Development and Feasibility of Augmented Depression Therapy for Complex Depression (ADepT+)

Participant Information Sheet

Summary

- This study aims to test a new talking therapy for depression called **A**ugmented **Dep**ression **T**herapy for comple**x** depression (ADepT+). ADepT+ is specifically designed for people with complex depression: difficulties managing emotions, relationships and/or their sense of self alongside depression.
- The therapy looks at building wellbeing by identifying what is important to you in life and doing things in line with this. Therapy also looks at tackling symptoms of complex depression when they get in the way of this. It involves up to 20 regular, one-to-one therapy sessions over 8 months, followed by up to 5 optional 'booster' sessions the following year. The sessions can be done online, by phone or in person.
- Taking part involves meeting with a researcher to see if the study is suitable for you. If it is, you will either receive the new therapy, or continue with your usual care without receiving the new therapy. This is decided at random and you will have a 50% chance of receiving the therapy.
- Whether or not you receive the therapy, during the time you are in the study (20 months) you will be asked to complete questionnaires at several time points: the information you provide is very important to the study.
- It is completely up to you whether you take part or not. You can choose to leave the study at any time. Deciding not to take part, or leaving the study, will not affect your standard NHS care.
- If you decide to take part, your family doctor (GP) will be informed of your participation in the study

My name is Laura Warbrick and I am looking at a psychological therapy for people with 'complex depression' that is specifically designed for people who experience difficulties managing emotions, relationships and/or their sense of self alongside depression. For some people, complex depression may be linked to difficult or traumatic early life experiences, or a lack of positive early experiences. This project is being carried out in Devon, with the University of Exeter and Devon Partnership NHS Trust.

Sixty people with complex depression will take part in the study. Half of these people will receive the new therapy; the others will continue with their usual care. This is so that we can compare the experiences of people who do, and do not, receive the therapy. Everyone will complete regular questionnaires and speak with our researchers on several occasions.

I would like to invite you to take part in this research. You are being invited because you, or your healthcare professional may have identified 'complex depression' might describe your current experiences. However, before you decide whether or not 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. Please read this information sheet carefully. If you are interested in participating, or you have any questions, please contact us using the details at the end of this information leaflet. Before you choose whether or not to take part, one of our team will go through the information sheet with you and answer any questions you might have. Please do talk to others about the study if you wish.

In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.
Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.
At the end of the study we will save some of the data in case we need to check it and for future, ethically approved research. We will make sure no-one can work out who you are from the reports we write.
The information that follows tells you more about this.

Contents

Part One: Main Details about the Study 5
1.1. The purpose of the study 5
1.2. Your choice whether or not to take part 6
1.3. What taking part involves 7
Part Two: The therapy programme 12
2.1. What does the therapy involve? 12
2.2. What if relevant new information about this therapy becomes available? 13
2.3. What happens when the research study stops? 13
Part Three: Further Supporting Information 14
3.1. How will we use information about you? 14
3.2. Are there any benefits of taking part? 19
3.3. Are there any possible disadvantages or risks of taking part? 20
3.4. Will my GP be informed that I am taking part? 23
3.5. Are expenses covered? 23

3.6. What are my alternatives for treatment? 24
3.7. What will happen if I don't want to carry on with the study? 24
3.8. What if there is a problem? 25
3.9. What will happen to the results of the study? 26
3.10. Who is organising and funding the research? 26
3.11. Who has reviewed the study? 26
3. 12. How have patients and the public been involved in this study? 27
3.13. Contact for further information 27

Part One: Main Details about the Study

1.1. The purpose of the study

Some people struggling with depression have difficulties managing their relationships, emotions and sense-of-self alongside this. Together, this combination of difficulties is known as 'complex depression'. For some people this may have been called personality difficulties or diagnosed as a personality disorder. For some people, complex depression may be linked to difficult or traumatic early life experiences, or a lack of positive early experiences.

Often people with complex depression are told they are too unwell or too 'complex' for standard care in NHS Talking Therapies services; and so are not offered care or don't fully benefit. However, they may also be told they are not unwell enough to receive support in community mental health teams. When this happens, the person is often discharged into the care of their GP and left with little or no support.

