PERSONAL CONSULTEE INFORMATION SHEET (2):Feasibility RCT

Title of study: A feasibility randomised controlled trial of Individual Cognitive Stimulation Therapy in People with Dementia and Learning Disabilities

Introduction

Your relative/friend 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 if 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 friend/relative 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?

Individual Cognitive Stimulation Therapy (CST) is a treatment for dementia that involves the individual with dementia taking 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 routinely used in people with dementia who have learning disabilities.

Sometimes it may be less appropriate to provide group based CST, for example in individuals who have mobility or behavioural problems. For these individuals, individual CST may be an alternative option. Individual CST involves a carer carrying out activities with the individual with dementia using a manual. However, there have been few studies of individual CST in the general population and they have shown mixed results in improving cognition. People with learning disabilities may find it more difficult to take part in group CST because the needs and abilities differ greatly

between individuals and they are more likely to have visual and hearing problems that could make participating in a group more challenging. Therefore we would like to find out if individual CST is helpful in people with learning disabilities.

At the moment there is very little evidence for the use of CST in people with dementia and learning disabilities. This is why we would like to carry out a small randomised controlled trial of individual CST to find out whether the treatment is feasible and acceptable to individuals with dementia and their carers. If it is acceptable and feasible, we then plan to carry out a larger, multicentre study in the future to find out if the treatment is effective in improving cognition and quality of life.

Does he/she have to take part?

No, it is entirely voluntary whether he or she should take part and there are no penalties for not taking part (e.g. it will not affect the care he or she receives). If you think that your friend/relative 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 relative /friend at any time and 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?

Your friend or relative and their carer will complete some baseline assessments that include tests and questionnaires about the person's cognitive functioning, daily living skills and quality of life, and questions about the carer's wellbeing carer burden and confidence in looking after someone with dementia. This will take your friend or relative up to 90 minutes to complete. We will include breaks if they are feeling tired or discontinue the tests if they do not wish to continue.

After this they will both be randomised by a computer programme to either the intervention group (individual CST) or the control group. If they are allocated to the control group the individual will not receive the intervention but will continue to receive "usual care", that is the person with dementia will continue to have access to medical and social care professionals and drug treatments. They have a 50% chance of being randomised to either group. They will be informed by a member of the team about which group you have both been randomly allocated to.

What will he or she have to do?

Intervention Group

If your friend or relative and his/her the carer are allocated to the intervention group, the carer will receive training on how to use the Individual CST manual and resources and how to administer the intervention. One to one training can be given to family carers at home or at the care home for paid carers, which lasts for half a day. Alternatively, they can attend a group training session if they prefer (1 day training).

Your friend or relative will take part in activities designed to be mentally stimulating with their carer who will choose activities from the manual. The sessions will take place for 30 minutes, twice a week at a time that is convenient, for 20 weeks.

The activities have been designed so that they can be tailored to the needs of the individual. It is hoped that the activities are enjoyable and that they will both enjoy doing them.

We will ask the carer to audio-tape two sessions, which will be used as part of the study's adherence checks (the extent to which the sessions follow the manual's guidance). The recordings will be transferred securely onto an encrypted computer and deleted from the recording device.

If your friend or relative is taking medication for dementia, they can carry on taking this medication.

At 11 weeks and at the end of the study (21 weeks), your friend or relative and their carer will complete the assessments that were carried out at baseline (before the trial began) again. This will take your friend or relative up to 90 minutes to complete each time. We will include breaks if they are feeling tired or discontinue the tests if they do not wish to continue.

These assessments will help us to find out if individual Cognitive Stimulation Therapy is potentially helpful in improving memory, daily living skills and quality of life.

At the end of the study, we will also ask your friend or relative to complete a feedback questionnaire about what they thought about the intervention.

Control Group

If your friend or relative and their carer are allocated to the "Treatment as usual group", they will not receive the cognitive stimulation therapy but will have access to their normal care as usual. They will be asked to complete the assessments again at11 weeks and 21 weeks. This will take your friend or relative up to 90 minutes to complete each time. We will include breaks if they are feeling tired or discontinue the tests if they do not wish to continue.

At the end of the study, your friend or relative will be offered the individual CST intervention. His/her carer will receive one to one training on the principles of CST and how to use the manual effectively to carry out the activities with the individual with dementia. They will not have to do any further assessments (and will not be given any gift vouchers) but we will offer the carer monthly telephone contacts to assist them if they have any difficulties. Your relative/friend will continue to be reviewed by their local team who will provide ongoing care and support.

At the end of the study, we will also invite ten carers and ten individuals with dementia who took part in both groups to give more detailed feedback in the form of a short interview, which he or she does not have to take part in. This will take about 45 minutes and will be audio-taped. We will ask you to indicate whether you think your friend or relative may be willing take part in this on the declaration form (but you can change your mind later).

What will I have to do?

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

What are the possible disadvantages and risks of taking part?

The main disadvantage of the study is that the intervention is quite burdensome. Your friend or relative will be asked to take part in activities for 30 minutes twice a week for twenty weeks. Their carer may find it difficult to carry out these activities for all the weeks or there may be days when your friend or relative does not wish to take part. If this happens it is fine as it is important for us to obtain information about whether it is possible for carers to carry out the intervention and whether individuals with dementia and learning disabilities are able to tolerate it.

There is also the possibility that your friend or relative may become upset if he or she is not in the intervention group (the group receiving the individual Cognitive Stimulation therapy). If you think that this may be an issue, then it may be more appropriate for him or her to not take part in the study. For participants who are in the control group (not receiving the intervention), they will be offered the intervention at the end of the study.

What are the possible advantages of taking part?

There may not be any advantages in your friend or relative taking part. However, we hope that he or she and the carer will both enjoy taking part in the activities and the intervention could lead to an improvement in cognition and daily functioning in your friend or relative.

The information from this study will be used to carry out a larger, definitive study of whether the intervention is effective in improving cognition, compared to treatment as usual.

Will there be any payment or reimbursement of expenses?

As a way of thanking your friend or relative for their time, he or she will receive a £10 gift voucher after completing the assessments at 11 weeks and a further £10 after completing the assessments at 21 weeks. They will receive this gift voucher irrespective of the group they are allocated to. In order to reduce travel costs and inconvenience, all the study procedures will take place at home.

If they go on to take part in the interview at the end of the study, your friend or relative will receive a further £10 gift voucher for their time.

Will the GP be informed?

If you think that your friend/relative would wish to take part, we will inform the GP about his/her participation in the study.

Will their taking part in this study be kept confidential?

All the information that is collected about your friend or relative 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 only situation where we may break confidentiality is if we have concerns about the person's welfare. If this occurs, local safeguarding procedures will be followed. This is standard practice.

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 friend or relative 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 friend or relative from the study at any time without giving a reason and this will not affect the care they receive. 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 Dr Afia Ali**,** University College London, who is the Chief Investigator of the research project, and is responsible for overseeing the research, and for the secure storage of data.

The study is being sponsored by University College London and it is funded by the Baily Thomas Charitable fund. They will have no involvement in the conduct of the study.

Who has reviewed the study?

The study has been reviewed by the Baily Thomas Charitable fund using an external peer review process. The study has also been given a favourable ethical opinion for conduct in the NHS by the Harrow 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 friend or relative 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),
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