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Towards targeted dietary support for shift-workers with type 2 diabetes (Shift-Diabetes Study): a mixed-methods case study protocol

Short running title: Shift-Diabetes mixed-methods study protocol

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Abstract

Background Blood glucose is higher in people working night-shifts compared to day-workers. Changes to eating behaviour, activity, and sleep patterns in addition to circadian disruption are likely to impact glucose management in night-shift workers with Type 2 diabetes.

Aim To investigate current dietary intake and glucose variability during night work, including barriers and facilitators to dietary behavior in this context.

Methods A mixed-methods case study will be conducted. Shift workers with Type 2 diabetes working in a hospital setting will be recruited to this two-part study. Part 1: 70 participants will complete a 10-day observational study collecting data on continuous glucose, diet (self-report diary), sleep and physical activity during a period covering night work, rest days and non-night workdays. Mean glucose concentration and variability, and the mean healthy diet index score, will be compared between days of night work, non-night work and rest, after adjusting for other individual factors (sleep/physical activity/demographics). Part 2: A sample (n~13) will complete semi-structured interviews based on behavioural science frameworks to explore barriers/enablers to dietary behaviour when working night shifts. This will inform a quantitative survey to explore the generalisability of interview findings.

Discussion Findings from Part 1 and 2 will be triangulated to identify potential intervention strategies to address key barriers and enablers to healthier eating, and in turn improved glucose control, in shift workers with Type 2 diabetes. This will be facilitated through stakeholder consultation and application of behavioural science frameworks.

Shift-Diabetes Study registration: ISRCTN11764942.

Key words: Type 2 diabetes, Shift work, Glycemic variability, Eating patterns, Theoretical Domains Framework

Background

Shift workers are at increased risk of developing type two diabetes (1) and are more likely to have diagnosed and undiagnosed Type 2 diabetes than day workers (2). Shift work in the UK is defined as working outside 7 a.m. and 7 p.m. (3) and includes various time arrangements for example, early, late, night, fixed, rotating and on call. Shift work results in changes to normal daily activities and physiology from altered eating, activity and sleep patterns to the disruption of circadian rhythms (4,5). Night-shift work requires the inversion of the working day and related activities and is therefore hypothesized to be a particular risk to health. The number of employees working night shifts increased by 9% between 2011 and 2016 in the UK (6) and with the move towards 24-hr economy it is forecast to continue to increase.

In terms of dietary behavior, night-shift workers compared to day workers are more likely to report a diet that is of a poorer quality, an increased number of eating occasions (7) and a redistribution of dietary intake across the 24-hr period (8). Timing of nutritional intake is an emerging area of nutritional research referred to as 'chrono-nutrition'. Observational research has shown that consuming a higher percentage of daily energy intake in the evening to be associated with poorer cardiometabolic health outcomes (9). Acute human feeding studies in healthy volunteers have demonstrated elevated and prolonged plasma glucose and triglyceride peaks following meals consumed in the biological evening (10). Additionally, consuming a high, compared to a low, glycemic index meal may potentiate the effect of postprandial glucose response when consumed in the evening compared to morning (11). Although studies are limited in people with Type 2 diabetes, increasing the proportion of energy consumed early in the day can improve glucose control, independent of energy intake (12). Additionally, night workers with Type 2 diabetes have been shown to have a higher HbA1c compared to people who do not work night-shifts (13).

In the UK, structured education programmes X-PERT and DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed) are available to support people with Type 2 diabetes to manage their condition. However, these programmes are based around a normal day working shift pattern, and do not cater - in practical or physiological terms - for employees with Type 2 diabetes working night-shifts. Research conducted in Danish healthcare workers reported that night workers were less likely to be engaged in workplace health interventions (14). Studies in non-healthcare shift working populations have highlighted that the lack of take-up of workplace health programmes was related to the programmes not being tailored to the specific environment and needs of shift working employees (15,16).

Currently there are no evidence-based workplace guidance or interventions specifically designed to support the growing number of people with Type 2 diabetes employed in jobs requiring night-shift work. Our pre-study hospital staff survey indicated that people with Type 2 diabetes who do shift-work believe that standard advice does not work for them, but have received no evidence-based, targeted support or advice. Understanding the impact of night-shift work on diet, sleep, activity and glucose control in employees with Type 2 diabetes is key to developing targeted interventions for night workers to improve health outcomes.

