

Dementia and Physical Activity (DAPA)

Personal Consultee Information Sheet

Introduction

We would like to invite your relative/friend 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.

However, we feel that your relative/friend is unable to decide for himself/herself whether to take part in this research. To help decide if he/she can take part we'd like to ask your advice about whether or not he/she would want to be involved. We ask you to consider what you know of his/her wishes and feelings, and consider his/her interests.

Before you decide if you want him/her to join in, it's important to understand why the research is being done and what it will involve.

The following information has also been provided to your relative/friend. Please take time to read this leaflet carefully. Talk to your family, friends, your relative/friend's doctor or nurse if you want to. One of our team will go through the information sheet with you and answer any questions you 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 has my relative/friend been invited?

Your relative/friend has been invited as someone who has mild to moderate dementia and who is well enough to take part in an exercise class.

Does my relative/friend have to take part?

No. It is up to you and your relative/friend to decide whether or not you wish your relative/friend to take part. If you do, we will ask you to sign a declaration form.

You can change your mind at any time and decide that your relative/friend does not want to continue to take part in the trial without giving a reason, even after you have signed the declaration form. This will not affect the usual care that your relative/friend will receive.

If my relative/friend decides to take part, what will he/she have to do?

If you decide that your relative/friend would like to take part then he/she will be seen at home by a researcher.

You will be asked to fill in a declaration form. A short questionnaire will be used to check if your relative/friend is eligible for the study.

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

If he/she has a carer we may ask them some questions about your relative/friend's condition too but will obtain the carer's consent to do this.

We would also like to look at your relative/friend's health care records for details of his/her general health and the services he/she receives. If you want your relative/friend to take part in the trial but don't want us to check his/her records, you can indicate this on the declaration form.

What happens after the first visit?

You and your relative/friend will be sent a letter telling you which group he/she is in. The researcher will contact you again for follow-up visits after 6 and 12 months.

If your relative/friend is allocated to the routine care group, he/she will continue with his/her normal routine.

What if he/she is allocated to take part in the exercise programme?

- Our specialist physiotherapist will invite your relative/friend for a brief pre-exercise assessment at a local exercise venue. The physiotherapist will look at how fit he/she is so that they can match exercises to their abilities. Your relative/friend can wear any clothes that are comfortable for them.
- Your relative/friend will take part in an exercise class with about 5 other people twice a week for 4 months. Each class will be 1 hour long.
- Your relative/friend will be given his/her own exercise programme using exercise bikes and weights and he/she will be closely guided by physiotherapy staff.
- They will help your relative/friend to exercise at a level to improve his/her muscle strength and fitness.
- He/she may also be asked to wear a small measuring device called a heart rate monitor. The device is small and comfortable and can be worn with his/her usual daily clothes.
- The physiotherapist will also encourage your relative/friend to include more physical activity into his/her daily life during the study and will help him/her to identify ways to add another hour of exercise to his/her weekly routine. After the initial 4 months are completed, the physiotherapist will encourage and assist your relative/friend 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 your relative/friend may be asked a few questions about how they are finding the exercise.

Will it cost my relative/friend 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 your relative/friend but we hope the information we get from this trial will help improve the treatment of people with dementia.

If your relative/friend is selected to take part in the exercise programme, this is likely to have a range of benefits for his/her health – for example, exercise is known to be good for his/her heart, lungs and 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 relative/friend's doctor be informed of my decision that he/she would like to take part in the trial?

If you give your permission, we will send a letter to inform your relative/friend's GP and mental health services that you have agreed that your relative/friend would like to take part in this trial. We will also contact the GP and/or mental health services if we have any concerns about your relative/friend's 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 trial participants and their consultees should be informed of the new information.

What if there is a problem?

It is unlikely that your relative/friend will be caused problems by taking part in this trial. If he/she becomes hurt or sick as a direct result of taking part in this trial, please contact his/her GP or nearest NHS drop in centre or accident and emergency department. If he/she is harmed due to someone's negligence, there may be grounds for legal action.

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

If you or your relative/friend has 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

What will happen if I decide that my relative/friend doesn't want to carry on with the trial?

In advising on your relative/friend's participation you are agreeing to them taking part in the full year of the study even if their condition advances. Your relative/friend can stop taking part in the trial at any time. If he/she decides to stop taking part in the exercise programme but carry on with the assessments, he/she can continue to take part in the trial. Withdrawing from the trial will not affect your relative/friend's usual care.

Will my relative/friend's details be kept confidential?

All information that is collected about your relative/friend 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 research 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	<i>[insert local contact details]</i>