EYE-D Study
EMDR Therapy for Depression
Participant Information Leaflet

We invite you to take part in a research study

- Before you decide whether to take part, it is important for you to understand why this research is being done and what it will involve.
- Please take the time to read the following information carefully. Discuss it with friends and relatives if you wish.
- You are free to decide whether or not to take part in this research. Take time to decide. If you choose not to take part, this will not affect the care you get from your GP.
- Ask us if there is anything that is not clear or if you would like more information.

Important things you need to know

- We are looking at a new way of treating depression.
- We know that for many people, depression occurs as a result of difficult or stressful experiences.
- Eye movement desensitisation and reprocessing therapy, or EMDR, is a type of psychological therapy that works on memories of those experiences.
- **We would like your help in evaluating this treatment for depression by taking part in the EYE-D study.**
- By taking part in the study and completing some questionnaires, you will help us to find out whether this treatment improves symptoms of depression, how it might work, and how acceptable it is.
- Taking part in this research is voluntary and you can withdraw at any time without giving a reason.

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How to contact us

If you have any questions about this study, please talk to the researcher:

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1 Why are we doing this study?

Depression is common but only around half of patients get better with the most common treatments – antidepressants or a type of talking therapy called cognitive behavioural therapy (CBT). We need new ways of treating depression.

Stressful life events (e.g. job loss, relationship breakdown) or traumatic experiences (childhood abuse and neglect, accidents and assaults) are associated with a higher risk of depression. Many people with depression talk about distressing past events related to their depression.

Eye movement desensitisation and reprocessing therapy or EMDR is a recommended trauma-focused psychological treatment for post-traumatic stress disorder (or PTSD). It has been adapted for depression.

The theory behind EMDR is that many psychological difficulties, including depression, are the result of stressful life events that have not been processed in the usual way. EMDR is one way of helping process these memories.

There is some evidence that EMDR may help improve depressive symptoms, but we need to run a large study to find out.

What do we hope to find out?

This study is trying to find out whether EMDR improves symptoms of depression, and how the treatment works. In order to do this, we are carrying out what is called a randomised controlled trial.

We also want to find out patients' views and experiences of EMDR and usual GP care for depression by carrying out interviews with a small number of participants.

Finally, we also want to find out how much it would cost to provide this treatment in the NHS.

2 How the study works

How do we find out whether EMDR helps?

We are hoping to include 380 people in this study. People who are experiencing symptoms of depression will be invited to take part.

People who join the study will receive one of two treatments: half will be offered a course of EMDR (which will include 12-18 sessions of therapy) in addition to usual GP care, and half will continue with usual GP care (which may include referral to other local psychological services). Anyone enrolled in the study can continue to take any antidepressant medication prescribed by their GP as well.

We then ask people about their health at 2, 8, 16, 26, 39 and 52 weeks after they enrol in the study using questionnaires.

How is it decided who gets EMDR?

A computer will choose which treatment you will receive – this is called 'randomisation'. It is a bit like tossing a coin to decide and it means you have an equal chance of being allocated to either continue with usual GP care or to receive EMDR in addition to usual GP care,.

3 Why have I been invited take part?

We have asked local GP surgeries to help us find people who might be interested in the study. You will have received an invitation letter and information leaflet from your GP, either during a consultation, or through the post if you have recently discussed low mood with your GP. You

may also have seen a poster in your GP surgery and discussed this study with your GP.

Your GP practice will **not** pass on your details to EYE-D researchers without your permission.

If you received an invitation in the post, we asked you to complete the reply form and return this to the research team in the prepaid envelope provided or complete the form online using the QR code.

If you are interested in the study, a researcher will arrange a time to explain the study in more detail.

If you decide that you are **not** interested or are unable to take part, it would be helpful if you tell us on the reply slip, or via the QR code, your reasons for declining and whether you would be willing to take part in a brief telephone interview with a researcher about your reasons for declining. A small number of those willing to be interviewed will be contacted by phone. The interview would take up to 15 minutes and would be audio-recorded with your consent. The recording would be typed up (transcribed). We will remove any information such as names from the transcript so that you cannot be recognised from it. The information will help us to understand people's views of the study and any concerns they may have about taking part.

