Research Study: Social Cognition and Quality of Life in Huntington's

We are inviting people with **Huntington's disease** (HD), plus their **close others (e.g. partners/family/friends/carers)** who don't have HD, to participate in a new study.

Our previous research suggests that reasoning about emotions and social events could be important for the symptoms seen in the movement disorder HD. This study will teach us more about how related psychological processes affect the everyday life and wellbeing of people with HD and those close to them. This will help us better understand more about issues relevant to diagnosis and the development of new treatments to support those affected by HD.

The study has different parts which involve either questionnaires, or cognitive tasks. You can choose how much of the study to take part in. Questionnaires can be completed by hand, on a computer, or over the telephone, and returned by email or post. Other tasks can be completed online (e.g. on MS Teams/Zoom), or in person at The Barberry, if you prefer.

This study is funded by the European Huntington's Research Network, so we are able to offer you shopping vouchers (e.g. Amazon) in return for your time.

For more information, please contact the research team:

Ms. Anika Miah anika.miah1@nhs.net 07812 621145

Dr. Clare M. Eddy clare.eddy1@nhs.net 07985 883014

BSMHFT Research bsmhft.researchandinnovation@nhs.net 0121 301 4343

Thank you for your attention.

General Information Sheet for Participants

Social Cognition and Quality of Life in HD

1. Invitation to take part in a research study

You are invited to take part in a research study that will help us learn more about how emotion and reasoning affect everyday life in Huntington's disease (HD). It is important for you to understand why the research is being done and what it involves. Please take time to read the following information carefully and, if you wish, discuss it with your family, friends and the medical team responsible for your care (or the patient's care). Please ask if you have questions and take time to decide if you wish to take part. **Thank you for reading this.**

2. What is the purpose of the study?

Our previous research which has shown that social cognition can be affected by HD. For example, it may become difficult to respond to other people's emotions, or some social situations may become confusing or overwhelming. Now we want to understand how changes in social cognition are related to the quality of life of both patients and their close others. We know that patients and their families sometimes report difficulties with social interaction, and that people with HD can say that the social and emotional domains of quality of life are negatively affected. However, we do not know how our measures of social cognition relate to patients' everyday life, or the wellbeing of those patients and their close others (spouses, family, carers etc.). This study will help answer that question.

3. Why have I been approached?

You have been asked to consider taking part in the study because either:

- **you have the HD gene**
- **or someone you are close to has the HD gene (but you do not)**

The HD service at the Barberry, clinical consultants and research team, are involved in this research project. We are aiming to recruit participants in pairs i.e. someone with the HD gene and someone who knows that person very well but doesn't have the HD gene. We want to compare data from people with the HD gene who have very mild (or no obvious) clinical symptoms of HD to those with moderate HD symptoms, and also to those who don't have the HD gene, including partners, and gene-negative family members e.g. siblings. This will help us identify what seems most important and at what stage any changes we identify in HD are likely to occur.

Please speak to the researcher if you wish to take part alone rather than as part of a patient and close other pair, as this may be possible.

4. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you are interested in taking part, we encourage you to discuss this with the research team. You can also let your consultant or a member of the HD team know on the day of an outpatient appointment. or by telephone, or you can e-mail or call the researcher for further information. If you decide to take part

and sign the consent forms 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.

5. What will happen to me if I take part?

There are two experiments, each involving questionnaires which can be filled in however/whenever it is easiest, and some cognitive tasks which can be done with the experimenter online (sessions are not recorded) or in person. We recruit for a single experiment at a time. You can do just one part of this experiment, or both parts. Each part will take 60-90 minutes to complete. *Please see the additional sheet on the experiment we are recruiting for now for more information.*

Both experiments include measures that look at social cognition, relationships, quality of life, and of other symptoms patients with HD often have (e.g. to do with movement, memory, low mood). We are including both patients and close others to them (e.g. their carers, partners, friends and family members) so that we gain a broader perspective on everyday life. We will also use data collected from close-others to compare to that from people with HD.

If you are taking part as a close other of someone who has HD, you will complete most of the same measures, but we will not need information about HD clinical symptoms. We will ask you to complete a few additional questionnaires that ask about the person taking part with HD, and your experience as a carer of someone with HD, as applicable.

6. Will the study involve taking a drug?

No.

7. Will the study affect my treatment?

No.

8. Is there a financial incentive for taking part in the study?

No. However, a shopping voucher (of up to £30 for completing both parts of one experiment) will be offered to compensate participants for their time. Please ask the researcher for details.

