

HELPclinic: Healthy Eating Lifestyle Programme by Clinicians

Information for young people age 16-19 years about the research

We are asking if you would take part in a research project to find out what you and your family or carers think of our new weight management programme. We also want to know if it helps you make changes to your lifestyle to enable you to control overweight.

Before you decide if you want to join in it's important to understand why the research is being done and what it would involve for you. So please consider this leaflet carefully. Talk about it with your family, friends, doctor or nurse if you want to.

PART ONE:

Why are we doing this research?

This study is testing a new weight management programme called HELPclinic. The programme aims to help young people gain control of their weight by increasing their confidence and motivation, and helping them work together with their friends and family to make changes to their lifestyle.

Why have I been invited?

You have been invited to join our study because you have seen us in the weight management clinic at University College London Hospital (UCLH) to think about fighting overweight. This study will involve 40 young people and their families.

Do I have to take part?

No: it's up to you to decide. Your doctor will tell you about the study and show you the information sheet, which will be yours to keep.

In the next week, a researcher from the University College London will phone you and your parents/carers to talk about the study. If you have any questions about the study, you can ask the researcher.

If you are willing to take part in the study, we will ask you and your parents to sign a consent form at the start of your first HELPclinic appointment.

It's okay if you change your mind and decide that you do not want to take part in the study. Simply tell us that you've changed your mind – you don't even have to give us a reason.

What will happen to me if I take part?

We will ask you to come to one 45-minute appointment each month for 5 months. Our aim is that you see the same clinician (doctor, nurse or dietician) each time, although this may not always be possible.

During this programme we aim to:

- Listen to what you want to do to about overweight.
- Listen to the ideas that you have about changing the way you eat and drink
- Listen to the ideas you have about increasing your activity levels
- Hear about the strengths and skills that you have that will help you make changes
- Hear about how your family and friends can help you make changes
- Help you think about changes you want to make and discuss scientific recommendations about food and drink, and activity levels.

Everyone who enters the study will take part in the HELPclinic programme. Around half of the young people will start the programme within one month, and half will be asked to wait around 4 months to start. We will choose by chance (random choice) who starts immediately and who waits to start: this is done so that we can test if the programme works to help young people control overweight.

At the start of the programme, you will have some blood tests. This is not part of the research programme – all young people who come to the weight management clinic have tests to check their health and look for any problems causing overweight.

At the end of the programme we would like to know what you think of the programme – what you liked, your ideas for improving the programme and any other feedback you may have. We will invite you, together with other families who have taken part in the study, to a meeting so that we can discuss your thoughts and ideas.

What are the possible benefits of taking part?

Potential benefits are:

- keeping your weight stable
- weight loss
- turn fat into muscle
- improve your confidence and motivation

We cannot promise that the study will help you but the information we get from this study might help improve care for young people with overweight in the future.

What happens when the study stops?

Your programme will last for 5 months. When it finishes, we will see you in a regular clinic within 3 months to discuss any other treatment that could help you.

What if there is a problem?

If there is a problem during the study, we'd like you to discuss it with us so that we can help sort it out. There is more information about this in part 2.

Contact details

If you would like to know more, please ask Billy White who can be contacted on 07954 540117.

Thank you for reading so far – if you are still interested, please go to Part 2.

PART TWO:

What if relevant new information becomes available?

Sometimes during research, new things are found out about how to care for patients. Your clinician will tell you if this happens. It may be best for you to either carry on with the study or stop the study and go back to your usual care.

What if there is a problem or something goes wrong?

If you have any problems during the study, or would like to discuss the study, you can call Billy White (telephone 07954 540717), who is one of the researchers in the team.

You can also speak to PALS, the Patient Advice and Liaison Service at University College London Hospital (ground floor of main building or telephone 020 7380 9975).

If you are still unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure.

Will anyone else know I am doing this?

We shall keep your information in confidence. This means we shall only tell those who have a need or right to know. If during the research you were to tell us that you were being harmed, we might have to give this information to an appropriate person. We would talk to you about this before we told anyone else.

With your permission:

- we will let your GP know that you are taking part in the study
- if needed, we would like to be able to contact you in the future about this project

What will happen to any samples I give?

Blood taken during the study will be sent to our laboratory for testing. You will have the same tests as other young people in the weight management clinic who are not in this research program. We will discuss the results to you in your first HELPclinic appointment within 4 weeks of your tests. If there are any results which we need to discuss urgently with you, we will phone you and your parents/carers immediately and arrange any treatment needed.

What will happen to the results of the research study?

The results of the research study will be published in a report that will be available on the Internet and in journals for doctors and other scientists. Your name will not appear in any report or publication. A short report will also be available to you and your parents through your clinic.

Who is organising and funding the research?

The research is being organised by researchers from the University College London Institute of Child Health. Some of the doctors in the UCLH Weight Management Clinic are also researchers at the UCL Institute of Child Health. No extra funding is required to carry out this research.

Who has reviewed this study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. The West London REC3 research ethics committee has checked your study.

For more information you can contact Billy White on 07954 540717.

Thank you for reading this – please ask any questions