Current recommended therapies for depression focus on reducing symptoms, yet people with depression say that building wellbeing is key to recovery. Further, people with complex depression often feel that current therapies are not tailored to their needs. We do not yet have a therapy that is designed to target wellbeing and that is tailored for complex depression.

Our team has been working on developing such a therapy. The long-term aim is to help the NHS to offer a treatment that can support people with complex depression in primary care.

This study is to test out aspects of the therapy and of the research processes in preparation for being able to run a large clinical trial in future. This study cannot give us the final answer on whether the therapy works in general: a larger study is needed for this. However this small study is a necessary step towards a bigger trial.

1.2. Your choice whether or not to take part

You are free 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: signing a consent form shows that you have understood what is involved in taking part and that you freely agree to take part. You can withdraw from the study at any time up to the end of your final assessment for the study. You do not have to give a reason. You can withdraw from the research by contacting any member of the research team by email (adept-plus@exeter.ac.uk); by phone (01392 726101), or by informing them during a research appointment.

A decision to withdraw at any time, or a decision not to take part, will not impact upon your NHS care. In other words it will not affect whether you receive other forms of treatment within the NHS, the standard of care you receive, or your opportunity to participate in future research. Information that you have provided up until the point of withdrawal will still be included in the study, other than the audio-recording of your feedback interview, which you can ask to be deleted up to 14 days after taking part in the interview.

1.3. What taking part involves

Stage 1: finding out if the study is right for you

Once you have had time to read this information sheet, we will speak with you on the phone or using an online video call to check that the study seems right for you. If it looks likely from this that the study is right for you, and you would like to proceed, we will invite you to attend a face-to-face meeting with one of our team, for around two hours. At the appointment the researcher will go through this information sheet with you and – if you are willing – invite you to complete the study consent form. They will then carry out an assessment, including talking about your current and past mood states. The purpose of this part of the meeting is to give you the chance to find out more about the study and to help you and the researcher decide if the study would be appropriate for you.

If the study is appropriate for you and you wish to go ahead, we will ask you to complete some further questionnaires (either during the meeting or at home), asking about how you generally feel, think and act. In order to take part, you will need sufficient English language to be able to complete these assessments and questionnaires, and take part in the therapy (if you are allocated to receive the therapy) without the need for a translator. This is to ensure everyone completes these assessments and questionnaires in the same way, and receives the therapy without the need for a translator.

If you are not eligible to take part in the study the research team will advise you about other sources of support that are available in the NHS and elsewhere. If your eligibility is likely to change during the time that the study is still open, you will have the option to be re-contacted by the research team.

Stage 2: what you will be invited to do if you consent to take part

The flow-chart on the next page shows a participant's journey through the study, to show what happens when.

Before the study:

If you give the research team permission to contact you, they will ring you for a screening call

Meet in person with a member of the research team for a intake eligibility assessment meeting to discuss the study further, give consent to take part, and find out if you are eligible.

Entering the study

If the study is suitable for you and you want to go ahead you will then enter the study.

Have a check-in call (within a couple of days) to see how you are doing and to check if there are any questions about the questionnaires.

Finding out whether or not you will receive the therapy

Within around a week of entering the study we will let you know whether you will receive the therapy, or have usual care.

If you receive the therapy you will be offered up to 20 individual sessions over up to 8 months, plus up to 5 "booster" sessions in the 12 months after that. You will be asked to complete short weekly questionnaires about your mood as part of the therapy.

If you have usual care you will not receive any treatments as part of the study.

Regardless of whether or not you receive the therapy, you will receive information about local and national sources of support, including emergency and crisis support available to you.

Have a check-in call (within a couple of days) to see how you are doing and check if there are any questions about randomisation or next steps in trial.

Eight months after you started the study

You will be invited to complete some of the questionnaires that you completed at the start.

Fourteen months after you started the study

You will be invited to complete some of the questionnaires that you completed at the start. You will be asked to give feedback about taking part, and you may be invited to an interview about your experiences of the therapy (if you received the therapy) and of taking part in the trial.

