StratCare Trial: information sheet

The IAPT Psychological therapy service is taking part in a study called **StratCare**. This information sheet explains what this study is about, how IAPT patients' information will be used, and how you can opt-out of the study if you wish to.

What is the study about?

People with depression and anxiety problems can access psychological therapies in the NHS. These treatments are organised in a "stepped care" model, usually starting with brief (up to 8 weeks) low intensity treatments, followed by high intensity treatments (up to 20 weeks) for patients who need ongoing help. Recent studies suggest that using "stratified care" could be a good way to offer therapies, by matching patients to specific treatments. StratCare is a model that involves recommending either low or high intensity treatments, on the basis of each patient's unique problems and life circumstances.

In this clinical trial, some therapists are using the usual "stepped care" method of recommending treatments, and other therapists are using the StratCare method. We have set up this study to find out if there are any differences in the effectiveness of treatment between the stepped care and StratCare method. This means that the treatment that was recommended by your therapist might be guided by current best practice guidelines (stepped care) or the new StratCare method. Either way, you will have been offered an appropriate treatment option available in the IAPT service, and your therapist will have discussed the options with you before recommending a treatment.

Why have I been chosen?

The IAPT therapist that assessed you is participating in the StratCare study. All patients going through routine assessments are included in the research, because the study investigates different ways to offer available treatments to new patients.

Do I have to take part?

You will be asked to provide verbal consent to be included in the study when you first contact the IAPT service. You can also refuse to take part without any consequences to your treatment in the service. 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?

After you provide verbal consent, there is nothing else that you need to do. The research team will collect fully anonymous information about your treatment from an NHS database to see how you got on with your treatment.

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

Your participation will help us to learn if using the StratCare method helps us to make better treatment recommendations 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. The only difference between usual "stepped care" and StratCare is that the StratCare method uses a computer programme to work out which treatment might be helpful for each patient. The computer programme requires therapists to enter some information about diagnosis and symptoms, and this does not use any personally identifiable information (like name, address, date of birth).

Will information collected in the study be kept confidential?

All the information that we collect about IAPT 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.

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

The researchers will apply statistical analyses to compare clinical outcomes (e.g. depression symptoms) between two groups of patients; those assessed by therapists who follow standard "stepped care" guidelines and those who use the

StraCare method. 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. 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, 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 anonymised 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 anonymised information about you 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.

If you want to find out more about how we use your information, or if you wish to withdraw your information from the StratCare study, please contact the Chief Investigator.

Contact details

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