Aim

Shift-Diabetes aims to address key research gaps which currently limit our ability to design lifestyle interventions tailored to the needs of night shift-workers with Type 2 diabetes, including:

1. How does blood glucose control differ quantitatively and qualitatively in those with Type 2 diabetes when they work night shifts compared to day shifts or rest days?
2. How does dietary intake change during night shifts, day shifts and rest days?
3. What are the individual, social and environmental factors influencing dietary behaviour in shift workers with Type 2 diabetes?

Study design

This is a mixed-methods quantitative and qualitative study involving two interrelated parts as shown in **Figure 1**. Part 1 is an observational study collecting data on glycaemia, diet, sleep and physical activity in free-living workers with Type 2 diabetes during a 10-day period covering night work, rest days and non-night workdays; outcome measures are summarised in **Table 1**. Part 2 comprises of theory-based qualitative interviews and quantitative surveys to explore influences on dietary behavior in night-shift workers.

Part 1: Quantitative observational study

Participant eligibility and recruitment

In the UK the caring services are one of the highest employers of night workers in the UK (6). This study will recruit shift workers working in hospital and care settings. The study will be advertised using posters distributed throughout hospitals and via a targeted social media campaign.

Male and female shift workers aged 18 to 60 years with diagnosed Type 2 diabetes who work night shifts as part of a mixed shift schedule will be recruited to the study. The study will recruit participants with Type 2 diabetes controlled by lifestyle and/or acarbose, metformin, dipeptidyl peptidase 4 (DPP4) inhibitors or sodium-glucose co-transporter-2 (SGLT2) inhibitors. Shift-workers managing their diabetes with medications with hypoglyceamia risk would potentially have different presenting barriers and behaviours (e.g. avoidance of hypoglyceamia) and warrant separate investigation.

Glycemic parameters

Participants will be fitted with a blinded CGM device (Dexcom G6, Dexcom, San Diego) at study visit 1 and this will remain in situ until removal and study visit 2. The CGM will measure glucose concentration in the interstitial fluid at 5-minute intervals. In addition to mean glucose concentrations, the CGM data will allow the calculation of validated metrics of glycaemic variability including mean amplitude of glucose excursions (MAGE), continuous overall net glycemic action (CONGA) and other indices of high-and low-blood glucose risk (17). The extracted CGM data will be analysed using a previously published protocol (Easy-GV) (18). Chosen metrics include variability independent of the mean (CV), size of excursion (MAGE), times in moderate and more severe hyperglycaemic ranges, and will be sub-analysed by time period, enabling participants to be their own controls, increasing the sensitivity of the analysis to potentially smaller changes.

Dietary intake

Participants will be asked to record their food intake during the 10-day monitoring period in a paper form diet record, adapted from a UK validated 7-day food record (19). Diet records currently provide the most reliable method of measuring dietary behaviour in shift workers (20). Predefined eating occasions have been removed to allow a timed recording for each eating occasion. At study visit 1 the diet record will be given to participants with detailed instructions to record all food and drink consumed, where they ate and the time. To assist in portion size estimation photographs will be provided (21). The dietary records will be coded (the process of translating self-report food intake into electronic nutrient and food intake data) by trained coders using nutritional software package (Nutritics, Research Edition, Dublin) following a previously established protocol (22). The dietary variables will be calculated across each type of work day (night work, rest day, non-night workday) detailed in **Table 1.**

Sleep, physical activity and shift type

Participants will be asked to wear a light-weight combined actigraphy and accelerometer device (ActiGraph GT9X Link, ActiGraph LLC; Pensacola, FL, USA) on their nondominant wrist for the duration of the monitoring period to measure physical activity and sleep parameters. Intensity, duration, and frequency of physical activity will be measured via the accelerometer over the 10-day monitoring period. Data will be collected in 30-second epochs and raw data generated using ActiLife software (ActiGraph LLC; Pensacola, FL) and processed using GGIR package in R (23). Wrist actigraphy is widely used as an objective measure of sleep in free-living study populations and has been validated against polysomnography (24). If participants are unable to comply to wearing the device on their wrist due to workplace health and safety requirements, during working hours participants will wear the device positioned at their waist during working hours. The parameters of sleep generated from actigraphy data are detailed in **Table 1.** In addition, over the 10-day period information on sleep quality and measures of daytime sleepiness/function will be recorded by participants. Participants we also record each day the hours worked (time shift start, and time shift end).

