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Towards targeted dietary support for shift-workers with type 2 diabetes

Submission date
24/02/2020

Recruitment status
No longer recruiting

Registration date
25/02/2020

Overall study status
Completed

Last Edited
20/07/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The number of people who work shift-work is on the rise, and this includes people with type 2 diabetes. Changes to circadian rhythms can increase blood glucose concentrations and the risk of heart disease. Our preliminary work shows that shift-workers with type 2 diabetes are not being supported to manage their diabetes. There is an urgent need to develop targeted interventions for these individuals. This study is the first step is to understand more about glucose control and dietary intake in shift-workers with type 2 diabetes and barriers to management. The overall purpose of this study is to collect information to help design guidance for shift-workers to manage their type 2 diabetes and ultimately improve their long term-health.

Who can participate?
Male and female shift workers aged between 18 and 60 years, with type 2 diabetes employed in a hospital or residential care setting will be eligible to participate. Diabetes should be managed only by lifestyle (diet, activity), or medications not associated with hypoglycemic risk (e.g. acarbose, metformin DPP4 inhibitors, SGLT2 inhibitors)

What does the study involve?
There are two parts to the Shift-Diabetes Study, the monitoring study and the semi-structured interview. Participants can volunteer for one or both parts of the study. If participants would like to take part in both the monitoring and the interview they will need to complete the monitoring study first.
The monitoring study:
The study will require participants to record their diet, sleep and activity and, to monitor their blood glucose over a 10-day period. This 10-day period needs to include 3 nightshifts (a work shift that includes a period between 11pm and 6am), other work shifts and at rest (days when not at work).
Following consent, participants have the following measurements taken: weight, height, body fat, and waist and hip circumference. They will be fitted with a continuous glucose monitoring device (a minimally invasive sensor which measures glucose underneath the skin every 5 minutes) and a non-invasive activity monitor. They will also be asked to complete a questionnaire that will include questions about chrono-type, working hours, general diet and lifestyle. A sub sample of participants will be selected to complete an in-depth semi-structured

interview identify factors related to food choices.
The semi-structured interview:
Taking part in the interview involves attending a 1-hour meeting with a researcher via secure online platform. During the meeting, the researcher will ask questions about how and when participants eat when they are working night shifts, and what factors may influence this.

What are the possible benefits and risks of participating?
Participants may benefit from the outcomes of this research for example, how to improve the management of their diabetes while working shifts. The continuous glucose sensor insertion can be associated with some discomfort, but the insertion devices are spring-loaded with introducers, making the process rapid and usually painless. The sensors have a very unlikely risk of infection – if infection occurs participants will be asked to remove the sensor and provided with support. The adhesive material from the sensor has a low risk of mild allergic reaction that causes discomfort. Participants will be asked to remove the sensor immediately if they experience any discomfort (e.g. itching, tenderness or pain) and will be advised to contact the study team for follow-up advice.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
April 2020 to January 2023

Who is funding the study?
Diabetes UK

Who is the main contact?
Dr Rachel Gibson
rachel.gibson@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Rachel Gibson

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Type(s)

Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HR-19/20-14630

Study information

Scientific Title
Towards targeted dietary support for shift-workers with type 2 diabetes: a mixed-method study

Acronym
SHIFT-diabetes

Study objectives
The purpose of this observational study is to understand the current status of management of type 2 diabetes in night-shift workers including barriers and facilitators to dietary management.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/12/2019, King's College London Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee (Research Ethics Office, Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road SE1 9NH, UK; +44 (0)20 7848 4020; rec@kcl.ac.uk), ref: HR-19/20-14630

Study design
Single- centre mixed methods cross sectional observational study with qualitative data collection

Primary study design

Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Current interventions as of 13/07/2021:

This is a mixed-methods study involving quantitative (objective, numeric) data collection on blood glucose, diet, sleep and physical activity (main study) and qualitative information about dietary behaviours while working night shifts (sub-study).