4 What does taking part involve?

Enrolling you in the study

The researcher will check if the study might be suitable for you by asking you some brief questions over the telephone (about any current treatment for your depression; current health; history of difficult or stressful events in your life, and availability to take part). At this point you will be able to ask any questions you might have.

This call will take about 15 minutes.

Who will be eligible to take part?

We are looking for adults who are currently depressed, not already receiving a talking therapy and who are willing to work on the memories of past stressful experiences related to their depression. We can't include people who: are currently receiving treatment from a psychiatrist; have PTSD or complex PTSD, other serious mental health problems such as schizophrenia, bipolar disorder, psychosis, moderate/severe personality disorder, dissociative disorder, or dementia; or who are dependent on drugs or alcohol. We also can't include people who are currently receiving another psychotherapy for depression; have a history of repeated contacts with mental health services or repeated self-harm. In order to take part, you would also need to be willing to receive a course of EMDR delivered by a qualified therapist in-person.

What happens next?

If the study is right for you, and you are interested in going forward, you are invited to an appointment with a researcher. This would either take place remotely (via videocall or telephone) or in-person (at your home, GP surgery, or the University where the research team are based) depending on local availability. Remote appointments will involve completing questionnaires online using your own smartphone, tablet or computer, and speaking to the researcher by videocall or telephone. If you want, you may also bring a trusted friend or family member to support you.

Appointments usually take 1-2 hours. The researcher would explain the study and answer any questions you may have. They will ask you to fill in a consent form to show your willingness to take part. You will then be asked to fill in some questionnaires about your background, health and previous treatment. The researcher will look at your answers and tell you whether you meet the study criteria.

If your answers suggest you are suitable for the study, and you are willing to take part, you will be asked some further questions about your health and to complete some simple computerised tasks online.

One of two treatments will then be randomly chosen for you by computer: either EMDR (in addition to usual GP care), or usual GP care. Taking part in the study will not stop your GP offering or changing your medication, or offering other therapy if this is considered the best thing to do.

5 What treatment will I be offered as part of this study?

This will depend on whether you are allocated to receive 'usual care' or 'EMDR in addition to usual care' as part of the study.

If you meet the study criteria and are one of the people allocated to receive 'usual care', you will continue to receive care from your GP.

If you are allocated to EMDR in addition to usual care, the researcher will arrange for you to start a course of EMDR with one of our study therapists. You will continue to receive your usual GP care alongside this.

The EYE-D therapists are all experienced EMDR practitioners. Each participant who is allocated EMDR will be offered 12-18 individual EMDR sessions with their therapist. Each session will last up to 90 minutes. Therapy will be provided in-person and would take place at your GP surgery, other NHS premises or local University site (depending on local arrangements). The expectation is that sessions will take place weekly. You will be supported by your therapist throughout the process.

EMDR is a type of psychological treatment that works on memories of difficult or stressful experiences. EMDR is one way of helping process these memories so that they become less distressing. **Please scan the QR code below or visit https://eyed.blogs.bristol.ac.uk/participants/ to watch a video about EMDR in the EYE-D study.**

EMDR is a structured therapy that involves a number of different stages. These include thinking about a memory of a stressful past experience while making eye movements from side to side, usually by following the movement of your therapist's finger (or a light bar) as they move it in your line of vision.

This side-to-side motion is called bilateral stimulation. It is not hypnosis; you remain fully conscious throughout. This bilateral stimulation is thought to enhance processing of memories so that they become less distressing, and self-beliefs become more positive.

While you are taking part in the study you will continue to be looked after by your GP, as normal. We will contact your GP to let them know you are taking part. No treatment will be withheld from you during the study.

Invitation to Take Part

You may receive a letter from your GP inviting you to take part

- Please fill in the paper reply form, and return this to the EYE-D research team in the prepaid envelope.
- Or, you can fill this in online using the QR code.
- We ask you to do this if you are interested in taking part in the study or not.

GP Referral

You discussed this study with your GP

- Your GP may have introduced the study to you during a consultation, or you saw a study poster and asked them about it.
- Your GP will have referred you to the study if you were interested in taking part and they thought you'd be suitable.
- They will have confirmed you were happy for them to provide the EYE-D study team with your contact details.

