



THE UNIVERSITY
of EDINBURGH

Usher
institute

NHS
Lothian

Bipolar
Scotland



— A KETOGENIC DIET —
FOR BIPOLAR DISORDER

MRC/CSO Social and Public Health Sciences Unit



Medical
Research
Council



CHIEF
SCIENTIST
OFFICE



PARTICIPANT INFORMATION SHEET ADDENDUM

A pilot study of the ketogenic diet in bipolar disorder

This addendum is intended to update you about a potential change to the way the above study will be run. Please refer to the main participant information sheet (V3 18 Feb 2022) for full details of the study. Participation is voluntary and we would like you to consider this additional information before making a final decision about taking part.

Please take the time to read the following information carefully. Talk to others about it if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether you wish to take part. You will have at least 3 days to do this, and you will not be expected to consent unless you have had time to read and consider this leaflet. Please note that we will follow ethical and legal practice and all your personal information will be treated in the strictest confidence.

What is different?

There have been some delays establishing legal contracts with the phone app companies that we plan to ask you to use during the study. We do not anticipate any problems finalising these, but unfortunately it has taken longer than expected. Until these contracts are in place, we cannot legally use these apps in the study. These include the ilumivu app, which we plan to ask you to use to record aspects of your mood each day, and the Ketomojo app, which we plan to ask you to use to upload daily ketone and glucose readings.

If these contracts aren't in place by the time you are due to have your first study appointment, there is a chance we may run the study slightly differently. Until the contracts are in place, we may need to text or phone you daily to ask for these measurements, and would ask you to text or relay your response to us. We hope that this would not take much longer than entering the data on the apps but understand that it may be less convenient. We may also send you a follow up text if you forget to text or ring us back with the required information. Once the contracts are in place, we would switch to using the apps as planned.

Do I have to take part?

You do not have to take part or give a reason for not doing so. After reading this information, you are free to withdraw at any time and without giving a reason. You have been sent this information sheet because you have already expressed an interest in the study.

Will there be any changes to the way we use information about you?

We will follow ethical and legal practice and all your personal information will be treated in the strictest confidence. There will be no changes to the way data is collected and stored. We will continue to allocate your data a code number, and if we used a texting system, we would store your number in a University of Edinburgh or NHS Lothian phone, using only your study ID number to identify you. We would not send you any personal identifiable information via text message (e.g. name, date of birth, address), and would ask you not to include this when replying. All text messages would be deleted as soon as we had recorded the data from them.

We will collect the data you provide us over text in the same way we would have done using the apps. This will be stored on a secure University of Edinburgh computer.

What if there is a problem?

If you have any questions or concerns about the study, please contact the researchers using the details below.

How do I take part?

If you are still interested in taking part in the study after reading this information sheet, please contact the research team at ketostudy@ed.ac.uk to inform them of this.

Thank you for reading this information sheet

If you have any queries about the study, please contact the study team:

Study email: ketostudy@ed.ac.uk **Study office telephone/answer machine:** 0131 5376531

Study website: www.bipolarketostudy.com

Dr Nicole Needham, Project Coordinator: nneedham@ed.ac.uk

Professor Harry Campbell, Chief Investigator: harry.campbell@ed.ac.uk

If you would like to speak to someone independent and not involved in the study, please contact:

Prof. Stephen Lawrie Professor of Psychiatry, Centre for Clinical Brain Science, The University of Edinburgh

Email: s.lawrie@ed.ac.uk **Tel:** 0131 537 6671

If you have a complaint, please contact:

The University of Edinburgh Research Governance Team

Email: resgov@accord.scot

NHS Patient Experience Team

2 – 4 Waterloo Place, Edinburgh, EH1 3EG

Email: feedback@nhslothian.scot.nhs.uk **Tel:** 0131 536 3370