	✓					
Step challenges								
Did step challenges increase awareness of daily steps?		✓	✓					
Did step challenges motivate an increase in step count?		✓	✓					
Text messages								
Was the frequency enough?		✓	✓					
Was the content relevant?		✓	✓					
Did the text messages motivate participants?		✓	✓					
Did participants feel supported?		✓	✓					
Were text messages efficient?		✓	✓					

Component	SHIFT intervention group				Control group			
	Baseline questionnaire	6-month questionnaire	Driver interviews/ focus groups	Interview with managers	Baseline questionnaire	6-month questionnaire	Driver interviews/ focus groups	Interview with managers
Overall impact of the study, factors influencing support and sustainability of the SHIFT intervention								
Workplace managerial support			✓	✓			✓	✓
Knowledge changes due to study participation			✓				✓	
Lifestyle changes due to study participation			✓				✓	
Fluctuations of changes			✓					
Barriers to a healthy lifestyle			✓					
Most important component			✓					
Future direction of the SHIFT intervention into CPC module			✓					
External impact on lifestyle		✓	✓			✓		✓
External fitness/diet tracking		✓	✓			✓		
Pandemic affecting study participation			✓	✓			✓	✓
Thoughts of being in the control group							✓	✓
Contamination between control and intervention			✓	✓			✓	✓
Managerial role				✓				✓
Management outcomes hoped to achieve				✓				✓
Operational difficulties				✓				✓
Sustainability of the SHIFT intervention				✓				✓

CPC, Certificate of Professional Competence.

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feedback about the usefulness of the baseline health assessment for awareness of health and what the most useful measurements were. The intervention follow-up questionnaire (given to intervention participants 1 month after the 6-month follow-up health assessment) sought feedback about the quality and usefulness of different elements of the health intervention, including the education sessions, booklets, cab workout equipment, Fitbit, step challenges, text message feedback and any other lifestyle or work changes that may have affected the results. In the questionnaire that was completed after their 6-month follow-up assessment, control participants were asked about both health assessments and any other lifestyle or work changes that may have affected the results. Open-ended questions were analysed by listing key responses into themes and calculating frequencies in each theme.

Qualitative data collection

Managers in intervention sites were asked to schedule three to six participants for an on-site focus group, during the drivers' working hours. A semistructured focus group schedule was developed and piloted with participants from six pilot sites. Questions related to each SHIFT intervention component, barriers to achieving health goals and recommendations for improvements to the SHIFT intervention. A semistructured interview schedule was developed and piloted for the managers in the pilot sites. Managers were also asked to schedule time for an interview on the same day as participants. These interview schedules were then analysed and revised, as needed, before commencing data collection for the main trial sites ($n = 19$).

Main trial interviews

Owing to the outbreak of COVID-19 and a national lockdown (March to July 2020), when face-to-face data collection (e.g. in-person interviews) was no longer feasible, mobile telephone interviews were completed for the main trial sites. As these interviews occurred during non-work hours, all participants were sent a text message to ask if they would be interested in participating, with the offer of a £5 high street voucher and a chance to win a Fitbit. The main liaison manager from each site was asked to participate via e-mail.

Data analysis

All focus groups and interviews were carried out by one or two researchers (AG and YLC). The focus groups were recorded on a digital audio device and transcribed verbatim (by AG) into Microsoft Word® (Microsoft Corporation, Redmond, WA, USA), before inputting into NVivo 12 software (QSR International, Warrington, UK) for analysis. Transcripts were then re-read, coded and developed into themes using the deductive method of thematic analysis, where themes were already preconceived based on the interview schedule and existing knowledge. This was followed by an inductive method where themes were identified entirely based on the data (by AG).[125] Each stage of the analysis was critically analysed from an informed external perspective. (Dr Anna Chalkley, an expert in qualitative research methods and programme evaluation, was independent to the research team and acted as a 'critical friend' throughout the analysis and reporting stage of this process evaluation.) Quantitative data, including dose, attrition and questionnaire data, such as multiple-choice and Likert scale answers, were analysed descriptively in IBM SPSS v25 (IBM Corporation, Armonk, NY, USA).

Results

Questionnaires

A total of 71.2% ($n = 272$) and 57.8% ($n = 167$) of the participants invited to complete a feedback questionnaire following the baseline and 6-month follow-up health assessments, respectively, responded.

Focus groups and interviews

During the internal pilot, on completion of the final follow-up measures, four focus groups and three interviews with 13 participants (i.e. an 83.3% site response rate) and eight individual interviews with managers (i.e. an 83.3% site response rate) were carried out to capture their views on and experiences

of implementation. In the main trial phase, 15 telephone interviews were conducted with participants from the remaining 19 sites (i.e. an 82.4% site response rate), and 13 telephone interviews were conducted with managers (i.e. a 76.5% site response rate) after the 16- to 18-month follow-up assessments.

Through synthesising the data, we found there to be no substantial differences between pilot testing and main trial sites in both the questionnaire responses and the content of the interviews and focus groups. Therefore, the combined findings from both the pilot and main trial sites are presented below.

Dose

It was intended that participants in the SHIFT arm would receive a total of 12 hours of face-to-face contact with the research team over 12 months, broken down into three 2-hour health assessments and one 6-hour education session. Control participants would receive 6 hours of face-to-face contact, consisting of three 2-hour health assessments. Owing to the COVID-19 pandemic, a national lockdown prevented all main trial participants from receiving a face-to-face final follow-up health assessment, hence a reduction of 2 hours of face-to-face contact with participants from the main trial.

Text messages

Throughout the duration of the study, the average number of text messages sent to each driver was 20.2 and the average number of text messages received from each driver was 3.8, which resulted in a 18.8% response rate. Although drivers did not engage much with the text messaging, it appeared that the overall use of text messages was relatively positive, and a number of drivers used this service at the end of the trial to relay their appreciation to the research team:

> *I haven't really text backwards and forwards, but when you sent me the, the little challenges like I thought good, yeah, I enjoyed that.*
>
> *Intervention participant, P06 – text messages*

> *. . . it's been interesting and enlightening and hopefully you and your team have added a few years to my life and others with the result of your research.*
>
> *Intervention participant, P03 – text messages*

> *Thank you to yourselves [students] your university, staff, teachers, etc., for all your endeavours helping me to take my health more seriously. Wishing you all the very best in the future.*
>
> *Intervention participant, M18 – text messages*

Cab workout equipment

Fifty-nine per cent of intervention participants said that they had used their cab workout equipment in the last 6 months, with few planning to use it in the future. For participants who did use it, the most common piece of equipment was the hand gripper, followed by the resistance bands. There was minimal reported use of the fitness ball. Of the participants who used the cab workout equipment, only 16.3% agreed/strongly agreed that it increased their physical activity levels. Reasons for low adherence levels were explained in more depth during the interviews. Some participants suggested that it was impractical to use the workout equipment in their cabs:

> *I mean to start doing all the . . . [demonstrates exercising], you know, just completely impractical. Really is . . . but . . . It's all right if you're office based.*
>
> *Intervention participant, P03, FG2 – cab workout*

Participants also reported that they prioritised sleeping and eating on their breaks:

> *. . . the only thing I do on my break is sleep.*
>
> *Intervention participant, P01, FG1 – cab workout*

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> *I don't, I don't think it's practical. You have 50 minutes' break and by the time you've been to the toilet, you've had your dinner, you need a nap, if you've done 3.5, 4 hours of driving, you need shut eye for 10, 15 minutes. There's just not enough time . . . To do those things.*
>
> *Intervention participant, M17 – cab workout*

Participants also suggested that, although not embarrassing for them, cab workouts would be embarrassing for some of the older drivers:

> *So the thing is . . . I think with a lot of like the old boys, like the drivers. Maybe they wouldn't want to do something like that because they'd feel like, stupid doing it to be honest. Do you know what you mean? Whereas I don't care. But like older drivers, they'd have just been like 'oh I'm not doing that'.*
>
> *Intervention participant, P03, FG1 – cab workout*

However, a small number of participants did carry out cab workouts regularly and seemed to benefit from this:

> *Yeah, the hand gripper, I use that, the stretchy bands, I used to use them more, because I could tie it to the bottom of the handrail in the cab and I could exercise my arms, both arms. And you could do it whilst you were driving. Right hand only. I mean obviously you've got to keep holding the steering wheel all the time, but when I were parked up, I used the gripper, and the ball. And you know, I kept up with that. I've still got them, and I still use them. So you know, they are, they are quite, you know. They're all right, they do what they're meant to do.*
>
> *Intervention participant, M14 – cab workout*

Fitbit

The majority (92.4%) of intervention participants were still using their Fitbit 6 months later, and 6.1% of participants had previously used their Fitbit but no longer use it. Only 1.5% of participants had never used their Fitbit and did not intend to in the future.

Participants who did not use the Fitbit mainly said that it was due to the Fitbit causing skin irritation, already having an activity monitor or not knowing how to use the Fitbit:

> *I haven't, I have been wearing it, but I had a rash on my wrist so I've had to take it off.*
>
> *Intervention participant, M17 – Fitbit*

> *Umm. Fitbit no, because to be honest, I've got one of these . . . I've got my own.*
>
> *Intervention participant, M18 – Fitbit*

> *If I remember, we were given the Fitbit at the end of the lesson weren't we? I have, still no idea. I have no idea how to use the watch. I have no idea how to . . . Yes. I have no idea how to use it. The only thing I do is, press the button, and it tells me the time and that's it. I mean, seriously. I mean, I mean, I'm hoping that this Fitbit thing is going to show me just how bone idle I am.*
>
> *Intervention participant, P03, FG2 – Fitbit*

Fidelity

Health assessment

Eighty-three per cent of main trial respondents agreed/strongly agreed that the baseline health assessment met their expectations, whereas 86.0% of respondents agreed/strongly agreed that the baseline health assessment made them more aware of their current health status. Most (90.3%) respondents agreed/strongly agreed that the health assessment was thorough and understandable. Participants were asked to rank the measurements in terms of most interesting and useful, and cholesterol was considerably the most valued measurement, with waist circumference the least valued measurement (*Table 39*).

TABLE 39 Participants' most valued measurements from the health assessments, as reported within the feedback questionnaires

Health assessment component	Frequency (*n*)
Cholesterol	147
BMI	108
Blood pressure	93
Blood sugar	90
Fat percentage	85
Grip strength	57
Waist circumference	31
None	5

Most (87.8%) intervention participants agreed/strongly agreed that the first health assessment motivated them to want to change aspects of their lifestyle, including increasing physical activity (73.2%) or improving diet (70.7%). Fewer control participants agreed/strongly agreed (63.6%) that the first health assessment motivated them to want to change aspects of their lifestyle, including increasing physical activity (49.5%) or improving diet (52.5%). Participants mentioned that it was 'eye-opening' to see their results within the health assessment:

> *But when you see it wrote down in front of you, it sort of clicked something in the back of your mind, thinking 'oh God'. You know what I mean. Numbers, numbers look a lot worse than looking at yourself because you're used to looking at yourself . . . you look in the mirror and you just tap your belly, and you say 'blimey I've got to lose some weight'. You know what I mean. But, when you're sitting there, and someone writes down, like . . . I can't think what it was, it was bleeding high, I know that! Yeah they said your BMI is this and that, then you start to think . . . You know what I mean. Because as I say, you look at the numbers and then it triggers something in you and you think 'oh blimey, I've gotta sort this out'. You know what I mean.*
>
> *Intervention driver, M15 – health assessment, eye-opening*

Participants (including control participants) also mentioned that it was motivational to improve their health:

> *I didn't realise I was overweight or, I've got a bit of belly but it's quite literally, yeah it's not too big but when they turned around and said you're obese and your BMI is like a little bit not where it should be and then you've got the graph and they point to you in a certain section . . . Mine wasn't too bad it was just a little bit above where I should have been so it gave me confidence that I could get there.*
>
> *Control driver, M23 – health assessment, motivating*

Six-hour structured education session

Most (90.9%) participants agreed/strongly agreed that the structured education session was the correct length of time, and participants agreed/strongly agreed that it motivated them to increase their physical activity (77.3%), reduce their sitting time while not at work (72.7%) and improve their diet (71.2%). When asked in the questionnaire about the key messages participants took away from the education session, 41% of 97 responses mentioned dietary knowledge changes and 31% mentioned exercise knowledge changes.

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Based on the interviews and focus groups, participants were happy overall with the information they received. Most participants recalled learning about diet, more so than other elements (e.g. physical activity, smoking, alcohol, sleep and mental health):

> *Yeah, I enjoyed the workshop with the, with all the information we received about the food, I thought it was really enjoyable. And the understanding, gave me a better understanding of food. And gave me a better idea of how I could balance my diet. So I thought that was one of the best things of the study, was actually that, that part of it and the information that was available to us.*
>
> *Intervention participant, P03, FG1 – education session feedback*

> *The way it was put across was great, the people we had in there was, was brilliant, and everyone partook in it brilliantly. But it was the information, the information that was there and available to us. And it was given to us in a way, it was given to us because it gives us a lasting knowledge of what was good for you and how easy it is to have the things you like, alongside the things you maybe no like to make a balanced diet, so you don't have to be daft and cut everything out and just have fruit and veg, you can have a bit of everything and still be healthy. So I mean it was really good.*
>
> *Intervention participant, P03, FG1 – education session feedback*

Fitbit

Participants agreed/strongly agreed that the Fitbit increased their awareness of their physical activity (90.5%), sitting time (73.8%) and sleep pattern (88.1%). In addition, the Fitbit motivated participants to make changes to their physical activity (81.0%) and their sitting time (69.0%), but less so their sleep pattern (40.5%). Three-quarters (75.4%) of participants engaged in the step challenges, 59.4% agreed/strongly agreed that step challenges were motivating and 54.7% agreed/strongly agreed that participating in the step challenges helped to increase their step count. Some participants reported that the free Fitbit was the main motivation for taking part:

> Interviewer: *. . . so why did you guys decide to take part in the SHIFT study?*
>
> Participant (P01, FG1 – participation reason): *Truthful answer . . . the free Fitbit.*

The Fitbit was also mentioned as a useful tool for goal-setting and for providing a consistent sense of achievement:

> *. . . with having the tracker thing [points at Fitbit]. It's like a reminder like, in better weather, I'd look at it, and if I hadn't got enough steps in I'd go and take the dogs around the block again, you know what I mean, just to get my counts up.*
>
> *Intervention participant, P06, FG1 – Fitbit, goal-setting/achieving*

> *Because of course, if you haven't done your 250 steps, it buzzes, so I'd actually get up and start walking up down the living room to get those 250 steps in! If it's nearly to midnight, I haven't done me 10,000 steps, I'd be up and walking wherever I could.*
>
> *Intervention participant, M18, Fitbit*

> *I think the Fitbit, because I think that motivated me more than anything else because it challenged us all the time, you know it buzzes and said come on let's go, 250 steps. That's . . . where I live on my boat we've got washrooms we can use, that's walking to the washrooms and coming back, I get my 250 steps so I maybe do that four times a day, whether I want to or not, I still like the challenge. You know, and I'm still getting that challenge now, which I try my best to carry out and get done. But I would say the Fitbit is the . . . it gets into your head, you get addicted to it. I am addicted, I always have it on, when the armband broke I actually used an elastic band and I wrapped it around so it stayed on my arm, ha ha ha! But that really got me addicted, and I'm still addicted to it now like you know.*
>
> *Intervention participant, M24 – Fitbit*

Text messages

Participants agreed/strongly agreed that the frequency (84.5%) and content (91.1%) of the text messages was appropriate and informative. Based on the focus groups and interviews, the consensus of participants was that the text messages were good at providing logistical information for the upcoming tasks and that it was beneficial to know that the SHIFT team were readily contactable:

> *Well, they were sent as they were needed, you know it wasn't an overload for the brain or anything but they were you know, when something had to be done, and yeah they were fine, unless you wanted . . . because I had the number I knew if I had any problems, any time I actually messaged you I did get a reply back . . . I did. Yeah every time I always got my reply back, and that's what I was happy about. At least I, I knew I was doing something at my end, and you's were taking it serious at your end . . . You were always there, because you said if you need us, we're there. You kept your word, like I said, I messaged you, you got back, and you had kept your word.*
>
> *Intervention participant, M24 – SHIFT components, text messages*

However, participants suggested that if the messages were to be used in a motivational capacity, then more frequent messages would be beneficial:

> *The only thing the only thing I could think of personally, would be to just ramp them up a little bit more. You know what I mean . . . Because they were quite well spaced out. You know what I mean. If I'm right, there were only about two of them, weren't there?*
>
> *Intervention participant, M15 – SHIFT components, text messages*

Adaptations

All baseline health assessments were conducted at the beginning of the drivers' shift. Carrying out baseline health assessments for all drivers was logistically challenging for both the researchers and transport managers because of the 24 hours a day, 7 days a week (24/7) nature of the job (i.e. drivers started their shifts at different times of the day and night). As a result, post-intervention measures were carried out at a time of day that was more feasible and occasionally this was at the end of the drivers' shifts. Drivers were still asked and reminded to fast for 4 hours prior to the assessment; however, this change in protocol may have affected body weight and blood pressure measurements.

The initial target was to include six participants per education session; however, it was logistically challenging for the transport managers to take six drivers off the road at any one time, particularly for the smaller sites, and, as a result, most education sessions consisted of fewer drivers per workshop (mean: 3.4 drivers; range: 1–7 drivers).

Owing to the COVID-19 pandemic, a national lockdown prevented all main trial participants from receiving a face-to-face final follow-up health assessment. Instead, in the 16- to 18-month follow-up health assessment, participants were asked to fill in the questionnaire, self-report their weight and wear the activPAL device (to monitor physical activity and sitting) while filling in the wear log continuously for 8 days. The pandemic also caused a 4- to 6-month delay in the final follow-up assessments for sites in the main trial phase, resulting in these taking place 16–18 months after randomisation.

Attrition

A total of 382 participants (SHIFT intervention, $n = 183$; control group, $n = 199$) received the baseline health assessment. Two hundred and sixty-two participants (68.6%) took part in the 6-month follow-up health assessments. The retention rate at 6 months was higher in the control group (73.9%) than in the intervention group (62.8%), and this may be because of intervention participants being ineligible to continue with the study if they failed to take part in the 6-hour structured education session. Of the 183 intervention participants, 145 (79.2%) took part in the education session. At 6 months, the retention rate for intervention participants who were eligible to continue after the education session ($n = 145$) was 79.3%. Participants who did not attend the session were removed from the trial.

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The dropout rate in the intervention group may have been a result of their expectations for greater health improvements among them:

> *I think that for them that dropped out they just . . . I think they'd realised that they'd not really made that much of a change, or they made them, but they were short-lived if you know what I mean?*
>
> *Intervention manager, M11, FG1 – feedback from drivers (manager perspective) – reasons for dropping out*

Table 40 shows reasons for discontinuation of the study.

Retention rate between the 6- and 16- to 18-month follow-ups was higher (78.2%). In this instance, retention was better in the intervention group (87.8%) than in the control group (70.7%). It may be that overall retention rate was higher after 6 months because participants who were disinterested in the programme had already dropped out. Participants in the intervention group were possibly more invested in the intervention, and yet little time spent engaged in the project was required of them during this time. From start to finish, 46.3% ($n = 177$) of participants dropped out of the RCT. Mangers were asked in interviews if they knew the reasons for participants dropping out. One of the primary reasons mentioned was that truck drivers are notoriously transient workers, with a high staff turnover rate. It was evident that a lot of drivers had left their company before the cessation of the programme:

> *Like I say, the drivers that had to drop out, they left, obviously that's one of those things, they left and went on to different contracts.*
>
> *Control manager, M12, interview – feedback from drivers (manager perspective) – reasons for dropping out*

TABLE 40 Disposition of participants and reasons for discontinuation

	Trial arm, *n/N* (%)		
	Control	SHIFT intervention	Overall, *n/N* (%)
At baseline			
Consented at baseline	199	183	382
Entered trial and gave data	199	183	382
At 6 months' follow-up			
Attended and gave data	147/199 (73.9)	115/183 (62.8)	262/382 (68.6)
At 16–18 months' follow-up			
Completed trial	104/199 (52.3)	101/183 (55.2)	205/382 (53.7)
Reasons for discontinuation			
Participant deceased	1/199 (0.5)	0/183 (0.0)	1/382 (0.3)
Lost to follow-up	61/199 (30.7)	51/183 (27.9)	112/382 (29.3)
Investigator decision	2/199 (1.0)	4/183 (2.2)	6/382 (1.6)
Left job	14/199 (7.0)	8/183 (4.4)	22/382 (5.8)
Long-term sickness	5/199 (2.5)	2/183 (1.1)	7/382 (1.8)
No longer interested	3/199 (1.5)	0/183 (0.0)	3/382 (0.8)
Cluster withdrawal	13/199 (6.5)	15/183 (8.2)	28/382 (7.3)
Significant protocol violation	0/199 (0.0)	1/183 (0.6)	1/382 (0.3)
Suspended from work	0/199 (0.0)	1/183 (0.6)	1/382 (0.3)

Other reasons for participants dropping out included long-term illness, and a few participants were isolating or on furlough:

> *Yeah, a couple on long term sick, and I think a couple that were shielding as well.*
>
> *Intervention manager, M11, interview – feedback from drivers (manager perspective) – reasons for dropping out*

Another commonly mentioned reason for participants dropping out was that some saw the timings of the health assessments as too inconvenient:

> *They just want to come in and go home. Yeah, they don't want to do anything else that adds on to their day. Which I totally get.*
>
> *Control manager, P05, interview – feedback from drivers (manager perspective) – reasons for dropping out*

Barriers to behaviour change

In the 6-month questionnaires, all participants were open-endedly asked to identify their main barriers to a healthy lifestyle. Among the 145 responses, 46% suggested that the biggest barriers were work related, predominantly the length, irregularity and start times of their shifts. The second biggest barrier was family (e.g. child care) commitments (12%) and this was followed by self-motivation (10%), with drivers referring to themselves as being 'lazy' or 'need[ing] more discipline'. *Table 41* shows a summary of the mentioned health barriers.

Using an inductive approach in the thematic analysis, we discovered that participants discussed barriers to living a healthy lifestyle both at work and at home. We deemed it important to mention these barriers, as this may influence guidance for future health interventions in this demographic. Participants mentioned that there was little time in the day to fulfil a healthy lifestyle:

> *The trouble is, is when do you get the time, isn't it? . . . You know, you finished at 10 o'clock in the morning, from 8 o'clock at night. All you want to do is go back and have a shower go to bed.*
>
> *Intervention participant, P03, FG2 – barriers, time*

TABLE 41 Most frequently mentioned barriers to a healthy lifestyle reported in the 6-month feedback questionnaire

Barrier	Frequency (%)
Work related	67
Long hours	23
Shift pattern	16
Diet at work	10
Lack of routine	5
Family	18
Diet	16
Self-motivation	14
Time (not explicitly work related)	10
Weather	4
Injury/illness	3
Sleep	3
Embarrassed to exercise in public	1

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You've got all the things to do, you know I don't have any chance to do any exercise, I don't.

Intervention participant, P03, FG2 – barriers, time

Linked to time pressure are the long, irregular shift patterns and early start times that almost all drivers from both control and intervention sites mentioned at least once in their interview:

. . . well, yeah, you know and the start times as well, I start between midnight and 4 a.m. in the morning and that's no, no good for your body rhythm if you like. It's not good for your body. By 2 o'clock in the afternoon you want to go to sleep.

Control participant, M09 – barriers, shift pattern

But I've done this for 35, 36 years now, umm, and it's just, it's just part of being a lorry driver, it is how it is, it's the territory that you're in. You know, the uncertainty of where you're going to work, whether you're going to go home that night, or it might be 5 days later.

Intervention participant, M14 – barriers, shift pattern

I think there should be, once you have worked a 12-hour shift, you should have a minimum of 12 hours off. Whereas you can actually work 15 hours and have 9 off. That's the legal requirement, 9, 9 minimum . . . because it's 15 and 9, that's your 24 hours in a day isn't it. Alright, so you could start at 6 in the morning, work till 9 at night and realistically you could start at 6 o'clock in the morning the next day.

Intervention participant, M14 – barriers, shift pattern

And, I mean, to say that the trouble with the HGV world is uh, it's poor wages long hours, you know. You can make a good life out of it, but you've got to put a lot of hours in, and when you put the hours in, it is detrimental to your health at the end of the day. You know, unfortunately that's the aim of the game, you know.