Blinding and compliance

The CGM and actigraphy devices will be set to 'blind' mode to avoid participants changing their typical diet, activity and sleep habits during the monitoring period. Participants will be asked to maintain usual dietary intake through the monitoring period however, it is possible that recording dietary intake may lead to reactivity bias. To date there is no comprehensive and objective measure of dietary intake available, or any effective way of recording temporal dietary intake.

Data analysis

Primary Analysis: Within individual average glucose variability (both CV and other measures) during night shifts, non-night workday and rest days will be calculated, and their differences tested by repeated measures ANOVA overall and in pairs by t test for dependent samples. The same statistical estimation and testing will be applied to the within individual healthy diet index score to assess differences between the three work conditions. To account for the potential effect of confounders, repeated measures ANCOVA will also be applied, i.e., to estimate the difference in glucose variability and healthy diet index between the type of shift/day independently of the potential influence of physical activity/demographics and additionally of the healthy diet index when the outcome is glucose variability.

Secondary analysis: Additionally, as this study is an observational study, multivariate statistical analyses considering the days as observational units will be undertaken to describe (i) the daily nutrient and food intake time patterns at specified intervals (hourly or by time of day) by dimensionality reduction techniques (Principal Component Analysis, Latent Class Analysis). The value of both PCA and LCA analyses is to be able to capture similarities between days/shift in the dietary behaviour patterns through the duration of the shift, thus facilitating the identification of so-called diurnal patterns. The rationale and application of these techniques to dietary data across the day and with repeated measures are explained in greater detail in previous studies (25,26). The association between the day scores (obtained by PCA) or the classes (obtained by LCA) thus obtained with the type of working day (e.g., night shift, rest day or non-night workdays) and with summary measures of glucose variability within the day will then be investigated by chi square tests and regression models. To bring together the primary and secondary analysis, further mixed-effects regression models will also be implemented with glucose variability index as the outcome and type of shift/day as exposure including diurnal eating pattern scores obtained by PCA and summary variables on sleep and physical activity as additional covariates, to try and disentangle the relationships among all important components of blood glucose control. In these mixed effect models, the observational unit of analysis will be days, with individuals as the clustering unit. Relevant confounders will be also accounted for at cluster level (e.g. age, sex). The analyses will be carried out via Stata 16 software.

Sample size

As the first study of its kind, there was no indication from the literature on the variability in a representative population sample. A sample size of 70 would grant a power of at least 80% to detect a shift type difference in the Coefficient of Variation (CV) of 10% from 32% (average CV reported previously in people living with Type 2 diabetes (27) to 42% when measuring the CV based on repeated measures every 5 minutes (assuming observational duration of 12 or 16 hours) in independent subjects, in a two-sided t test with 5% type I error (28). This was an overestimate of the sample size as the within subject design would require lower numbers than the between subject design to achieve the same power. A sample size of 70 additionally provides a 99% power of detecting a difference of 2 points in the diet index from 3.6 to 5.6 assuming SD 3.1(29) and a correlation between paired data of 0.2 in a paired mean test. The detectable differences would be considered of clinical significance for both %CV and dietary index score. The aim is to recruit 100 participants, assuming a drop-out of 30%.

Part 2: Behavioral analyses

Semi-structured interviews

Based on sample size estimations for qualitative research (30), an initial sample of ~13 participants will be recruited for the in-depth semi-structured interviews, conducting additional interviews as required until thematic saturation is deemed achieved (i.e. no new themes emerge from additional participants interviewed). The inclusion criteria will be the same as the monitoring study (Part 1). Participants will either be recruited to take part in the qualitative interview or recruited to the qualitative interview following completion of Part 2 of the study. This will avoid potential changes in habitual diet in participants that have participated in the interview.

