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UNIVERSITY of York

Good Life with Dementia Research Project

Feasibility study of a post-diagnostic peer-led dementia course: Addressing uncertainties for a randomised controlled trial of the Good Life course

Information Sheet- Full study

Hi, I'm Mandy. I work as a researcher at the University of York. You are being invited to take part in some research about a course for people newly diagnosed with dementia.

The Good Life course is a peer-led course for people with dementia. It is designed by people with dementia and has people with dementia as tutors alongside professionals.

We don't know yet how well the Good Life course works, and we want to find the best way of evaluating it.

You are being invited to take part in some research about the Good Life with Dementia course. This leaflet has more information about why we're doing this research and how you could be involved. It's up to you whether you take part in the research. If you have any questions, please ask.

What is the research about? The Good Life course is a 6-week peer-led course run by people with dementia and professionals. We want to learn how to evaluate the Good Life course and how it could run in different communities. If you choose to join the study, we will collect information from you at the start of the study and then after 3 and 6 months. It is important to compare the course against the usual support people get after a diagnosis of dementia. This means that not everyone who takes part in the study will go on a Good Life course. We will ask 18 people with dementia to join the study in your area. Two thirds of these (12 people) will attend a Good Life course and continue to receive their usual support, whilst the other one

third (6 people) will just continue to receive their usual support with no changes. This will be allocated randomly by a computer system, the researchers and healthcare professionals will not have any input into which group you are allocated to.

The project is a small-scale practice run to see if doing a larger study would work. This type of study is called a feasibility study.

There is a possibility that you might be disappointed with which group you are allocated to, Good Life course or usual support. Both groups are **equally important** to the research. There is no evidence yet of the outcomes of attending a Good Life course, so we do not know which group will be best for you.

Why have you been invited to take part? You have been diagnosed with dementia and live in an area near to a Good Life course being run for this study.

What does taking part in the research involve?

For you to be included as a participant in the research we would need your consent to use your information to inform the study.

Both groups (Good Life and Usual support):

Taking part in questionnaires about your health and wellbeing: A researcher would visit you at home or somewhere else of your choosing and ask you some questions about your current health, wellbeing and ability to do everyday activities. The researcher will record your answers on a computer. We would do this 3 times during the study, initially before the course starts, after the course has finished and after 6 months. Each visit would take 45-60 minutes. Everybody in the study will be asked to complete the questionnaires at the 3 time points over the 6 months regardless of whether you are in the Good Life group or usual support group.

The Good Life group:

Attend the 6-week Good Life with Dementia course: If you get allocated to the Good Life group, you will be invited to attend a 2-hour (with a break) group session each week for 6 weeks with other people living with dementia at an accessible venue. You will be given further information about the course location and timings by the people running the course. They can reimburse your travel expenses (taxi/bus fare/petrol) to get to and from the venue each week. You can still attend other support offered by your healthcare provider.

Observation of one or more session of the Good Life course: So that we can check all the courses are being run in the same way we will be observing 1 or more of the course sessions. A researcher will join the session(s) and take some notes. They will **not** be taking notes about what you or other people on the course say or do, they will be observing how the course is run.

Usual support group:

If you get allocated to the usual support group, you **will not** attend a Good Life course but can attend other support offered by your healthcare provider.

What parts of the study are optional?

Both groups (Good Life group and Usual support):

Informing your GP: We would like your permission to inform your GP that you are taking part in this study. This is just so they are aware you are involved in a research study. You do not have to agree to this to take part in this study. If you agree we will ask you for your GP's contact details.

Informing a close family member/friend: We would like your permission to inform a family member or friend (who could be contacted in an emergency or if we couldn't contact you) that you are taking part in this research. You do not have to agree to this to take part in the study. If you agree we will ask you for their contact details.

We will also ask you to choose someone who could act as a consultee if required. This is someone who could make decisions on your behalf about whether you would want to continue in the study or Good Life course if your capacity to make that decision yourself changed. This could be a family member/friend or professional who knows you well. We will ask you for their contact details.

