



MedEx-UK

Mediterranean Diet, Physical Activity and Brain function in UK Adults

PARTICIPANT INFORMATION SHEET

INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

We would like to invite you to take part in a research study which is a collaboration between the Universities of East Anglia, Newcastle and Birmingham. Before you decide whether to volunteer or not it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and do not hesitate to contact us if there is anything that is not clear or if you would like more information. *The study is funded by Alzheimer's Research UK (ARUK), has been approved by the NHS Health Research Authority, and has received a favourable opinion from Health and Social Care Research Ethics Committee A (HSC REC A).*

The local Chief Investigator of the study is **Professor Anne Marie Minihane**

Members of the study team who can be contacted are:

Dr Amy Jennings, Research Fellow and Ms Rachel Gillings, Research Associate.

To contact the study team: Tel: **01603 597961** Email: **medexuk@uea.ac.uk**

This Participant Information Sheet tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully and contact the research team if you have any questions about anything that you do not understand or want to know more about. Before deciding whether or not you would like to take part, you may wish to talk about it with a relative, friend or your local doctor.

Participation in this research is entirely voluntary. If you do not wish to take part, there is no obligation and this will not affect any other care you are receiving.

If you decide you want to take part in the research project, you will be asked to sign a consent form. By signing it you are telling us that you:

- understand what you have read
- consent to take part in the research project
- consent to have the tests and treatments that are described
- consent to the use of your personal and health information as described
- consent to being recorded by audio equipment in the group sessions

Why are we doing this research?

Dementia (of which Alzheimer's disease is one type) is a growing problem. There are currently about 850,000 people with dementia in the UK, and this is forecast to increase to over 2 million by 2051.

Researchers want to understand what causes dementia so that they can help prevent or delay it as people age. Although there are some drugs available to treat the symptoms, there is currently no cure, and little is known about how to slow its progression.

Over the past 10 years, scientists have identified certain factors which are associated with a lower risk of dementia, including eating a 'Mediterranean Diet', and taking regular exercise. However, we need more evidence from human studies to show that these factors improve brain function.

What is the MedEx-UK study?

Across three sites, Norwich, Newcastle and Birmingham, we will be running a new study called the Mediterranean Diet, Exercise and Dementia Risk Reduction Programme (MedEx-UK) to help further this research. The study has been funded by Alzheimer's Research UK, and is the first of its kind in the UK. We will be testing if a Mediterranean diet along with regular exercise improves brain function (cognition) in individuals aged 55-74 years, at risk of developing dementia. In the MedEx-UK study, we will attempt to change the diet and exercise habits of people over a short period of time (24 weeks). If this is successful, we hope to run a larger trial in the future.

To identify those at risk of dementia we will look at cardiovascular risk, as this has shown associations with dementia incidence in older ages. Cardiovascular risk is assessed by looking at a range of factors, including sex, age, blood pressure and family history of angina or heart attack.

Who can take part in the study?

We are aiming to recruit 108 volunteers between 55 and 74 years old, who have no diagnosis of dementia but may be at risk of developing it in later life (as identified through cardiovascular health risk factors).

Unfortunately, you will not be able to volunteer if you:

- Have COPD, HIV, epilepsy or any previous history of cardiovascular disease (heart attack, stroke, TIA) or cancer
- Have a clinical diagnosis of liver or kidney disease
- Have a serious mental illness
- Suffer from moderate to severe anxiety or depression
- Have suffered a significant head trauma
- Have a BMI over 40kg/m²

- Are currently engaged in a weight loss or exercise programme
- Have any medical conditions (to be determined by the researchers) that may affect the study outcome
- Take certain medications (to be determined by the researchers) that may affect the study outcome
- Are not suitable to take part in this study because of your screening results
- Are already taking part in another research study

As this trial requires you to make changes to your diet and physical activity levels you would need to be prepared to try to make these changes throughout the trial period. The trial involves being part of a group which will meet together on up to four occasions, depending on which group you are allocated to. You will also need to be able to access the internet to use a website that will provide information to you during the trial period

If you are unsure whether you meet the criteria for our study please get in touch with the study team and we can talk to you about your suitability.