The semi-structured interview topic guide will be based on two behavioural science frameworks: the COM-B model (Capability, Opportunity, Motivation- Behaviour)(31) and the Theoretical Domains Framework (TDF) (32), which integrates 33 behaviour change theories into 14 domains representing the range of individual, socio-cultural and environmental influences on behavior (i.e. knowledge, perceived consequences, social norms, identity, environmental context and resources) **Figure 2**. These frameworks have been used to explore influences on a wide range of behaviours (33), including barriers/enablers attendance for diabetic retinopathy screening (34,35) and sustained self-management in type 1 diabetes (36). The interview guide will contain at least one question to investigate the influence of each of the framework domains on dietary behaviour. The interview topic guide will be developed in collaboration with our research steering group, which includes shift workers with Type 2 diabetes.

Interviews lasting a maximum of 1-hour will be conducted either face-to-face or remotely according to participant preference. Interviews will be digitally recorded, transcribed verbatim, and fully anonymised to remove any identifiable information. Transcripts will be analysed according to best practice guidance for applying the TDF (37), using a combined deductive framework and inductive thematic analysis approach. Individual participant responses will be first deductively coded according to the TDF domain they are judged to best represent. Similar responses coded to each domain will be grouped, and a theme label inductively generated summarising the role that domain plays in facilitating/hindering dietary behaviour.

Survey

All remaining participants in Part 1 (excluding interview participants) will be sent an email inviting them to complete the on-line survey, including a link to the survey and participant information sheet. The survey will aim to explore the generalizability of the interviews in a larger more representative sample. The survey will collect data on participant demographics (age, gender, years of diagnosis Type 2 diabetes). To explore barriers/enablers to dietary behavior, themes generated in the analysis of interview data will be converted to survey items, to which participants will be asked to rate their agreement on a Likert-type scale from 1 – Strongly disagree to 7-Strongly agree. At least 1 item for each of the 14 TDF domains will be included. For instance, 'I regularly pay attention to and monitor what I am eating' would tap into the domain 'Behavioural Regulation;' 'It is not a priority for me to eat healthily' would tap into the domain 'Motivation' and 'There are plenty of readily accessible, healthy food options during my night shift' would tap into the domain 'Environmental Context and Resources.' The survey will be developed by our research steering group and will be piloted to ensure clarity, comprehension and face validity. The survey will aim to be exploratory rather than predictive, therefore responses will be analysed and summarised using descriptive statistics as appropriate. Scale scores will be calculated for each TDF domain by averaging scores on items mapped to each domain (38).

The outcome for Part 2 is to identify the key individual, socio-cultural and environmental factors influencing dietary behaviour in shift workers with Type 2 diabetes and their association with dietary behavior and glucose control.

Integration of Part 1 and Part 2 results

The data collected in Part 1 and Part 2 will be triangulated – a standard approach to integrate qualitative and quantitative data in mixed methods studies (39). Through this process potential intervention strategies to address key barriers and enablers to healthier eating, and in turn improved glucose control, in shift workers with Type 2 diabetes will be identified. This will be facilitated through stakeholder consultation and application of behavioural science frameworks.

The Behaviour Change Wheel (40) and Taxonomy of behavior change techniques (41) will be consulted to generate descriptions of potential candidate intervention strategies to address the key barriers/enablers identified in our TDF-based surveys and interviews. The Behaviour Change Wheel is a synthesis of 19 frameworks of intervention strategies. It proposes 8 intervention functions and 9 policy categories which represent broad means by which behaviour may be changed (e.g. education, modelling, environmental restructuring, persuasion) (40), **Figure 2.** These functions are made up of smaller component techniques (e.g. goal setting, action planning, self-monitoring, prompts, cues), summarised in a Taxonomy of 93 behaviour change techniques (41). These interlinked frameworks have been increasingly applied to develop interventions for a range of complex behaviours (40).

The potential candidate interventions will be presented in a joint half-day workshop which will be attended by night shift workers with Type 2 diabetes, our research steering and executive committee members, and other key stakeholders (e.g., from facilities, catering, occupational health). Attendees will be asked to discuss each candidate intervention against the APEASE criteria (Acceptability, Practicability, Effectiveness/cost-effectiveness, Affordability, Safety/side-effects, Equity) (40). On this basis, we will identify the best candidate intervention(s) will be identified and taken forward in future research applications for development, piloting and evaluation.

