The University Of Sheffield.

StratCare Trial:

Pragmatic randomised controlled trial of a stratified care model for depression and anxiety

You are invited to take part in a research project. Before you decide whether or not to participate, it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully and ask us if anything is unclear or if you would like more information.

What is the study about?

People with depression and anxiety problems can access stepped care psychological interventions in the NHS, which usually start with low intensity treatments, followed by high intensity treatments for patients who need ongoing help. One major problem with stepped care is that patients with more complex clinical presentations are less likely to benefit from low intensity treatment and they tend to drop out early, or deteriorate by the time they access high intensity treatments. Recent studies suggest that using "stratified care" could improve treatment outcomes, by matching patients to specific treatments. StratCare is a model that involves recommending either low or high intensity treatments, on the basis of the complexity of the patient's clinical presentation. Complexity is assessed using an evidence-based model that combines demographic, personality and diagnostic information.

In this clinical trial, we will randomly assign some psychological therapists to an experimental group, and others to a control group. All participating therapists will use an online tool called the StratCare App, in which they will input some information about the patients that they screen in routine care. The StratCare App will provide a personalised treatment-matching recommendation to therapists in the experimental group, but no recommendation will be provided to therapists in the control group. In this way, we will be able to assess if the StratCare treatment recommendations are any different to the recommendations made in routine care, and if they help to improve treatment outcomes.

Why have I been chosen?

All qualified psychological therapists who carry out routine screening contacts in the IAPT service are invited to take part. We are aiming to recruit at least twelve therapists.

Do I have to take part?

Participation is voluntary. If you do decide to take part after reading this information sheet, please complete and sign the attached consent form. You can withdraw from the study at any time without any negative consequences, and you do not have to give a reason. If you wish to withdraw from the research, please use the contact details at the end of this form.

What will happen if I take part? What do I have to do?

You will be invited to attend a training day where you will learn how to use the StratCare App. After the training day, you will enter some fully anonymised information into the App every time you screen a new patient, which only takes about 3 minutes. If you are in the experimental group, the App will provide a treatment recommendation which you will discuss with your patients. If you are in the control group, all you have to do is enter and store data into the App every time you screen a patient. It's all very simple and quick. You will be doing this for one year, and we will also ask you to complete a brief online survey once during the study to gather some basic (fully anonymised) information about your role and how you make treatment recommendations in routine care.

What are the possible advantages, disadvantages and risks of taking part?

Whilst there are no direct benefits for therapists participating in the study, your participation will help us to learn if using stratified care improves clinical outcomes for patients accessing IAPT services. We do not expect that taking part in the study will lead to any disadvantages or risks to therapists or to any patients.

Will information collected in the study be kept confidential?

All the information that we collect about you and your patients will be entirely anonymised, making it impossible to personally identify anyone. Information will be kept strictly confidential and will only be accessible to members of the research team. If you agree to us sharing the anonymised information you provide with other researchers (e.g. as a data archive), no personal details will be included.

What will happen to the data and the results of the research project?

The researchers will link the screening data stored in the StratCare App with fully anonymised clinical care records for patients accessing the IAPT Service. We will apply statistical analyses to compare clinical outcomes (e.g. depression symptoms, dropout rates) between two groups of patients; those assessed by therapists in the experimental and control groups. Our results will be communicated to the IAPT Service in a summary newsletter. We will also communicate our results through publications in scientific journals and presentations at conferences.

The research team will store the study data for 10 years. If you consent to this, we may share fully anonymised data with other researchers, which is considered good practice according to new trends in open and transparent scientific research. This data sharing policy ensures that other independent researchers can verify the authenticity and quality of new research (e.g. through systematic reviews of clinical trials), and also ensures that new scientific findings can be made through the re-analysis of data.

Who is organising and funding the research?

The study is led by the University of Sheffield and partly funded by a technology company called MindLife UK. The University of Sheffield is responsible for collecting all study data and for ensuring that it is used properly.

Does the study have ethical approval?

This study was independently reviewed and approved by an NHS Research Ethics Committee (Ref: 18/WS/0114).

What if something goes wrong and I wish to complain about the research?

If you wish to discuss the study or make a complaint you can contact the Principal Investigator.

Legal statement under the General Data Protection Regulation (GDPR)

The University of Sheffield is the sponsor for this study based in England. We will be using anonymized information from you and from your service's clinical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. We will not keep identifiable information; but anonymized information about you and patients that you assess during the study will be kept for 10 years after the study has finished until 2028. 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 not gather or keep any identifiable information.

Information obtained from you or obtained from clinical records will not identify any individuals and will not be combined with other information in a way that could identify individuals. The information will only be used for the purpose of health and care research, and cannot be used to contact or to affect the care of any individuals. It will not be used to make decisions about future services available to you, such as insurance.

You can find out more about how we use your information by contacting the Chief Investigator.

Contact details

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Thank you for taking time to consider participating in this study.