TRUST LOGO (if applicable), or a placeholder, 'local logo/letterhead'

Departmental Header if desired.

Ms. Kate Tudor, Chief Investigator
Nuffield Department of Primary Care Health Sciences
Woodstock Road
Oxford, OX26GG

Participant Information Sheet - GPs

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. Specifically, the study involves GPs delivering a brief intervention advising patients to attend a commercial weight management service in one of two ways. We are interested in GPs opinion on which is the most appropriate way to word the brief intervention to inform the development of a larger randomised controlled trial. We are also interested in understanding whether GPs think it is helpful and appropriate to refer patients to a weight management service that they would need to pay for themselves. We will compare the responses patients have to the GPs referring them to a commercial weight management service by following them up at 3 weeks and recording whether they attended the programme. The current

study is a feasibility study and we will use this information to inform the development of a larger scale study (randomised controlled trial). In the long term, this will examine whether it is beneficial and cost effective to refer patients to self-funded commercial weight management programmes in clinical practice.

Why have I been invited?

You are one of the General Practitioners that will be delivering the opportunistic brief interventions. We are hoping to recruit 5 GP's from your practice into this study.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information leaflet to keep and 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. If you decide to withdraw we will use your data up to the point you withdraw unless you request that we do not do so.

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

- You will complete a questionnaire before you start delivering the brief interventions. This questionnaire will ask about your attitudes towards delivering brief interventions to patients who are obese in primary care. You can complete this at anytime before you deliver the intervention to patients. The questionnaire will take approximately 5 minutes to complete.
- You will complete a questionnaire after the final patient in your GP practice is randomised, and you have delivered your last intervention. This questionnaire will ask about your attitudes about the brief intervention that was delivered, and your experiences of taking part in the trial. You will complete this on the last day that you will deliver the intervention to patients (i.e. following involvement in the trial). This questionnaire will take approximately 5-10 minutes to complete.
- You will complete a brief interview with a researcher about your experience in delivering the brief intervention during the trial. This will take approximately 5-10 minutes. This will be audio-recorded so it can be transcribed, unless you request that we do not do so.

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?

It is not envisaged that taking part in this research will have any direct benefit to you. However, 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. None of the data collected will contain any identifiable information. The questionnaires, audio-recorder, and transcribed interview data will be stored in a locked storage facility at the University of Oxford. The audio-recording will be deleted immediately after the data has been transcribed (up to two-weeks after recording). Responsible members of the University of Oxford and host institution 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 data securely at the University of Oxford so it may be used in the future for other ethically approved studies. 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. Please contact Kate Tudor (BWeL-B researcher) using the contact details provided at the end of this information sheet.

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. We will send this via email if you have provided us with an email address. Alternatively, we will post it where email is not an option. Anonymised transcripts of these audio recordings may be used in future qualitative research, but you will not be personally identifiable from any publication.

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/)

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 ctrg@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

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.