

**Enhancing the quality of psychological interventions delivered by telephone (EQUITY):
A cluster randomised trial of a service quality improvement intervention**

Questionnaire Study

Information about the research

You are being invited to take part in a research project that aims to improve the quality of care of psychological interventions delivered by telephone. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve.

Please take time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

ABOUT THE RESEARCH

➤ **Who will conduct the research?**

The research will be conducted by Kelly Rushton and Cintia Faija, researchers from the School of Nursing Midwifery & Social Work, The University of Manchester. Please note that researchers from other institutions are collaborating with us, i.e. Janice Connell (University of Sheffield).

➤ **What is the purpose of the research?**

Telephone treatment is one of the recommended 'Improving Access to Psychological Therapies (IAPT)' services offered by the NHS to help people with common mental health problems (anxiety, depression). However, despite a strong evidence, a significant number of people are not starting or finishing telephone treatment, meaning they are not getting all the help they need/could get.

This is a five-year research programme aiming to enhance the way that psychological interventions are delivered over the telephone. The name of the research programme is **EQUITY** and it started in April 2018. As part of our research, we developed an intervention package that aims to help services to improve the quality of telephone treatments. The EQUITY intervention package includes three components:

- 1- Professional training to enhance the delivery of telephone treatment,
- 2- Information resources to help patients understand what telephone-delivered treatments are like and what's involve
- 3- Guidelines for services to promote and sustain telephone work.

Services do not follow up patients after discharge. We are contacting you because we are interested to know how you are doing over time after the end of your treatment. We would like to invite you to complete a few questionnaires to explore how you are feeling and to know about your telephone treatment experiences.

➤ **Why have I been chosen?**

You have been chosen because you are 18 years or over and have recently been referred to/received telephone treatment from an IAPT service for a common mental health problem (anxiety, depression).

➤ **How many patients are we intending to recruit?**

We intend to recruit 26 services and an average of 100 patients per service.

➤ **Will the findings of the research be published?**

At the end of the research, the findings will be made available in reports, academic papers and/or online (e.g. research website, research blog). A summary of the findings will be sent to you if you provide consent for us to do so. When we write up the results, all personal details will be removed so that no-one will know who you are.

➤ **Disclosure and Barring Service (DBS) Check**

All researchers involved in this programme have undergone an appropriate level of DBS check.

➤ **Who has reviewed the research project?**

This study has been reviewed by an independent group of people, called the Research Ethics Committee, to protect your safety, rights, well-being and dignity. The study has been given a favourable opinion by North West - Preston Research Ethics Committee (REF: 21/NW/0218).

➤ **Who is funding the research project?**

This study is organised and sponsored by the University of Manchester. The funder is the National Institute for Health Research.

WHAT WOULD MY INVOLVEMENT BE?

➤ **What would I be asked to do if I took part?**

If you decide to take part, we would like to invite you to complete a few short questionnaires at 6 and 12 months after you finished your treatment. Specifically, you will be asked to complete 5 questionnaires at your 6 months follow-up, and 4 questionnaires at your 12 months follow-up.

The completion of the questionnaires will take around 15-20 minutes. The questionnaires will ask you about:

- your mood (e.g. feeling tired or little energy, feeling nervous)
- your health (e.g. mobility, self-care)
- the relationship with your psychological wellbeing practitioner (e.g. support, partnership)
- the use of services (e.g. hospital, A&E, GP surgery, community)

If you decide to take part, you will receive an email with a link to complete the questionnaires **online**. If you require any support to complete the questionnaires, we would be happy to assist you and we would complete the questionnaires with you over the **telephone**.

➤ **Will I be compensated for taking part?**

You will receive a £5 gift voucher each time you complete each set of questionnaires as a thank you for taking part.

➤ **What happens if I want to take part?**

It is up to you to decide if you would like to take part or not.

