



diamonds.

We invite you to take part in a research study

We are looking at a new support programme for people who have type 2 diabetes and a mental illness. The programme aims to help people to manage their conditions. It has been created in partnership with people who have these conditions.

We are inviting adults to take part who have been diagnosed with:

Type 2 diabetes *and*

a mental illness such as:
Bipolar disorder
Schizophrenia
Schizoaffective disorder
Severe depression
Psychosis

Key things you need to know

- Before you decide whether to take part, we want to tell you more about why the research is being done and what it will involve. **Please read through this information sheet for more details about the study. Different coloured versions of this information sheet are available, please contact us below to let us know your requirements.** You can discuss the study with others if you wish, such as friends, relatives, your GP, diabetes nurse, or mental health service provider.
- It is entirely up to you whether or not you take part. If you choose not to take part this will not affect the care or any benefits you currently receive.
- **A member of the research team will contact you in the next few days to discuss the study.** If you are unsure, please feel free to contact us in the meantime with any questions you may have, or if you would like any further information.

How to get in touch with us

If you have any questions about the study, you can contact [\[TRIAL SITE\]](#) on [\[SITE CONTACT DETAILS\]](#)

A friend or relative may speak to us on your behalf if you wish. There is an answering machine available 24 hours a day, so please leave a message and we will return your call as soon as possible.

We also have a website that includes information about the study: www.diamondscollaboration.org.uk

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Study Involvement Overview



**YOU
ARE
HERE**

RECRUITMENT

After receiving this information you will receive a phone call to answer any queries you have and to ask you to consider taking part in DIAMONDS. If you choose to participate your DIAMONDS journey as a participant begins:

BASELINE DATA COLLECTION

At the researchers appointment you will be asked to give a blood sample, answer some questionnaires and have your height and weight measured. We will also give you a wrist watch to wear for 7 days to measure your physical activity levels.

RANDOMISATION

You will then be randomly allocated to receive the DIAMONDS support programme, detailed below or usual NHS clinical care.

DIAMONDS SUPPORT PROGRAMME

For those allocated to this group. You will receive a 6-month programme, receiving 1-1 coaching to support your diabetes self-management. In this 6 months you can receive as many sessions (lasting approx. 30-50 minutes) as you choose and decide where the meetings take place. There is also an optional workbook and app you can access between appointments

USUAL CARE GROUP

For those allocated to this group. You will continue to receive your usual NHS clinical care. This group plays an important role to the research study.

STUDY TIMEPOINTS

Both groups at 6 and 12 months, you will be asked to give a blood sample and answer some questionnaires. We will also ask you to wear the wrist watch device for 7 days at 6 months.

INTERVIEWS ABOUT THE SUPPORT PROGRAMME

You may be asked to take part in an interview where you give your feedback on the DIAMONDS support programme.

STUDY END

Thank you for your participation. We will let you know when your involvement in the study has finished, and send you a shopping voucher as a thank you

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Thank you for your participation. We will let you know when your involvement in the study has finished, and send you a shopping voucher as a thank you

Why are we doing the study?

What are we studying?

The study is part of a research programme that aims to help people manage diabetes and a mental illness. Managing diabetes involves doing things like taking medications, monitoring symptoms, preventing complications, and leading a healthy lifestyle. This is called 'self-management' because it is about doing things to look after yourself.

Why do we think this is important?

People living with a mental illness are more likely to have diabetes than other people. Diabetes self-management can be harder for people with a mental illness. This can be for different reasons.

Diabetes support programmes are available in the NHS but they may not be suitable for people who also have a mental illness. We have created a new support programme called DIAMONDS to address this. DIAMONDS was created together with people who have diabetes and a mental illness.

What do we need to do?

We want to find out if the DIAMONDS support programme improves people's health by lowering their blood sugar (HbA1c). We also check if it is good value for money for the NHS.

2 Why am I being asked to take part?

You have been identified as someone who lives with diabetes and a mental illness (such as bipolar disorder, schizophrenia, schizoaffective disorder, or severe depression). You may have been given an information pack by your general practice or community mental health team and sent us a form with your contact details. You may have seen advertisements for the study and contacted the

study team directly. We have also contacted some people who have joined a research register and agreed to be contacted about relevant research studies. The research team have used your name and contact details to provide you with this information about the research study.

