A Study of

Trauma-Focused Online Guided Self Help Versus Trauma-Focused Cognitive Behavioural Therapy For Post-Traumatic Stress Disorder

PARTICIPANT INFORMATION BOOKLET

RAPID

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Pragmatic RAndomised Controlled Trial of a Trauma-Focused Guided Self Help Programme versus InDividual Trauma-Focused Cognitive Behavioural Therapy for Post-Traumatic Stress Disorder (RAPID)

We would like to invite you to join the RAPID research study set up by Cardiff University. We are carrying out a study comparing two treatments for Post-Traumatic Stress Disorder (PTSD). One is conducted face-to-face with a therapist and the other is conducted online with some support from a therapist. Our goal is to find out if they are equally effective at helping people with PTSD. Our results will inform the NHS about which treatments to recommend.

Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

If anything is not clear, or if you would like more information, please contact the study team using the details below.

You will also have an opportunity to ask questions at your first assessment with our researcher.

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

Contact Details—RAPID Trial Manager
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Why is this study needed?

Trauma-focused talking therapies such as Trauma-Focused Cognitive Behavioural Therapy have been shown to be effective for helping people with PTSD. Unfortunately, there are not enough trained NHS therapists to deliver this treatment and waiting times are often long.

To make access to treatment quicker and easier, we have developed an online guided self help programme. The programme is based on trauma-focused therapy and combines some online sessions at home with regular guidance meetings with a therapist. A number of people with PTSD have completed the programme and have found it to be an acceptable and useful alternative to face-to-face therapy.

We now need to compare the online programme with regular face-to-face therapy in a large study to determine whether it is equally effective at helping people with PTSD. Similar treatments seem to be effective for depression and other anxiety disorders. If it proves to be an effective treatment, it could significantly shorten waiting times for PTSD treatment in the NHS.

Why have I been asked to take part?

The RAPID study aims to recruit nearly 200 people with PTSD following a single traumatic event, across England and Wales. You have been invited to take part because you have PTSD following a single traumatic event and are attending one of the clinics taking part. The rest of the booklet details what taking part would involve, if you chose to join the study.

What therapy will I receive?

You will be allocated to receive either Individual Trauma-Focused Cognitive Behavioural Therapy OR Trauma-Focused Online Guided Self Help.

You will be allocated by a process called **'randomisation'**. This means a computer programme will be used to decide which therapy you will receive and you will have an equal 50:50 chance of being allocated to either group. You or your clinician will not be able to choose, therefore if you agree to take part, it is important that you would be happy with either treatment. This is because at the moment, we do not know which treatment would suit you best.

Trauma-Focused Cognitive Behavioural Therapy (TFCBT)

TFCBT is one of the current recommended talking therapies for PTSD. It involves meeting with a trained therapist once a week for up to 12 weeks. The meetings will last for about 60-90 minutes and you will work with the therapist to identify how the traumatic event has affected your thinking. You will be helped to develop skills to deal with negative thoughts and triggers that now cause you difficulty and make you feel anxious. Your therapist will ask you to complete some tasks between sessions.

Trauma-Focused Online Guided Self Help (GSH)

The GSH programme is based on TFCBT. Before you start the programme, you will meet with a trained therapist who will talk to you about your symptoms and show you the programme. This will last about 1 hour. You can then follow the programme online in your own time on your computer, laptop, tablet or mobile phone. There are 8 steps based on trauma focused cognitive behavioural therapy which will teach you more about PTSD and interactive activities to complete. The programme will last 8 weeks, and during that time you will have fortnightly contact (either face-to-face or on the telephone) with your therapist. This is to discuss your progress and tackle any problems and will last about 30 minutes. It is up to you how much time you dedicate to the programme.

What does taking part in the study involve?

Taking part in the RAPID study will involve:

- Completing a **short telephone assessment** with a researcher to check that you are suitable for the study. This will include some questions about your symptoms, at a time to suit you and will last around 20 minutes.

