**STATISTICAL ANALYSIS PLAN**

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

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LIST OF ABBREVIATIONS

|  |  |
| --- | --- |
| AE | Adverse event |
| ANCOVA | Analysis of covariance |
| AUDIT | Alcohol use disorders identification test |
| BMI | Body mass index |
| BPM | Beats per minute |
| CI | Chief Investigator |
| CC | Complete case |
| CM | Centimetre |
| CONSORT | Consolidated Standards of Reporting Trials |
| COVID-19 | Coronavirus Disease 2019 |
| CTU | Clinical trials unit |
| CVD | Cardiovascular disease |
| DBP | Diastolic Blood Pressure |
| DESMOND | Diabetes Education and Self-Management for Ongoing and Newly Diagnosed Programme |
| DQS | Dietary Quality Score |
| FFQ | Food Frequency Questionnaire |
| HADS | Hospital Anxiety and Depression Scale |
| HbA1c | Glycated hemoglobin |
| HDL | High-Density Lipoproteins |
| HGV | Heavy Goods Vehicle |
| HR | Heart Rate |
| ICC | Intraclass correlation coefficient |
| ICH | International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use |
| ITT | Intention-to-treat |
| KG | Kilogram |
| LCTU | Leicester Clinical Trials Unit |
| LDC | Leicester Diabetes Centre |
| LDL | Low-Density Lipoproteins |
| MEQ-SA | Morningness-Eveningness Questionnaire Self-Assessment |
| MI | Multiple imputation |
| mmHg | Millimetre of mercury |
| MMI | Multilevel multiple imputation |
| mmol/mol | Millimoles per mole |
| mmol/l | Millimoles per litre |
| MVPA | moderate-to-vigorous physical activity |
| NIHR | National Institute for Health Research |
| NHS | National Health Service |
| NMES | Non-milk extrinsic sugars |
| OFER | Occupational Fatigue Exhaustion Recovery |
| PP | Per-protocol |
| QoL | Quality of life |
| RCT | Randomised controlled trial |
| SAF | Safety population |
| SAP | Statistical analysis plan |
| SBP | Systolic Blood Pressure |
| SD | Standard Deviation |
| SHIFT | Structured Health Intervention for Truckers |
| SMART | Specific, Measurable, Attainable, Relevant, and Timely |
| SNQ | Standardized Nordic Questionnaire |
| TSC | Trial Steering Commitee |
| UWES | Utrecht Work Engagement Scale |
| WHO | World Health Organisation |

Contents

[1 Introduction 8](#_Toc70589907)

[1.1 Study Objectives 8](#_Toc70589908)

[1.1.1 Primary Objectives 8](#_Toc70589909)

[1.1.2 Secondary Objectives 8](#_Toc70589910)

[1.2 Study Design 9](#_Toc70589911)

[1.2.1 Overview 9](#_Toc70589912)

[1.2.2 Participants 9](#_Toc70589913)

[1.2.3 Intervention arms 10](#_Toc70589914)

[1.2.4 Sample size 11](#_Toc70589915)

[1.2.5 Randomisation and blinding 12](#_Toc70589916)

[1.3 Original visit schedule 12](#_Toc70589917)

[2 Outcomes and other variables 13](#_Toc70589918)

[2.1 Primary Outcome 13](#_Toc70589919)

[2.1.1 Definition and Derivation of Primary Outcome 13](#_Toc70589920)

[2.1.2 Hypothesis to be investigated 13](#_Toc70589921)

[2.2 Secondary Outcomes 13](#_Toc70589922)

[2.2.1 Definition of Secondary Outcomes 13](#_Toc70589923)

[2.2.2 Hypotheses to be investigated 16](#_Toc70589924)

[2.3 Subgroups and/or interactions 16](#_Toc70589925)

[2.4 Compliance 16](#_Toc70589926)

[3 Analysis Sets/Populations 16](#_Toc70589927)

[3.1 Complete Case Population 16](#_Toc70589928)

[3.2 Intention-to-treat Population / Full analysis set 17](#_Toc70589929)

[3.3 Per-protocol (PP) Population 17](#_Toc70589930)

[3.4 Safety Population (SAF) 17](#_Toc70589931)

[3.5 Protocol deviations 17](#_Toc70589932)

[4 Statistical Analysis 17](#_Toc70589933)

[4.1 Derived / Computed Variables 17](#_Toc70589934)

[4.2 Interim Analysis and Multiple Testing 17](#_Toc70589935)

[4.3 Analysis Software 18](#_Toc70589936)

[4.4 Disposition 18](#_Toc70589937)

[4.5 Demographic and Baseline Characteristics 18](#_Toc70589938)

[4.6 Primary Outcome Analysis 19](#_Toc70589939)

[4.6.1 Primary Analysis of Primary Outcome 19](#_Toc70589940)

[4.6.2 Secondary Analysis of Primary Outcome 19](#_Toc70589941)

[4.6.3 Sensitivity Analyses 19](#_Toc70589942)

[4.6.4 Subgroup Analyses 20](#_Toc70589943)

[4.7 Secondary Outcome Analyses 20](#_Toc70589944)

[4.7.1 Primary Analysis of Secondary Outcomes 20](#_Toc70589945)

[4.7.2 Sensitivity Analyses 21](#_Toc70589946)

[4.7.3 Subgroup Analyses 21](#_Toc70589947)

[4.8 Changes to the Planned Analysis 21](#_Toc70589948)

[5 Safety and Adverse events (AEs) 21](#_Toc70589949)

[5.1 Adverse Events and Tolerability 21](#_Toc70589950)

[6 References 22](#_Toc70589951)

[7 Appendix 1 – Scoring protocols for questionnaire-based secondary outcomes (Section 2.2.1) 23](#_Toc70589952)

# Introduction

This Statistical Analysis Plan (SAP) describes the planned analysis and reporting for the Clemes\_16\_300\_SHIFT trial. All work planned and reported for this SAP will follow internationally accepted guidelines, published by the American Statistical Association and the Royal Statistical Society for statistical practice.

The reader of this SAP is encouraged to also read the trial protocol.

The purpose of this SAP is to outline the planned end of trial analyses that are to be performed on the data to support the completion of the Study Report (SR). The SAP will be amended if there are substantial changes to the planned analyses, and in any case will be finalised before the database lock for this study. Exploratory post-hoc or unplanned analyses not necessarily identified in this SAP may be performed on these data as required. These analyses will be clearly identified in the SR.

**Throughout the document: Any verbatim text from the protocol is provided inside a box:**

Text from the protocol

## Study Objectives

### Primary Objectives

The original primary objective of this study was to investigate whether the SHIFT programme leads to increases in objectively measured physical activity (expressed as steps/day) compared to usual care at 12-month follow-up.

However, due to the restrictions faced by the study, including the COVID-19 pandemic, following discussions with the funder, the National Institute for Health Research (NIHR), it was decided that the primary analysis will be carried out using the 6-month follow-up data. activPAL-determined activity data will still be collected at 16-18 months follow-up (the original primary outcome was at 12 months follow-up), as will a number of self-report measures. These will be secondary outcomes.

The updated primary objective 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-month follow-up.

