

LSHTM Ethics Application & CARE Form

Project Information

1. Full project title

Investigating the timing of nutrients (carbohydrates) intake in the National Diet and Nutrition Survey Rolling Programme (2008-2014)

2. Is this Project in fulfillment of a degree?

☒ Yes ☐ No

2a. Degree registered for

MSc

2e. Indicate student type

☐ Distance Learning
☒ Face-to-Face

2f(MSc) Is this an original submission, or are you responding to a request for clarification or insufficient information notification from the LSHTM Ethics Committee?

☒ Original submission
☐ Responding to the Ethics Committee

Student Details

3a. Student details

Title

First Name

Surname

[Redacted]

[Redacted]

[Redacted]

Address

[Redacted]

[Redacted]

City

[Redacted]

Postcode

[Redacted]

Telephone

[Redacted]

Email

[Redacted]

3a(i). MSc course

Medical Statistics

3a(ii). Indicate proposed project length:

- ☒ Standard
☐ Extended

3b. Are you studying as a full or part time student?

Full time

3c. Supervisor's name.

[REDACTED]

3c (i). Supervisor's email address (if more than one, please only provide the email address of your main supervisor)

Email

[REDACTED]

3 c(ii). Supervisor's institution

[REDACTED]

3c (iii). Supervisor status

Confirmed

Project Type

Note: Completing the filter will enable and disable sections of the form so you may not see all questions.

4. Does the research involve primary data collection, secondary analysis or a mix of both?

- ☐ Primary
☒ Secondary
☐ Mixed

4a(iii). Select type of project:

Project using data from secondary sources

Samples

6a. Does this research project involve the collection/use of human tissue samples e.g urine, stool, blood etc? (Please select yes even if the samples are not considered relevant material under the Human Tissue Act)

- ☐ Yes
☒ No

6b. Will this project use living animals (either laboratory, livestock or wild animals) AND/OR biological material that has been obtained from animals in the experiments planned?

- ☐ Yes
☒ No

Fast-Track

7. Does this project use anonymised and unlinkable secondary datasets only?

- ☒ Yes
☐ No

7a. Will this project be conducted within the NHS?

- ☐ Yes
☒ No

7b. Is this application for fast-track? Note: MSc applications are not currently available for fast-track

- ☐ Yes
☒ No

Vulnerable Groups

8c. Does this research project involve vulnerable groups? Vulnerable groups include: children, individuals with mental disability or learning difficulties, pregnant women, prisoners etc (see information icon for full description).

- ☐ Yes
☒ No

8d. Does this research involve access to and/or storage of security sensitive research material? (please see information icon for what is considered security sensitive material)

- ☐ Yes
☒ No

Geography

9. List the countries where the research project is to be conducted (For example: if you are conducting a secondary data analysis for your project and you will be based in the UK, select UK regardless of where the original data has come from):

United Kingdom

Outline

Note: Please do not copy and paste directly from the protocol. Applications where large portions of text have been copied and pasted directly from the protocol, and therefore do not properly answer the question, will be invalidated

- 10b. Give an outline of the proposed project, including background to the proposal. Include information from any systematic reviews that have been conducted. Sufficient detail must be given to allow the Committee to make an informed decision without reference to other documents.

It is believed that the time of day of food intake has an effect on health. For example, skipping breakfast is associated with an increased risk of obesity whereas regular meal patterns are associated with a reduced risk of obesity. However, currently few studies have investigated when people consume food throughout the day. Some initial work based on eating occasions at hourly time intervals throughout the day from nutrition survey data, revealed using latent class analysis the presence of 3 groups of eaters: grazers, early eaters, and late eaters. This was based on total energy consumption (total calories consumed).

The project will aim at investigating the relationship between the timing of eating within the day and specific nutrients, like carbohydrates, potentially broken down further into some of their components (eg. starch). It will aim at finding time patterns of consumption for such nutrients by latent class analysis or potentially other cluster methods to find groups in the data. An additional potential aim, depending on the findings of the latent class analysis will be exploring the association between eating time patterns with diabetes and/or obesity. The data on which the project will be based are from the UK National Diet and Nutrition Survey Rolling Programme (NDNS RP) which is a representative sample of the the population in England. The focus of this study will be subpopulation of adults.

