MedEx-UK

MedEx-UK 2: (Mediterranean diet, exercise and dementia risk in UK adults): a Randomised Controlled Trial investigating the feasibility of a digital intervention to increase Mediterranean Diet (MedDiet) Score in older UK adults who are at risk of dementia

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 Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle University and the University of East Anglia. 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 the UK Nutrition Research Partnership, and has received favourable opinion from the London Harrow Research Ethics Committee". (IRAS No. 282160).*

The local Chief Investigator of the study is **Professor Emma Stevenson**

Members of the study team who can be contacted are:

Dr Amanda Robe, Project Manager and Rachel Gillings, Research Associate.
To contact the study team: Tel: **01603 591995** 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 first be asked to provide initial online consent to participate in the study and complete an online questionnaire. Subsequently, if you are eligible to undergo full screening to take part in this study (which will take place via videoconferencing software), you will also be asked to sign a paper-based 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

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'. This includes consuming plenty of fruit and vegetables, legumes, nuts and seeds, fish and olive oil, and only small amounts of red and processed meat alongside sugary foods and drinks. However, we need more evidence from human studies to show that this type of diet can help improve brain function.

What is the MedEx-UK2 study?

The Mediterranean Diet, Exercise and Dementia Risk Reduction Programme (MedEx-UK) is an ongoing study exploring the potential effects of eating a Mediterranean diet and increase physical activity as a way of reducing dementia risk. The original MedEx-UK study was funded by Alzheimer's Research UK, and was testing if a Mediterranean diet along with regular exercise improves brain function (cognition) in individuals aged 55-74 years, at risk of developing dementia.

The current study, called 'MedEx-UK2' is a follow on study to the initial MedEx-UK study, and is funded by the UK Nutrition Research Partnership. The MedEx-UK2 study will explore whether it is possible to change the dietary habits of people over a short period of time (24 weeks). Unlike the original MedEx-UK study, which involved intensive support including a digital intervention, group sessions, and food vouchers, the MedEx-UK 2 study will only involve the digital intervention component. We believe this will be a more time and cost effective strategy to improve peoples diets. If this trial is successful, we hope to run a larger trial in the future. This type of study is known as a feasibility study, which means that it is designed to help us learn more about the strengths and weaknesses of our study design to determine if a larger trial is possible and whether any modifications to the study design may be required.

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, body weight and family history of angina or heart attack.

Who can take part in the study?

We are aiming to recruit 36 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). It is also important to note that as part of the study you will be asked to have someone (friend/relative) available to complete questionnaires which will evaluate your ability to take part in the study.

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/m^2
- 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 you would need to be prepared to try to adapt your diet throughout the 24-week trial period. You will also need to be able to access the internet to use a website that will provide information on the digital intervention designed to help you change your dietary behaviour.

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 (for example, contacting the study researchers via telephone or email for further details) does not commit you to participation.

What do we aim to do?

We will run the study at two UK Universities (Newcastle University and the University of East Anglia). At each site, we will recruit volunteers and see if we can change their diet over a 24 week period via a digital intervention. The results will be compared

against findings from the original MedEx-UK study to see if the digital intervention is as effective as a more intensive intervention for helping change diet behaviour.

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:**
1st consent and online screening	1	30 minutes	Home
2nd consent and screening via videoconferencing software	1	1.5 hours	Home
At home study testing session via videoconferencing software	2	3 hours	Home
5-day online food record	2	1 hour 40 minutes	Home
3-day online food record	2	1 hour	Home

1st consent and online screening

We will initially screen you using an online questionnaire and ask a series of questions to establish your general health status and suitability for the study. This will include questions about your height and weight, any health conditions you might have, any medication you might be taking, and what your current diet and activity levels are like. We will compare your answers to the study inclusion/ exclusion criteria (see information on 'who can take part in this study?' above), and if we think you are suitable for the trial, we will contact you via email and/or telephone and invite you to complete a full screening via videoconferencing software (e.g. Zoom).

