



Health Services Research Unit Nuffield Department of Population Health

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Diagnosis and management of coeliac disease: Quality of life and patient's experiences of healthcare services

Information Sheet for Survey Participants

What is the purpose of this research?

The purpose of this research is to develop and validate a questionnaire that measures the impact of coeliac disease on quality of life. The questionnaire has been developed with input from people with coeliac disease, healthcare professionals, and researchers. In this survey, we would like to assess how well the questionnaire measures quality of life in people with coeliac disease and improve the questionnaire prior to its use in future research. This research study is part of a larger study which aims to explore experiences of living with coeliac disease and using healthcare services to diagnose and manage the condition.

Who is doing the research?

The research is led by Helen Crocker, a researcher in the Nuffield Department of Population Health at the University of Oxford, under the supervision of Professor Crispin Jenkinson and Dr Michele Peters. The research is funded by the Medical Research Council and is part of a doctoral research programme. The research is being undertaken with the support of Coeliac UK.

How can I take part?

Taking part in this study is voluntary and confidential. If you would like to take part, please complete the enclosed questionnaire and return it to the research team in the pre-paid envelope provided. The questionnaire asks about your experiences of living with coeliac disease. If you have any questions that you would like to ask, please contact Helen Crocker by telephone: 01865 289431 or by email: Helen.Crocker@dph.ox.ac.uk. Returning the completed questionnaire means that you understand the purpose of this study and are happy to take part. 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.

What will happen with the information that I provide?

The results of this survey will be used to improve the questionnaire. The improved questionnaire will be used in a further survey to assess experiences of healthcare services and quality of life in coeliac disease. It is intended that the results of this second survey will inform healthcare policy to improve the quality of healthcare for people with coeliac disease and find out how coeliac disease affects the quality of life of those living with the condition. It is also intended that the improved questionnaire will be available for use in other research studies and clinical trials to measure quality of life in coeliac disease.

Who can take part?

Participants should be aged 18 years or over, live in the UK, and have a medical diagnosis of coeliac disease. You have been made aware of this study as a Member of Coeliac UK who has agreed you may be contacted for research purposes. We are interested in all experiences of coeliac disease however well you manage your condition and whatever the extent of your symptoms.

Will participation be confidential?

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 in accordance with the current Data Protection Act. In accordance with guidelines produced by the Medical Research Council, data will be kept for a period of ten years to allow the research to be reviewed if necessary.

Participation is anonymous. No personal data (e.g. name and contact details) has been made available to or will be collected by the research team.

What will happen with the results of the study?

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, presented at conferences, and as a doctoral thesis. On successful submission of the thesis, it will be deposited in the University archives to facilitate its use in future research. The thesis will be available in print and online.

Are there any risks involved in taking part?

We do not foresee any risks involved in taking part in this study. If participating in this research raises questions about the condition that you would like to discuss, you can contact Coeliac UK on their Helpline: 0845 305 2060 or visit their website: www.coeliac.org.uk.

Are there any benefits in taking part?

The information that you provide will help improve the questionnaire which will be used in a further study intending to inform healthcare policy and improve healthcare services in the future. There are no direct benefits in taking part.

What can I do if I have any concerns about the research study?

This study has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee. If you have a concern about any aspect of this project, please speak to the relevant researcher (Helen Crocker, tel: 01865 289431, email: Helen.Crocker@dph.ox.ac.uk) or her supervisor (Professor Crispin Jenkinson, tel: 01865 289441, email: Crispin.Jenkinson@dph.ox.ac.uk) who will do their best to answer your query. The researcher or supervisor should acknowledge your concern within 10 working days and give you an indication of how he/she intends 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 (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). The chair will seek to resolve the matter promptly.