6.5 Appendix – 5: Patient Information sheet

Study title: Reduction of disability in Leprosy through enhanced self care in Janjgir-Champ district, Chhattisgarh, India

Introduction

We would like to invite you to take part in a research study. Joining the study is entirely up to you. Before you decide, you need to understand why the research is being done and what it would involve. One member of our team will go through this information sheet with you and answer any questions you may have. Ask questions if anything you read or hear is not clear or you would like more information. Please feel free to talk to others about the study if you wish. Take time to decide whether or not to take part.

Who is organising and funding the study?

The study is being organised by The Leprosy Mission Trust India in collaboration with the University of Birmingham, UK. The study is funded by the UK National Institute for Health Research.

What is the purpose of the study?

Leprosy ulcers are not caused by the leprosy germ but by loss of sensation leading to repetitive injury. As a result, patients (and their families) face stigma, social isolation as well as a lot of economic burden.

The purpose of our research study is to the improve the self-care practice of patients in the community, which will help reduce the ulcer and its associated complications. If required, we will observe while performing self-care to understand how people affected by leprosy undertake self-care practice.

Why have I been asked to take part?

You have been invited to take part because you have impairments due to leprosy in your limbs. Those who have had ulcers in their foot are invited take part in this study.

Do I have to take part?

No. It is up to you to decide to take part or no. If you do not want to take part, that is ok.

We will discuss the study together and give you a copy of this information sheet. If you agree to take part, we will then ask you to sign a consent form.

What will happen to me if I take part?

If you are willing to take part in this study, we will first ask you to sign a consent form which is your indication that you understand the study and agree to take part.

We will then issue you with a unique study identification number to ensure that any details we collect remain secure.

If you agree to take part in this study, you will be trained on self-care practice by Mitanins of your village and you will be asked questions about your hand and foot impairments and take photo of the foot. We may ask you in more detail about how you self-care and to show us how you self-care.

What will I have to do?

You will be expected to take part in self-care teaching by Mitanins, individual interviews, and to answer questions about the impairments and foot ulcers. We may ask you to show us how you self-care.

What information will be collected?

Only your name will be collected. However, the information you give will be anonymised and only ever be viewed by your unique identification number. We will keep this information separate from other information.

During the interview, you are expected to share information about your disability details, foot impairments in particular and ulcer details if present. We will take the picture of your both feet. The picture will not have any personal identification details except the unique identification number.

What will happen to information collected about me?

All information collected about you will be kept private. Only the study staff and authorities who check that the study is being carried out properly will be allowed to look at information about you. Data may be sent to other study staff at University of Birmingham but this will be anonymised. This means that any information that includes your name and address will be removed so that you cannot be recognized.

Anything you say during the interview will have names of people and places removed. We may use direct quotations in the reports or publications from the study, but they will not be linked to you. All the data will be securely stored in safe place.

The collected data may also be used for future research following approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project. For further information, please refer to the University of Birmingham Research Privacy Notice which is available here: https://www.birmingham.ac.uk/privacy/index.aspx or by contacting the Information and Data Compliance Team at dataprotection@contacts.bham.ac.uk.

What if something goes wrong?

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. You can also contact Dr. Joydeepa Darlong, joydeepa.darlong@leprosymission.in, the investigator of this study for any queries. If you remain unhappy and wish to complain formally, you can do this by contacting Professor Richard Lilford, University of Birmingham UK, r.j.lilford@bham.ac.uk

Can I change my mind about taking part?

Yes. You can withdraw from the study at any time. You just need to tell your research fellow that you do not want to be in the study anymore. Information collected may still be used.

What will happen to the results of this study?

The study results will be published in a medical journal so that other people can learn from them. Your personal information will not be included in the study report and there is no way that you can be identified from it.

Who has reviewed the study?

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the [insert name of ethics committee here]

Who should I contact if I want further information?