Control participant, M25 – barriers, shift pattern

Therefore, there's often unrealistic, unrealistic expectations required of drivers, and long hours. And short breaks. And that doesn't help at all with this side of things, which is looking at trying to keep healthy. Try to have a diet, a decent diet. When you've got guys going out for 13, 14 hours a day, when you get home . . . when I'm on 12 hours a day, I get home, I have a snack and go to bed practically. A snack, a shower and bed and up in the morning. And it's a snack, and into work, when I'm on my 12-hour shift. So the guys that are getting a couple of 15 hour shifts on the bounce, they get home, go straight to bed. And they're actually back the next day driving, munching as they go down the road because that's their time for having something to eat. So, the fact that the pressures that are put on us in the workplace, and often or not the uhhh . . . the mismanagement of that is, is a factor towards the healthiness and well-being of the driver himself.

Intervention participant, P03 – barriers, shift pattern

A lack of managerial support and excessive expectations also affected drivers:

It's operational requirements, like. It's, it's operational requirements, because you can't always eat when you're supposed to eat, or sleep when you're supposed to sleep or anything like that. It all revolves around your working day. And that's how it is.

Intervention participant, P03, FG2 – barriers, shift pattern

It's not doing one 12-hour shift or one 15-hour shift, it's one after another, after another, after another. You know, they think you're machines like these trucks, you can drive them for 24 hours a day, 7 days a week, they're just trucks, put some more diesel in, put some more oil in, they'll go forever, we can't do that. They think we can.

Intervention participant, M14 – barriers, shift pattern

I'll be honest, well, me and my partner have now gone part time, because it had just got ridiculous. And they just expect so much of you. And like, especially . . . for some reason, I don't know why. In our place, the night drivers are just the dirt on their feet . . . They've just, no respect for them . . . but you try working

nights. They don't seem to understand that, you know, your natural body clock, even no matter how many years you work nights, your natural body clock is, you go sleep at night.

Intervention participant, M18 – barriers, shift pattern

Another key barrier included unavailability of healthy foods while at work:

Well, umm, basically being lorry driver is . . . the diet is shocking, you can't really get healthy food it's all fast food. Basically working the shift that I do I finish my day at the end of the night, around 11 o'clock at night. And if I'm parked up somewhere, the only thing that's available is McDonald's [McDonald's Corporation, San Bernardino, CA, USA], or Burger King [Jacksonville, FL, USA] or sandwiches from WHSmith [WHSmith, Swindon, UK].

Intervention participant, M14 – barriers, diet at work

*. . . you're feeling knackered, you're feeling drowsy, you're feeling, you know, you need to be doing something, you eat. And unfortunately that's the nature of the beast. And it's not necessarily good for you, but you can also have the mindset, well, it's better that I eat than crash. Because I could kill somebody, or myself, you know. And it's one of those, umm, it's not ideal, and I do try and eat more healthily when I'm snacking, but sometimes you are thinking an apple ain't doing it, a banana ain't doing it, grape ain't doing it, dried fruit's not doing it. **** it, I'm having a choccy bar.*

Control participant, M22 – barriers, diet at work

But yeah, the biggest problem is, when you go to a service station, what's the first thing you see there? It's fast food. They are trying to change it but it is fast food, burger bars, so . . . They are popping up aren't they. You don't see enough healthy food options, certainly in the UK, and whether that's because of the climate we have I don't know.

Intervention manager, P01 – barriers, diet at work

Less mentioned, and more debated, was physical activity, with some drivers suggesting that they do a lot of physical activity at work and others saying that they do not:

Well, the thing is my exercise regime did go out the window a little bit. Because I was starting an hour earlier . . . I was starting at . . . getting up at 2 and starting at 3 in the morning. And of course you know, that knocks you right up, you know, you come in and all you want to do is have a sit down an hour, half an hour, you have your food and then you're back in the bed, you know.

Control participant, M25 – barriers, physical activity

It's a shame, we haven't sort of got a place, a room or something with gym equipment in it. Because I mean, you know, for example, like drivers, they sometimes sat down there for like 2 or 3 hours waiting for a job. I mean, if you have like gym facilities on site, rather than just sitting there, you could just come in and do a bit of something, you know what I mean?

Intervention participant, P03 – barriers, physical activity

Yeah, so, and the pumping weights, well I do enough of that at work, loading and unloading trailers.

Intervention participant, M11 – exercise

My job is quite physical anyway. Umm and you know you unload like 300, 400 tyres, umm, so yeah you know that's quite a good workout.

Intervention participant, M19 – exercise

Self-motivation was also a key barrier that was mentioned, and this appeared to be at both home and work:

Just being lazy . . . That's it. Me just telling myself 'oi get your big fat ass out of there and go for a walk!' or do this, or do that!

Intervention participant, M24 – barriers, self-motivation

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> *I just think it's that lazy mindset really, like I said I've been preparing, like when I get home now like, my fruit or anything that I'm going to bring with me today, umm, it was a lot easier before to maybe just get to shop to buy sandwich. It's pretty packed. It's just lazy that mindset. Isn't it?*
>
> *Intervention participant, P03, FG1 – barriers, self-motivation*

Suggested improvements to the SHIFT intervention

By a significant margin, the most frequently suggested improvement from both drivers and managers was that the SHIFT team could have had more regular contact and engagement with the participants:

> *I suppose, how could I say it. I think if I was to say anything, and this is not being negative or nothing, but you just asked to think of something so . . . Umm, maybe just the odd phone call just to cheer you up and keep you going. You know what I mean . . . Barring that, I couldn't imagine anything else. You know what I mean. But yeah, a bit of a phone call every now and again, how are you keeping, how are you doing? We're keeping an eye on you like. If you know like, someone is watching you, it makes you, it pushes you along a bit more. You know what I mean.*
>
> *Intervention participant, M15 – improvements to SHIFT*

> *I haven't really text backwards and forwards, but when you sent me the, the little challenges like I thought good, yeah, I enjoyed that. And that's one thing I would say. There could have been a lot more of that. Yeah, a lot more challenges, like, you know, you know, let's say, look, everybody's gotta hit 15 . . . But if there was more goals in there . . . And sort of push us along because I would rise to the occasion with the goals. I like that sort of thing. If I've got a target, that's my goal that, you know me. But when there's no targets, you tend to take a backward step.*
>
> *Intervention participant, P06 – improvements to SHIFT*

> *I think for them they were given all the information and then there was quite a long gap, so that was the only negative thing I would say, that gap was too long, they were saying what's happening and they were starting to lose interest.*
>
> *Intervention manager, P01 – improvements to SHIFT*

Lots of drivers and managers would have liked to have seen more feedback about the results:

> *Yeah, just better . . . more publication of results for, for me, personally, I would have got something out for that. And I would have probably been able to get more of the guys talking about it if they have that data as well.*
>
> *Control participant, M22 – improvements to SHIFT*

> *I'd have liked to have been able to have access to the results of the monitors that we were wearing to see over the period of time that we were wearing them how things fluctuated as well.*
>
> *Control participant, M22 – improvements to SHIFT*

From the perspective of the managers, more clarity at the beginning would have been helpful in organising and managing expectations:

> *Umm, I think the only thing for me would be, at the very, very beginning, having a more understanding of what was involved . . . [exhales] it was a little bit, um, it was a little bit, 'it won't affect your business, it won't affect your everyday' bla bla bla, bla bla bla. But it does affect it when it's 2 or 3 hours and it, and you've got to umm, plan that around the drivers' times, rest days, and all that kind of stuff. Umm you know that alone, the admin side from myself or one of my managers, to prep it, umm, probably, it's a few hours in a day, each time, to try and prep that. And it's not about not doing that part of the role, I don't mind doing it, but it's about understanding that's what is involved. Because at first it was sort of addressed, that 'yeah, there's no problems, there's no impact to yourselves', etc., etc., etc., but that is 2 or*

> *3 hours of the drivers days that then have to rearrange his job for the day so that he can complete his job within legal time.*
>
> *Intervention manager, M17 – improvements to SHIFT*

Future sustainability

All managers were asked if they could see the SHIFT intervention becoming sustainable in the future, and if they would support it. All managers said that they would support the SHIFT intervention:

> *Absolutely. 100%. I can say that without even speaking to my, my higher tiers . . . But I know they'll be on board, they will, yes . . . Again, it's all about the well-being of drivers isn't it?*
>
> *Control manager, M12 – support SHIFT in the future*

> *I think to have it as part of a CPC [Certificate of Professional Competence] I think certainly, would be, be a much easier route and you'd obtain a lot more numbers to be involved.*
>
> *Intervention manager, M17 – support SHIFT in the future*

However, some managers caveated this support with comments about issues with practicalities:

> *Umm, I suppose within DHL to get everybody done for the assessments and stuff would take some major planning. You know what I mean, just on my contract alone you've got 650 drivers. Umm, within DHL you've got 7500 drivers. Umm, so you imagine trying to have consultations and assessments with their health and things on site with 7500 people . . . Umm, and that's just like 7500 driving colleagues, staff at the moment. Within DHL . . . It's quite big . . . If you want to start planning your days around, you can plan 7500 in if you want to haha . . . Keep you busy until 2029 I think! Haha.*
>
> *Intervention manager, M18 – support SHIFT in the future*

> *Yes, it could. Ummm, you would have to work around sort of different areas or different drivers, because not all drivers would want to participate. Not everybody would want to be part of it. Like I said, in the planning of the drivers and getting the drivers back, it's sometimes not that easy to be able to manage small contracts and get drivers back on site, the time that you need them.*
>
> *Control manager, M22 – support SHIFT in the future*

Intervention participants were asked about their thoughts on turning the education session into a Certificate of Professional Competence (CPC) module, and all drivers said that it would be a good idea:

> *Now that would be interesting that would. That would be interesting . . . yeah, I think that would be a good thing actually. It would be well educational actually for a lot of the drivers.*
>
> *Intervention participant, M24 – education session, CPC module*

However, almost all participants said that the education session would need a medical professional rather than a driver trainer to lead the workshop:

> *Well I think I'd prefer it to be a health professional, uh, because it just seems more appropriate that it comes from a health professional. You'd think that you'd take it more seriously.*
>
> *Intervention participant, M14 – education session, CPC module, driver trainer*

> *But no with that thing I think a health professional could present it better than a driver trainer because driver trainers understand driving but they don't understand . . . other things . . . it's always better to have an expert talking about something they know, then somebody talking about something they've been told to talk about.*
>
> *Intervention participant, M17 – education session, CPC module, driver trainer*

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> *No . . . because they haven't got the depth of knowledge that you guys have, I don't think it would work. I really don't think it would work. All they'd do is just read it. And then ask you five questions at the end of it and say right, you sign that, then sign the form to say that you understood. And people will just be saying, god is it time to go home?*
>
> *Intervention participant, P03, FG2 – education session, CPC module, driver trainer*

One driver mentioned that cost would prevent DHL Supply Chain from doing the CPC module:

> *They have a programme that the whole of DHL use and that's all you're doing, not doing nothing else. Because we may have to register for something else, or we may have to pay out for something else. So we're not going to do that. So . . . companies would then have to pay for it, they'd have less interest . . . Is it going to help them get a truck down the road?*
>
> *Intervention participant, P03 FG1 – education session, CPC module*

All drivers said that moving the education session to an app-based workshop would be detrimental:

> *I mean if you're in the classroom and that, with other people and that, then you get involved more, I think if you're on your own, doing an app, I think a lot of people probably won't bother.*
>
> *Intervention participant, M19 – education session, app based*

> *I'd rather have face to face because you can ask questions and that can't you really. And if you're there with a group of people, which you can't do at the moment, everybody would be coming up with different questions . . . I might be asking one question and the guy next to me asks another question that I never even thought about asking.*
>
> *Intervention participant, M24 – education session, app based*

> *Being honest. I wouldn't have paid much attention to it at all. I'd have flicked it on and flicked it back off just to say I'd been on it! I'm being totally honest. I've always worked with face to face, and I work well that way. I'm more of your audio kinetic sort of learner and everything. Umm, on a web page or on an app, you're going to have loads of writing and all that sort of thing. I'm not going to read it and that's being honest.*
>
> *Intervention participant, P03, FG1 – education session, app based*

Control site participants

There was a lack of awareness from participants and managers in the control group with regard to whether they were in the control or intervention arm, suggesting that the SHIFT team could have provided more communication and explanation to both the managers and participants of their allocated arms and what this means for participants:

> Interviewer: *So were you aware that there was two different groups in the SHIFT study, one was called control and one was called intervention?*
>
> Participant (control participant, M12 – intervention or control?): *Yeah, yeah, yeah. That's what we've been told before, yeah, before we started . . .*
>
> Interviewer: *Do you know which one your site was put into?*
>
> Participant (control participant, M12 – intervention or control?): *The . . . I think that second one as far as I can remember . . .*
>
> Interviewer: *Oh, the intervention?*
>
> Participant (control participant, M12 – intervention or control?): *Yes.*
>
> Interviewer: *Were you aware that there were two different groups in the SHIFT study, one called control and one called intervention?*

Manager (control manager, M12 – intervention or control?): *Umm I can't remember, it possibly was mentioned to me but it's that long ago that I can't remember to be honest with you.*

Interviewer: *OK, and did you know that there were two different groups in the SHIFT study, one was called control and one was called intervention?*

Manager (control manager, M21 – intervention or control?): *Yes, yes I did.*

Interviewer: *OK, and did you know which one your site was allocated to?*

Manager (control manager, M21 – intervention or control?): *No.*

Contamination

Randomisation occurred at the site level to ensure that there was a minimal risk of contamination between intervention and control participants. All participants and managers were asked in the interviews if they had spoken about the SHIFT intervention to anybody from any other depot, and all participants and managers confirmed that they had not.

The COVID-19 pandemic

A large, unforeseen confounding variable to the SHIFT intervention was the COVID-19 pandemic, which caused three major lockdowns in the UK from March 2020 to June 2021. Fortunately, almost all (254/262, 96.9%) participants who were still enrolled in the trial at the time had completed the 6-month follow-up health assessment before the national lockdown. However, the final follow-up was greatly affected by the pandemic and, as such, all main trial sites required remote data collection, where participants were asked to fill out the questionnaires, self-report their weight, wear the activPAL and complete the sleep/work diary by themselves. Although this method has clear shortcomings, this was deemed the most appropriate, pragmatic and safe form of data collection at this time to assess the key main outcomes. When the COVID-19 pandemic was discussed in the interviews, it appeared that all sites were affected by the pandemic in different ways. For example, participants who delivered essential items were busier and worked longer hours:

Manager (intervention manager, M18 – contamination, COVID-19, more hours): *In fact, we went through a stage where we were actually really short of drivers.*

Interviewer: *Oh wow, was that due to sickness?*

Manager (intervention manager, M18 – contamination, COVID-19, more hours): *No it was due to operational demand because people were panic buying so our stores we deliver to, were ordering bigger and things like that . . . Oh lots of hours and double shifts and things like that, just to keep the business going and to keep stocks up and things like that.*

Some drivers mentioned that it was business as usual:

It was the same run on the same start times, so not many changes if you like.
Control participant, M12 - Contamination, COVID-19, business as usual

The same, whatever happens. Our job is the same. It never ever changes. We go out, two runs a day. Fourteen pallets, it might be a bit less. But it all depends how much the shop's selling. But yeah, that's it, it never changes. It's just the same every day.
Intervention participant, M15 - contamination, COVID-19, business as usual

Some drivers mentioned being on furlough for most of the year. However, there was ambiguity between the furlough status of all sites. Several sites furloughed staff on a rotational basis, some sites furloughed

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all staff, other sites made it optional for drivers to choose furlough and the remainder of sites, which provided essential goods, did not make furlough an option:

> *I was put onto furlough, I was put on that until August . . . then we were locked down again in November, so we were put on furlough then . . . Since April I have probably done less than . . . 10 days' work?*
>
> *Control participant, M21 – contamination, COVID-19, furlough*

Some managers also mentioned that the pandemic halted the enthusiasm for the study, with priorities moving elsewhere:

> *It's just after that the, the communication and the engagement because of the COVID-19, where that stopped, then obviously, this . . . the SHIFT stopped as well, well in the drivers' minds. So they just said 'it's not continuing anymore obviously'. Nobody's ringing us, and everybody else had obviously their personal interests in their minds during this pandemic as well. So they just lost focus on it.*
>
> *Intervention manager, M10 – contamination, COVID-19, impacted study enthusiasm*

Behavioural changes

The primary outcome measure was the difference in steps per day at 6 months between the SHIFT and control arms, measured using the activPAL3 accelerometer. Although a significant difference in daily steps was observed at 6 months, in favour of the SHIFT arm, drivers (from both trial arms) commented that the biggest modifications they made were to their diet, with 57 comments/references to dietary changes recorded, whereas only 27 comments/references were made with regard to changes in physical activity. There were no significant differences in fruit and vegetable intake or dietary quality observed between trial arms at either follow-up period:

> Participant (control participant, M09 – behavioural changes, dietary): *Well, as I say I cut down my sugars and the, is it . . . saturated fats? Is it? . . . I try and do a little bit more exercise although that's a little bit more difficult haha!*
>
> Interviewer: *Mmm, yeah yeah, understandable. Right OK, and you mentioned there that exercise was a bit harder to control than the diet, what makes you think . . . what makes you say that?*
>
> Participant (control participant, M09 – behavioural changes, dietary): *Well, I mean it's easy to change from butter to margarine you just buy a different one on the shop haha, whereas to get your mind to want to go out and do a bit of exercise is a bit harder, ha ha.*
>
> *Control participant, M09 – behavioural changes, dietary*

> *Well, the barriers are still there, but you've just got to, it just puts thoughts in your mind because of the training you've had, I consider this to be like a training exercise to me, you know, I'm thinking about things before you just go in. So I used to like, when I got meals at McDonalds, I used to get the large meal. Now, I never do that. Always just your standard meal. I know there might not be many calories difference between a large and a medium meal, but there is some difference. So, that's, that's what I do now, and I manage with that. You know, I used I used to think I've got to have a large meal to be sort of, satisfied but now I don't. I just have a standard meal, I have that, and that's it.*
>
> *Intervention participant, M14 – behavioural changes, dietary*

> *I don't eat as much chocolate as I used to do now. I take an apple or something like that for work, whilst I'm travelling down the motorway.*
>
> *Intervention participant, M17 – behavioural changes, dietary*

> *The small snack thing, before I just, I don't know. I'd eat . . . in the truck for example, I'd always have a . . . I don't know, say humbugs or something. And I'm eating a packet of biscuits and you'd just happily munch on them. Whereas now, I deliberately won't have them in the vehicle, because if they're not in the*

vehicle, I can't . . . I can't . . . do you know what I mean? I can't eat them . . . I'd rather take like a bag of like roasted monkey nuts or something like that instead.

Control participant, M20 – behavioural changes, dietary

I've started eating more fruit . . . Rather than when I get hungry going for a chocolate bar, I go for some grapes, a banana or an orange or something like that.

Control participant, M23 – behavioural changes, dietary

Participant (intervention participant, M24 – behavioural changes, dietary): *Well put it this way, I now eat vegetables around four times a week now, never touched them before.*

Interviewer: *Oh OK, you never ate them before?*

Participant (intervention participant, M24 – behavioural changes, dietary): *Never. I ate them once a week on Sunday if I had a Sunday dinner . . . But like I say, I live on a marina and there's a pub, when it was open we'd go across for a meal, but I'd get burger and chips or, steak and chips, and I never really touched the vegetables. But since the lockdown as well like, I just sort of looked at them and said 'I'll try them' and I tried them and like I say I'm now on four times a week on vegetables. In summer every night I was having salad. So my way of thinking about food now, I'm trying as they said in the study, how to portion your food as well.*

Intervention participant, M24 – behavioural changes, dietary

My diet changed very much straight away . . . from not eating any fruit because I wasn't interested, because I was a biscuit sweet person, I take fruit with me at work, I got down from nearly 14 stone to 13 [stone], 3 [pounds].

Intervention participant, P01, FG1 – behavioural changes, dietary

At 6 months, significant differences in steps, sitting and standing time were evident on non-workdays between trial arms, with no differences in these variables seen between groups on workdays, and this is reflected by the drivers' and managers' opinions about the inherent characteristics of the job:

Interviewer: *Were the shifts a barrier to actually live the healthy lifestyle, did you just do it around it?*

Participant 1 (intervention participant, P01, FG1 – barriers to a healthy lifestyle, at work): *Just had to do it around it.*

Participant 2 (intervention participant, P01, FG1 – barriers to a healthy lifestyle, at work): *It's more just, not doing it at work, just everything at home.*

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Chapter 6 Discussion

Drivers of HGVs drivers have been identified as a high-risk occupational group who have traditionally been underserved in terms of health promotion initiatives.[4,25] This trial aimed to evaluate the effectiveness and cost-effectiveness of the multicomponent SHIFT intervention in a sample of long-distance HGV drivers. Participants were recruited across 25 transport sites across the Midlands region of the UK, with sites operating within the transport, retail, hospitality, health-care, pharmaceutical, construction, oil and gas, and automotive industries. The average age of our sample at baseline [48 (SD 9) years] and our sex split (99% male) matches the average age of HGV drivers and the sex proportions seen nationally.[26]

A high prevalence of overweight and obesity were observed in our sample at baseline, which exceeds the prevalence of overweight and obesity seen in males aged 45–54 years across the general population (89% vs. 79%).[126] Five per cent of our sample had severe obesity (i.e. a BMI $\geq$ 40 kg/m^2) at baseline, which is more than double the prevalence of severe obesity seen in a national sample of aged-matched males (2%).[126] Furthermore, over half the sample had pre-hypertension (51%) or hypertension (28%), 84% had clinically elevated circulating LDL-C concentrations (i.e. > 2 mmol/l), and 67% had high total cholesterol levels (i.e. > 4 mmol/l). Participants accumulated high volumes of sitting, particularly on workdays, and high levels of physical inactivity. The characteristics of our recruited sample support previous observations of the high-risk health profile of UK-based HGV drivers,[36] and highlight the need for health promotion initiatives to be prioritised in this workforce.

Main findings from the randomised controlled trial

Primary outcome

The primary outcome was device-measured physical activity, expressed as mean steps per day across all monitored days, assessed at 6 months. At baseline, the sample accumulated 8583 steps per day, which is comparable to daily step counts recorded previously in a sample of UK-based HGV drivers,[36] and to daily step counts seen in office-based workers.[127] The complete-case analysis revealed a statistically significant difference in mean daily step counts at 6 months' follow-up, in favour of the SHIFT group, with this group accumulating 1008 more steps per day than the control group. The findings showed a similar pattern in the sensitivity analyses (examining the effect of the number of valid activPAL days), although the results were mixed in the ITT and per-protocol analyses. Although the difference in the primary outcome measure between the SHIFT and control arms at 6 months (i.e. 1008 steps/day) was lower than 1500 steps per day, which formed the basis of our sample size calculation, it has recently been reported that 500 steps per day is the minimum clinically important difference for inactive individuals, applying equally to men and women.[128] Therefore, the difference observed in the intervention group relative to the control group is potentially clinically meaningful and potentially of a sufficient magnitude to impact longer-term health and mortality risk.[128]

Closer inspection of the changes in mean daily step counts recorded between baseline and 6 months revealed that a decrease in daily steps occurred in the control group, whereas activity levels (i.e. steps/day) measured at baseline were maintained in the SHIFT group. Although large increases in overall daily steps were not observed in the intervention group, the SHIFT intervention appears to be effective in mitigating a reduction in overall activity over at least a 6-month period, observed in the control group. As baseline and 6-month follow-up measures were distributed evenly over a 6-month data collection period (i.e. baseline measures were undertaken between the months of January and July) for all groups, with the corresponding follow-up measures taking place 6–8 months later, it is unlikely that the reduction in steps seen in the control group could be explained by seasonal effects. As physical inactivity is widely associated with an increased risk of many adverse health conditions,[129] the prevention of a decline in habitual activity in any population/individual is important when considering longer-term health outcomes.

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Therefore, the observed differences in steps between groups at 6 months remain potentially clinically important.[128]

Despite the high-risk health profile of HGV drivers globally,[4] limited health promotion interventions have been conducted in this occupational group. A systematic review[25] of health promotion interventions in HGV drivers (which included only eight studies) observed that the interventions generally led to improvements in health and health behaviours; however, the review cautioned that the strength of the evidence was limited because of poor study designs, with no control groups, small samples and no or limited follow-up periods.[25] Of the available literature, only one other study[31] of HGV drivers has examined the potential impact of a wrist-worn device to help monitor and self-regulate physical activity levels and healthy dietary choices. In a sample of 26 Australian HGV drivers, similar to the present findings, Gilson *et al.*[31] observed that participants' daily step counts [measured using the Jawbone UP accelerometer (Jawbone, San Francisco, CA, USA)] remained constant across the 20-week intervention, with daily steps averaging 8743 steps per day across the first 4 weeks, and averaging 8944 steps per day across the last 4 weeks. Across the 20-week intervention, the logging of dietary choices using the associated Jawbone UP app declined steadily, and the authors concluded that step counts were more successfully monitored than dietary choices.[31]

The process evaluation revealed that the Fitbit was a favoured component of the SHIFT intervention. Fitbits, along with similar commercially available wearable activity trackers, and their associated apps, contain a number of behaviour change techniques, including self-monitoring, feedback and goal-setting.[130] Recent systematic reviews and meta-analyses[131–133] have revealed that commercially available wearables are associated with favourable increases in physical activity in controlled trials in adults over the short term (note that the duration of the interventions included in these reviews typically ranged between 3 and 6 months). In their meta-analysis, which included 12 controlled trials that incorporated the use of a commercial wearable as an intervention tool, Brickwood *et al.*[131] reported greater intervention effects when the wearable was part of a multicomponent intervention (as applied in the present study), as opposed to when the wearable was utilised as the primary intervention tool. Within both trial types, however, meta-analyses revealed significant increases in daily step counts in intervention groups relative to control groups (multicomponent interventions, +685 steps/day; wearable-only interventions, +475 steps/day).