Eligibility Screening

A researcher will contact you via telephone to check if the study might be suitable for you

- They will ask you some brief questions about you, any current treatment for your depression, your current health, any history of difficult or stressful events in your life, and your availability to take part.
- You will be able to ask any questions you might have.
- If the study is right for you, and you are interested in taking part, you will be invited to an appointment with a researcher.

Baseline Appointment

During this appointment (may take around 1 to 2 hours)

- The researcher will explain the study and answer any questions you may have.
- You will fill in a consent form if you are willing to take part.
- You will fill in some questionnaires about your background, health and previous treatment.
- If the study is suitable for you, and you are willing to take part, you will fill in some more questionnaires about your health, and be asked to complete some simple computerised tasks online.

You will be randomly allocated to **either** usual GP care, or EMDR therapy, in addition to usual GP care.

Usual Care

- You will continue to receive usual care from your GP.

EMDR Therapy + Usual Care

- You will be offered up to 18 individual EMDR sessions with a therapist.
- Each session will last up to 90 minutes, and will usually take place weekly.
- Therapy will be provided in-person.

Follow Up (both groups)

- We will ask you to fill in short questionnaires at 2, 8, 16 and 39 weeks, and some longer questionnaires at 26 and 52 weeks after joining the study.
- You may be approached for an interview about your views of EMDR and/or your experiences of taking part in the study.

6 What else will I be asked to do?

Follow-up

You will be in the study for one year. You will be asked to answer some short questionnaires over the telephone or by videocall 2, 8, 16 and 39 weeks after joining the study. This will take about 15- 30 minutes and will be scheduled at a time convenient to you. These will mostly be tick box, multiple choice answers.

You will also be asked to fill in some questionnaires 26 weeks and 52 weeks after joining the study, which will take about 30-50 minutes to complete. These will mostly be tick box, multiple choice answers.

You will meet with a researcher to complete these questionnaires so you will have an opportunity to discuss the study or any questions with them. These appointments will be scheduled at a time convenient to you. These appointments would either take place remotely (via videocall or telephone) or in-person (at your home/GP surgery/local University) depending on local availability.

It is important that we follow-up as many people as possible – both those who are allocated to continue with usual care from their GP and those allocated to EMDR in addition to usual GP care. Only by following up people in **both** groups are we able to find out whether EMDR helps people with depression. Even if you do not receive EMDR as part of the study, we still want to follow you up for one year and find out how you are. This will help us to better answer our research question and will make the results of the study much more useful.

If scheduling a follow-up appointment is difficult for you, the researcher can arrange to collect your answers by post or online.

Participants will be offered a £10 shopping voucher at the 8-, 16- and 39-week follow-ups, and £20 at the 26- and 52- week follow-ups, for each of the corresponding questionnaires completed.

As part of the consent process, we will ask for your permission for us to have access to your medical records in order to collect information on your use of health services and other treatments received during the 12 months of the study. This is optional but giving us permission to collect this information will help us to understand if the therapy has had an effect on how often you see your GP or have other contacts with the health service. If you agree, any information we record will have your name and address removed so that you cannot be recognised from it.

If you receive EMDR, therapy sessions would be audio-recorded and used by your therapist, their supervisor and their trainers as part of supervision for the therapist. We will also ask whether you are willing for these audio-recordings to be used for research purposes. This is optional. If you give permission, a small number of independent EMDR experts would listen to a sample of recorded sessions to check on the quality of treatment provided in the study. Recordings will be deleted at the end of the study.

If you receive EMDR, we will also ask whether you are willing to provide consent for the research team to access your therapy records. This is optional, but giving us permission to collect this information will help us find out more about the types of stressful events worked on in therapy. In addition, we would collect information on depression scores during therapy, ratings of distress related to the memories worked on in therapy, and strength of beliefs during therapy. This will help us understand how EMDR works.

We will not collect detailed information of the event(s).

Any information we record will be anonymised so that you cannot be recognised from it.

(Optional) Interview study

If you are eligible for the study, we may also ask if you would consider being interviewed by a researcher about your views of EMDR and/or of taking part in the study.