Interview to find out about what taking part in the research was like: Towards the end of the study, we would like to ask a few people from each group (Good Life course and usual support) to take part in a short interview with a researcher to find out what they thought about taking part in the study. The interview would take place in your home or other venue of your choice and be audio recorded with your permission. It would take no more than 45 minutes. You do not need to agree to this to take part in the rest of the study. You do not need to decide about this now, we would just like to know whether you would like more information about this later.

Do you have to take part? No. It is up to you to decide if you would like to take part in this research. If you decide you are happy to take part, you will be asked to complete a consent form (you can do this verbally if you'd prefer). You are free to change your mind about taking part at any time during the study without giving a reason. Even if you withdraw from the study you can continue to the Good Life course if you are in that group.

What are the possible benefits of taking part? The research will not benefit you directly but studying the Good Life course could help us to improve dementia support for people diagnosed with dementia in the future. We will give you a £20 gift voucher each time (3 times) the researcher comes to ask you the series of questionnaires as a thank you, and a fourth time if you take part in an additional interview.

Are there any risks to taking part? There are no known risks to taking part in this research. You may find answering the questionnaires tiring, but we can take a break or stop at any time. We will be asking you questions about your health and wellbeing, which some people may find upsetting. You can take a break, pause or skip questions. If the researcher is concerned that you are finding the questions difficult or upsetting, we will pause the questionnaire and check you are okay.

The following sections tell you how we will use your data and keep it secure.

Will my taking part in this study be kept confidential If you decide to take part in the study, what you *tell us* will be kept confidential No one outside of the research team other than members of your usual care team will know that you have taken part in the study except if you agree to us informing your GP/family member or are allocated to the Good Life group. The course facilitator for the group in your area will know you are taking part in the study and be securely given your contact details so they can contact you to arrange your attendance on the course.

We will write our reports in a way that no-one can tell that you took part in the study.

Data collected for the study may also be looked at by authorised people to check that the study is being carried out correctly. All have a duty of confidentiality to you as a research participant.

The only time we would break our duty of confidentiality is if we are worried that you – or someone else – was being, or was likely to be, harmed. If that happens, we will talk with you about it.

How will we use the information about you? We will need to use information from you for this study.
This information that we collect for the research will include:

- The information from your completed questionnaires
- Your signed consent form
- Your name and contact details

People will use this information only to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
The University of York is the sponsor of the research and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Allocating you with a unique study ID number to be associated with all your study records
- Securely storing study records on backed-up servers, password protected and only accessible by members of the research team.
- Research records including your signed consent form will be securely stored for 10 years and then destroyed or archived.

International transfers

Your data will not be shared outside the UK.

How will we use information about you after the study ends? Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 10 of years. The study data will then be fully anonymised and securely archived or destroyed.

What will happen to the results of the study? Researchers from the University of York will analyse the information collected. The results of the study will be published in academic journals and plain English summaries.

One way we can get the most benefit from this work is to make the study data available to researchers for related research at the end of this study. The study data may be reused by the research team or researchers in other institutions but will not be used or released in such a way that you could be identified.

What are your choices about how your information is used? You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we have already collected.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

What if there is a problem?

Complaints

If you have a concern about any aspect of this study, you can ask to speak to the research team who will do their best to answer your questions. You can also contact the Chief Investigator kate.gridley@york.ac.uk . She will be happy to discuss your concerns. If you are unhappy with Kate's response, you can contact Mark Wilberforce mark.wilberforce@york.ac.uk

If you remain unhappy following this and you wish to complain formally, please contact the Patient Advice and Liaison Service (PALS team) via email: [TBC] or telephone: [TBC].

Data Protection

The University of York is the data controller for the information collected for this research, which means we are responsible for looking after your personal information and using it properly. If you are unhappy with the way your personal information has been handled, please contact the University's Data Protection Officer at dataprotection@york.ac.uk. If you are not satisfied with our response, you have a right to complain to the Information Commissioner's Office. For information on reporting a concern to the Information Commissioner's Office, see www.ico.org.uk/concerns.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- https://www.york.ac.uk/records-management/dp/guidance/gdprcompliantresearch/
- by sending an email to mark.wilberforce@york.ac.uk
- by emailing the University of York's data protection officer on dataprotection@york.ac.uk
- https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/

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Further information: For further information about the study please contact Mandy Willcox at University of York.
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Thank you for reading this information sheet