Findings from a systematic review and meta-analysis,[133] which specifically examined the use of Fitbits as an intervention tool, reported significant increases in daily steps across 16 studies, with a mean difference of +951 steps per day seen in intervention participants, relative to control participants. The majority of RCTs included in this meta-analysis examined the effectiveness of multicomponent interventions, and had a duration of < 5 months. Only five studies incorporated a 6-month follow-up (as applied in the present trial), with only two further studies including a 12-month follow-up.[133] Given the unique population targeted in the present study, and the limited scope to compare the present findings with other studies using HGV drivers,[31] the difference in our primary outcome (i.e. +1008 steps/day) observed between intervention and control participants at 6 months appears promising, especially when compared with the findings reported in the recent meta-analyses of wearable interventions, highlighted above.[131,133]

Secondary outcomes

activPAL variables on workdays and non-workdays

Complete-case analyses for these secondary outcomes revealed statistically significant differences, in favour of the SHIFT group, in time spent sitting, standing and stepping, and time in MVPA, at 6 months' follow-up, across all monitored days. Further analyses revealed that the positive changes in overall activity and sitting seen at 6 months were driven by differences in these behaviours occurring between groups on non-workdays. No statistically significant differences were observed in any variables assessed using the activPAL between groups at 6 months (or at 16–18 months) on workdays.

A common theme, which emerged as part of the process evaluation, was the irregularities of shifts and the long duration of shift patterns, which many drivers reported as a barrier to being able to engage in beneficial health behaviours. Owing to the constraints of their job, it appears, therefore, that participants in the SHIFT arm were more likely to adopt positive behaviours in terms of physical activity and reduced sitting on non-workdays than on workdays. Relative to the control group, at 6 months, participants in the SHIFT group accumulated 2012 more steps per day on non-workdays. This was accompanied by an extra 21 minutes per day spent stepping, which was broken down into an extra 10 minutes per day spent in light physical activity and 11 minutes per day spent in MVPA. Similarly, participants in the SHIFT arm accumulated 40 minutes per day less sitting, relative to control participants, at 6 months. The mean differences in MVPA and sitting observed between groups on non-workdays are greater in the present study than those observed in Ringeval *et al.*'s[133] meta-analysis of Fitbit interventions, where mean differences in MVPA of 6 minutes more per day and 11 minutes less per day of sedentary time were seen in intervention groups, relative to control groups.

As with the primary outcome, further interrogation of the data revealed that the favourable changes in behaviours observed on non-workdays at 6 months between intervention and control participants were largely driven by the reductions in physical activity and increases in sitting seen in control group participants, alongside small positive behaviour changes seen in the SHIFT group. It appears, therefore, that the SHIFT intervention was successful in mitigating the unhealthy behaviour changes seen at 6 months in the control group. Furthermore, as highlighted in the recent World Health Organization physical activity guidelines update,[134] doing some physical activity is better than none, and even modest increases in activity seen in the SHIFT arm on non-workdays could be beneficial to health.

At baseline, all participants accumulated high volumes of sitting on workdays (≈ 12 hours/day) and non-workdays (≈ 9 hours, 40 minutes), which, unsurprisingly, owing to the nature of their work, demonstrates that HGV drivers accumulate greater sitting times than most occupational groups.[135] At baseline, there was no evidence that participants compensated for their highly sedentary occupation by being more active on non-workdays, with participants actually accumulating less physical activity on non-workdays. Sedentary behaviour, defined as 'any waking behaviour characterised by an energy expenditure $\leq$ 1.5 metabolic equivalents while in a sitting, reclining or lying posture',[136] has been identified as a risk factor for a number of chronic conditions, including CVD, type 2 diabetes and all-cause mortality.[120,137–140] Although recent studies suggest that the detrimental effects of sedentary behaviour can be mitigated by engagement in regular MVPA, with at least 150 minutes of moderate intensity activity accumulated per week required,[141] the relatively low volumes of MVPA seen in the present sample is unlikely to reduce the risk of the detrimental health effects associated with sedentary behaviour. Furthermore, recent studies have reported potential thresholds, ranging from 6–8 hours per day[140] to 9.5 hours per day,[120] spent sedentary where all-cause mortality risk is substantially increased, independent of physical activity. Our sample exceed both of these thresholds when looking at their overall daily sitting times.

Periods of prolonged sitting have been associated with negative health outcomes, and regularly breaking up sitting (every 20–30 minutes) has been associated with favourable changes in blood glucose control, particularly in individuals who are overweight or have obesity and/or individuals who are at high risk of type 2 diabetes.[142] Accumulating prolonged periods of sitting is unavoidable in long-distance HGV drivers on workdays; however, non-workdays provide an opportunity where prolonged bouts of sitting can be minimised. A noticeable observation from the descriptive analyses of the activPAL data revealed that, at 6 months, control participants exhibited an increase in the time spent sitting (and the proportion of sitting) in prolonged bouts. No such changes were observed in the intervention group, again suggesting that the SHIFT intervention likely mitigated increases in time spent in prolonged sitting bouts at 6 months.

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Despite the favourable differences seen in the SHIFT arm, relative to the control arm, at 6 months, particularly on non-workdays, limited differences between groups were seen in the majority of activPAL variables assessed at 16–18 months' follow-up. Although not statistically significant ($p = 0.10$), at 16–18 months, daily step counts on non-workdays were 1391 steps per day more in the SHIFT group, relative to the control group, suggesting some evidence of sustainability. The COVID-19 pandemic, however, is a major confounding factor that occurred for the majority of participants between the 6- and 16- to 18-month follow-up assessments. Furthermore, a disproportionately larger number of control participants (58%) were furloughed at some point between the 6- and 16- to 18-month follow-up assessments, relative to participants in the SHIFT arm (24%). Questionnaire-based data collected from a subsample of participants during the first national lockdown, along with qualitative responses provided on the 16- to 18-month follow-up CRFs, indicated that participants who were furloughed were more likely to engage in new forms of physical activity while away from work. In contrast, it is likely that drivers who continued to work throughout the national lockdowns had extended driving hours and, therefore, even less time to engage in healthy lifestyle behaviours because of the relaxation in drivers' hours that came into force.[101]

Markers of cardiometabolic health and functional fitness

The changes in weight and BMI observed at 6 months demonstrated favourable trends in the direction of the SHIFT group. At 6 months, participants in the SHIFT arm recorded an average weight loss of 1.4 kg (i.e. a change of −1.2 kg relative to control participants; $p = 0.08$) and a reduction in BMI of 0.4 kg/m^2 (i.e. a change of −0.4 kg/m^2 relative to control participants; $p = 0.09$). Fifty-eight per cent of participants in the SHIFT arm experienced a reduction in weight at 6 months, compared with 48% of control participants. Although these findings look promising, it should be cautioned that this level of change in weight ($\approx$ 1.4%) would not be considered clinically meaningful and could be an artefact of natural variations in hydration status occurring between measurement sessions. Interventions predominantly focusing on physical activity have been shown to have small to no effects on weight loss.[143] To have a bigger impact on weight, the SHIFT intervention could be revised to include a greater emphasis on diet. In a weight-loss intervention conducted in US truck drivers, Thiese *et al.*[30] reported a median weight loss of 3.2 kg in participants following the completion of their 12-week intervention. However, this was a single-arm trial involving only 12 participants.[30]

There were no other beneficial changes in markers of cardiometabolic health (e.g. blood pressure, waist circumference, waist–hip ratio, biochemical measures) seen in the SHIFT arm relative to the control group at 6 months. Given the strong links between adiposity and a number of these cardiometabolic markers, and the small change in weight, it is perhaps not surprising that no changes in markers of cardiometabolic health were observed. Albeit in a smaller sample, similar findings were observed in the weight-loss intervention in US truck drivers reported by Thiese *et al.*[30] Similarly, no noticeable differences were observed between groups in the present study in their psychophysiological reactivity to stress at 6 months.

Descriptive analyses suggested that the SHIFT group demonstrated favourable increases in average grip strength at 6 months, whereas no changes were detected in the control group. Lower hand grip strength, indicative of lower muscle function, has been shown to be strongly associated with a wide range of adverse health outcomes, including all-cause mortality and incidence of, and mortality from, CVD, respiratory diseases and cancer.[144,145] The potential improvements in grip strength observed in the SHIFT group are promising, and are likely to be linked to the inclusion of a hand gripper as part of the cab workout equipment. Although the process evaluation revealed that the cab workout was the least-favoured part of the intervention, participants did highlight that they enjoyed using the hand gripper. Therefore, this simple piece of equipment, which could help maintain and/or improve upper-limb muscle function, holds promise as an effective tool for drivers to use during breaks.

Dietary quality and fruit and vegetable intake

There were no statistically significant differences observed between groups in reported fruit and vegetable intake or overall dietary quality at both 6 months and 16–18 months. These findings contrast with the numerous comments made as part of the process evaluation from drivers, where favourable changes to their diets were reported. This contrast in findings may be attributable to the sensitivity of the FFQ used to assess diet, as previous studies[146] have demonstrated questionable validity of FFQs when compared with 4-day weighed food records. However, the feasibility of assessing dietary intake using weighed records in the present study population was uncertain at the planning stages of this trial. The overall dietary quality score derived from the FFQ for our sample (11/15 at baseline) is comparable to that observed from a large randomly selected general population sample from Northern England (11.4/15).[60] In comparison to this population sample, overall intake of fruit and vegetables appears to be lower in our driver sample (≈ 240 g/day), with intake decreasing further at 16–18 months (≈ 200 g/day), indicating that participants are falling short of the government's recommendations of at least 400 g/day of a variety of fruit and vegetables.[147] This finding suggests that more needs to be done to support drivers in making healthier dietary choices, with improved access to fresh fruit and vegetables.

Sleep

A notable observation within this trial was the short sleep duration observed across the sample at baseline and at 6 months' follow-up. Although the SHIFT intervention did not specifically target sleep in detail, sleep duration and efficiency were assessed in the present study as secondary outcomes using a wrist-worn device, and processed using a validated algorithm.[89] Of the participants providing valid GENEActiv data at baseline ($n = 349$), the average sleep duration across all monitored days for the whole sample was 6 hours and 10 minutes (SD 54 minutes), and this reduced slightly to 6 hours (SD 60 minutes) on workdays. At baseline, 41% of participants exhibited an average sleep duration across all monitored days of < 6 hours per 24-hour period, and 82% of participants exhibited an average sleep duration of < 7 hours per 24-hour period. These proportions increased further on workdays to 45% and 85%, respectively.

Of concern, a consistent finding observed across both the SHIFT and control groups at 6 months' follow-up was a further reduction in sleep duration. The average sleep duration for the sample at 6 months across all monitored days was 5 hours and 56 minutes (SD 57 minutes), and this fell to an average of just 5 hours and 21 minutes (SD 69 minutes) on workdays. At 6 months, just over half of the sample (51%) providing valid GENEActiv data ($n = 221$) exhibited an average sleep duration across all monitored days of < 6 hours per 24-hour period, and 87% exhibited an average sleep duration of < 7 hours per 24-hour period. These proportions increased further on workdays to 71% and 91%, respectively. The reductions in sleep duration appear to be solely driven by reductions in the duration of the sleep window (i.e. at follow-up, drivers were allowing themselves less time in bed to sleep, as opposed to reductions in overall sleep quality). At the 6-month follow-up, although there was a consistent trend across groups for sleep duration (and sleep window duration) to increase on non-workdays [mean increase across the sample: 41 (SD 99) minutes/24-hour period], participants were still only accumulating 6 hours and 52 minutes (SD 85 minutes) of sleep on these days, which falls short of the recommended minimum of 7 hours per 24-hour period required for optimum health.[148] Similar to that discussed above in relation to the activPAL data (see *Primary outcome*), as both baseline and 6-month follow-up measures were distributed evenly over a 6-month data collection period for both groups, it is unlikely that seasonal changes can fully explain the net reduction in sleep observed.

Systematic review-level evidence has demonstrated that people habitually sleeping less than 6–7 hours per night have a significantly increased prevalence of type 2 diabetes, obesity and CVD, higher cortisol and cholesterol levels, reduced cognitive functioning, depression and other psychiatric conditions, and premature all-cause mortality.[149,150] Some of these associations may be mediated by sleep-related changes in glucose metabolism and appetite regulation. Sleep restriction impairs glucose tolerance,[151] reduces circulating leptin, and increases hunger and the consumption of carbohydrate-rich foods.[152]

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Short sleep can also lead to daytime fatigue and suppresses the volume and intensity of physical activity undertaken.[153] Indeed, a common theme that emerged from the process evaluation when discussing the cab workout component of the intervention was that a high proportion of participants reported prioritising trying to catch-up with their sleep when at a rest stop, as opposed to using the cab workout equipment. As a result, the cab workout was a less favourable intervention component.

In addition to the individual-level cardiometabolic risks associated with short sleep duration,[150] and of particular relevance and concern within the present sample, is the association between short sleep duration and reduced driving performance and increased accident risk,[154,155] as this has wider public health and safety implications for all road users. For example, a US Department for Transportation study observed that both severe sleep apnoea (a condition common in commercial drivers, which drivers are required to inform the Driver and Vehicle Licensing Agency about[156]) and sleeping < 6 hours per night were equally, and independently, associated with impaired driver performance.[157]

A limitation of the measurement of sleep used in the present study is the fact that naps were not assessed, and it appears from the process evaluation that a number of participants did attempt to nap during their breaks. Therefore, it is possible that total sleep durations are underestimated in this study. Nevertheless, sleep duration was a recurrent theme highlighted within the process evaluation, and this, in combination with the sleep data collected from the GENEActiv, suggests that the drivers in this sample are chronically sleep deprived. These findings have important implications, suggesting that participants are at an increased risk of excessive daytime sleepiness, road traffic accidents and chronic disease.[158] Indeed, a UK Department for Transport review concluded that insufficient sleep, leading to daytime sleepiness, impaired vigilance and poor concentration, is responsible for the 'disproportionately high number of fatigue related accidents' involving drivers of large goods vehicles (contains public sector information licensed under the Open Government Licence v3.0).[159]

The findings from this secondary outcome measure, along with the concerning observation of a further reduction in sleep duration and sleep window duration at 6 months in this sample of drivers, suggests that the SHIFT intervention should be expanded to include a much greater focus on sleep. Increasing sleep quantity through interventions targeting improved sleep management in drivers will potentially offer dual public health benefits of reducing accident risk (through reduced fatigue and improved vigilance performance) and reducing cardiometabolic risk within the individual (through improved glucose tolerance and appetite regulation, and increased engagement in physical activity). This recommendation is particularly pertinent at the present time, given the increased number of HGV driver shortages within the UK[29] and the relaxation of drivers' hours rules as a result of COVID-19 and Brexit.[160] There is a risk that the current sleep profile of HGV drivers may be even worse than that observed in this study, given our 6-month follow-up assessments were completed just prior to the COVID-19 outbreak and Brexit, and the associated relaxation in drivers' hours rules and substantial increase in driver shortages. The long hours worked by our participants suggests that drivers may also not completely recover from work-related fatigue between shifts. High levels of 'need for recovery' have been associated with sleep complaints in coach drivers,[161] and with longer-term sickness absence in HGV drivers.[162] Further work examining interventions to improve drivers' sleep should also take into account, therefore, working hours and the potential impact of the need for recovery between shifts.

In the present study, within both groups, no changes in device-measured sleep quality (i.e. sleep efficiency) or chronotype score were observed between baseline and follow-up. Despite the reduction in device-measured sleep duration observed in both groups at 6 months, there were no changes in ratings of situational sleepiness observed across groups, although this measure should be treated with caution because of the variability in the exact timing within the day/night that this questionnaire was completed across follow-up periods. Furthermore, other studies have demonstrated no associations between self-reported sleepiness and reduced cognitive performance across a range of tasks, including driving, resulting from sleep deprivation.[157,163]

Mental well-being, cognitive function, musculoskeletal symptoms and work-related psychosocial variables

In contrast to previous observations of relatively high levels of poor mental health within drivers,[4] reported symptoms of anxiety and depression were low in the present sample at baseline, with limited changes in symptoms occurring across the follow-up assessments in either group. At baseline, 13% of participants reported borderline symptoms of depression and 17% of participants reported borderline symptoms of anxiety, whereas 2% and 5% of participants reported abnormal scores for depression and anxiety, respectively. Similarly, low levels of social isolation were reported across all assessment points throughout this study. No noticeable differences in changes in cognitive function were observed between groups at 6 months' follow-up. Likewise, there were no observable differences between groups in changes in musculoskeletal symptoms or any work-related psychosocial variables (i.e. work engagement, occupational fatigue, job satisfaction and performance, sickness absence and presenteeism, work ability and perceived job demands) occurring at either follow-up. In addition, no differences were observed between groups in terms of reported driving-related safety behaviours.

Lifestyle-related behaviours and cardiovascular disease risk

At baseline, 25% of participants reported drinking more than 14 units per week of alcohol, and this is a lower proportion than that reported[126] in a nationally representative sample of aged-matched males, where 35% of the sample reported drinking more than 14 units per week of alcohol. No noticeable differences were observed between groups at any assessment point in terms of alcohol intake, and alcohol intakes observed in the present sample appear lower overall than what has been reported elsewhere in HGV drivers from other countries.[4] However, this observation should be treated with caution, as the tools used to assess alcohol intake in HGV drivers have varied extensively across studies, making it difficult to draw comparisons.[4]

The prevalence of smoking within the sample at baseline (19.4%) was similar to that seen in males aged 45–54 years living in England (20%).[126] When split by study group, there was a tendency for a higher smoking prevalence to be seen in the control group than in the SHIFT group across all assessment points. For participants completing the baseline and 6-month follow-up assessments, smoking prevalence changed from 17% to 19% in the control group, and from 13% to 11% in the SHIFT group. In the smaller sample of participants who completed the baseline and 16- to 18-month follow-up assessments, smoking prevalence decreased by 1% in both groups at 16–18 months. The impact of the SHIFT intervention on smoking is, therefore, uncertain, and limited effects on smoking (and alcohol intake) are perhaps to be anticipated, as these topics were covered only briefly in the structured education session, with the focus of this session being predominantly on physical activity, diet and sitting.

When examining the proportion of participants with an estimated CVD risk of $\geq$ 10% over the next 10 years, 23.6% of control participants and 24.3% of SHIFT participants fell into this category at baseline, and this increased to 26.4% in the control group and reduced to 23.4% in the SHIFT group at 6 months. These findings suggest that participants in the SHIFT group experienced a modest reduction in risk of a cardiovascular event over the next 10 years, relative to control participants. Reducing the risk of a CVD-related event in HGV drivers has important implications, not only for the individual, but also for the wider public, given the serious consequences should a driver have a CVD event while driving. Although not specifically related to CVD events, Ronna *et al.*[23] reported that, based on 10-year CVD risk calculated using the Framingham Risk Scale, the odds of having an accident doubled in US truck drivers with a Framingham Risk Scale score > 13. Ronna *et al.*[23] also observed a statistically significant association between prevalence of accidents and increased risk scores, further highlighting the public health importance of improving the overall health of this occupational group.

COVID-19

The COVID-19 pandemic had a large impact on the overall running of this trial, with the first government national lockdown occurring at the time that the final follow-up measurements within the main trial phase were about to commence. In addition, 6-month follow-up measurements were scheduled to take place in

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one intervention site during the week commencing 23 March 2020 (i.e. the start of the first national lockdown), and this was the last site to undergo the 6-month follow-up measurements. As a result of the national lockdowns that followed, the 6-month follow-up assessments in this intervention site, as well as all final follow-up assessments, were severely delayed. A change to the original protocol was approved in June 2020, where it was confirmed that the primary outcome would be daily steps recorded at the 6-month follow-up assessment, as opposed to daily steps recorded at 12-month follow-up, which was not feasible given the suspension of data collection. This required change in protocol is a limitation of the trial, as the switch in timing of the primary outcome analysis (from 12 months to 6 months) means that we cannot completely rule out any seasonal changes in behaviour affecting our findings. However, it should also be acknowledged that this change in timing affects both the intervention and control arms.

Within the main trial phase, the easing of government COVID-19 restrictions enabled a range of secondary outcome measures to be collected approximately 16–18 months after randomisation in sites. Owing to restrictions on external visitors to DHL Supply Chain sites throughout the pandemic, face-to-face physiological measurements were not able to be conducted at the final follow-up phase. These follow-up assessments, therefore, did not contain the complete set of measures included at baseline and at 6 months. Furthermore, for the one intervention site due their 6-month measures at the start of the first national lockdown, the delayed 6-month assessments did not contain the physiological health measures included for all other sites, and this led to a reduction in the sample size within the intervention arm for some of these secondary outcomes. Although a strength of this study is the fact that we were able to follow-up participants at 16–18 months, the pandemic presents a major confounding factor that limits our ability to draw firm conclusions regarding the sustainability of the SHIFT intervention. In particular, a greater proportion (58%) of control participants than intervention participants (24%) reported being furloughed, which may have had a large impact on their lifestyle health behaviours and markers of well-being at the final follow-up assessments.

Despite the associated challenges, the pandemic also provided an opportunity to collect further information on its impact on our sample of HGV drivers, who were classed as a key worker group. A subsample of participants completed an additional questionnaire during the first national lockdown. The questionnaire was developed in partnership with colleagues at DHL Supply Chain in response to the relaxation of permitted maximum driving hours.[101] Despite the change in permitted driving hours, respondents to our COVID-19 questionnaire did not report any changes to their working, driving, in-cab waiting or rest hours. Similarly, participants reported no changes in the time spent sitting, standing and walking/moving around on a workday during the pandemic, and there were no negative impacts on symptoms of anxiety or depression, or markers of occupational fatigue. The responses to the COVID-19 questionnaire should be treated with caution, however, as the responses represent only 41% of the sample invited to complete the questionnaire, and non-responders may have been experiencing the pandemic very differently.

The questionnaire did enquire whether or not participating in the study had provided participants with the right knowledge to maintain a healthy lifestyle during the COVID-19 restrictions, and, interestingly, 63% of both intervention and control participants answered ‘yes’. Responses to this question were similar between intervention and control participants, and largely centred around an increased understanding of the importance of activity and diet. The responses received from control participants to this question support observations from the process evaluation that a number of control participants were not aware of the two trial arms, with some participants believing that they were experiencing an intervention as a result of the regular health assessments they were invited to (note that control participants received the same feedback on their physiological measures as the intervention participants).

The questionnaire also enquired whether or not participants had spent time in nature (which could include time in their garden/allotment, in parks, in woodland, at the coast and in open green spaces) during the pandemic, along with whether or not participants habitually spent time in nature prior to the pandemic. These questions were included following recent reports of a wide range of both physiological

and psychological health and well-being benefits associated with exposure to nature.[164,165] In this subsample, we observed novel associations between reported time in nature and reductions in measures of occupational fatigue. Further analyses, reported elsewhere,[102] revealed that after controlling for covariates, drivers who visited nature at least once a week exhibited 16% less chronic fatigue prior to the COVID-19 pandemic, and 23% less chronic fatigue and 20% less acute fatigue during the COVID-19 pandemic. These novel findings suggest that nature exposure may have the potential to provide a promising remedy for many of the negative health outcomes associated with HGV driving,[102] and further research into the use of nature exposure as a potential low-cost intervention to promote physical and mental health in drivers is recommended.

Main findings from the cost-effectiveness analysis

The within-trial analysis showed that the SHIFT intervention reduced QALYs and increased costs. The small improvements in physical activity seen as a result of the intervention generated potential for slight improvements in QALYs in the longer term. Despite this, under a range of alternative scenarios and assumptions, the SHIFT intervention in its current delivery format is unlikely to be considered cost-effective when compared with usual practice at commonly used threshold values of a QALY.

