Insert NHS trust logo

Patient Information Sheet

Introduction

We are inviting you to take part in a clinical trial (research study) called DAPA (Dementia and Physical Activity). This trial aims to understand whether a programme of exercise improves the cognition (e.g. memory and understanding) of people with mild to moderate dementia.

It is important that you understand why the research is being done and what it will involve before you decide whether or not to join.

To help you decide please read this information sheet carefully. Talk to your family, friends, doctor or nurse about it. Or if you prefer, one of our team can answer any questions you may have.

What is the purpose of this trial?

We are testing an exercise programme and comparing it to the routine care that people with dementia receive. Participants will be randomly put into two groups.

- About two thirds of people will take part in an exercise programme but also continue with their routine care.
  The remainder, about one third, will continue with their routine care. This is so that we can compare the results from each group at the end of the trial to assess the effect of the exercise programme.
- The group you go into will be decided by chance but you will have a greater chance of being placed in the exercise programme.

Why have I been invited?

You have been invited as someone who has mild to moderate dementia and who is well enough to take part in an exercise class.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part. If you do, we will ask you to sign a consent form. If you decide to take part and your condition advances, this will not affect your continued participation in the study. If you decide to stop taking part in the exercise programme you can continue with the follow-up visits from the researcher.

You can change your mind at any time during the trial without giving a reason, even after you have signed the consent form. This will not affect the usual care you receive.

If I take part what will I have to do?

Everyone who decides to take part will be seen at home by a researcher. You will be asked to fill in a consent form.

A short questionnaire will be used to check if you are eligible for the study.

If eligible, the researcher will ask you some questions about your memory, understanding, quality of life and mood. This will take up to 1 ½ hours.

If you have a carer we may ask them some questions about your condition too.

We would also like to look at your health care records for details of your general health and the services you receive. If you want to take part in the trial but don't want us to check your records, you can indicate this on the consent form.

What happens after the first visit?

We will contact you to let you know which group you are in. The researcher will contact you again for follow-up visits after 6 and 12 months.

If you are allocated to the routine care group, you will continue with your normal routine.

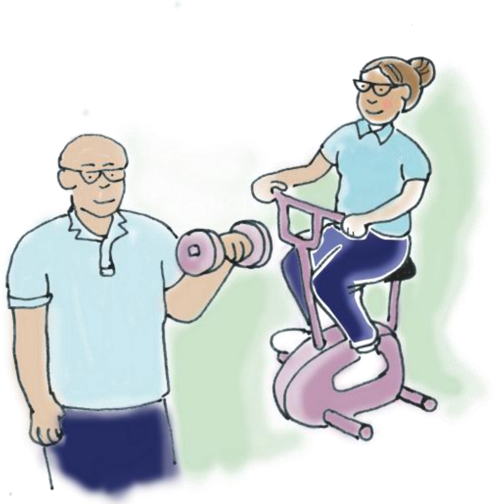
What will happen if I am allocated to take part in the exercise programme?

Our specialist physiotherapist will invite you for a brief pre-exercise assessment at a local exercise venue. The physiotherapist will look at how fit you are so that they can match exercises to your abilities. You can wear any comfortable clothes.

You will take part in an exercise class with around 5 other people twice a week for 4 months. Each class will be 1 hour long.

You will be given your own exercise programme using an exercise bike and weights and you will be closely guided by physiotherapy staff.

They will help you to exercise at a level to improve your muscle strength and fitness.



You may also be asked to wear a small measuring device called a heart rate monitor. This device is small and comfortable and is worn with your usual daily clothes.

The physiotherapist will also encourage you to include more physical activity into your daily life during the study and will help you to identify ways to add another hour of exercise to your weekly routine. After the initial 4 months are completed, the physiotherapist will encourage and assist you to find ways to continue exercising regularly at home and/or in the community (an information pack will also be provided).

Some exercise classes will be observed by one of the study researchers and you may be asked a few questions about how you are finding the exercise.

Will it cost me anything?

No, classes are free and we will pay travel costs for attending.

What are the possible risks and benefits of taking part?

We cannot promise that the trial will help you but we hope the information we get from this trial will help improve the treatment of people with dementia.

For those taking part in the exercise classes, these may give other health benefits – for example exercise is known to be good for your heart, lungs, circulation and general well-being.

The exercise classes will be closely supervised by specially trained physiotherapists, so there should be very little risk of falling, injury or other health problems.

Will my doctor know that I am taking part in the study?

Yes, if you agree we will inform your GP and your mental health services doctor by letter. We will also contact them if we have any concerns about your health or well-being during the trial.

What if new relevant information becomes available?

The trial monitoring committee will be informed and they will decide whether the trial should continue and whether trial participants should be informed of the new information.

What if there is a problem?

It is unlikely that you will be caused problems by taking part in this trial. If you have become hurt or sick as a direct result of taking part in this trial, please contact your GP or nearest NHS drop in centre or accident and emergency department. If you are harmed due to someone’s negligence, you may have grounds for legal action.

You can contact your Patient Advice and Liaison Service at www.pals.nhs.uk for more advice, or if you are unhappy with the trial.

If you have a complaint, please contact:
Jo Horsburgh, Deputy Registrar, Deputy Registrar's Office, University House, University of Warwick, Coventry, CV4 7AL. Tel: 024 765 75686. Email: j.horsburgh@warwick.ac.uk

Will my details be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. This information will be kept in a secure place in Warwick Clinical Trials Unit and only people involved in the trial will have access to it.

Who is paying for this trial?

The National Health Services Health Technology Assessment Programme funds the trial. They have identified this as an important piece of research that the NHS should pay for.

What will happen to the results of the trial?

At the end of the trial, you will have an opportunity to find out the results as they will be published in medical journals. They will not contain details which could identify any person who took part.

Who has reviewed the trial?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. Research Ethics Committees safeguard the rights, safety, dignity and well-being of people participating in research in the National Health Service. They review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical. This study has been reviewed and given a favourable opinion by the National Research Ethics Committee South West - Frenchay.

Contact details for further information

For further details or if you have any concerns you can contact the following:

Our address for correspondence is	Or Locally
DAPA Trial Team Warwick Clinical Trials Unit University of Warwick Gibbet Hill Campus CV4 7AL Tel: 02476 150 955	Insert local contact