Camden and Islington NHS
NHS Foundation Trust

Patient Participant Information Sheet – Full Trial

Study Title: Problem Adaptation Therapy for individuals with mild to moderate dementia and depression. The PATHFINDER Trial.

Invitation to participate in a research study

We would like to invite you to join our research study that is being funded by the National Institute for Health Research. Before you make a decision, it is important for you to understand why the study is being carried out, and what it will involve. Please take your time to read the following information carefully, and discuss it with your partner, relatives or friends if you wish. Please feel free to ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The purpose of this study is to adapt a form of talking therapy called Problem Adaptation Therapy for people with Alzheimer's disease who have become depressed. We would like to see how acceptable this newly adapted therapy is to people with Alzheimer's disease, and whether it is possible to provide it to patients in the NHS. This research will also compare the Problem Adaptation Therapy to standard NHS treatment provided to people with Alzheimer's disease who have become depressed, this type of research is called a randomised clinical trial and means that not everybody who participates in the study will receive the new treatment, half will continue to receive standard NHS treatment and the decision will be made at random.

Why do people with Alzheimer's disease become depressed?

Difficulties with memory and concentration often mean that people with Alzheimer's disease give up some of the activities that they previously enjoyed. This, together with changes that take place in the brain as part of the illness, means that people with Alzheimer's disease are vulnerable to developing depression in which they feel persistently unhappy and distressed, and are unable to enjoy what would normally be pleasurable experiences.

Why do we need to research Problem Adaptation Therapy for depression in people with Alzheimer's disease?

Problem Adaptation Therapy is a new form of talking therapy that aims to help people with Alzheimer's disease and their caregivers to find ways that they can change their environment and activities so that they can enjoy a more positive state of mood. This has already been shown to be helpful in a small group of patients with very mild Alzheimer's disease in the United States. We are carrying out this research to find out if Problem Adaptation Therapy can be used within the National Health Service to improve depression in people with Alzheimer's disease. The research is important because antidepressant drugs and more commonly used talking therapies such as Cognitive Behavioural Therapy (or CBT) are not

always effective in improving depression in people with Alzheimer's disease.

Why have I been chosen?

You have been chosen because you have been diagnosed with Alzheimer's disease and your doctor or nurse have also recognised that you have symptoms of depression. You have been given this information sheet because you, or the person who cares for you, have expressed an interest in the study.

Do I have to take part?

No. It is up to you to decide whether you would like to take part in this study. We will go through this information sheet with you, and you will be able to ask any questions you have about it. If you do decide to take part you will be given this information sheet to keep and you will both be asked by the researcher to sign a consent form. If you decide to take part you will be free to withdraw from the study at any time without having to give a reason as to why you want to withdraw. A decision to withdraw at any time or a decision not to take part will not affect the standard of care you receive or your future medical care or legal rights.

How will my capacity to give informed consent affect my involvement in the research?

At some point in their illness, many people with Alzheimer's disease may lose capacity to understand and make decisions about their involvement in research. For this reason, as for many other aspects of decision-making, it is usual to have identified someone that you would trust and choose to continue to make decisions for you. We will ask you to identify somebody that you have chosen for this role when you enter the study. If at any point, the members of the research team or the person who cares for you become concerned that you may no longer have capacity to give consent to continue to be involved in the research, this person will be asked to make decisions for you in relation to the research.

What will the study involve if I take part?

If you are interested in taking part in the study, you will meet initially with a researcher who will discuss the study with you and ask you some questions to find out whether you are suitable to participate in the study, the amount of time you spend with the person who cares for you and determining how severely affected by Alzheimer's disease you are and the nature and seriousness of your symptoms of depression. This is the screening stage of the research. Much of this information may already be in your medical records. As part of this screening, the research team will review your medical records to confirm your diagnosis and will assess your memory and other cognitive functions and the severity of your depression. Your cognitive function will be tested with the Mini-Mental State Examination and the severity of your depression with a 19-item scale called the Cornell Symptoms of Depression in Dementia Scale. Together, these will take about 20 minutes to complete with a researcher. The meeting can take place in your home, at your GP's surgery or at the Memory Service depending on your preference.

If you are not suitable for inclusion in the study our questions will end and no further information will be collected by the study team. Your care and treatment will continue as normal with your GP or memory service.

If you are suitable for the study and agree to participate, then there is a 50% chance that you will be offered eight, one-hour sessions of Problem Adaptation Therapy over three months. The therapy will consist of 2 assessment sessions, 5 sessions focused on problem solving, and 1 review session. You will also be provided with a personalised therapy booklet to assist with the therapy. The first two of these sessions will take place in your own home, and subsequent sessions will be in a local clinic, at your home or at your GP's surgery, depending upon your ability to travel to appointments and your preference. There will also be two additional 1-hour 'booster' sessions, three months and six months later which will "top up" any potential benefits from the initial therapy by reviewing the problem-solving strategies used earlier.