- If you are suitable, you would be asked to **monitor** your own symptoms for 2 weeks using a simple diary. If after 2 weeks, you still have significant symptoms, you will be asked to continue with the next steps of the study.

- Completing a **face-to-face assessment** with a researcher. This could be conducted in the research clinic or in your own home, at a time to suit you and will take around 60-90 minutes.

- Taking part in **treatment**; either the 8 week online Guided Self Help or the 12 week face-to-face therapy.

- Completing **follow-up assessments** at 16 weeks after you first started treatment and again at 52 weeks. These can be conducted in the clinic or in your own home, at a time to suit you and will last around 1 hour.

- A proportion of people taking part will also be asked to complete an **interview** with a researcher before they start treatment and after they have finished treatment. This is to help us understand people's views of the two treatments. With your permission these will be audio recorded to help the interviewer remember what you say. We may use direct quotes from the interviews but these will be anonymous.

- The meetings with your therapist may also be audio recorded. This is so we can supervise the therapist and check the therapy is being delivered as planned. The recordings will be kept confidential and what you say will not be shared. The only time we will share what you tell us is if you advise us of a possible risk of harm to yourself or others, in which case we would need to inform your GP or other qualified person.

What are the possible benefits of taking part?

TFCBT is a standard treatment for people with PTSD and can improve symptoms. GSH has also been shown to be useful for people in previous studies and may help you.

You will also be helping to find out if GSH is a suitable and accessible treatment for people in the future, which may help to reduce waiting times for treatment.

Are there side effects or risks to taking part?

There are no known side effects or risks to either the TFCBT or GSH, although some people may find that addressing their experiences can be upsetting. You will be monitored throughout your treatment by your therapist who will provide support as required if you do experience upset. You are also free to leave the study at any time if you would like to do so.

Do I have to take part?

No, it is completely up to you. If you decide to take part you will be asked to sign a consent form to say that you have read this information and are happy to join the study.

What will happen if I do not want to carry on with the study?

The study will be most helpful if people who join are able to continue their treatment and assessments through to the end. Therefore it is important to discuss any concerns you have with a member of the research team before you agree to join. But of course, once you have joined, you are free to leave at any time without giving a reason. This will not affect your usual NHS/clinical care.

How will information about me be kept confidential?

If you decide to join the study you will be given a unique number to identify you. All of your assessment and treatment data will use this number and will not include any personal identifiable data. All data will be stored on a restricted access database and in accordance with the Data Protection Act 1998. No individual will be able to be identified in any publications that result from the study.

Will my General Practitioner (GP) be told that I am taking part?

With your permission, we will let your GP know that you are taking part.

What will happen to the results of the research study?

We hope that the results of the study will help to inform the future care of people with PTSD. We will present the findings at conferences and in academic journals and will discuss them with voluntary organisations and NHS commissioners. We will send you a copy of the findings. We would also like to store your details on the National Centre for Mental Health PTSD register, so that we can contact you about future research. There is further information on this at the end of the booklet.

What if I have concerns or something goes wrong?

If you have a concern about any aspect of the study, you should speak to the researchers who will do their best to answer your questions (see inside front cover). If you remain unhappy and wish to complain formally about the research, you can do this by contacting James Walters at Cardiff University on 02920 688434 or waltersjt@cardiff.ac.uk.

The risk of anything going wrong or of you experiencing any harm as a result of taking part is minimal. In the very unlikely event this occurs and this is due to someone's negligence, then you may have grounds for legal action for compensation, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

Will I receive travel expenses?

You will receive travel expenses to attend the research (but not therapy) appointments. You will also receive a £10 shopping voucher at the 16 week and 52 week assessments as a thank you for your time.

Who is organising and funding the study?

The RAPID project is funded by the National Institute for Health Research's (NIHR) HTA Programme. They have awarded the money to Cardiff University, who are sponsors for the study.