Main findings from the process evaluation

The process evaluation indicated that the SHIFT intervention had a positive impact on the intervention participants, as reported in both the questionnaire and interview responses. Participants reported an increase in knowledge, awareness and motivation regarding the importance of increased physical activity and a healthy diet. The Fitbit was the most favoured component of the intervention, whereas the cab workout appeared the least favoured and too cumbersome for the majority of participants. The most common suggested improvement to the intervention was to increase the frequency of communication with participants. The barriers to health were still very apparent throughout, with the irregularity and long duration of their shift patterns highlighted by many drivers. These barriers required a high level of extrinsic motivation to overcome within this at-risk occupational group to enable them to change health-related behaviours, and, therefore, regular contact from those administering any future interventions would likely be needed to help motivate participants to maintain improved behaviours.

Using the MRC process evaluation framework,[94] the discussion of findings from the process evaluation will focus on the implementation process and the mechanisms of impact that influenced the findings, followed by the contextual factors that may have affected the RCT outcomes.

Implementation process

This RCT was complex in terms of multiple components, environments and outcome measures. The intervention comprised the amalgamation of five different components (the 6-hour structured education session, the Fitbit, step count challenges, cab workout equipment and text messages) among 25 heterogeneous worksites (pilot sites, $n = 6$; main trial sites, $n = 19$) and aimed to influence the health behaviours of participants in numerous ways (e.g. daily steps, sitting and standing time, time spent in MVPA and nutritional intake).

The structured education session was regarded as valuable by all interviewed intervention participants, who reported that it increased their knowledge, particularly about healthy diets. However, only 145 of 183 (79.2%) intervention participants took part in the education session, mainly because of logistical challenges and operational requirements, which made scheduling the education sessions across sites and ensuring driver availability particularly challenging. This shows that although the education session was beneficial to those participants who attended, it was not wholly feasible in this occupational group,

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with key issues being the varying start times, operational demand and time-critical deliveries. However, in a 'real-world' context, it is estimated that currently only 15–30% of people in the UK newly diagnosed with diabetes attend structured education sessions organised through the NHS, despite high referral rates by GPs.[166] Based on this information, it could, therefore, be argued that, although challenging to organise, if such sessions can be embedded within the workplace of at-risk occupational groups, then their reach could be substantially improved. In the context of HGV drivers, if such health promotion programmes can be embedded within compulsory professional competency training that drivers are required to undertake to maintain their licenses, which take place within working hours, the potential reach and impact of such programmes could be considerable.

The Fitbit worked as an important tool for increasing understanding of current activity levels, providing participants with feedback on their activity and acting as a motivational tool to increase daily steps. There was high adherence to the Fitbit throughout the intervention, suggesting that it was an effective tool to encourage behaviour change, specifically physical activity, but less so regarding sleep (although the Fitbit provides feedback on sleep, this was not a primary focus of the SHIFT intervention). There was less agreement on the step count challenges. Some participants liked the competition of the step count challenges, but other participants did not like competing with 'strangers'. The text messages were regarded as useful for logistical purposes (e.g. for reminding participants about their up-and-coming health assessments); however, overall, there were minimal replies to the messages, with an average response rate of 18.8%. Participants mentioned that more frequent, personalised messages would be required to stimulate motivation.

The cab workout was a less favourable intervention component, with participants stating that they had more important priorities than using this equipment in their breaks, particularly catching up on lost sleep and eating. However, some participants did use the cab workout equipment, with the most popular device provided being the hand gripper, and 20% of participants agreed the cab workout equipment increased their overall levels of activity. As the adherence to the cab workout equipment appeared low overall, however, the cab workout is regarded as a poor tool to encourage behaviour change within this occupational group.

Mechanisms of impact

The SHIFT intervention used Bandura's SCT as the theory of behaviour change for intervention development.[42] Bandura's SCT suggests that learning can occur through observing and imitating someone else's behaviour, and is most effective when the observer witnesses a model with similarities (e.g. another HGV driver) carrying out the behaviour. Bandura's SCT focuses on the triadic model, in which personal factors, environmental influences and behaviour continually interact.[167] Bandura argues that goal-setting and self-monitoring are relevant components in effective interventions. In addition, Bandura suggests that the key concepts that affect health behaviour change interventions include self-control, self-efficacy, observational learning and reinforcement. Based on the SHIFT logic model (see *Figure 1*), self-efficacy and self-monitoring were to be utilised with the Fitbit. The supportive social environment was to be facilitated via the education session and through health coach support from the text messaging service. The acquisition of the essential knowledge relating to behaviours came from the education session. However, the SCT has a shortcoming regarding this RCT, as truck drivers are inherently isolated from each other and, therefore, they rarely learn behaviours from each other's doing. A further model applicable to the SHIFT intervention is the behaviour change wheel, which uses the capability, opportunity, motivation – behaviour framework, where participants require capability, opportunity and motivation to change their health behaviours.[168] The opportunities to foster motivation can be created through the health assessments, notifying the individual of their current health status and that they may be at risk of certain lifestyle-related diseases and conditions. Capabilities are highlighted through the education sessions, where individuals acquire essential knowledge relating to health behaviours and lifestyle choices. Opportunity is derived from receiving the Fitbit and cab workout equipment, and then turning these changes into habits through regular reminders and feedback from the Fitbit, step count challenges and health coach support from the text messages.

It is also important to recognise that there is no 'one size fits all' solution with regard to behaviour change, and this is explained by Resnicow and Vaughan's[169] chaos theory and complex dynamic systems. Theories such as the SCT view change as an interaction of self-efficacy, belief, knowledge, attitude and intention, which creates a linear mechanism for an individual to assess the positives and negatives in a consistent manner. However, Resnicow and Vaughan's[169] chaos theory and complex dynamic systems argue that it is impossible to make predictions on human behaviour, likening this to the impossibility of mathematically predicting the course of two identical balls rolling down a rocky mountain, with the balls ending up in two very different places because of an almost infinite number of variables. Behaviour change encompasses these infinite interacting variables that impact the outcome.[169] According to Resnicow and Vaughan,[169] regarding human behaviour, there may be common patterns of behaviour change that occur across and within individuals that may follow complex non-linear patterns. Resnicow and Vaughan[169] highlight that identifying these recurrent patterns of change will be useful to aid identification of target groups who could benefit from common intervention components.

Context

All participants were asked in the follow-up questionnaires during each measurement session about any major changes to their life over the past 6 months. The biggest changes reported were moving house, followed by family illness and relationship break-ups. There were no apparent biases between trial groups regarding external factors influencing study participation.

The COVID-19 pandemic caused three major lockdowns in the UK from March 2020 to July 2021, which had wide-ranging impacts on each site that was involved in the study. Although there appeared no systematic differences between intervention and control sites in terms of the impact of the pandemic, it was a rapidly changing, dynamic situation that was unable to be adequately reported. We cannot, therefore, say with certainty that there were no differences in the impact of the pandemic between intervention and control groups. Indeed, as highlighted above, a greater proportion of control participants reported being furloughed than intervention participants, which may have affected participants' lifestyle health behaviours and markers of well-being, either positively or negatively, prior to the final follow-up assessments.

The outcomes of the study were measured using health assessments, which all intervention and control participants attended. The health assessments were followed by short feedback sessions where the results were explained to each participant. Although not part of the intervention, the health assessments did have an impact on awareness and knowledge about a healthy lifestyle in both intervention and control participants, and this was an unintended outcome of the study, which, although it did not in turn lead to observed behavioural changes in control participants, provided participants with a more holistic understanding of their own current health status.

Process evaluation strengths and limitations

The triangulation of data led to a more comprehensive understanding and rigorous analysis, as we were able to capture data using different dimensions of the same phenomenon.[170] Data were also collected at multiple levels, including driver-, manager- and site-level data, to provide a more complete understanding of the specific context of the RCT. Data for the process evaluation were collected from baseline to the completion of the study (i.e. 16–18 months later), and this enabled us to follow the participants' reflections throughout their experience of the study. The length of follow-up at the end gives the participant and managers time to reflect and provide more holistic responses about their experiences. The representativeness of each depot was considered when stratified sampling of the drivers and managers for the interviews took place. This method gives the reader a more thorough comprehension of the study, as every site was heterogeneous. The process evaluation was undertaken primarily by a single integrated evaluator, which was beneficial for effective communication, avoids duplication of efforts and reduces participant burden.[94] Very much part of the intervention team, the evaluator used this first-hand experience to understand thoroughly every part of the intervention, and this, in turn, helped to minimise the Hawthorne effect while collecting observational data about the operational challenges for both for the implementation team and the sites.

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Assessing the reach of the SHIFT intervention across the included 25 depots was not appropriate or feasible within the context of the programme, as the present trial aimed to recruit approximately 14 participants per site because of financial and time restrictions. It was apparent that in most sites there was a large interest in the study, highlighting the necessity of such health interventions in this at-risk population. Indeed, at baseline, the trial over-recruited, with 382 participants providing informed consent, which exceeded our recruitment target of 336 participants from our sample size calculation. However, despite the initial high interest in the study, the total loss to follow-up was high (46.3%) and this potentially may have resulted in attrition bias, whereby there may have been systematic differences between participants who left and participants who stayed.

All participants were asked to participate in the interviews and incentivised to do so, and this may have led to a sampling bias, although this was mitigated as best as possible by involving one participant from each depot. The limitation of having an integrated process evaluator may increase risk of potential biases in the process evaluation outcome. However, this was mitigated through having an external, and independent from the trial, 'critical friend' (Dr Anna Chalkley), and all findings were discussed with the principal investigator (SC).[171] As the process evaluation data were analysed without the knowledge of the main trial outcomes, bias was also minimised so as to reduce influenced interpretations.

Process evaluation conclusions and recommendations

The SHIFT intervention demonstrated effectiveness in the primary outcome (i.e. daily steps); however, future replication and extension of this study should consider more valid measures of nutritional intake to best capture dietary behavioural changes, as regularly reported in the interviews. More frequent contact with both control and intervention participants was suggested as a key improvement, which, in turn, would lessen attrition rates. Attrition rates were high throughout the study, which supports the existing understanding that HGV drivers are a hard-to-reach population,[7] not least due to the transient nature of the workforce. The COVID-19 pandemic had a mixed impact on participating sites, which would make any conclusions about the final follow-up uncertain. Overall, participants were enthusiastic about the SHIFT intervention, with particular emphasis on the dietary lessons from the education session and the activity monitoring and motivation from the Fitbit.

Trial strengths and limitations

A major strength of this study was the implementation of a lifestyle health behaviour intervention within the workplace environment of a very underserved and at-risk occupational group. The characteristics of our sample at baseline highlight the poor health profile of HGV drivers within the UK, and emphasise the urgent need to improve the health of this shrinking, yet essential, workforce.[29] The study involved 25 different transport sites spread throughout the Midlands region, operating within subcontracts across eight different industries. The range of industries represented by these sites, together with the demographic characteristics of our sample (mean age at baseline 48 years and 99% male, which matches exactly the characteristics of UK HGV drivers[26]), suggests that the included sample likely represents the 278,700 HGV drivers currently in employment.[1]

Our multicomponent lifestyle health behaviour intervention (i.e. the SHIFT intervention) was evaluated through a fully powered cluster RCT, where randomisation occurred at the site level (reducing the risk of contamination) after baseline assessments had been undertaken (reducing bias). The trial incorporated immediate (6-month) and longer-term (16- to 18-month) follow-up periods to enable the examination of the effectiveness and potential sustainability of the SHIFT intervention. The trial also included a mixed-methods process evaluation and a full economic analysis. To the best of our knowledge, this is the first cluster RCT to examine the effectiveness and cost-effectiveness of a lifestyle health behaviour intervention within HGV drivers, with the few earlier intervention studies[25,30,31] reported in this workforce limited by small sample sizes, no control groups and limited follow-up durations.

The SHIFT intervention has a strong theoretical underpinning.[42] The SHIFT intervention was created and refined based on our earlier work,[7,36–38] and the planning of this study, and subsequent conducting of it, has been informed by extensive PPI.

The use of the activPAL accelerometer as the primary outcome measure is a further strength, with this device being shown to provide a highly accurate measure of steps and posture.[53–55] Furthermore, we were able to confirm the validity of this device in our particular sample by demonstrating that, within the HGV cab, the activPAL is not affected by vehicle vibrations. Compliance to the activPAL wear protocol was relatively high in the present study, and this was facilitated by checking the activPAL data on return of the devices and requesting re-wears where possible. At baseline, 90% of participants provided at least 1 day of activPAL data. Of the sample of participants returning the device at 6 months, 89% provided at least 1 day of activPAL data, of whom 84% provided valid activPAL data at both baseline and 6 months. On average, participants wore the activPAL for 6.8 days at baseline and 7.2 days at 6 months. These compliance rates are similar to those seen recently in a large sample of office-based workers.[172] Although a minimum number of days of device wear are usually specified to allow for day-to-day variation in behaviours,[173] to maximise our sample, owing to the high loss to follow-up experienced (discussed below), in our main analysis we included all participants who provided at least 1 day of activPAL data, as applied elsewhere.[86] However, to test the robustness of our findings, we performed a sensitivity analysis including only participants who provided more valid days of activPAL data, and our findings remained unchanged. Although the activPAL provides a device-based measure of physical activity (and participants were blinded to the data recorded), reducing bias associated with self-report measures, participants were still aware of the purpose of the activPAL. Therefore, reactivity to this measure may have occurred, although any potential reactivity is likely to have affected the SHIFT and control groups equally. The trial included a range of validated secondary outcomes, enabling a comprehensive evaluation of the SHIFT intervention on markers of adiposity and cardiometabolic risk, mental well-being, a range of lifestyle health-related behaviours and measures of work-related psychosocial factors.

A major limitation of the present study was the high loss to follow-up experienced, which was beyond that initially predicted. We experienced a 31.4% loss to follow-up at the 6-month assessments, with the sample included in the primary outcome analysis reduced further (55% of the initial randomised sample) after taking into account activPAL compliance across the two assessment points. Further losses to follow-up were experienced at the final follow-up, with 54% of the original sample attending this assessment. We also lost two sites/clusters during the trial due to the collapse of their contracting companies. It was emphasised by managers as part of our process evaluation that HGV drivers are notoriously transient workers, with a high staff turnover rate. A large proportion of drivers not completing this study had left their role before the cessation of the programme. Sick leave and missed assessment sessions were also common reasons for non-completion. Future trials with this, or similar, occupational groups will need to take into account potentially high loss to follow-up rates within sample size calculations, along with consideration of compliance rates to device-based measures, if appropriate. Within the present study, we overrecruited at baseline, which is perhaps further evidence of the need for such health improvement interventions in HGV drivers. Nevertheless, the initial larger sample recruited meant that the larger than expected loss to follow-up rates were mitigated to a certain extent within our primary analysis, where sufficient statistical power remained to detect a significant difference between trial arms in our primary outcome.

The overall day-to-day running of the trial was extremely complex, and it was very challenging to schedule the measurement sessions in some sites because of the demand on the workforce, which led to overall delays with data collection. Owing to the 24/7 working nature of the logistics sector, a number of site visits took place during the night/very early hours of the morning, which led to further challenges for the research team in terms of scheduling and undertaking these visits. It was also extremely challenging to schedule the 6-hour education sessions within intervention sites, as, owing to the pressures faced by the industry, a number of managers found it difficult to facilitate the

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time for their drivers to be away from their driving duties. The overall challenges associated with the scheduling of measurement visits and education sessions, along with the challenges faced by the drivers to incorporate healthy lifestyle behaviours on workdays, emphasise and confirm the hard-to-reach nature of this male-dominated occupational group.

Owing to the multicomponent nature of our intervention, it should be highlighted that the SHIFT structured education session did not focus on one specific element of lifestyle health behaviours. It was not focused on physical activity, diet or sitting alone; all three elements were included. With the education session linked to the feedback participants had received from their baseline health measurements, intervention participants could choose to work on and improve any single behaviour or a combination of behaviours. Therefore, for some participants, step count targets may have increased if this is what they chose to focus on; for other participants, it could have been dietary choices and/or weight. Therefore, in some respects, owing to the multiple health behaviours covered, our overall results for each individual behaviour (i.e. steps, diet, weight, sitting) could have been 'watered down'.

Conclusions and recommendations

The SHIFT intervention may have had a degree of success in positively impacting physical activity levels and reducing sitting time in HGV drivers at 6 months' follow-up. Owing to the nature and demands of the occupation, the statistically significant differences observed between groups in these behaviours were largely driven by changes occurring on non-workdays, and are also largely attributable to the maintenance of physical activity levels in the SHIFT arm and a decline in physical activity levels in the control arm. The process evaluation revealed favourable attitudes towards the SHIFT intervention 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 a sense of necessity for the SHIFT intervention to be included in future CPC training for professional drivers in the UK.

Although most intervention participants reported positive improvements to both knowledge and behaviour around their dietary intake within the process evaluation, the dietary outcome measures did not substantiate these findings within the RCT. Owing to the modest differences in physical activity seen between groups, and there being no differences between dietary variables, no statistically significant differences were observed between groups in terms of markers of adiposity or cardiometabolic outcomes. No differences in any outcome measure were seen between groups during the final follow-up assessments, suggesting that the positive impacts of the SHIFT intervention were not sustained beyond the duration of the 6-month intervention. However, the pandemic presents a major confounding factor that limits our ability to draw firm conclusions regarding the sustainability of the SHIFT intervention, particularly in light of the imbalance in participants on furlough between the two trial arms. The economic evaluation revealed that the SHIFT intervention is not likely to be cost-effective in its current delivery format.

The high prevalence of drivers with obesity, along with the poor cardiometabolic health profile and sleep deprivation seen in our sample, accompanied by the challenges experienced in scheduling data collection and the education sessions, highlight substantial health inequalities in this at-risk and hard-to-reach occupational group. Given the current, and increasing, shortfall of HGV drivers in the UK, which has risen from 60,000[28] to an estimated 100,000 in 2021,[29] the government and sector urgently need to address working conditions and the poor health profile of this ageing workforce to attract employees to the role. The already challenging working conditions are likely to be only exacerbated currently, as the small number of drivers have to compensate for driver shortages by expanding their own working hours, as relaxations in drivers' hours rules have been re-introduced as a result of driver shortages, COVID-19 and Brexit.[160] Driver recruitment and a prioritisation of driver health is essential to combat the current challenges seen in maintaining critical supply chains, and to support the UK's

economic recovery from the COVID-19 pandemic. In addition, improving drivers' health has significant implications, not only for the individual or their employer (through reductions in sickness absence and staff turnover), but also for the wider public through improving road safety for all users. Although the longer-term impact of the SHIFT intervention is unclear, the intervention (with ongoing development and 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.

Based on the findings of the present study, we recommend the following:

- To support the development and implementation of the SHIFT intervention as a CPC training module for HGV drivers, further work involving stakeholder engagement is needed to refine the content of the intervention, based on findings of the present study, and to examine an appropriate delivery mode that is cost-effective with maximal reach. On the translation of the SHIFT intervention into a CPC module, further work should be conducted to evaluate the scaling-up of this intervention over the longer term, in a real-world setting.
- Effective strategies targeting improvements in dietary behaviours that, in turn, promote weight loss in HGV drivers need to be researched and incorporated into the SHIFT intervention to further impact the high prevalence of drivers with obesity.
- Effective interventions targeting improvements in drivers' sleep duration need to be created and evaluated and, subsequently, incorporated into the SHIFT intervention to combat the high levels of sleep deprivation observed in this study. Increasing sleep quantity through interventions targeting improved sleep management in drivers will potentially offer dual public health benefits of reducing accident risk (through reduced fatigue and improved vigilance performance) and reducing cardiometabolic risk within the individual.

Further research

Based on the findings of the present study relating to the high levels of sleep deprivation seen in our sample, members of the research team, along with colleagues with expertise in sleep science, have been awarded a MRC Public Health Intervention Development grant (reference MR/W004070/1; principal investigator Dr Iuliana Hartescu; start date 1 November 2021) to co-develop (with target users and stakeholders) an app-based intervention to improve sleep quality and quantity in commercial drivers within the road freight sector.

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Contributions of authors

Stacy A Clemes (https://orcid.org/0000-0001-5612-5898) (Reader in Active Living and Public Health) the principal investigator, had overall responsibility for the study (including funding acquisition, study design and methods development) and report writing, drafted *Chapters 1–3* and *6*, and provided a detailed review and edit of *Chapters 4* and *5*.

Veronica Varela-Mato (https://orcid.org/0000-0003-4070-6609) (Research Associate) was responsible for the day-to-day management of the project (years 1–3), conducted and oversaw all fieldwork and data collection, co-delivery of the SHIFT education sessions and quantitative process evaluation data, contributed to the study design and methods development, and obtained funds to complete the project.

Danielle H Bodicoat (https://orcid.org/0000-0002-2184-4865) (Medical Statistician) was responsible for the statistical analysis and the preparation and presentation of the quantitative results in *Chapter 3*.

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Yu-Ling Chen (https://orcid.org/0000-0002-6976-4055) (Research Associate) supported the day-to-day management of the project (years 1–2.5), conducted fieldwork, co-delivered the SHIFT education sessions and supported the processing of the activPAL data (blinded).

Edward Cox (https://orcid.org/0000-0001-8981-0699) (Research Fellow) contributed to the health economic analysis plan, conducted the economic analysis and drafted the economic analysis reported in *Chapter 4*.

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Amber Guest (https://orcid.org/0000-0002-3610-347X) (Doctoral Researcher) supported the day-to-day running of the project, conducted fieldwork, co-delivered the SHIFT education sessions, and undertook the process evaluation and drafted *Chapter 5*.

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All authors were members of the internal Project Committee for the trial. All authors read drafts and provided revisions on the content of the report and have given final approval for submission.

Publications

Clemes SA, Varela Mato V, Munir F, Edwardson CL, Chen YL, Hamer M, *et al.* Cluster randomised controlled trial to investigate the effectiveness and cost-effectiveness of a Structured Health Intervention For Truckers (the SHIFT study): a study protocol. *BMJ Open* 2019;**9**:e030175.

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to available anonymised data may be granted following review.

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Appendix 1 Baseline characteristics: completers versus non-completers

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TABLE 42 Baseline characteristics: completers vs. non-completers

Characteristic	Control		SHIFT intervention		Total	
	Non-completers (*n* = 69)	Completers[a] (*n* = 130)	Non-completers (*n* = 83)	Completers (*n* = 100)	Non-completers (*n* = 152)	Completers (*n* = 230)
Cluster size, *n* (%)						
Small	31 (44.9)	50 (38.5)	52 (62.7)	41 (41.0)	83 (54.6)	91 (39.6)
Large	38 (55.1)	80 (61.5)	31 (37.4)	59 (59.0)	69 (45.4)	139 (60.4)
Demographics						
Age (years), median (IQR)	49.95 (42.50–56.41)	49.25 (40.64–55.16)	49.82 (43.77–54.96)	50.04 (41.66–55.40)	49.82 (43.07–55.47)	49.45 (41.12–55.24)
Number of years as a HGV driver, median (IQR)	19.50 (11.33–28.25)	12.34 (5.17–24.02)	17.50 (9.00–25.83)	17.00 (10.50–25.00)	17.88 (10.00–27.00)	14.50 (7.38–25.00)
Biometric measures						
BMI (kg/m^2), median (IQR)	30.57 (27.86–32.84)	28.89 (26.64–32.90)	29.58 (26.56–33.54)	30.03 (26.93–34.30)	30.06 (27.08–32.96)	29.71 (26.87–33.47)
activPAL variables						
Number steps at baseline (steps/day) (IQR)	7969.4 (6718.7–9894.9)	8579.5 (6920.0–10,327.0)	8813.6 (7208.6–11,973.3)	8605.5 (6978.6–11,067.7)	8531.7 (6879.8–10,678.6)	8597.5 (6964.9–10,695.7)

a Defined as providing valid activPAL data at 6 months.

Appendix 2 Quotes provided by participants completing the additional online COVID-19 questionnaire

BOX 1 Quotations provided by participants completing the additional online COVID-19 questionnaire, relating to how participating in the study has helped them maintain a healthy lifestyle during the pandemic: 1

Statement: participating in the SHIFT study has given me the right knowledge to maintain a healthy lifestyle during the COVID-19 restrictions

Responses from participants in the control group

Eating, exercise, sleep.
Makes you more aware of your health.
Eating healthy and taking daily exercise.
Confirmation of prior knowledge.
Understanding how food effect your body.
Aware of a better way of living.
It has given me an insight to what I should be doing.
Better understanding of health and well-being. The importance of exercise.
I am quite sporty in my home life, but shift has given me tools to make some small but good changes in my work life.
Maintenance of exercise and trying to eat healthier and in moderation.
I'm more aware of the effects of not enough sleep.
Motivation to eat healthy and exercise.
Started eating better and going for a walk most days.
Learnt the importance of a balanced diet – conscious of my sugar intake.
Knowing what diet I should follow.
I'm eating more fruit and cycling every other day.
Being more conscious of my diet and health.
I've taken action appropriately given the results from the continued assessments in an effort to improve health and fitness.
Healthy outlook on life diet.
Finding out my blood pressures, good and bad cholesterol. Which has made me think more about what I put in my body and fitness.
Been given exercise and healthy food advice.
By making me aware of a healthy lifestyle using websites.
I understand what I should eat better and in what amounts. Keeping to the limit is still hard though.
More fruit better diet.
Health check feedback during visit at work.