3 What will happen to me if I take part?

We will contact you again in a few days' time to discuss the study with you. You can also contact the study team directly to let them know you are interested in taking part. Our contact details are on page 1.

When you speak with us, you can ask any questions you have about the study. You do not have to take part in the study.

We will check you are eligible to take part in the study. If you are not eligible, or if the study isn't quite right for you, your involvement will finish at this point. We will explain this to you.

If you are happy to proceed with the study, an appointment with a member of the research team will be arranged at a time that works for you.

First appointment

The meeting will be at a local clinic and you can have someone with you if you like. Some parts can also be done over the phone. The researcher will discuss this with you, and you will decide together what will work best. The appointment will last no longer than 60 to 90 minutes.

The researcher will:

- Explain the study.
- Answer any questions you may have.
- Check you understand what the study involves.
- Ask you to sign a consent form.
- Ask you to fill in a questionnaire about your health and help you with this if needed.

- Take a blood sample from you, or use your most recent blood results
- Take some measurements such as your height, weight, and blood pressure.

You will be asked to wear a wrist-band (a bit like a digital watch). It measures if you are moving or staying still throughout the day and night. It does not track where you are or record any other information. The researcher will explain this to you, and you do not have to agree to wear it. If you do agree, you will be asked to wear the wrist-band for one week and then someone from the team will return it to us. The information we get from the watch is completely anonymous, meaning it will not include any identifiable information.

You don't have to agree to wear this device and you can stop wearing it at any time if you change your mind.

After all the information above has been collected you will then be **randomly allocated to one of two groups**. This means you have an equal chance of receiving the DIMAONDS programme, in the same way that tossing a coin gives an equal chance of getting 'heads' or 'tails'. If you do not receive the DIAMONDS programme you will receive your usual NHS clinical care and treatment as normal.

DIAMONDS PROGRAMME GROUP

The DIAMONDS programme aims to help you manage your diabetes and mental health. This will be in addition to the care you normally receive.

The DIAMONDS support programme runs for six months. During that time, you will have sessions with a DIAMONDS Coach. Your Coach will be a professional who has been trained to deliver the DIAMONDS support programme. You can meet your Coach as often or as little as you like. Sessions can happen in person, on the phone, or as a video call.



1-1 Sessions

DIAMONDS Sessions

The first session will last between 60-90 minutes. You will agree with your Coach where this meeting takes place. The DIAMONDS

Coach will work with you to decide which parts of diabetes self-management to support you with. Together you will make a plan to help you change one thing about your self-management e.g:



You will then work towards this goal for the next couple of weeks.

You will speak to your DIAMONDS Coach as many times as you wish over the 6-month support programme. In these sessions the Coach will provide information about diabetes and support you to make healthy lifestyle changes. They will review how you get on with your self-management plans and help you find ways to overcome any challenges.

These sessions can vary in length but may last between 30 and 60 minutes. They can be in person, by telephone, or video call. Some sessions may be audio recorded.



In between your appointments you will use a workbook every day to help you with your self-management plans. There is also a mobile app which you can use on your own smart phone if you like. The DIAMONDS Coach will set you up with the workbook or app and they will help you use it. The workbook and app can:

- Remind you to do important things such as take your medication.
- Give you information about the benefits of self-management.
- Suggest activities you can do to improve your mood.
- Log how you are getting on with your chosen self-management plans.

In the sessions, the DIAMONDS Coach will look at the workbook or app with you to see how you are getting on. They will make a note of some of this information to help us better understand how the app and workbook are being used.

You don't have to decide right away if you want to use the app; you can start using it at any time during the 6 months. You can also stop using the app at any point. This will not affect your participation in the study or the care you are receiving.

You do not have to use the digital app if you do not want to. The paper-based workbook can be used instead to do the same tasks.