Twenty months after you started the study

You will be invited to complete some of the questionnaires that you completed at the start, and give feedback about the booster sessions and longer term impacts of the therapy (If you received the therapy).

If you go ahead and take part in the study you will find out whether you will receive the new therapy, or be in the "usual care" arm of the study, where you would continue with your usual NHS care without receiving the new therapy. This is decided randomly, and there is a 50% chance of you receiving the therapy.

The therapy programme involves attending up to 20 individual therapy sessions of therapy over up to eight months, plus up to five "booster" sessions over twelve months. Each session last around 60 minutes. More details about the programme are given in part 2 of this information sheet.

Questionnaires, your feedback and research assessments:

- At the first research meeting we will ask you about: your current mood and also about some of the mood experiences you have had in the past, as well as some other questions to check that the study is a good fit for you.
- If it is, and you choose to continue, you will be asked to complete a set of around 16 questionnaires (including about your current mood and experiences) at four points. These are: at the very start of the study, 8 months after you start, 14 months after you start, and 20 months after you start.
- These can be done at home in your own time, online or on paper. You will also be asked to attend a research meeting where a researcher will ask you questions about your mood, and about any recent significant events that have occurred, such as any medical treatment that you have received. This appointment should take around 35 mins to

complete, and can take place either in person, by phone or video-conferencing.

- In addition to this, if you do receive the therapy you will be asked to complete three weekly questionnaires as part of this; and 4 extra questionnaires every 4 sessions.
- At the end of study you will be invited to give us some written feedback on how you found it. If you received the therapy you will also be asked to give us some written feedback on how you found the therapy.
- If you received the therapy you may also be invited to take part in a more detailed interview with a member of our research team about your experiences of the study. This will last around 1 hour.

In total you will be in the study for up to around 20 months unless you choose to leave earlier.

Audio-recording of Therapy sessions

At the start of the study, you will be asked whether you would be willing for therapy sessions to be audio recorded. This is to allow us to maintain good standards of care and support within the therapy.

If you agree to sessions being recorded you will have the option of your recordings being used only for this study, for additional research studies in which the research team are involved, and for training purposes.

You do not have to agree to all or any of these, and you can change your mind in either direction at any point.

Part Two: The therapy programme

2.1. What does the therapy involve?

Up to 20 individual therapy sessions of an ADepT+ therapy, over up to 8 months, delivered by the AccEPT clinic. The AccEPT clinic is a research clinic that offers novel psychological therapies to adults in Devon. These can be face to face (at the AccEPT clinic, University of Exeter), via online video calls or by phone, according to your preference. Each session will last around one hour, but you can choose for them to be shorter or longer, and you will agree with the therapist things to practice between sessions. There are up to five additional sessions over twelve months after the therapy finishes, to help consolidate what you learned in the therapy.

standard care in the NHS is often Cognitive Behavioural Therapy (CBT), which is recommended by the National Institute for Health and Care Excellence (NICE). However, individuals with depression often report that it can be hard to experience a sense of wellbeing. This is the ability to experience a positive mood, to have meaning and purpose in life, and to feel socially connected with the world around them. People with complex depression often also report that standard care is not tailored to their needs.

We have developed a novel psychological therapy, alongside people with depression and complex depression; that aims to both build wellbeing and alleviate depression symptoms; and is tailored for people with complex depression.

2.2. What if relevant new information about this therapy becomes available?

Sometimes we get new information about the treatment being studied which could indicate unexpected risks or benefits. If there are concerns about the therapy because of this, one of the study team will tell you and discuss whether you should continue in the study. If you decide not to carry on, we will discuss alternative options with you and your referring clinician. If the study is stopped for any other reason, we will tell you and work with local services to identify alternative care wherever possible.

2.3. What happens when the research study stops?

When the research study stops, you will continue to receive your usual NHS care. Because it is part of a research project, the therapy provided within the study will not be available after the end of the study period. We would advise that you talk with your mental health care team or your GP if at this point you would like to pursue further psychological therapy. If you have said you would like one, you will receive a summary of the findings of the study once the entire study is complete.