Study population: Employees with type 2 diabetes who work shifts (including regular night work) in a hospital or residential care setting. Participating in the study will require two 30-45 minute study visits 10 days apart. A sample of 10 to 15 participants will be recruited for a semistructured audio-recorded interview requiring one 1-hour study visit. All study visits will take place at the Metabolic Research Unit (MRU), Franklin-Wilkins Building, 150 Stamford Street, SE1 9NH.*

*COVID-19 Impact Protocol implemented July 2021:
Due to the COVID-19 pandemic, measures have been taken to enable participants to complete study visits remotely as an alternative option.
Participants can volunteer for the both or one part of the study. If they are interested to volunteer for the interview and the monitoring study they will need to undertake the monitoring study first to avoid potential bias and change of habitual behaviour.

Study Visit 1:
Height, weight, waist and hip circumference, and % body fat (bio electrical impedance) will be measured using standard protocols (department of Nutritional Sciences). Participants will be asked to complete standard occupational, general health and lifestyle questionnaires. Participants will be fitted with a continuous glucose monitoring device (CGM) by one of the research team. The sensor is a small needle placed in the skin over the abdomen, which measures glucose underneath the skin every 5 minutes. Attached to the sensor is a small transmitter. The sensors lasts 10 days and will be removed when participants attend their second study visit. Participants will also be asked to wear a non invasive monitor that will monitor activity and sleep. This monitor can be worn on the wrist, waist, ankle or thigh. Full instructions and training on using the continuous glucose and activity monitor will be provided to the participants at study visit 1.

Remote option –The above listed study equipment will be posted to the participants and the researcher will arrange a mutually convenient time to meet via videocall to talk through what is required. Written instructions will be provided together with the posted equipment. Participants will be asked to measure their height, weight, waist and hip circumferences at home. Written and visual instructions will be provided to participants to standardise measurements. Participants will be asked to complete standard occupational, general health and lifestyle questionnaires.
Study period:
The continuous glucose monitor will be in place for the 10-day period and participants will also

be required to wear the activity and sleep monitor provided. We will also provide participants with a standard diet diary where they will be required to record food, drink and medications consumed. Participants will also be asked to record their sleep and work hours for each day of the 10-day monitoring period. Details of how to complete these materials and use these devices will be provided to the participant during study visit 1.

Study visit 2:
After 10-days participants will attend the MRU where the devices, food diary and sleep log will be returned to the research team. During this visit, participants will be asked to complete a brief survey to explore factors influencing their dietary behaviour when undertaking shift work.
Remote option (on-line) – After 10-days participants will be asked to remove the CGM themselves (instructions will be provided) and return the devices, food diary and sleep log either via courier collection at an agreed time or pre-paid postage. They will also be asked to complete the brief survey, previously posted, and return it together with the devices.
Semi-structured interview:
We will recruit a sample of 10-15 participants (adhering to the same inclusion and exclusion criteria) to take part in in-depth, semi-structured qualitative interviews. Participants can volunteer for the both or one part of the study. If they are interested to volunteer for the nterview and the monitoring study they will need to undertake the monitoring study first to avoid potential bias and change of habitual behaviour.
Participants invited will be sent via email or post a participant information sheet. If they are interested in participating written consent will be obtained at least 24-hours before the interview will take place. The semi-structured interview will last approximately 1hr. The semistructured interview data will be audio recorded and then transcribed verbatim to allow for thematic analysis. Interviews transcripts will be fully anonymised so that no individual or organisation may be identified from the data

We will analyse data from the 10 first interviews conducted. Following this, we will analyse the remaining 5 interviews sequentially, one by one, checking whether the themes identified in that transcript correspond to those identified in the earlier batch of 10 transcripts analysed. If no new themes emerge after analysis of three sequential interviews, we will deem thematic data saturation achieved and case data collection. However, if new themes continue to emerge, we will conduct a further three interviews, and re-assess for saturation, in an iterative manner until saturation is deemed achieved.

Analysis:
The data collected from the glucose monitors will be analysed using an appropriate statistical package to measure patterns in blood glucose over the monitoring period (key measurements will be the time spent within a specified blood glucose range and the variability and fluctuations in these levels). We will analyse the the food diaries (using dietary analysis software) to measure intakes of foods and nutrients across each day. The dietary data combined with the physical activity and sleep data will be mapped to the blood glucose data. We will summarise survey responses on factors influencing dietary behaviour using descriptive statistics as appropriate and calculate a mean scale score for items corresponding to each domain of the COM-B model and Theoretical Domains Framework. We will compare differences on scale scores according to demographic characteristics (e.g. age, gender) and use regression analyses to explore associations with blood glucose.

