

**Participant Information Sheet/Consent Form**

**Non-Interventional Study** -*Adult providing own consent*

**Title:** The Prevalence and Impact of Social Media to Seek Support and Health Information in Women with Endometriosis

**Short Title:** Social Media and Endometriosis

**Protocol number:**

**Project sponsor:** The Royal Women’s Hospital, Gynaecology 2 Unit

**Coordinating Principal Investigator:** Dr Kelly van den Haspel

**Associate Investigator(s):** Dr Charlotte Reddington

 Dr Claudia Cheng

 A/Prof Martin Healey

**Location:** Royal Women’s Hospital. Melbourne, VIC 3052

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project because you are a woman who has a proven diagnosis of endometriosis and are undertaking care at the Royal Women’s Hospital. This study is looking at the use and impact of Social Media to seek support and health information specifically in women with Endometriosis. ‘Social Media’ can be defined as websites and applications that enable users to create and share content or to participate in social networking online. By participating in this study, we hope to gain a better understanding of the number of women who are using Social Media for these reasons, the behaviours of women online, potential risks and benefits and gaps in information associated with using Social Media for health information and support. You DO NOT have use Social Media to participate in this study.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor. Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to the tests and research that are described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep

**2 What is the purpose of this research?**

The aim of this study is to identify how many women with endometriosis are using Social Media to seek health information and support directly related to their condition. Endometriosis is a common disease affecting women all over the world and has known mental and social impacts in addition to physical symptoms. Finding understanding and knowledgeable contact networks and resources for these women can be challenging; the internet therefore becomes a key resource for seeking support and information.

Previous research has shown that Social Media can be beneficial as a self-management strategy for patients suffering from chronic pain. As Social Media becomes more popular, health practitioners and hospitals want to know more about the potential therapeutic role these platforms can play in healthcare. This study could possibly lead to the development of online resources and Social Media platforms designed specifically to help women suffering with endometriosis. This research has been initiated by the study doctor, Dr Kelly van den Haspel

**3 What does participation in this research involve?**

This research involves the completion of a once-off questionnaire related to general information about yourself, questions specific to your endometriosis and questions about your use of Social Media. This questionnaire will take less than 20 minutes to complete.

The first step is completing this consent form. No part of the study will be completed without the consent of the participant.

You are considered eligible to be a part of this study if you have a proven diagnosis of endometriosis via surgery. This surgery does not have had to be done at the Royal Women’s Hospital. You DO NOT have to use Social Media for health information to be involved in the study. The questionnaire will be distributed to you via electronic or paper copy. You can elect which you would prefer to complete. The online copy can be accessed via your personal electronic devices through the “SurveyMonkey” service. A link with be sent to you via QR code or email. We plan to have 100 women who are patients of the Royal Women’s Hospital complete the questionnaire over a period of 6 months.

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. There are no costs associated with participating in this research project, nor will you be paid.

**4 What do I have to do?**

Participation in this study involves completion of a once-off questionnaire. Participants should undergo treatment and care as usual, with management not affected by their enrolment in this study.

**5 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Royal Women’s Hospital.

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

There will be no clear benefit to you personally from your participation in this research.

**7 What are the possible risks and disadvantages of taking part?**

This research does not involve any interventional treatment, as such there are no additional risks or side effects from participating in this project. If you become upset or distressed from any of the questions asked as part of this research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

**8 What if I withdraw from this research project?**

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. If you do withdraw your consent during the research project, all data and information collected from you up to the time of withdrawal will be destroyed and excluded from the study. This will be the case unless it is not possible to do so, e.g. such information has already been included as part of the results that cannot be re-identified and extracted/excluded.

**9 Could this research project be stopped unexpectedly?**

There is no foreseeable reason why this research project would be stopped unexpectedly.

However, this research project may be stopped unexpectedly for a variety of reasons including if other studies are performed yielding new information.

**10 What happens when the research project ends?**

After completion of the project the information will be gathered and analysed. The results of this project may be presented at scientific meetings or published in a medical journal. The results of this study may lead to the development of new guidelines for treating patients in the future.

A summary of the results of the project will be made available to all participants at the completion of the study. This can be requested by email to the principal investigator.

**Part 2 How is the research project being conducted?**

**11 What will happen to information about me?**

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Upon enrolment in the study you will be assigned a study number and information collected on you will only be expressed by this number. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records regarding the staging and diagnosis of your endometriosis for the purpose of this research. By signing the consent form, you agree to the research team accessing health records if they are relevant to your participation in this research project. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

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

This research project is being conducted by Dr Kelly van den Haspel. Dr van den Haspel has not currently obtained any funding for the completion of this study, however a clinical research funding grant application has been made to Australasian Gynaecological Endoscopy and Surgery (AGES) society. No member of the research team will receive any personal financial benefit from your involvement in this research project (other than their ordinary wages).

**13 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of The Royal Women’s Hospital. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2018). This statement has been developed to protect the interests of people who agree to participate in human research studies.

**14 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on 03 8345 2000 or any of the following people:

 **Clinical contact person**

|  |  |
| --- | --- |
| Name | Dr Kelly van den Haspel  |
| Position | Lead clinical investigator  |
| Telephone | 03 8345 2000 |
| Email | Kelly.vandenhaspel@thewomens.org.au  |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | The Royal Women’s Hospital Consumer Advocate  |
| Telephone | 03 8345 2000 |

**Consent Form -** *Adult providing own consent*

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Short Title: Social media and Endometriosis

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Coordinating Principal Investigator: Dr Kelly van den Haspel

Associate Investigator(s): Dr Charlotte Reddington

 Dr Claudia Cheng

 A/Prof Martin Healey

Location: Royal Women’s Hospital. Melbourne, VIC 3052

**Consent Agreement**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

**Declaration by Participant – for participants who have read the information**

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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| --- |
|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

**Form for Withdrawal of Participation -** *Adult providing own consent*

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Associate Investigator(s): Dr Charlotte Reddington

 Dr Claudia Cheng

 A/Prof Martin Healey

Location: Royal Women’s Hospital. Melbourne, VIC 3052

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with The Royal Women’s Hospital.

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| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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| --- |
|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.