If you do decide to take part, you should keep this information sheet in a safe place and do one of the following:

If you have any questions and would like to speak to a member of the research team before you consent you can:

1. Complete the consent-to-contact form online or return it by email to Kelly Rushton - equityresearch@manchester.ac.uk
2. Or, if you have spoken to a practitioner about the study, you can ask them to pass your contact details to the research team

If you do not have any questions, you can provide consent to take part in the study without making contact with the research team by completing the online consent form (via the link provided).

If you do not wish to provide consent online, you can let the research team know (equityresearch@manchester.ac.uk) and they will contact you to audio-record your verbal consent.

If you decide to take part, you will be asked to consent to two things 1. To complete the questionnaires at 6 and 12 months after your treatment; and 2. To us contacting your IAPT service provider to gain access to the data from responses to questionnaires that you completed as part of your telephone treatment. This will include answers to questionnaires you complete at sessions and details about you (such as your age, gender, ethnicity, health problems and employment status). Having access to this information will allow us to explore how you were doing during the course of your treatment and compare this over time. We will only ask for your responses to the questionnaires, no information about your personal difficulties/experiences or what you discussed with your practitioner during the sessions will be provided. For us to be able to do this, we will ask you to provide your date of birth after you have consented to take part in the study.

➤ **What happens if I change my mind?**

If you decide to take part but you change your mind later, you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part, you do not need to do anything further.

If you change your mind about taking part, you have up to two weeks to withdraw your data. If you withdraw your data, we will destroy your data and no one will be able to look at your data again after you have changed your mind.

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. To safeguard your rights, we will use the minimum personally-identifiable information possible (e.g. contact details).

You can find out more about how we use your information by contacting the Programme Manager, Judith Gellatly (email: judith.l.gellatly@manchester.ac.uk).

➤ **What are the possible advantages and disadvantages of taking part?**

Although we cannot promise the study will help you personally, the information you provide might help improve the quality of telephone treatments for IAPT patients in the future.

Occasionally, people can feel upset completing the questionnaires if they think about something distressing that has happened to them. If this happens, you may like to make use of the support services listed at the end of this information sheet or you may wish to contact the Programme Manager for this study: Judith Gellatly (email: judith.l.gellatly@manchester.ac.uk).

In the unlikely 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 the NHS Trust providing your care but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

DATA PROTECTION AND CONFIDENTIALITY

➤ **What information will you collect about me?**

In order to participate in this research project we will need to collect information that could identify you, called “personal identifiable information”. Specifically we will need to collect:

- Your contact details: name, address, phone number and/or email address (pending on your preference mode to be contacted)
- Date of birth – so we can link the questionnaire data we collect from you as part of the study to the questionnaires you completed as part of your telephone treatment.

You will be asked to provide consent by returning the consent form provided via **email/online** or you can contact the researcher directly (Kelly Rushton, equityresearch@manchester.ac.uk) and your verbal consent will be audio-recorded using an encrypted audio recorder (this will involve the recording of your voice only). Please note that you will be asked to provide consent to contact your IAPT service provider to gain access to the responses of the questionnaires you completed as part of your telephone treatment.

➤ **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law, which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

➤ **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including the audio recording if you provided verbal consent.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](http://documents.manchester.ac.uk/display.aspx?DocID=37095) (<http://documents.manchester.ac.uk/display.aspx?DocID=37095>).

➤ **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

Only EQUITY study team at the University of Manchester, the Manchester Clinical Trials Unit (CTU) and those at other universities involved in the EQUITY study (i.e. University of York, University of Sheffield) with the necessary approvals will have access to your contact information and questionnaire responses. Your name and any other identifying information such as date of birth, will be removed from the responses you provide and replaced with a random ID number. Only EQUITY study team at the University of Manchester, the Manchester Clinical Trials Unit (CTU) and those at other universities involved in the EQUITY study will have access to the key that links this ID number to your personal information. Your personal details will only be used to contact you about this research project and to provide you with a summary of the research findings when it is complete (if you indicate that you would like us to do so).