Who has approved the study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee. They are there to protect your safety, rights, wellbeing and dignity. This project has been reviewed and given a favourable opinion by Wales REC 3.

What Next?

It is likely that you will have made an appointment with one of our researchers to complete the first assessment. They will ask you some questions about your symptoms. If you are suitable for the study, they will explain the next steps. If you do not yet have an appointment and would like to take part, please contact the research team to express your interest (see inside front cover).

Additional Information

Joining the National Centre for Mental Health (NCMH) Cohort

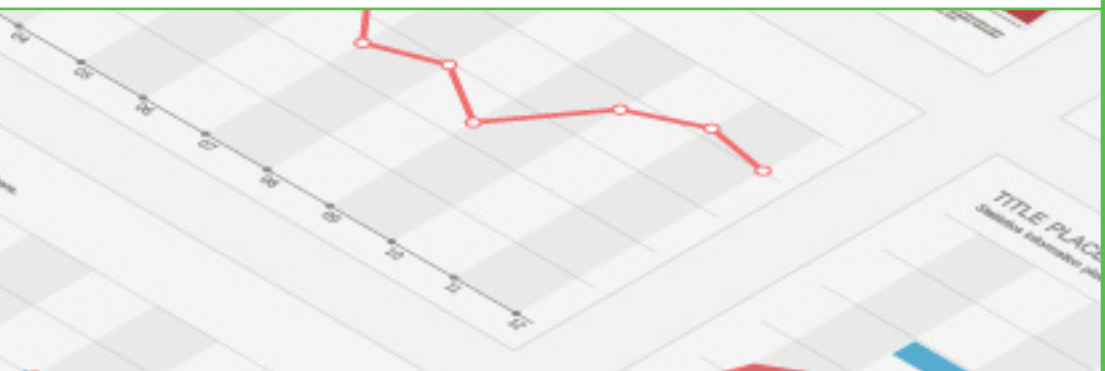
In addition to the main study, we would like to tell you about the National Centre for Mental Health (NCMH) to see if you would like to join their cohort. The NCMH is made up of researchers from Cardiff, Swansea and Bangor Universities. They are working to find out more about what causes mental health problems such as depression, bipolar disorder, schizophrenia, ADHD and PTSD.

What is the NCMH Cohort?

Researchers at the NCMH are trying to understand why some people experience problems with their mental health in order to improve understanding of conditions such as PTSD and help find better treatments in the future. The researchers aim to invite several thousand people to join the NCMH cohort and we would be grateful if you would like to help.

What would it involve for me?

Joining the NCMH cohort will not require you to do anything in addition to the main study. We will simply share the information collected through the main study with researchers at the NCMH. They will keep this information strictly confidential. They may contact you in the future with updates about the research and may invite you to complete some further questionnaires or give you information about other studies that you may want to take part in, but there will be **no obligation** for you to get involved with these future opportunities.



What data will NCMH use?

They may look at your medical records in strict confidence to gain further details about the kind of symptoms and treatments you have had. The information you provide in the main study may be linked anonymously to routinely collected data, for example, general practice records or hospital records. This is called data linkage.

All data linkage is undertaken in line with the Data Protection Act (1998) and University Governance. The information collected through this study may also be shared anonymously with other researchers, but the NCMH will never pass on personal/ identifying information (for example, your name, address, date of birth).

Do I have to join the cohort?

No, you do not have to join the cohort to take part in the main study. However, if you do join, we are able to get more from the data you share with us in the main study.

Can I withdraw form the cohort?

If you choose to join the NCMH cohort and change your mind in the future, you can withdraw by contacting the RAPID research team.

What Next?

When you attend your first appointment for the main study, the researcher will ask you if you would also like to be added to the NCMH cohort. You can opt in or out at this time and it will not affect your ability to take part in the main study or your usual clinical care.

If you would like to find out more you can contact the RAPID team (details on the front cover).

My Questions

You can use this space to note down any questions you have about the study and use them as a prompt at your first appointment.

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