USUAL CARE GROUP

If you have been randomised to the usual care group (also called the "control group"), you will not receive the DIAMONDS support programme. Instead, you will continue to receive your usual healthcare. Your GP will be able to support you if you want to make changes to your lifestyle.

It is important that we include people in the study who do not receive the support programme so that we can compare the two groups. Your participation in the usual care group is important and very much appreciated.

STUDY APPOINTMENTS

All participants will be contacted by a member of the study team six months after joining the study and then again after 12 months. We will ask you to give another blood sample and go through some follow-up questionnaires with you. At the 6 months, we will also ask you to wear the wrist-band (same as the one when you joined the study) again for another week.

Blood samples will be sent to a centralised laboratory where they will be analysed. The results will then be sent back to the research team at the University of York. All samples and results will be anonymised, so will not include any of your identifiable information.

At the end of the study we will ask a small number of people who received the DIAMONDS programme to speak with a researcher about their experiences. If we ask you to do this, we will give you more information about what it would involve. If you agree to do this we will ask you to fill in a separate consent form. If you do not wish to do this, you can still take part in the rest of the study.

The image below shows the steps involved with taking part in the study.

4 What are the possible benefits of taking part?

Taking part could help improve future support for people who have diabetes and a mental illness. Although we cannot promise that taking part in the study will help you, you may learn more about your diabetes which could help you to manage this better.

What are the possible disadvantages of taking part?

Taking part in the study will require you to attend appointments, have body measurements and blood taken, and complete a study questionnaire which will take time. Taking part in this study will not require you to travel further than a local NHS site.

5 More information about taking part

Do I have to take part?

No, it is entirely up to you to decide whether to take part or not. Please feel free to contact us if you would like more information, or to ask us any questions. Our contact details are on page 1. Please also discuss the study with family or friends if you wish.

You will be asked to sign a consent form if you decide to take part to confirm that you are happy to participate in the study and that you understand what is involved. The consent form will ask if you have fully understood the information provided to you and that you understand your right to withdraw at any time throughout the study. It will also ask for your consent to store information collected about yourself and sharing your participation in the study with your GP. We will give you a copy of this for you to keep. Please also keep this information sheet. Even if you agree to take part in the study, you are free to stop at any time, without giving a reason. We will still use the information we have received from you up to the point you stop taking part.

In some circumstances we may ask consent to be provided verbally, over the phone or via video. A member of the research team will read out the verbal consent script and the consent form to you. If you provide verbal consent, they will record this on the consent form and send you a copy of the completed form.

The care or any benefits you normally receive will not change if you decide not to take part, or if you decide to stop taking part once you have joined the study.

Will I receive any payment for taking part?

We will pay all postage and travel costs in relation to the study. We can also pay any carer cost you have because you're taking part in the study. This includes childcare costs. Please let us know in advance if there are any carer costs you'd like us to cover. We would also like to offer you a £10 gift voucher for completing the study questionnaire at 6 months and another £10 gift voucher at 12 months. You do not have to accept this.

Will my GP be involved?

We will tell your GP if you agree to take part in the study. We will also ask for your permission to get in touch with your GP if we have any concerns about your health whilst you are taking part in the study. You can provide this permission in your consent form. You can contact your GP for support at any time during your involvement in the study.

How will we use information about you?

We will need to use information from you and your medical records. This information will include your initials, NHS number, name, contact details and address. People will use this information to do

the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will use your personal information only to do the research. Other authorised individuals may check your records to make sure that the research is being done properly.

Your name and contact details will be kept separate from the other information that we obtain from you in this research. Your research records will contain a unique code number instead, so you are not directly identifiable when we use your data in our research.

Your name and contact details and research records will be stored electronically on a secure server at the University of York. Access to this information will be restricted to authorised persons only.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data for at least ten years. This will enable us to complete our publications and reports. We will write our reports in a way that no-one can work out that you took part in the study.

It will then be destroyed securely. Paper records will be handled by the study team and kept in locked cabinets. Electronic records will be held on a secure computer server approved by the University of York. Notes on DIAMONDS support sessions will be held in accordance with the service delivering the DIAMONDS support and in line with University of York and NHS Trust procedures. These will always be confidential and secure. Only authorised members of the study team will have access to your information.