Responses from participants in the intervention group

Maintaining a healthy diet and getting enough exercise.
Learning that doing a little bit every day is better than doing nothing.
It made me realise that it's not that difficult to eat healthier by thinking about what I really need to eat.
Take more care at checking calories and fat in foods before buying.
Exercise healthy eating body and mind balance.
Cut out the crap and keep moving.
Keep off the junk food.

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BOX 1 Quotations provided by participants completing the additional online COVID-19 questionnaire, relating to how participating in the study has helped them maintain a healthy lifestyle during the pandemic: 1 (*continued*)

It has shown me that even small changes can make a big difference.
Understanding my calorie intake has had the most effect on my health.
It helped me chose the correct diet.
More aware of the minor alterations to make in diet to maintain good healthy weight.
I was more educated on sugar content in some foods I was regularly eating and also cut down on alcohol consumption.
Its given me the knowledge not necessarily stuck to it.
Full health check showed how unhealthy I was and how close to becoming diabetic I was, this has changed my eating habits and taking care of my body more seriously.
Small changes can make a big difference, plus help focus and motivate to do more exercise.
Healthy eating and exercise is the key to life.
Made me aware how unhealthy I am with not enough exercise I get the food that is good and bad And the problem this causes.
Choosing healthy options and understandings calories.
Healthy lifestyle booklet.
Education and highlighting the advantages of better eating.
To keep doing my steps.
Keeping moving and standing as much as possible, eating more healthier diet.
Health workshop.
Eating better.
Insight into healthy diet and exercise needs.

BOX 2 Quotations provided by participants completing the additional online COVID-19 questionnaire, relating to how participating in the study has helped them maintain a healthy lifestyle during the pandemic: 2

Question: since the COVID-19 restrictions, have you experienced any changes in your lifestyle and/or work that you feel may have a positive or negative impact on your overall health?

Participants reporting a positive impact

Cycle/walk more when furloughed.
Felt mentally better while off work, feeling a bit stressed and anxious now back working.
More sleep. Better diet.
Increased exercise.
Being on furlough gave me time to de-stress. It was a very positive experience.
More time to do things, like walking, golfing, gardening and DIY.
Change of shift at work, better sleep, feeling more alert and energetic.
I've started landscaping again and I feel healthier for moving more in the day.
More exercise.
Cycling.
Rediscovered the joy of cycling.
Positive impact on sleeping and eating.
Not so tired eating at regular times bit more exercise.
Exercising more.
The roads were not as busy as usual and so less stressful.
Everybody seems anxious . . . although I'm not . . . I think it's been blown up out of all proportion.

BOX 2 Quotations provided by participants completing the additional online COVID-19 questionnaire, relating to how participating in the study has helped them maintain a healthy lifestyle during the pandemic: 2 (*continued*)

Running more and healthy eating.
Going for more walks than ever before.
Getting more quality sleep but due to social distancing I'm not jogging or going for really long walks or bike rides.
Cycling to work.

Participants reporting a negative impact

Unable to go to the gym cannot sustain the same level of fitness as before.
Less movement. No work.
Shielding.
Eating more treats at home, picking.
Poor eating choices out on the road.
More drinking alcohol and eating slightly worse.
Not getting as much exercise as sitting longer.
Am doing a lot less physical activity.
Working days, less chance of preparing dinner and end up buying food out instead.
Access to the right sort of food.
I haven't done as much exercise while being off work.
Can't go swimming.
Gyms closed.
More difficult to create motivation, getting lazier, eating less veg and fruit.
Had a very sore knee for the last month.
I have become considerably lazier.
Nothing available at the services. I had to rediscover pot noodles to survive on nights out.
Less walking.
Increase in weight.

DIY, do it yourself.

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Appendix 3 Tables and figures associated with the health economics analysis

TABLE 43 Unit costs

Resource	Unit cost (£)	Source
Primary care		
GP: surgery visit	34.09	PSSRU 2019[174]
GP: home visit	110.60	PSSRU 2010[175]
GP: telephone call	15.83	PSSRU 2019[174]
General practice nurse: surgery visit	5.88	PSSRU 2019[174]
General practice nurse: home visit	32.48	PSSRU 2010[175]
General practice nurse: telephone call	6.20	PSSRU 2019[174]
Secondary care		
Outpatient appointment	142.12	NHS reference costs 2017/18[176] [General Surgery]
Accident and emergency visits	116.11	PSSRU 2010[175]
NHS walk-in centre visit	47.52	NICE 2018[177]
NHS urgent care centre visit	69.21	NICE 2018[177]
Mental health care		
Mental health nurse	92.00	PSSRU 2019[174]
Occupational services		
Occupational health nurse	39.42	NHS reference costs 2017/18[176]
Physiotherapist	88.35	NHS reference costs 2017/18[176] [Adult, One to One]

PSSRU, Personal Social Services Research Unit.

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TABLE 44 Available-case resource use: the SHIFT intervention

	Baseline			Month 6			Months 16–18[a]		
Available-case resource use	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum
Primary care									
GP: surgery visit	177	0.9 (1.87)	0, 20	110	0.59 (0.99)	0, 4	90	0.43 (0.91)	0, 4
GP: home visit	184	0 (0)	0, 0	114	0 (0)	0, 0	92	0.02 (0.21)	0, 2
GP: telephone call	181	0.14 (0.72)	0, 8	112	0.11 (0.45)	0, 3	89	0.31 (1.27)	0, 10
General practice nurse: surgery visit	176	0.24 (0.7)	0, 6	112	0.24 (0.66)	0, 4	89	0.1 (0.37)	0, 2
General practice nurse: home visit	184	0.01 (0.07)	0, 1	114	0 (0)	0, 0	92	0.03 (0.31)	0, 3
General practice nurse: telephone call	183	0.01 (0.15)	0, 2	114	0.04 (0.26)	0, 2	91	0.05 (0.35)	0, 3
Secondary care									
Inpatient days	183	0.09 (0.57)	0, 5	114	0.11 (0.7)	0, 6	92	0.57 (3.87)	0, 34
Outpatient visits	178	0.23 (0.61)	0, 4	112	0.23 (0.78)	0, 5	90	0.22 (0.7)	0, 4
Accident and emergency visits	182	0.08 (0.62)	0, 8	114	0.09 (0.31)	0, 2	92	0.11 (0.38)	0, 2
NHS walk-in centre visit	183	0.04 (0.22)	0, 2	113	0.01 (0.09)	0, 1	91	0.02 (0.15)	0, 1
NHS urgent care centre visit	184	0.01 (0.1)	0, 1	114	0 (0)	0, 0	92	0.01 (0.1)	0, 1
Other hospital-based services	180	0.1 (0.95)	0, 12	111	0.01 (0.09)	0, 1	90	0.12 (0.58)	0, 4
Mental health care									
Mental health nurse	184	0.01 (0.07)	0, 1	114	0 (0)	0, 0	91	0.01 (0.1)	0, 1
Occupational services									
Occupational health nurse	184	0.04 (0.22)	0, 2	114	0.03 (0.21)	0, 2	92	0.03 (0.23)	0, 2
Physiotherapist	183	0.34 (1.39)	0, 12	113	0.67 (2.41)	0, 20	90	0.34 (1.36)	0, 10

a Observed resource use (participant response referring to resource use in the past 6 months).

TABLE 45 Available-case resource use: usual practice

Available-case resource use	Baseline			Month 6			Months 16–18[a]		
	n	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum
Primary care									
GP: surgery visit	190	1.18 (2.37)	0, 20	140	0.86 (1.43)	0, 10	101	0.34 (0.85)	0, 5
GP: home visit	201	0 (0.07)	0, 1	146	0 (0)	0, 0	102	0 (0)	0, 0
GP: telephone call	200	0.25 (1.5)	0, 20	145	0.12 (0.42)	0, 2	97	0.27 (0.6)	0, 3
General practice nurse: surgery visit	196	0.34 (1.32)	0, 16	143	0.29 (0.68)	0, 4	99	0.07 (0.29)	0, 2
General practice nurse: home visit	201	0 (0.07)	0, 1	146	0 (0)	0, 0	102	0 (0)	0, 0
General practice nurse: telephone call	201	0.01 (0.1)	0, 1	146	0.08 (0.83)	0, 10	101	0.02 (0.14)	0, 1
Secondary care									
Inpatient days	201	0.06 (0.4)	0, 3	146	0.01 (0.17)	0, 2	102	0.02 (0.14)	0, 1
Outpatient visits	197	0.31 (1.05)	0, 10	145	0.21 (0.53)	0, 3	102	0.2 (0.78)	0, 7
Accident and emergency visits	201	0.1 (0.39)	0, 3	145	0.06 (0.29)	0, 2	102	0.07 (0.29)	0, 2
NHS walk-in centre visit	200	0.04 (0.25)	0, 3	144	0.04 (0.29)	0, 3	100	0.02 (0.14)	0, 1
NHS urgent care centre visit	201	0.01 (0.1)	0, 1	146	0.01 (0.12)	0, 1	102	0.02 (0.14)	0, 1
Other hospital-based services	200	0.21 (1.67)	0, 20	146	0.1 (0.53)	0, 5	102	0.09 (0.55)	0, 5
Mental health care									
Mental health nurse	201	0.01 (0.14)	0, 2	146	0.03 (0.34)	0, 4	102	0.03 (0.22)	0, 2
Occupational services									
Occupational health nurse	200	0.02 (0.17)	0, 2	146	0.01 (0.08)	0, 1	102	0 (0)	0, 0
Physiotherapist	199	0.34 (2.94)	0, 40	146	0.42 (3.36)	0, 40	100	0.14 (0.67)	0, 5

a Observed resource use (participant response referring to resource use in the past 6 months).

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TABLE 46 Complete-case resource use: the SHIFT intervention

	Baseline			Month 6			Months 16–18[a]		
Complete-case resource use	***n***	**Mean (SD)**	**Minimum, maximum**	***n***	**Mean (SD)**	**Minimum, maximum**	***n***	**Mean (SD)**	**Minimum, maximum**
Primary care									
GP: surgery visit	67	0.88 (2.53)	0, 20	72	0.56 (0.96)	0, 4	72	0.4 (0.93)	0, 4
GP: home visit	72	0 (0)	0, 0	72	0 (0)	0, 0	72	0.03 (0.24)	0, 2
GP: telephone call	70	0.17 (0.61)	0, 3	72	0.06 (0.29)	0, 2	72	0.35 (1.4)	0, 10
General practice nurse: surgery visit	67	0.15 (0.4)	0, 2	72	0.19 (0.52)	0, 2	72	0.08 (0.37)	0, 2
General practice nurse: home visit	72	0 (0)	0, 0	72	0 (0)	0, 0	72	0 (0)	0, 0
General practice nurse: telephone call	71	0.03 (0.24)	0, 2	72	0.03 (0.24)	0, 2	72	0.07 (0.39)	0, 3
Secondary care									
Inpatient days	72	0.1 (0.63)	0, 5	72	0.08 (0.71)	0, 6	72	0.51 (4.02)	0, 34
Outpatient visits	69	0.25 (0.63)	0, 3	72	0.28 (0.91)	0, 5	72	0.25 (0.75)	0, 4
Accident and emergency visits	70	0.14 (0.97)	0, 8	72	0.1 (0.34)	0, 2	72	0.13 (0.41)	0, 2
NHS walk-in centre visit	72	0.06 (0.23)	0, 1	72	0.01 (0.12)	0, 1	72	0 (0)	0, 0
NHS urgent care centre visit	72	0.03 (0.17)	0, 1	72	0 (0)	0, 0	72	0.01 (0.12)	0, 1
Other hospital-based services	70	0.06 (0.48)	0, 4	72	0 (0)	0, 0	72	0.06 (0.37)	0, 3
Mental health care									
Mental health nurse	72	0.01 (0.12)	0, 1	72	0 (0)	0, 0	72	0 (0)	0, 0
Occupational services									
Occupational health nurse	72	0.04 (0.2)	0, 1	72	0.03 (0.24)	0, 2	72	0.04 (0.26)	0, 2
Physiotherapist	72	0.18 (0.78)	0, 4	72	0.69 (2.76)	0, 20	72	0.31 (1.34)	0, 10

a Observed resource use (participant response referring to resource use in the past 6 months).

TABLE 47 Complete-case resource use: usual practice

Complete-case resource use	Baseline			Month 6			Months 16–18[a]		
	n	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum
Primary care									
GP: surgery visit	80	1 (1.68)	0, 10	84	0.9 (1.36)	0, 7	84	0.37 (0.9)	0, 5
GP: home visit	84	0 (0)	0, 0	84	0 (0)	0, 0	84	0 (0)	0, 0
GP: telephone call	84	0.1 (0.33)	0, 2	84	0.1 (0.37)	0, 2	84	0.24 (0.55)	0, 2
General practice nurse: surgery visit	84	0.25 (0.64)	0, 3	84	0.24 (0.55)	0, 2	84	0.07 (0.3)	0, 2
General practice nurse: home visit	84	0 (0)	0, 0	84	0 (0)	0, 0	84	0 (0)	0, 0
General practice nurse: telephone call	84	0 (0)	0, 0	84	0.13 (1.1)	0, 10	84	0.02 (0.15)	0, 1
Secondary care									
Inpatient days	84	0.07 (0.46)	0, 3	84	0 (0)	0, 0	84	0.02 (0.15)	0, 1
Outpatient visits	83	0.33 (1.22)	0, 10	84	0.24 (0.57)	0, 3	84	0.23 (0.86)	0, 7
Accident and emergency visits	84	0.1 (0.4)	0, 3	84	0.04 (0.24)	0, 2	84	0.08 (0.32)	0, 2
NHS walk-in centre visit	83	0.02 (0.15)	0, 1	84	0.04 (0.19)	0, 1	84	0.02 (0.15)	0, 1
NHS urgent care centre visit	84	0.01 (0.11)	0, 1	84	0.02 (0.15)	0, 1	84	0.02 (0.15)	0, 1
Other hospital-based services	84	0.46 (2.55)	0, 20	84	0.12 (0.63)	0, 5	84	0.11 (0.6)	0, 5
Mental health care									
Mental health nurse	84	0.02 (0.22)	0, 2	84	0.05 (0.44)	0, 4	84	0.04 (0.24)	0, 2
Occupational services									
Occupational health nurse	84	0 (0)	0, 0	84	0 (0)	0, 0	84	0 (0)	0, 0
Physiotherapist	84	0.65 (4.49)	0, 40	84	0.65 (4.41)	0, 40	84	0.17 (0.73)	0, 5

a Observed resource use (participant response referring to resource use in the past 6 months).

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TABLE 48 Available-case costs: the SHIFT intervention

	Total[a]			Baseline			Month 6			Months 16–18[b]		
Available-case cost	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum
SHIFT intervention	185	369.57 (0)	370, 370	185	0 (0)	0, 0	185	369.57 (0)	370,370	185	0 (0)	0, 0
Primary care												
GP: surgery visit	81	46.68 (79.63)	0, 404	177	30.82 (63.85)	31, 64	110	20.14 (33.71)	0, 136	90	29.05 (61.16)	0, 268
GP: home visit	85	5.12 (47.17)	0, 435	184	0 (0)	0, 0	114	0 (0)	0, 0	92	4.73 (45.34)	0, 435
GP: telephone call	81	11.36 (42.94)	0, 311	181	2.27 (11.46)	2, 11	112	1.7 (7.16)	0, 47	89	9.79 (39.42)	0, 311
General practice nurse: surgery visit	81	2.16 (6.4)	0, 35	176	1.4 (4.12)	1, 4	112	1.42 (3.89)	0, 24	89	1.17 (4.29)	0, 23
General practice nurse: home visit	85	0 (0)	0, 0	184	0.18 (2.39)	0, 2	114	0 (0)	0, 0	92	2.08 (19.97)	0, 192
General practice nurse: telephone call	84	0.87 (5.63)	0, 49	183	0.07 (0.92)	0, 1	114	0.22 (1.64)	0, 12	91	0.67 (4.21)	0, 37
Secondary care												
Inpatient days	83	380.24 (2305.49)	0, 18,984	178	132.78 (839.69)	133, 840	112	59.09 (566.01)	0, 5978	91	339.78 (2203.86)	0, 18,984
Outpatient visits	82	99.47 (235.03)	0, 1118	178	32.74 (86.49)	33, 86	112	32.99 (111.21)	0, 711	90	62.1 (195.48)	0, 1118
Accident and emergency visits	85	36.42 (106.36)	0, 573	182	8.93 (71.65)	9, 72	114	10.19 (36.43)	0, 232	92	24.81 (86)	0, 457
NHS walk-in centre visit	84	1.68 (11.38)	0, 93	183	1.82 (10.41)	2, 10	113	0.42 (4.47)	0, 48	91	2.05 (13.77)	0, 93
NHS urgent care centre visit	85	1.6 (14.76)	0, 136	184	0.75 (7.2)	1, 7	114	0 (0)	0, 0	92	1.48 (14.19)	0, 136
Other hospital-based services	85	8.47 (54.86)	0, 360	184	4.93 (66.94)	5, 67	114	0.4 (4.24)	0, 45	92	7.82 (52.76)	0, 360

Available-case cost	Total[a]			Baseline			Month 6			Months 16–18[b]		
	n	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum
Mental health care												
Mental health nurse	84	0 (0)	0, 0	184	0.52 (7.01)	1, 7	114	0 (0)	0, 0	91	2.05 (19.59)	0, 187
Occupational services												
Occupational health nurse	85	3.78 (21.12)	0, 160	184	1.55 (8.9)	2, 9	114	1.07 (8.5)	0, 81	92	2.61 (18.58)	0, 160
Physiotherapist	82	106.91 (435.38)	0, 3504	183	29.93 (122.69)	30, 123	113	59.42 (212.66)	0, 1767	90	59.83 (236.04)	0, 1737
Total costs												
Overall total observed costs	74	1008.56 (2646.22)	370, 22348	170	251.85 (906.77)	252, 907	106	563.24 (724.97)	370, 7267	84	480.84 (2421.34)	0, 21,787
Total costs excluding inpatient-related services	74	704.3 (813.55)	370, 5761	170	113.7 (237.36)	114, 237	106	503.12 (310.13)	370, 2137	84	217.49 (551.33)	0, 3624

a Total costs calculated using interpolated costs between month 6 and months 16–18.
b Interpolated costs between month 6 and months 16–18.

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TABLE 49 Available-case costs: usual practice

	Total[a]			Baseline			Month 6			Months 16–18[b]		
Available-case cost	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum
SHIFT intervention	201	0 (0)	0, 0	201	0 (0)	0, 0	201	0 (0)	0, 0	201	0 (0)	0, 0
Primary care												
GP: surgery visit	90	40.91 (65.08)	0, 307	190	40.19 (80.81)	0, 682	140	29.22 (48.65)	0, 341	101	11.48 (29.04)	0, 170
GP: home visit	96	0 (0)	0, 0	201	0.55 (7.8)	0, 111	146	0 (0)	0, 0	102	0 (0)	0, 0
GP: telephone call	91	5.57 (10.65)	0, 32	200	3.88 (23.72)	0, 317	145	1.97 (6.7)	0, 32	97	4.24 (9.56)	0, 47
General practice nurse: surgery visit	90	1.76 (3.89)	0, 18	196	1.98 (7.76)	0, 94	143	1.69 (3.99)	0, 24	99	0.42 (1.73)	0, 12
General practice nurse: home visit	96	0 (0)	0, 0	201	0.16 (2.29)	0, 32	146	0 (0)	0, 0	102	0 (0)	0, 0
General practice nurse: telephone call	95	0.85 (6.43)	0, 62	201	0.06 (0.62)	0, 6	146	0.47 (5.15)	0, 62	101	0.12 (0.87)	0, 6
Secondary care												
Inpatient days	95	51.25 (460.47)	0, 4475	197	73.28 (557.02)	0, 5978	145	26.28 (316.4)	0, 3810	102	47.74 (444.42)	0, 4475
Outpatient visits	95	61.34 (153.25)	0, 1137	197	44.73 (149.36)	0, 1421	145	29.4 (74.71)	0, 426	102	27.87 (111.42)	0, 995
Accident and emergency visits	96	14.51 (53.94)	0, 348	201	12.13 (45.57)	0, 348	145	7.21 (34.13)	0, 232	102	7.97 (33.72)	0, 232
NHS walk-in centre visit	92	2.58 (10.83)	0, 48	200	1.66 (12.03)	0, 143	144	1.98 (13.62)	0, 143	100	0.95 (6.69)	0, 48
NHS urgent care centre visit	96	2.88 (13.9)	0, 69	201	0.69 (6.89)	0, 69	146	0.95 (8.07)	0, 69	102	1.36 (9.64)	0, 69
Other hospital-based services	96	1.01 (9.9)	0, 97	201	14.06 (198.06)	0, 2808	146	0.66 (8.02)	0, 97	102	0 (0)	0, 0

Available-case cost	Total[a]			Baseline			Month 6			Months 16–18[b]		
	n	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum
Mental health care												
Mental health nurse	96	6.93 (44.14)	0, 380	201	0.95 (13.41)	0, 190	146	3.25 (32.38)	0, 380	102	2.8 (20.96)	0, 190
Occupational services												
Occupational health nurse	96	0 (0)	0, 0	200	0.81 (7.02)	0, 81	146	0.28 (3.37)	0, 41	102	0 (0)	0, 0
Physiotherapist	94	67.67 (377.83)	0, 3534	199	29.75 (259.98)	0, 3534	146	37.52 (297.1)	0, 3534	100	12.37 (58.93)	0, 442
Total costs												
Overall total observed costs	84	277.02 (695.27)	0, 4800	187	232.92 (815.96)	0, 6542	138	147.23 (481.52)	0, 4168	95	125.3 (529.02)	0, 4800
Total costs excluding inpatient-related services	84	217.9 (466.85)	0, 3602	187	140.61 (457.84)	0, 5474	138	118.92 (336.89)	0, 3602	95	74.05 (181.03)	0, 1409

a Total costs calculated using interpolated costs between month 6 and months 16–18.
b Interpolated costs between month 6 and months 16–18.

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TABLE 50 Complete-case costs: the SHIFT intervention

	Total[a]			Baseline			Month 6			Months 16–18[b]		
Complete-case cost	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum
SHIFT intervention	72	369.57 (0)	370, 370	72	0 (0)	0, 0	72	369.57 (0)	370, 370	72	0 (0)	0, 0
Primary care												
GP: surgery visit	72	45.94 (80.19)	0, 404	67	30.02 (86.31)	30, 86	72	18.94 (32.81)	0, 136	72	27 (62.29)	0, 268
GP: home visit	72	6.04 (51.26)	0, 435	72	0 (0)	0, 0	72	0 (0)	0, 0	72	6.04 (51.26)	0, 435
GP: telephone call	72	11.69 (45.33)	0, 311	70	2.71 (9.71)	3, 10	72	0.88 (4.52)	0, 32	72	10.81 (43.44)	0, 311
General practice nurse: surgery visit	72	2.11 (6.5)	0, 35	67	0.88 (2.35)	1, 2	72	1.14 (3.06)	0, 12	72	0.96 (4.23)	0, 23
General practice nurse: home visit	72	0 (0)	0, 0	72	0 (0)	0, 0	72	0 (0)	0, 0	72	0 (0)	0, 0
General practice nurse: telephone call	72	1.02 (6.08)	0, 49	71	0.17 (1.47)	0, 1	72	0.17 (1.46)	0, 12	72	0.85 (4.72)	0, 37
Secondary care												
Inpatient days	72	312.72 (2262.17)	0, 18,984	69	121.29 (989.59)	121, 990	72	5.47 (46.43)	0, 394	72	307.24 (2262.44)	0, 18,984
Outpatient visits	72	109.34 (247.36)	0, 1118	69	35.02 (89.24)	35, 89	72	39.48 (128.94)	0, 711	72	69.86 (208.42)	0, 1118
Accident and emergency visits	72	39.83 (112.38)	0, 573	70	16.59 (112.32)	17, 112	72	11.29 (39.75)	0, 232	72	28.54 (93.36)	0, 457
NHS walk-in centre visit	72	0.66 (5.6)	0, 48	72	2.64 (10.96)	3, 11	72	0.66 (5.6)	0, 48	72	0 (0)	0, 0
NHS urgent care centre visit	72	1.89 (16.04)	0, 136	72	1.92 (11.45)	2, 11	72	0 (0)	0, 0	72	1.89 (16.04)	0, 136
Other hospital-based services	72	0 (0)	0, 0	72	12.61 (107.01)	13, 107	72	0 (0)	0, 0	72	0 (0)	0, 0

Complete-case cost	Total[a]			Baseline			Month 6			Months 16–18[b]		
	n	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum
Mental health care												
Mental health nurse	72	0 (0)	0, 0	72	1.32 (11.2)	1, 11	72	0 (0)	0, 0	72	0 (0)	0, 0
Occupational services												
Occupational health nurse	72	4.47 (22.9)	0, 160	72	1.7 (8.19)	2, 8	72	1.13 (9.6)	0, 81	72	3.34 (20.98)	0, 160
Physiotherapist	72	114.43 (462.6)	0, 3504	72	15.95 (68.48)	16, 68	72	61.35 (243.49)	0, 1767	72	53.08 (232.58)	0, 1737
Total costs												
Overall total observed costs	72	1019.69 (2682.07)	370, 22,348	66	248.31 (1044.38)	248, 1044	72	510.09 (348.44)	370, 2137	72	509.6 (2612.97)	0, 21,787
Total costs excluding inpatient-related services	72	706.97 (823.8)	370, 5761	66	123.75 (283.76)	124, 284	72	504.62 (341.69)	370, 2137	72	202.35 (577.39)	0, 3624

a Total costs calculated using interpolated costs between month 6 and months 16–18.
b Interpolated costs between month 6 and months 16–18.

