



- 🍏 **Do you feel overweight?**
- 🍏 **Are you currently feeling a bit down, low, tired or stressed?**
- 🍏 **Are you between 18-75 years old?**
- 🍏 **Do you want to take part in a trial of food supplements and/or behaviour coaching to change mood & wellbeing?**

We need 250 volunteers to help test new ways of maintaining health and wellbeing through nutrition and lifestyle changes

Please read through this information booklet carefully to decide whether or not you would like to take part.

Summary Information

- 🍏 This study tests new food-related interventions to change mood.
- 🍏 Everyone will take multivitamin supplements or placebo - free of charge - for a year.
- 🍏 Half of volunteers will also receive behavioural and lifestyle coaching.
- 🍏 You will see the research team 5 times during the year.
- 🍏 Tests will include an interview, a questionnaire pack on symptoms, thoughts and behaviour, and body fat composition analysis.
- 🍏 We would like you to also give blood samples for nutrient analysis.
- 🍏 Your GP will be informed of your participation in the study.

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Study Principal Investigator

My name is Professor Ed Watkins and together with my European colleagues, we are testing new ways that could maintain mental health and wellbeing through nutrition and food-related lifestyle coaching in a project called MoodFOOD. The project is investigating the links between mood, food, and being overweight. You may have already completed an online assessment, returned a form, or spoken to one of the team about the study or carried out a telephone interview, if so as noted, we are sending you further information. I would like to invite you to take part in this research. However, before you decide, please read this information sheet carefully. If you have any questions after reading this, please feel free to contact us directly (see contacts on the back of this booklet).

1. Why are we doing the research?

Mood problems, or even experiencing depression, often go hand in hand with being overweight. Research has shown that nutrition may be an important way to promote mood and health, but so far we don't know which aspects of nutrition and behaviour are most important. This is why we are evaluating different nutritional and lifestyle strategies. The study is a collaboration between the UK, Germany, the Netherlands and Spain, funded by the European Commission and we are looking for 250 people from Exeter to take part.

2. What are we doing?



We are comparing different nutritional and lifestyle strategies that might promote mood and health in people who are overweight. Participants will be allocated using random selection (by chance, like tossing a coin) to different combinations of interventions. One intervention is the daily use of multivitamin and mineral supplement pills for one year. Research suggests that these could help improve mood by supporting and protecting the brain, but there is not enough evidence for this yet. To test this, the supplements will be compared to inert placebo supplements that are identical in look and taste but include no active ingredients. Another intervention is lifestyle and behavioural coaching. This intervention focuses on changing behaviour to build up healthy habits and reduce unhealthy habits, especially around food, diet, and activity. We will keep an eye on everyone in the study to see how they are doing. If anyone shows signs of depression we will help ensure they have access to appropriate help. You will also be compensated for any travel expenses and given a small gift voucher worth £10 for each completed assessment visit as a 'thank you' for your help.

This involves individual and group meetings with a trained therapist. It could maintain wellbeing in a number of ways including finding helpful alternatives to behaviours that are known to be linked with low mood and increasing overall consumption of a healthy diet.



Participants will be allocated through random selection (by chance, like tossing a coin) to one of four combinations:

- (1) multivitamin and mineral supplements alone;
- (2) placebo supplements alone;
- (3) multivitamin and mineral supplements plus lifestyle and behavioural coaching;
- (4) placebo supplements plus lifestyle and behavioural coaching.

So, all participants will be asked to take pills for the course of the study and 75% of participants will receive at least one of the interventions (multivitamin and mineral supplements or the lifestyle and behavioural coaching). If you are a vegetarian or vegan, you need to be aware that the pill casings do include gelatin.

We don't know which aspects of nutrition and behaviour, separately or combined are likely to be the most helpful for mental health, which is why we are comparing these strategies. To properly assess the effects of the multivitamin and mineral supplements, you will not be aware which pills you are given. The total study lasts for 12 months and involves an initial assessment of your mood, weight, depression history, and then further assessments at 3, 6, and 12 months.