Part Three: Further Supporting Information

3.1. How will we use information about you?

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

This information will include your NHS number, name and contact details. 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 Exeter is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Only storing personally identifiable information about you where necessary
- Storing information about you either on an encrypted password protected computer, or in a locked cabinet in a secure office at the University of Exeter or Devon Partnership NHS Trust, which can only be accessed by the research team.
- Using a secure online questionnaire system (REDCap) to collect data from any online questionnaires. This system is hosted by an external healthcare technology company who specialise in supporting research of this kind. Please be assured that agreements will be in place with the company and the University of Exeter regarding the protection of your information. To use the system you will need to enter your email address so that the system can send you alerts when questionnaires are due.
- Allocating you a unique participant number, to ensure your information will be protected and cannot be identified outside of the research team.

- Storing any audio recordings of research interviews or therapy sessions separately from information obtained from the research.
- Transcribers who are not members of the research team may help us to type up audio recordings of research interviews: these individuals will sign a confidentiality agreement with the study sponsor. You can change your mind about the making and use of recordings at any time.

Confidentiality will be broken only in exceptional circumstances, for example if it is felt by the researcher or therapist that you or someone else may be at immediate risk, or we need to take action to safeguard someone. In such circumstances we will follow our usual safeguarding procedures. As part of this it may be necessary for us to share some of your information with others, for example your GP, but as far as possible we will do this in discussion with you. Research and therapy audio-recordings will be available only to members of the research team, unless you have given consent for them to be used for other purposes (such as for research in other projects involving members of the research team, or in training of clinicians).

An anonymised database of information collected in the research may be accessed by other researchers. Access to this database will be controlled by the Chief Investigator (Laura Warbrick) and it will not be possible to identify you from the data it contains.

It will not be possible to identify you from the report that we produce about the findings of the study, which will be available to the general public. This may

include quotations from interviews (such as comments about the experience of receiving the therapy) but these will not identify individuals.

If you are allocated to receive the new therapy, you will be referred to a local NHS psychological therapies service in order to receive the therapy there. Information collected about you during your time with the service, including therapy recordings, will be treated in accordance with usual NHS standards concerning care of patients and data protection. Some of the information you provide during your treatment will be shared with members of the study team for research purposes, including weekly measures of mood that you are asked to complete, number of sessions you attended, and therapy audio recordings as described previously.

It is important that your therapist is aware of some of the information you give to the researchers, as this will be relevant to your clinical care. Therefore, once you have been referred to the AccEPT clinic, the research team will pass to your therapist the information you have told them about your current and past patterns of mood, and how this affects your current situation. Your therapist will also liaise with your G.P. and / or mental health team as they usually would in order to request referral information and to inform them that you are receiving care in the service and once you have been discharged.

Whether or not you receive the new therapy, some parts of your medical records held by your therapy service, and the data collected for the study, may be looked at by authorised people (for example from the local NHS Research and Development Service) to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant.

International transfers

We may share data about you outside the UK for research related purposes to:

- Support future, ethically approved research

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Higher Educational Establishments (e.g. universities); or Health services for research purposes only

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- (some of) the countries your data may be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and

confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing

- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website

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.

Your data will be used to support other ethically approved research in the future and may be shared anonymously with other researchers.

We will keep your study data for a maximum of **20** years. All personally identifiable information (including audio-recordings of research interviews) will only be kept for one year after the end of the study. The study data will then be fully anonymized and securely archived or destroyed.

If you agreed to your therapy sessions to be audio recorded for the purposes of this study only, these will be securely destroyed one year after the end of the study (at the point all the study data is anonymised). If you agreed for your audio recordings to be used for additional research studies in which the research team are involved, and/or for training purposes; we will securely store your audio-recordings for a maximum of **20** years. Your audio-recordings will then be securely destroyed. You can change your mind in either direction about the use of your therapy audio-recordings at any point.

What are your choices about how your 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 remove, change or delete data we hold about you for the purposes of the study. 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 you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- our leaflet **www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team

If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information can be obtained from the University of Exeter's Data Protection Officer via the link; https://www.exeter.ac.uk/aboutoursite/dataprotection/dpo/

If you have any concerns about how your data is controlled and managed for this study, then please contact the Sponsor Representative, Suzy Wignall, or Data Protection Officer (contact details at the end of the information sheet).