If you provided verbal consent, the audio recording of your verbal consent will be transferred to a secure University server and it will be labelled with an assigned ID number.

All documents (such as your consent form) will be stored on a password-protected encrypted University server. After the end of the EQUITY programme, all documents will be sorted in an approved electronic storage facility. Your consent form will be retained for 7 years after the study has finished and will then be destroyed. Identifiable data such as date of birth will be permanently deleted at the end of the study.

There may be occasions where researchers of the team working at the other universities may help to collect or analyse data. If they do, the data that is collected will be securely transferred electronically in an encrypted format or in person and will be stored as detailed above as per the University of Manchester research storage and transfer guidance.

When you agree to take part in a research study and with your informed consent, the information about you will be shared with researchers running other studies here or at other organisations. The future research will be of a similar nature to this research project and will concern improving mental health services for people experiencing mental health problems. Your information will only be used in order to support additional research in accordance with the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) (<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>).

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of such research, and cannot

be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you.

Your answers are completely confidential. The only exception to this would be if you share something with us which reveals that your safety or the safety of others is at risk of harm. In this case, we may be required to act on this information but we would not do this without involving you in the process. If, from your responses, we have any other concerning issues, we may need to report this to an appropriate level, such as IAPT service/GP/care team/family member.

If, during the study, you disclose information about misconduct/poor practice, we have a professional obligation to report this and will therefore need to inform your IAPT Service/professional body.

If, during the study, you disclose information about any current or future illegal activities, we have a legal obligation to report this and will therefore need to inform the relevant authorities.

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.

If you would like more general information on how researchers use data about patients, please visit: www.hra.nhs.uk/information-about-patients/

What if I have a complaint?

➤ Contact details for complaints

If you have a concern about any aspect of this research project you should ask to speak to the Programme Manager, Judith Gellatly (email: judith.l.gellatly@manchester.ac.uk) or one of the Lead Investigators, Penny Bee (email: penny.bee@manchester.ac.uk) who will do their best to answer your questions.

If you have a complaint, then you need to contact the researcher(s) in the first instance:

Kelly Rushton
The University of Manchester
Division of Nursing, Midwifery and Social Work
Jean McFarlane Building
Oxford Road
Manchester M13 9PL

Email: equityresearch@manchester.ac.uk

Formal complains

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact:

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner's Office about complaints relating to your personal identifiable information](https://ico.org.uk/make-a-complaint/) (<https://ico.org.uk/make-a-complaint/>). Tel 0303 123 1113

ADDITIONAL INFORMATION:

ABOUT COVID-19

➤ **Is it safe to take part in this research project considering the COVID-19 pandemic?**

Due to the current COVID-19 pandemic, we have made some adjustments to the way in which this research project will be conducted, ensuring we are adhering to the latest government advice as well as taking all reasonable precautions in terms of limiting the spread of the virus. Therefore, as mentioned above, if you decide to take part, you will be asked to complete the questionnaires **online** or via telephone (in case you need assistance); we are not doing any face-to-face contact, what will ensure to keep everyone safe.

If you would like to know about the latest government advice on COVID-19, you can visit the following websites:

Information about coronavirus: <https://www.gov.uk/coronavirus>

Daily update for data and insights on coronavirus: <https://coronavirus.data.gov.uk>

LIST OF SUPPORT SERVICES

If you require further support, we recommend that you contact/attend one of the following:

- Your GP
- The Samaritans 116 123 (available 24/7)
- NHS 111 (available 24/7)
- Your local A&E department

CONTACT DETAILS

If you have any queries about the study or if you are interested in taking part, then please contact the researcher(s):

Kelly Rushton
The University of Manchester
Division of Nursing, Midwifery and Social Work
Jean McFarlane Building
Oxford Road
Manchester M13 9PL

Email: equityresearch@manchester.ac.uk

THANK YOU FOR TAKING TIME TO READ THIS INFORMATION SHEET