Find out more about our study!











Healthy Weight Coaches Study Participant Information Sheet: Patients and Companions Consultation Recording and Surveys

What is this study about?

- There is a new role at some GP practices in England called a 'Healthy Weight Coach'. Because it's so new we want to find out what people think about it.
- We need **your help** to understand more about how Healthy Weight Coaches can help people.
- Before you decide if you would like to take part, we would like you to understand why the research is being done and what it would involve for you.

Will I be reimbursed for taking part?

Receive a shopping voucher

to say thank you for your time

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surveysDr Charlotte AlburyIRAS Ref: 335395Ethics Ref: 24/YH/0204

If you have any questions at all about this study please contact our friendly study team.

Getting in contact with us:

Address: Healthy Weight Coaches Study Team Nuffield Department of Primary Care Health Sciences University of Oxford



Telephone: 01865 289301 Email: hwc@phc.ox.ac.uk

Why have I been chosen?

Because you were offered an appointment with a Healthy Weight Coach or you are accompanying someone who were offered an appointment with a Healthy Weight Coach.

Do I have to take part?

No, it is up to you whether you take part or not. If you do decide to take part in the study, you will be asked to sign a consent form before your appointment with the Healthy Weight Coach. You are free to withdraw from the study at any time without giving a reason.

What will I have to do?

• Have your appointment with the Healthy Weight Coach recorded

We would like to record appointments with Healthy Weight Coaches to find out about how Healthy Weight Coaches and their patients communicate together. We hope to include about 100 patients in this study. We will use what we learn to make new training for Healthy Weight Coaches. **You can choose** if your appointment is video recorded (sound and videos), or is audio recorded (just sound).

• Two short telephone surveys after your appointment

After you see the healthy weight coach we would like to ask you a few short questions about what happened. We will get in touch by phone a few days after your/your companion's appointment, and again about 12 weeks later. **Both surveys together will take about 15 minutes.**

We might also ask if you would be willing to talk to our researchers in an audio recorded telephone 'research interview' to find out what you thought about your/your companion's healthy weight coach appointment, or ask if you would like to join a workshop to discuss what you thought about the new 'healthy weight coach' role. We will provide you with further information about these interviews and workshops and ask you to consent separately.

Are there benefits or risks of taking part?

There are no known risks to taking part in the study. What we learn from this study could help us train Healthy Weight Coaches to help people in the future. If for any reason you find taking part in the research upsetting you can tell the researcher and discuss this or you can stop taking part, and we will understand and support this.

What if I don't want to be involved anymore?

You can leave the study at any point, and you do not have to tell us why. Your decision to do so will not affect your legal rights or the treatment you receive. We would still like to use the data you have already provided, as this will be really important to our research. If you have any objection to this please let us know. You can decide to withdraw up to 48 hours after you have been interviewed. If you decide this, we will delete your interview and any notes taken

What if there are any issues?

If you would like to take part, but cannot access a telephone, do let us know and we can either provide you with a phone to borrow, do an in-person interview or do the interview over email. If you would like to see this document in alternative formats or layouts (easy read, bigger font, printed out and posted, different language etc) or there is something else we can do to support access to this study, please contact the researcher at 01865 289301 or email <u>hwc@phc.ox.ac.uk</u> and we will try to help.

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint.

For queries about this study, please contact the study team on 01865 289301 or email <u>hwc@phc.ox.ac.uk</u>. If you wish to complain about any aspect of the way in which you have been approached or treated during the study, or how your information is handled during the course of this study you can contact the chief investigator, Dr Charlotte Albury on 01865 617826 or <u>charlotte.albury@phc.ox.ac.uk</u>

or the University of Oxford Research Governance, Ethics & Assurance (RGEA) at <u>rgea.complaints@admin.ox.ac.uk</u> or on 01865 616480.

What about confidentiality ?

We will remove all information from audio recordings and transcriptions that could identify you, like your name, as soon as we can. The information you provide will be coded with a trial identification number so you cannot be identified from it by anyone other than the research team. If we use any direct quotations and video or audio clips in publications or training materials, we will remove anything that could be used to identify you.

Responsible members of the University of Oxford, regulatory authorities 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. We will not share any data that could be used to identify you, only access to anonymised data will be granted.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study. It is the data controller, and is responsible for looking after your information and using it properly.

We will be using information from you in order to undertake this study and will use the minimum personally-identifiable information possible. We will securely send the recordings of your consultation recordings to an external transcriber, who has been approved by the University of Oxford. The transcriber will return transcriptions to the research team and delete all copies they hold of the transcriptions and audio/video recordings.

We will store any research documents with personal information, such as consent forms, securely at the University of Oxford until study completion (or up to five years after end of study if you say you are happy to be contacted about future research) as part of the research record. If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form securely until such time as your details are removed from our database. We will keep the consent form and your details separate from one another and any research data.

We will store your de-identified research data for 12 months after the last publication of this study. Or, if you give us permission to use the data for other studies, we will retain this for up to 20 years.

The local study team will use your name and contact details to contact you about the research study, and to oversee the quality of the study. Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at <u>https://compliance.web.ox.ac.uk/individual-rights</u>

You can find out more about how we use your information by contacting <u>hwc@phc.ox.ac.uk</u>.

What will happen to the results?

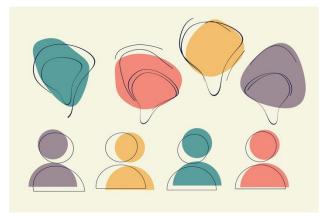
The results of this research study will be used to update the training for Healthy Weight Coaches. They will also be published in a scientific medical journal and on the University website and may be used in future training materials. Data may also be used by students as part of an educational project. Your individual details will not be identifiable nor would you be identified in any report or publication.

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

Patients and the public helped us decide on the study methods and processes. They also helped us design this information sheet. Patient views will be included all through the study as well.

Who is organising and funding the study?

This study is being funded by the National Institute for Health Research and sponsored by the University of Oxford. It is being run by a team from the University of Oxford, University of Leeds, Leeds



Beckett University and University of Western England

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 a favourable opinion by Yorkshire & The Humber - Leeds West Research Ethics Committee.

Taking part in in future research:

You will be asked if you would be happy for us to contact you about taking part in other research studies in future. Agreeing to be

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contacted does not oblige you to participate in any further studies. If you say yes, your contact details would be held securely, separately from this study on password protected drives at the Nuffield Department of Primary Care Health Sciences, University of Oxford accessible by the study team.

Thank you for considering taking part

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