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Previous interventions:

This is a mixed-methods study involving quantitative (objective, numeric) data collection on blood glucose, diet, sleep and physical activity (main study) and qualitative information about dietary behaviours while working night shifts (sub-study).

Study population: Employees with type 2 diabetes who work shifts (including regular night work) in a hospital setting.
Participating in the study will require two 30-45 minute study visits 10 days apart. A sub-sample of 10 to 15 participants will be asked to attend an additional voluntary 1-hr study visit for an in semi-structured audio-recorded interview requiring one 1-hour study visit. All study visits will take place at the Metabolic Research Unit (MRU), Franklin-Wilkins Building, 150 Stamford Street, SE1 9NH.

The main study:

Study Visit 1:
Height, weight, waist and hip circumference, and % body fat (bio electrical impedance) will be measured using standard protocols (department of Nutritional Sciences). Participants will be asked to complete standard occupational, general health and lifestyle questionnaires. Participants will be fitted with a continuous glucose monitoring device (CGM) by one of the research team. The sensor is a small needle placed in the skin over the abdomen, which measures glucose underneath the skin every 5 minutes. Attached to the sensor is a small transmitter. The sensors lasts 10 days and will be removed when participants attend their second study visit. Participants will also be asked to wear a non invasive monitor that will monitor activity and sleep . This monitor can be worm on the wrist, waist, ankle or thigh. Full instructions and training on using the continuous glucose and activity monitor will be provided to the participants at study visit 1.

Study period:
The continuous glucose monitor will be in place for the 10-day period and participants will also be required to wear the activity and sleep monitor provided. We will also provide participants with a standard diet diary where they will be required to record food, drink and medications consumed. Participants will also be asked to record their sleep and work hours for each day of the 10-day monitoring period. Details of how to complete these materials and use these devises will be provided to the participant during study visit 1.

Study visit 2:
After 10-days participants will attend the MRU where the devices, food diary and sleep log will be returned to the research team. During this visit, participants will be asked to complete a brief survey to explore factors influencing their dietary behaviour when undertaking shift work.

Semi-structured interview (sub study):
A sub-sample of 10-15 participants will be purposefully sampled to achieve a representative sample based on sex, age range and job role. Participants invited will be sent via email or post a participant information sheet. If they are interested in participating written consent will be obtained at least 24-hours before the interview will take place. The semi-structured interview will last approximately 1hr. The semi-structured interview data will be audio recorded and then transcribed verbatim to allow for thematic analysis. Interviews transcripts will be fully anonymised so that no individual or organisation may be identified from the data.

We will analyse data from the 10 first interviews conducted. Following this, we will analyse the remaining 5 interviews sequentially, one by one, checking whether the themes identified in that transcript correspond to those identified in the earlier batch of 10 transcripts analysed. If no

new themes emerge after analysis of three sequential interviews, we will deem thematic data saturation achieved and case data collection. However, if new themes continue to emerge, we will conduct a further three interviews, and re-assess for saturation, in an iterative manner until saturation is deemed achieved.

Analysis:
The data collected from the glucose monitors will be analysed using an appropriate statistical package to measure patterns in blood glucose over the monitoring period (key measurements will be the time spent within a specified blood glucose range and the variability and fluctuations in these levels). We will analyse the the food diaries (using dietary analysis software) to measure intakes of foods and nutrients across each day. The dietary data combined with the physical activity and sleep data will be mapped to the blood glucose data. We will summarise survey responses on factors influencing dietary behaviour using descriptive statistics as appropriate and calculate a mean scale score for items corresponding to each domain of the COM-B model and Theoretical Domains Framework. We will compare differences on scale scores according to demographic characteristics (e.g. age, gender) and use regression analyses to explore associations with blood glucose.

