

Information about participation in a study on Tuberous Sclerosis Complex

Title of the study

Burden of Tuberous Sclerosis Complex (TSC) in adults.

Introduction

Dear Sir / Madam,

We would like to ask you to participate in a research study. We approach you because:

- 1) You have Tuberous Sclerosis Complex (TSC), or
- 2) You are the parent, caregiver, legal representative and/or counselor of someone who has TSC.

Before you decide on participating in the study, it is important to know more about the study. Please read the letter of information carefully and discuss this with your partner, friends, or family.

Do you have any questions after reading the information? Please do not hesitate to contact the researcher. On page 3 you will find contact information.

1. What is the aim of the study?

The aim of the study is to develop a questionnaire to investigate the burden and restrictions that people with TSC are experiencing. The questionnaire is called CHAT-TSC which is an abbreviation for: Checklist for Adults with TSC.

2. What is the reason for this study?

Little research has been done on the impact of TSC on people's daily life. Therefore, we are studying the aspects of TSC and its impact on quality of life. The results will help us to improve care for those diagnosed with TSC. Also, we want to use the questionnaires in clinics to prepare visits.

3. What is the topic of the study?

This study is about developing a questionnaire for adults with TSC. The questionnaire has to be filled out by the patient or a parent or other representative.

4. How was this questionnaire developed?

Interviews with patients with TSC, parents of patients with TSC and a literature search revealed the topics of the questionnaire. Next to that, we discussed the questionnaire with experts who are working closely with patients that have TSC. Furthermore, we evaluated and adjusted the questionnaire with TSC patients, parents and patient representatives.

5. What do we ask you?

We would like to ask you to fill out the questionnaire about yourself or the individual with TSC. Accomplishing the questionnaire will take about 20 minutes. Two other questionnaires are attached. Those questionnaires will be used to determine and check whether our questionnaire was well set up. Filling out those questionnaires will take another 20 minutes. In total, it will take about 40 minutes to fill out all questionnaires.

6. Permission

You decide whether you want to participate or not.

In case the individual with TSC is not able to decide on participation, the legal representative decides on behalf of that person. The legal representative will either fill in the questionnaires or ask someone else who knows the person well to fill in the questionnaires.

7. What are possible (dis)advantages of participating in this study?

There is no advantage of participation for you. However, this study will yield useful information to improve care for adults with TSC in the future. One disadvantage of participation is that it takes some time.

8. What is the consequence if you do not want to participate?

Participation is voluntary. If you decide not to participate, you do not have to do anything. You do not have to sign, nor you have to explain why you do not want to participate. In case you want to participate, you are always allowed to stop participation at any time.

9. What about the entered data?

Each participant will receive a unique code. This code is linked to your contact information. The principal investigator and the research assistant are the only two that have access to this code. The responses that you entered are not traceable to anyone else. Your information will be anonymously processed.

10. Will I receive a compensation for participation?

You will not receive a financial compensation if you participate in the study.

11. What Medical Ethics Committee has approved this study?

The Medical Ethics Committee of the Erasmus Medical Center in the Netherlands has been consulted, and has confirmed that this project is compliant with research guidelines.

12. Would you like to have more information?

If you have any other questions, please contact the research team. You can contact us by sending an email to chat.tsc@erasmusmc.nl.



Yours sincerely,

The research team – chat.tsc@erasmusmc.nl

Dr. Agnies van Eeghen, principal investigator