### Secondary Objectives

To investigate the impact of the SHIFT programme, compared to usual care, at 6-months follow-up on;

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

9. psychosocial variables and mental health (e.g. anxiety and depression, work engagement, job performance and satisfaction, presenteeism, sickness absence, health-related quality of life, and driving related safety behaviour)

Due to Covid-19, the sustainability of the SHIFT programme, compared to usual care, will also be investigated at 16-18 months follow-up (i.e. 10-12 months following completion of the intervention) on:

1. steps/day (activPAL), time spent in light and moderate-to-vigorous physical activity (MVPA) (activPAL)
2. sitting time (activPAL)
3. fruit and vegetable intake and dietary quality
4. sleep (self-reported)
5. psychosocial variables and mental health (e.g. anxiety and depression, work engagement, job performance and satisfaction, presenteeism, sickness absence, health-related quality of life, and driving related safety behaviour)

The study will also conduct full process and economic evaluations. These will not be carried out by the LCTU and are not included within this SAP.

## Study Design

### Overview

This is a workplace two-armed 6-month cluster RCT, which will incorporate an internal pilot. Clusters (different worksites/depots within the same company) will be randomised, following the completion of baseline measurements, to receive either the ‘SHIFT programme’ or usual care condition. The impact of the intervention will be assessed following the 6-month intervention, and approximately 16-18 months follow-up (i.e. 10-12 months after completion of the intervention period).

### Participants

All long-distance HGV drivers (>18 years of age) within participating depots will be eligible to participate, with the exception of those who meet the exclusion criteria below.

Participants will be excluded if they are not in full-time contracts with DHL. This means that agency drivers and those with reduced-hours contract will not be included in the study. Participants will be excluded if currently suffering from cardiovascular disease, haemophilia, or have any blood-borne viruses or mobility limitations. In addition, depots containing HGV drivers who make many delivery stops, for example, drivers who deliver consumer goods to domestic customers throughout the day will be excluded.

### Intervention arms

#### Intervention group

The 6-month SHIFT intervention, grounded within the Social Cognitive Theory for behaviour change, consists of a group-based interactive 6-hour education session tailored for HGV drivers, delivered by trained educators. It includes information about physical activity, diet and sitting and risk factors for Type 2 diabetes and cardiovascular disease. The educational component is derived from the award-winning DESMOND programme, created by educators at the Leicester Diabetes Centre (LDC) and used throughout the NHS. The education session is supported by specially developed resources for HGV drivers and participant support materials. The session will include the discussion of feasible strategies for drivers to increase their physical activity, improve their diet and reduce their sitting time (when not driving) during working and non-working hours.

During the education session, participants will be provided with a wearable physical activity tracker and encouraged to use this to set goals (agreed at the session) to gradually increase their physical activity predominately through walking-based activity. The physical activity tracker will provide drivers with information on their daily step counts and will be used as a tool for self-monitoring and self-regulation. Physical activity tracking using pedometers has been associated with significant reductions in BMI and blood pressure, with interventions incorporating goal setting being the most effective.

The education session will adopt 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 will be encouraged to establish their own action plan with SMART goals for the duration of the 6-month intervention.

‘Step count challenges’ (1-week competitions between and within intervention depots) will run on a 6-weekly basis throughout the intervention which will be facilitated by local worksite champions. A “cab workout” will be introduced and practised at the education session and drivers will be provided with resistance bands and balls, and grip strength dynamometers to take away. Drivers will be encouraged to undertake the cab workout during breaks when not permitted to leave their vehicle. Drivers will be able to keep the intervention tools and encouraged to continue with their use beyond the 6-month intervention period.

#### Control arm

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

### Sample size

Our earlier exploratory pre-post study revealed that on average HGV drivers achieve 8786 steps/day across both workdays and non-workdays with a standard deviation of 2919 steps (Varela Mato, Caddick et al. 2018). We have powered this study to look for a difference in step counts (the primary outcome) of 1500 steps/day (equivalent to approximately 15 minutes of moderately paced walking) between the intervention group and control group. Evidence demonstrates a linear association between step counts and a range of morbidity and mortality outcomes, as well as with markers of health status including inflammation and adiposity, insulin sensitivity and HDL cholesterol in adults (Ewald, Thomson). The linear association between step counts and health outcomes indicate that regardless of an individual’s baseline value, even modest increases in daily step counts can yield clinically meaningful health benefits. For example, a difference in daily steps of 1500 steps/day has been associated with around a 5-10% 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 (Yates, Haffner et al. 2014, Dwyer, Pezic et al. 2015). The proposed level of change has been chosen based on findings from our exploratory pre-post intervention, whilst also being clinically meaningful.

Based on a cluster size of 10, a conservative ICC of 0.05 (as there is no previous data to inform this, we have been informed by recommendations of (Campbell, Fayers et al. 2005)), 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 partner company data) we will require 110 participants from 11 clusters per arm. From experience in conducting such studies, it is estimated that retention and compliance rates will be approximately 70% at 12-months follow-up; therefore, the sample size will be inflated by 30% to ensure we have adequate power in our final analysis. We will also inflate the number of clusters by 2 to allow for whole cluster drop out. We will recruit 24 clusters with an average of 14 participants per cluster, giving a total of 336 participants.

Due to 1 pilot site (a BP site) not allowing participants to wear the accelerometers during working hours for health and safety reason, thus limiting the collection of the primary outcome measure (activPAL-determined steps/day) to non-working hours only, the TSC approved the recruitment of an additional site in the main trial phase. The total number of sites recruited will now be 25 as opposed to 24.

### Randomisation and blinding

The clusters will be assigned to an intervention arm by a CTU statistician using a pre-generated list. Pilot stage clusters will be randomly assigned to one of the two arms using simple randomisation. Randomisation of the main trial clusters will be stratified by cluster size, Small (<40) vs. Large (≥40). Due to the nature of the intervention it was impossible to blind the participants and the frontline research staff to the treatment group allocations.

## Original visit schedule

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Baseline** | **6 months** | **12 months** |
| Consent form | X | X | X |
| Physiological measures | X | X |  |
| Health Screen Questionnaire | X | X |  |
| Demographic information | X | X | X |
| Short Form Dietary Questionnaire  | X | X | X |
| Smoking and alcohol use | X | X | X |
| Nordic Musculoskeletal Questionnaire | X | X | X |
| Hospital Anxiety and Depression Scale (HADS) | X | X | X |
| Social Isolation – Short Form | X | X | X |
| Utretcht Work Engagement scale | X | X | X |
| OFER scale | X | X | X |
| Job satisfaction scale | X | X | X |
| Job performance scale | X | X | X |
| Self-reported sickness absence | X | X | X |
| Self-reported presenteeism | X | X | X |
| Work ability question | X | X | X |
| Work Demands Questionnaire | X | X | X |
| Karolinska Sleepiness Scale | X | X | X |
| Morningness-Eveningness Questionnaire | X | X | X |
| Self-reported Driver Safety Behaviour questionnaire | X | X | X |
| Self-reported EQ-5D-5L | X | X | X |
| Health-related resource use questionnaire | X | X | X |
| activPAL and GENEActiv | X | X | X |

The full health screen questionnaire, physiological measurements, and GENEActiv data were not collected at 12 months due to restrictions associated with COVID-19.