Both the Behaviour Change Wheel and Taxonomy have been mapped to the TDF to guide decision making and facilitate systematic, transparent intervention design, by suggesting which types of intervention functions and techniques are likely more/less relevant and effective to addressing barriers/enablers within a given TDF domain.

Pilot data

Prior to commencing this project, a workplace survey was carried out at a local hospital to anonymously assess workers views of managing their diabetes in the workplace. This survey found that shift-workers with diabetes report a lack of time-off, and the structured education being based on normal working and eating patterns as barriers to their enrolment in a workplace structured education program. This survey informed the design of this study. In addition, the study will be overseen by a steering committee which includes current/previous shift workers and healthcare workers with Type 2 diabetes.

Research ethics approval

Ethics approval has been obtained from King's College London BDM Research Ethics Subcommittee (Ref: HR-19/20-14630).

Discussion

This study, the first of its kind, aims to assess the current status of Type 2 diabetes management in night shift workers in the UK. The ultimate aim of this work is to develop tailored structured education programmes which are co-designed by night-shift workers with Type 2 diabetes to meet the needs of this unique group. While there is increasing literature describing lifestyle behaviours in shift workers (42), there is a paucity of research that has focused on shift workers with diabetes.

The strengths of using a mixed method approach are two-fold. Firstly, the collection of temporal diet, activity, and sleep data will allow us to map key modifiable behaviors against real-time blood glucose variability. Secondly, the quantitative data will be combined with qualitative data exploring the facilitators and barriers to behaviours associated with glucose variability measures of concern. A further strength of this study will be the inclusion of a steering group which includes people living with Type 2 diabetes, shift-workers, Human Resources leads, facilities, dietitians working in workplace wellbeing and diabetes. This will ensure the offshoots of this study and future intervention work are feasible and meet the needs of relevant stakeholders and patients themselves.

Despite the strengths of this approach there are potential pitfalls. This study has selected to recruit a sample population from one of largest shift working employers in the UK. The authors acknowledge that the totality of findings from the study may not be generalizable to employees in different worksite settings (e.g., paramedics, firefighters), due to different occupational exposures. As Type 2 diabetes is not an occupational health notifiable condition it is not possible to determine how representative this population sample will be of all those working shifts with Type 2 diabetes. Therefore, the study will help to characterise this population group. The COVID19 pandemic is disproportionally affecting healthcare workers and changes to working patterns may increase night work exposure across the healthcare work force. The challenges that people employed in night work face during the pandemic may not be representative of the challenges at other times. There may also be difficulties in recruitment due to the additional demands on the time of healthcare workers.

The COVID19 pandemic may also add to the urgency of this work. Emerging evidence suggests that people with Type 2 diabetes are at increased risk of death from COVID19, with those with uncontrolled blood glucose being at highest risk (43). This study supports the recommendations made by Public Health England to improve blood glucose to reduce the adverse outcomes associated with COVID19 (44).

In summary, this study aims to answer key questions around diet behaviours and glucose control in shift workers. Through a mixed method approach, it will be able to determine key targets for future intervention development. These could include policy level interventions or structural interventions (i.e., around food outlets/availability in hospitals) and individual targeted ones (diaries, action plans, habit formation, self-monitoring etc.). The next step after the Shift-Diabetes study would be to pilot the developed intervention for feasibility and acceptability.

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Table 1 Research outcomes for Part 1 of SHIFT-Diabetes

Domain	**Method of measurement**	**Outcome measurements**
Blood glucose variability	Continuous glucose monitoring	• Coefficient of variation • Mean amplitude of glycemic excursion (MAGE) • Duration of time in target and time (time above target (>10 and >15mmol/L) and subdividing the data into day and night across hourly time blocks. • Duration of time with target blood glucose of range [3.9-10 mmol/l].
Dietary measures	Daily dietary record	• Diet quality: UK-DRV index - to determine adherence to UK healthy eating guidelines • Eating patterns: temporal distribution (time, frequency) of energy intake from total carbohydrates, added sugar, total fat, saturated fat and protein, fiber and sodium. • Food choices: food groups recorded by time of day: fruit and vegetables, whole grains, confectionary and sugar sweetened beverages) • Location of eating: workplace, commute, home, out of home.
Sleep	Daily sleep record and continuous actigraphy	• Sleep occasions (time, duration and frequency) • Sleep latency • Sleep efficiency.
Physical activity	Continuous actigraphy	• Periods of sedentary, moderate and high activity