Dr Joydeepa Darlong, The Leprosy Mission Trust India E-mail: joydeepa.darlong@leprosymission.in

Professor Richard Lilford, University of Birmingham, r.j.lilford@bham.ac.uk

****Thank you for taking time to read this information leaflet. If you think you will take part in the study please read and sign the consent form. ****

6.6 Appendix – 6: Patient consent form

Study title: Reduction of disability in Leprosy through enhanced self care in Janjgir-Champ district, Chhattisgarh, India

Name of Investigator (s): Dr. Joydeepa Darlong, The Leprosy Mission Trust India, and Professor Richard Lilford, University of Birmingham, UK

A. I ____ understand that researchers from The Leprosy Mission Trust India and representatives at University of Birmingham are involved in a study regarding evaluation of self-care intervention and measurement of impairments including ulcers. Part of this study involves talking to people who had had or having ulcers. You are being invited to take part in an individual interview, disability assessment and consent to take picture of your feet.
B. I consent to be approached for more detailed interview and taking photographs of hands and feet with impairments.
C. I consent to be asked to be observed undertaking self-care.
D. The study has been explained to me and I understand what is expected of me.
E. I confirm that I am 18 years old or above.
F. I understand that once my data has been incorporated with others, it might not be possible for it to be withdrawn, though every attempt will be made to extract my data, up to the point of publication.
G. I understand that my name will not be revealed in any published material concerning this study.
H. I agree that my data can be used in reports, publications, conferences, and training events,
I. I agree that my data can be used for further research in future. YES/NO*
J. Please delete as appropriate. Please note that participants may say 'NO' to this question and still take part in the study. I understand that I can leave the study at any time for any reason and I will still receive support and care for my condition.
K. I have received enough information about the study in a language I understand. I have had the opportunity to discuss it and ask questions, and those questions have been answered to my satisfaction.

L. I agree to take part in the study.

Printed Name & Signature (or fingerprint) Date
Name of Patient ______________________________
Signature/Fingerprint __________________________ _____/______/20____
Name of Witness ______________________________
Signature/ Fingerprint __________________________ _____/______/20____
Name of Researcher____________________________

6.7 Appendix – 7: Study participants Information sheet

Study title: Reduction of disability in Leprosy through enhanced self care in Janjgir-Champ district, Chhattisgarh, India

Introduction

We would like to invite you to take part in a research study. Joining the study is entirely up to you. Before you decide, you need to understand why the research is being done and what it would involve. One member of our team will go through this information sheet with you and answer any questions you may have. Ask questions if anything you read or hear is not clear or you would like more information. Please feel free to talk to others about the study if you wish. Take time to decide whether or not to take part.

Who is organising and funding the study?

The study is being organised by The Leprosy Mission Trust India in collaboration with the University of Birmingham, UK. The study is funded by the UK National Institute for Health Research.

What is the purpose of the study?

People affected by leprosy with impairments are at risk of developing ulcers and further worsening of limbs due to lack of self-care practice.

The purpose of part of this study is to understand your role in identifying and managing people affected by leprosy with impairments who needs self-care.

Why have I been asked to take part?

Part of this study involves talking to and observing people who are in position to potentially identify and/or help manage people affected by leprosy with impairments. We believe you have important knowledge and experiences that can help to improve the care of patients with impairments in the community.

Do I have to take part?

No. It is up to you to decide to take part or no. If you do not want to take part, that is ok.

We will discuss the study together and give you a copy of this information sheet. If you agree to take part, we will then ask you to sign a consent form.

What will happen to me if I take part?

If you are willing to take part in this study, we will first ask you to sign a consent form which is your indication that you understand the study and agree to take part.

We will then issue you with a unique study identification number to ensure that any details we collect remain secure.

If you agree to take part in this study, you may be observed undertaking your normal job and/or interviewed about your role.

What will I have to do?

You may; be asked to carry out your normal role while a researcher observes you; ; you will be asked questions about your usual role.

What information will be collected?

The information you give will be anonymised and only ever be viewed by your unique identification number. We will keep details of your name separately and destroy it once the data analysis is complete.

During interviews or observations, you will be asked about how you undertake your role in relation to people affected by leprosy and what helps or hinders you in this role. Notes may be made, or the discussions audio-recorded so that we can listen to it afterwards and write it down.