3.2. Are there any benefits of taking part?

If you take part you have a 50% chance of receiving a new therapy. Although we cannot guarantee any specific treatment benefits, cognitive-behavioural

therapies for people with depression and for people with difficulties managing emotions, relationships and sense of self have been found to be beneficial overall, and the early-stage studies we and have done with people with complex depression suggests that ADepT+ may be a helpful approach.

In addition, whether or not you are offered the therapy, by taking part in this study you are helping to shape the future healthcare of people with complex depression. If we find the therapy and research seem to be acceptable to people, we plan to test whether it works in a future, large trial with the ultimate aim of rolling it out in the NHS if it does seem to be an effective and acceptable treatment.

Taking part in the study will also involve some monitoring of your mood: you are welcome to receive a summary of the information you provide over the study period if you wish.

You will (if you wish) receive an honorarium payment of £20 for taking part in each of the four main assessment points (at the start of the study, and at 8, 14 and 20 months after the start); and the detailed experiences of therapy interview (if you are asked to attend this); a maximum of £100 in total. In accordance with HMRC guidance we do not believe you would be expected to pay tax on these payments, nor should they affect any benefits you claim. If you have any concerns about this please speak to the study team.

3.3. Are there any possible disadvantages or risks of taking part?

Receiving a therapy that is in development

If you take part in this study, you may receive the ADepT+ therapy programme which is focused on building wellbeing, based on cognitive-behavioural

therapy principals. While cognitive-behavioural therapy is recommended for people with complex depression, ADepT+ is not presently recommended for people with complex depression.

This is because there is very little research looking at whether this approach is helpful for this particular issue, hence the need for this study. Nevertheless, previous studies have shown the standard ADepT (not adapted for complex depression) has potential to be helpful for depression generally.

We do not anticipate that this therapy programme will place you at any more risk than you would face if you attended other therapeutic programmes. Our therapists work hard to create a welcoming, supportive and safe environment, including protecting your confidentiality. Naturally some of the material that is discussed during therapy sessions can be emotional in content and you may experience a range of feelings as you go through the therapy programme. If the therapy process opens up subjects or issues which may mean you need further support we will discuss this with you, and work with you to access that support as far as possible.

Being asked some questions about potentially sensitive topics

Some of the questionnaires you will complete as part of the research study ask about personal and sensitive areas (such as your current and past mood, and your typical patterns of thinking and acting). In our experience people have different experiences of completing these sorts of questionnaires, including finding them distressing, interesting, frustrating or helpful. You are free to decide not to answer any question at any time, and you may also contact the researchers if there are parts of the questionnaires, or your reaction to them, that you would like to discuss. Some of the questionnaire sets include a

number of measures and can take a while to complete, however as you complete most of the questionnaires in your own time you can do them in as many sittings as you wish.

Insurance

Insurance companies sometimes require to know about participation in medical research. Before participating in this research, you should consider whether it affects any insurance that you have (e.g. private medical insurance, life insurance), and take advice if necessary.

The University of Exeter has insurance cover in place in case anyone involved in, or taking part in, the study believes that they have been harmed by it.

3.4. Will my GP be informed that I am taking part?

If you take part in this study, with your permission, we would inform your GP that you are taking part. We would also let them know if you are to receive the therapy. It is our standard practice to involve GPs in this way, so that they are aware of what care you are receiving and can take this into account in their work with you. If you receive the therapy the therapists will liaise with your GP in the way they normally would (for example, to let your GP know you have finished the therapy). In addition, your regular care team and / or your GP may be asked to send information relevant to your current and previous care to the AccEPT Clinic providing the therapy to support your treatment there, as per usual clinical practice. Information that you share with researchers as part of the research assessments will be shared with your care team only in circumstances where the researcher is very concerned about you or someone else, such as a report that you or somebody else is at significant risk.

We will follow local NHS Trust procedures about noting your participation in the research project on your electronic patient record.

