



Participant Information Sheet



Successful self-monitoring of oral anticoagulation therapy

You are being invited to take part in a research study. This information sheet explains why the research is being conducted and what it will involve if you choose to take part. Please read it carefully. Talk to others about the study if you wish.

Part 1 of this sheet describes the purpose of the study and what will happen if you choose to take part. Part 2 gives more detailed information about the conduct of the study. Please contact us if there is anything that is not clear or you would like more information. Take time to decide whether or not you wish to take part.

Part 1

1. What is the purpose of this study?

The purpose of this study is to learn more about how people self-monitor their oral anticoagulation therapy. Self-monitoring involves measuring your own INRs with a portable device. We want to find out more about factors that influence people's self-monitoring behaviour and the effect self-monitoring has on their condition and daily life.

2. Why have I been invited?

You have been invited to participate in the study because you have a 'CoaguChek' device for monitoring your INR. The study is being funded by the Department of Health's National Institute of Health Research and run by University of Oxford. We aim to invite 375 people who are self-monitoring their INR to participate in our study.

3. Do I have to take part?

It is your decision. If you decide not to take part, or if you consent to participate but later decide to withdraw from the study, you will still receive the same standard of medical care. You are free to withdraw from the study at any time, without giving a reason.

4. What will happen to me if I take part? (see flowchart on page 4)

4.1 Considering participation and providing consent

If, after reading this information sheet, you are willing to participate in the study, you will need to fill in the enclosed consent form and return it to University of Oxford in the post paid envelope provided. If you think you might like to participate but would prefer to discuss the study with one of the research team before completing the consent form you are welcome to contact us (see section 12 for contact details). The consent form will also ask for your consent to record your interviews and for anonymous quotations to be used in reports or papers.

4.2 Informing your GP and information from your medical records

If you decide to participate in the study, we will need to ask your GP to give us your medical history related to your anticoagulation therapy and information about your OAT related consultations over the 12 months you are on the study.

4.3 Phone interview

Once we have received your consent form, a member of the research team will phone you to ask a few questions. We will record this interview to allow us to better analyse the information, your name will not be recorded.

4.4 Questionnaire

We will also post you a questionnaire and a recording sheet for your INR readings. The questions you will be asked will have been carefully selected during a pilot phase of the study in consultation with people who are on anticoagulation therapy. If we do not receive the questionnaire back from you we will write to you to remind you to post it back to us.

4.5 Monitoring your INR and study follow-up

Each time you test your INR using your CoaguChek machine we would like you to write the result on the recording sheet along with the date of the reading and your dose of anticoagulant. We would like you to send us a recording sheet once every 3 months. A researcher will phone after 3, 6 and 12 months and ask you about your self-monitoring experiences. The calls will be recorded to help us analyse the range of experiences. We may ask you if you are willing to be interviewed face-to-face by a researcher (see 4.5 below). We aim to interview 30 people in total.

4.5 Face-to-face interview

If you are willing to be interviewed, a researcher will telephone you and make arrangements to visit you at home. To ensure accuracy, the face-to-face interviews with the researcher will be recorded on digital recording equipment and later transcribed to a document. The interviewer will ask you about your self-monitoring experiences and how you feel about self-monitoring. The face-to-face interview will take approximately 60 minutes.

5. What are the possible benefits or disadvantages of taking part?

There is no direct benefit to you from taking part but you will be helping to improve the future well-being of some people taking oral anti-coagulant medication.

If the information in Part 1 has interested you and you are considering taking part in the study, please read the additional information in Part 2 before making any decision.

Part 2

6. Will my taking part in this study be kept confidential?

All of the information collected will be made anonymous. The information you provide will be coded with a study number so you cannot be identified from it. The research team has a duty of confidentiality to you as a research participant. We will keep digital copies of the face-to-face interviews and phone calls but not identify you by name on the recording. We will keep all the data we collect, including the recordings, for 5 years after the study has been published in line with the current University of Oxford policy. All data will be kept securely according to the Data Protection Act 1998.

7. What will happen if I don't want to carry on with the study?

If you decide you no longer wish to participate in the study, you can phone, write to or e-mail the research team (see section 12 for contact details). You can withdraw from the study at any time and you do not need to give a reason.

8. What if there are any problems?

If you have any concerns about this study or the way it has been carried out, you should contact the lead investigator, Dr Alison Ward (Tel: 01865 289294). Given the nature of this study, it is highly unlikely that you will suffer harm by taking part, however, if you are harmed by participation in the study, you may have grounds for legal action against the University of Oxford.

9. What will happen to the results of the research study?

The results of the study will be published in a peer-reviewed medical journal and will be made available on websites for people on anticoagulation therapy. We will be producing a newsletter, if you would like a copy of this you can e-mail or telephone us (see Section 12 for contact details).

10. Who is organising and funding the research?

The research is being conducted by University of Oxford, Department of Primary Health Care and is funded by National Institute for Health Research (NIHR), School for Primary Care Research.

11. Who has reviewed the study?

This study was given a favourable ethical opinion for conduct by the Berkshire Research Ethics Committee.

12. Further information and contact details

If you would like any further information, or have any further questions concerning the research study you are encouraged to contact the research team.

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Study Flowchart