In the sessions, you and your caregiver will work together with a therapist to identify the difficulties that you may have been experiencing that have contributed to your feelings of low mood. You and your caregiver will be helped to find ways to change the impact of these difficulties on your mood. For example, by making small changes to your home environment or by helping you to spend more time engaged in activities that you previously enjoyed. The therapist will help you to develop a pattern of living in which you spend as much time as possible doing things that are likely to help you to be able to feel happy and as little time as possible involved with things that are frustrating or difficult for you and that may have contributed to your feelings of low mood.

If Problem Adaptation Therapy does not suit you, or if you or your carergiver find it difficult participating in the sessions then you will be free to finish them at any point. This will not affect the standard of care you receive or your future medical care or legal rights.

While receiving Problem Adaptation Therapy, you will be asked to avoid receiving other forms of talking therapy (such as Cognitive Behavioural Therapy) as taking part in different types of therapy at the same time may be confusing for you. Although it is preferable that you do not receive other forms of talking therapy at the same time as Problem Adaptation Therapy, we cannot insist on this. Therefore, we will ask you about other treatments you may have received while receiving Problem Adaptation Therapy at the end of therapy.

You will be asked to complete some questionnaires with a researcher on four separate occasions in order for us to see how you find Problem Adaptation Therapy and to assess any effects that the therapy has had in improving your feelings of low mood. These will be before therapy starts and at three, six and twelve months after starting the therapy. Each of these assessments will take around one and a half hours to complete and will involve you and your caregiver. Any travel expenses incurred by yourself during the course of the study will be reimbursed.

Why is there only a 50% chance that I will receive Problem Adaptation Therapy if I participate in the study?

Because this is a randomised clinical trial, 50% of people who agree to participate will be randomly selected to receive the new therapy that we are studying and 50% will be selected to receive treatment as usual from their memory service, mental health care team and GP. This is so that we can test whether the new treatment is better than usual treatment and whether it is acceptable to people with Alzheimer's disease and their carers. Whether you are allocated to receive Problem Adaptation Therapy or treatment as usual, you will be in the study for 12 months and will be contacted by a researcher to complete the study assessments.

What are the possible benefits of taking part?

You may benefit from taking part in this study because you will receive a new type of talking therapy that within the United States has been shown to benefit people with depression who are at the very earliest stages of Alzheimer's disease. This is not yet widely available to people with depression and Alzheimer's disease in the UK. Although we are hopeful that you would see the same benefits as other people, this may not be the case. Throughout your participation in the study, you and your caregiver will have the opportunity to work and interact with the research team and other healthcare professionals both at your home and in the clinic. You may find this experience to be helpful for yourself and your caregiver. You will also receive reimbursement of travel expenses if you travel to the clinic for your appointments.

What are the possible disadvantages or risks of taking part?

The risk of taking part could be that you experience some distress when discussing your current difficulties in assessments, interviews and therapy sessions, or your mood may worsen by the end of therapy. As is the case with all talking therapies, we cannot guarantee that Problem Adaptation Therapy will benefit everyone who receives it. However, we will monitor how you are feeling throughout the study. If your mood does get worse and you express an intention to harm yourself or another person, we will notify your memory service, mental health care team and GP so that you can receive more support, if necessary. Similarly, if you continue to experience significant symptoms of anxiety or depression at the end of therapy then we will notify your memory service, mental health care team and GP so that you can be referred for further support.

Will my taking part in this study be kept confidential?

Yes. During this research we will collect your contact details, your responses to screening questions, audio recordings of therapy sessions, and your response to interview questions and paper questionnaires. All of the information we collect about you will be anonymised using a unique identification number so that it will not be possible to identify you from any of your information. Your data will be stored using this unique identification number and not your contact details (i.e. names or addresses) so that you cannot be identified from it. All data will be kept strictly confidential, and will only be seen by members of the research team.

Two types of data will be collected from you during this study; personal data so that we can contact you throughout your participation in the research and send you the study results if you have asked for this, and the research data which is the information we have collected from you during all the activities you have taken part in as part of the research. Research data is always saved in anonymised form, this means that the information you share cannot be linked to you but will be assigned under a unique identification number. Personal data will be stored for no longer than we need to contact you, so until your participation in the study has ended or until we have written up the study results so that we can send them to you if you have requested this. Research data will be kept for up to 25 years so that the information can be verified at a later date if necessary.

What will happen to my information?

All of the information about you and the person who cares for you for will be stored in one of two ways; electronic and paper copies. Some of the research data originally collected in paper format may be converted electronically so that we can store it on a secure computer network. All electronic data will be held on a secure database on a password-protected, encrypted computer and on University College London's password-protected, encrypted secure electronic network. Data in paper format (e.g. consent forms, completed questionnaires) will be stored securely in locked cabinets at NHS sites or at University College London and then sent away to be securely archived. All data will be securely destroyed after the retention period.

If any of the sessions that you have been involved in have been recorded, once recordings have been transcribed they will be deleted.

