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The effectiveness and cost-effectiveness of a structured health intervention for truckers (The SHIFT Study)

Submission date
17/02/2017

Recruitment status
No longer recruiting

Registration date
01/03/2017

Overall study status
Completed

Last Edited
02/08/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English Summary

Background and study aims
Long distance lorry drivers are more likely to be overweight or obese than those working in other occupations. This increases their risk of diseases such as heart disease, diabetes, and sleep disturbances. Due to the nature of their jobs, lorry drivers are faced with many barriers when it comes to leading a healthy lifestyle. They spend long periods of time sitting, their opportunities to be physically active while at work are limited, the food available at rest stops tends to be unhealthy, and working shifts means they get less sleep. As a consequence of these working conditions and unhealthy lifestyle choices, lorry drivers have a lower life expectancy than the average working person. They are currently an 'at-risk' and underserved group in terms of health promotion efforts. Given the well-being of lorry drivers can directly affect the safety of other road users, strategies are needed to improve the health of this group. In partnership with lorry drivers and Health and Safety personnel from a UK transport company, the SHIFT programme was created in order to increase physical activity, improve diet and reduce sitting (during breaks and non-work time) in long distance lorry drivers. This programme involves a six hour interactive education session, provides drivers with a step counter to set goals to increase steps, provides equipment for drivers to do stretching exercises whilst in the lorry, sets individual and group based step count competitions, and gives access to free fruit. In a previous study, this programme was found to be effective in encouraging drivers to become more active and it is hoped that the same will be found in a larger group of lorry drivers. The aim of this study therefore is to see if the SHIFT programme leads to increases in physical activity, reductions in sitting time, and improvements in diet and markers of health (such as blood pressure and body weight) in a group of long distance lorry drivers, in comparison to a group continuing with their normal daily routine.

Who can participate?
Long distance lorry drivers between the ages of 18 to 65 years old.

What does the study involve?
After undergoing a health check and taking body measurements, all participants are given a small device to wear that records their daily step counts, time spent sitting, time spent standing

and time being active. This is worn on the thigh for seven days. Participants are then randomly allocated to one of two groups. Those in the first group receive the six month SHIFT programme which includes education sessions that discuss the possible ways for the drivers to increase their activity, improve their diet and reduce their sitting time (when not driving) during working and non-working hours. Participants are invited to take part in step count challenges and are given equipment to do stretching exercises for them to do in their vehicles. Participants in the control group continue as normal. Participants are followed up at the end of the study to evaluate the health and the physical activity level of the participants.

What are the possible benefits and risks of participating?
Participants may benefit from participating in this study as it could result in them marking positive changes to their physical activity levels and/or diet which could reduce their risk of heart disease or diabetes. Participants also receive three free health checks that includes detailed feedback. There are no notable risks with participating.

Where is the study run from?
The study is run from Loughborough University (UK) and takes place within 24 transport depots owned by DHL within the Midlands (UK).

When is the study starting and how long is it expected to run for?
February 2017 to August 2021

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Stacy Clemes
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NIHR PHR 15/190/42

Study information

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

Acronym
SHIFT

Study hypothesis
Current study hypothesis as of 10/09/2021:
The aim of this study is to investigate whether the SHIFT programme leads to increases in objectively measured physical activity (expressed as steps/day) compared to usual care at 6 months follow-up.
It is hypothesised that participants randomised to the SHIFT intervention arm will exhibit increases in physical activity levels (expressed as steps/day), relative to those in the control arm at 6 months follow-up.

Previous study hypothesis:
The aim of this study is to investigate whether the SHIFT programme leads to increases in objectively measured physical activity (expressed as steps/day) compared to usual care at 12 months follow-up.
It is hypothesised that participants randomised to the SHIFT intervention arm will exhibit increases in physical activity levels (expressed as steps/day), relative to those in the control arm at 12 months follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Loughborough University Ethics Approvals (Human Participants) Sub-Committee, 28/03/2017, ref: R17-P063

Study design
Two armed cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Condition
Obesity and chronic disease prevention, specifically cardiovascular disease and type 2 diabetes

Interventions
Current interventions as of 10/09/2021:
This study involves two phases: an internal pilot and the full study. Participants are allocated to clusters which are randomised to receive either the six month "SHIFT programme" or the usual care (control). Clusters are randomised at the worksite level and takes place in two phases: The first six clusters (n=84) are involved in the internal pilot and the second phase of the study will begin a year after which consists of the remaining clusters (18 depots, n=252 drivers). In both study phases, randomisation takes place upon completion of baseline measurements. The internal pilot examines issues surrounding worksite and participant recruitment, randomisation, compliance to the primary outcome, and retention rates at 6-months following randomisation. After the completion of the internal pilot, the remaining depots start the study.