# Outcomes and other variables

## Primary Outcome

### Definition and Derivation of Primary Outcome

The primary outcome will be physical activity, expressed as steps/day, at 6 months follow-up. Physical activity will be objectively measured using the activPAL micro accelerometer, worn continuously on the anterior aspect of the thigh, for 24 hours/day over eight days during each assessment period. activPAL data will be processed by a member of the research team (blinded) and each participant’s average number of steps per day will be calculated by summing average daily number of steps across valid days and dividing by number of valid wear days. A valid activPAL wear day is defined as having ≥10 hours wear time per day, ≥ 1,000 steps per day and <95% of the day spent in any one behaviour.

### Hypothesis to be investigated

The null hypothesis for the primary analysis is that there is no difference between the intervention arm and control arm in the primary outcome at 6 months follow-up.

## Secondary Outcomes

### Definition of Secondary Outcomes

Please see below a list of all secondary outcomes collected. Please also see scoring protocols for questionnaire-based measures in Appendix 1.

**Adiposity**

* Weight (kg)
* Body fat (%)
* Fat mass (kg)
* Fat free mass (kg)
* Body mass index (BMI) (kg/m2)
* Waist circumference (cm)
* Hip circumference (cm)
* Waist-hip ratio
* Neck circumference (cm)

**Physiological measures (3 measures taken. Average of the last two calculated)**

* Systolic blood pressure (mmHg)
* Diastolic blood pressure (mmHg)
* Heart rate (bpm)

**Biochemical assessments**

* Glycated haemoglobin (mmol/mol)
* Glycated haemoglobin (%)
* Triglycerides (mmol/l)
* HDL cholesterol (mmol/l)
* LDL cholesterol (mmol/l)
* Total cholesterol (mmol/l)

**Objectively measured sitting and physical activity (activPAL):** The variables below will be derived by calculating the average across the number of valid days. The variables will be analysed in 3 different time periods: 1) daily (i.e. across all waking hours on all valid days); 2) during work days; 3) during non-work days.

* Average sitting time (minutes/day) – total
* Average sitting time (minutes/day) - in prolonged bouts lasting 30+ mins
* Average standing time (minutes/day) – total
* Average stepping time (minutes/day) – total
* Average number of transitions from sitting to an upright posture
* Average time in moderate-to-vigorous physical activity (MVPA) (minutes/day), calculated as total stepping time at a step cadence threshold of 100 steps/min (in bouts lasting 1+ min)
* Average time in light physical activity (minutes/day)

The variables below will also be summarised descriptively at each time point and time period:

* Average number of valid days
* Average waking wear time (minutes/day)
* Average percent 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 time (%)

**Objectively measured sleep (GENEActiv wrist accelerometer) –** The variables below will be derived by calculating the average across the number of valid days. The variables will be analysed in 3 different time periods: 1) daily (i.e. across all waking hours on all valid days); 2) during work days; 3) during non-work days.

* Sleep window duration (average duration between ‘lights out’ and ‘out of bed’ time, minutes)
* Sleep duration (average time spent asleep during the sleep window, minutes)
* Sleep efficiency (%)

The variables below will also be summarised descriptively at each time point and time period:

* Average number of valid days (days)
* Average wear time (minutes)

**Dietary behaviours, smoking and alcohol**

* Fruit intake (grams/day)
* Vegetable intake (grams/day)
* Dietary quality score (DQS)
* Alcohol intake (AUDIT Score)
* Smoking status (and quantity [cigarettes/day] in smokers)

**Self-reported sleep**

* Morningness-Eveningness Questionnaire Self-Assessment Version (MEQ-SA)
* Karolinska Sleepiness Scale (1=extremely alert; 9=very sleepy great effort to keep awake)

**Cognitive function measure (Stroop Test)**

* Reaction time
* Sensitivity to interference
* Ability to suppress an automated response - reading colour names in favour of naming the font colour.

**Psychophysiological Reactivity**

* + Mirror tracing task:
	+ Systolic blood pressure (mmHg) (2 measures in addition to physiological measures)
	+ Diastolic blood pressure (mmHg) (2 measures in addition to physiological measures)
	+ Heart rate (bpm) (2 measures taken)
	+ Systolic blood pressure psychophysiological reactivity (mmHg) (Δ resting SBP and average SBP taken during the stress task)
	+ Diastolic blood pressure psychophysiological reactivity (mmHg) (Δ resting DBP and average DBP taken during the stress task)
	+ Heart rate psychophysiological reactivity (mmHg) (Δ resting HR and average HR taken during the stress task)
	+ Number of errors
	+ Stress felt during task (Likert scale ranging from 1=not stressed at all to 5=very stressed)

**Functional Fitness**

* + Hand-grip strength:
* Right hand (kg)
* Left hand (kg)
* Average of right and left hand (kg)

**Work-related health**

* Job performance: 7-point likert scale (1=dissatisfied; 7=extremely satisfied)
* Job satisfaction: 7-point likert scale (1=very poorly; 7=extremely well)
* Work engagement - Utrecht Work Engagement Scale (UWES) (0=never; 6=always)
* Musculoskeletal symptoms - Standardised Nordic Questionnaire (SNQ)
* Presenteeism (self-reported):
	+ Duration of self-reported presenteeism (total number of days in work despite not feeling well in the past six months)
* Sickness absence (self-reported):
	+ Duration of self-reported sickness (total number of days of missed work because of sick leave in the past six months)
* Workload and relations - Health and Safety Executive Management Standards Indicator Tool (HSE MSIT) (1=never; 5=always)

* Workability (0=worst; 10=best)
* Driving-related safety behaviour: 6-item measure

**Mental health, well-being and quality of life**

* Health-related quality of life - EQ-5D-5L
* Anxiety and depression - Hospital Anxiety and Depression Scale (HADS). (0 to 3 likert scales)
* Social isolation - Patient-Reported Outcomes Measurement Information System: 8-item form

(1=Never; 5=Always)

* Acute and Chronic Fatigue, and inter-shift recovery - Occupational Fatigue Exhaustion Recovery (OFER 15) Scale. (0=strongly disagree; 6=strongly agree)
* CVD risk measured using QRISK3 10-year risk score

### Hypotheses to be investigated

The null hypothesis is that no difference exists between the intervention arm and control arm in the secondary outcomes at 6 months and at 12 months (now 16-18 months). Statistical testing will only be carried out for the following key outcomes: steps/day (at 16-18 months), activPAL determined time spent sitting, standing and stepping, and time in LPA and MVPA daily across any valid days, during work days and during non-work days at 6 and 16-18-months. Fruit and vegetable intake (grams/day) and dietary quality score will also be analysed at 6 and 16-18 months.

Fruit and vegetable intake (grams/day) and dietary quality score (at 6 and 16-18 months) and the following markers of cardiometabolic health (at 6 months) will be compared statistically: weight, BMI, % body fat, waist circumference, Glycated haemoglobin (mmol/mol), Triglycerides (mmol/l), HDL cholesterol (mmol/l), LDL cholesterol (mmol/l), and Total cholesterol (mmol/l). Differences between groups in other outcomes will be evaluated descriptively. Please see Section 4.7 for more details.