Do I have to take part in the study?

It is up to you to decide whether or not you wish to take part. If you decide to take part you will be free to withdraw at any time and without giving a reason. If you choose to take part, or withdraw from the study, this will not affect your future health care. An expression of interest does not commit you to participation.

What do we aim to do?

We will run the study at three UK Universities (Norwich, Newcastle, and Birmingham). At each site, we will recruit volunteers and see if we can change their diet and exercise behaviours over a 24 week period. Our volunteers will be allocated to one of three groups:

Group 1. Mediterranean Diet and Physical Activity Group

Group 2. Mediterranean Diet only Group

Group 3. 'Control' group

You will be assigned to a group at random and cannot choose which group you are in.

What will I have to do?

There are a number of stages to the study, which are listed below, along with their approximate time burden (see also Appendix 1 for a more detailed version):

	No. of sessions:	Approximate time burden:	Where:
1 st consent and online screening	1	30 minutes	Home
2 nd consent and on-site screening	1	1.5 hours	University
On-site measurement morning	2	3 hours	University
MRI brain scan	2	1 hour	University/Hospital
5-day online food record	2	1 hour 40 minutes	Home
3-day online food record	2	1 hour	Home
Group training session	1	1 hours	University
Group sessions (depending on group allocation)	4	2 hours each	University

1st consent and online screening

We will initially screen you using an online questionnaire and ask series of questions to establish your general health status and suitability for the study. If we think you are suitable for the trial, we will invite you to your nearest university site for a full screening.

2nd consent and on-site screening visit

You will be asked to attend the clinical trials unit at your nearest university. A member of the study team will go through the details of the study with you, and you will be encouraged to ask questions. When you are satisfied with the information provided and if you remain interested in taking part, you will be asked to complete a consent form for your participation in the study.

Your height, weight and blood pressure will be measured, plus we may ask to take a small venous blood sample (up to 4ml) to measure your cholesterol levels. We will also ask you to complete some short questionnaires to assess certain aspects of your health, two of which we will ask you to take home for a relative or close friend to fill out. A short pen-and-paper cognitive test (a test of your memory and brain function) will then be carried out.

Once we have all your results from the screening visit, we will telephone you to let you know if you are suitable to take part in the study. If you are suitable and happy to proceed, we will arrange your on-site measurement appointment.

On-site measurement morning at the start and end of the study

Lead up to your appointment

Before your first measurement appointment we will give you an activity monitor that looks like a wrist watch. You will need to start wearing this 7 days before your measurement appointment, and continue to wear it for the 24 weeks.

We would like you to collect a faecal (poo) sample in the 24-hours before your appointment, and samples of the first urine you produce in the morning for 4 separate days during the week before your appointment. We will provide you with collection pots and instructions to explain how to collect your samples. On one of the days leading up to your appointment we ask that you wear a blood pressure monitor for 24 hours (which takes numerous automatic blood pressure readings throughout the day and night).

We ask that you avoid alcohol and organised exercise on the day before your appointment and fast from 10pm onwards (no food or drink apart from water).

The day of your appointment

You will need to come to your nearest university site for a morning of measurements. Your appointment will take approximately 4 hours and we will ask you to arrive at around 9am.

We will first measure your blood pressure and then assess the extent to which your blood vessels widen when blood flow is increased; a cuff, like those used when you have your blood pressure taken, will be inflated on your arm for 5 minutes, before being deflated again. We will look at the response of your blood vessels to this using an ultra sound machine which produces pictures of the inside of the body using sound waves. Following this a trained nurse or phlebotomist will take a 30ml blood sample from you.

We will then give you some breakfast before you go on to complete a series of cognitive tests. These tests will assess different aspects of your memory and overall brain function.

