Dementia and Physical Activity (DAPA)
Carer Information Sheet

Introduction
As you are a carer of a person with mild to moderate dementia, we would like to invite 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. Please read this leaflet carefully. Before you decide to join in, it's important to understand why the research is being done and what it will involve for you. Talk to your family, friends, doctor or nurse if you want to. One of our team will also 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 the person you care for goes into will be decided by chance but he/she will have a greater chance of being placed in the exercise programme.

Why have I been invited?
You have been invited because you are the carer for a person with mild to moderate dementia who might be interested to take part in the DAPA trial.

When we assess the person you care for as part of the research, we would also like to ask you a few questions about how you see their quality of life, about their abilities, as well as a few questions about how all these issues affect your life.

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.

You can change your mind at any time during the trial without giving a reason, even after you have signed the consent form.

If I take part what will I have to do?
If you do decide that you would like to take part in the trial as a carer, you will be visited at home by a researcher. You will be asked to fill in a consent form. The researcher will ask you a series of questions. about the quality of life and abilities of the person you care for, as well as a few questions about how all these issues affect your life.

- We expect the questions with you to take up to 60 minutes. It will take place at a suitable local venue as part of the visit for the person you care for.

What happens after the first visit?
Both you and the person you care for will be sent a letter telling you which group he/she is in. The researcher will contact you both again for follow-up visits after 6 and 12 months.

If the person you care for is allocated to the routine care group, he/she will continue with his/her normal routine.

What will happen if the person I care for is allocated to take part in the exercise programme?

- Our specialist physiotherapist will invite the person you care for a brief pre-exercise assessment at a local exercise venue. You will also be invited. The physiotherapist will look at how fit he/she is so that they can match exercises to their abilities. He/she can wear any clothes that are comfortable for them.
- The person you care for 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. You can choose to stay and watch the class or have the hour to yourself.
- The person you care for 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 the person you care for 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 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 the person you care for 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 your experience of this study.

Will it cost me anything?
If you provide transport for the person you care for to attend the exercise classes we will also pay for these travel costs.

What are the possible risks and benefits of taking part?
We cannot promise that the trial will help the person you care for but we hope the information we get from this trial will help improve the treatment of people with dementia.

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. You can contact your Patient Advice and Liaison Service at www.pals.nhs.uk for more advice, or if for any reason 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

What will happen if I don't want to carry on with the trial?
You can stop taking part in the trial at any time. If you do decide to withdraw, it will not affect the continued participation of the person you care for.

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 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*