## Subgroups and/or interactions

There are no pre-specified subgroup analysis.

## Compliance

We will ensure good compliance with this device by checking each device on return and requesting a re-wear if the participant does not provide enough valid days.

activPAL valid wear days and valid wear time across all valid days, across work days as well as during non-work days will be summarised for the whole group and between arms. The primary analysis will include participants who provide a minimum of 1 valid wear day in the respective time periods (i.e. daily, across work days, non-work days) both at baseline and at follow-up. 1 valid day has been chosen to maximise our sample and is line with previous similar studies (Healy, Eakin et al. 2016, Edwardson, Yates et al. 2018).

# Analysis Sets/Populations

## Complete Case Population

The primary analysis will test the effect of the intervention on outcomes using a complete case (CC) population. That is, all clusters randomised and the recruited participants in these clusters, excluding those with missing outcome data (i.e. without at least 1 valid day of activPAL data at baseline and follow-up) and complete stratification variable data. The analysis will follow the intention-to-treat principle, that is, clusters and participants will be analysed in the arm to which they were randomised.

## Intention-to-treat Population / Full analysis set

A full intention-to-treat (ITT) analysis population will consist of all clusters randomised and the recruited participants within these clusters. Clusters and participants will be analysed in the arm to which they were randomly allocated, regardless of if they received the assigned intervention, or any protocol deviations or violations.

We will use multiple imputation to deal with missing data in the following types of variables: the outcome variable, covariates in final analysis model and any additional auxiliary variables in the imputation model. This will be a sensitivity analysis just for the primary outcome and for a single secondary outcome (BMI at 6 months).

## Per-protocol (PP) Population

The effect size will also be estimated using a PP analysis, which will only include those who were compliant with the protocol and follow-up visits.

Participants with the protocol deviations in the Protocol Deviations Section 3.5 will be excluded. No missing data will be imputed in this population. This will be a sensitivity analysis for the primary outcome and for a single secondary outcome (BMI at 6 months).

## Safety Population (SAF)

There will be no safety population.

## Protocol deviations

This section outlines protocol deviations that will affect inclusion in populations, e.g. exclusion from the per-protocol population.

Participants who did not provide valid activPAL primary outcome data at baseline or at the 6-month follow-up will be excluded from this analysis.

In addition, participants with time window deviations for their follow up (>+/- 2 months) in terms of their activPAL data will also be excluded.

# Statistical Analysis

## Derived / Computed Variables

Ethnicity

The ethnicity variable will be categorised into White vs. Other.

BMI

MACRO database derives BMI at baseline and 6 months. Due to a database error, BMI at 12 months requires calculating based on weight recorded at 12 month follow-up assessment and height recorded at 6 month follow-up.

Time employed at company and as a lorry driver

Time in years to 2 decimal places requires deriving from baseline assessment fields for years and months. Where either month or year is missing a value of 0 will be imputed.

## Interim Analysis and Multiple Testing

The study included an internal pilot stage using the first six clusters (depots). The internal pilot examined issues surrounding worksite and participant recruitment, randomisation, compliance to the primary outcome, and retention rates at 6-months after randomisation. After this period, continuation to the full trial was conditional on meeting the following progression criteria:

1. All 24 depots required for the full sample size agree to take part in the study. 6 depots selected to take part in the pilot (3 randomised to the intervention arm and 3 to the control arm). This will demonstrate that depot recruitment and intervention delivery is on-track.
2. According to our criteria, 84 drivers need to agree to participate in the internal pilot, based on an average of 14 participants per cluster.
3. An average of 75% of drivers opting into the study, randomised into the intervention arm, attend the education session across the 3 intervention depots. This figure is based on the intervention uptake rate seen in our exploratory pre-post intervention study (87%), (Varela Mato, Caddick et al. 2018) whilst also recognising that take-up rates tend to be lower when moving from an efficacy to a larger multi-centre effectiveness trial.
4. No more than 20% of participants fail to provide valid data for the primary outcome measure (activPAL step counts) at baseline and at 6 months post randomisation or withdraw/are lost to follow-up during the six-month intervention phase. This threshold is necessary as study power requires total withdrawal or loss to follow-up of no higher than 30% during the six-month intervention and six-month follow-up (12 months post randomisation).

The Trial Steering Committee (TSC) for the study met by teleconference on 11-December-2019 to review progress and the pilot stage data. On the basis of the data reviewed, the TSC recommended continuation of the trial according to the version of the protocol at that time with no changes (version 2.0 25-Oct-2017).

## Analysis Software

The clinical data will be extracted from a MACRO database. Accelerometer data will be processed by a member of the research team (blinded to arm, as described in the protocol) and transferred to the CTU via validated EXCEL sheets. The analysis will be performed with any current version of SAS, Stata or R.

The statistical analysis will be based on published standards (ICH E9, Gamble). The date of data extraction from the database will be included in each report.

## Disposition

A flow of clusters through the trial will be summarised in a the extension for cluster trials CONSORT diagram (Campbell, Elbourne et al. 2004), including the eligibility, reasons for exclusion, numbers randomised to the arms, lost to follow-up and numbers analysed.

Participant disposition will be presented with respect to completion status, non-completion reason, protocol deviations, intervention compliance and length of stay in the trial. Results will be tabulated and summarised over time by arm and in total. Data completeness will be summarised.

## Demographic and Baseline Characteristics

Cluster and participant level baseline characteristics will be summarised by arm and in total.

* Demographics and other self-report measures include:
* Cluster size category (Small <40; Large ≥40)
* Age
* Gender
* Work shift (Morning; Afternoon; Night)
* Duration working at the company (years)
* Duration working as a HGV driver (years)
* Average hours worked per week
* Total IMD rank as an indicator of neighbourhood socio-economic status
* Marital status
* Level of education
* Ethnicity
* Diabetes history
* Smoking status

Continuous data that are approximately normally distributed will be summarised in terms of the mean and standard deviation. This will be evaluated using histograms. Skewed data will be presented in terms of the medians and interquartile range. Ordinal and categorical data will be summarised in terms of frequency counts and percentages.

We will also carry out a descriptive comparison of key baseline data between completers (i.e. participants who provide valid activPAL data at 6 months) vs. non-completers within treatment arms and overall. This will include the following variables: cluster size, age, BMI, number of years as a HGV driver, number of steps at baseline.

## Primary Outcome Analysis

### Primary Analysis of Primary Outcome

The primary analysis will be performed using a linear multilevel model. Analysis of Covariance (ANCOVA) will be used with each participant’s daily average number of steps (measured using activPAL) at 6-month follow-up as the outcome, adjusting for their daily average number of steps at baseline and for the average waking wear time across baseline and 6-month follow-up. The model will also include a categorical variable for randomisation group (control as reference) and terms for the stratification factor (cluster size).

Depots will be included as a random effect to model driver heterogeneity within depote sites. The variance-covariance matrix for the random effect will be assumed to be identity and the models will be estimated using restricted maximum likelihood. Also, level 1 and level 2 model residuals are assumed to follow a normal distribution and to have constant variance and these assumptions will be investigated using residual diagnostic plots. Alternative parameterisations and variable transformations will be considered where appropriate and if assumptions are not satisfied.

