

PARTICIPANT INVITATION LETTER

LREC number: 07/H0201/113

Dear

We have enclosed some information regarding a study in which we would like to invite you to participate. The study itself will examine the relationship between the senses of vision and smell.

Please read the information provided and return the reply slip if you may consider participating. When we receive your reply slip we will telephone to discuss further details and to answer any questions you may have.

You will then be given time to decide whether to take part in the study – the investigations involved will occur on a day that is convenient to you. You can change your mind later if you so wish. Not taking part in the study, or a later change of mind will not affect the quality of care you receive.

Thank you for your consideration.

Yours sincerely

Dr Ahmed Khattab
Professor of Medical Research & Clinical Practice
Centre of Postgraduate Medical Research & Education
Faculty of Health & Social Sciences, Bournemouth University

.....

Reply slip

I am interested/not interested in taking part (please delete as applicable).

Please indicate which day - and which morning/afternoon - would be more suitable to you to take part in our study.

.....

Your daytime telephone number.....

Or contact E-mail address.....

Name Signature

**Please send your reply slip to Prof. A Khattab at Faculty of Health & Social Sciences, Bournemouth University, 17 Christchurch Road, BH1 3LH.
Tel: 01202 967281**

PARTICIPANT INFORMATION SHEET

LREC number: 07/H0201/113

Date: 10/07/09

Visual perception and smell testing

We would like to invite you to take part in a research study. Before you decide we would like you to read the following information in order for you to understand why the research is being done and what it will involve.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. Take time to decide whether or not you wish to take part.

PART ONE

What is the purpose of the study?

Minor changes in the sense of vision have been described in some patients with Parkinson's disease (PD). Measuring these changes with a computerised piece of equipment that is easy to use, would allow better understanding of these changes in a group of patients with varying degrees of severity of PD. This will allow us to: (i) detect when these changes develop, (ii) the factors associated with their development and (iii) relationship to other senses such as sense of smell.

Why have I been chosen?

We are interested in all patients with Parkinson's disease who will be able to complete the tests, as well as people who do not have Parkinson's disease.

Do I have to take part?

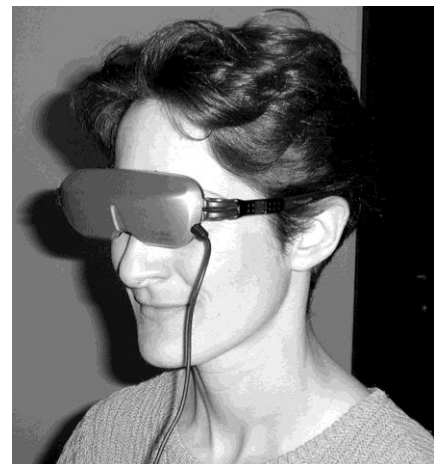
No, it is up to you to decide whether or not to take part. If you do, you will be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

You will be contacted for an appointment to assess whether you are suitable to proceed with the test. The assessment will take approximately an hour to complete, while the test for vision and smell will take approximately half an hour.

(Photograph 1)

You will be asked to wear a pair of video glasses which are connected to a computer (see Photograph 1). These glasses will fit over your normal glasses. It will be like



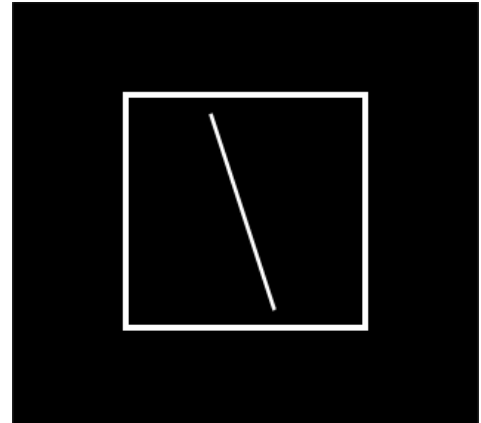
viewing a cinema screen. On the screen you will see a white rod inside a square frame (Photograph 2). Your task will be to rotate the rod using two buttons until you think that the rod is vertical, and then press a third_button. This task will be repeated several times – taking approximately 10-15 minutes in all.

(Photograph 2)

Can I wear my normal glasses?

Yes – the video glasses can be worn over your normal glasses, or contact lenses.

Your sense of smell will also be tested using a set of scratch cards with different odours. You will be asked to identify the odour by choosing from a menu of possible smells. This test will be repeated several times, using different odours – taking approximately 10 minutes in all.



Are there any risks associated with taking part?

The assessment will involve completing a questionnaire, the testing for vision and smell. These tests do not have any lasting effects.

What are the possible benefits of taking part?

The study will not provide any direct benefit to you, but the information we obtain might help improve the diagnosis and treatment of people with Parkinson’s disease in the future.

Will my taking part in the study be kept confidential?

Yes, all the information about your participation in this study will be kept confidential. The details are included in Part 2.

Contact details: Professor Ahmed Khattab, 01202 967281, Bournemouth University.
Or Dr Khaled Amar, Royal Bournemouth Hospital

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART TWO

What will happen if I don’t want to carry on with the study?

You can let us know at any time if you do not wish to participate in the study and your data will be removed from our records.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential.

The researchers carrying out this study will have access to your information which will be stored on a database.

In the analysis of results, your data will be used anonymously.

Our procedures for handling, processing, storing and destroying data relating to your participation in the study are compliant with the Data Protection Act 1998.

With your consent, we will inform your GP of your participation in our study.

However, we will not share with them the data about you that we obtain from your participation in the research.

What will happen to the results of the research study?

We will gather the results from individual participants and then look at the information we obtain about smell test results and their relation to the results of the visual perception test.

We hope to publish our overall results in a scientific journal.

Who is organising and funding the research?

The researchers are a group of doctors from Royal Bournemouth Hospital foundation trust and Bournemouth University and the Chiropractic College who have an interest in Parkinson's disease.

Who has reviewed the study?

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

This information sheet is for you to keep.

If you decide to take part you will be given a copy of the consent form which you sign when you agree to participate in the study.

Thank you very much for reading this information and considering taking part in the study.