

**PARTICIPANT INFORMATION SHEET**

**A questionnaire study of the use of ketogenic diet in bipolar disorder**

**Bipolar disorder is a major lifelong condition which significantly impacts the lives of those who live with it. Our current understanding of the cause of bipolar and its treatment is limited, but there is some evidence that a ketogenic diet may be an effective treatment. With this research we aim to explore the experiences of people with bipolar disorder who have followed the ketogenic diet. This will help us to understand where further research should be targeted.**

***We are inviting you to take part in a research study.***

***Participation is voluntary and will involve completing a one-off questionnaire, taking 20-40 minutes***

To help you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take the time to read the following information carefully. Contact us if there is anything that is not clear, or if you would like more information. We will follow ethical and legal practice and all your personal information will be treated in the strictest confidence.

**What is the purpose of the study?**

The purpose of the study is to determine whether people with bipolar disorder report any changes in their mood, energy, anxiety and other health and quality of life related factors when on a ketogenic diet.

**Who can take part?**

To be eligible to take part in the study you need to have a diagnosis of bipolar disorder from a psychiatrist. You must not currently be experiencing an episode of major depression, mania or hypomania. You need to be aged 18 or over, and you must be able to read and understand English. You must have been following the ketogenic diet for at least 2 weeks, or have done so in the past.

**Do I have to take part?**

No, you do not have to take part or give a reason for not doing so. If you do decide to take part, please keep this information sheet and complete the consent form to show that you are happy to participate. If you do decide to take part you are free to withdraw at any time without giving a reason. Please note down your participant number (which is on the consent form) and provide this to the lead researcher if you seek to withdraw from the study at a later date.

**What will happen if I decide to take part?**

You will be asked several questions regarding your use of the ketogenic diet, the effects of a ketogenic diet on your health and well being, and your experience of bipolar disorder prior to following the diet. The questionnaire will be available to you after reading this information sheet and agreeing to the consent points, and can be completed at a time that is convenient to you. The questionnaire should take around 20-40 minutes to complete.

**What are the possible benefits of taking part?**

By sharing your experiences with us, you will be helping psychiatrists, the wider scientific community and people with bipolar disorder to better understand whether there may be risks or benefits of following a ketogenic diet for people with bipolar disorder.

**Are there any risks associated with taking part?**

It can sometimes be upsetting to reflect on details of illness. Your well-being is the highest priority to us and if you have concerns about the effect on your mental wellbeing we encourage you to stop and contact our research team (ketostudy@ed.ac.uk) or a member of your healthcare team.

**What if I want to withdraw from the study?**

If, at any stage, you no longer want to be part of the study, please inform the project team at ketostudy@ed.ac.uk. You should note that your data may be used in the production of formal research outputs prior to your withdrawal and so you are advised to contact the research team at the earliest opportunity should you wish to withdraw from the study. Please make a note of your ID number when you complete the questionnaire and quote this to us. On specific request or withdrawal from the study all of your data will be deleted with the exception of our record of your consenting participation.

**Data Protection and Confidentiality**

Your data will be processed in accordance with UK Data Protection Law. All information collected about you will be kept strictly confidential. Your data will be referred to by a unique participant number rather than by name. Your data will only be viewed by the research team. All electronic data will be stored on a password-protected computer file for at least 3 years after the end of the study, which is expected to last for 18 months. For general information about how we use your data please go to: <https://www.ed.ac.uk/records-management/privacy-notice-research>

**What will happen with the results of this study?**

The results of this study may be summarised in published journal articles, reports and presentations. Quotes or key findings will always be made anonymous in any formal outputs unless we have your prior and explicit written permission to attribute them to you by name. Information may also be kept for future research.

**Who is organising and funding the research?**

This study has been organised and Sponsored by University of Edinburgh.

**Who has reviewed the study?**

All research is looked at by an independent group of people called a Research

Ethics Committee. A favourable ethical opinion has been obtained from the Edinburgh Medical Scholl Research Ethics Committee.

**Who can I contact?**

If you have any further questions about the study or require this information in different form (e.g. braille or large font), please contact the research team: ketostudy@ed.ac.uk

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact

Prof. Stephen Lawrie: s.lawrie@ed.ac.uk

If you wish to make a complaint about the study, please contact:

resgov@accord.scot