



Participant Information Sheet: Community-based Prevention of Diabetes: A trial of the Living Well, Taking Control programme

We are inviting you to take part in a research project running in the local area over the next two years. To help you decide if you want to take part, we want to explain:

- Why the research is being done, and
- What it will involve for you if you take part.

One of our research team will go through this information sheet with you and answer any questions you have before you make a final decision. In the meantime, please take time to read the information and feel free to discuss it with others, such as family, friends or your GP.

What is the purpose of the research?

More and more people are getting Type 2 diabetes (also called adult-onset diabetes). A person's risk of getting diabetes is strongly related to their lifestyle. Our research project aims to find out whether a new programme to support people to make healthier lifestyle choices can reduce people's risk of getting diabetes. This programme is called "Living Well, Taking Control". It is designed to help people who are at risk of getting diabetes to eat healthily, get more physical activity and lose weight. We hope that if the programme works, this will help improve health services for all people who are at risk of getting diabetes.

Why have I been invited?

We are inviting you to take part because your medical records show that your blood sugar is higher than normal (based on a blood test that you had in the last year). This condition is sometimes called "pre-diabetes". It means that you are at an increased risk of getting diabetes in the future.

What will happen to me if I take part?

Our researcher should have already arranged a convenient time to see you in your home or another suitable location (for example, your GP surgery). If not, please contact them to arrange this using the contact details at the end of this information sheet. When you meet, the researcher will make sure you are happy to take part. If you are, they will get you to sign a consent form. They will then take some measures of your weight, blood pressure and blood sugar, and collect information on your lifestyle and health. There is more detail on what you will do with the researcher below.



After this, to see if the Living Well, Taking Control programme works, we will divide people into two groups that we can compare:

1. A group that will start attending the Living Well, Taking Control programme at a local venue straight away.
2. A group that will go onto a waiting list and will be able to attend the Living Well, Taking Control programme in 6 months time.

There is more information on the programme below. No matter which group you end up in, you will continue to receive your usual medical care from your GP surgery. To make sure that the groups are the same as each other to start with, each person taking part will be put into a group by chance (randomly). So, you will have an equal (50/50) chance of being asked to attend the programme straight away or in 6 months time.

Six months after the first visit from the researcher, they will visit you again to take measures and collect information as before. Comparing the measures for the two groups after 6 months will show how good the programme is at helping people to make lifestyle changes, lose weight and reduce their risk of diabetes. People who attended the programme from the start will also be visited after one year to see whether they have maintained any changes they made.

What is the Living Well, Taking Control programme?

The Living Well, Taking Control programme provides education about diabetes and healthy lifestyles and support to help people make lifestyle changes. The focus is mainly on healthy eating and physical activity. At the start, a trained lifestyle coach will assess what you currently eat and how active you are. With this information they will help you to identify changes you might make to achieve a healthier lifestyle and lose weight. You will then be given further support to help you to continue with these healthy lifestyle changes.

To begin with you will be invited to attend four to six sessions lasting up to two hours. These are offered once per week for up to six weeks. At these sessions you will work with the coach and meet with a group of 10-12 other people with pre-diabetes from your local community. If you have a partner or other individual who you would like to support you in your efforts, they can also attend these sessions.

After these group sessions, the lifestyle coach will be in touch with you regularly to provide extra support, for example by phoning you. You can also choose to attend five additional physical activity and healthy eating classes over the next year. All sessions are held in a local venue and will be offered at various times to suit your availability.

After you have completed the initial group sessions you will also be asked to complete a questionnaire about your satisfaction with the Living Well, Taking Control programme. At the end of the research project, we may also ask you to take part in an interview to ask for your views and how we might improve the programme.

What will I have to do with the researcher?

Our researcher should have already arranged a time to visit you. This first visit will last around an hour and the researcher will:

1. Discuss the study, answer any questions, and make sure you are happy to take part. They will also ask you to sign a consent form if you agree to be involved. You will be given a copy of the signed consent form and this information sheet to keep.
2. Take measures of your weight, height, and blood pressure.
3. Prick your finger to take a drop of blood to test your blood sugar levels. This tells us important information about your risk of developing diabetes.
4. Help you to fill out a brief questionnaire about your physical activity, diet and general health and well-being.
5. Provide you with a small device (called an accelerometer) that measures physical activity. You will be asked to wear this on your belt or waist at all times when you are awake over the next 7 days. The researcher will provide you with a free-post envelope to return this at the end of the week.
6. Tell you which group you are in and what happens next.

