1) What is this study about?

You are invited to take part in a research study exploring quality of life in patients accessing medicinal cannabis. People accessing medicinal cannabis may have a range of conditions and symptoms that impact their quality of life. We would like to know how these conditions and symptoms impact quality of life and if this changes over time while accessing medicinal cannabis. The results from this study will help future patients with these conditions to make better informed decisions about their treatment.

You have been invited to participate in this study because you have a condition with symptoms being treated with medical cannabis. This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:
- Understand what you have read.
- Agree to take part in the research study as outlined below.
- Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement to keep.
2) Who is running the study?

The study is being carried out by the following researchers:

- Dr Claudia Rutherford, Senior Research Fellow, School of Psychology, University of Sydney
- Ms Margaret-Ann Tait, Senior Research and Administration Officer, School of Psychology, University of Sydney

Margaret-Ann Tait is conducting this study as the basis for the degree of Doctor of Philosophy at The University of Sydney. This will take place under the supervision of Dr Claudia Rutherford.

This study is being funded by an Australian manufacturer of medicinal cannabis, Little Green Pharma Ltd.

3) What will the study involve for me?

Your doctor will identify if you are eligible for the study and enter some basic information about you into the study register. This includes your age, sex, health condition, and which medicinal cannabis product you are receiving. Your doctor will ask if you agree to provide an email address to receive an invitation to the study. We will not collect any information that can identify you such as your name, physical address, or birth date.

You will be sent an electronic link via email to join the study. When you open the link you will be asked if you consent to taking part.

If you decide you do not want to take part, select 'opt-out'. Your email address will be removed from the study. If you do not open the link, two reminders will be sent to you, after which you will automatically 'opt-out' and your email address will be removed from the study.

If you do wish to take part in the study, select 'yes' to agree to take part in the research study.

After choosing to take part in this study, you will automatically proceed to the first questionnaire pack. You will need internet access to complete the questionnaires, or you may be able to download a study App to complete them on your smartphone or other mobile device. You will then receive notifications on your mobile phone, or by email to complete follow-up questionnaires.

The questionnaire pack starts with some general information about you. For example, this information includes your living arrangements, whether you are employed, and what other medications you may be taking. This information is for research purposes only and will not be shared with your doctor.

You will then be asked about your quality of life and symptoms. Completing questionnaires involves choosing an answer to a set of questions. An example of a question that you might be asked is:

**During the past week: (select the number response that best applies to you)**

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>A little</th>
<th>Quite a bit</th>
<th>Very much</th>
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<tbody>
<tr>
<td>Have you had trouble sleeping?</td>
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This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions. Your anonymised, completed questionnaire will be used only by researchers involved in the project and will be stored securely in Australia on the University of Sydney's servers for Research Data Storage. However, if you want to share your progress with your doctor regarding your quality of life and symptoms, for example ‘improvement in pain’, you can choose to do so through the Mobile App. Please ask your doctor for details about downloading the App.

You must be able to read and understand English and complete the questionnaires without interpretation from others.

4) How much of my time will the study take

You will complete questionnaires at the time you join the study, and then again at 2 weeks after starting medicinal cannabis therapy, monthly for 3 months, then every two months (i.e. 5, 7, and 9 months after starting medicinal cannabis therapy), and once again at 12 months. On each occasion, the questionnaires will take approximately 30 minutes to complete.
5) Who can take part in the study?

All of the following must be satisfied for enrolment in the study:
- you are an adult (aged ≥18 years)
- you are able to read and understand English
- you are able to provide informed consent
- you have a life-expectancy of >3 months
- you have been identified as eligible to receive medicinal cannabis by a TGA approved Authorised Prescriber, or any doctor using the special access scheme (SAS-B) (or equivalent in other countries and jurisdictions) and your prescribing doctor has TGA approval to prescribe Little Green Pharma products.
- you have:
  - not received any prescribed medicinal cannabis therapy in the previous 4 weeks, or
  - started prescribed medicinal cannabis therapy (Little Green Pharma product), within the previous 2 days and not received any prescribed medicinal cannabis therapy in the previous 4 weeks.

Patients will be excluded from the study if any of the following criteria apply:
- are unconscious, confused or cognitively impaired
- are pregnant or breastfeeding
- are unable to speak, read and/or write in English
- are denied access to medicinal cannabis under the relevant Special Access Scheme in your country
- are unable to provide informed consent
- are currently receiving prescribed medicinal cannabis treatment for more than 2 days

6) Do I have to be in the study? Can I withdraw from the study once I’ve started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney, and will not affect your current or future treatment at the clinic you are having treatment or relationships with your doctor or treating team.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by contacting the doctor who prescribed medicinal cannabis. If you withdraw from the study, you will no longer receive the study participant discount on the cost of your medicinal cannabis prescription.

Submitting your completed questionnaire is an indication of your consent to participate in the study. You can withdraw your responses if you change your mind about having them included in the study, up to the point that we have analysed and published the results.

7) Are there any risks or costs associated with being in the study?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

8) Are there any benefits associated with being in the study?

Little Green Pharma have agreed to subsidise the cost of their products across Australia and UK so that all patients taking part in this study will be charged the same discounted rate. The cost of medicinal cannabis products for participants will be set at AUD150.00 per unit (bottle) plus delivery fee of $15.00. If you withdraw from the study, you will no longer receive the study participant discount on the cost of your medicinal cannabis prescription.
(9) What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Personal and health information may include your age, health conditions, and the treatments that you have received. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

All study information will be collected via the University of Sydney research data capture system, REDCap, a secure web application that runs on The University of Sydney’s servers, ensuring data stays within the Sydney University data centre. Information will be stored electronically on a secure, password-protected server at the University of Sydney for at least 7 years, only accessible by the researchers, Dr Rutherford and Ms Tait. Any information that may identify you (such as email addresses) will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications.

All information collected by and through the Mobile App is password protected, held, stored and transmitted securely to the University of Sydney server, including that it is encrypted at rest and in transit. The App developers will not use the data and will not transfer or disclose information to any third party without your consent.

We intend to give the information from this project to other researchers so that they can use it in their projects. Before we do so, we will take out all the identifying information so that the people we give it to won’t know whose information it is. They won’t know that you participated in the project and they won’t be able to link you to any of the information you provided.

10) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

11) What if I would like further information about the study?

When you have read this information, your doctor prescribing you medicinal cannabis will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Margaret-Ann Tait, Senior Research and Administration Officer, at margaret-ann.tait@sydney.edu.au or phone +61 2 8627 1558

12) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form. This feedback will be in the form of a one page lay summary. You will receive this feedback after the study is finished.

13) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney [INSERT protocol number once approval is obtained]. As part of this process, we have agreed to carry out the study according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:
Telephone: +61 2 8627 8176
Email: human.ethics@sydney.edu.au
Fax: +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep.

The ethical aspects of this study have been approved by the Human Research Ethics Committee of the University of Sydney [project number: 2020/89].