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Participant Information Sheet

Study: The availability and cost of gluten-free food and their impact on coeliac disease

Background and aims of the study

The only treatment for coeliac disease is a life-long gluten-free diet. This can be difficult as gluten-free food is not always easily available, and it tends to be expensive. It is known that there is variation in the availability and cost of gluten-free food across different regions. This study aims to understand how the availability and cost of gluten-free food impacts on people with coeliac disease.

Who is conducting this research?

This research is being conducted by researchers in the Nuffield Department of Population Health at the University of Oxford. The team includes Dr Michele Peters (Team Lead) and Helen Crocker (Research Officer). The study is funded by Coeliac UK.

Why have I been invited to take part?

You have been invited to take part as a member of Coeliac UK who has agreed to be contacted for research purposes. To participate in the study, you need to be over 18 years of age and have been given a diagnosis of coeliac disease by a medical professional (e.g. your GP or a gastroenterologist).

How can I take part?

Participating in this study involves completing the enclosed questionnaire and detachable consent form and returning them to the research team in the prepaid envelope. The consent form can be found on page 3 of the questionnaire and will be separated from your questionnaire answers on its return. The questionnaire asks about the availability of gluten-free food to you, financial challenges that you may face in relation to following a gluten-free diet, the impact of coeliac disease, and some questions about you and your general health. The questionnaire may take up to 30 minutes to complete.

Participation in the study is voluntary. If you return a completed questionnaire, you are agreeing for your answers to be used in the analysis. Names and contact details will not be included in any publications about the study and it will not be possible to identify you in any research reports. You may withdraw from the study without penalty at any time and without giving a reason.

Some people who complete the questionnaire will be invited to take part in an interview to discuss their questionnaire answers in more depth. If you are willing to be invited for an interview, please provide your name and address on the consent form. Any contact details you provide will be kept separately from your questionnaire answers. Agreeing to be invited to an interview does not mean you have to participate or that you will be invited. It will be up to you to decide whether or not you want to be interviewed once you receive an invitation and further information about the interview.

Coeliac UK may wish to conduct a follow-up study to evaluate changes to the availability and cost of gluten-free foods and their impact over time. If this study is carried out, you may be asked to complete a similar questionnaire for a second time. The University of Oxford will provide Coeliac UK with the questionnaire ID numbers of those who return the first questionnaire and give permission to be contacted to complete a second questionnaire. The ID number is printed on the front of the questionnaire, and Coeliac UK has recorded this number against your name and contact details. Coeliac UK will not have access to your questionnaire answers and the University will not know your contact details unless you choose to provide them because you wish to be considered for interview. In a follow-up study, the same ID number would be printed on the questionnaire to allow the University to match responses from both your questionnaires.

What are the possible risks and benefits of taking part?

It is unlikely that you will suffer any harm as a result of participating in this study. If you find any of the questions on the questionnaire distressing, we advise that you discuss this with a health professional or Coeliac UK (Helpline: 0333 332 2033, www.coeliac.org.uk). There are no direct benefits in taking part, however, the information you provide will lead to a better understanding of how well-being in coeliac disease is affected by the availability and cost of gluten-free food. This information will be valuable in determining how to best support people in the effective management of their condition.

What will happen to the data that I provide?

All information collected as part of this research will be stored securely. Paper documents will be stored in locked filing cabinets in University offices with restricted-access, and electronic files will be encrypted and stored on a password-protected computer on the secure University of Oxford computer network. All data use is strictly within the terms of the Data Protection Act (DPA 1998).

If you choose to provide your contact details to be invited for an interview, this information will be kept confidential and will be accessible to the research team only. To keep your information confidential, each questionnaire will be marked with an ID number and not your name. A separate file, kept by the research team, will match the questionnaire's ID number to any contact details you provide. Any contact details that you provide will be deleted at the end of the study. Paper questionnaires will be destroyed when the data is published and anonymised electronic data files will be kept for 15 years to allow the research to be reviewed if necessary.

Will the data be used by others?

Only the research team will have regular access to information collected as part of this study. Research data may also be seen by responsible persons from the University of Oxford or regulatory authorities for monitoring purposes. Any data that is shared with others will have names and any other personal information removed so that you cannot be identified from it (this is referred to as anonymised data).

In accordance with Coeliac UK policy, anonymised data will be made available through the Oxford Research Archive (www.ora.ox.ac.uk). The data will only be available for research purposes and will not contain any information that can identify you. Sharing data with other research teams means that data usage can be maximised, thereby increasing the likely impact of the research, without placing undue burden on research participants by asking them to participate in similar studies. You will be able to indicate on the consent form whether you give permission for your anonymised data to be shared in this way. If you prefer not to share your data in this way, it will be removed from the data file before it is shared with other researchers.

What will happen with the results of the study?

The results of the study will be reported to Coeliac UK, published in the scientific literature, and presented at scientific conferences. Names and contact details will not be included in any publications about the study and it will not be possible to identify you in any research reports.

You will not receive individual feedback on the study, but a summary of the study's findings will be reported by Coeliac UK, and available on the University of Oxford's website (www.ndph.ox.ac.uk/research/health-services-research-unit-hsru/research/coeliac-disease-research).

Who has reviewed this project?

This study has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee (REC Reference no: R45890/RE002). The study has also been reviewed by Coeliac UK's Health Advisory Council.

Who do I contact if I have concerns about the study?

If you have a concern about any aspect of this project, please contact the Research Officer (Helen Crocker, telephone: 01865 289431, email: Helen.Crocker@dph.ox.ac.uk) or Principal Investigator (Dr Michele Peters, telephone: 01865 289428, email: Michele.Peters@dph.ox.ac.uk) who will do their best to answer your query. The researchers should acknowledge your concern within 10 working days and give you an indication of how they intend to deal with it. If you remain unhappy or wish to make a formal complaint, please contact the chair of the Research Ethics Committee at the University of Oxford (using the contact details below) who will seek to resolve the matter promptly: Chair, Medical Sciences Inter-Divisional Research Ethics Committee; Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford, OX1 2JD.

Further information

For further information or to ask any questions you may have in relation to this research, please contact Helen Crocker (Research Officer) by telephone: 01865 289431 or by email: Helen.Crocker@dph.ox.ac.uk.