2nd consent and full screening assessment

You will be asked to complete a full screening assessment at home via videoconferencing software to assess your eligibility to participate in this study. 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.

We will ask you to provide measures of your height and weight. 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 give to 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. We will post all relevant documents to you prior to the screening assessment (including the questionnaires and paper-based tests mentioned above), so that you have a copy ready to use on the day.

Once we have all your results from the screening visit, we will contact via email or 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. If you are not eligible to take part, we can explain why this is, and you will be encouraged to contact your GP if you have any concerns. We will provide your GP with a copy of the screening results, including your cognitive test and questionnaire results, for their records.

You should be aware that in the unlikely event of a loss of capacity, the research team would retain tissue (including blood samples) and personal data collected, for up to 5years, and continue to use it confidentially in connection with the purposes as outlined in this Participant Information Sheet. This could include further research (e.g., into the prevention of dementia or other health conditions) after the current project has ended following approval by an appropriate ethics panel.

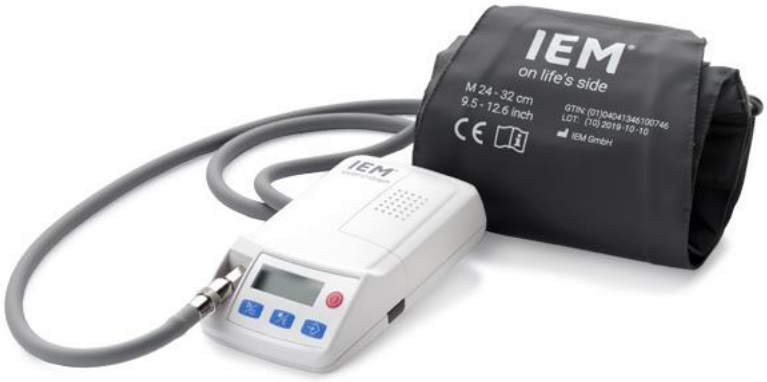
Assessment at the start and end of the study

Lead up to your appointment

Before your first measurement appointment we will give you an activity monitor that looks like a wristwatch (see image below). You will need to start wearing this before your measurement appointment. We ask that you wear the device for as much of the day as possible, except when you need to take it off for charging (every few days). You can sleep in the device and it is also waterproof, so can be worn whilst showering/ bathing (however, you can take it off during these times if you'd prefer). We will ask you to wear the device for up to 1 month. During this time it will record your heart rate, energy expenditure, and step count. We will not track your GPS or record where you have been. This information will all be collected without any input from you, and so the only time burden linked with wearing the activity tracker is associated with occasionally charging the device. The device will be collected from you by one of the researchers following your assessment visit, and they will download the relevant data from the watch at that stage.

Physical activity tracker

We will also send you an envelope containing some questionnaires and paper-based cognitive tests, alongside a collection kit for obtaining a fingertip blood sample, which will use on the day of your appointment. Finally, we will provide you with a 24-hour blood pressure monitor (see image below), which you will be asked to wear for a full 24-hour period of your convenience around the time of your appointment. There is a small time burden of ~5 minutes required to put on the blood pressure monitor, after which the monitor will automatically collect measurements for the 24-hour period.



24-hour blood pressure monitor

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

All study assessments will be carried out remotely via videoconferencing software, such that you will be able to complete the study appointment without having to leave your home. On the morning of the appointment, you will be asked to collect a small blood sample from your fingertip using instructions and a collection kit provided by the

research team (which will take ~10 minutes in total). After collecting the fingertip blood sample, you can eat a light breakfast such as toast or cereal prior to your assessment, which will take place around 9-10 am. We ask that you do not consume any caffeine on the morning of the assessment as this can impact the results obtained.