Health care research is sometimes monitored to ensure that it is being conducted satisfactorily and that the interests of those taking part are protected. Such monitoring will be organised by the regulators responsible for healthcare research, the sponsor (Camden and Islington NHS Foundation Trust) or the NHS trusts responsible for your mental health service. These monitors will need to look at information collected for this research which may include sections of your medical notes and research notes. No personal information is ever collected.

Will my doctor be informed?

If you decide to take part in the study, with your permission, we will write to your GP and memory service or mental health care team to inform them of this, and again at the end of your treatment to update them regarding the outcome. As outlined above, we will also contact your GP and memory service or mental health care team during the study if we become concerned for your safety or another person's safety (e.g. if you express an intention to harm yourself or another person). This is so that you can be referred for more support.

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

If you don't want to carry on with the study, you will be free to withdraw from it at any time, without having to give a reason. Withdrawing from the study will not affect the standard of care you receive or your future medical care or legal rights. If you were to withdraw from the study, then we would use any information collected in the study up to the point that you withdrew from the study.

What will happen once the study has ended?

Once the study has ended your clinical care will continue to be managed by your GP and memory service or mental health care team and the research team will not be able to provide further treatment or support. If you continue to experience significant symptoms of depression (or other symptoms that need addressing) at the end of therapy then your GP and memory service or mental health care team will be notified so that you can be referred for further treatment, if necessary.

What will happen to the results of the study?

At the end of the study, we will analyse all of your information together with other participants' information. We will then publish our findings in an academic journal and at relevant conferences. We will also send you a summary of these if you request this. Your information will not be identified in any publication arising from this study. Although we hope that the strategies and problem-solving techniques that you will be introduced to as part of your involvement in the study will be useful, until the trial is completed we will not have positive evidence to support their use in people with Alzheimer's disease who are depressed.

Who is organising and funding the research?

This study is funded by the NIHR Health Technology Assessment (HTA) Programme (ref: 16/155/01). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health. The research is being led by Professor Robert Howard who is a Research Psychiatrist at University College London and an Honorary Consultant Psychiatrist at Camden and Islington NHS Foundation Trust. The research is sponsored by Camden and Islington NHS Foundation Trust and organised by University College London.

Who has reviewed the study?

All NHS research is looked at by an independent group of people, called a Research Ethics Committee in order to protect participants' safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by [Research Ethics Committee] ([reference number]).

Who can I contact for further information?

You can contact Professor Robert Howard, who is the Chief Investigator of the study, if you have any questions or require any further information about this study. His details are: Professor Robert Howard, Division of Psychiatry, University College London, Wing A, 6th Floor Maple House, 149 Tottenham Court Rd, London W1T 7NF. Tel: 020 3549 5114. Email: robert.howard@ucl.ac.uk.

What if there is a problem?

If there is a problem or if you have any concerns about the way you have been approached or treated during this study, then please contact: Professor Robert Howard, Division of Psychiatry, University College London, Wing A, 6th Floor Maple House, 149 Tottenham Court Rd, London W1T 7NF. Tel: 020 3549 5114. Email: robert.howard@ucl.ac.uk.

What if something goes wrong?

If something goes wrong or if you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed because of someone's negligence, then you may have grounds for a legal action for compensation against Camden and Islington NHS Foundation Trust, but you may have to pay for your legal costs.

What if I have a complaint about this study?

If you have a complaint about this study or are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution. If you remain unhappy and wish to complain formally about any aspect of the way you have been approached or treated during the course of this study, then please contact the Chief Investigator or your local site's Principal Investigator who is Dr XXXXX. If, for any reason, you are not satisfied with the response that your receive or the action taken following your complaint, then you can contact the Research Governance Sponsor of this study, which is Camden and Islington NHS Foundation Trust, Advice and Complaints Service, 1st Floor, East Wing, St Pancras Hospital, 4 St Pancras Way, London NW1 0PE. Telephone 020 3317 7102. Email feedback@candi.nhs.uk quoting study PATHFINDER IRAS Ref. 238724'.

You can also make a formal complaint by following the standard NHS Complaints Procedure: you can find more details about this by contacting your local hospital Patient Advice and Liaison Service: [local contact details for each site to be added].

Thank you for considering taking part in this research study.

This study is funded by the NIHR Health Technology Assessment (HTA) Programme (ref: 16/155/01). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Funded & supported by NHS National Institute for Health Research

Your Information, NHS Research, and the General Data Protection Regulation (GDPR)

Camden and Islington NHS Foundation Trust is the Sponsor for this study, and **University College London** is a collaborator that is organising this research, both organisations are based in the United Kingdom. Camden and Islington NHS Foundation Trust will be using information from you and your medical records in order to undertake this study. Camden and Islington NHS Foundation Trust will act as the data controller for this study, this means that we are responsible for looking after your information and using it properly. University College London will keep identifiable information about you for no longer than 12 months after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at https://www.hra.nhs.uk/information-about-patients/.

[NHS/other site] will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Camden and Islington NHS Foundation Trust, University College London, and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

[NHS/ other site] and your healthcare team will keep identifiable information about you from this study that is relevant to your ongoing healthcare in accordance with the NHS standard data retention period.