

The Coeliac Disease Assessment Questionnaire

What is the purpose of the research study?

Researchers at the University of Oxford recently developed the Coeliac Disease Assessment Questionnaire to measure the impact of coeliac disease on quality of life. The questionnaire contains 32 questions asking about different aspects of living with coeliac disease. It is intended that the questionnaire will be used in a number of different settings, including clinical practice, clinical trials, and other research studies.

The purpose of this research is to assess how well the questionnaire can measure quality of life in coeliac disease and any changes that might occur over time. The results of the study will provide further information about how well the questionnaire works.

Who is doing the research?

The research is being carried out by researchers in the Nuffield Department of Population Health at the University of Oxford. Helen Crocker is leading the research in collaboration with Dr Michele Peters and Professor Crispin Jenkinson. The research is jointly funded by Coeliac UK and the University of Oxford.

Why have I been invited to take part?

You have been invited to take part in this study as a Member of Coeliac UK who has agreed you may be contacted for research purposes. To participate in the study, you should be aged 18 years or over, live in the UK, have a medical diagnosis of coeliac disease, and have been diagnosed for less than one year. We are interested in your responses whatever the extent of your symptoms.

How can I take part?

Taking part in this study involves completing the Coeliac Disease Assessment Questionnaire *at two points in time*, now and for a second time in four months. Completing the questionnaire twice will allow us to see how well the questionnaire can measure quality of life in coeliac disease and any changes that might occur.

Participating in this study is voluntary and confidential. If you would like to take part, please complete the enclosed questionnaire and consent form and return to the research team in the pre-paid envelope provided. In order for us to send you the second questionnaire, please also complete the name and address slip on the front of the questionnaire. Returning the completed questionnaires means that you understand the purpose of this study and are happy to take part. It may take up to 30 minutes to complete the questionnaire. You are free to withdraw from the study at any point in time without providing a reason, without penalty, and you will not be contacted further.

If you have any questions that you would like to ask before deciding whether to take part, please contact Helen Crocker by telephone: 01865 289431 or by email:

Helen.Crocker@dph.ox.ac.uk.

Is participation confidential?

Yes, all information you give will be treated confidentially. No personal data (e.g. name and contact details) has been made available to the research team by Coeliac UK. If you participate and choose to provide your name and address, these details will be used to send you a second questionnaire only. You will be assigned an identification number which serves to match up both your questionnaires. Both questionnaires will be marked with this identification number and not your name. A separate password-protected data file will match your name to the questionnaires' ID number. This will only be accessible to the researchers and will be destroyed as soon as the second questionnaire data has been collected.

What happens to the data that I provide?

Personal details and other data collected as part of this research will be accessible to the research team only. Paper documentation will be stored in locked filing cabinets and electronic files will be stored on a password-protected computer, on the secure University of Oxford computer network, in accordance with the current Data Protection Act. Personal data (e.g. name and contact details) will not be kept beyond your involvement in the study. In accordance with guidelines produced by the Medical Research Council, anonymised data will be kept for a period of ten years to allow the research to be reviewed if necessary.

Are there any risks involved in taking part?

This is a low risk study and it is unlikely that you will experience any adverse events from taking part. In the unlikely event that you feel concerned about any effect the study has on you or if you have any questions about coeliac disease, contact the research team, your GP or Coeliac UK on their Helpline: 0845 305 2060 or visit their website: www.coeliac.org.uk.

Will the results of the research study be published?

The University of Oxford is committed to the dissemination of its research for the benefit of society. Therefore, it is intended that the research will be written up as one or more papers to be submitted for publication in scientific journals and presented at conferences. Your name or any other identifying details will not be included in any of the research reports. If you are interested in the results of the study, they will be available on the University of Oxford's website from end July 2016, please visit: www.ndph.ox.ac.uk/research/health-services-research-unit-hsru/research/coeliac-disease-research

Who has reviewed this research study?

This study has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee.

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

If you have a concern about any aspect of this project, please contact the Research Officer (Helen Crocker, tel: 01865 289431, email: Helen.Crocker@dph.ox.ac.uk) or Senior Research Scientist (Dr Michele Peters, tel: 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.