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TABLE 51 Complete case costs: usual practice

Complete-case cost	Total[a]			Baseline			Month 6			Months 16–18[b]		
	n	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum
SHIFT intervention	84	0 (0)	0, 0	84	0 (0)	0, 0	84	0 (0)	0, 0	84	0 (0)	0, 0
Primary care												
GP: surgery visit	84	43.42 (66.59)	0, 307	80	34.09 (57.4)	0, 341	84	30.84 (46.32)	0, 239	84	12.58 (30.76)	0, 170
GP: home visit	84	0 (0)	0, 0	84	0 (0)	0, 0	84	0 (0)	0, 0	84	0 (0)	0, 0
GP: telephone call	84	5.28 (10.52)	0, 32	84	1.51 (5.28)	0, 32	84	1.51 (5.82)	0, 32	84	3.77 (8.73)	0, 32
General practice nurse: surgery visit	84	1.82 (3.98)	0, 18	84	1.47 (3.75)	0, 18	84	1.4 (3.24)	0, 12	84	0.42 (1.78)	0, 12
General practice nurse: home visit	84	0 (0)	0, 0	84	0 (0)	0, 0	84	0 (0)	0, 0	84	0 (0)	0, 0
General practice nurse: telephone call	84	0.96 (6.84)	0, 62	84	0 (0)	0, 0	84	0.81 (6.79)	0, 62	84	0.15 (0.95)	0, 6
Secondary care												
Inpatient days	84	57.96 (489.64)	0, 4475	83	110.89 (741.81)	0, 5978	84	0 (0)	0, 0	84	57.96 (489.64)	0, 4475
Outpatient visits	84	65.98 (161.28)	0, 1137	83	46.23 (173.51)	0, 1421	84	33.84 (81.42)	0, 426	84	32.15 (121.54)	0, 995
Accident and emergency visits	84	13.82 (52.25)	0, 348	84	11.06 (46.37)	0, 348	84	4.15 (28.19)	0, 232	84	9.68 (36.97)	0, 232
NHS walk-in centre visit	84	2.83 (11.31)	0, 48	83	1.15 (7.33)	0, 48	84	1.7 (8.87)	0, 48	84	1.13 (7.29)	0, 48
NHS urgent care centre visit	84	3.3 (14.83)	0, 69	84	0.82 (7.55)	0, 69	84	1.65 (10.61)	0, 69	84	1.65 (10.61)	0, 69
Other hospital-based services	84	1.15 (10.58)	0, 97	84	0.21 (1.96)	0, 18	84	1.15 (10.58)	0, 97	84	0 (0)	0, 0

Complete-case cost	Total[a]			Baseline			Month 6			Months 16–18[b]		
	n	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum
Mental health care												
Mental health nurse	84	7.92 (47.14)	0, 380	84	2.26 (20.74)	0, 190	84	4.53 (41.48)	0, 380	84	3.39 (23.08)	0, 190
Occupational services												
Occupational health nurse	84	0 (0)	0, 0	84	0 (0)	0, 0	84	0 (0)	0, 0	84	0 (0)	0, 0
Physiotherapist	84	72.57 (398.71)	0, 3534	84	57.85 (397.13)	0, 3534	84	57.85 (389.96)	0, 3534	84	14.72 (64.08)	0, 442
Total costs												
Overall total observed costs	84	277.02 (695.27)	0, 4800	80	277.24 (1023.41)	0, 6542	84	139.42 (412.11)	0, 3602	84	137.6 (561.3)	0, 4800
Total costs excluding inpatient-related services	84	217.9 (466.85)	0, 3602	80	161.96 (624.95)	0, 5474	84	138.27 (412.37)	0, 3602	84	79.64 (190.43)	0, 1409

a Total costs calculated using interpolated costs between month 6 and months 16–18.
b Interpolated costs between month 6 and months 16–18.

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TABLE 52 Imputed costs (including follow-up): the SHIFT trial

Imputed cost	Total[a]			Month 6			Months 16–18[b]		
	n	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum
SHIFT intervention	185	369.57 (0)	0, 0	185	369.57 (0)	370, 0	185	0 (0)	0, 0
Primary care									
GP: surgery visit	185	52.37 (104.03)	37, 68	185	22.55 (53.73)	23, 54	185	29.82 (81.91)	18, 42
GP: home visit	185	5.29 (62.01)	−4, 14	185	0 (0)	0, 0	185	5.29 (62.01)	−4, 14
GP: telephone call	185	11.85 (44.81)	5, 18	185	1.79 (8.74)	2, 9	185	10.05 (41.75)	4, 16
General practice nurse: surgery visit	185	3.08 (9.63)	2, 4	185	1.55 (4.75)	2, 5	185	1.53 (6.38)	1, 2
General practice nurse: home visit	185	2.74 (26.9)	−1, 7	185	0 (0)	0, 0	185	2.74 (26.9)	−1, 7
General practice nurse: telephone call	185	1.14 (7.65)	0, 2	185	0.21 (2.87)	0, 3	185	0.93 (6.34)	0, 2
Secondary care									
Inpatient days	185	440.24 (3405.4)	−63, 943	185	75.05 (690.61)	75, 691	185	365.19 (3048.45)	−85, 816
Outpatient visits	185	102.67 (331.89)	54, 151	185	35.3 (134.49)	35, 134	185	67.37 (284.68)	25, 109
Accident and emergency visits	185	37.88 (137.35)	18, 58	185	12.58 (52.22)	13, 52	185	25.3 (107.95)	9, 41
NHS walk-in centre visit	185	3.86 (24.99)	0, 8	185	0.78 (10.58)	1, 11	185	3.08 (22.07)	0, 6
NHS urgent care centre visit	185	2.01 (20.01)	−1, 5	185	0.13 (1.55)	0, 2	185	1.88 (19.48)	−1, 5
Other hospital-based services	185	7.68 (64.73)	−2, 17	185	0.58 (8.27)	1, 8	185	7.1 (63.86)	−2, 16
Mental health care									
Mental health nurse	185	3.8 (44.29)	−3, 10	185	0.77 (35.23)	1, 35	185	3.03 (35.16)	−2, 8
Occupational services									
Occupational health nurse	185	3.93 (25.71)	0, 8	185	1.44 (11.68)	1, 12	185	2.49 (23.34)	−1, 6
Physiotherapist	185	114.4 (408.15)	55, 174	185	58.72 (259.05)	59, 259	185	55.68 (235.03)	21, 90
Total costs									
Overall total observed costs	185	1162.5 (3976.2)	576, 1749	185	581.03 (881.33)	581, 881	185	581.47 (3456.29)	71, 1092
Total costs excluding inpatient-related services	185	722.26 (873.19)	595, 850	185	505.98 (379.27)	506, 379	185	216.28 (629.36)	124, 308

a Total costs calculated using interpolated costs between month 6 and months 16–18.
b Interpolated costs between month 6 and months 16–18.

TABLE 53 Imputed costs (including follow-up): usual practice

Imputed cost	Total[a]			Month 6			Months 16–18[b]		
	n	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum	*n*	Mean (SD)	Minimum, maximum
SHIFT intervention	201	0 (0)	0, 0	201	0 (0)	0, 0	201	0 (0)	0, 0
Primary care									
GP: surgery visit	201	57.72 (115.81)	41, 74	201	29.11 (54.24)	22, 37	201	15 (44.78)	9, 21
GP: home visit	201	3.46 (183.48)	−22, 29	201	0 (0)	0, 0	201	2.42 (71.08)	−7, 12
GP: telephone call	201	13.66 (40.7)	8, 19	201	2.16 (7.73)	1, 3	201	5.69 (18.51)	3, 8
General practice nurse: surgery visit	201	3.13 (9.06)	2, 4	201	1.73 (4.49)	1, 2	201	0.71 (2.97)	0, 1
General practice nurse: home visit	201	1.76 (23.3)	−2, 5	201	0 (0)	0, 0	201	0.87 (10.67)	−1, 2
General practice nurse: telephone call	201	1.17 (7.82)	0, 2	201	0.44 (5.46)	0, 1	201	0.41 (3.04)	0, 1
Secondary care									
Inpatient days	201	306.95 (2740.31)	−80, 694	201	37.91 (473.08)	−28, 104	201	161.45 (1458.6)	−45, 368
Outpatient visits	201	112.97 (348.93)	64, 162	201	32.1 (109.8)	17, 48	201	38.92 (164.33)	16, 62
Accident and emergency visits	201	33.32 (133.51)	14, 52	201	8.52 (45.8)	2, 15	201	12.54 (60.59)	4, 21
NHS walk-in centre visit	201	4.17 (23.75)	1, 7	201	1.73 (13.19)	0, 4	201	1.5 (12.4)	0, 3
NHS urgent care centre visit	201	3.42 (23.05)	0, 7	201	0.83 (8.11)	0, 2	201	1.14 (10.59)	0, 3
Other hospital-based services	201	3.75 (48.38)	−3, 11	201	0.78 (9.19)	−1, 2	201	2 (68.34)	−7, 11
Mental health care									
Mental health nurse	201	8.02 (53.42)	1, 15	201	2.58 (29.5)	−2, 7	201	2.84 (27.44)	−1, 7
Occupational services									
Occupational health nurse	201	1.93 (20.61)	−1, 5	201	0.55 (6.81)	0, 2	201	0.98 (9.95)	0, 2
Physiotherapist	201	82.24 (462.83)	17, 147	201	45.98 (335.9)	−1, 93	201	17.43 (114.71)	1, 34
Total costs									
Overall total observed costs	201	637.66 (3251.62)	179, 1096	201	164.41 (724.49)	63, 266	201	263.9 (1673.24)	27, 501
Total costs excluding inpatient-related services	201	330.71 (809.67)	217, 444	201	125.72 (411.2)	68, 183	201	100.45 (336.25)	53, 148

a Total costs calculated using interpolated costs between month 6 and months 16–18.
b Interpolated costs between month 6 and months 16–18.

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TABLE 54 Primary outcomes by treatment arm and follow-up for available-case, complete-case and imputed approaches to missing data

Primary outcome	Available case, mean (SD)			Complete case, mean (SD)			Imputed analysis, mean (SD)		
	SHIFT intervention, mean (SD)	Usual practice, mean (SD)	Differential, mean (95% CI)	SHIFT intervention, mean (SD)	Usual practice, mean (SD)	Differential, mean (95% CI)	SHIFT intervention, mean (SD)	Usual practice, mean (SD)	Differential, mean (95% CI)
Preference scores									
EQ-5D-3L (base case)									
Baseline	0.853 (0.146)	0.838 (0.14)	0.014 (−0.014 to 0.043)	0.846 (0.143)	0.835 (0.135)	0.011 (−0.031 to 0.052)	0.852 (0.146)	0.839 (0.141)	0.013 (−0.016 to 0.042)
6 months	0.832 (0.135)	0.867 (0.129)	−0.035 (−0.067 to −0.002)	0.831 (0.138)	0.862 (0.13)	−0.031 (−0.071 to 0.008)	0.838 (0.155)	0.864 (0.147)	−0.026 (−0.056 to 0.003)
16–18 months	0.794 (0.173)	0.801 (0.139)	−0.007 (−0.052 to 0.037)	0.796 (0.174)	0.801 (0.14)	−0.005 (−0.052 to 0.041)	0.797 (0.188)	0.795 (0.197)	0.002 (−0.039 to 0.042)
EQ-5D-5L (scenario)									
Baseline	0.909 (0.113)	0.902 (0.108)	0.007 (−0.015 to 0.029)	0.906 (0.114)	0.902 (0.101)	0.005 (−0.027 to 0.037)	0.909 (0.113)	0.902 (0.108)	−0.016 (−0.039 to 0.007)
6 months	0.9 (0.112)	0.922 (0.094)	−0.023 (−0.048 to 0.002)	0.899 (0.115)	0.92 (0.094)	−0.021 (−0.052 to 0.01)	0.905 (0.121)	0.922 (0.103)	−0.016 (−0.016 to 0.029)
16–18 months	0.869 (0.142)	0.877 (0.112)	−0.008 (−0.044 to 0.028)	0.871 (0.141)	0.878 (0.114)	−0.007 (−0.045 to 0.031)	0.875 (0.153)	0.869 (0.166)	0.006 (−0.027 to 0.04)
QALYs									
EQ-5D-3L (base case)									
0–6 months	0.419 (0.065)	0.427 (0.06)	−0.008 (−0.023 to 0.008)	0.42 (0.062)	0.424 (0.058)	−0.004 (−0.022 to 0.014)	0.422 (0.063)	0.426 (0.061)	−0.003 (−0.016 to 0.009)
16–18 months	0.813 (0.143)	0.832 (0.117)	−0.019 (−0.058 to 0.019)	0.813 (0.143)	0.831 (0.116)	−0.017 (−0.056 to 0.021)	0.817 (0.146)	0.83 (0.145)	−0.012 (−0.042 to 0.017)
Total	1.235 (0.197)	1.253 (0.168)	−0.018 (−0.073 to 0.036)	1.235 (0.197)	1.253 (0.168)	−0.018 (−0.073 to 0.036)	1.24 (0.198)	1.256 (0.194)	−0.016 (−0.054 to 0.023)
EQ-5D-5L (scenario)									
0–6 months	0.451 (0.053)	0.456 (0.045)	−0.005 (−0.017 to 0.007)	0.452 (0.051)	0.455 (0.044)	−0.003 (−0.017 to 0.011)	0.454 (0.051)	0.456 (0.045)	−0.002 (−0.012 to 0.007)
16–18 months	0.885 (0.117)	0.899 (0.089)	−0.014 (−0.045 to 0.016)	0.885 (0.117)	0.898 (0.089)	−0.013 (−0.044 to 0.018)	0.89 (0.115)	0.895 (0.114)	−0.005 (−0.028 to 0.018)
Total	1.339 (0.161)	1.352 (0.128)	−0.014 (−0.057 to 0.03)	1.339 (0.161)	1.352 (0.128)	−0.014 (−0.057 to 0.03)	1.344 (0.157)	1.351 (0.148)	−0.007 (−0.038 to 0.023)

TABLE 55 Secondary outcomes by treatment arm and follow-up: available-case analysis

	Baseline			Month 6			Months 16–18		
Available case	SHIFT intervention, mean (SD)	Usual practice, mean (SD)	Differential, mean (95% CI)	SHIFT intervention, mean (SD)	Usual practice, mean (SD)	Differential, mean (95% CI)	SHIFT intervention, mean (SD)	Usual practice, mean (SD)	Differential, mean (95% CI)
Absenteeism									
Number of sick days	3.478 (15.303)	3.825 (12.895)	−0.347 (−3.17 to 2.476)	1.456 (4.639)	3.048 (7.214)	−1.592 (−3.117 to −0.067)	7.076 (21.701)	2.386 (11.269)	4.69 (−0.128 to 9.507)
Productivity									
Employee-assessed job performance[a]	6.022 (0.902)	5.975 (0.859)	0.047 (−0.13 to 0.223)	5.991 (0.955)	5.986 (0.897)	0.005 (−0.221 to 0.231)	6.011 (0.994)	5.96 (0.871)	0.051 (−0.213 to 0.314)
Employee-assessed work ability[b]	8.37 (1.363)	8.275 (1.51)	0.095 (−0.195 to 0.385)	8.377 (1.525)	8.138 (1.517)	0.239 (−0.134 to 0.612)	8.371 (1.562)	8.25 (1.376)	0.121 (−0.303 to 0.544)
Employee work-related well-being									
Presenteeism (days worked while sick)	4.852 (11.99)	3.854 (7.173)	0.997 (−0.968 to 2.962)	7.886 (25.554)	3.34 (5.504)	4.546 (0.253 to 8.838)	4.652 (10.989)	4.273 (16.335)	0.379 (−3.599 to 4.358)
Job satisfaction	4.803 (1.42)	4.995 (1.336)	−0.192 (−0.468 to 0.084)	4.737 (1.476)	4.924 (1.354)	−0.187 (−0.533 to 0.158)	4.846 (1.541)	5.079 (1.339)	−0.233 (−0.641 to 0.174)

a Employee-assessed job performance on a scale from 0 to 7 ['7' at its best (extremely well); '0' at its worst (very poorly)].
b Employee-assessed work ability on a scale from 0 to 10 ('10' at its best; '0' at its worst).

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TABLE 56 Secondary outcomes by treatment arm and follow-up: complete-case analysis

	Baseline			Month 6			Months 16–18		
Complete case	SHIFT intervention, mean (SD)	Usual practice, mean (SD)	Differential, mean (95% CI)	SHIFT intervention, mean (SD)	Usual practice, mean (SD)	Differential, mean (95% CI)	SHIFT intervention, mean (SD)	Usual practice, mean (SD)	Differential, mean (95% CI)
Absenteeism									
Number of sick days	3.059 (16.84)	2.245 (7.261)	0.814 (–2.923 to 4.551)	1.494 (5.068)	2.596 (7.119)	–1.102 (–2.929 to 0.726)	5.541 (18.469)	2.298 (11.474)	3.243 (–1.216 to 7.703)
Productivity									
Employee-assessed job performance[a]	6.048 (0.923)	5.957 (0.793)	0.091 (–0.162 to 0.345)	6 (0.969)	6 (0.842)	0 (–0.266 to 0.266)	6.036 (0.924)	5.957 (0.891)	0.078 (–0.189 to 0.345)
Employee-assessed work ability[b]	8.575 (1.3)	8.539 (1.349)	0.036 (–0.365 to 0.436)	8.463 (1.307)	8.258 (1.45)	0.205 (–0.21 to 0.62)	8.317 (1.578)	8.326 (1.304)	–0.009 (–0.441 to 0.424)
Employee work-related well-being									
Presenteeism	5.298 (14.304)	3.934 (7.254)	1.364 (–1.959 to 4.686)	8.271 (27.89)	3.462 (5.907)	4.809 (–1.056 to 10.674)	4.6 (11.251)	3.923 (15.958)	0.677 (–3.429 to 4.782)
Job satisfaction	4.88 (1.292)	5.183 (1.375)	–0.303 (–0.699 to 0.092)	4.774 (1.434)	5.106 (1.121)	–0.333 (–0.709 to 0.044)	4.857 (1.522)	5.106 (1.372)	–0.249 (–0.674 to 0.176)

a Employee-assessed job performance on a scale from 0 to 7 [‘7’ at its best (extremely well); ‘0’ at its worst (very poorly)].
b Employee-assessed work ability on a scale from 0 to 10 (‘10’ at its best; ‘0’ at its worst).

TABLE 57 Base-case multilevel cost regression: non-intervention total trial costs

Trial cost	Coefficient	SE	*t*-value	*p*-value	95% CI	Significant
Treatment	181.495	348.230	0.520	0.603	−506.132 to 869.121	
Female	250.552	1536.169	0.160	0.871	−2768.186 to 3269.289	
Age: 40–49 years	356.792	472.001	0.760	0.450	−571.187 to 1284.772	
Age: 50–59 years	944.670	533.017	1.770	0.079	−110.112 to 1999.451	*
Age: ≥ 60 years	981.036	864.525	1.130	0.260	−743.358 to 2705.429	
Overweight	−1031.631	624.262	−1.650	0.101	−2268.692 to 205.429	
Obese	−530.971	607.802	−0.870	0.384	−1733.962 to 672.019	
Morbidly obese	−361.152	954.029	−0.380	0.705	−2244.036 to 1521.731	
A Levels	−249.189	524.562	−0.480	0.635	−1280.347 to 781.968	
University graduate	−63.010	674.593	−0.090	0.926	−1385.772 to 1259.753	
Master's degree	−427.618	1233.818	−0.350	0.729	−2845.937 to 1990.702	
Other education	−333.910	509.610	−0.660	0.513	−1336.781 to 668.961	
Non-white	−398.073	711.787	−0.560	0.577	−1804.189 to 1008.043	
Diabetes	−539.520	726.935	−0.740	0.459	−1975.310 to 896.269	
Ex-smoker	114.403	372.197	0.310	0.759	−619.019 to 847.825	
Current smoker	825.426	562.951	1.470	0.147	−296.766 to 1947.617	
Cluster size	6.735	36.909	0.180	0.855	−65.873 to 79.342	
Work years	−30.626	26.244	−1.170	0.245	−82.388 to 21.137	
_cons	802.571	900.506	0.890	0.374	−970.736 to 2575.878	

*$p < 0.1$.
A Level, Advanced Level; SE, standard error.