- 10b(i). Upload the study protocol, including data collection forms, questionnaires and topic guides. Please upload each document separately, ensuring that the date and version number of each document is correct.
11. State the intended value of the project, detailing why the topic is of interest or relevance. If this project or a similar one has been done before what is the value of repeating it? Give details of overviews and/or information on the Cochrane database. This area is of increasing importance – please ensure you give a full response.

The project will aim at investigating the relationship between the timing of eating within the day and specific nutrients, like carbohydrates, potentially broken down further into some of their components (eg. starch) rather than the timing of total energy consumption. It will aim at finding time patterns of consumption for such nutrients by latent class analysis or potentially other cluster methods to find groups in the data. An additional potential aim, depending on the findings of the latent class analysis will be exploring the association between eating time patterns with diabetes and/or obesity.

12. Hypothesis statement.

There are different eating time patterns specific for carbohydrate consumption in the general population in the UK. The timing of carbohydrate consumption is associated with obesity and/or diabetes.

13. Overall aim of project

Find the subgroups of carbohydrate consumption by eating time patterns.

14. Specific objectives of project

We aimed at defining the eating time patterns of carbohydrate consumption rather than the total energy consumption in the general population in the UK. Additionally, we also aimed at exploring the association between the subgroups defined in the first step, and obesity and/or diabetes.

Methods

Note: Please do not copy and paste directly from the protocol. Applications where large portions of text have been copied and pasted directly from the protocol, and therefore do not properly answer the question, will be invalidated

15a. Specify the procedures/methodology to be conducted during the project. Please include outcome measures and plans for data management and analysis. For literature reviews, include details on search strategy, search terms, inclusion and exclusion criteria.

The data are from the National Dietary and Nutrition Survey Rolling Programme (NDNS RP) can be downloaded from the database of "UK Data Service" (www.ukdataservice.ac.uk). The NDNS RP has now completed and analyzed its sixth year. A subset of the data will be analyzed using STATA or R. Time patterns of carbohydrate consumption will be defined through latent class analysis. As for the association between subgroups of carbohydrate eaters and obesity/diabetes, we will use logistic regression.

16. Proposed start date of the project

11/06/2018

17. Proposed end date of the project

04/09/2018

18. In terms of the feasibility of your project, what could stop this project from succeeding, or prevent you from achieving your objectives?

*Please indicate any aspects of your proposed approach which could potentially experience difficulties, e.g. delays with permissions, data collection or storage problems, lack of sufficient comparable information, etc. You may also wish to mention any wider matters which could affect your project, e.g. civil unrest, natural disasters, transport availability.

Application of the usage of the data is already done and stored in LSHTM computers. Even the data does not enable any clear relationships to be identified that will still be of interest. There is no more obstacle can be anticipated here. We only need statistical software packages to complete the project (STATA can be accessed through LSHTM license, R is also freely available).

19a. What alternative plans do you have in case you encounter any of the potential problems you have identified? Please troubleshoot all points raised in question 18.

Not expecting any potential problem.

19b. What specific facilities or resources will you personally expect to make use of for your project (eg a local university library, lab facilities, project placement with a specific organisation etc)?

None.

20. List key references (no more than 5), including for methods to be used.

1. Collins, L. & Lanza, S. Latent class and latent transition analysis. Hoboken. NJ: Wiley, 2010
2. Leech, R. M., Worsley, A., Timperio, A. & McNaughton, S. A. Temporal eating patterns: a latent class analysis approach. International Journal of Behavioral Nutrition and Physical Activity 14, 3 (2017).
3. NatCen Social Research, MRC Elsie Widdowson Laboratory, University College London. Medical School. (2017). National Diet and Nutrition Survey Years 1-6, 2008/09-2013/14. [data collection]. 8th Edition. UK Data Service. SN: 6533, <http://doi.org/10.5255/UKDA-SN-6533-7>
4. Rindskopf, D. & Rindskopf, W. The value of latent class analysis in medical diagnosis. Stat Med 5, 21–27 (1986).

