Participant Information Sheet

Title of Project: Developing informational resources for people with carbapenem resistant organisms.

Name of Investigators: Dr Ryan Hamilton, Prof Iain Williamson, and Mr Benjamin Lond

You have been invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish to. Ask 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 or not. Thank you for reading this.

What is the study about?

Antimicrobial resistance is when microorganisms (e.g., bacteria and viruses) develop a resistance to various forms of drugs, like antibiotics and antivirals. This can make these organisms very hard to treat; and can result in the worsening of symptoms and other related difficulties.

Carbapenem resistant organisms is one such example of an antimicrobial resistant infection which can occur when a type of bacteria develops a resistance to carbapenem antibiotics, that are often used to treat against severe infections. Despite the various physical and psychological challenges that people living with carbapenem resistant organisms experience, to date there are few informational resources available to support these individuals especially at the point of diagnosis. This study therefore aims to develop informational resources for people with carbapenem resistant organisms.

What does the study involve?

This study will conduct a series of online focus groups using **Microsoft Teams**. Each focus group would last up to two hours, and will be led by two researchers, and be attended by up to seven participants. The researchers will invite participants to share their views for what kinds of informational resources may be developed to help people with carbapenem resistant organisms; such as, what information to include and how to present this. Participants would be able to share either verbal or written responses to questions, answer questions however they wish, and decline to answer any number of questions.

The focus groups will not be recorded. Rather, the written responses participants provide will be saved and researchers will also make notes to keep a record of the views and ideas expressed by participants. Participants may choose to have their webcams on or off during the focus group.

Participants would be invited to attend up to three focus groups, with each session conducted several weeks apart from the last so as to allow researchers time to process feedback and develop resources. Participants would receive a gift voucher as financial compensation for their attending each workshop.

Why have I been chosen?

You have been chosen because you are a person living with a health condition, or a patient representative, and are thus able to provide a range of views and ideas informed by your experiences that would help us develop tailored resources for people living with antimicrobial resistance.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form.

I am interested in taking part, what do I do next?

Please email Benjamin Lond (benjamin.lond@my365.dmu.ac.uk) stating your interest to participate. Benjamin will reply to your email within 5 working days to discuss your participation, and will attempt to answer any questions that you may have.

What if I agree to take part and then change my mind?

You can withdraw at any time before or during the focus group without needing to provide a reason. This will include the withdrawal and deletion of all email messages and signed consent forms, though please be advised that any written contributions and/or researcher notes regarding views you shared in the workshops up to the point of withdrawal would be retained.

Also be advised that if you withdraw your participation before attending the online workshop that you would not be eligible to receive the voucher payment for your attendance. However, if you withdraw your participation at any time in the focus group then you would still be eligible to receive the voucher payment for your attendance.

What are the possible disadvantages and risks of taking part?

While we hope you have a positive experience of this research, please be advised that taking part will require you to give up some of your time to attend the online focus group. In addition, the focus group questions will address the development of patient resources relating to health and illness which some people may find uncomfortable. As such, the following measures are available to help make you feel more comfortable throughout the study.

When taking part, you can leave the focus group and enter a separate online breakout room supported by a member of the research team for a comfort break whenever you feel uncomfortable. You will be able to answer all questions however you wish, and may decline to answer any number of questions. You may also withdraw any time before or during the focus group.

If you have any concerns before, during or after the study, you may contact a member of the research team whose details are provided nearer the bottom of this form (see Contact for further information). Alternatively, if you would like to seek independent support, you may contact 'AMR Action UK', who offer specialist help, and whose details are provided at the end of this form (see Independent support).

What are the possible benefits of taking part?

By taking part, you will be able to share your views and ideas for how best to develop patient resources aimed at supporting people living with a carbapenem resistant organism.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal University complaints mechanisms should be available to you.

If you become distressed during the focus group, you will be able to take a comfort break in a dedicated online breakout room supported by a member of the research team. You will be able to take a break as often and for as long as you wish during the course of the focus group, and may choose to withdraw your participation and not return to the focus group as well.

Who can I complain to?

If you have a complaint regarding anything to do with this study, you can initially approach the lead investigator, Dr Ryan Hamilton using the contact details below:

Dr Ryan Hamilton
Hawthorn Building,
De Montfort University, The Gateway, Leicester, LE1 9BH
Email: ryan.hamilton@dmu.ac.uk

If this achieves no satisfactory outcome, you should then contact the Administrator for the Faculty Research Ethics Committee using the contact details below:

Administrator for the Faculty Research Ethics Committee
Research & Innovation Office, Faculty of Health & Life Sciences, 2.14 Heritage House,
De Montfort University, The Gateway, Leicester, LE1 9BH
Email: hlsfro@dmu.ac.uk

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept on a password protected database and is strictly confidential. Any identifiable information you give will be removed and anonymised.

All research data, including consent and focus group data, will be digitally stored on 'DMU Figshare', which is a secure repository for research data hosted by De Montfort University. All such data will be accessible only to members of the research team.

Be advised, it is DMU policy for raw research data to normally be retained for 5 years following a study, after which time it is deleted. Please also be advised, that I may be duty bound to pass on information that you provide that reveals harm has occurred to yourself, a child, or other vulnerable individual.

What will happen to the results of the research study?

All data collected in this study will be anonymised and analysed to help inform the co-development of resources for people living with a carbapenem resistant organism. Anonymous focus group data may also be included as part of future research publications reporting the development of these resources, and may also feature as part of future research presentations.

Who is organising and funding this research?

This research is being organised and conducted by staff at De Montfort University, and is funded by a financial support grant from Pfizer Ltd. and by De Montfort University.

Who has reviewed the study?

This study has been reviewed and approved by De Montfort University, Faculty of Health and Life Sciences Research Ethics Committee.

Contact for further information

If you have questions or concerns, please email Benjamin Lond: benjamin.lond@my365.dmu.ac.uk
Alternatively, you may email the lead investigator, Dr Ryan Hamilton: ryan.hamilton@dmu.ac.uk

Thank you for your consideration and time to take part in this study.

Independent support

If you have any concerns before, during or after the study and would like to seek independent support, you may wish to contact 'AMR Action UK', who provide specialist information, advice, and support to people affected by antimicrobial resistance. Their contact details are provided below:

AMR Action UK
Telephone: 07367 784 114
Website: https://amr-action-uk.org/
Email: patient.support@amr-action-uk.org