



UNIVERSITY OF
BIRMINGHAM

INFORMATION SHEET

Lumir Mission UK Medicinal Cannabis Use Study

You are being invited to take part in a research study carried out by researchers from the University of Birmingham. Before you decide about taking part, it is important for you to understand why the research is being done, and what it will involve. Please take some time to read the following information carefully. Please ask the researcher who gave you this sheet if there is anything that is not clear or if you would like more information.

Thank you.

What is the purpose of the study?

The study aims to help over 1 million patients worldwide and to contribute to the scientific evidence base for medicinal cannabis (MC) through a range of research activities.

There are hundreds of cultivated varieties of cannabis, and thousands of cannabis products on the market. Not only does cannabis contain the major phytocannabinoids, tetrahydrocannabinol (THC) and cannabidiol (CBD), but it also contains minor phytocannabinoids and terpenes (essential oil-like substances) which also have therapeutic effects. Different cannabis flowers therefore have different amounts of these components - a different 'phytochemical profile'. The same can be said of individual MC products. Relatively little is known about which characteristics of MC products are most effective in alleviating a range of medical conditions and associated common symptoms. This study aims to collect data from tens of thousands of MC users, in Australia, the UK, Australia and the US to help answer this question.

This study is being conducted in the UK, Australia, and the US. This Participant Information sheet is relevant to the UK study only.

This study will collect data on selected brands of MC products prescribed in Australia. These cannabis product brands are supplied in the UK by Cannim Group (the study sponsor) and selected MC companies supporting the study. The full list of participating cannabis companies can be found on the Lumir Mission website (www.thelumirmission.com) and this list may change over time as more cannabis companies join the Lumir Mission. The reason for only investigating a limited number of brands is that the study is trying to investigate the characteristics of MC products that work best for particular conditions and to do so, must include the phytochemical (plant chemical) profiles of all the products included in the study

in its statistical analysis. There are thousands of products in the market now. So, for logistical reasons, we need to confine analysis to a few hundred products.

Who Can Participate in the Study?

It is strongly advised that anyone taking MC is under the care of a qualified healthcare practitioner trained in MC. In the UK, MC products containing tetrahydrocannabinol (THC, one of the major constituents of cannabis) is available by prescription only from a medical specialist. Some hemp-based MC products containing cannabidiol (CBD) (and very low amounts of THC) are available over-the-counter in the UK.

Inclusion Criteria:

- Individuals who are 18 years and over and living in the UK.
- Individuals who have been prescribed medicinal cannabis products from within the Study Product Formulary and agree to remain on these products for as long as they remain in the study. The Study Product Formulary includes cannabis products of the study sponsor Cannim Group and may include products of other medicinal cannabis companies supporting the study.*

Exclusion Criteria:

- Individuals using illegal sources of cannabis (even if self-medicating)
- Individuals using prescription medicinal cannabis products who are not under the care of a medical practitioner in relation to their use of medicinal cannabis.
- Individuals who have not been prescribed medicinal cannabis products from within the Study Product Formulary.
- Individuals who are not willing to only use medicinal cannabis products from within the Study Product Formulary.

*Medicinal cannabis companies supporting the study are listed on the Lumir Mission website www.lumirmission.com

What Am I Required to Do?

This study is only open to those patients prescribed MC products supplied by Cannim Group (Lumir brand products) and those supplied by study partner companies (see the Lumir Mission website for an up-to-date list of participating MC companies, as this will change over time as new companies join the Lumir Mission study).

In the UK you need to have MC products containing tetrahydrocannabinol (THC) prescribed by a medical specialist. Some hemp products containing CBD (and very low amounts of THC) may be purchased over-the-counter, however it is recommended that advice is obtained from a medical specialist in relation to any type of cannabis product. If you do not have a prescription for MC and/or need advice on the type of MC products suitable for you, Lumir Clinic UK has medical specialists who are trained in MC and can help you find the right MC product(s). There are also other clinics where MC may be prescribed in the UK.

A key component of this study is finding out if MC helps your primary condition as well as if it impacts on pain, sleep, anxiety, mood, general functioning and energy level. We also want

to know if you experience any side effects, positive or negative, and if your use of pharmaceuticals for your main condition changes over time.

To participate in the study, you need to download the Lumir Study App to your phone or click the link to the survey which will allow you access to the web-based survey platform- you can choose which way you would like to participate in the study. You will need to read and agree to the terms of participation in the study. Then you need to fill in some demographic details about yourself including age, gender, level of education, regular treatments and so on. You are required to nominate a primary complaint (for which you are using MC).

Monthly Surveys

You then complete the baseline survey which asks you to rate the severity of your primary complaint and some associated common symptoms (mood, anxiety, pain, energy level, general functioning, quality of sleep) on a sliding scale from 0 to 10. There are also two questions about any side effects experienced and whether your use of pharmaceutical medications has changed over the past week (note that these last two questions are not relevant if you are filling out the baseline survey just prior to beginning your first MC product).

This survey is sent to you again on a monthly basis.

What Do I Gain from Participating?

Continuous tracking of your health can help inform you and you can also share the information with your healthcare provider if you so choose.

You will also be contributing to the knowledge base around MC which may help a larger community of people in the future.

In addition, as a thank you for participation in the study and ongoing incentive to log their study data on a monthly basis, completion of the baseline survey and each monthly survey will unlock a study discount coupon which can be redeemed on the purchase of their prescribed MC products through partner pharmacies (pharmacies are the organisations that dispense the MC medicines, not MC companies) for up to 20% off the retail price of MC products, provided that these are Cannim MC products or study partner MC products.

How will the Information I Give Be Used?