Experience

22a. State the personal experience of the applicant and of senior collaborators in the research project in the field concerned, and their contribution to this project. Indicate any previous work done related to the project topic including student and/or professional work, or publications

My tutor/supervisor is an assistant professor of Medical Statistics at LSHTM, he is an expert in nutrition epidemiology as well as in biostatistics.
Doctor Suzana Almoosawi, who is an expert nutritionist from Newcastle University, will also be part of the team for this project.
My background was nutrition science as well. I obtained my Ph.D. in Epidemiology from Nagoya University in 2016. I have some experience in conducting nutritional epidemiological studies and I have also published some academic papers in the corresponding field.

22b. Upload the CVs for all main investigators working on the project. For MSc students, please upload your CV only.



Informed Consent - Secondary Data

24. Is consent in place for secondary use of the data?

- ☐ Yes
☒ No

24a. Will you be obtaining retrospective consent from the participants in each original project for the use of the data?

- ☐ Yes
☒ No

24b. Please explain why retrospective consent will not be sought and how you will obtain permission to use the data without participant consent?

The data is already anonymized and cannot be traced back to individuals.

Confidentiality & Data

28. State how your data will be stored and what will be done with it at the end of the project.

The data will be stored on the LSHTM network only where it can be accessed by a specific individual.

Funding

33. Do you have external funding for this project?

- ☐ Yes
☒ No

33a(ii). Are you in receipt of any funding from the United States? Or will you be collaborating with (or with individuals from) a US Institution/organisation?

- ☐ Yes
☒ No

33b. If no, how will the project go ahead without funds?

There is no cost. No equipment or travel required.

34. Has the project been sent out for peer/independent scientific review?

- ☐ Yes
☒ No

34a. If no, why has the project not been sent peer/independent scientific review?

There is no related publication yet.

36. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

- ☐ Yes
☒ No

37. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

- ☐ Yes
☒ No

Local Approval

49a. For projects using previously-collected human data, give details of all approvals under which the original project(s) took place. Please quote names of Ethics Committees and approval reference numbers (required even if previous approval was from LSHTM); if possible give web link to original project application. If there are no original approvals (e.g. for audit or DHS data) please explain this.

Ethics approval for the NDNS RP was obtained from Oxfordshire A Research Ethics Committee.
<https://www.gov.uk/government/statistics/national-diet-and-nutrition-survey-results-from-years-1-to-4-combined-of-the-rolling-programme-for-2008-and-2009-to-2011-and-2012>

49c. Will your analyses be for purposes entirely covered by the original ethics application where the data was collected, as detailed above?

- ☒ Yes, this falls within the aims and scope of the original project
☐ No, the analyses and aims differ from the original project

49d(i) Summary of purpose and methods of the original project(s)

The aims of the NDNS RP include:

1. providing quantitative data on the food and nutrient intakes, sources of nutrients and nutritional status of the UK population;
2. providing information on trends in food consumption, nutrient intake and nutritional status in different age groups;
3. describing the characteristics of individuals with intakes of specific nutrients above/below the national average;
4. monitoring the extent to which the diets of population sub-groups vary from expert recommendations;
5. measuring blood/urine indices that provide evidence of nutritional status/dietary biomarkers;
6. monitoring the diet of the population to establish the extent to which it is adequately nutritious/varied; and
7. assessing total energy expenditure and physical activity levels/patterns in the study population.

49d(iii). Indicate how you will obtain permission to use the data from the principal investigator responsible for each original project

The data is already available upon application of using from the UK Data service
(<https://discover.ukdataservice.ac.uk/catalogue?sn=6533>).

Data Sources, Results & Permissions

50a. If you expect to use existing data, how will you obtain it?

*Indicate who holds the data, who specifically you will contact, and by when. Any contact so far, especially anything confirmed in writing, should be mentioned.

The data is already available upon application of using from the UK Data service
(<https://discover.ukdataservice.ac.uk/catalogue?sn=6533>).

50a(i). Please upload any documents confirming that you have requested/been granted permission to use any existing data. This can include email correspondence as well as formal letters of permission.

Type	Name	File Name	Date	Version	Size
Other	approval email	approval email.pdf	12/04/2018 0:00:00	1st	558.8 KB

50b. If you expect to use any public domain data, please give further details.

*Make clear how you will gain access. Public domain data must be freely available to any member of the public, without any restrictions or requirement for special permission, and must not enable the identification of living people.

