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PATIENT INFORMATION SHEET



A brief GP intervention for weight loss: The BWEL-B feasibility trial

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

The aim of this study is to find out whether it helps people if a GP talks to them about their weight. In the study, GPs will talk to their participants about the best way to manage their weight. GPs will phrase this in one of two ways. We will compare the responses people have to the GP discussing weight in two different ways with them. We also aim to get patients feedback about whether the brief conversation initiated by the GP was helpful and appropriate. We will use this information to design a larger scale study. The GPs in your surgery are also taking part, and we will get their feedback about talking to their patients about their weight as part of the study. In the long-term we want to see whether it is beneficial to patients and cost effective for the NHS for GPs to talk to their patients about weight management in routine practice.

Why have I been invited?

We are inviting patients whose body mass index (BMI) is above 30, and therefore may benefit from losing weight. We have just taken your height, weight and body fat percentage, and these measurements suggest that your health may benefit from losing weight. We are inviting 60 patients in total. We are also inviting GPs to take participate by giving us feedback about how they talk to patients about weight management.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you are interested in taking part you will be given this information leaflet to keep and if happy be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time, without giving a reason. A decision not to take part or to withdraw at any time will not affect the standard of care you receive from your healthcare team. The research will not interfere with your usual GP appointment.

What will happen to me if I decide to take part?

- You will see your GP as normal.
- If your GP decides it is right to talk to you about your weight, s/he will open the research envelope give to you by the researcher before your appointment. The GP will then talk to you about your weight. What s/he says will depend upon what is in the envelope; neither you nor the GP will know what your GP will say to you because this will be decided randomly (that is like tossing a coin). Your GP may ask whether s/he can audio-record part of your consultation relating to the study for the purpose of this research.
- After the consultation we will ask you to answer two questions about whether you thought the discussion you had with your GP was helpful and appropriate.
- The researchers will telephone you in three weeks to ask about what you have been doing to control your weight and your thoughts about your consultation with your GP. If we are unable to contact you, we will try again two more times only. This telephone conversation will take about ten minutes.
- If you give consent, we will ask if you would be willing to be contacted in the future about participating in any other ethically approved research studies. However, you are not obligated to take part in future research. You can take part in this study and opt-out of being contacted in the future.

What are the possible disadvantages and risks of taking part?

- We do not anticipate any risks from the study.

What are the possible benefits of taking part?

Taking part in the study may help you to lose weight and improve your overall health. In addition, taking part in the study may help the research team to establish the best way for GPs to deliver weight loss interventions, and help design a larger randomised controlled trial.

Will my taking part in the study be kept confidential?

Yes. All information collected will be anonymised using a unique code and stored in a locked storage facility at the University of Oxford. If applicable, audio-recorded information from your consultation will be transcribed, anonymised and stored securely. Responsible members of the University of Oxford and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

What will happen to my data?

It costs a lot of time and money to collect data on people for medical research. It is possible that the data we collect on you for this study may help researchers doing other medical research. So we are asking people taking part in this study to let us keep your anonymised data securely at the University of Oxford. This data may be used in other ethically approved research studies in the future. This does not include personal details and contact information. This is your choice and you can take part in the study without agreeing to let us keep your data. Anonymised research data will be stored for a period of 5 years.

What if I don't want to carry on with the study?

If you do not want to take part in the research you can withdraw at any time without affecting your care and we will not contact you again. Please contact Kate Tudor (BWeL-B researcher) using the contact details provided at the end of this information sheet. If you decide to withdraw we will keep the data that we have already collected unless you tell us you would like it to be destroyed.

What will happen to the results of the research study?

We will publish the results so that scientists and doctors know whether they should talk to people about their weight and how they might do this. We will send you a copy of the results of the study via email if you have provided us with an email address. Alternatively, we will post it where email is not an option. We will also provide your GP practice with a copy for them to display. If you agree to your consultation being audio-recorded anonymised quotes may be published in this or other research, but you will not be personally identifiable from any publication.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Kate Tudor [insert phone and email here] or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 (6)16480, or the head of CTRG, email ctrig@admin.ox.ac.uk. If you remain unhappy or wish to complain formally then you can do this through the NHS Complaints Procedure. You can contact NHS England on 0300 311 22 33 or email England.contactus@nhs.net

How have patients and the public been involved in this study?

We have conducted a survey and focus groups with patients who have helped to develop the research study question and procedures. These patients volunteer their time to help develop clinical research studies. (See, for more information, www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-study/)

Who is organising and funding the study?

The researchers are from the University of Oxford, who are also acting as sponsor for this research. The study is funded by the Oxford Biomedical Research Centre

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by _____ Research Ethics Committee.

Further information and contact details:

If you want to discuss the study please contact Kate Tudor, BWeL-B researcher, either via telephone [insert phone number here]. If you want to email [insert trial email address here].

Thank you for reading this information.