

Participant Information Sheet

Title of study: Validity and Reproducibility of the Prime Diet Quality Score (PDQS) in adults against a four-day food diary.

You are being invited to take part in a research study which is being conducted by researchers from the Centre for Public Health, Queen's University Belfast and University College Dublin. This is a dual-centre study which is recruiting participants from across the island of Ireland. Before you decide whether or not to take part it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Thank you for reading this.

1. What is the purpose of the study?

The aim of this study is to improve the way we measure dietary intake (e.g. what people are eating and how much they are eating) in individuals. Accurate measurement of dietary intake is important to determine how diet is linked to a range of diseases. However, estimation of dietary intake is difficult and many of the techniques are time-consuming to complete and have many sources of error. New methods to measure dietary intake are being developed, and it is important to make sure that they are measuring dietary intake accurately. In this study we would like to determine how accurately a new, shorter, dietary assessment tool, the Prime Diet Quality Score (PDQS), measures diet compared with other dietary assessment methods. The other dietary assessment measure we will ask you to complete for comparison is a food diary. We are also interested in finding out how this new dietary score compares with other widely-used dietary quality scores such as a Mediterranean Diet Questionnaire. Testing this new dietary score may enable us to use it in future research and allow us to more easily and accurately assess dietary intake and find out how it relates to disease risk.

2. Why have I been chosen?

You have been invited to participate because you are aged 45 years or over and are either overweight, a smoker, have high blood pressure or high cholesterol. This means you meet our study eligibility criteria. We assessed your eligibility to take part in the study when you completed our screening questionnaires with the researcher over the telephone. We are recruiting a group of 100 participants across the island of Ireland to find out how the new Prime Diet Quality Score (PDQS) questionnaire measures dietary intake compared with a food diary.

3. Do I have to take part?

No, you do not have to take part. It is up to you to decide whether or not to take part in this research study. If you do decide to take part, you will be given this information sheet to keep and you will be asked to complete a consent form. If you choose to take part, you can change your

mind at any time and withdraw from the study without giving a reason. Please ask us if there is anything that is not clear or if you would like more information. *Our contact details are given below.*

We will also give you the option of agreeing to be contacted at a later date to take part in any future studies of a similar nature. We will only ask you whether or not you would agree to this in our consent form and you are under no obligation to take part in any future studies. If you decide to take part in the current research but decide not to consent to being contacted in future it will not influence your involvement in this particular research study and will not affect the standard of care that you would receive.

4. What will happen to me if I take part?

If you consent to take part, a researcher from Queen's University Belfast will invite you to complete some diet and health questionnaires at two timepoints, three months apart. You can complete all questionnaires at home and the researcher will be available via email or phone if you have any questions.

At Month 0, you will be asked to complete the short Prime Diet Quality Score (PDQS) questionnaire and a Mediterranean Diet Questionnaire online. These questionnaires should take no longer than 15-20 minutes to complete. Following this, you will be posted a 4-day food diary. You will be asked to complete the food diary over 3 week days and 1 weekend day over the following week. In this food diary we ask you to record everything you eat and drink for the 4-day period and we will give you a stamped addressed envelope so you can post the completed diary back to the researcher.

At Month 3, you will once again be asked to complete the short Prime Diet Quality Score (PDQS) questionnaire, the Mediterranean Diet Questionnaire, and another 4-day food diary. We will also ask you to complete an additional short health and lifestyle questionnaire online to ask whether you have had any significant changes in lifestyle or health over the previous 3 months since the study began.

If we need you to clarify any of the information you provide in either of your food diaries, a researcher will telephone you to check details if necessary after you return your food diary.

We ask you not to change your usual pattern of eating while taking part in the study as our aim is to examine your **usual** dietary intake. As a token of gratitude for participation, participants will be offered personalised dietary feedback and advice based on the food diary data they provide at the end of the study.

5. What are the possible risks or disadvantages of taking part?

We do not foresee any risks or disadvantages that may arise as a result of taking part in this study. You will be expected to adhere to the study protocol over the course of the 3 months and complete the questionnaires at the required time. The researcher will send you the questionnaires at both timepoints. There are no invasive procedures involved. There are no foreseeable risks associated with completing any of the questionnaires or the food diary. You will be able to contact the researcher at any time if you have any questions or concerns about the study.

6. What are the possible benefits of taking part?

By taking part in this study, you will help us to potentially improve the way we measure habitual dietary intake in scientific studies. This will allow us to more accurately examine the association between dietary intake and health related outcomes. This study will therefore provide information to allow further studies and research to be carried out which may have public health benefits.

7. What if something goes wrong?

It is very unlikely that something will go wrong as a result of this research study. If you have any concerns about any aspect of the study, you can contact the Chief Investigator, Professor Jayne Woodside (please see contact details below). Should you remain unhappy and wish to make a formal complaint, you can contact the Research Governance Team at Queen's University Belfast (Telephone: 028 9097 2529; Email: researchgovernance@qub.ac.uk). Any complaints will be dealt with in accordance with the University's Complaints from Research Participants Standard Operating Procedure. If you are harmed by taking part in this research, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it.

8. Will my taking part in this study be kept confidential?

All information collected about you during the course of this research will be kept strictly confidential. Information may be looked at by responsible individuals from Queen's University Belfast University College Dublin or from regulatory authorities and retained on University premises. No identifiable information will ever be used in any publications or reports. All information collected will be stored in password-protected databases or secure locked filing cabinets as required by the university and in line with the General Data Protection Regulations (2016) and Data Protection Act (2018).

9. What will happen to the results of the research?

In any publications that arise from this study, volunteers will be acknowledged for their participation. However, names of volunteers will not be published in any of these releases so no-one will be identifiable in any data collected in the study.

10. Who is organising and funding the research?

This research is being carried out by the Centre for Public Health, Queen's University Belfast and is funded by the HSC Research & Development Office in Northern Ireland.

11. Who has reviewed the study?

This study has been reviewed by the Faculty of Medicine, Health and Life Sciences Research Ethics Committee, Queen's University Belfast.

12. Contact for Further Information

Researcher:

Dr Sarah Brennan RD, Research Fellow, Centre for Public Health, School of Medicine Dentistry & Biomedical Sciences, Institute of Clinical Science Block A, Grosvenor Road, Belfast BT12 6BJ.

Email: sarah.brennan@qub.ac.uk

Tel: 028 9097 6420

Chief Investigator:

Prof. Jayne Woodside, Centre for Public Health, School of Medicine Dentistry & Biomedical Sciences, Institute of Clinical Science Block A, Grosvenor Road, Belfast BT12 6BJ.

E-mail: j.woodside@qub.ac.uk

Tel: +44 (0)28 9097 8942

This research will be conducted in compliance with data protection legislation. For more information about how we look after your information, how to access your rights and who to contact if you have any queries or concerns about data protection please visit the Queen's University Belfast website -

www.qub.ac.uk/privacynotice/Research/ListofResearchPrivacyNotices/PrivacyNoticeforResearchParticipants

Thank you for your interest in this study and for taking the time to read through this information sheet.