You will also be required to have an MRI brain scan which will take approximately 1 hour. This will allow us to look at the structure of your brain and in particular the hippocampus which is the area most associated with memory, and also to look at brain blood flow. Before you go in the MRI scanner you will be asked to complete a short questionnaire regarding any metal you have in your body such as metal plates or a pacemaker. As the scanner contains a strong magnet anyone with metal in certain areas of their body might not be able to take part in the study. (Please note that your MRI scan may be on a different day to your onsite measurements).

What you need to do over the 24 week study period

All groups will initially attend a group training session, where we will explain what we would like you to do over the 6 months. Groups 1 and 2 (the 'intervention' groups) will also receive support for change in diet, and physical activity. This will include up to four face-to-face group sessions with a trained facilitator, and peer support from within the group (please note: group sessions will be audio recorded for facilitator training purposes). Support will also be given through a website, which you can access from your home computer/tablet device. The website will provide recipe ideas, display foods and ingredients you can order from a supermarket, and help create tailored exercise plans. Group 3 (the 'control' group) will be given general diet and exercise advice at the beginning of the study.

We will ask you to record your diet using an online food record at given time points during the study. Your physical activity will be measured using a wrist based activity monitor that you will wear throughout the study period.

We will ask that you continue to take your usual medication or supplements over the 24 week period. Please inform us if any of your prescribed medications change whilst you are taking part in the study.

At the end of the study we would like to get your views on how the study has run. We will do this by running focus groups. There will be no obligation to attend one of these but your feedback and insight would be very valuable to us. Should you take part in this research trial we would give you further information about this, including how we anonymise anything that you say.

What will be measured in the samples collected?

The blood samples collected during your on-site visits will be analysed for blood fats, markers of brain function, vascular health, inflammation, and levels of antioxidants. In addition, using DNA taken from your blood sample, the variation in a number of genes known to be associated with cognitive decline will be determined. It is important to stress that any DNA analysis performed as part of this study has no direct clinical relevance and we will be unable to tell you the results of this analysis directly.

The blood samples we collect, including DNA, will be analysed within 5 years from collection and disposed safely within this time. These blood samples will be securely stored in the university laboratory which is only accessible by approved personnel with swipe card access. These samples will be de-identified and only have your study ID on them.

We will analyse your urine sample for various plant compounds to see if their levels affect cognition.

In the faecal samples we will quantify the different types of bacteria and their activity, as recent evidence suggests that gut bacteria may be important in overall health, including brain function.

Are there any side effects or risks of taking part in the study?

It is normal that you feel some discomfort when giving a blood sample and there is a risk of slight bruising. The research nurses and phlebotomists involved in our study are experienced at taking blood samples.

The measurement of blood vessel widening can be slightly uncomfortable. During the 5 minutes that the cuff is inflated on your arm you might experience a numb feeling in your hand. However, this is normal and nothing to worry about.

The MRI scanner is shaped like a tunnel and is a bit tight for space, so we recommend that if you suffer from claustrophobia you do not participate in this part of the study. You will be able to communicate with the study staff at all times who will be able to stop the scan at any time on request. The scanner also makes a loud noise.

If any abnormal results emerge when analysing your blood samples, brain scans (extremely rare), or cognitive tests, with your consent, we will contact your GP who may request you come to see him/her to further investigate, and perhaps do a retest.

Who has access to my personal information?

All of the study sites comply by law with the recent General Data Protection Regulations 2018 (GDPR), which is designed to protect your personal data.

UEA is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Any personal information supplied by you during the study will be handled by trained research staff and will be treated as strictly confidential and not shared.

All participants will be assigned a random code number when they enrol into the study, and all paperwork, samples and results will be coded with this number to protect their identity. Any documents that link your name to this code will be stored securely and will be only accessible to delegated members of the research team. UEA will keep identifiable information about you for up to 5 years after the study has finished, or until no longer necessary. Any identifiable information that is collected at NHS sites will be transferred to UEA within 12 months and then deleted from the NHS site.

