South East Wales Trials Unit (SEWTU)
School of Medicine, Cardiff University
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Heath Park
Cardiff
Wales
CF14 4YS

Carer Information Sheet

Study title: A study of anti-psychotic drug reduction in primary care for adults with learning disabilities (ANDREA-LD)

Part 1 of the Information Sheet

The person you act as carer or representative for has already very kindly agreed to help us with the main study. We would also like to invite you to be involved in the study. But before you decide if you would like to take part, you need to know why the study is being done and what it will involve. Please read the main trial information sheet first.

Part 1 tells you the purpose of this part of the study and what will happen to you if you decide to take part. Part 2 gives more detailed information about how the study will be organised. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of my involvement in the study?

There are two main areas – the first is for the assessments which the person you care for will be attending. At these appointments, the researchers will ask him/her to complete some questionnaires which may require your help. In addition, you will be asked questions regarding the person you care for. The assessments take place at your first meeting with the researchers then at 4 other time points as described in the main study information sheet. It is very important that you are happy to answer these questions as they provide the main answers for the study.

The second part of your involvement will be to discuss the experiences you and the person you care for have had in taking part in the study in a telephone interview. Not everyone will be asked to take part in the interviews but if you are, it will take place between 9 and 12 months after the start of the study.

Why have I been approached?

Because you are the carer for the participant in this study. For the interviews, we are inviting a sample of around 30 carers of patients who took part in the study. We will also be asking their corresponding GP to take part.

Do I have to take part?

No, you do not need to take part. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What will I have to do if I agree to take part?

You will be required to attend the assessments (as laid out in the main trial information sheet) with the person you care for and answer various questions about that person. Each assessment may take up to 2 hours. If you are asked to take part in a telephone interview, this will last up to 30 minutes and you will receive a £10 High Street shopping voucher as a thank you. You will have an opportunity to tell us about your experiences in more detail. We will ask you about what it was like for you and the person you care for to be involved in the study and your views on reducing medication. With your permission we will record the interview so that we do not miss what you say. After the interview, the recording will be typed up so that we can explore what you said in more detail and compare it to what others have said.

What are the possible benefits of taking part?

You will be able to provide valuable information about the person you care for and their behaviour. The information you provide may benefit future research and practice.

What are the possible disadvantages and risks of taking part?
You will be asked to give up your time to travel to the assessments and possibly take part in the interview. Also, it is possible that some people may find it upsetting talking about their experience if they feel that they had a bad experience.

Part 2 of the Information Sheet

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time, without giving a reason. If you withdraw at any time, or decide not to take part, it will not affect the standard of care you receive now or in the future.

What if there is a problem?
If you have concerns about any aspect of this study, you can speak to the researcher team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through Cardiff University.

Mr Chris Shaw, Research Governance Officer
Cardiff University Research and Commercial Division
30-36 Newport Road, Cardiff, CF24 0DE
Tel: 029 2087 9140 or 029 2087 9277

Harm
If something does go wrong and you are harmed during the research which is as a result of someone's negligence, you may have grounds for a legal action against Cardiff University but you may have to pay your legal costs.

Will my taking part in this study be kept confidential?
Yes, we will follow ethical and legal practice and all information about you will be handled in confidence. Your personal information (name, address etc.) will continue to be kept confidential, the interview recording will be kept in a locked cabinet, and any information that we use will not have your name or anything else that would identify you attached to it.

What will happen to the results of the research study?
A report of the research results will be completed and sent to the funder. Results will be published in scientific journals and presented at scientific meetings. You will not be identified in any report, publication or presentation. Once the research study is complete the results will be posted on: http://www.cardiff.ac.uk/medic/subsites/sewtu/whatwedo. If you would like the results sent to you please contact the Trial Manager.

Who is organising and funding the research?
This study is being organised by the South East Wales Trials Unit, Cardiff University. The research is being paid for by the National Institute of Health Research Health Technology Assessment Programme.

What will happen to my data at the end of the study?
In line with the regulations, at the end of the study your data will be securely archived for a 15 years. Arrangements for confidential destruction will then be made.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Research Ethics Committee for Wales.

Contact for further information
Elizabeth Randell (Trial Manager)
Tel: 029 20687608

THANK YOU FOR CONSIDERING TAKING PART IN THIS STUDY.

NHS
National Institute for Health Research