3. What will I have to do in the study?

Step 1

A member of the research team will contact you in the next few days to talk through this information sheet and give you the opportunity to ask any questions you may have. You may already have had a telephone interview with a researcher. If not, we will ask you a range of questions, some of them potentially sensitive, including about your medical history, weight and symptoms of depression. Our researchers are trained to conduct these interviews sensitively and you do not have to answer any questions that you do not want to.

If you are happy to continue after that, you will be asked to complete a questionnaire pack either online or on paper before or during the first assessment. This consists of 12 brief questionnaires that ask about your mood (depression symptoms), eating behaviour, physical activity, quality of life, habits and food intake and typically takes about 45 minutes to complete.

Step 2

First Assessment

At assessment, a researcher will ask you about your medical history and symptoms, especially your current and past history of depression. The interview will take place at a time that is convenient for you, and typically takes about 1 hour. After you have completed this interview, the research team will be able to confirm your suitability for the study. If you are eligible you will be asked to sign a consent form to continue with the research study. We have enclosed a copy of the consent form so you know what to expect on the day.

If you agree, we will also ask you to have your body composition measured in a piece of equipment called a BodPod™. This is a totally painless way of measuring weight and volume to calculate body fat measurements. To enable us to measure accurately, we will ask you to bring with you tight fitting clothes, such as a swimming costume, and will provide you with a swimming hat. You will get changed in a private room and have your height, weight, hips and waist measured. You will be asked to sit in the BodPod™ with the door closed for approximately 1 minute. The door will then be opened and the process will be repeated once more. The computer will then analyse and generate body composition results. The BodPod™ is located behind a privacy curtain in a private room. It has a clear Perspex front panel to allow you to see what is happening outside. A member of the research team will be with you at all times. If you feel uncomfortable, the door can be opened to allow you to leave the machine. It usually takes about 10-15 minutes to go through the whole BodPod™ procedure.

If you agree, we would also like to take a small sample of blood to measure nutrient levels, as well as other indicators of health and illness (cholesterol, full blood count). This is important to have a better understanding of the mood and food relationship at the end of the study. You do not have to do this to participate in the study. Your blood sample will be given a numerical code before being stored in a freezer.

Step 3

Allocation to an intervention group

You will then be allocated by random selection (by chance, like tossing a coin) to one of the intervention groups and given your first supply of pills. If you are allocated to lifestyle and behavioural coaching you will be contacted by your therapist within a week with more information about your sessions.

Step 4

Seeing how you are doing

Half the participants in the study will have regular contact with their therapist but everyone will meet with a researcher at 3, 6, 9 and 12 months to see how things are going, collect more pills and to give blood again at 6 and 12 months. You will complete the same questionnaires as at the first assessment and at 3, 6 and 12 months you will repeat the same interview as before. This process will help us to learn which strategies work best in helping to improve mood and wellbeing. Even if, at any time, you decide to leave the study, we would like to collect this information. This is very important to enable us to properly compare the strategies.

4. Who can take part?

You may be eligible to take part in the study if you are aged 18 - 75 and able and willing to consent to participate in the study for up to a year, and willing to allow your GP to be notified of participation in the trial. To participate, you need to (i) be overweight as defined by a Body Mass Index (BMI) between 25-40 (BMI is a guide to the healthy weight range for your height)(ii) have low mood but not meet criteria for major depression currently or in the last 6 months (iii) not be currently using antidepressants or under psychological treatment for your mood (iv) not currently pregnant, planning pregnancy in the year ahead, or breastfeeding (v) are prepared to visit the study centre for the 4 interviews and also attend the lifestyle and behavioural coaching (vi), do not have a calcium disorder, and (vii) have not had or are not planning weight loss surgery. With your permission, your interviews and any therapy sessions may be audio/video-recorded for research purposes.

5. What are the interventions in this study?

Supplement & placebo pills

The supplements contain Vitamin D, Calcium, Folic Acid, Selenium and Omega 3 fatty acids. The placebo pills contain sunflower oil and an inactive substitute. If you are currently taking certain over-the-counter dietary supplements, we ask that you stop taking them until the study is over. We will provide the supplements to you for free for the 12 months of the study. This does not include medicine managed by your General Practitioner.