3.5. Are expenses covered?

We are able to cover reasonable travel expenses to face-to-face research appointments. In keeping with usual practice in the NHS we do not provide travel expenses for attending therapy sessions however some people are eligible to claim these back through the NHS: https://www.nhs.uk/nhs-services/help-with-health-costs/healthcare-travel-costs-scheme-htcs/

3.6. What are my alternatives for treatment?

If you do not take part in this study we would advise you to talk to your clinical care team about the treatment and support options that might be available to you locally.

3.7. What will happen if I don't want to carry on with the study?

You are free to leave the study at any point without it affecting the general standard of care you receive in the health service, or your access to other treatments. If you decide not to continue with the therapy, we will assume you are willing to continue with the research assessments unless you tell us otherwise. Similarly, you may choose not to take part in the research assessments but stay in the therapy (if you are receiving this).

People's circumstances can change whilst taking part in a study like this (e.g. moving house to another area, having a major operation): this may not necessarily affect your eligibility for the study. Please do let the research team know if you have concerns about this. At any point in the study, if the research team believe that you have lost capacity to positively choose to continue with the study (for example, if you were to become very unwell and it affects your ability to make a free and informed choice), they will let you know this, and will pause your involvement in the study. Once you are feeling better they will contact you to see if you would like to continue.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the

information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

3.8. What if there is a problem?

If you have a concern about any aspect of this study you should ask to speak to the researchers, who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can contact the study sponsor which is the University of Exeter (res-sponsor@exeter.ac.uk, 01392 726621).

Address: Research Ethics, Governance & Compliance
University of Exeter
Lafrowda House
St Germans Road
Exeter
Devon
EX4 6TL

If your complaint concerns the NHS service that you are receiving treatment through, you should let them know that you would like to make a complaint through their usual complaints process.

In the event that something does go wrong and you are harmed during the research and this is due to someone‘s negligence then you may have grounds for legal action for compensation against the University of Exeter, but you may have to pay your legal costs.

3.9. What will happen to the results of the study?

The researchers aim to publish the work in an academic journal and to report the findings at academic and clinical conferences. We will also give all patient participants who request one a summary of the results of the research, and will give this summary to the organisations who assisted with advertising our study. Generally, our research is reported on the University of Exeter Mood Disorders Centre website at: http://www.centres.ex.ac.uk/mood. Findings may also be shared in publications for non-academic audiences including relevant voluntary sector newsletters/magazines. Your identity will not be revealed in any report or publication.

The longer-term aim of this research is to inform a larger, future trial of the programme that will be able to say whether or not this therapy approach would be a helpful and affordable addition to the care that is currently available in the NHS.

3.10. Who is organising and funding the research?

The research sponsor is the University of Exeter. The researchers will not obtain any payment for conducting this research above their usual salaries. The study is funded by the National Institute for Health and Care Research (NIHR).

3.11. 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 your interests. This study has been reviewed and given favourable opinion by **East Midlands – Leicester South**

Research Ethics Committee.

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

A group of people from across the country with lived experience of depression / complex depression, or with a relative with complex depression, are involved in various different ways. They have helped to develop this information sheet and also some of the study documents. They have also helped to develop the therapy itself. Throughout the project they will be giving guidance to the research team on how we run the study.

3.13. Contact for further information

If you would like any independent advice about participating in research you can contact Exeter PALS (the local Patient Advice and Liaison Service) at rde-tr.PALS@nhs.net or on 01392 402093, or INVOLVE at www.invo.org.uk/

If you have any further questions please contact the research team at adept-plus@exeter.ac.uk. You may also contact the Chief Investigator, Laura Warbrick, at laura.warbrick2@nhs.net or on 01392 722420

Or for an independent, confidential contact for complaints please contact the Sponsor Representative via res-sponsor@exeter.ac.uk.

The University of Exeter Data Protection Officer (Brenda Waterman) can be contacted at:

The University of Exeter

Compliance, Governance and Risk

Lafrowda House

St. German's Road

Exeter

EX4 6TL

Email: informationgovernance@exeter.ac.uk

Tel: 01392 726842

Thank you for your interest in the project.