In both phases participants undertake a baseline assessment. This takes two hours per driver. After the baseline assessments, participants are given two accelerometers to monitor their physical activity and sitting time levels for 24 hours over a seven day period. The depots involved in the internal pilot are then randomised to either the intervention or the control groups by the Leicester Clinical Trials Unit (CTU).

Intervention group (SHIFT):
The six month SHIFT intervention, grounded within the Social Cognitive Theory for behaviour change, consists of a group-based interactive six hour education session tailored for heavy goods vehicle (HGV) drivers, delivered by trained educators. This includes information about physical activity, diet, health factors associated to long periods of sitting, risk factors for type 2 diabetes and cardiovascular disease. The educational component is derived from the award winning DESMOND programme, created by educators at the Leicester Diabetes Centre (LDC) and used throughout the National Health service (NHS). The education session is supported by

specially developed resources for HGV drivers and participant support materials. The sessions include the discussion of feasible strategies for drivers to increase their physical activity, improve their diet and reduce their sitting time (when not driving) during working and non-working hours. During the education session, participants are provided with a wearable physical activity tracker and encouraged to use this to set goals (agreed at the session) to gradually increase their physical activity predominately through walking-based activity. The physical activity tracker provides drivers with information on their daily step counts and is used as a tool for self-monitoring and self-regulation. The education session adopts the promotion of the "small changes" philosophy using the Specific, Measurable, Attainable, Relevant, and Timely (SMART) principle to encourage drivers to build-up their daily activity levels, within the confines of their occupation, to meet the current UK Physical Activity guidelines. For example, drivers are encouraged to establish their own action plan with SMART goals for the duration of the 6-month intervention.

The structured education session is delivered by trained personnel from within DHL (the lorry company). These individuals are trained and mentored by educators from the LDC. The LDC Team successfully developed, evaluated and disseminated to the NHS the DESMOND programme for type 2 diabetes, and the Let's Prevent Diabetes Programme. The educational component is derived from these programmes and tailored to HGV drivers. The educational session can be delivered in either one 6-hour session, or as two 3-hour sessions. The educational sessions take place within appropriate training rooms within DHL. Within the education session participants are not 'taught' in a formal way, but supported to work out knowledge and develop individual goals and plans to achieve over the six month intervention period.

Within each intervention depot an employee is recruited to act as a local champion, shown to enhance the effectiveness of worksite physical activity interventions. They receive training on how to provide ongoing health coach support to intervention participants (during and after the six month intervention period) and are responsible for facilitating monthly step count challenges. Participants also are able to contact the trained educators within their company throughout the intervention for one-to-one support in person, or via the telephone.

Step count challenges (1-week competitions between and within intervention depots) run on a monthly basis throughout the intervention and are facilitated by the local worksite champions. A "cab workout" is introduced and practised at the education session and drivers are provided with resistance bands and balls, and grip strength dynamometers to take away. Drivers are encouraged to undertake the cab workout during breaks when not permitted to leave their vehicle. Drivers are able to keep the intervention tools and encouraged to continue with their use beyond the six month intervention period.

Control group:
Depots assigned to the usual practice control arm are asked to continue with their usual care conditions. Participants in the control depots receive an educational leaflet at the outset detailing the importance of healthy lifestyle behaviours (i.e., undertaking regular physical activity, breaking up periods of prolonged sitting, and consuming a healthy diet) for the promotion of health and well-being. Control participants are requested to complete the same study measurements as those in the intervention worksites, at the same time points. Upon completion of the study, control depots are provided with all of the educational material provided to the intervention participants as part of the SHIFT programme.

In both study phases, the impact of the intervention is assessed immediately following the intervention delivery (six months after randomisation). Measurements take place at the same time for participants in each of the intervention arms.

