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Let's Talk 2: A study of a peer delivered intervention for people with experience of psychosis and stigma-related concerns

Participant Information Sheet

We are inviting you to take part in a study of the Let's Talk programme. Please take time to read this information sheet. Feel free to ask us if anything isn't clear, or if you would like more information. Please also let us know if there is anything else that could help make this sheet more accessible for you, such as a version with larger text or having a trial team member read it out loud.

What is this study about?

People who experience psychosis can face negative attitudes from others about psychosis; this is called **stigma**. People who experience psychosis also say that they can be treated unfairly; this is called **discrimination**. Stigma and discrimination can make some people think or feel badly about themselves, this is called 'internalised stigma.' It can be difficult knowing whether to talk to others about a mental health difficulty because of stigma.

The Let's Talk programme was designed to help people who are concerned about talking about their mental health difficulties because of stigma. Let's Talk aims to help people think about the upsides and downsides of talking about mental health in everyday life, to learn ways to talk about mental health, and support you to make the best decisions for yourself. It is carried out by peer support workers, who meet with study participants for confidential discussions. A peer support worker is a mental health worker who has also experienced similar mental health difficulties and understands the negative effects of stigma personally.

We ran a small trial of Let's Talk and found that it is practical and safe to do. Now we are running a larger research trial at four locations in the UK to test if this approach helps people with their personal recovery. This means testing whether having the Let's Talk programme leads to improved mental health wellbeing afterwards. We will also try to understand which parts of the programme are most helpful.

Why have I been invited, and do I have to take part?

We would like to speak to people who have experience of psychosis who feel that mental health stigma has affected how they feel about themselves and how they feel about talking to others about their mental health. You have been invited to take part because either you have referred yourself to the study, or a healthcare worker or researcher you are working with has said this may be of interest to you.

You do not have to take part. It is completely up to you to decide to take part or not. You should not feel under any pressure to decide. **Even if you decide to take part you are still free to stop taking part at any time and without giving a reason.** No one will be upset with you and this will not affect the care you receive now or in the future from mental health services.

What will happen if I choose to take part?

Consent and first assessment

If you would like to take part, you will be asked to complete a Consent Form saying that you agree to be a part of this research study. If you want more time to think about it that's okay, you can take the time you wish.

A researcher working for the Let's Talk 2 trial will then check with you whether you are eligible for the study. This will take around 30 minutes and involve discussing mental health stigma and its impact on your wellbeing, and you will be asked to complete a questionnaire that has just one question. Please note that after this assessment, you may **not** be eligible for the study.

If you **are** eligible, you will be asked to complete eight questionnaires with the researcher about your wellbeing. The researcher will discuss with you how and when you want to complete these. **You do not have to answer all these questions, you can take breaks, and no-one will be upset with you if you decide you do not want to complete a questionnaire.**

Study allocation

For each person who is eligible for the study, a computer will then randomly assign them to receive **either** standard care **or** standard care plus the Let's Talk programme. This will be decided randomly by a computer, and everyone has a 50% chance of being assigned to either group.

Standard care: The care you would usually receive with your care team, **OR**

Standard care plus The Let's Talk programme: The care you would usually receive with your care team **plus** up to four months (up to 16 one-to-one sessions) of the Let's Talk programme with a peer support worker who is employed by the NHS. This provides an opportunity to meet with another person who shares similar mental health experiences and now works in a role to help support others.

The Let's Talk programme helps you to think about the upsides and downsides of talking about your mental health experiences in everyday life. With a peer support worker, you can explore ways to talk about your mental health that have worked for others and find ways that work for you. Let's Talk

is about supporting you to reach a decision that feels right for you before deciding what, if anything, you want to share with others. Let's Talk can help people to make the best decisions for themselves. You will be given a workbook containing information to help you make these decisions, and your peer support worker will work with you as you move through the sections of the workbook together.