The data is already anonymised and cannot be traced back to any individual who participated in the survey. The data can be obtained from the UK Data service upon application. (<https://www.ukdataservice.ac.uk/>)

50b(i) Please provide the links to all public domain data that you expect to use.

<https://discover.ukdataservice.ac.uk/catalogue?sn=6533>

50c. Will any specific data rights permissions or usage limitations be required regarding data to be used or collected in the project?

- ☐ Yes
☒ No

50d. Will any agreements be required regarding data to be used or collected in the project (for example, material transfer agreements or data transfer agreements)?

- ☐ Yes
☒ No

50e. Are there any existing obligations regarding ownership of results to third parties (e.g. employer)?

- ☐ Yes
☒ No

Type of risk

51a. Where will the project be carried out?

*Note that work away from LSHTM or outside the UK means any form of work for your project, not just primary data collection. Some courses may have specific restrictions on this.

All work will take place either at LSHTM, personal residence, or in libraries that are easily accessible as part of my daily life

51a(i). Please indicate all locations you expect to work at, and the approximate total amount of project work you intend to carry out at each (in %, including 0% where necessary)

<input checked="" type="checkbox"/> At home	<input type="text" value="20%"/>
<input checked="" type="checkbox"/> In local libraries	<input type="text" value="50%"/>
<input type="checkbox"/> In a Laboratory	<input type="text"/>
<input type="checkbox"/> At place of employment	<input type="text"/>
<input checked="" type="checkbox"/> Other work away from home	<input type="text" value="30%"/>

51b. Will the project involve working with or handling any of the following materials?

- ☐ Pathogenic organisms
- ☐ Human tissue
- ☐ Radiochemicals
- ☐ Genetically modified organisms
- ☒ None of the above

51c. Are any other potentially hazardous activities likely to be carried out during the project?

- ☐ Yes
- ☒ No

51d. Do any special requirements (e.g. disability-related issues or other concerns) need to be taken into account?

- ☐ Yes
- ☒ No

Signature Instructions

The form should be completed and finalised prior to signing or requesting signatures. Students should ensure that the Supervisor signs prior to the Course Director/Project Module Organiser. For external supervisors, please ensure that they have registered for an account prior to requesting the signature.

Signature - Applicant

I declare that:

- I undertake to abide by the ethical principles underlying the Declaration of Helsinki (1964, as amended) and good practice guidelines on the proper conduct of research.
- I Have read and understood, and agree to abide by the LSHTM Good Research Practice policy
- I undertake to abide by the UK Data Protection Act 1998 and any applicable local laws.
- I undertake to abide by all local rules for non-UK research.
- I agree to conduct my project on the basis set out in this form, and to consult staff (initially, my Supervisor) if making any subsequent changes – especially any that would affect the information given with respect to ethics approval.
- I undertake to adhere to all conditions set out by review bodies in giving approval and will not start the project until all required approvals are in place
- I agree to comply with the relevant safety requirements, and will submit a separate request for LSHTM travel insurance where relevant.
- I confirm that there are no conflicts of interest that preclude my participation in the project

Supervisor signature

I declare that:

- I agree that the information submitted in this application is a reasonable summary of the proposed project.
- I agree that this form correctly indicates whether or not ethics approval will be required.
- I agree that this form contains adequate information for the ethics committee to form an opinion of the proposed project.
- I agree that all required supporting documentation is attached to this application.
- (For MSc projects only) I agree that responses in the Risk Assessment section address the main risks connected with a project of this nature
- I have reviewed the risk of the project, including travel, and agree that it is an acceptable risk to the student
- I confirm that there are no conflicts of interest that preclude my role as supervisor for this project
- I Have read and understood, and agree to abide by the LSHTM Good Research Practice policy

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Course Director / Project Module Organiser Signature

I declare that:

- I agree that the proposed project's academic content is suitable for this MSc

Signed: This form was signed by Dr Richard Silverwood (Richard.Silverwood@lshtm.ac.uk) on 16/04/2018 22:51

Signature - Other

Note:

The form will automatically submit upon receipt of all required signatures.

After submission, you will receive a confirmation email with further details.

If you have not received a confirmation email within 5 working days please email ethics@lshtm.ac.uk (staff) or MScethics@lshtm.ac.uk (students) to check the status of your submission.