The study team would be happy to answer any questions you may have about how we use the

information we receive from you as part of the study.

Research which is similar to this study might be carried out in the future, either by us or by other researchers. With your agreement, we would like to send you information about these related studies. The information will only be sent to you by a member of our study team. We will not pass your personal details to anyone outside of the study team. This will be controlled by strict University of York and NHS Trust procedures. You can choose whether or not you agree to this when you fill in your consent form.

What are your choices about how your information is used?

The University of York is a publicly funded organisation that conducts research to improve health and healthcare services. In legal terms, we are using your information for this research as part of 'a task in the public interest'. The ability to change the data that we have collected, however, is limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- At <https://www.york.ac.uk/healthsciences/research/trials/trials-gdpr/>
- At <https://www.york.ac.uk/healthsciences/research/trials/trials-gdpr/research-participants/>
- by sending an email to diamonds-trial-group@york.ac.uk

- by emailing the University of York's data protection officer on dataprotection@york.ac.uk

Will my taking part in this study be kept confidential?

Data collected for the study may be looked at by authorised persons who are organising the research. Data may also be looked at by other authorised people to check that the study is being carried out correctly. All have a duty of confidentiality to you as a research participant.

What if there is a problem?

If you have concerns about the study or if there is anything you would like to ask about the study, please get in touch with us. Our contact details are on page 1. If you would prefer you may contact the Chief Investigator: Prof Najma Siddiqi, Tel 01904 321681, email: najma.siddiqi@york.ac.uk.

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of the study, the normal NHS complaints processes are available to you through your local Patient Advice and Liaison Service Tel:

[Insert PALS contact details]

Data protection

The University of York is the data controller for the information collected for this research, which means we are responsible for looking after your personal information and using it properly. If you are unhappy with the way your personal information has been handled, please contact the University's Data Protection Officer at dataprotection@york.ac.uk. If you are not satisfied with our response, you have a right to complain to the Information Commissioner's Office. For information on reporting a concern to the Information Commissioner's Office, see www.ico.org.uk/concerns.

What will happen to the results of the study?

When the study has finished and the results have been published, we will send you a summary of the study results if you agree for us to do so. You can contact the study team directly if you decide not to take part in the study, but would still like to receive a summary of the results. We will also keep our study website up to date with news about our research. One way we can get the most benefit from this work is to make the study data available to researchers for related research at the end of this study. The study data may be reused by the research team or researchers in other institutions but will not be used or released in such a way that you could be identified.

Who is organising and funding the study?

This study is organised by Bradford District Care NHS Foundation Trust and the Universities of York, Southampton, Leicester and Leeds. This group is working with NHS Trusts and GP practices in England.

The study has been funded by the Department of Health's National Institute for Health Research Programme Grants for Applied Research programme.

Who has reviewed the study?

The study has been reviewed by an independent group of people, called a Research Ethics Committee. This is to protect your safety, rights, wellbeing and dignity. This study was looked at and approved by the **[insert REC information and reference]**

How have patients and public helped to design the study?

Patients and family carers with experience of living with mental health and diabetes, known as DIAMONDS Voice, have contributed to the development of the study, design the workbook and app and will continue to support the study.

More information of the DIAMONDS Voice group can be found here:

<https://www.diamondscollaboration.org.uk/diamonds-voice>

Are there any independent organisations I can contact?

For general information about research you might wish to contact INVOLVE (Tel. 023 8059 5628). For information about diabetes you may wish to contact Diabetes UK (diabetes.org.uk or Tel. 0345 123 2399). For more general information about mental illness, you may wish to contact Rethink (rethink.org or Tel. 0300 5000 927).

6 What do I need to do now?

What do I need to do if I would like to take part in the study?

You can either wait until we contact you in the next few days or you can contact us (see page 1).

Do I need to do anything if I don't want to take part in the study?

Simply tell us that you do not want to take part when we contact you within the next few days. You will not have to give a reason for this. The care you receive will not be affected in any way.

Thank you for reading this information sheet and for considering whether to take part in the study