Follow-up appointments with a researcher

All the people taking part in the study will be asked to meet with a researcher for a follow-up assessment after 4 months and 12 months. These meetings will involve a conversation with the researcher about mental health stigma and its impact on wellbeing, plus nine questionnaires. These are the same questionnaires as at the first appointment. **You do not have to answer all these questions if they feel difficult or upsetting, and you can take breaks if you like. No-one will be upset with you if you decide you do not want to complete a questionnaire.**

When you speak to the researcher, we ask that you **do not** tell them whether you received sessions with a peer support worker or not. This is because the researcher should not be aware of this as they go through the questionnaires for the study with you in case it influences their assessment. We understand that occasionally someone may tell them by accident, and no-one will be upset with you if this happens. It will not change what you receive from the study.

The appointments with the researcher and the peer support worker will normally be done in-person and they will do their best to meet you at a location of your choice, which may be your home. If necessary, meetings with Let's Talk staff can be done over the telephone or video-call.

And whether you are allocated to receive the Let's Talk programme or not, we appreciate ALL study participants equally.

Will I receive any payment for taking part?

All eligible participants will be given a payment of £25 at each of the three assessment meetings: once at the beginning, at 4 months, and at 12 months. We can provide this payment by bank transfer or voucher. If you would prefer this payment in cash, we will do our best to provide that. We won't be able to provide payments for separate sessions with the peer support worker because only half of the people taking part will have these.

What are the advantages and disadvantages to taking part?

Possible advantages

For those assigned to receive the Let's Talk programme we hope it will be helpful. It is possible, but not guaranteed, that Let's Talk may be helpful in several ways:

- It is an opportunity to talk to someone who has experienced similar mental health difficulties and can offer understanding and support.
- It is possible that they will help reduce the impact that stigma has on your life, by sharing information and ways to manage any distress caused by stigma.

- Let's Talk can help by supporting you to think through the upsides and downsides of talking about mental health with others.
- It can help to learn ways to talk about yourself that have worked for others to make the best decisions for yourself about this.

We also hope that for everyone who takes part, it will be helpful to talk about mental health stigma with a researcher who is trained and supportive.

Possible disadvantages
It is possible that talking about some of these issues may be upsetting. The researcher will let you know before completing any interview or questionnaire what topics it covers. You can decide not to answer a question, stop the assessment or session, or stop taking part in the study at any point. **We will always support your choice, and no one will be upset with you.**

There are lots of reasons why people choose to take part in research, but we understand that some people have a preference to be allocated to receive the intervention (i.e., the Let's Talk programme) and that not being allocated to the intervention can be disappointing. If you are not allocated to receive the Let's Talk programme, we will still offer to send you useful information from the Let's Talk workbook after your final research assessment.

What happens if I can no longer decide to take part?

People can sometimes lose the ability to decide for themselves whether to continue taking part in a study. This could happen if you become unwell, for example. Although this is unlikely, if it were felt that you were unable to personally give your consent to continue taking part, we would withdraw you from the study and no further information would be collected. Any information already collected would be kept and used in the study.

What will happen to the results of the study?

We will write up our study results to publish them in scientific journals. We will share results at scientific conferences. All study results and information will be anonymous, meaning no-one who takes part could be identified by anyone else. We will publish the results of the study here: www.psychosisresearch.com.

What if I have concerns or complaints?

If you have concerns about any aspect of this study, you can ask to speak to the researchers who will do their best to answer your questions. Please speak to the Principal Investigator [insert name and email for site PI] or the Chief Investigator Dr Melissa Pyle by emailing Letstalk2management@gmmh.nhs.uk.

If you wish to complain formally, you can do this by contacting the [INSERT NHS TRUST CUSTOMER COMPLAINTS].

What if something goes wrong during the study?

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 sponsor organisation, Greater Manchester Mental Health NHS Foundation Trust (GMMH NHS FT), who provide indemnity cover. You may have to pay your legal costs. Indemnity means that NHS bodies are liable for clinical negligence and other negligent harm to individuals, as part of their duty of care. The normal National Health Service complaints mechanisms will still be available to you. If you would like to find out more about this, please contact researchoffice@gmmh.nhs.uk.

Thank you for reading information on the background to the study, why you have been invited to take part and what taking part would involve. This next section is about how we would use your information if you chose to take part.

How will we use information about you?