The models will only include participants who provide at least 1 valid wear day from the activPAL data at both baseline and 6 months.

The estimate of the difference between intervention arm and control for daily average number of steps at 6 months and the corresponding 95% confidence intervals and p-values will be presented, statistical tests will be two-sided. Furthermore, the intra-class (clusters) correlation coefficient (ICC) will be given to assess the strength of the clustering effect. An ICC will also be estimated for a model with only the randomisation variable included as a covariate and for a model without any covariates included.

### Secondary Analysis of Primary Outcome

None.

### Sensitivity Analyses

The sensitivity analyses will be conducted using similar methodology as the primary analysis of the primary outcome (Section 4.6.1). There will be no formal adjustment for multiple significance testing.

#### Per Protocol Population

The effect size will also be estimated excluding those with protocol deviations. The per protocol (PP) population are those who do not have the protocol deviations outlined in the Protocol Deviations Section 3.5.

#### Intention-To-Treat Population

Sensitivity analysis will be 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 dataset, missing data from variables included in the primary analysis model will be imputed using a multiple imputation procedure which substitutes predicted values from a regression equation. The following variables will be used as predictors of the primary outcome in the regression equation: baseline BMI, gender, 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 will also be imputed if needed. The imputation will be carried out by the MI command in Stata (StataCorp). MI replaces missing values with multiple sets of simulated values to complete the data, performs standard analysis on each completed dataset, and adjusts the obtained parameter estimates for missing-data uncertainty using Rubin’s rules to combine estimates (Rubin). Twenty imputations will be estimated and a seed will be set to allow reproducibility. Since ANCOVA does not support the MI approach, a linear mixed-effects model will be used instead, with the same specification as the ANCOVA model in section 4.6.1.

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

#### Effects on the number of valid activPAL days

We will assess the effect of the number of valid activPAL days chosen for the primary analysis and how the results obtained are affected by this change. This analysis will be performed by including participants who wore the activPAL for the following criteria:

* 2 valid days or more at both baseline and 6 months.
* 3 valid days or more at both baseline and 6 months.
* 4 valid days or more at both baseline and 6 months.

### Subgroup Analyses

No subgroup analysis will be carried out.

## Secondary Outcome Analyses

### Primary Analysis of Secondary Outcomes

Secondary outcomes, including those measured at other time-points, will be analysed using similar methodology to the primary outcome. This will only apply to the following key secondary outcomes: steps/day (at 16-18 months), time spent sitting, standing and stepping, and time in LPA and MVPA at 6 and 16-18-months – daily, during work days and during non-work days calculated from the activPAL data variables. These models will only include participants with ≥1 valid day of the respective time period (i.e. daily, work days or non-work days) at both baseline and follow-up. The models for each of these outcomes will adjust for their respective variable at baseline and for the respective average wear time period (i.e. daily, work days or non-work days) across baseline and follow-up.

Fruit and vegetable intake (grams/day) and dietary quality score will also be analysed at 6 and 16-18 months. The models for each of these outcomes will adjust for their respective baseline levels.

Furthermore, the following markers of cardiometabolic health will also be compared statistically at 6-months: weight, BMI, % body fat, waist circumference, Glycated haemoglobin (mmol/mol), Triglycerides (mmol/l), HDL cholesterol (mmol/l), LDL cholesterol (mmol/l), and Total cholesterol (mmol/l). The models for each of these outcomes will adjust for their respective baseline levels.

The models above will also include a categorical variable for intervention group (control as reference) and the stratification factor, cluster size. No corrections for multiple testing will be made. P-values and 95% CIs will be presented for these variables only.

Outcomes that are binary, categorical (unordered) or ordinal will be analysed using multilevel binary, multinomial or ordinal logistic regression models, respectively (Rabe-Hesketh, Pickles et al. 2001). There will be no formal adjustment for multiple significance testing. The estimates of the treatment effect will be presented with the associated standard error. 95% confidence intervals and p-values will not be presented. The statistical tests will be two-sided.

For the other secondary outcomes defined in Section 2.2, continuous data that are approximately normally distributed will be summarised in terms of the mean and standard deviation. Skewed data will be presented in terms of the medians and interquartile range. Ordinal and categorical data will be summarised in terms of frequency counts and percentages. We will summarise all variables by intervention arm.

### Sensitivity Analyses

Sensitivity analyses will be conducted for one secondary outcome: BMI at 6 months. Methodology similar to that proposed for the sensitivity analyses of the primary outcome will be employed (Section 4.6.3).

### Subgroup Analyses

None.

## Changes to the Planned Analysis

None.

# Safety and Adverse events (AEs)

## Adverse Events and Tolerability

As this is not a trial of an investigational medicinal product, only AEs that are potentially related to or may impact on the study interventions will be recorded. These are:

* Skin irritation from thigh monitor
* Skin irritation from wrist monitor
* Pain related to the intervention or other intervention components
* Feeling unwell during blood test

AEs will be presented by arm and overall, under the headings seriousness and relatedness to the intervention. A listing providing full details of each event will also be produced. If there are too few events, only the listing will be produced.

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# Appendix 1 – Scoring protocols for questionnaire-based secondary outcomes (Section 2.2.1)

**Alcohol intake**

The two questions below were taken from the Alcohol use disorders identification test (AUDIT) tool developed by the World Health Organisation (WHO). The responses to these 2 questions will be scored as suggested in the tool (score range: 0 to 8).

|  |  |
| --- | --- |
|  | Scoring system |
| Questions | 0 | 1 | 2 | 3 | 4 |
| How often do you have a drink containing alcohol? | Never | Monthly or less | 2 to 4 times/month | 2 to 3 times/week | 4 times or more/week |
| How many units of alcohol do you drink on a typical day when you are drinking? | 0 to 2 | 3 to 4 | 5 to 6 | 7 to 9 | 10 or more |

**Musculoskeletal Problems**

Musculoskeletal symptoms - Standardised Nordic Questionnaire (SNQ)

* + Trouble in last 12 months (Y/N)
		- * Neck
			* Upper extremity (shoulder, upper back, elbow or hand)
			* Lower back
			* Lower extremity (hip, knee, or feet)
			* Any site
	+ Prevented from doing normal activities in last 12 months due to this trouble (Y/N)
		- * Neck
			* Upper extremity (shoulder, upper back, elbow or hand)
			* Lower back
			* Lower extremity (hip, knee, or feet)
			* Any site
	+ Trouble in last 7 days (Y/N)
		- * Neck
			* Upper extremity (shoulder, upper back, elbow or hand)
			* Lower back
			* Lower extremity (hip, knee, or feet)
			* Any site
	+ Rating of pain in last 12 months (1=no pain; 10=most pain can imagine)

Higher scores indicate greater pain.

* + - Neck
		- Upper extremity = $\frac{shoulder + upper back + elbow + hand}{4}$
		- Lower back
		- Lower extremity = $\frac{hip + knee + feet}{3}$
		- Any site = $\frac{neck+shoulder+upperback+elbow+hand+lowerback+hip+knee+feet}{9}$

**Anxiety and Depression**

Hospital Anxiety and Depression Scale (HADS). (0 to 3 likert scales).