Aside from your own use and reports within your personal Lumir Mission App, all data collected is deidentified (your name removed) and added to the anonymous data from other study participants within the UK as well as combined with data from similar studies being conducted in Australia and the US. This deidentified global data set will then be analysed to inform future research directions in pursuit of furthering the understanding of applications of medical cannabis.

A report on the results of the study will be provided to the study sponsor, Cannim Group. Results of the study will be written up as journal papers and submitted to peer reviewed journals and may also be presented at medical and other healthcare conferences. In all cases, results presented are statistical analysis of de-identified, collated data that will not identify any individual. In addition, you may also choose to share your own personal survey data with your healthcare practitioner (this is not compulsory and is entirely your

choice). A summary of the key findings from this study will be made available on the Lumir Mission website at the completion of the study (interim findings may also be published).

Are There Any Risks Involved in the Research?

This study simply measures and tracks a range of patient outcomes in a formal sense in people already using MC products that are legally obtained in the UK. The risks associated with MC use should be discussed with your doctor and you remain under the care of your medical practitioner in relation to your MC.

Known side effects of MC, both cannabidiol (CBD) and tetrahydrocannabinol (THC), include fatigue, sedation, vertigo, nausea, vomiting, fever, decreased or increased appetite, dry mouth and diarrhoea. THC and products containing high amounts of THC have also been associated with convulsions, feeling high, feeling dissatisfied, depression, confusion, hallucinations, paranoid delusions, psychosis, and cognitive distortion (having thoughts that are not true) (for more information please see: <https://www.tga.gov.au/publication/guidance-use-medicinal-cannabis-australia-patient-information>). It is important that you discuss any personal or family history of psychosis, schizophrenia or depression or other serious mental health conditions with your prescribing doctor when considering MC as a treatment option.

Note that:

- participants should not drive or operate heavy machinery if consuming THC-containing medicines.
- if at any stage you are feeling unwell, you should contact your general practitioner or MC prescriber (doctor/specialist) or alternatively, if you were to experience any serious symptoms or signs, you should seek medical assistance at a hospital.
- if you are taking prescription MC products and you decide to not continue under the care of a medical practitioner in relation to MC use, you may not remain in the study and should remove yourself from the study.

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Potential Risks Associated with Data Breaches

As the study is collecting data via an App and web-based survey, all due care is given to ensuring the privacy of your data, as set out in the Lumir App Data and Privacy Policy that is required to be read on initial opening of the Lumir Mission study App. However, there is always a risk that a data breach could occur. Should a data breach be detected that could infringe on the confidentiality of your personal data, the appropriate steps will be taken to rectify this including notifying any participants affected by the security

Note that it is the responsibility of study participants to ensure that unauthorised access to any personal information on their mobile device (cell phone) including information within the study App is minimised by ensuring that your phone is password protected and/or utilises facial recognition technology for access.

Withdrawing from the Study

Participation in this study is voluntary. You may withdraw from the study at any time. Withdrawing from the study will in no way impact on your medical care. To do this via the App or the Web-based Survey platform, you can delete your account from within the Account

Settings section. A pop-up message will appear to confirm that you want to delete the account.

Note that deleting the App from your phone or tablet is not sufficient to withdraw from the study. You must delete your account then delete the App.

All data that you have provided up to that point will still be included in the study analysis- it will be de-identified (your name and any other identifying details are removed) and collated with de-identified (anonymous) data from other participants and analysed statistically. In other words, if you withdraw from the study, the de-identified data you have provided already cannot be withdrawn and will be used in analysis.

Privacy and Confidentiality

At all times your data will be managed with the strictest adherence to the data legislation relevant in your region. This includes (but is not limited to); UK GDPR compliance (UK), HIPAA compliance (USA), and The Privacy Act 1988 and Australian Privacy Principles (Australia). All data collected for statistical analysis will be de-identified (this means your name is removed) and aggregated (combined with the data of other participants). Your participation in this study therefore remains confidential.

Who is Conducting the Study?

The study is being conducted by the University of Birmingham, School/Department of Inflammation and Ageing. This study is sponsored by Cannim Group Pty Ltd, a MC company based in Australia, with business interests in the US, UK, Canada, Jamaica and Germany and which owns the Lumir Clinic UK.

The following people are involved in the study:

Chief Investigator:

Professor Zubair Ahmed, Professor of Neuroscience, Department of Inflammation and Ageing, College of Medicine and Health, University of Birmingham, Edgbaston, Birmingham, B15 2TT.

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Associate Investigators:

Professor Kylie O'Brien PhD (Chief Scientific Officer, Cannim Group Pty Ltd and Adjunct Professor Torrens University and Adjunct Fellow NICM Health Research Institute, Western Sydney University, Australia)

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Dr Anup Matthew Registered Psychiatrist UK, Medical Director Cannim UK and Lumir Clinic UK

Email: avmathew@doctors.org.uk

Who Do I Contact for Any Questions in Relation to the Study?

Contact the Chief Investigator: Professor Zubair Ahmed; email: z.ahmed.1@bham.ac.uk

Ethics Approval, Queries and Complaints

The conduct of this research project in the UK has been approved by the University of Birmingham Science, Technology, Engineering and Mathematics (STEM) ethics committee (see: The [University of Birmingham's central HASS and STEM ethics committees](#)).

If you have any queries or complaints about the way you have been treated or your rights as a participant, you may contact the Research Ethics Officer, at the following email address:

Email: aer-ethics@contacts.bham.ac.uk.

Other Helpful Support Services

Mental Health Services

If you require mental health support in the UK, here are some organisations that may be able to assist:

- Mental Health Foundation: www.mentalhealth.org.uk/explore-mental-health/get-help
- Mind UK: www.mind.org.uk

Medical Practitioner Complaints

For complaints about doctors, See

www.ombudsman.org.uk/sites/default/files/How_to_raise_concerns_about_a_general_practice_0.pdf