During the appointment, you will be asked to obtain a measure of your height and weight. The research team can provide equipment such as digital scales to measure your weight if you do not already have your own set. We can also provide you with a tape measure to measure your height, which can be temporarily stuck to a wall to allow you to measure your own height if you do not have a friend/ partner available to help. You will also be asked to complete some cognitive tests. These tests will assess different aspects of your memory and overall brain function, such as your processing speed (the time it takes you to do a mental task) and executive function (which includes processes such as problem solving and reasoning). The entire appointment should take no more than 3 hours in total.

How will this study be affected by the COVID-19 pandemic

The safety of participants and researchers is of primary importance to us. Therefore, in light of the ongoing COVID-19 pandemic, we will complete all testing sessions remotely using videoconferencing software and by sending you some relevant items in the post, such as cognitive testing documents. You will not be asked to do anything that you do not feel comfortable with, and we will monitor the ongoing pandemic closely to ensure we follow government guidelines at all times.

If you develop any COVID-19 symptoms, or test positive for COVID-19, we ask that you inform the study team.

What you need to do over the 24 week study period

Support will be given through a website, which you can access from your home computer/tablet device. The website will provide recipe ideas and advice as to how you can change your diet.

We will ask you to record your diet using an online food record at given time points during the study. Your physical activity will also be measured at the start and end of the study, each time for a one month 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

the focus group 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 fingertip blood samples collected during your assessment 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 following completion of the trial. These blood samples will be securely stored in the university laboratory, for up to 5 years, 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.

Are there any risks of taking part in the study?

It is normal that you feel some mild discomfort when giving a fingertip blood sample and there is a risk of slight tenderness on the tip of your finger and occasional bruising. There is also some risk of becoming distressed from completing the questionnaires and/or cognitive tests, and of symptoms of cognitive decline being identified due to participating in the research. The study researchers will do everything they can to make you feel comfortable during the testing, and you can stop at any point if you feel too stressed or do not wish to continue.

If any abnormal results emerge when analysing your fingertip blood samples 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. In addition, in the event that the research team become concerned about your safety/ wellbeing throughout the research, we will break confidentiality and contact your GP. The research team will also encourage you to seek support from your GP if you are anxious about any of your results. In addition, they will be able to direct you to appropriate online resources if you are experiencing high levels of anxiety or emotion during the study.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name and contact details. People will use this information 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.

We will keep all information about you safe and secure.

Some of your information will be sent to a third party outside of the EEA (Survey Monkey) as this is necessary for the study. They must follow our rules about keeping your information safe.

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.

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 already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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

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

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to aaron.jackson@nhs.net
- by ringing us on 0191 2825789

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. As noted above, 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 study is sponsored by the Newcastle upon Tyne Hospitals NHS Foundation Trust and has been reviewed and received a favourable opinion from Health Research Authority and the associated Research Ethics Committee .

Expense Payments

Participating in this study is on a voluntary basis. Participants will receive a one off payment of £50 in the form of a gift voucher, to cover costs incurred. This will be provided by a member of the research team upon completion of the 24-week study period. You may also claim reimbursement for travel costs.

Insurance

Insurance for the study is provided by the Newcastle upon Tyne Hospitals NHS Foundation Trust covers both public liability, professional negligence and clinical trials indemnity. The trial design is covered by Newcastle University.

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 Emma Stevenson (Emma.Stevenson@ncl.ac.uk)

If you prefer to raise your concerns with someone not involved in your care, you can contact the Patient Advice and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:
Telephone: 0191 223 1382 or 0191 223 1454
Email: nuth.patient.relations@nhs.net
Address: Patient Relations Department
The Newcastle upon Tyne Hospitals NHS Foundation Trust
The Freeman Hospital
Newcastle upon Tyne
NE7 7DN

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 591995** or email **medexuk@uea.ac.uk**

* This study has received ethical approval from the London Harrow Research Ethics Committee*

An expression of interest (for example, contacting the study researchers via telephone or email for further details) does not commit you to take part

Appendix 1: **Overview of the MedEx-UK2 study**