NELFT NHS
NHS Foundation Trust

NOMINATED CONSULTEE INFORMATION SHEET : CST-IDD

Title of study: Cognitive Stimulation Therapy for people with learning Disabilities and Dementia (CST-IDD). A mixed methods feasibility study.

Introduction

Your client has been invited to take part in this research study but we feel that he/she is unable to decide for him/herself whether to participate or not. To help us decide whether he/she should take part, we would like to consult with you to find out what you think would be his or her wishes and feelings about taking part. If he or she has made any advance decisions that you are aware of and could affect participation in this study, then these will need to take precedence.

Before you give your opinion about whether you think your client would wish to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully. If anything is not clear, feel free to ask any questions and to discuss it with your friends, relatives or others. If you are unsure about taking on this role, you may seek independent advice. We will understand if you do not want to take on this responsibility. Thank you for reading this.

What is the purpose of the study?

Group Cognitive Stimulation Therapy (CST) is a treatment for dementia that involves the individual with dementia taking part in a group that meets twice a week for 45 minutes and take part in activities such as a life story, discussion of current affairs, puzzles and being creative, which is designed to be mentally stimulating. There is evidence that group CST is effective in improving cognition in people with dementia in the general population. CST is now widely available for people with dementia in the general population but it is not used in people with dementia who have learning disabilities.

At the moment CST is not available for people with learning disabilities. We have modified the existing CST manual, which is used in the general population, so that the activities are more relevant and appropriate for people with learning disabilities and dementia. We would like to find out if the manual and activities that we have proposed are enjoyable and are easy to follow.

We are looking to recruit individuals with dementia to take part in this study, half of them will be allocated to take part in the groups and the other half to be allocated to the control group. Participants will be required to be assessed before and after the groups in order to assess feasibility.

Does he/she have to take part?

No, it is entirely voluntary whether he or she should take part. If you think that your client would wish to take part, you will be given this information sheet and asked to sign a Consultee Declaration form.

You are free to withdraw your client at any time from the study without giving a reason. This will not affect the standard of care that he/she receives and it will not have any influence on future care that he/she receives.

What will happen if he/she takes part?

If you agree that your client would wish to take part, his/her carer will be asked to carry out an assessment measuring cognition and quality of life before being randomly allocated to the intervention or control group. Those in the intervention group will be offered the opportunity to take part in a Group CST intervention, those in the control group will carry out their normal activities and be invited to repeat the assessments after 8 weeks

This information will help us to check whether running a large study evaluating the effects of CST is feasible.

What will I have to do?

You will be asked to sign the declaration form if you think that your client would wish to take part in the study.

What are the possible advantages and disadvantages of taking part?

There are no direct advantages for your client in taking part. However, by taking part, he or she will help to potentially shape an intervention, which will then be used as part of a trial, and could be of benefit for future patients. It is very unlikely that any harm should come to your client in this study.

Will their taking part in this study be kept confidential?

All the information that is collected about your client during the course of the research will be kept strictly confidential and will not be made available to anyone who is not directly connected with the study. Personal information will not be included on any of the study questionnaires, and instead, he or she will be identified by a study ID number. There will only be one list that links his or her study ID number to his or her name and personal details, and this will be kept in a locked cabinet, within a locked room. The list that links the ID numbers to their identity will be kept separately from the data. Personal data will be stored for 6-12 months locally by NHS research sites and then archived in line with their trust's policy. Any direct quotations from recordings that are used will be anonymised.

Although what your client says to us is confidential, should they disclose anything to us which we feel puts them or anyone else at any risk, we may feel it necessary to report this to the appropriate persons. If we have to breach confidentiality in this way you will be informed and we will try to manage these situations as sensitively as possible

How will we use information about them?

We will need to use information about your client in this research project.

This information will include their;

- Name
- Age
- Gender
- Ethnicity
- Contact details (address and telephone numbers)
- Diagnosis
- NHS number

People will use this information to do the research or to check their records to make sure that the research is being done properly.

People who do not need to know who they are, will not be able to see their name or contact details. Their data will have a code number instead.

We will keep all information about them 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 they took part in the study

What are your choices about how your client's information is used?

Your client can stop being part of the study at any time, without giving a reason, but we will keep information about them that we already have.

We need to manage your client's records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about them.

Where can you find out more about how your client's information is used?

You can find out more about how we use their information;

- At www.hra.nhs.uk/information-about-patients/
- By calling our research team with any questions on…
- By sending an email to our data protection officer on robert.paley@nelft.nhs.uk

What will happen to the results of the research?

The study will be registered on a public web-based database where the study design and results can be viewed. The results of the trial will also be published in a peer reviewed journal and presented at conferences but your client will not be identified. We will produce a summary of the research findings for the participants of the study and can send this to you if you wish.

What will happen if I don't want him or her to carry on with this study?

You are free to withdraw your client from the study at any time without giving a reason. He or she will not be asked to complete any further questionnaires but the ones they have already completed may still be used.

Who is organising and funding the research?

The study is being organised by Prof Aimee Spector who is the Chief Investigator of the research project. The study is being sponsored by North East London NHS Foundation Trust and it is funded by the National Institute of Health Research. They will have no involvement in the conduct of the study.

Who has reviewed the study?

The study has been reviewed by XXX and has also been given a favourable ethical opinion for conduct in the NHS by (insert name)…..Research Ethics Committee

What if there is a problem?

If you have any concerns or wish to discuss the project with someone then you can speak to the research assistant who will do their best to answer your question or resolve any difficulties that you have. If you are not satisfied with the response then you can contact the Chief Investigator (see details below) who will do her best to address the issues. You can also contact the Patient Advice and Liaison Service (PALS) for independent advice (see below). They can give you information about how you can complain formally through the NHS Complaints Procedure. You can also obtain details from your local NHS Trust.

In the event that something goes wrong and your client is harmed during the research and this is due to someone's negligence, then you may have grounds for legal action in order to obtain compensation from the Trust. However, you may have to pay the legal costs.

PALS address: Whipps Cross University Hospital (main building),
Whipps cross Road, E11 1NR
PALS Telephone number: 0203 594 2040
Email: pals@bartshealth.nhs.uk

Contact for Chief Investigator:

Prof Aimee Spector
Add address
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Email:a.spector@ucl.ac.uk