Positive answer should be lowest score (0). Negative answer should be highest score (3).

NOTE: Reverse scoring is in place for some items, these will need to be cross-check against the scoring guide to confirm which items are reverse scored.

* + Anxiety (0-21) = $butterfies+frightened+restless+ease relaxed+sudden panic+tense+worrying thoughts$

Higher scores indicate greater anxiety.

* + Depression (0-21) = $appearance+cheerful+enjoy book tv+enjoy things+funny side+look forward+slowed down$

Higher scores indicate greater depression.

**Social Isolation Short Form**

8-item Social Isolation short form from the Patient-Reported Outcomes Measurement Information System form (1=Never; 5=Always).

* + Raw score (8 to 40)
	+ Scale score (33.9 to 76.9)

Each of the 8 questions has five response options (1=Never; 5=Always). To find the total raw score with all questions answered, sum the values of the response to each question. For example, for this 8-item form, the lowest possible raw score is 8 and the highest is 40.

A score can be approximated if a participant skips a question. If items are missing, confirm that at least 50% of items were answered (i.e. at least 4 questions). After confirming that enough responses were provided, use the formula below to obtain a pro-rated raw score:

Pro-rated raw score = $\frac{raw score × 8 (i.e. number of items in questionnaire) }{number of items that were actually answered (must be \geq 4)}$

For example, if a respondent answered 5 of 8 questions and answered all items with the second lowest response option (2), sum all responses (10), multiply by the number of items in the short form (8) and divide by the number of items that were answered (5). Here (10x8)/5=16. If the result is a fraction, round up to the nearest whole number.

Locate the applicable score conversion table and use this table to translate the total raw score or pro-rated score into a T-score for each participant. The T-score rescales the raw score into a standardized score with a mean of 50 and a standard deviation (SD) of 10. Therefore a person with a T-score of 40 is one SD below the mean. The standardized T-score is reported as the final score for each participant.

For the Social Isolation 8a short form, a raw score of 10 converts to a T-score of 41.4 with a standard error (SE) of 2.4. Thus, the 95% confidence interval around the observed score ranges from 37.0 to 45.8 (T-score + (1.96\*SE) or 41.4 + (1.96\*2.4).

For pro-rated scores, this calculation assumes that responses are missing at random. This isn’t always true. Therefore, use caution when interpreting the final pro-rated T-score.

Higher scores indicate greater perception of social isolation.



**Work Engagement**

Utrecht Work Engagement Scale (UWES) (0=never; 6=always)

* + Vigour = $\frac{burst energy+vigorous+morning }{3}$

Higher scores indicate greater vigour.

* + Dedication = $ \frac{enthusiastic+inspired+proud}{3}$

Higher scores indicate greater dedication.

* + Absorption =$ \frac{intense+immerse+carried away}{3}$

Higher scores indicate greater absorption.

* + Overall = $\frac{energy+vigorous+enthusiasm+inspired+morning+intense+proud+immersed+carried away }{9}$

Higher scores indicate greater work engagement overall.

**Work Demands**

Health and Safety Executive Management Standards Indicator Tool (HSE MSIT) (1=never; 5=always)

* Demands= $\frac{diff. demands+unachievable+intense+neglect tasks+sufficient breaks+long hours+fast+unrealistic}{8}$

Higher scores indicate greater demands.

* Control= $\frac{when break+speed+how work+what work+way work+flexible}{6}$

Higher scores indicate greater control.

* Support = $\frac{feedback+rely+talk+encourage+emotional support+help+support+respect+listen}{9}$

Higher scores indicate greater support.

**Self-reported Driver Safety Behaviour**

The agree/strongly agree and disagree/strongly disagree variables will be combined into agree and disagree and then the proportion of participants that say agree, neither or disagree for each item will be described.

**Fatigue**

Occupational Fatigue Exhaustion Recovery (OFER 15) Scale. Fatigue and strain at work and home OVER THE LAST 6 MONTHS. (0=strongly disagree; 6=strongly agree).

Positive items were reverse scored (r).

Positive answers should be lowest score (0). Negative answers should be highest score (6).

|  |
| --- |
| OFER Scale 15-items |
| **Chronic fatigue** |
| 1) I often feel I’m ‘at the end of my rope’ with my work |
| 2) I often dread waking up to another day of my work |
| 3) I often wonder how long I can keep going at my work |
| 4) I feel that most of the time I’m just “living to work” |
| 5) Too much is expected of me in my work |
| **Acute fatigue** |
| 6) After a work shift I have little energy left |
| 7) I usually feel exhausted when I get home from work |
| 8) My work drains my energy completely every day |
| 9) I usually have lots of energy to give to my family or friends |
| 10) I usually have plenty of energy left for my hobbies and other activities after I finish work |
| **Inter-shift recovery** |
| 11) I never have enough time between shifts to recover my energy completely |
| 12) Even if I’m tired from shift, I’m usually refreshed by the start of the next shift |
| 13) I rarely recover my strength fully between shifts |
| 14) Recovering from work fatigue between shifts isn’t a problem for me |
| 15) I’m often still feeling fatigued from one shift by the time I start the next one |

* + Chronic fatigue = $\frac{at end of my rope + dread + keep going + living to work + expected }{30}×100$

Higher scores indicate greater chronic fatigue.

* + Acute fatigue = $\frac{little energy+exhausted + drain energy + energy family \left(r\right)+energy hobbies (r) }{30}×100$ Higher scores indicate greater acute fatigue.
	+ Inter-shift recovery = $\frac{time to recover +refreshed (r) +rarely recover + not a problem (r) + fatigued}{30}×100$

Higher scores indicate greater inter-shift recovery.

**Morningness-Eveningness Questionnaire - Self-Assessment Version (MEQ-SA)**

This questionnaire has 19 questions, each with a number of points. First, add up the points for each question and enter the total morningness-eveningness score. Scores can range from 16 to 86. Scores of 41 and below indicate "evening types" Scores of 59 and above indicate "morning types". Scores between 42-58 indicate "intermediate types".

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 16-30 | 31-41 | 42-58 | 59-69 | 70-86 |
| definite evening | moderate evening | intermediate | moderate morning | definite morning |

**QRISK3**

**General Health**

Health-related quality of life - EQ-5D-5L:

The EQ-5D-5L is summarised in a continuous score (called a TTO value set), ranging from -0.285 to 1.000, where a higher score indicates higher health utility. The scoring algorithm, available on the EuroQol website [EuroQolweb], is

$$1-\sum\_{i=1}^{5}score\\_i$$

where $score\\_i$ is the score of question $i$ according to the following table:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Selected option | 1 | 2 | 3 | 4 | 5 |
| Question |  |  |  |  |  |
| 1 Mobility | 0 | 0.058 | 0.076 | 0.207 | 0.274 |
| 2 Self care | 0 | 0.050 | 0.080 | 0.164 | 0.203 |
| 3 Usual activities | 0 | 0.050 | 0.063 | 0.162 | 0.184 |
| 4 Pain & discomfort | 0 | 0.063 | 0.084 | 0.276 | 0.335 |
| 5 Anxiety and depression | 0 | 0.078 | 0.104 | 0.285 | 0.289 |

If a subject selects option 3 “Moderate problems walking about” in Q1, score\_1 = 0.076.

