Investigating the association between IBD distress and medication adherence in patients with Crohn’s Disease and Ulcerative Colitis

Sponsor: King’s College London
Chief investigator: Professor Christine Norton
Principal Investigator: Dr Mahmood Wahed

Participant Information Sheet
(Version 3.0; Date 30/06/2018)

Invitation to take part

We would like to invite you to take part in a research study for patients living with Inflammatory Bowel Disease (IBD). Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve.

Talk to others about the study if you wish.

What is the purpose of the study?

The purpose of the study is to assess if there is a relationship between patient’s level of compliance with treatment and the level of distress caused by IBD. This study is being undertaken for educational purposes.

Why have I been invited?

You have been invited to take part in this study because you are over 16 years old, have been diagnosed with Ulcerative Colitis or Crohn’s Disease and are currently on treatment with any approved medication.

About 200 people will be recruited in this study.

Do I have to take part?

It is completely up to you to decide if you want to take part. Before you make your decision, someone from the study team will describe the study and go through this information sheet with you. If you decide to take part, you will be asked to sign a consent form. You will be given a copy of Patient Information Sheet Version 3.0 30/Jun/2018
IRAS ID: 239755
Investigating the association between IBD distress and medication adherence in patients with Crohn’s Disease and Ulcerative Colitis

this information sheet and the consent form to take home with you. You may withdraw from the study at any point if you wish to do so and this will not affect in any way the standard of care you receive. You do not have to provide a reason for withdrawing from the study.

What will happen to me if I take part?

If you are interested in participating, we will schedule a convenient time to discuss the study and you will be given the opportunity to ask any questions you might have and to clarify any doubts. When possible, this will be done during your routine appointments at the hospital.

You will be asked to complete six questionnaires when you first join the study and then four of them at month 3 and month 6. You will receive all the material during your appointment at the hospital or by post (we will include a pre-paid envelope so that you can return the questionnaires to us after completion). Each questionnaire will take approximately 5 minutes to complete. The distress questionnaire might take up to 20 minutes.

In the questionnaires you will be asked to provide some information about you (e.g. age, gender, working status), about the type of IBD that you have and the treatment that you have been prescribed. You will also be asked to provide details regarding your level of adherence to treatment (e.g. do you always take your medications as directed?) and your current level of distress.

If you are a patient at Chelsea and Westminster Hospital, some of your details might be extracted from your medical records.

The table below summarizes the questionnaires that you will have to complete each time:

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<th>Day 1</th>
<th>Month 3</th>
<th>Month 6</th>
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<tr>
<td>Demographic</td>
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<tr>
<td>questionnaire</td>
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<tr>
<td>Disease specific</td>
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<tr>
<td>questionnaire</td>
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<tr>
<td>Disease activity</td>
<td>X</td>
<td>X</td>
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<td>index</td>
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<tr>
<td>Adherence</td>
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<td>questionnaire</td>
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<tr>
<td>Treatment</td>
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<tr>
<td>questionnaire</td>
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<tr>
<td>Distress scale</td>
<td>X</td>
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</tbody>
</table>

You may be contacted by telephone or by email to remind you to return completed questionnaires.

A small group of participants will be offered the possibility of taking part in a one to one interview to better explore the difficulties of living with IBD and complying with treatment. The location of the interviews will be agreed in advance (researcher’s office, hospital room, skype). The interviews will last approximately 1 hour, and they will be recorded by the researchers. The interviews may occur at any agreed time during your participation in the study.

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Your overall participation in the study will be around 6 months.

Expenses and payments

No expenses are available for this study.

What are the possible disadvantages and risks of taking part?

There are no known risks to participating in this study. However, there is a possibility that you might find some of the topics discussed upsetting. Please contact the researcher if this is the case and we will assist you in finding appropriate support.

What are the possible benefits of taking part?

The information that you will provide will help us in understanding more about IBD distress and the issues with taking medications as directed. The study aims at informing future research. However, there is no direct benefit to you as a participant.

What if there is a problem?

Any complaint about the way you have been dealt with during the study will be addressed. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.

Please address any complaints to:

Principal Investigator: Dr Mahmood Wahed, telephone number: 02033151076.

Email: Mahmood.wahed@chelwest.nhs.uk

In the event that something does go wrong and you are harmed during this research, then you may have grounds for legal action for compensation against King’s College London but you may have to pay your legal costs. King’s College London maintains adequate insurance to cover any liabilities arising from the study.

Will my taking part in the study be kept confidential?

King’s College London is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. King’s College London will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting Elisa Bisdomini on 02033156135.

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Chelsea and Westminster Hospital will collect information from you and/or your medical records for this research study in accordance with our instructions.

Chelsea and Westminster Hospital will keep your name, NHS number and contact details confidential and will not pass this information to King’s College London. Chelsea and Westminster Hospital will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from King’s College London and regulatory organisations may look at your medical and research records to check the accuracy of the research study. King’s College London will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. Chelsea and Westminster Hospital will keep identifiable information about you from this study for 10 years after the study has finished.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

**What will happen to the results of the research study?**

Information about you will be collected and analysed as part of the study. The study may be published in a scientific journal in an anonymized form.

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

This research study is being conducted as part of an academic dissertation. The Sponsor is King’s College London.

**Who has reviewed the study?**

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Yorkshire and the Humber-Bradford Leeds Research Ethics Committee.

**Thank you for reading this information sheet.**

**Contact details:**

Dr Mahmood Wahed (Principal Investigator): 02033151076

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