Preventing depression study: PERSUADE
Participant information sheet for trial

We invite you to take part in a study

Before you decide, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information and ask us if there is anything that is not clear or if there is more you would like to know. Discuss it with others if you wish. Take time to decide whether or not you want to take part.

The PERSUADE study - the essentials

We are inviting people who have been feeling 'sad' or 'flat' or have 'low mood' to take part in a trial aiming to help with their mood. It has been shown that people with low mood are at more risk of becoming depressed.

We are looking at a new way to support people with low mood to hopefully stop them from becoming depressed. The new support is delivered by a guided workbook and attendance at a one day or two half-day group sessions.

In the study some people will receive the new type of support. Others will continue to get usual care that they can access through the NHS. These people will be selected by chance, like tossing a coin.

The study is being run by the University of Manchester and the information collected will also be used as part of a PhD study by Mel Safari.

What do I do now?

If you want to take part, fill in the contact and consent forms and post them to us in the envelope provided.

Please turn over to read the full information about the study

Contents

How to get in touch with us:

If you have any questions, please contact:

Cassandra Kenning
University of Manchester
M13 9PL
0161 275 7610

Cassandra.kenning@manchester.ac.uk

1 Why are we doing this study?

Depression affects many people worldwide. Treatments for depression have shown limited usefulness and have only led to a 35% reduction of cases of depression, as compared to those receiving no treatment. People with early untreated depression symptoms are at an increased risk of developing persistent depression. We need to develop treatments that can be delivered at a very early stage of the illness thus preventing progression of early symptoms into depression.

Sub-threshold depression is a condition where the person has developed some of the symptoms of stress and low mood but the number of symptom, and their severity, is lower than the threshold that we would use to diagnose someone with depression. We want to recruit people who have these sub-threshold symptoms for depression and work with them to try and reduce those symptoms in order to reduce the likelihood of them developing depression.

2 Why am I being asked to take part?

You are being asked because you have either been referred by your GP or have identified yourself as having low mood.

We aim to recruit 64 people to the study.

It is entirely up to you whether or not you decide to take part. Taking part is voluntary.

3 What will happen to me if I take part?

If you are interested in taking part, you will need to let us know either by phone, email or by returning the contact form. A member of the research team will then contact you to ask you a few questions to make sure this study is right for you.

You will be asked to complete a short survey, **taking around 30 minutes**, about how you are feeling and your current health. If you do not meet all the criteria for inclusion or do not wish to be randomised to the study the information taken at screening will be destroyed securely.

If you complete the consent form and are accepted into the trial, you will then be told which group you have been randomly assigned to.

- **Group 1** will continue to get the care they would usually receive from the NHS.

- **Group 2** will be given the new type of support as well as the usual care provided by the NHS.

We can't offer everyone the new type of support, so these people will be selected by chance, like tossing a coin.

For those people that go into group 2, they will be invited to a group intervention session at a convenient community location. The session will last up to 8 hours or can be split over 2 half day sessions. The session will be delivered by a specially trained voluntary sector worker and you will receive a workbook to help you. Sessions will be audio-recorded to assess how well the facilitators deliver the sessions. These will only be listened to by the research team and will not be transcribed.
Travel costs for attending the sessions will be reimbursed. All receipts/tickets will need to be presented to claim monies back.

After 12 weeks, everyone from both groups 1 and 2 will be asked to complete another survey to see how their mood has changed in that time.

We will also ask a few people to take part in an interview at the end of the study to talk about their experiences and to see what they thought

of the support. You can indicate on the consent form if you would consider taking part in an interview. All interviews will take place over the telephone and with consent, be audio recorded and then transcribed by the research staff. **Interviews will take around 45-60 minutes.** Anonymised quotes may be used in publications arising from this study.

4 Do I have to take part?

No, it is completely up to you whether you take part. If you decide not to take part, you will receive your usual care from your care team. No other aspect of your care will be affected.

If you decide to take part, you can still change your mind at any time, without giving a reason. The data that has already been collected will continue to be used confidentially in connection with the purposes for which consent is being sought.

5 Possible benefits and disadvantages

We cannot promise that taking part will help you personally. However, the information we get from this study may help us improve support for people with low mood.

We are not aware of any side effects, disadvantages or risks to you for taking part in this research.

6 More information about taking part

Who is running and funding the study?

This study is being run by the University of Manchester. The research has been funded by the National Institute for Health Research.

All people who take part will get access to a summary of the results. You can also request copies of any published data by contacting the study co-ordinator.

All research in the NHS is looked at by an independent body, called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This research has been reviewed and approved by XXXX. (Ref:XXX).

Confidentiality

Data will be stored on an encrypted hard drive and only loaded onto a secure server. Access to confidential research information including any recordings is restricted to the research team. Participant consent forms will be stored in a locked office by the principal researcher. All computers in use will be password protected; if data is transferred it will be done electronically via an encrypted USB memory stick. Recordings will be destroyed after transcription which will be done by a member of the research team.

Individuals from the University of Manchester, NHS Trust or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data but all individuals involved in auditing and monitoring the study, will have a strict duty of confidentiality to you as a research participant.

Any information you provide to us in the PERSUADE study will be treated in confidence. If you consent, your data might be used, anonymously, in future studies. Your data will remain completely anonymous. Any identifying information will remain confidential. Participant numbers will be used to store study data and the information will be stored securely at the University of Manchester.

When we publish the results of the study, your name will not be mentioned and we will ensure that no-one taking part can be identified from the study results. If you decide to stop taking part in the study, the information you had provided up to that point would be used.

All information related to this study will be kept for 10 years at the University of Manchester.

What if there is a problem?

Insurance:
In the event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against The University of Manchester or NHS but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Minor complaints:
If you have a minor complaint then you need to contact the researcher(s) in the first instance. Contact **Dr Cassandra Kenning**
Tel: 0161 275 7610 or Email:
cassandra.kenning@manchester.ac.uk

Formal Complaints:
If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact the
Research Governance and Integrity Manager,
Research Office, Christie Building,
University of Manchester, Oxford Road,
Manchester, M13 9PL,

by emailing:
research.complaints@manchester.ac.uk

or by telephoning **0161 275 2674 /2046**.