 The TTO value set will not be derived for any participants who have any missing items.

Higher scores indicate higher health utility.

**Psychophysiological Reactivity**

* + Mirror tracing task:
	+ Systolic blood pressure (mmHg) (2 measures in addition to physiological measures)
	+ Diastolic blood pressure (mmHg) (2 measures in addition to physiological measures)
	+ Heart rate (bpm) (2 measures taken)

To calculate reactivity to stress, the mean SBP, DBP and HR taken from these 2 measures recorded during the stress task will be calculated. The mean SBP, DBP and HR values taken at rest will be then be subtracted from the mean measures taken during the stress task, the differences in values indicate the stress reactivity measure (for SBP, DBP, HR).

**Dietary Quality Score**

|  |  |  |  |
| --- | --- | --- | --- |
|  Score allocated: | 1 | 2 | 3 |
| Fruit | <= 2 servings/wk | >2 servings/wk and < 2 servings/day | >= 2 servings/day |
| Vegetables | <=1 servings/day | 1 – 3 servings/day | >= 3 servings/day |
| Oily Fish | No intake | 0 – 200g/wk | >= 200g/wk |
| Fat | >= 1 ½ x UK recommendations (127.5g/day) | 1 – 1 ½ x UK recommendations | <= UK recommendations (85g/day) |
| NMES | >= 1 ½ x UK recommendations (90g/day) | 1 – 1 ½ x UK recommendations | <= UK recommendations (60g/day) |
| DQS | Sum of fruit, vegetables, oily fish, fat and NMES. (Range: 5 to 15) |

- Fruit

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Frequency info (grams/day) | No response | Rarely or never | Less than 1 a Week | Once a Week | 2-3 times a Week | 4-6 times a Week | 1-2 times a Day | 3-4 times a Day | 5+ a Day |
| Fruit  | 0 | 0 | 4 | 11.2 | 28.8 | 56.80 | 120 | 280 | 480 |

Create fruit frequency information to allocate fruit consumption score.

|  |  |
| --- | --- |
| Frequency | Score allocated |
| <22.9  | 1 | <= 2 servings/wk |
| >22.9 & <160 | 2 | >2 servings/wk and < 2 servings/day |
| >160 | 3 | >= 2 servings/day |

- Vegetables

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Frequency info (grams/day) | No response | Rarely or never | Less than 1 a Week | Once a Week | 2-3 times a Week | 4-6 times a Week | 1-2 times a Day | 3-4 times a Day | 5+ a Day |
| Salad | 0 | 0 | 4 | 11.20 | 28.80 | 56.70 | 120 | 280 | 480 |
| Vegetables | 0 | 0 | 4 | 11.20 | 28.80 | 56.80 | 120 | 280 | 480 |

Sum frequency information for salad and vegetables to obtain overall vegetables frequency information to allocate vegetable consumption score.

|  |  |
| --- | --- |
| Frequency | Score allocated |
| <80 | 1 | <=1 servings/day |
| >80 & <240  | 2 | 1 to 3 servings/day |
| >240 | 3 | >= 3 servings/day |

- Oily fish

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Frequency info (grams/day) | No response | Rarely or never | Less than 1 a Week | Once a Week | 2-3 times a Week | 4-6 times a Week | 7+ times a week |
| Oily fish | 0 | 0 | 4.5 | 12.6 | 32.4 | 63.9 | 102.6 |

Create oily fish frequency info to obtain oily fish consumption score.

N.B. 28.6 grams/day × 7 days = 200.2 grams/week

|  |  |
| --- | --- |
| Frequency | Score allocated |
| <0.001 | 1 | No intake |
| >0.001 & <28.6  | 2 | 0 to 200g/wk |
| >28.6 | 3 | >= 200g/wk |

- Fat

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fat content info | No response | Rarely or never | Less than 1 a Week | Once a Week | 2-3 times a Week | 4-6 times a Week | 1-2 times a Day | 3-4 times a Day | 5+ a Day |
| Fruit | 0.00 | 0.00 | 0.01 | 0.03 | 0.07 | 0.14 | 0.30 | 0.70 | 1.20 |
| Fruit juice | 0.00 | 0.00 | 0.00 | 0.01 | 0.02 | 0.03 | 0.07 | 0.17 | 0.29 |
| Salad | 0.00 | 0.00 | 0.50 | 1.39 | 3.58 | 7.06 | 14.91 | 34.78 | 59.63 |
| Vegetables | 0.00 | 0.00 | 0.13 | 0.36 | 0.94 | 1.85 | 3.90 | 9.11 | 15.62 |
| Chips | 0.00 | 0.00 | 0.35 | 0.97 | 2.49 | 4.90 | 10.36 | 24.18 | 41.44 |
| Beans | 0.00 | 0.00 | 0.02 | 0.05 | 0.14 | 0.27 | 0.56 | 1.32 | 2.26 |
| Cereal | 0.00 | 0.00 | 0.23 | 0.65 | 1.66 | 3.28 | 6.93 | 16.18 | 27.73 |
| Wholemeal | 0.00 | 0.00 | 0.28 | 0.78 | 2.00 | 3.94 | 8.33 | 19.44 | 33.33 |
| Cheese | 0.00 | 0.00 | 0.64 | 1.79 | 4.61 | 9.10 | 19.22 | 44.85 | 76.88 |
| Crisps | 0.00 | 0.00 | 6.39 | 17.88 | 45.98 | 90.68 | 191.58 | 447.02 | 766.32 |
| Biscuits | 0.00 | 0.00 | 1.10 | 3.08 | 7.92 | 15.61 | 32.98 | 76.95 | 131.92 |
| Ice cream | 0.00 | 0.00 | 0.59 | 1.65 | 4.24 | 8.35 | 17.65 | 41.18 | 70.59 |
| Fizzy drinks | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.01 | 0.02 | 0.04 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Fat content info | No response | Rarely or never | Less than 1 a Week | Once a Week | 2-3 times a Week | 4-6 times a Week | 7+ times a week |
| Whole meats: | Red meat | 0 | 0 | 0.599595 | 1.678865 | 4.317081 | 8.514243 | 13.67076 |
| White meat | 0 | 0 | 0.408262 | 1.143133 | 2.939484 | 5.797316 | 9.308367 |
| Processed meats: | Sausage | 0 | 0 | 1.179906 | 3.303738 | 8.495325 | 16.75467 | 26.90186 |
| Nuggets | 0 | 0 | 0.393676 | 1.102294 | 2.834471 | 5.590206 | 8.975824 |
| Fish: | Battered fish | 0 | 0 | 0.479844 | 1.343563 | 3.454875 | 6.813781 | 10.94044 |
| White fish | 0 | 0 | 0.115315 | 0.322882 | 0.830269 | 1.637475 | 2.629185 |
| Oily fish | 0 | 0 | 0.675167 | 1.890467 | 4.8612 | 9.587367 | 15.3938 |