If you agree to be interviewed, this would take place remotely (by phone or videocall) at a time that is convenient for you. The interview will take less than 60 minutes and will be audio-recorded with your consent so that we have an accurate record of the conversation. The interview will be typed up (transcribed) by an external, approved transcribing service and the recording will then be destroyed. The external approved transcribing service will have a confidentiality agreement in place, and will not share your information. Only members of the research team and transcribing service will have access to the recorded interview. We will remove any identifiable information such as names from the transcript so that you cannot be recognised from it. The transcript will then be stored for use in future research studies and may be shared with other researchers.

What you say in the interview will not affect the care you receive from your GP or therapist in any way. You will not need to do anything to prepare for the interview.

As we will only interview around 40 of our participants, not everyone will be invited to take part in an interview. Each interviewee would be offered an additional goodwill gesture of a £20 shopping voucher.

7 How is taking part in the study different from usual GP care?

While you are taking part in the study you will continue to be looked after by your GP, as normal. You can see your GP as often as you and they think necessary.

No treatment will be withheld from you during the course of this study.

If you are eligible and allocated to **'usual care'** as part of this study, we will write to your GP to ask them to continue to offer the usual treatments available - this may include antidepressants and/or referral to a local psychological service, depending on your needs and preferences.

Participants who are eligible and allocated **EMDR (in addition to usual care)** will be offered 12-18 sessions of one-to-one EMDR, with an experienced EYE-D therapist.

While GPs can routinely refer patients to psychological services for assessment, available treatments (and waiting lists) will vary depending on the local provider and patient's needs.

Everyone who takes part in the study will be asked to fill in some questionnaires and computer tasks at the beginning of the study, and some questionnaires at the follow-up points detailed in Section 6.

8 Possible benefits and disadvantages of taking part

Possible benefits

Participants will have an opportunity to help us evaluate this new treatment for depression, and we hope they will find this interesting and rewarding. Whether you are allocated to continue with usual GP care or to receive EMDR in

addition to usual GP carely, we hope that this treatment will help you develop ways of managing your depression better, however this cannot be guaranteed.

Possible disadvantages

As with any talking therapy for depression, participants may find EMDR therapy sessions emotionally challenging or upsetting. Our experienced therapists will be able to provide support within the EMDR sessions.

As part of the questionnaires, you will be asked about difficult or stressful events that have happened in your life. You will also be asked about the memories of events that you think might be related to your depression. This will help us to understand how EMDR therapy works. These questions may be difficult to answer. The researchers will also approach the screening appointment and interviews in a sensitive and supportive way. We will be able to contact a study clinician to offer support if necessary.

If there are concerns about your safety, or the safety of others, we may have to inform your GP. Wherever possible we would speak with you before doing this. We would only pass information to your GP without your agreement if we had immediate concerns for your welfare, or the welfare of others (for example, if you told us that you were having thoughts of harming yourself, or someone else)

9 More information about taking part

Do I have to take part?

We will describe the study and go through this information leaflet with you. It is up to you to decide whether or not to take part. If you decide not to take part, you will continue to be looked after by your GP.

If you choose to take part, you are free to withdraw from the study and/or the EMDR therapy at any time, without giving a reason. You can withdraw from the study and/or the EMDR therapy by contacting your local researcher or your EMDR therapist and letting them know. If you withdraw from EMDR therapy, you will be asked if you are still willing to fill in the questionnaires, and/or take part in a qualitative interview. If you withdraw from EMDR therapy and agree to continue filling in the study questionnaires, we will ask you why you withdrew from therapy. If you completely withdraw from the study, you will not be contacted again. This would not affect the standard or type of care you receive from your GP. If you withdraw from the study, we will use the data collected prior to your withdrawal.

What information will be shared with my GP?

We will inform your GP of the outcome of the screening assessment, and whether you have been allocated 'EMDR' or to 'usual care'. We will also inform your GP if you have completed (or withdrawn from) EMDR therapy, or the study as a whole. With your permission, the letter(s) will include some summary scores from your questionnaires, which your GP may find helpful. As mentioned earlier, we would need to contact your GP if there were immediate concerns for your safety or the safety of others.

Will I receive any payment?