We need to use information from your electronic patient record for this study. This information will include:

- **First and last name**
- **NHS number and electronic medical record ID**
- **Contact details**
- **Mental health diagnosis to confirm your eligibility for the study.**
- **Details of the types of mental health services you have received during your time in the study, and any significant changes in your wellbeing.**

Members of the research team will use this information to do the research. The study will be checked to make sure it is being done correctly. These checks may be made by the study sponsor Greater Manchester Mental Health (GMMH) NHS Foundation Trust, or by the NHS Trust providing your care or another regulatory authority. **People who do not need to know who you are will not be able to see your name or contact details, as your information will have a code number instead.**

The study sponsor, GMMH NHS Foundation Trust, is responsible for looking after your information. GMMH will share your information related to this research project with the NHS Trust involved in your care, or a University, when a member of the research team for the study is employed at that University. This means we will save and store your information on a secure NHS or University computer, or in a locked NHS or University office. We will enter your questionnaire data into a secure database that is hosted by the University of Aberdeen. This is because the research team members who will analyse the data are employed by the University of Aberdeen. The data entered is anonymised and this means that it cannot identify you.

We will keep all information about you safe and secure by taking the following steps:

- **Electronic data**: will be on a secure NHS or University computer network password protected and only accessed by the research team, the sponsor, or another regulatory authority.
- **Paper data**: paper data such as the questionnaires you complete will be stored in locked cabinets on NHS or University premises and only accessed by the research team, the sponsor, or another regulatory authority. Questionnaire data will be kept strictly confidential by the research team and will be 'coded' using a number instead of your name.

International transfers

Your data will not be shared outside the UK.

Who will we let know you are taking part in the study?

We will let your NHS mental health team know that you are taking part in this study and following each contact with a member of the Let's Talk team, we will make a contact note in your electronic patient record at the NHS Trust that provides your mental health care. This is to document that either a research assessment or Let's Talk session has taken place. The details of your conversations with Let's Talk staff will NOT be shared in this contact note, unless you tell us that you wish us to share this with your care team. The only time that information you give may be shared with others is if you tell us something which suggests that either you or another person is at risk of harm. In that case we would need to share that information with someone involved in your care such as a care coordinator or another member of your NHS mental health team. We would always try to discuss this with you beforehand.

How will we use audio recording?

If you complete the first appointment on a phone or video-call, we will need to audio-record your completion of the study consent form to properly show that you have agreed to take part. If you do the first appointment in-person with the researcher we would not ask to audio record this.

As part of the conversation about consent, we will ask if you agree to some of the research assessments and/or sessions with a peer support worker being audio recorded. We do this so we can check the quality of assessments and sessions. The recording can be stopped at any time and words can be deleted or replaced. **You do not have to agree to the research assessments or the sessions being recorded - it is your choice**. You can also change your mind at any point.

To ensure recordings are secure and to protect your confidentiality, we will follow the rules for audio recording at the NHS Trust that provides your care. Our researchers will transfer audio recordings to secure NHS computer network where they can only be accessed by members of the research team who have permission. Once recordings have been transferred to a secure drive then it will be deleted from the recording device.

How will we use information about you after the study ends?

We will destroy any personal data that can identify you including your name and contact details and any audio recordings of assessments or Let's Talk sessions 12-months after the study ends in 2029. The exception to this is the consent form or audio recording of consent, which contains your first and last name, as we are required to keep this for 15 years after the end of the study, in 2043. We will destroy the paper questionnaire data five years after the study has ended in 2033. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to access, remove, change, or delete information we hold about you for the purposes of the study. You can also object to our processing of your information. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this. If you agree to take part in this study, you will have the option to take part in future research using your information saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information at:

- www.hra.nhs.uk/patientdataandresearch
- https://www.gmmh.nhs.uk/research
- by asking one of the research team
- by sending an email to researchoffice@gmmh.nhs.uk

Thank you for taking the time to read this information.
Helpful contact details are below.

Helpful Contact Details

Research Assistant
[insert RA name, work mobile number, and email address]

[insert principal investigator details for the sites including name and email address]