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TABLE 58 Complete-case regression: non-intervention total trial costs

Trial cost	Coefficient	SE	*t*-value	*p*-value	95% CI	Significant
Treatment	368.025	323.623	1.14	0.255	−266.26 to 1002.31	
Female	839.412	1958.667	0.43	0.668	−2999.51 to 4678.33	
Age: 40–49 years	132.369	461.301	0.29	0.774	−771.76 to 1036.50	
Age: 50–59 years	499.180	465.811	1.07	0.284	−413.79 to 1412.15	
Age: ≥ 60 years	480.275	789.373	0.61	0.543	−1066.87 to 2027.42	
Overweight	−1312.879	503.439	−2.61	0.009	−2299.60 to −326.15	***
Obese	−1182.842	514.908	−2.3	0.022	−2192.05 to −173.64	**
Morbidly obese	−60.663	879.860	−0.07	0.945	−1785.16 to 1663.84	
A Levels	−354.948	498.249	−0.71	0.476	−1331.50 to 621.60	
University graduate	159.329	681.412	0.23	0.815	−1176.21 to 1494.87	
Master's degree	−360.348	999.944	−0.36	0.719	−2320.20 to 1599.51	
Other education	−200.862	482.003	−0.42	0.677	−1145.57 to 743.85	
Non-white	−416.044	728.603	−0.57	0.568	−1844.08 to 1011.99	
Diabetes	−460.849	828.743	−0.56	0.578	−2085.16 to 1163.46	
Ex-smoker	69.339	356.872	0.19	0.846	−630.12 to 768.80	
Current smoker	985.603	464.262	2.12	0.034	75.67 to 1895.54	**
Cluster size	11.619	33.660	0.35	0.73	−54.35 to 77.59	
Work years	−19.340	22.171	−0.87	0.383	−62.79 to 24.11	
_cons	1006.965	838.3473	1.2	0.23	−636.1671 to 2650.098	

***$p < 0.01$, **$p < 0.05$.
A Level, Advanced Level; SE, standard error.

TABLE 59 Exclusion of inpatient-related costs: non-intervention total trial costs

Trial cost	Coefficient	SE	*t*-value	*p*-value	95% CI	Significant
Treatment	14.939	61.372	0.24	0.808	−105.895 to 135.774	
Female	200.851	278.603	0.72	0.471	−346.038 to 747.740	
Age: 40–49 years	16.952	82.734	0.2	0.838	−145.341 to 179.245	
Age: 50–59 years	73.872	85.762	0.86	0.389	−94.544 to 242.289	
Age: ≥ 60 years	133.119	127.140	1.05	0.296	−116.911 to 383.150	
Overweight	−90.753	100.704	−0.9	0.368	−288.705 to 107.200	
Obese	−42.250	98.658	−0.43	0.669	−236.075 to 151.576	
Morbidly obese	203.445	163.397	1.25	0.214	−117.670 to 524.560	
Female	−46.492	91.606	−0.51	0.612	−226.158 to 133.174	
A Levels	50.390	133.168	0.38	0.705	−211.140 to 311.920	
University graduate	−118.803	230.057	−0.52	0.606	−569.717 to 332.112	
Master's degree	−44.462	95.787	−0.46	0.643	−233.023 to 144.100	
Other education	−40.019	122.656	−0.33	0.744	−281.296 to 201.257	
Non-white	26.475	127.226	0.21	0.835	−223.925 to 276.875	
Diabetes	−25.188	72.128	−0.35	0.727	−167.611 to 117.234	
Ex-smoker	41.225	92.479	0.45	0.656	−141.639 to 224.090	
Current smoker	−2.328	6.611	−0.35	0.725	−15.312 to 10.657	
Cluster size	−3.905	4.704	−0.83	0.407	−13.164 to 5.354	
Work years	314.568	153.726	2.05	0.041	12.936 to 616.199	**
_cons	14.939	61.372	0.24	0.808	−105.895 to 135.774	

**$p < 0.05$.
A Level, Advanced Level; SE, standard error.

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TABLE 60 GLM modelling framework (family – gamma; link – log): non-intervention total trial costs

Trial cost	Coefficient	SE	*t*-value	*p*-value	95% CI	Significant
Treatment	0.062	0.383	0.16	0.872	−0.695 to 0.819	
Female	0.604	1.460	0.41	0.679	−2.262 to 3.469	
Age: 40–49 years	0.513	0.624	0.82	0.412	−0.721 to 1.748	
Age: 50–59 years	1.028	0.608	1.69	0.093	−0.176 to 2.233	*
Age: ≥ 60 years	0.788	0.928	0.85	0.399	−1.061 to 2.638	
Overweight	−0.893	0.651	−1.37	0.173	−2.183 to 0.397	
Obese	−0.134	0.555	−0.24	0.809	−1.226 to 0.958	
Morbidly obese	0.366	0.876	0.42	0.677	−1.355 to 2.086	
Female	−0.136	0.646	−0.21	0.833	−1.414 to 1.141	
A Levels	0.451	0.842	0.54	0.593	−1.207 to 2.109	
University graduate	−0.455	1.323	−0.34	0.731	−3.050 to 2.140	
Master's degree	−0.332	0.543	−0.61	0.541	−1.402 to 0.737	
Other education	−0.285	0.889	−0.32	0.75	−2.058 to 1.489	
Non-white	−0.196	0.716	−0.27	0.785	−1.608 to 1.217	
Diabetes	0.184	0.418	0.44	0.661	−0.643 to 1.011	
Ex-smoker	0.625	0.556	1.12	0.263	−0.476 to 1.726	
Current smoker	−0.005	0.040	−0.14	0.892	−0.084 to 0.074	
Cluster size	−0.040	0.030	−1.3	0.194	−0.100 to 0.020	
Work years	6.272	1.056	5.94	0	4.187 to 8.358	***
_cons	0.062	0.383	0.16	0.872	−0.695 to 0.819	

***$p < 0.01$, *$p < 0.1$.
A Level, Advanced Level; SE, standard error.

TABLE 61 Base-case multilevel QALY regression: QALYs measured using crosswalk EQ-5D-3L preference values

Trial QALYs	Coefficient	SE	*t*-value	*p*-value	95% CI	Significant
Baseline EQ-5D-3L cw	0.796	0.056	14.160	0.000	0.685 to 0.907	***
Treatment	−0.028	0.015	−1.820	0.070	−0.059 to 0.002	*
Age: 40–49 years	−0.042	0.020	−2.060	0.040	−0.081 to −0.002	**
Age: 50–59 years	−0.056	0.021	−2.690	0.007	−0.096 to −0.015	***
Age: ≥ 60 years	−0.076	0.032	−2.340	0.021	−0.140 to −0.012	**
Overweight	0.002	0.023	0.090	0.926	−0.043 to 0.047	
Obese	−0.024	0.025	−0.940	0.347	−0.074 to 0.026	
Morbidly obese	−0.030	0.041	−0.740	0.459	−0.110 to 0.050	
Female	−0.043	0.078	−0.560	0.577	−0.197 to 0.110	
A Levels	0.003	0.022	0.130	0.899	−0.041 to 0.047	
University graduate	0.032	0.033	0.990	0.325	−0.032 to 0.096	
Master's degree	−0.023	0.055	−0.420	0.675	−0.131 to 0.085	
Other education	0.000	0.025	−0.020	0.987	−0.050 to 0.049	
Non-white	0.028	0.029	0.960	0.338	−0.029 to 0.085	
Diabetes	−0.029	0.034	−0.850	0.395	−0.097 to 0.039	
Ex-smoker	−0.003	0.016	−0.170	0.868	−0.035 to 0.030	
Current smoker	−0.028	0.019	−1.450	0.147	−0.067 to 0.010	
Cluster size	0.001	0.002	0.680	0.495	−0.002 to 0.004	
Work years	0.001	0.001	0.620	0.533	−0.001 to 0.003	
_cons	0.608	0.062	9.880	0.000	0.487 to 0.730	***

***$p < 0.01$, **$p < 0.05$, *$p < 0.1$.
A Level, Advanced Level; cw, crosswalk; SE, standard error.

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TABLE 62 Multilevel QALY regression using EQ-5D-5L preference weights

Trial QALYs	Coefficient	SE	*t*-value	*p*-value	95% CI	Significant
Baseline EQ-5D-5L cw	0.839	0.059	14.210	0.000	0.721 to 0.956	***
Treatment	−0.015	0.012	−1.270	0.207	−0.038 to 0.008	
Age: 40–49 years	−0.034	0.016	−2.170	0.030	−0.065 to −0.003	**
Age: 50–59 years	−0.040	0.016	−2.520	0.012	−0.072 to −0.009	**
Age: ≥ 60 years	−0.065	0.026	−2.540	0.012	−0.116 to −0.014	**
Overweight	0.002	0.018	0.120	0.906	−0.034 to 0.038	
Obese	−0.019	0.020	−0.940	0.349	−0.059 to 0.021	
Morbidly obese	−0.034	0.032	−1.050	0.294	−0.098 to 0.030	
Female	−0.058	0.065	−0.890	0.375	−0.186 to 0.071	
A Levels	−0.005	0.017	−0.310	0.755	−0.039 to 0.028	
University graduate	0.018	0.025	0.750	0.455	−0.030 to 0.067	
Master's degree	−0.017	0.042	−0.410	0.680	−0.100 to 0.065	
Other education	−0.010	0.019	−0.510	0.613	−0.048 to 0.028	
Non-white	0.028	0.021	1.300	0.195	−0.014 to 0.070	
Diabetes	−0.029	0.027	−1.050	0.298	−0.083 to 0.026	
Ex-smoker	0.006	0.013	0.490	0.622	−0.018 to 0.031	
Current smoker	−0.011	0.016	−0.680	0.499	−0.043 to 0.021	
Cluster size	0.001	0.001	0.620	0.539	−0.002 to 0.003	
Work years	0.001	0.001	0.740	0.462	−0.001 to 0.002	
_cons	0.605	0.058	10.390	0.000	0.490 to 0.720	***

***$p < 0.01$, **$p < 0.05$.
A Level, Advanced Level; cw, crosswalk; SE, standard error.

TABLE 63 Complete-case QALY regression using EQ-5D-3L cross-walk preference weights

Trial QALYs	Coefficient	SE	*t*-value	*p*-value	95% CI	Significant
Baseline EQ-5D-3L cw	0.863	0.067	12.96	0	0.732 to 0.993	***
Treatment	−0.027	0.019	−1.44	0.149	−0.063 to 0.010	
Age: 40–49 years	−0.036	0.027	−1.34	0.182	−0.089 to 0.017	
Age: 50–59 years	−0.069	0.027	−2.62	0.009	−0.121 to −0.017	***
Age: ≥ 60 years	−0.097	0.045	−2.16	0.031	−0.185 to −0.009	**
Overweight	−0.009	0.031	−0.29	0.769	−0.070 to 0.052	
Obese	−0.056	0.032	−1.72	0.085	−0.120 to 0.008	*
Morbidly obese	0.000	0.054	0	0.998	−0.105 to 0.105	
Female	0.016	0.085	0.19	0.849	−0.150 to 0.183	
A Levels	0.023	0.029	0.79	0.429	−0.034 to 0.079	
University graduate	0.050	0.040	1.24	0.215	−0.029 to 0.129	
Master's degree	−0.006	0.061	−0.09	0.927	−0.125 to 0.114	
Other education	−0.021	0.029	−0.71	0.477	−0.078 to 0.036	
Non-white	0.007	0.043	0.16	0.876	−0.077 to 0.090	
Diabetes	−0.053	0.045	−1.19	0.236	−0.141 to 0.035	
Ex-smoker	0.010	0.021	0.45	0.65	−0.032 to 0.051	
Current smoker	−0.023	0.026	−0.88	0.379	−0.074 to 0.028	
Cluster size	0.003	0.002	1.64	0.1	−0.001 to 0.007	
Work years	0.000	0.001	0.05	0.957	−0.002 to 0.003	
_cons	0.532	0.076	6.97	0	0.383 to 0.682	***

***$p < 0.01$, **$p < 0.05$, *$p < 0.1$.
A Level, Advanced Level; cw, crosswalk; SE, standard error.

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TABLE 64 Scenario 1: no within-trial differences in costs (non-intervention costs) and outcomes (QALYs)

Analysis	Cost (£) (95% CI) [*p* (most costly)]	QALYs (95% CI) [*p* (most effective)]	ΔCost (95% CI)	ΔQALYs (95% CI)	ICER (£)	INHB (95% CI) [probability of being cost-effective]		
						£15,000	£20,000	£30,000
Cost-effectiveness analysis: Ekelund *et al.*[120] MVPA minutes/day (1)								
Usual practice	419.18 (−243.05 to 1073.04) [0.151]	16.15429 (16.15429 to 16.15429) [0.007]				[0.784]	[0.752]	[0.704]
SHIFT intervention	783.15 (139.94 to 1480.03) [0.849]	16.15989 (16.1552 to 16.16918) [0.993]	363.97 (−352.74 to 1067.48)	0.00559 (0.001 to 0.015)	65,071.33	−0.019 (−0.068 to 0.03) [0.216]	−0.013 (−0.05 to 0.025) [0.248]	−0.007 (−0.031 to 0.019) [0.296]
Cost-effectiveness analysis: Ekelund *et al.*[120] sedentary minutes/day (2)								
Usual practice	419.18 (−243.05 to 1073.04) [0.151]	16.15429 (16.15429 to 16.15429) [0.002]				[0.774]	[0.736]	[0.664]
SHIFT intervention	783.15 (139.94 to 1480.03) [0.849]	16.16141 (16.1562 to 16.16798) [0.998]	363.97 (−352.74 to 1067.48)	0.00711 (0.002 to 0.014)	51,173.91	−0.017 (−0.065 to 0.032) [0.226]	−0.011 (−0.048 to 0.026) [0.264]	−0.005 (−0.03 to 0.02) [0.336]
Cost-effectiveness analysis: MOVES MVPA minutes translated into metabolic equivalents (3)								
Usual practice	13,336.41 (7657.31 to 19927.97) [0]	14.16817 (13.78574 to 14.56869) [0.003]				[0.876]	[0.739]	[0.534]
SHIFT intervention	13,676.33 (8011.48 to 20230.24) [1]	14.17978 (13.8056 to 14.57744) [1]	339.92 (286.86 to 369.46)	0.01161 (0 to 0.029)	29,286.70	−0.011 (−0.024 to 0.009) [0.124]	−0.005 (−0.018 to 0.014) [0.261]	0.000 (−0.012 to 0.019) [0.466]

TABLE 65 Scenario 2: EQ-5D-5L preference values

Analysis	Cost (£) (95% CI) [*p* (most costly)]	QALYs (95% CI) [*p* (most effective)]	ΔCost (95% CI)	ΔQALYs (95% CI)	ICER (£)	INHB (95% CI) [probability of being cost-effective]		
						£15,000	£20,000	£30,000
Cost-effectiveness analysis: Ekelund *et al.*[120] MVPA minutes/day (1)								
Usual practice	403.76 (−215.63 to 1045.02) [0.049]	17.79441 (17.79441 to 17.79441) [0.777]				[0.967]	[0.968]	[0.958]
SHIFT intervention	958.51 (299.02 to 1639.83) [0.951]	17.78524 (17.76123 to 17.8101) [0.223]	554.75 (−119.64 to 1228.65)	−0.00918 (−0.033 to 0.016)	Dominated	−0.046 (−0.098 to 0.002) [0.033]	−0.037 (−0.079 to 0.003) [0.032]	−0.028 (−0.061 to 0.006) [0.042]
Cost-effectiveness analysis: Ekelund *et al.*[120] sedentary minutes/day (2)								
Usual practice	403.76 (−215.63 to 1045.02) [0.049]	17.79441 (17.79441 to 17.79441) [0.732]				[0.96]	[0.957]	[0.942]
SHIFT intervention	958.51 (299.02 to 1639.83) [0.951]	17.78705 (17.76319 to 17.81083) [0.268]	554.75 (−119.64 to 1228.65)	−0.00737 (−0.031 to 0.016)	Dominated	−0.044 (−0.094 to 0.005) [0.04]	−0.035 (−0.074 to 0.005) [0.043]	−0.026 (−0.056 to 0.006) [0.058]
Cost-effectiveness analysis: MOVES MVPA minutes translated into metabolic equivalents (3)								
Usual practice	13,336.41 (7657.31 to 19927.97) [0.066]	13.96258 (13.5914 to 14.34303) [0.568]				[0.894]	[0.883]	[0.85]
SHIFT intervention	13,843.20 (8049.98 to 20393.84) [0.934]	13.96043 (13.58123 to 14.34193) [0.432]	506.79 (−145.31 to 1180.41)	−0.00215 (−0.03 to 0.026)	Dominated	−0.036 (−0.089 to 0.019) [0.106]	−0.027 (−0.071 to 0.017) [0.117]	−0.019 (−0.056 to 0.018) [0.15]

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TABLE 66 Scenario 3: costs and outcomes (QALYs) discounted at 1.5%

Analysis	Cost (£) (95% CI) [*p* (most costly)]	QALYs (95% CI) [*p* (most effective)]	ΔCost (95% CI)	ΔQALYs (95% CI)	ICER (£)	INHB (95% CI) [probability of being cost-effective]		
						£15,000	£20,000	£30,000
Cost-effectiveness analysis: Ekelund *et al.*[120] MVPA minutes/day (1)								
Usual practice	430.66 (−249.8 to 1063.12) [0.063]	21.81795 (21.81795 to 21.81795) [0.902]				[0.978]	[0.975]	[0.97]
SHIFT intervention	984.76 (298 to 1692.76) [0.937]	21.79758 (21.76676 to 21.82906) [0.098]	554.1 (−143.82 to 1219.61)	−0.02037 (−0.051 to 0.011)	Dominated	−0.057 (−0.115 to −0.001) [0.022]	−0.048 (−0.097 to 0) [0.025]	−0.039 (−0.08 to 0.001) [0.03]
Cost-effectiveness analysis: Ekelund *et al.*[120] sedentary minutes/day (2)								
Usual practice	430.66 (−249.8 to 1063.12) [0.063]	21.81795 (21.81795 to 21.81795) [0.874]				[0.975]	[0.975]	[0.967]
SHIFT intervention	984.76 (298 to 1692.76) [0.937]	21.79968 (21.7684 to 21.83111) [0.126]	554.1 (−143.82 to 1219.61)	−0.01827 (−0.05 to 0.013)	Dominated	−0.055 (−0.112 to 0.001) [0.025]	−0.046 (−0.093 to 0) [0.025]	−0.037 (−0.077 to 0.003) [0.033]
Cost-effectiveness analysis: MOVES MVPA minutes translated into metabolic equivalents (3)								
Usual practice	18,504.27 (11013.09 to 28649.04) [0.071]	17.00305 (16.47525 to 17.53415) [0.777]				[0.941]	[0.929]	[0.914]
SHIFT intervention	19,030.49 (11421.75 to 29261.56) [0.929]	16.98962 (16.4497 to 17.51692) [0.223]	526.22 (−160.34 to 1184.87)	−0.01343 (−0.048 to 0.027)	Dominated	−0.049 (−0.105 to 0.013) [0.059]	−0.040 (−0.088 to 0.013) [0.071]	−0.031 (−0.071 to 0.014) [0.086]

TABLE 67 Scenario 4: costs estimated using a generalised linear model

Analysis	Cost (£) (95% CI) [*p* (most costly)]	QALYs (95% CI) [*p* (most effective)]	ΔCost (95% CI)	ΔQALYs (95% CI)	ICER (£)	INHB (95% CI) [probability of being cost-effective]		
						£15,000	£20,000	£30,000
Cost-effectiveness analysis: Ekelund *et al.*[120] MVPA minutes/day (1)								
Usual practice	433.24 (−232.16 to 1126.61) [0.056]	16.15429 (16.15429 to 16.15429) [0.931]				[0.987]	[0.987]	[0.983]
SHIFT intervention	980.85 (302.95 to 1659.46) [0.944]	16.13240 (16.10182 to 16.16267) [0.069]	547.61 (−153.37 to 1251.63)	−0.0219 (−0.052 to 0.008)	Dominated	−0.058 (−0.115 to −0.006) [0.013]	−0.049 (−0.096 to −0.005) [0.013]	−0.040 (−0.078 to −0.002) [0.017]
Cost-effectiveness analysis: Ekelund *et al.*[120] sedentary minutes/day (2)								
Usual practice	433.24 (−232.16 to 1126.61) [0.056]	16.15429 (16.15429 to 16.15429) [0.931]				[0.987]	[0.987]	[0.983]
SHIFT intervention	980.85 (302.95 to 1659.46) [0.944]	16.13240 (16.10182 to 16.16267) [0.069]	547.61 (−153.37 to 1251.63)	−0.0219 (−0.052 to 0.008)	Dominated	−0.058 (−0.115 to -0.006) [0.013]	−0.049 (−0.096 to −0.005) [0.013]	−0.040 (−0.078 to −0.002) [0.017]
Cost-effectiveness analysis: MOVES MVPA minutes translated into metabolic equivalents (3)								
Usual practice	13,336.41 (7657.31 to 19,927.97) [0.063]	14.16817 (13.78574 to 14.56869) [0.833]				[0.963]	[0.955]	[0.947]
SHIFT intervention	13,854.37 (8093.36 to 20,362.03) [0.937]	14.15197 (13.7727 to 14.54723) [0.167]	517.96 (−176.82 to 1230.79)	−0.0162 (−0.049 to 0.019)	Dominated	−0.051 (−0.108 to 0.004) [0.037]	−0.042 (−0.091 to 0.004) [0.045]	−0.033 (−0.074 to 0.009) [0.053]

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TABLE 68 Scenario 5: costs exempt from inpatient-related resource usage

Analysis	Cost (£) (95% CI) [*p* (most costly)]	QALYs (95% CI) [*p* (most effective)]	ΔCost (95% CI)	ΔQALYs (95% CI)	ICER (£)	INHB (95% CI) [probability of being cost-effective] £15,000	£20,000	£30,000
Cost-effectiveness analysis: Ekelund *et al.*[120] MVPA minutes/day (1)								
Usual practice	203.21 (94.95 to 321.97) [0]	16.15429 (16.15429 to 16.15429) [0.931]				[0.999]	[0.995]	[0.988]
SHIFT intervention	585.47 (472.91 to 700.95) [1]	16.13240 (16.10182 to 16.16267) [0.069]	382.26 (260.23 to 504.72)	−0.0219 (−0.052 to 0.008)	Dominated	−0.047 (−0.079 to −0.016) [0.001]	−0.041 (−0.073 to −0.01) [0.005]	−0.035 (−0.066 to −0.004) [0.012]
Cost-effectiveness analysis: Ekelund *et al.*[120] sedentary minutes/day (2)								
Usual practice	203.21 (94.95 to 321.97) [0]	16.15429 (16.15429 to 16.15429) [0.908]				[0.998]	[0.992]	[0.984]
SHIFT intervention	585.47 (472.91 to 700.95) [1]	16.13350 (16.10327 to 16.16419) [0.092]	382.26 (260.23 to 504.72)	−0.02079 (−0.051 to 0.01)	Dominated	−0.046 (−0.077 to −0.014) [0.002]	−0.040 (−0.07 to −0.008) [0.008]	−0.034 (−0.064 to −0.002) [0.016]
Cost-effectiveness analysis: MOVES MVPA minutes translated into metabolic equivalents (3)								
Usual practice	13,336.41 (7657.31 to 19,927.97) [0]	14.16817 (13.78574 to 14.56869) [0.833]				[0.982]	[0.965]	[0.937]
SHIFT intervention	13,689.02 (8025.72 to 20,233.77) [1]	14.15197 (13.7727 to 14.54723) [0.167]	352.61 (220.95 to 479.72)	−0.0162 (−0.049 to 0.019)	Dominated	−0.040 (−0.075 to −0.003) [0.018]	−0.034 (−0.068 to 0.003) [0.035]	−0.028 (−0.062 to 0.009) [0.063]

TABLE 69 Scenario 6: complete-case analysis

Analysis	Cost (£) (95% CI) [*p* (most costly)]	QALYs (95% CI) [*p* (most effective)]	ΔCost (95% CI)	ΔQALYs (95% CI)	ICER (£)	INHB (95% CI) [probability of being cost-effective]		
						£15,000	£20,000	£30,000
Cost-effectiveness analysis: Ekelund *et al.*[120] MVPA minutes/day (1)								
Usual practice	240.34 (−374.56 to 846.11) [0.009]	16.15429 (16.15429 to 16.15429) [0.848]				[0.996]	[0.995]	[0.983]
SHIFT intervention	990.74 (290.55 to 1695.8) [0.991]	16.13454 (16.09685 to 16.17373) [0.152]	750.39 (154.47 to 1338.79)	−0.01975 (−0.057 to 0.019)	Dominated	−0.070 (−0.123 to −0.016) [0.004]	−0.057 (−0.104 to −0.011) [0.005]	−0.045 (−0.088 to −0.003) [0.017]
Cost-effectiveness analysis: Ekelund *et al.*[120] sedentary minutes/day (2)								
Usual practice	240.34 (−374.56 to 846.11) [0.009]	16.15429 (16.15429 to 16.15429) [0.866]				[0.995]	[0.992]	[0.987]
SHIFT intervention	990.74 (290.55 to 1695.8) [0.991]	16.13411 (16.09789 to 16.16793) [0.134]	750.39 (154.47 to 1338.79)	−0.02018 (−0.056 to 0.014)	Dominated	−0.070 (−0.123 to −0.018) [0.005]	−0.058 (−0.104 to −0.012) [0.008]	−0.045 (−0.085 to −0.005) [0.013]
Cost-effectiveness analysis: MOVES MVPA minutes translated into metabolic equivalents (3)								
Usual practice	13,336.41 (7657.31 to 19,927.97) [0.01]	14.16817 (13.78574 to 14.56869) [0.781]				[0.989]	[0.98]	[0.961]
SHIFT intervention	14,057.15 (8253.15 to 20,585) [0.99]	14.15236 (13.76664 to 14.55025) [0.219]	720.74 (125.86 to 1303.86)	−0.01581 (−0.056 to 0.026)	Dominated	−0.064 (−0.119 to −0.006) [0.011]	−0.052 (−0.101 to −0.002) [0.02]	−0.040 (−0.085 to 0.005) [0.039]

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TABLE 70 Sensitivity analysis: continuation of SHIFT treatment benefit – no within-trial differences in costs and QALYs

Time period	Ekelund *et al.*:[120] MVPA			Ekelund *et al.*:[120] sedentary			MOVES model		
	Incremental cost (£)	Incremental QALY	ICER (£)	Incremental cost (£)	Incremental QALY	ICER (£)	Incremental cost (£)	Incremental QALY	ICER (£)
Base case	364	0.00559	65,071	364	0.00711	51,174	340	0.01161	29,287
1 year	364	0.00844	43,130	364	0.01072	33,938	320	0.01882	17,024
2 years	364	0.01111	32,751	364	0.01429	25,464	302	0.02522	11,988
3 years	364	0.01419	25,644	364	0.01842	19,763	288	0.03080	9354
4 years	364	0.01676	21,714	364	0.02201	16,538	273	0.03602	7572
5 years	364	0.02035	17,884	364	0.02558	14,227	260	0.03971	6536
6 years	364	0.02243	16,228	364	0.03000	12,131	242	0.04482	5408
7 years	364	0.02641	13,780	364	0.03399	10,708	229	0.04947	4633
8 years	364	0.02920	12,464	364	0.03786	9613	214	0.05299	4043
9 years	364	0.03190	11,410	364	0.04279	8506	204	0.05615	3637
10 years	364	0.03545	10,267	364	0.04677	7782	178	0.06171	2884

TABLE 71 Sensitivity analysis: ICER matrix at alternative additional cost and continuation of treatment benefit combinations – no within-trial differences in costs and QALYs

ΔCost (£)	Continuation of SHIFT treatment benefit and additional cost profiles: ICER (£)																	
	Ekelund *et al.*:[120] MVPA						Ekelund *et al.*:[120] sedentary						MOVES model					
	1 years	2 years	3 years	4 years	5 years	6 years	1 years	2 years	3 years	4 years	5 years	6 years	1 years	2 years	3 years	4 years	5 years	6 years
−370	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant
−200	19,430	14,754	11,553	9782	8057	7311	15,289	11,471	8903	7450	6409	5465	6397	4058	2861	2020	1500	946
−100	31,280	23,753	18,599	15,748	12,970	11,770	24,613	18,468	14,333	11,994	10,318	8798	11,710	8023	6108	4796	4018	3177
Base case	43,130	32,751	25,644	21,714	17,884	16,228	33,938	25,464	19,763	16,538	14,227	12,131	17,024	11,988	9354	7572	6536	5408
100	54,980	41,750	32,690	27,680	22,798	20,687	43,262	32,460	25,193	21,081	18,135	15,464	22,337	15,953	12,601	10,348	9054	7639
200	66,830	50,748	39,736	33,646	27,711	25,146	52,587	39,456	30,622	25,625	22,044	18,797	27,651	19,918	15,848	13,125	11,573	9871
370	86,924	66,007	51,684	43,763	36,043	32,706	68,398	51,320	39,830	33,330	28,672	24,448	36,661	26,642	21,353	17,832	15,843	13,654
500	102,380	77,743	60,874	51,544	42,452	38,522	80,560	60,445	46,912	39,257	33,771	28,796	43,592	31,814	25,588	21,453	19,127	16,564
1,000	161,630	122,736	96,103	81,374	67,021	60,816	127,182	95,426	74,061	61,975	53,315	45,460	70,160	51,639	41,821	35,335	31,718	27,719

Notes
Light purple shading indicates that the ICER is < £15,000 per QALY.
Dark purple shading indicates that the ICER is between £15,000 and £20,000 per QALY.
Blue shading indicates that the ICER is between £20,000 and £30,000 per QALY.