UEA will collect information from you for this research study in accordance with our instructions. UEA will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Published data we generate from

your involvement during the study will be averaged across participants, and anonymised, so that no individual can be identified. The biological samples we collect will be analysed within 5 years from collection and disposed safely within this time. Data from the study will be used for up to 10 years after collection and disposed of according to University confidential information disposal routes.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Research staff (including university researchers and NHS research nurses) will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from UEA and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The Norfolk and Norwich University Hospital will pass these details to UEA along with the information collected from you. The only people in the UEA who will have access to information that identifies you will be people who need to contact you to make appointments, report any incidental findings or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

You can find out more about how we use your information by contacting University's Data Protection Officer, Ellen Paterson on 0160359 2431 or dataprotection@uea.ac.uk .

What will happen to the results of the research study?

The results of this research study will be published in scientific journals and presented at national and international scientific meetings. All results will be in an anonymised format. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance. Once the data has been made public, we will invite you to a presentation of a summary of our findings. Unfortunately, we cannot report on the findings of specific individuals.

Who has reviewed the study?

The research study has been reviewed and has received a favourable opinion from Health and Social Care Research Ethics Committee A (HSC REC A)

Expense Payments

Participating in this study is on a voluntary basis. Participants in groups 1 and 2 will receive money or vouchers to compensate for any increase in food costs and to cover

food delivery from an online supplier (up to £30 per week). Participants in the control group will also receive money or vouchers to acknowledge their participation (£10 per week). Transportation costs to and from your local University site will also be reimbursed. Participants travelling by car will be reimbursed at 45p/mile (up to a 30 mile radius). Free parking will be available. Those participants travelling by public transport will be reimbursed costs on production of a ticket or receipt.

Insurance

Insurance for the study is provided by UEA (through Zurich Municipal), and covers both public liability, professional negligence and clinical trials indemnity.

What if I want to complain?

If you have any concerns about the study and your participation in it, or wish to make a complaint, please contact Professor Alistair Forbes at Alastair.Forbes@uea.ac.uk

Contact for eligibility and further information

Thank you for reading this and for showing an interest in the study. If you would like us to check your suitability for the study, please complete the questionnaire at the following web address: <https://www.surveymonkey.co.uk/r/medex-uk>

Alternatively, if you would like further information about the study, you can contact the study team on **01603 597961** or email **medexuk@uea.ac.uk**

An expression of interest does not commit you to take part

Appendix 1: Overview of the MedEx-UK study: what is involved over the 24 week study period and the approximate time needed for each activity.

Week	Group 1 (MDP plus PA)	Group 2 (MDP)	Group 3 (Control)
-9			
-8			
-7		Online screening (questionnaire) 30 minutes	
-6			
-5			
-4			
-3			
-2			
-1		On-site screening (questionnaires, cognitive tasks, buccal swab) 1.5 hours	
-1			
-1	Home BASELINE measurements (24 hour blood pressure monitor, faecal sample, urine sample) 24 hours		
	On-site BASELINE measurements (weight/height, blood sample, vascular measurements, cognitive tasks, MRI scan) 4 hours		
	Online dietary assessment (5 x 24 hour recall) 1 hour 40 minutes		
0	Group training session (initial training, learn to use the online platform) 1 hour		
0	Group session 1 (group work, peer support) 1 hours		
1			
2	Group session 2 (group work, peer support) 2 hours		
3			
4	Group session 3 (group work, peer support) 2 hours		
5			
6		Online dietary assessment (3 x 24 hour recall) 1 hour	
7			
8			
9			
10			
11			
12		Online dietary assessment (3 x 24 hour recall) 1 hour	
12	Group session 4 (group work, peer support) 2 hours		
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24	Home OUTCOME measurements (24 hour blood pressure monitor, faecal sample, urine sample) 24 hours		
24	On-site OUTCOME measurements (weight/height, blood sample, vascular measurements, cognitive tasks, MRI scan) 4 hours		
24	Online dietary assessment (5 x 24 hour recall) 1 hour 40 mins		