Previous interventions:
This study involves two phases: an internal pilot and the full study. Participants are allocated to clusters which are randomised to receive either the six month "SHIFT programme" or the usual care (control). Clusters are randomised at the worksite level and takes place in two phases: The first six clusters (n=84) are involved in the internal pilot and the second phase of the study will begin a year after which consists of the remaining clusters (18 depots, n=252 drivers). In both study phases, randomisation takes place upon completion of baseline measurements. The internal pilot examines issues surrounding worksite and participant recruitment, randomisation, compliance to the primary outcome, and retention rates at 6-months following randomisation. After the completion of the internal pilot, the remaining depots start the study.

In both phases participants undertake a baseline assessment. This takes two hours per driver. After the baseline assessments, participants are given two accelerometers to monitor their physical activity and sitting time levels for 24 hours over a seven day period. The depots involved in the internal pilot are then randomised to either the intervention or the control groups by the Leicester Clinical Trials Unit (CTU).

Intervention group (SHIFT):
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Within each intervention depot an employee is recruited to act as a local champion, shown to enhance the effectiveness of worksite physical activity interventions. They receive training on how to provide ongoing health coach support to intervention participants (during and after the six month intervention period) and are responsible for facilitating monthly step count challenges. Participants also are able to contact the trained educators within their company throughout the intervention for one-to-one support in person, or via the telephone.

Step count challenges (1-week competitions between and within intervention depots) run on a monthly basis throughout the intervention and are facilitated by the local worksite champions. A "cab workout" is introduced and practised at the education session and drivers are provided with resistance bands and balls, and grip strength dynamometers to take away. Drivers are encouraged to undertake the cab workout during breaks when not permitted to leave their vehicle. Drivers are able to keep the intervention tools and encouraged to continue with their use beyond the six month intervention period.

Control group:
Depots assigned to the usual practice control arm are asked to continue with their usual care conditions. Participants in the control depots receive an educational leaflet at the outset detailing the importance of healthy lifestyle behaviours (i.e., undertaking regular physical activity, breaking up periods of prolonged sitting, and consuming a healthy diet) for the promotion of health and well-being. Control participants are requested to complete the same study measurements as those in the intervention worksites, at the same time points. Upon completion of the study, control depots are provided with all of the educational material provided to the intervention participants as part of the SHIFT programme.

In both study phases, the impact of the intervention is assessed immediately following the intervention delivery (six months after randomisation) and the six months following completion of the intervention (12 months after randomisation). Measurements take place at the same time for participants in each of the intervention arms.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 10/09/2021:
Physical activity (steps per day) is measured using the activPAL3 micro accelerometer (worn on the thigh 24 hours a day during the 7 day assessment period) at baseline and 6 months

Previous primary outcome measure:
Physical activity (steps per day) is measured using the activPAL3 micro accelerometer (worn on the thigh 24 hours a day during the 7 day assessment period) at baseline, 6 months and 12 months.

Secondary outcome measures
Current secondary outcome measures as of 10/09/2021:
1. Light and moderate-to-vigorous physical activity (MVPA) is measured using the GENEActiv accelerometer (worn on the wrist 24 hours a day for the 7 day assessment period at baseline, 6 months, and 8-11 months
2. Sitting time is measured using the activPAL3 micro at baseline, 6 months, and 8-11 months
3. Adiposity measured using the portable Tanita 418 bioelectrical impedance analyser at baseline and 6 months