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TABLE 72 Secondary cost-effectiveness analysis from a private perspective

		Month 6			Months 16–18			Average total trial results		
Secondary cost-effectiveness analysis	Baseline, mean differential	Mean differential	Difference in difference[a]	ICER (£)	Mean differential	Difference in difference[a]	ICER (£)	Mean differential	Difference in difference[a]	ICER (£)
Costs (£)										
Intervention	0	369.59	369.59		0	0		369.59	369.59	
Absenteeism	−57.98	−227.41	−169.43		494.07	552.05		266.66	324.64	
Total	−57.98	142.18	200.16		494.07	552.05		636.25	694.23	
Outcomes and cost-effectiveness										
Employee-assessed job performance[a]	0.045	0.045	0.000	Dominated	0.126	0.081	6816	0.086	0.041	17,142
Employee-assessed work ability[a]	0.074	0.222	0.148	1353	0.228	0.154	3585	0.225	0.151	4598
Presenteeism (days worked while sick)	0.902	3.259	2.357	Dominated	−0.287	−1.189	465	1.486	0.584	Dominated
Job satisfaction	−0.199	−0.163	0.036	5560	−0.048	0.151	3656	−0.101	0.094	7425

a Difference from baseline values.

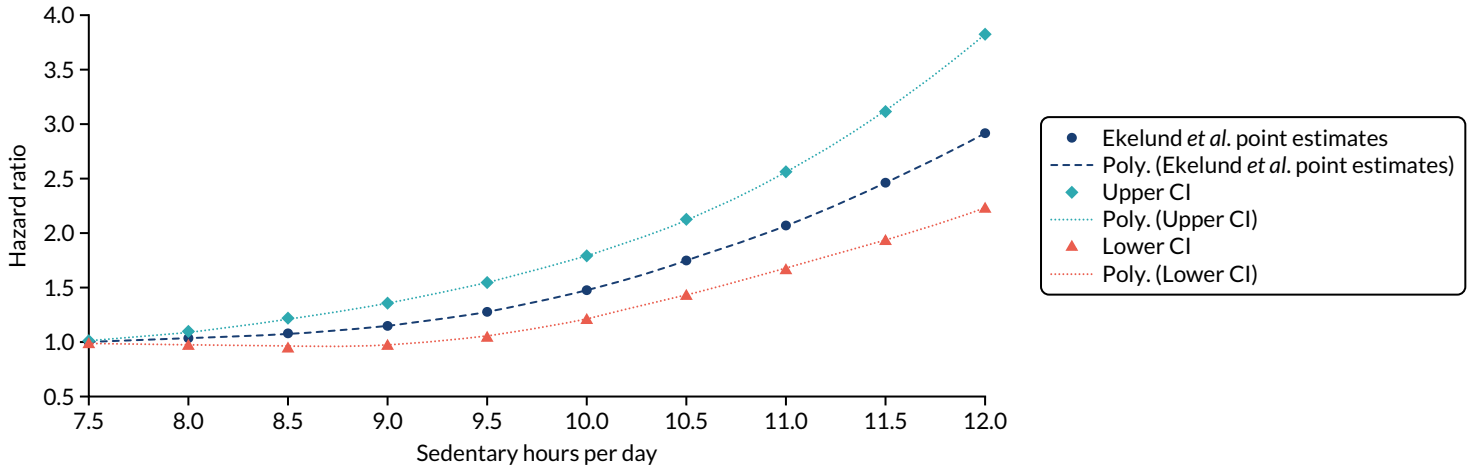

FIGURE 4 Interpolated dose–response relationship between all-cause mortality hazard ratios and sedentary behaviour: Ekelund *et al.*[120] Poly., interpolated dose–response relationship.

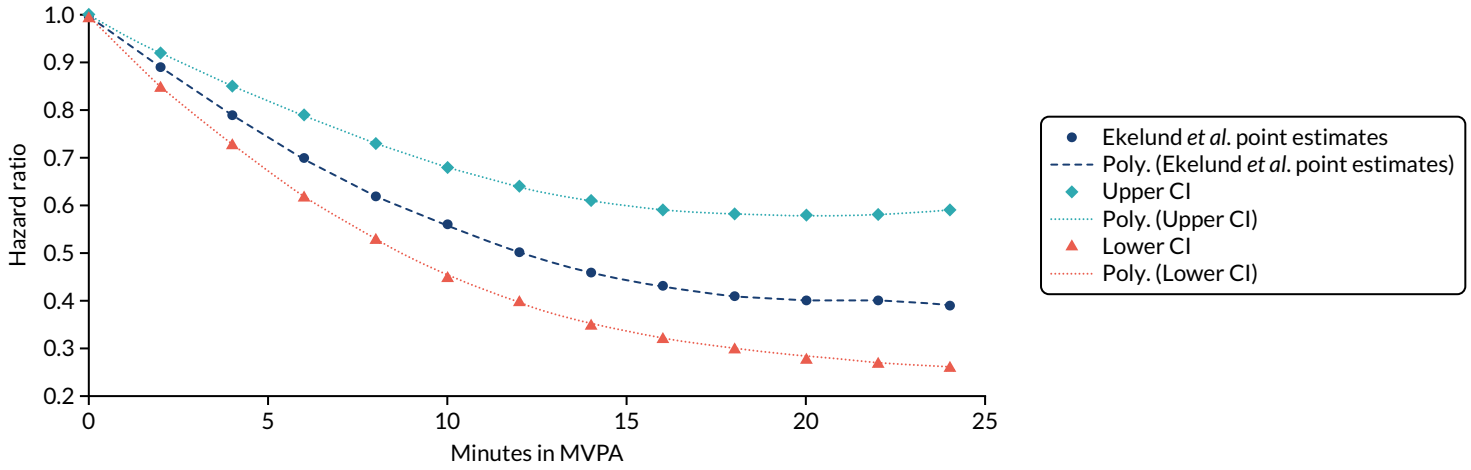

FIGURE 5 Interpolated dose–response relationship between all-cause mortality hazard ratios and time spent in MVPA: Ekelund *et al.*[120] Poly., interpolated dose–response relationship.

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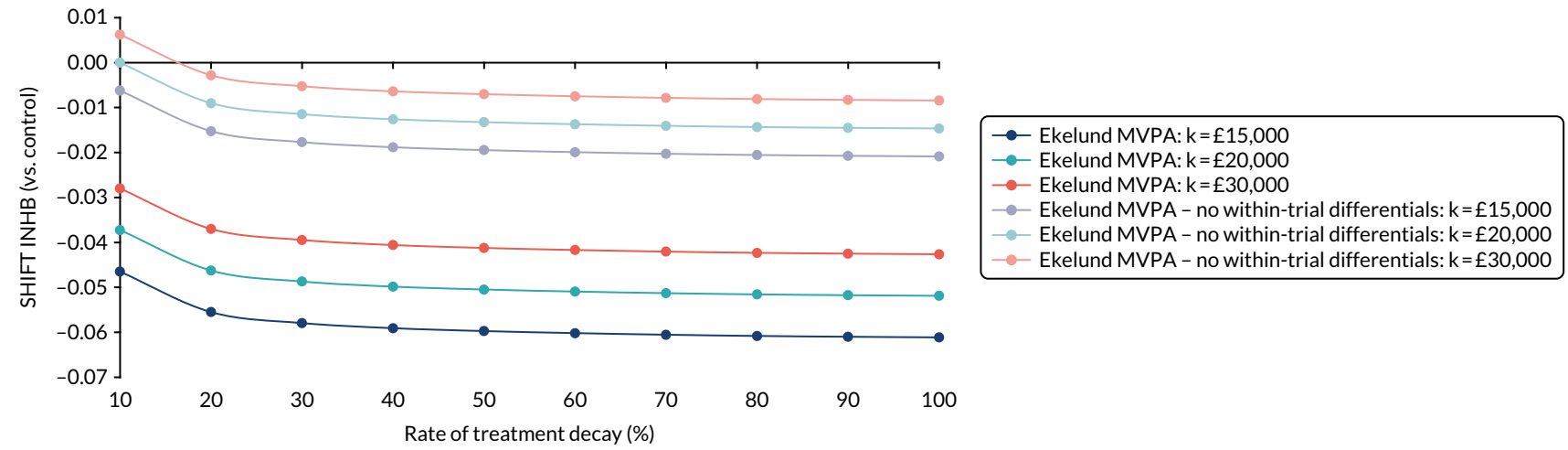

FIGURE 6 Incremental net health benefit of the SHIFT trial relative to usual practice for alternative rates of treatment decay using Ekelund *et al.*[120] all-cause mortality estimates with changes to MVPA minutes/day.

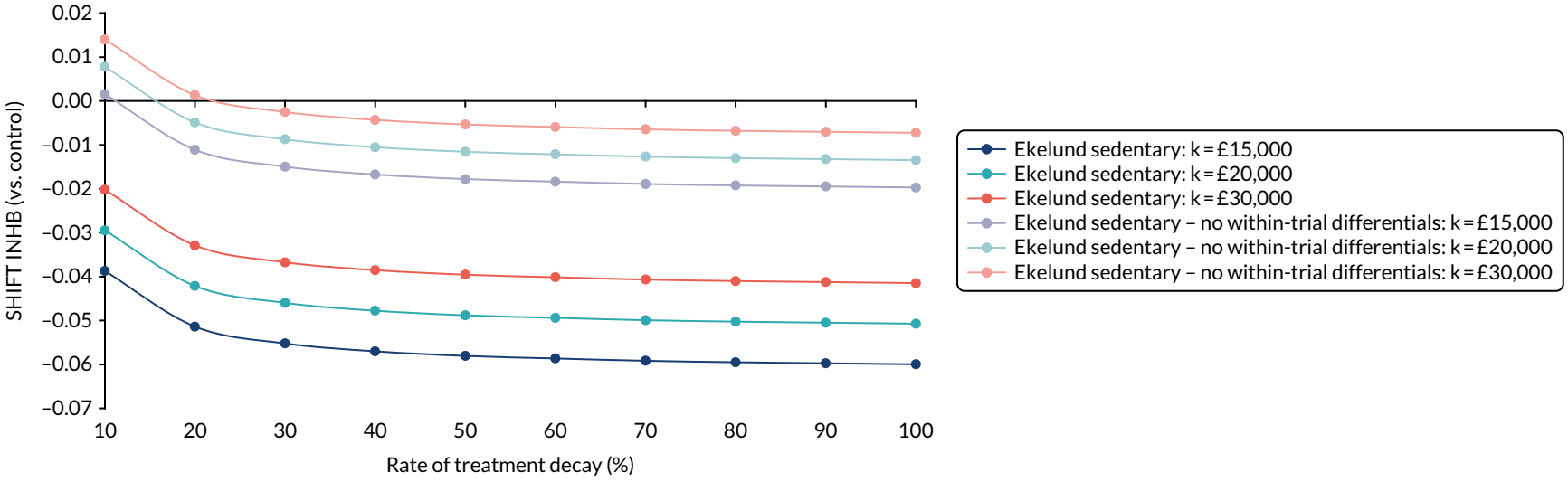

FIGURE 7 Incremental net health benefit of the SHIFT trial relative to usual practice for alternative rates of treatment decay using Ekelund *et al.*[120] all-cause mortality estimates with changes to sedentary minutes/day.

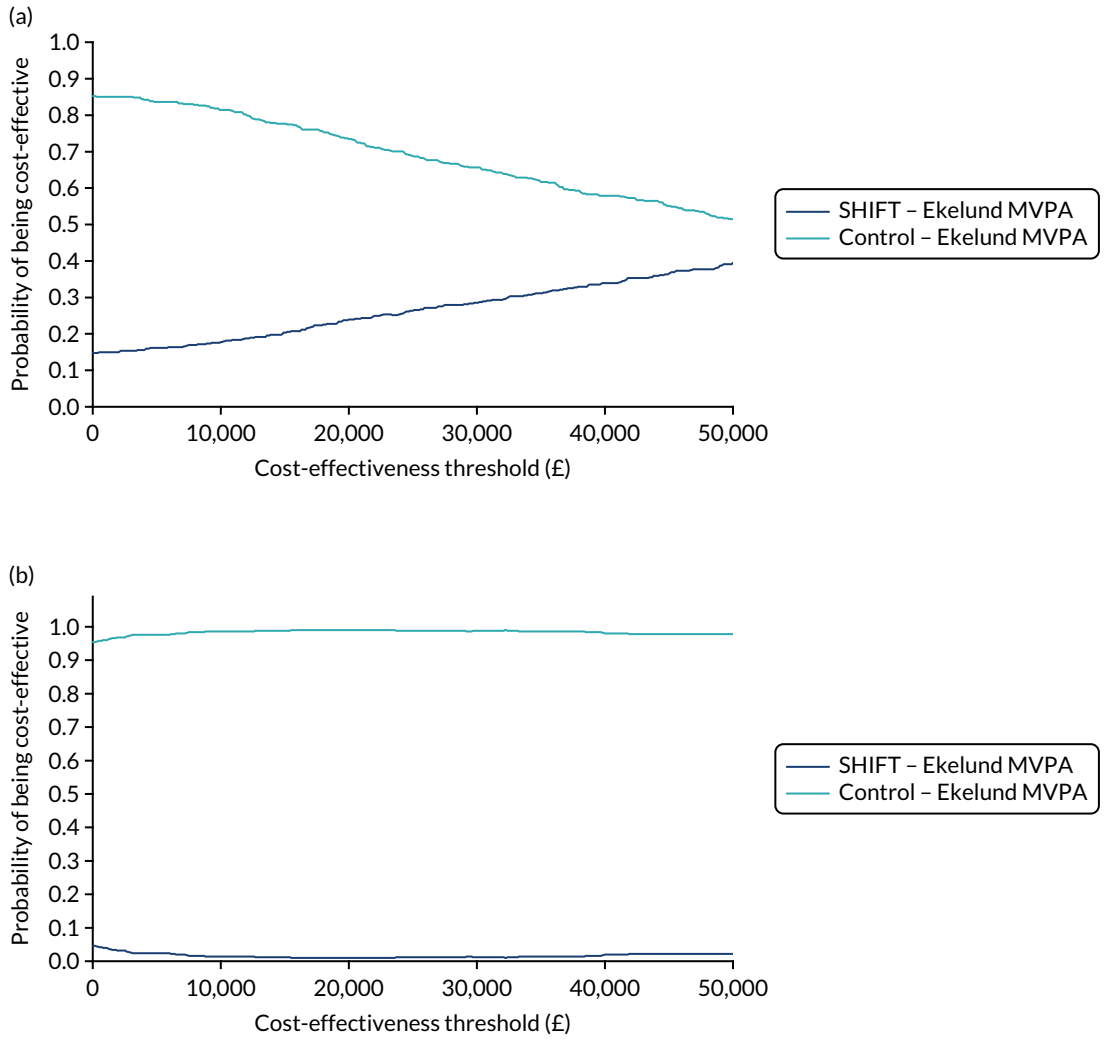

FIGURE 8 Cost-effectiveness acceptability curves using Ekelund *et al.*[120] all-cause mortality estimates with changes to MVPA minutes/day, including and excluding within-trial differentials. (a) No within-trial differences; and (b) within-trial differences.

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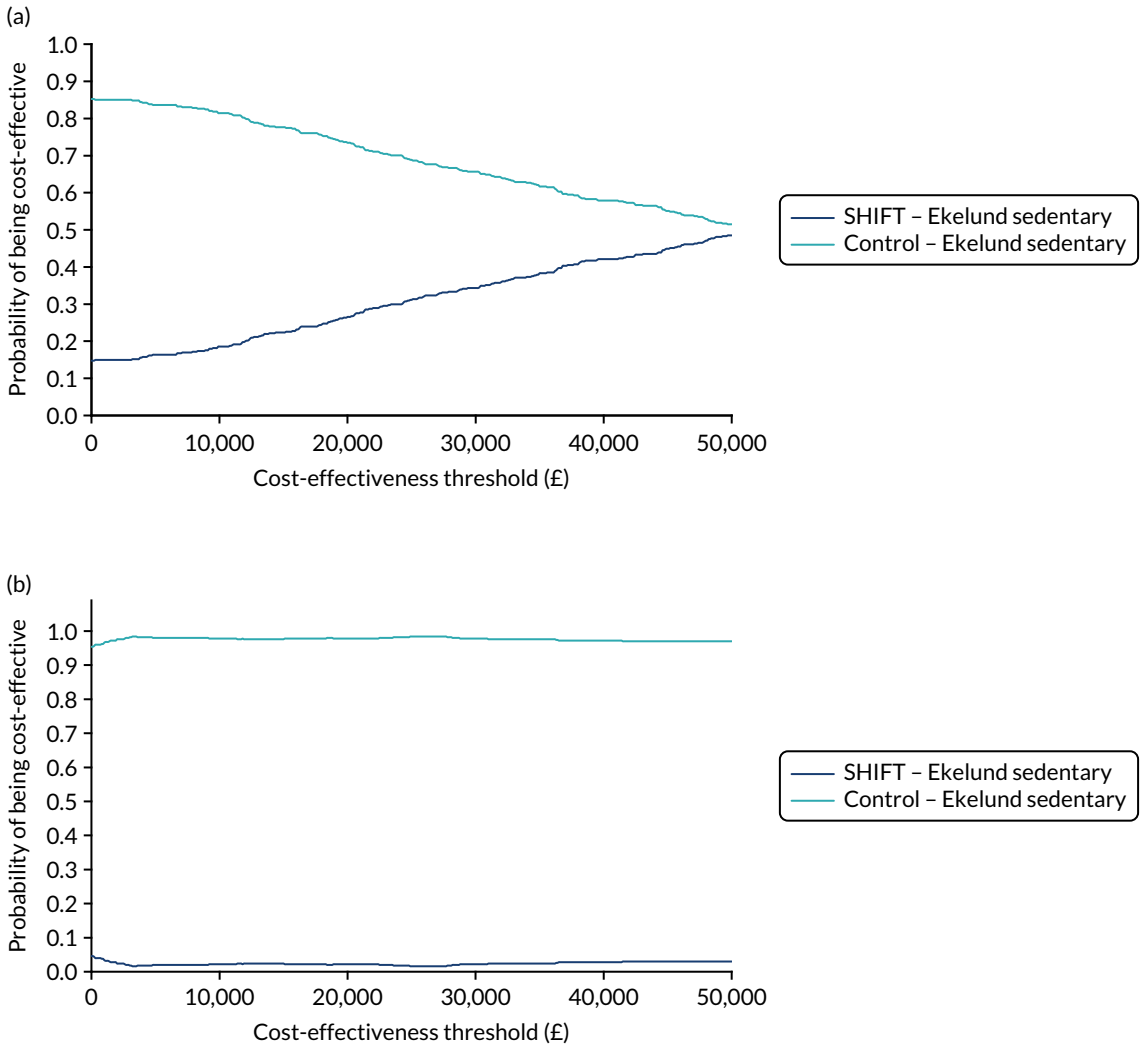

FIGURE 9 Cost-effectiveness acceptability curves using Ekelund *et al.*[120] all-cause mortality estimates with changes to sedentary minutes/day, including and excluding within-trial differentials. (a) No within-trial differences; and (b) within-trial differences.

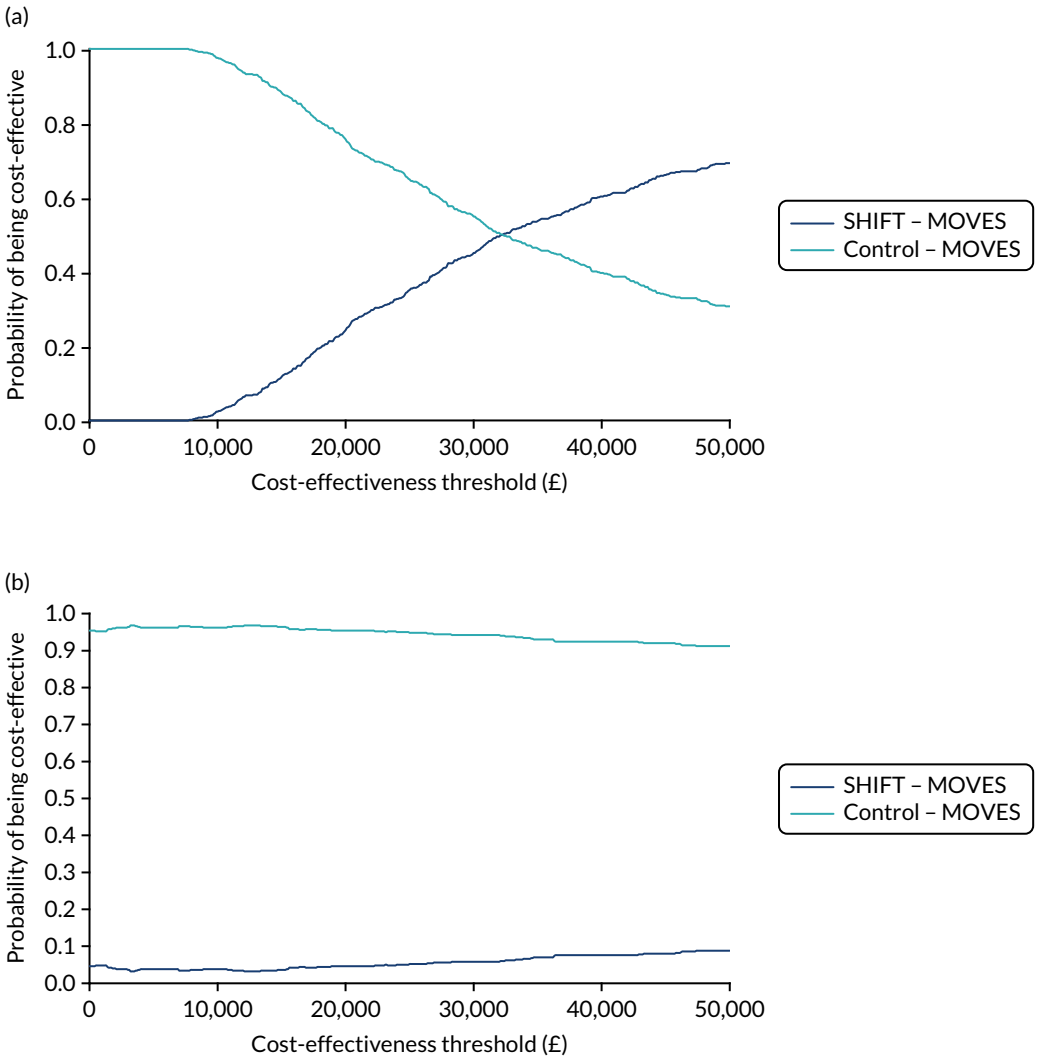

FIGURE 10 Cost-effectiveness acceptability curves using MOVES model with changes to sedentary minutes/day, including and excluding within-trial differentials. (a) No within-trial differences; and (b) within-trial differences.

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