Six months after the first visit, the researcher will contact you again to arrange another visit lasting around 45 minutes. If you are in the group which attends the Living Well, Taking Control programme straight away, the researcher will make an additional visit one year after the first visit lasting no more than 45 minutes. At each visit the researcher will take the measures, help you to fill out questionnaires and ask you to wear an accelerometer as per steps 2-5 above.

At the time when you are scheduled to start attending the Living Well, Taking Control programme (from the start or after 6 months), the researcher will pass your details onto Westbank. This is the local voluntary sector organisation providing the programme. A lifestyle coach will then contact you and arrange for you to attend the first session.

Whether you choose to attend the Living Well, Taking Control programme or not we hope you would be happy for the researcher to contact you to arrange the next visit. If you are interested, at the end of the study we can send you a report of the findings from the research. You will also get a copy of your own test results when you attend the Living Well, Taking Control programme.

Do I have to take part?

No. You are free to choose whether or not to take part in this research project. You can, if you want, take part in the Living Well, Taking Control programme without participating in this project. If you would like to do this please speak to the researcher, who will forward your contact details to Westbank so that your name is added to the standard waiting list. If you do decide to take part in our project, you are free to withdraw at any time without giving a reason. A

decision not to take part or withdraw will not affect the care you receive from your GP surgery.

If you stop attending the Living Well, Taking Control programme or choose not to make any changes to your lifestyle, this is not a problem. There is no obligation to take any action. In this case, the researcher would still contact you to visit you again after 6 months. We would like to get information from people who do not make changes as well as from people who do. Again, withdrawing from the research project in this way will not affect your care.

Please do not volunteer to take part if you are already taking part in another research project that involves losing weight or making changes to your physical activity or eating habits.

What are the possible benefits of taking part?

Firstly, we hope that thinking about your diet and physical activity will be useful for you. We expect that those people who successfully improve their diet or increase their physical activity will lose weight. This will reduce their risk of developing diabetes, and may lower their blood pressure and cholesterol, and improve their general health and well-being. Secondly, you may gain social benefits from taking part in the programme, by meeting other people in your area and sharing experiences of making lifestyle changes. Thirdly, by taking part in the study you will help us to develop better services to prevent diabetes in the local area, and in the health service more widely.

Will my taking part in the study be kept confidential?

Your GP will be informed if you take part in the study and will receive copies of your blood test and blood pressure results. However, we will not pass this information on if you ask us not to do so. Your contact details will be used by the researcher to contact you about your participation in the study. It will also be passed on securely to the lifestyle coaches so that they can contact you to arrange for you to start in the Living Well, Taking Control programme. Your name and contact details will not be shared with any other person or organisation and at all times will be kept securely on password protected computers accessible only to members of the research team. Any other written or recorded information that you give us during the study will be 'anonymised' – this means that you are assigned a number and the information will be kept separately from your name and other personal details.

Who is organising and funding the research?

This research has been funded by the National Institute for Health Research, with support to run the programme provided by the Big Lottery Fund. There is no funding from any commercial organisations. The research is being run by researchers from the University of Exeter Medical School, the University of Birmingham, the University of the West of England, Health Exchange in Birmingham and Westbank Healthy Living Centre in Devon.

What will happen to the results of this study?

We will provide summaries of the results to GP surgeries and other local health professionals and researchers. We will also aim to publish the results in academic journals read by other researchers and health professionals interested in preventing diabetes. If you wish to receive a summary of the findings at the end of the study, we would be pleased to provide these. If the programme performs well and is shown to be successful in reducing people's risk of diabetes, we would recommend its wider use.

Who has approved and checked this study?

The <Name> Research Ethics Committee and the funders have looked at this project and approved it. The University of Exeter will also check that the research is being properly conducted.

Who do I contact if I have any complaints?

If you have any health or other problems you think may have resulted from taking part in the research, these will be dealt with through standard complaint procedures at the University of Exeter Medical School. In the first instance, please contact the lead researcher:

Dr Jane Smith, University of Exeter Medical School, St Luke's Campus, Exeter EX1 2LU. Tel: 01392 725402 or Jane.Smith@exeter.ac.uk

What happens next?

Our researcher will call to confirm arrangements before you are due to meet them. If you are happy that you have received enough information about the research after reading this and discussing it with others and the researcher, you will be asked to sign a consent form when the researcher visits you. You will be able to change your mind about taking part at any point if you wish. If you would like further information, have any questions or would like to discuss taking part in the study further before the researcher visits please contact:

RESEARCHER NAME & CONTACT DETAILS TBC.

Thank you very much for your reading this and for your interest in our research. Please keep this information sheet for future reference if you decide to take part.