Sum fat content info for all items to obtain fat score info to allocate fat consumption score.

|  |  |
| --- | --- |
| Frequency | Score allocated |
| >127.5 | 1 | >= 1 ½ x UK recommendations (127.5g/day) |
| >85 & <127.5 | 2 | 1 to 1 ½ x UK recommendations |
| <85 | 3 | <= UK recommendations (85g/day) |

- NMES

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| NMES content info | No response | Rarely or never | Less than 1 a Week | Once a Week | 2-3 times a Week | 4-6 times a Week | 1-2 times a Day | 3-4 times a Day | 5+ a Day |
| Fruit | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Fruit juice | 0.00 | 0.00 | 0.30 | 0.83 | 2.13 | 4.20 | 8.88 | 20.72 | 35.52 |
| Salad | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Vegetables | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Chips | 0.00 | 0.00 | 0.03 | 0.08 | 0.20 | 0.39 | 0.83 | 1.93 | 3.31 |
| Beans | 0.00 | 0.00 | 0.13 | 0.37 | 0.95 | 1.86 | 3.94 | 9.19 | 15.76 |
| Cereal | 0.00 | 0.00 | 1.18 | 3.31 | 8.51 | 16.79 | 35.47 | 82.76 | 141.87 |
| Wholemeal | 0.00 | 0.00 | 0.20 | 0.56 | 1.44 | 2.84 | 6.00 | 14.00 | 24.00 |
| Cheese | 0.00 | 0.00 | 0.35 | 0.97 | 2.50 | 4.94 | 10.44 | 24.35 | 41.75 |
| Crisps | 0.00 | 0.00 | 0.22 | 0.62 | 1.58 | 3.12 | 6.60 | 15.40 | 26.40 |
| Biscuits | 0.00 | 0.00 | 2.12 | 5.93 | 15.26 | 30.10 | 63.58 | 148.36 | 254.33 |
| Ice cream | 0.00 | 0.00 | 0.87 | 2.44 | 6.27 | 12.36 | 26.11 | 60.92 | 104.43 |
| Fizzy drinks | 0.00 | 0.00 | 0.21 | 0.58 | 1.49 | 2.94 | 6.21 | 14.50 | 24.86 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| NMES content info | No response | Rarely or never | Less than 1 a Week | Once a Week | 2-3 times a Week | 4-6 times a Week | 7+ times a week |
| Whole meats: | Red meat | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| White meat | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Processed meats: | Sausage | 0 | 0 | 0.14675 | 0.4109 | 1.0566 | 2.08385 | 3.3459 |
| Nuggets | 0 | 0 | 0.028088 | 0.078647 | 0.202235 | 0.398853 | 0.640412 |
| Fish: | Battered fish | 0 | 0 | 0.000938 | 0.002625 | 0.00675 | 0.013313 | 0.021375 |
| White fish | 0 | 0 | 0.010378 | 0.029059 | 0.074723 | 0.14737 | 0.236622 |
| Oily fish | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Sum NMES content info for all items to obtain NMEs score info to allocate NMES score.

|  |  |
| --- | --- |
| Frequency | Score allocated |
| >90 | 1 | >= 1 ½ x UK recommendations (90g/day) |
| >60 & <90 | 2 | 1 to 1 ½ x UK recommendations |
| <60 | 3 | <= UK recommendations (60g/day) |

- DQS (range 5 to 15)

$$DQS=fruit score+vegetables score+oily fish score+fat score+NMES score$$

Worked example:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Category** | **Answer** | **Score info** | **Score category** | **Score** |
|  | **Fruit** | 2-3 times/week | 28.8 | >22.9 & <160 frequency info | 2 |
|  | **Veg** | 2-3 times/week | 29+28.8 = 57.8 | <80 frequency info | 1 |
|  | **Oily fish** | 2-3 times/week | 32.4 (i.e. 226.8/week) | >28.6 | 3 |
|  |  |  |  |  |  |
| **Fat score calculation:** | Fruit | 2-3 times/week | 0.07 |  |  |
|  | Fruit juice | 2-3 times/week | 0.02 |  |  |
|  | Salad | 2-3 times/week | 3.58 |  |  |
|  | Vegetables | 2-3 times/week | 0.94 |  |  |
|  | Chips | 2-3 times/week | 2.49 |  |  |
|  | Beans | 2-3 times/week | 0.14 |  |  |
|  | Cereal | 2-3 times/week | 1.66 |  |  |
|  | Wholemeal | 2-3 times/week | 2 |  |  |
|  | Cheese | 2-3 times/week | 4.61 |  |  |
|  | Crisps | 2-3 times/week | 45.98 |  |  |
|  | Sweet biscuits | 2-3 times/week | 7.92 |  |  |
|  | Ice cream | 2-3 times/week | 4.24 |  |  |
|  | Fizzy drinks | 2-3 times/week | 0 |  |  |
|  | Red meat | 2-3 times/week | 4.317081 |  |  |
|  | White meat | 2-3 times/week | 2.939484 |  |  |
|  | Sausage | 2-3 times/week | 8.495325 |  |  |
|  | Nuggets | 2-3 times/week | 2.834471 |  |  |
|  | Battered fish | 2-3 times/week | 3.454875 |  |  |
|  | White fish | 2-3 times/week | 0.830269 |  |  |
|  | Oily fish | 2-3 times/week | 4.8612 |  |  |
|  | Total |  | 101.382705 |  |  |
|  | **Fat score** |  |  | >85 & <127.5 | 2 |
|  |  |  |  |  |  |
| **NMES score calculation:** | Fruit | 2-3 times/week | 0 |  |  |
|  | Fruit juice | 2-3 times/week | 2.13 |  |  |
|  | Salad | 2-3 times/week | 0 |  |  |
|  | Vegetables | 2-3 times/week | 0 |  |  |
|  | Chips | 2-3 times/week | 0.2 |  |  |
|  | Beans | 2-3 times/week | 0.95 |  |  |
|  | Cereal | 2-3 times/week | 8.51 |  |  |
|  | Wholemeal | 2-3 times/week | 1.44 |  |  |
|  | Cheese | 2-3 times/week | 2.5 |  |  |
|  | Crisps | 2-3 times/week | 1.58 |  |  |
|  | Sweet biscuits | 2-3 times/week | 15.26 |  |  |
|  | Ice cream | 2-3 times/week | 6.27 |  |  |
|  | Fizzy drinks | 2-3 times/week | 1.49 |  |  |
|  | Red meat | 2-3 times/week | 0 |  |  |
|  | White meat | 2-3 times/week | 0 |  |  |
|  | Sausage | 2-3 times/week | 1.0566 |  |  |
|  | Nuggets | 2-3 times/week | 0.202235 |  |  |
|  | Battered fish | 2-3 times/week | 0.00675 |  |  |
|  | White fish | 2-3 times/week | 0.074723 |  |  |
|  | Oily fish | 2-3 times/week | 0 |  |  |
|  | Total |  | 41.670308 |  |  |
|  | **NMES score** |  |  | <60 | 3 |
|  |  |  |  |  |  |
|  | **DQS** |  |  |  | 11 |