Figure 1 SHIFT-Diabetes Study Schematic

Figure 2 Theoretical Domains Framework, COM-B Model and Behaviour Change Wheel

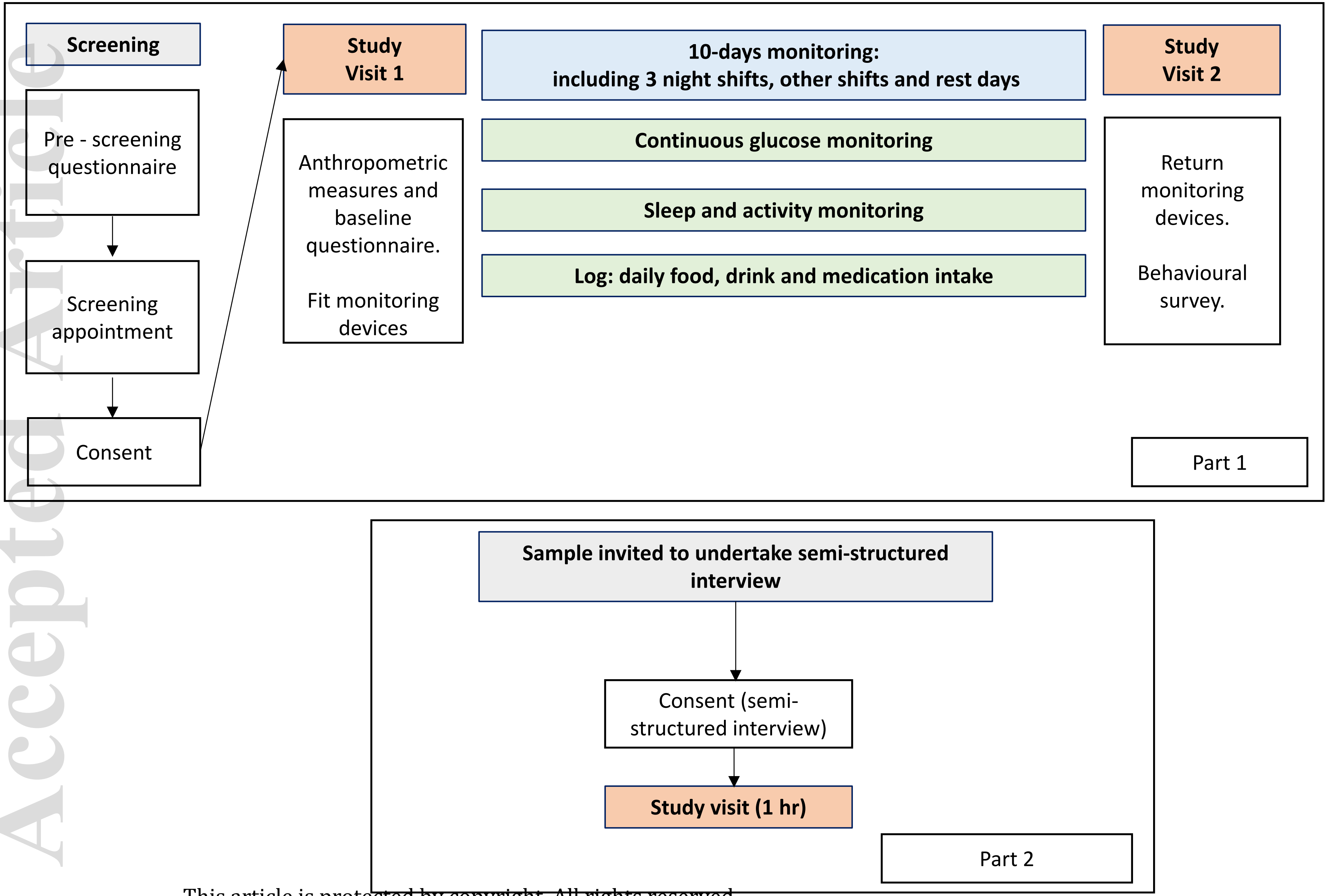
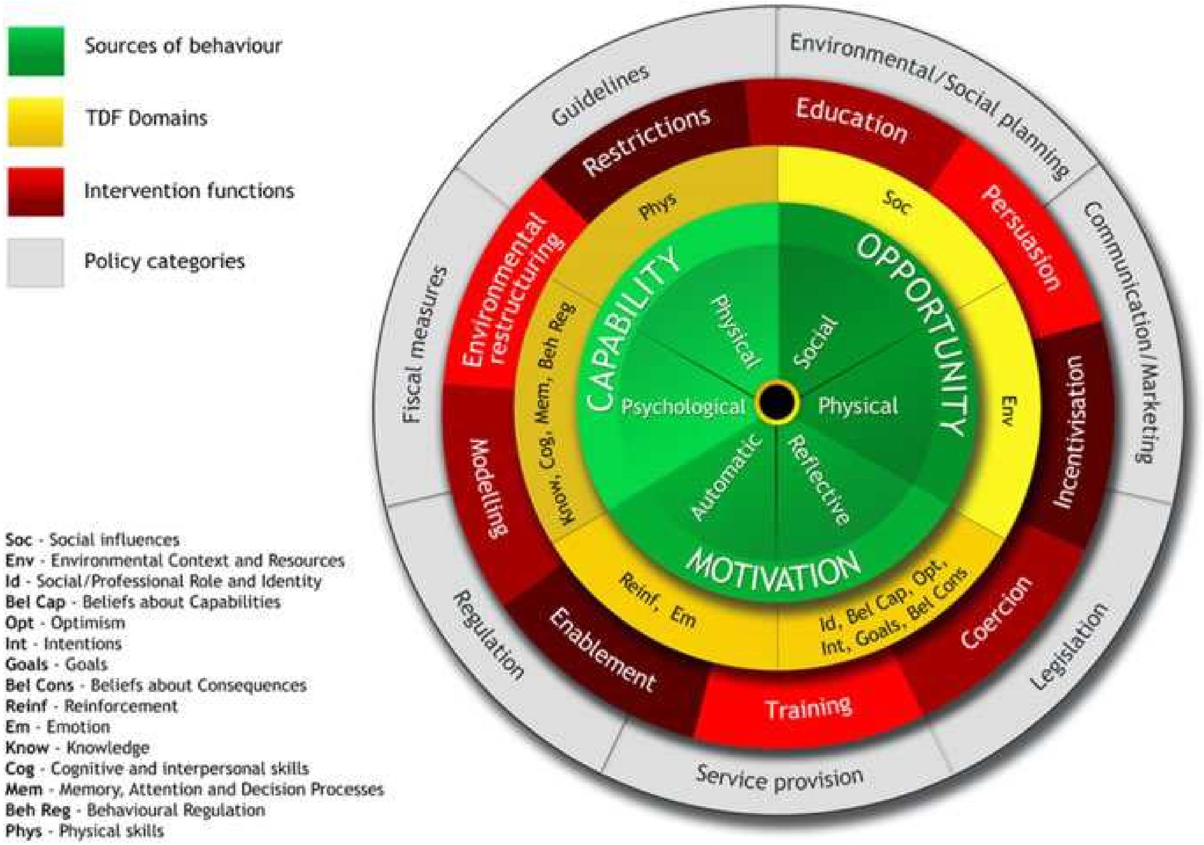

Screening
Pre - screening questionnaire
Screening appointment
Consent
Study Visit 1
Anthropometric measures and baseline questionnaire.
Fit monitoring devices
10-days monitoring:
including 3 night shifts, other shifts and rest days
Continuous glucose monitoring
Sleep and activity monitoring
Log: daily food, drink and medication intake
Study Visit 2
Return monitoring devices.
Behavioural survey.
Part 1
Sample invited to undertake semi-structured interview
Consent (semi-structured interview)
Study visit (1 hr)
Part 2

Figure 2 Theoretical Domains Framework, COM-B Model and Behaviour Change Wheel



Michie S, Atkins L, West R. The behaviour change wheel. A guide to designing interventions. 1st ed. Great Britain: Silverback Publishing. 2014:1003-10.