4. Neck circumference is measured using anthropometry tape at baseline and 6 months
5. Blood pressure is measured using automated blood pressure analysers at baseline and 6 months
6. Blood markers (total cholesterol, HDL, LDL, glycated haemoglobin) are assessed using a finger-prick blood sample at baseline and 6 months
7. Dietary quality is measured using a short-form food frequency questionnaire at baseline, 6 months, and 8-11 months
8. Binge eating is measured using The Three-Factor Eating Questionnaire at baseline, 6 months, and 8-11 months
9. Sleep duration is measured using the GENEActiv for 7 days at baseline and 6 months
10. Sleep quality is measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline and 6 months
11. Cognitive function is measured using the Stroop test at baseline and 6 months
12. Musculoskeletal symptoms are assessed using the Standardised Nordic Questionnaire at baseline and 6 months
13. Work engagement (characterised by vigour, dedication, and absorption) will be measured using the Utretcht Work Engagement Scale (UWES) at baseline, 6 months, and 8-11 months
14. Occupational fatigue is measured using the Need for Recovery Scale at baseline, 6 months, and 8-11 months
15. Job performance and job satisfaction is measured using single-item 7-point Likert scales atbaseline, 6 months, and 8-11 months
16. General quality of life is assessed using the WHO QOL-BREF at baseline, 6 months, and 8-11 months
17. Presenteeism is assessed using the Work Limitations Questionnaire and the Work Productivity and Activity Impairment Questionnaire (WPAI-GH 2.0) at baseline, 6 months, and 8-11 months
18. Perceptions of work demand and support are assessed using four subscales from the Health and Safety Executive Management Standards Indicator Tool (HSE MSIT) at baseline, 6 months, and 8-11 months
19. Driving-related safety behaviour is assessed using a 6-item measure at baseline, 6 months, and 8-11 months
20. Anxiety and depression are measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 6 months, and 8-11 months
21. Sickness absence is collected via self-report and employer records and will include frequency and duration of self-certified and certified sickness at baseline, 6 months, and 8-11 months
22. Cost-effectiveness and health related resources of the trial is assessed using the self-reported EQ5D at baseline and 6 months
23. Basic demographics (e.g. age, education level, years as a HGV driver) are measured using self-reported measures at baseline and 6 months

Previous secondary outcome measures:
1. Light and moderate-to-vigorous physical activity (MVPA) is measured using the GENEActiv accelerometer (worn on the wrist 24 hours a day for the 7 day assessment period at baseline, 6 and 12 months
2. Sitting time is measured using the activPAL3 micro at baseline, 6 and 12 months
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23. Basic demographics (e.g. age, education level, years as a HGV driver) are measured using self-reported measures at baseline, 6 and 12 months

Overall study start date
10/02/2017

Overall study end date
02/12/2020

Eligibility

Participant inclusion criteria
1. Long distance heavy goods vehicle (HGV) drivers
2. Aged 18 to 65 years
3. Male and female (with the exception of females who are pregnant)
4. Free of cardiovascular disease, haemophilia, or blood-borne viruses
5. Must not have any mobility issues which prevent them from going about their normal work duties

Participant type(s)

Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
110 participants are required from 11 clusters per arm. To allow for participant drop out, the sample size has been inflated by 30%. The cluster size will also be inflated by 2 to allow for whole cluster drop out. 14 participants will therefore be recruited per cluster, 336 participants in total, across 24 clusters. Due to restrictions at one pilot site in terms of participants wearing the primary outcome measure, it was agreed that an additional site would be recruited in the main trial phase, providing a total cluster number of 25.

Total final enrolment
382

Participant exclusion criteria
1. Cardiovascular disease
2. Haemophilia
3. Any blood-borne viruses or mobility limitations

Recruitment start date
01/09/2017

Recruitment end date
24/07/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Loughborough University
Ashby Road
Loughborough
United Kingdom
LE11 3TU

Study participating centre
DHL Supply Chain
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United Kingdom
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Sponsor information

Organisation
Loughborough University

Sponsor details
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LE11 3TU

Sponsor type
University/education

ROR
https://ror.org/04vg4w365

Funder(s)

Funder type
Government

Funder Name
Public Health Research Programme

Alternative Name(s)
NIHR Public Health Research Programme, PHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned dissemination of findings through presentations at national and international conferences (e.g. ISBNPA, ACSM, European Congress on Obesity) and publications (e.g. International Journal of Obesity, IJBNPA, BMC Public Health, NIHR PHR Journal). Open access journals will be targeted where appropriate. Publications will include: the trial protocol (to be published by December 2017), and papers detailing the study findings, including a paper on the cost-effectiveness of the study, and a process evaluation paper. These outputs will be published upon completion of the study, likely by February 2021.

Intention to publish date
20/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Stacy Clemes (s.a.clemes@lboro.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/11/2019	27/11/2019	Yes	No
Results article	RCT results	24/05/2022	24/05/2022	Yes	No
Results article	Process evaluation	07/07/2022	08/07/2022	Yes	No
Other publications	Secondary analysis of response in obese and non-obese participants	23/11/2022	02/08/2023	Yes	No