Participants who are eligible for the study will be given a goodwill gesture of a £10 shopping voucher for completing the 8-, 16- and 39-week follow-ups, and £20 for completing the 26- and 52- week follow-ups, with a further £20 for taking part in an interview.

What if there is a problem?

If you have a concern about any aspect of this study, including any problems or symptoms from treatment you should ask to speak to the local researcher, Debbie Tallon. Alternatively, you can speak to the Lead Investigator, or the Trial Manager. Contact details are listed in section 10. If a symptom is troublesome, please seek medical help in the normal way by dialling 111 or contacting your GP. In an emergency, please phone the emergency services or attend an Emergency Department.

If you wish to make a formal complaint, the normal NHS complaints process is available to you. Details can be obtained from the Trial Manager listed in section 10. In the event that something goes wrong and 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 against the University of Bristol, (or other University site if you were recruited elsewhere), or the employer of the responsible individual, but you may have to pay your legal costs. Appropriate legal liability insurance is in place. Any reports of misconduct or malpractice will be dealt with according to the University of Bristol's Regulations on Research Misconduct, Preventing harm in research (safeguarding) and Whistleblowing policies.

What will happen to information about me collected during the study?

The research team will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. As explained earlier, members of the research team may access your medical records to collect information on your use of health services during the study, if you agreed to this. Individuals from the University of Bristol and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

We will keep your questionnaire data and any interview transcripts separate from your personal details. We can only link this information together with a secure code.

If you receive EMDR, therapy sessions will be audio-recorded so that the recordings can be used by your therapist, their supervisor and their trainers as part of supervision for the therapist. If you give permission, a small number of independent experts may also listen to a sample of recorded sessions to check on the quality of therapy provided. All recordings will be deleted at the end of the study once they have been assessed.

We will ask whether or not you are willing for the research team to access your therapy records. If you give permission, we will record information on the types of events worked on in therapy, depression scores during therapy, distress related to the memories and beliefs that you worked on in therapy. Any information we record will be anonymised and used for research purposes.

We will use the information we collect to evaluate the efficacy and acceptability of EMDR, to understand how EMDR works and the cost of delivering EMDR in the NHS. Information may also be used to support other research in the future and may be shared anonymously with other researchers.

We will write our reports in a way that no-one can work out that you took part in the study.

How will you use information about me?

We will need to use information from you and your GP for this research project.

This information will include your:

- Initials
- Name
- Contact details
- Medical history relating to depression
- Questionnaire answers

Optionally, this will include your:

- Medical records
- Interview transcripts
- Audio recorded therapy sessions for research purposes
- The type of stressful event(s) worked on in therapy; depression scores during therapy; and ratings of distress related to the memories and strength of beliefs during therapy

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. The University of Bristol is the Sponsor of this research. We are responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Your GP practice
- Coordinating study centres (the University of Exeter and University College London)
- Regulatory organisations

We will keep all information about you safe and secure by:

- Only authorised members of the research team, and those responsible for auditing the research process, will have access to your personal information.
- All information will be held securely and in strict confidence.
- Only authorised members of the research team, and those responsible for auditing the research process, will have access to your personal information.

International transfers

Your data will not be shared outside the UK.

How will you use information about me after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

We will keep anonymised, electronic research data indefinitely.

What are my choices about how my information is used?

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. You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can I find out more about how my information is used?

You can find out more about how we use your information:

- by reading the Health Research Authority leaflet www.hra.nhs.uk/patientdataandresearch

- by asking one of the research team
- by contacting the Trial Manager (contact details are in Section 10)

What will happen to the results of the study?

The results will be published in an academic journal so that health care professionals can see them. We will share our findings with those who are responsible for providing NHS services, and with patient groups and the public. No named information or identifiable information about you will be published in any report.

We will also provide you with a summary of our findings from the study.

Who is funding the study?

This has been funded by the National Institute for Health and Care Research Efficacy and Mechanism Evaluation Programme (reference 160513). This study has **not** received any commercial funding.

Who has reviewed the study?

This study has been reviewed by an independent group of people, called the Research Ethics Committee, to protect your safety, rights, well-being and dignity. The study has been given a favourable opinion by the South West - Frenchay Research Ethics Committee.

10 Contacts for further information

Local Researcher

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Thank you for taking the time to consider taking part in this study.