What will happen to information collected about me?

All information collected about you will be kept private. Only the study staff and authorities who check that the study is being carried out properly will be allowed to look at information about you. Data may be sent to other study staff at University of Birmingham but this will be anonymised. This means that any information that includes your name and address will be removed so that you cannot be recognized.

Anything you say during the interview will have names of people and places removed. We may use direct quotations in the reports or publications from the study, but they will not be linked to you. All the data will be securely stored in safe place.

The collected data may also be used for future research following approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project. For further information, please refer to the University of Birmingham Research Privacy Notice which is available here: https://www.birmingham.ac.uk/privacy/index.aspx or by contacting the Information and Data Compliance Team at dataprotection@contacts.bham.ac.uk.

What if something goes wrong?

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. You can also contact Dr. Joydeepa Darlong, joydeepa.darlong@leprosymission.in, the investigator of this study for any queries. If you remain unhappy and wish to complain formally, you can do this by contacting Professor Richard Lilford, University of Birmingham UK, r.j.lilford@bham.ac.uk

Can I change my mind about taking part?

Yes. You can withdraw from the study at any time. You just need to tell your research fellow that you do not want to be in the study anymore. Information collected may still be used.

What will happen to the results of this study?

The study results will be published in a medical journal so that other people can learn from them. Your personal information will not be included in the study report and there is no way that you can be identified from it.

Who has reviewed the study?

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the [insert name of ethics committee here]

Who should I contact if I want further information?

Dr Joydeepa Darlong, The Leprosy Mission Trust India E-mail: joydeepa.darlong@leprosymission.in
Professor Richard Lilford, University of Birmingham, r.j.lilford@bham.ac.uk

****Thank you for taking time to read this information leaflet. If you think you will take part in the study please read and sign the consent form. ****

6.8 Appendix – 8: Participant consent form

Study title: Reduction of disability in Leprosy through enhanced self care in Janjgir-Champ district, Chhattisgarh, India

Name of Investigator (s): Dr. Joydeepa Darlong, The Leprosy Mission Trust India, and Professor Richard Lilford, University of Birmingham, UK

1. I ____ understand that researchers from The Leprosy Mission Trust India and representatives at University of Birmingham are involved in a study regarding the evaluation of self-care program to reduce impairments. Part of this study involves talking to and observing people in the community who have an interest in preventative health projects, including health care leaders, health professionals, master trainers, Mitanins, and volunteers. Participating will allow you to share your knowledge, experiences and thoughts. Findings will help us understand how the self-care intervention reduce risk of ulcers and their associated complications
2. The study has been explained to me and I understand what is expected of me.
3. I confirm that I am 18 years old or above.
4. I understand that if I am being interviewed this will be audio recorded and then made into an anonymised written transcript.
5. I understand that if I am being observed doing my normal job, then the researcher may write comments (field-notes) about my practice, and these will be anonymised and pooled with data from others. Findings will only be used to improve the study and not be reported to your employer.
6. I understand that any audio recordings and field-notes will be destroyed at the end of the study but transcripts will be kept for ten years after the study has finished.
7. I understand that the things I say will have the names of people and places removed, may be pooled with other participants' responses, and may be published.
8. I understand that once my data has been incorporated with others, it might not be possible for it to be withdrawn, though every attempt will be made to extract my data, up to the point of publication.
9. I understand that my name will not be revealed in any published material concerning this study.
10. I agree that my data can be used in reports, publications, conferences, and training events, or for further research in future.
11. I understand that I can leave the study at any time for any reason and if I am a member of the group, I will still receive support and care for my condition.
12. I have received enough information about the study in a language I understand. I have had the opportunity to discuss it and ask questions, and those questions have been answered to my satisfaction.
13. I agree to take part in the study.

Printed Name & Signature (or fingerprint) Date
Name of Patient _______________________________
Signature/Fingerprint ____________________________ _____/______/20____
Name of Witness _______________________________
Signature/ Fingerprint ____________________________ _____/______/20____
Name of Researcher_____________________________