Trust Logo

Dementia and Physical Activity (DAPA)

Nominated Consultee Information Sheet

Introduction

We would like to invite you to act as a nominated consultee for the purpose of inviting a person who lacks capacity 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 this person 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'd 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 this person. Please take time to read this leaflet carefully. One of our team will go through the information sheet with you and answer any questions you have.

What is the purpose of this research?

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 will be decided by chance but there will be a greater chance of being placed in the exercise programme.

Why has he/she been invited?
This person has been invited as someone who has mild to moderate dementia and is well enough to take part in exercise.

Does the person who lacks capacity have to take part?
No. It is up to you and this person to decide whether or not you wish this person to take part. If you do, we will ask you to sign a declarationform.

You can change your mind at any time and decide that this person does not want to continue to take part in the trial without giving a reason, even after you have signed the declaration form.

If the person who lacks capacity decides to take part, what will he/she have to do?
If you decide that this person 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 from. A short questionnaire will be used to check if they are eligible for the study.

If eligible, the researcher will ask the person 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 the carer some questions too but will obtain the carer's consent to do this.

- We would also like to look at this person's heath care records for details of his/her general health and the services he/she receives. If you want this person 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 the person will be sent a letter telling you which group he/she is in.
If he/she 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 him/her 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. Any comfortable clothes can be worn.
- He/she 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.
- He/she will be given their own exercise programme using exercise bikes and weights and will be closely guided by physiotherapy staff.
- They will help him/her 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 them to include more physical activity into their daily life during the study and will help them to identify ways to add another hour of exercise to their weekly routine. After the initial 4 months are completed, the physiotherapist will encourage and assist them 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 this person may be asked a few questions about how they are finding the exercise.

Will it cost the person 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 this person but we hope the information we get from this trial will help improve the treatment of people with dementia.

If this person 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 the person who lacks capacity'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 this person's GP and mental health services that you have agreed that this person 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 this person'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 this person 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 this person is unhappy with the trial.

If the person who lacks capacity 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 the person who lacks capacity doesn't want to carry on with the trial?
In advising on this person's participation you are agreeing to them taking part in the full year of the study even if their condition advances. This person 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 this person's usual care.

Will the person who lacks capacity's details be kept confidential?
All information that is collected about this person 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	*[Insert local contact details]*