9. Are there any disadvantages, side effects or risks associated with taking part?

There should be no risks to your safety when taking part in this questionnaire type study which we will typically complete remotely (by email/telephone/online). Should you prefer to complete the study in person, please contact us so we can arrange to carry the study out at The Barberry.

There should be no disadvantages of taking part. However, it is possible that completing the tasks could highlight difficulties that you may be concerned about (e.g. changes in memory/ mood). You can choose to skip questions if you need to, but we won't ask for any sensitive details about your experiences. Responses will be confidential and the data will be anonymised before analysis. Please remember that this is an exploratory research study, and so the tasks are not intended for diagnosis. Indeed, people can respond very differently to the measures, regardless of HD. Therefore we do not intend to give you specific feedback about your data, but we can provide you with information about the overall study findings at the end of the study. You can discuss any concerns with the

research team and your consultant and multidisciplinary HD team at The Barberry. There are other external sources of support and information for people affected by HD, including the Huntington's Disease Association (www.hda.org.uk) and WeHaveAFace (www.wehaveaface.org).

10. What are the possible benefits of taking part?

Participation in the study is not likely to result in immediate clinical benefit for you. However, this research will enhance our knowledge about HD and we believe that this will be beneficial for patients, their families and clinicians. This study has been funded by the European Huntington's Disease Network supporting its potential value.

This research will help us understand which tasks and questionnaires are most helpful in our assessments. This is useful for future diagnosis and treatment planning. We can also use this information to plan follow-on research which will develop a new assessment especially for social difficulties in HD, which can be used to develop and evaluate new treatments.

We know that people with HD can have difficulties with speech. Let us know if you need support and we will try our best to support involvement in the research where we can.

11. What if new information becomes available?

The study will not directly affect your treatment. The availability of new information will not, therefore, affect the way your treatment is managed.

12. What will happen when the research stops?

As the research will not directly affect your treatment, your care will not be affected when the study ends.

13. What if something goes wrong?

The study is non-invasive and will not interfere with your normal treatment. Even if there was a problem during the study, it is most unlikely to affect your welfare.

If you have a concern about anything related to this research, you can contact the researchers, who will do their best to answer your questions (contacts below). If you remain unhappy and wish to complain formally, you can contact our Trust Customer Relations Team and Patient Advice and Liason Service (tel. 0800 953 0045).

14. 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. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it.

You may wish to answer the questions alone, unless it is helpful to have assistance (e.g. support from a close other when answering questionnaires). We will not discuss your responses with anyone else unless you make a disclosure (e.g. of intended harm) which would necessitate communication with the appropriate emergency services.

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

We hope that the study results will published in scientific journals and presented at scientific conferences. It will not be possible for you to be identified in any report or publication.

16. Who is organising and funding the research?
This research was awarded a competitive grant by the European Huntington's Disease Network. Some aspects of the research are supported by Birmingham and Solihull Mental Health NHS Foundation Trust.

17. Who has reviewed the study?
The study has been given a favourable opinion by Coventry and Warwick Research Ethics Committee.

18. How will we use information about you?
We will need to use information from you, and in some cases from your medical records, for this research project.

- This information will include your name, date of birth and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.
- People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
- We will keep all information about you safe and secure.
- Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

19. What are your choices about how your information is used?
For the study data, we will replace your name with a code number, and the code breaker will be kept separately from the research data, on the secure NHS drive. We will need to keep the code breaker during the study so that we can add information from your medical record about HD that we have asked permission for on the consent form. We will also ask to keep your contact details (separately and securely) during the study in order to make the participation arrangements.

We would like to keep the code breaker after the study has ended so we could link your data from any future research. For example, we may ask you if we can collect data on the same tasks in the future, and compare the data to look at any changes over time (that would be a new and separate experiment, which you would need to give consent for in the future). Separately, we would like to keep a record of contact details for those participants who wish to take part in future research and hear about the outcome of this research. These points are optional and if you agree on the consent form you can opt out later by emailing clare.eddy1@nhs.net.

If you change your mind about taking part, you can withdraw from the study. If you want us to delete data we have already collected, we can only do this if your name is in the code breaker at that point in time. We need to manage your records in specific ways for the research to be reliable. You can request to see or change the data we hold about you, but these rights are limited – we may not be able to grant them in every case. The research team can explain what information is held in the database in relation to your participation in this study.

