CARER PARTICIPANT INFORMATION SHEET (3)

Title of study: A feasibility randomised controlled trial of Individual Cognitive Stimulation Therapy in people with dementia and learning disabilities

Introduction

You are being invited to participate in a research project. Before you decide, 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.

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.

Why have I been invited?

You have been invited because you care for someone with learning disabilities who has been diagnosed with dementia. You could be a paid carer or a family carer.

Do I have to take part?

No, it is up to you whether you would like to take part and there will be no penalty for choosing not to take part. If you decide to participate, you will be required to sign a consent form. You can withdraw your consent at any time without having to give a reason.

What will happen to me if I take part?

If you and the person with dementia that you look after agree to take part (or their personal consultee/nominated consultee agrees) you will both complete some baseline measures that include tests and questionnaires about the person's cognitive functioning, daily living skills and behaviour and quality of life. You will also be asked questions about your wellbeing, carer burden and how well you feel you are able to look after a person with dementia (competence). These questionnaires are not an assessment of your knowledge or skills but will ask you to rate your own thoughts and feelings regarding your work with individuals with dementia. If you indicate that you feel you need more support with caring for a person with dementia we can discuss ways to help you access this.

In total the questionnaires will take between 90 minutes to two hours for you to complete. The assessments with the individual with dementia may take up to 90 minutes.

After this you will both be randomised by a computer programme to either the intervention group (individual CST) or the control group. If you 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. You have a 50% chance of being randomised to either group. You will be informed by a member of the team about which group you have both been randomly allocated to.

What will I have to do?

Intervention group

If you are both allocated to the intervention group, you 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).

You will then be asked to follow the instructions on the manual and to complete the activities with the individual with dementia for 30 minutes twice a week over a period of 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 you will both enjoy doing them.

We will ask you to keep a diary to record the days that you carry out the activities and the types of activities that have been carried out.

A research assistant will keep in regular touch with you to help you with any problems that you may have. We will ask you to audio-tape two sessions (a digital recorder will be provided). This 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.

At 11 weeks after randomisation and at the end of the 20 weeks, we will ask you both to complete the baseline measures again. This will take you between 90 minutes to two hours to complete, and the individual with dementia up to 90 minutes to complete. We will also ask you and the person with dementia to complete a feedback questionnaire about your thoughts on the intervention.

Control group

If you were allocated to the control group, we will ask you to complete the baseline measures again 11 weeks after randomisation and at the end of the study (21 weeks). This will take you between 90 minutes to two hours to complete, and the individual with dementia up to 90 minutes to complete. At the end of the study, you will be offered the individual CST intervention. We will provide 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. You will not have to do any further assessments (and will not be given any gift vouchers) but we will offer you monthly telephone contacts to assist

you if you have any difficulties. The person with dementia will continue to be reviewed by their local team who will provide ongoing care and support.

At the end of the study, we will 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 you do 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 would be willing to do this on the consent form (but you can change your mind later).

What are the possible disadvantages and risks of taking part?

The main disadvantage of the study is that the intervention is quite burdensome. You will be asked to carry out the activities for 30 minutes twice a week for twenty weeks. You may find it difficult to carry out these activities for all the weeks or there may be days when the individual with dementia does not wish to take part. If this happens you do not need to worry as it is important for us to obtain information about whether it is possible for carers to carry out the intervention. We will encourage carers to report any adverse effects that may occur as a result of the intervention.

What are the possible advantages of taking part?

There may not be any advantages of taking part. However, we hope that you will both enjoy taking part in the activities and the intervention could lead to an improvement in cognition and daily functioning in the person with dementia.

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?

If you are randomised to the CST treatment arm, you will be asked to complete a training session on the use of the individual CST manual. We will be able to provide the training at home but if you complete the training at a different location, we will reimburse your travel expenses.

If you have been allocated to the CST treatment arm, in order to thank you for your time and effort in delivering the intervention, we will provide you with a £10 gift voucher after completing the questionnaires at 11 weeks and a further £10 after completing the questionnaires at the end of the study (21 weeks). You will receive a further £10 gift voucher for completing each audio-taped session (2 sessions; £20). You will receive

these vouchers even if you and the participant with dementia are not able to complete all the individual CST sessions. We will also give the participant with dementia a £10 gift voucher after completing the assessments at each of the follow up points.

If you are in the control arm, where no treatment is being offered, you and the participant with dementia will each receive a £10 gift voucher after completing the questionnaires at 11 weeks and at 21 weeks.

If you volunteer to take part in the interview at the end of the study you will receive a further £10 gift voucher for your time.

Will my GP be informed?

We will not inform your GP but we will inform the GP about the individual with dementia who is taking part, providing they or their personal consultee or nominated consultee agrees to the GP being informed.

Will my taking part in this study be kept confidential?

All the information that is collected about you 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, you will be identified by a study ID number. There will only be one list that links your study ID number to your 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 welfare of the individual taking part in the study or other vulnerable individuals living with the person. If this occurs, we would follow local safeguarding procedures. 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 will also be published in a peer reviewed journal and presented at conferences but you 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 to carry on with this study?

You are free to withdraw from the study at any time without giving a reason and will not be penalised in any way. You will not be asked to complete any further questionnaires but the ones that you have completed will 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 you are 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 your 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

Research Team details:

Emma Brown
Research Assistant
Division of Psychiatry
University College London
6th Floor, Maple House
149 Tottenham Court Road
London W1T 7NF
Tel: 07525 279810 / 0203 108 6978
Email: Emma.Brown@ucl.ac.uk

Dr Afia Ali
Chief Investigator
Consultant Psychiatrist and Senior Clinical Lecturer
Waltham Forest Learning Disability Service
30 Coleridge Road
Walthamstow
E17 6QU
Tel: 0208 928 8300
Email: afia.ali@nelft.nhs.uk; afia.ali@ucl.ac.uk