Lifestyle and behavioural coaching



The goal of the lifestyle and behavioural coaching is to develop better ways to manage mood and food and encourage health and wellbeing. The coaching includes a detailed analysis of each person's life and seeks to replace unhealthy habits with healthy ones. A trained therapist will hold the sessions and the content will be tailored to meet the needs of each person. Some common themes covered will include self-monitoring, activity scheduling, changing habits, meal preparation, food shopping, meal and snacking practices, as well as discussion of healthy diet guidelines.

The coaching will consist of up to 21 sessions over 12 months, with the first 15 individual sessions with your therapist, occurring at first weekly and then every two weeks, and the final 6 sessions in groups of up to 10 people occurring monthly and then bimonthly.

6. What are the advantages of taking part?

It is possible that the intervention you receive will have a positive impact on your mood and wellbeing. We hope that some combination of lifestyle coaching and/or using nutritional supplements will improve mood for study participants; however, we cannot guarantee that these strategies will benefit you.

Although the study is not designed to improve physical health, it might be that some aspects of what you are doing will result in you feeling healthier and even losing weight. Again we cannot guarantee that this will be true for any individual. The information we get from this study may help us understand and develop future strategies to prevent depression for people by giving them better ways of coping with everyday problems and stresses.

7. What you should agree to, to join the study

Being part of this research will involve a commitment of some of your time over the course of 1 year. All participants will need to complete questionnaires, take pills and meet with one of the researchers 5 times in a year, and half of participants will also see their therapist regularly. There are no known side-effects to taking the nutrient supplements or placebos. In fact all the ingredients are available in the shops. Although unlikely, it is possible that you may have a reaction to taking them. We will monitor this closely throughout the study and make sure that you stop taking them if you do. We are not aware of any other side effects, disadvantages, or risks to you in taking part in this research.

8. Will my taking part be kept confidential?



We will inform your GP that you are participating in the study. All information collected about you during the course of the research will normally be kept strictly confidential. The main exception would be if the interview revealed a significant risk of harm to yourself or others, in which case information may be fed back to your GP and the study team but normally only after discussion with you. All records are kept securely and password protected. These are accessible only by the research team. Your personal information will be stored anonymously with a study code number rather than your name.

The blood samples to measure nutrients and cholesterol will initially be stored in the Clinical Research Facility, Exeter, before being securely and anonymously sent, stored, and analysed in Spain as part of a new MoodFOOD biobank.

In addition, we would like you to gift your blood samples and your clinical data to the Peninsula Research Bank, which will provide your samples anonymously to medical research projects approved by a lay Steering Committee. This research may take place in the UK or overseas, and may include work with scientists within companies. Samples will not be sold for profit, will not be used in animal research or reproductive cloning, will not be tested for rare severe diseases (e.g. Huntington's), nor shared with non-research organisations. These samples will be stored securely in Exeter for future analysis related to health and illness including vascular disease and depression, which may include DNA testing. This is optional and is not a condition of entry into the study.

9. Further information

What will happen to the results of the research study?

We will analyse all the data from the study to see which, if any, strategies have an impact on mood and wellbeing. The researchers aim to publish the work in academic journals and as a report to the European Commission. These will be listed on the central MoodFOOD website: www.moodfood-vu.eu/Publications. Your identity will not be revealed in any report or publication. It is hoped that the results of the research can inform European and national policy on preventing depression.

Who has reviewed the study?



All research in the UK is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Southwest-Exeter NHS Research Ethics Committee (15/SW/0153).

What if something goes wrong or I have a complaint? We do not expect any harm coming to you from being in this study. However, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the *Patient Advice & Liaison Service* is available to you (01392 402093). If you wish to complain about any aspect of the research team's work you can contact the Study Principal Investigator. **In the event that you feel that you are at risk of self-harm or suicide then please contact your G.P. , NHS 111 (dial 111) or the Samaritans (0845 790 90 90).**

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