20. Where can you find out more about how your information is used?
You can find out more about how we use your information

- by sending an email to anika.miah1@nhs.net, clare.eddy1@nhs.net or the host research department bsmhft.researchandinnovation@nhs.net
- by ringing us on 0121 301 4343

21. For further information about the study please contact:
Research Assistant Ms Anika Miah (anika.miah1@nhs.net; 07812 621145) or
Chief Investigator Dr Clare Eddy (clare.eddy1@nhs.net; 07985 883014).

For more general advice you can contact the Patient Advice and Liason Service via bsmhft.customerrelations@nhs.net or Tel: 0800 953 0045.

Specific Information Sheet for Participants

Social Cognition and Quality of Life in HD

Experiment 1

What will happen to me if I take part?

You can choose to take part in just one part, or both parts of the experiment.

- **Part A is just questionnaires, and part B involves cognitive tasks.**
- Part A can be completed on paper/on the computer and returned by post or email. We can also fill in answers for you over the telephone or in an online meeting if that is easier. The questionnaires should take about 60 minutes to complete. You will receive a £10 shopping voucher for your time.
- Part B is completed in an online meeting where possible, as we have to explain the tasks to you. We can also do this part in person at The Barberry if you prefer. The session is not recorded. It usually takes 90 minutes to complete and we can have a break. You will receive a £20 shopping voucher for your time.
- You will complete a consent form first for the experiment you take part in. It can be completed by hand or electronically, and emailed, posted/handed in to The Barberry.

Most of the tasks completed by people with HD and their close others without the gene will be the same. Some tasks may involve thinking about emotionally sensitive topics and use emotive language. For example, we will ask you to think about quality of life, your emotional reactions to people and situations, or about symptoms of depression. Other topics include self awareness and motivation for everyday life.

- **If you have the HD gene,** we will ask for permission to gain specific information about HD, medications and recent motor and functional capacity assessments, from medical records at The Barberry.
- **If you don't have the HD gene and are taking part as the close other of a patient with HD,** there are a few additional tasks where we will ask about things that involve the patient (e.g. communication, social interaction). If applicable, you may also be asked to reflect on things that you offer support with and how this can affect you personally.

If you would like to know more about the exact tasks we will ask you to complete, please ask the researcher. You do not have to answer any questions that you feel uncomfortable with. If you would like to discuss any sensitive issues that are raised you can talk to your consultant and the clinical team.

In this research study we will use information from you, and in some cases, your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data confidential, safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data in case we need to check it. We will make sure no-one can work out who you are from the reports we write. The information pack tells you more about this. After you have finished taking part, we can explain more about why we are running the study and the other related experiments we have conducted before.

Thank you for reading this.

Specific Information Sheet for Participants

Social Cognition and Quality of Life in HD

Experiment 2

What will happen to me if I take part?

You can choose to take part in just one part, or both parts of the experiment.

- **Part A is just questionnaires, and part B involves cognitive tasks.**
- Part A can be completed on paper/on the computer and sent to the hospital by post or email. We can also fill in answers for you over the telephone or in an online meeting if that is easier. The questionnaires should take 60-75 minutes to complete. You will receive a £10 shopping voucher for your time.
- Part B is usually completed after part A in an online meeting if possible, as we have to explain the tasks to you. We could do this part in person at The Barberry if you prefer. The session is not recorded. It usually takes 75-90 minutes to complete and we can have a break. You will receive a £20 shopping voucher for your time.
- You will complete a consent form first for the experiment you take part in. It can be completed by hand or electronically, and emailed, posted/handed in to The Barberry.

Most of the tasks completed by people with HD and close others of those patients will be the same. Some tasks may involve thinking about emotionally sensitive topics and use emotive language. For example, we will ask you to think about quality of life, your emotional reactions to people and situations, or about symptoms of depression. Other topics include self awareness and motivation for everyday life.

- **If you have the HD gene,** we will ask for permission to gain specific information about HD, medications and recent motor and functional capacity assessments, from medical records at The Barberry.
- **If you don't have the HD gene and are taking part as the close other of a patient with HD**, there are a few additional tasks where we will ask them about things that also involve the patient (e.g. communication, social interaction). Close others may be asked to reflect on things they offer support with and how this can affect them personally.

If you would like to know more about the exact tasks we will ask you to complete, please ask the researcher. You do not have to answer any questions that you feel uncomfortable with. If you would like to discuss any sensitive issues that are raised you can talk to your consultant and the clinical team.

In this research study we will use information from you, and in some cases, your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data confidential, safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data in case we need to check it. We will make sure no-one can work out who you are from the reports we write. The information pack tells you more about this.

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