Intervention Type
Mixed

Primary outcome(s)
Current primary outcome measure as of 27/10/2020:
During night, day and rest conditions:
1. Blood glucose variability measures (continuous glucose monitor):
1.1. Coefficient of variation
1.2. Mean amplitude of glycemic excursion (MAGE)
1.3. Time in target and time
2. Dietary measures (diet diary):
2.1. Eating patterns (temporal distribution energy and nutrient intake)
2.2. Food choices (food group and type of food)
3. Qualitative (semi-structured questionnaires):
3.1. Identifying the individual, socio-cultural and environmental factors influencing dietary behaviour

Previous primary outcome measure:
During night, day and rest conditions:
1. Blood glucose variability measures (continuous glucose monitor)
1.1. Coefficient of variation
1.2. Mean amplitude of glycemic excursion (MAGE)
1.3. Time in target and time
2. Dietary measures (diet diary)
2.1. Eating patterns (temporal distribution energy and nutrient intake)
2.2. Food choices (food group and type of food)
3. Sleep (sleep diary and activity monitor)
3.1. Sleep patterns
4. Physical activity (activity monitor)
4.1. Temporal physical activity patterns
5. Qualitative (semi-structured questionnaires):
5.1. Identifying the individual, socio-cultural and environmental factors influencing dietary behaviour

Key secondary outcome(s))
Current secondary outcome measures:
During night, day and rest conditions:
1. Sleep (sleep diary and activity monitor):
1.1. Sleep patterns (time, duration, frequency)
2. Physical activity (activity monitor):
2.1. Temporal physical activity patterns (time, duration, intensity)

Previous secondary outcome measures:
There are no secondary outcome measures

Completion date
23/01/2023

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 27/01/2022:

1. Male and female
2. Aged between 18 and 60 years old
3. Type 2 diabetes diagnosed by healthcare professional
4. Diabetes should be managed only by lifestyle (diet, activity), or medications not associated with hypoglycemic risk (e.g. acarbose, metformin DPP4 inhibitors, SGLT2 inhibitors)
5. Currently work a rotating and/or mixed shift pattern that includes regular night shifts (a minimum of 4 nights per month) as well as other types of shifts (e.g., days, early, or late shifts). A night shift is defined as a period of work between 11 pm and 6 am. The monitoring period needs to include 3-night shifts (either arranged in 3 consecutive night shifts or 2 consecutive night shifts and another single night shift), another type of shift (for example, day or early shifts), and rest days
6. Work in a hospital or residential care setting - any job role. Healthcare sector employees represent one of the largest employers of night workers in the UK.
7. Not diagnosed with or currently requiring active treatment (e.g. chemotherapy, immunotherapy, or radiotherapy for cancer) for any of the following conditions: heart attack, stroke, angina, thrombosis, kidney disease, liver disease, cancer
8. No recent history (last 5 years) of excess alcohol intake or substance abuse
9. No recent weight change (lost or gained) by more than 3 kg/7 lb (in the last 2 months)
10. Not started new medication within the last 3 months likely to interfere with energy metabolism, appetite regulation, and hormonal balance, including anti-inflammatory drugs or steroids, antibiotics, androgens, phenytoin, erythromycin, or thyroid hormones

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Previous inclusion criteria as of 21/09/2021:

1. Male and female
2. Aged between 18 and 60 years old
3. Type 2 diabetes diagnosed by healthcare professional
4. Diabetes should be managed only by lifestyle (diet, activity), or medications not associated with hypoglycemic risk (e.g. acarbose, metformin DPP4 inhibitors, SGLT2 inhibitors)
5. Currently work a rotating and/or mixed shift pattern that includes regular night shifts (a

minimum of 4 nights per month) as well as other types of shifts (e.g., days, early or late shifts). A night shift is defined as a period of work between 11 pm and 6 am. The monitoring period needs to include 3-night shifts (either arranged in 3 consecutive night shifts or 2 consecutive night shifts and another single night shift), another type of shift (for example, day or early shifts) and rest days
6. Work in a hospital or residential care setting - any job role. (Healthcare sector employees represent one of the largest employers of night workers in the UK.)
7. No history of heart attack, stroke, angina, thrombosis, liver or kidney diseases, chronic gastrointestinal disorder or cancer
8. No history of excess alcohol intake or substance abuse
9. No recent weight change (lost or gained) by more than 3 kg/7 lb (in the last 2 months)
10. Not started new medication within the last 3 months likely to interfere with energy metabolism, appetite regulation and hormonal balance, including anti-inflammatory drugs or steroids, antibiotics, androgens, phenytoin, erythromycin or thyroid hormones

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Previous inclusion criteria as of 13/07/2021:

1. Male and female
2. Aged between 18 and 60 years old
3. Type 2 diabetes diagnosed by healthcare professional
4. Diabetes should be managed only by lifestyle (diet, activity), or medications not associated with hypoglycemic risk (e.g. acarbose, metformin DPP4 inhibitors, SGLT2 inhibitors)
5. Current night shift worker (a night shift is defined as a period of work between 11 pm and 6 am) and work 4 to 10 night shifts per month. The monitoring period needs to include 3-night shifts (either arranged in 3 consecutive night shifts or 2 consecutive night shifts and another single night shift), another type of shift (for example, day or early shifts) and rest days.
6. Work in a hospital or residential care setting - any job role. (Healthcare sector employees represent one of the largest employers of night workers in the UK.)
7. No history of heart attack, stroke, angina, thrombosis, liver or kidney diseases, chronic gastrointestinal disorder or cancer
8. No history of excess alcohol intake or substance abuse
9. No recent weight change (lost or gained) by more than 3 kg/7 lb (in the last 2 months)
10. Not started new medication within the last 3 months likely to interfere with energy metabolism, appetite regulation and hormonal balance, including anti-inflammatory drugs or steroids, antibiotics, androgens, phenytoin, erythromycin or thyroid hormones

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Previous inclusion criteria as of 07/10/2020:

1. Male and female
2. Aged between 18 and 60 years old
3. Type 2 diabetes diagnosed by healthcare professional
4. Diabetes should be managed only by lifestyle (diet, activity), or medications not associated with hypoglycemic risk (e.g. acarbose, metformin DPP4 inhibitors, SGLT2 inhibitors)
5. Current night shift worker (a night shift is defined as a period of work between 11 pm and 6 am) and work 4 to 10 night shifts per month with blocks of 3 consecutive night shifts
6. Work in a hospital setting - any job role. (Healthcare sector employees represent one of the largest employers of night workers in the UK.)
7. No history of heart attack, stroke, angina, thrombosis, liver or kidney diseases, chronic

gastrointestinal disorder or cancer
8. No history of excess alcohol intake or substance abuse
9. No recent weight change (lost or gained) by more than 3 kg/7 lb (in the last 2 months)
10. Not started new medication within the last 3 months likely to interfere with energy metabolism, appetite regulation and hormonal balance, including anti-inflammatory drugs or steroids, antibiotics, androgens, phenytoin, erythromycin or thyroid hormones

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Previous inclusion criteria:

1. Male and female
2. Aged between 18 and 60 years old
3. Type 2 diabetes diagnosed by healthcare professional
4. Diabetes should be managed only by lifestyle (diet, activity), or medications not associated with hypoglycemic risk (e.g. acarbose, metformin DPP4 inhibitors, SGLT2 inhibitors)
5. Current night shift worker (a night shift is defined as a period of work between midnight and 6 a.m.) and work 6 to 10-night shifts per month with regular blocks of 3 consecutive night shifts
6. Work in a hospital setting: healthcare sector employees as they represent one on the largest employers of night workers in the UK)
7. No history of heart attack, stroke, angina, thrombosis, liver or kidney diseases, chronic gastrointestinal disorder or cancer
8. No history of excess alcohol intake or substance abuse
9. No recent weight change (lost or gained) by more than 3 kg/7 lb (in the last 2 months)
10. Not started new medication within the last 3 months likely to interfere with energy metabolism, appetite regulation and hormonal balance, including: anti-inflammatory drugs or steroids, antibiotics, androgens, phenytoin, erythromycin or thyroid hormones

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Females, who are pregnant or intending to become pregnant, or currently breastfeeding
2. Taking medications associated with hypoglycaemia (e.g. insulin, sulphonylureas (such as glicazide or glimepiride)
3. No travel arrangements outside UK within the period of data collection - data needs to be

collected across a persons typical working period
4. Not already participating in a clinical trial - as likely to influence behaviour and/or glucose variability

Date of first enrolment
01/10/2020

Date of final enrolment
10/01/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London
Franklin Wilkins Building
150 Stamford Street
London
United Kingdom
SE1 9NH

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK

Alternative Name(s)

The British Diabetic Association, DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/07/2023	20/07/2023	Yes	No
Protocol article		06/10/2021	26/08/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes