Middlesex University London

Chocolate as a dietary adjunct in sickle cell anaemia: a clinical trial.

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

You are being invited to take part in a research study. Before you decide, 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 others if you wish. 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.

Thank you for reading this.

What is the purpose of the study?

Sickle Cell disease is a serious, inherited medical condition which causes recurrent health crises and shortens the lifespan of sufferers. Currently 250,000 UK residents and millions of people worldwide are living with sickle cell disease. Recent research on the cocoa bean, used to make dark chocolate, shows that it has beneficial effects on red blood cells, blood vessels, the heart and circulation. This research means that the cocoa bean may have protective effects for people living with sickle cell disease, reducing health problems and extending life expectancy. This clinical trial will be the first to test whether dark chocolate is beneficial for people living with sickle cell disease.

This study is being conducted by Marcos Patchett, a medical herbalist, in conjunction with Middlesex University's Integrative Medicine department. The study aims to test whether dark chocolate can improve the symptoms and quality of life for people living with sickle cell disease over a period of three months. The results of the trial may be used in dietary guidelines to help people living with sickle cell disease, and to inform future research developing effective treatments for this 'incurable' disorder.

Why have I been chosen?

You have been asked to take part because you are an individual living with sickle cell disease. The trial needs 60 participants living with sickle cell disease to take part, otherwise the numbers will be too low to draw any conclusions.

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. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

The method of testing the chocolate is called a placebo-controlled, randomised double-blind clinical trial. This means you will be randomly assigned to one of three groups of 20 people; each group will then receive a different treatment, and the results are compared after the trial. The groups are selected by a computer which has no information about the individuals – i.e. by chance. One group will be given the 'real' chocolate, another group will be given 'placebo' (fake) chocolate, and the third group will receive no chocolate. The last group is called the 'control group', and is important because it provides a 'baseline' group of people who are receiving no treatment at all.

The three groups (Real, Placebo, and Control) will enable the researchers to work out whether any improvement in Sickle Cell symptoms is due to the chocolate or a 'placebo effect' (wishful thinking). Nobody will know who has been sent the real chocolate or the fake chocolate until after the trial is finished, so that the results will not be affected by wishful thinking. The fake chocolate will be made from carob, cocoa butter, sugar and natural flavourings e.g. coffee or peppermint essence, and will be designed to look and taste identical to the real chocolate used in the trial.

You will therefore have a one in three chance of receiving the 'real' chocolate during the trial. It is important that some people receive the 'fake' chocolate or no chocolate at all during the trial so that the researchers can work out whether the real chocolate is helping people or not.

The main method of collecting information on symptoms will be through a short questionnaire, and a one-page self-assessment quiz called MYMOP (Measure Your Medical Outcome Profile), both filled out by you before and after the 12 week trial period. These forms can easily be filled out at home in your own time. No clinic visits or medical tests are required.

You will be contacted by telephone prior to the trial beginning and a participation pack will be posted to you, containing:

1. a Sickle Cell Symptom Questionnaire and a MYMOP New Patient Questionnaire with a Consent Form and a stamped addressed envelope, to complete and return before the trial begins;
2. a Sickle Cell Symptom Follow-Up Questionnaire and a MYMOP Follow-Up Questionnaire with a stamped addressed envelope, to complete and return at the end of the twelve-week trial period;
3. The pack *may or may not* contain a *12-week supply of chocolate,* divided into daily portions, with instructions on how much to eat daily. If your pack doesn't contain any chocolate, then you have been assigned to the control group, and only need to complete the questionnaires & MYMOP sheets before and after the trial period.

What do I have to do?

Firstly, you will need to complete and return the *Sickle Cell Symptom Questionnaire,* the *MYMOP New Patient Questionnaire* and the *Consent Form* in the stamped addressed envelope provided.

Secondly, *during the 12 week trial period,* **all participants must avoid eating or drinking chocolate or cocoa in any form, except for that provided in the participation packs**. If you receive chocolate in your participation pack, you will need to eat one portion of the chocolate in your pack every day for 12 weeks, beginning on the trial start date. If you receive no chocolate, you do not need to do anything except avoid eating or drinking any chocolate or cocoa during the 12 weeks.

After the 12 weeks have passed, you will be contacted by telephone and asked to complete and return the *Sickle Cell Symptom Follow-Up Questionnaire* and the *MYMOP Follow-Up Questionnaire* in the stamped addressed envelope provided.

The results of the trial will be made available to you once they have been processed. If you have any questions, you can contact the research team at any time via the Park Clinic in Hendon on 020 84114411.

What are the side effects of any treatment received when taking part?

There is a very low chance of side-effects in the trial.

- It is possible that heartburn or weight gain may occur for some participants because of the fat, flavouring (peppermint) and sugar found in the chocolate. However weight gain should not occur if participants are not eating more calories than usual.
- Because chocolate contains caffeine, participants who are sensitive to caffeine or who suffer from insomnia should eat the chocolate before 4pm.
- People who suffer from migraine headaches should also be cautious if chocolate has given them headaches in the past, because chocolate (like hard cheeses and red wine) contains Tyramine, which can trigger migraine headaches in some people.
- Those who are allergic to chocolate should not participate.

If you suffer these or any other symptoms you should report them in the *Sickle Cell Symptom Follow-Up Questionnaire* after the trial.

If you think you may be experiencing side-effects during the trial and are concerned, please contact the research team via the Park Clinic in Hendon on 020 84114411, or email m.patchett@mdx.ac.uk.

What are the possible disadvantages and risks of taking part?

There are currently no known risks in participating in this project.

What are the possible benefits of taking part?

We hope that participating in the study will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future participants with sickle cell anaemia better, and the results of the study will be made available to you so you can decide whether including dark chocolate in your diet will be beneficial.

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 strictly confidential. All data will be stored, analysed and reported in compliance with UK Data Protection Legislation, and any information about you which is used will have your name and address removed so that you cannot be recognised from it.

What will happen to the results of the research study?

The results of this research will be published in a peer-reviewed journal either later this year or in 2016. You will be informed of the article's publication, and a copy of the article will be made available to you. You will not be identified in any publication.

Who has reviewed the study?

The Middlesex University, School of Health and Education, Health and Education Ethics Sub-committee has reviewed and approved this trial.

Contact for further information

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Thank you for taking part in this study!