Participant information sheet – A study into the effectiveness of MBT for older adults with a diagnosis of personality disorder.

Study Title

Does the psychological therapy, *Mentalisation Based Treatment* (MBT) help people over 65 with personality disorders improve their personality functioning and decrease social isolation?

Invitation and brief summary

You are being invited to participate in a study that will investigate whether a form of psychological therapy, called MBT, helps older people who meet the criteria for a diagnosis of personality disorder to improve their personality functioning and decrease social isolation.

The study will take place over 2 years. All participants that meet the inclusion criteria for the study will be provided with 18 months of twice weekly sessions of psychological therapy. Participants will be asked to fill out 2 questionnaires each week, which will take roughly 2-5 minutes. Every 6 months, participants will also be asked to complete 3 further questionnaires, which will take approximately 5 minutes to complete. Participants will be asked to complete these measures every 6 months until the end of the study.

At the end of the therapy, a researcher will contact you each month, for a period of 6 months, to ask you to fill out the questionnaires. This will help us understand what effect MBT has once a person has finished the therapy.

The study is being sponsored by Greater Manchester Mental Health's research and innovation team, and is academically supported by Professor Arjan Videler and Machteld Owens of Tilburg University in the Netherlands. The lead investigator, who is responsible for the study, is Luke Jordan.

What's involved?

After you have read this information sheet and spoken to a member of the research team, you will have the opportunity to think about whether you would like to participate in the study or not. You are under no obligation to participate, and can withdraw your consent to participate up until the study has been completed.

If you decide to participate in the study, you will be invited to attend 1-4 initial appointments. The purpose of these appointments will be to complete an assessment of your needs, and to complete a diagnostic interview which will determine whether you meet the criteria for the diagnosis of 'personality disorder'.

If you meet the criteria for the study, or have difficulties which are considered' subthreshold' to personality disorder you will be invited to a 12 week 'introductory' group, which will take place prior to the start of MBT treatment. The introductory group is part of standard MBT treatment, and is necessary to help you understand how MBT works, to give you more information about what MBT involves, as well as to provide some early support to manage the mental health issues that you currently face.

Following the introductory group, if you decide you would like to continue with the study, you will be assigned an individual MBT therapist, who will work with you to assess and understand your difficulties. At this point in the study, you will be asked to complete two questionnaires each week, which will take roughly 2-5 minutes. The answers you record will not be seen by the MBT therapy team, and will be stored securely using a pseudonym so that you cannot be identified.

During this assessment period, you will be randomly assigned to a waiting period between 4-8 weeks. When your waiting period has ended, you will then be invited to start the treatment phase, which will last 18 months. During this phase you will see the same individual therapist, at the same time each week for 50-60 minutes. You will also be invited to attend a weekly group, which takes place at the same time each week, and lasts 75 minutes. During your therapy appointments, you and your therapist will spend time discussing events that occur in your life. The aim of MBT is to build a strong relationship with your therapist, whilst trying to understand different perspectives about events that happen to you in your life, and the impact that those events may have on you and those around you.

Transport to and from your appointments can be provided, free of charge. All appointments take place at The Therapy Hub, 70 Daisy Bank Road, Longsight, Manchester. The treatment is provided by Greater Manchester Foundation Trust, which is an NHS foundation trust.

If you decide that you do not wish to participate in the research, then you will be allowed to continue MBT if you and your treatment team believe it will be effective for the difficulties that you have. You can choose to leave the research project at any time, and for any reason. Up until the end of the study, you can choose to withdraw your consent to share any information that you have provided to the research team.

The background and purpose of the research

There is a lack of research into effective psychological therapies for people over 65. Although MBT has found to be effective in treating personality disorders for people under the age of 65, no research currently exists which tells us whether the MBT is effective in treating people aged over 65. We believe the study is important, as it could help us to understand whether MBT may be effective for individuals over 65 that meet the criteria for a diagnosis of personality disorder. Many older people with complex emotional needs such as personality disorder, are never provided diagnosis or treatment of their problems, and as such this study may help us raise awareness of this issue throughout the NHS.

MBT is an intensive psychotherapy that takes place over 2 years. It was designed to treat people with personality disorders, which are serious mental health problems that occur commonly within in the population. Many older people in the UK are not diagnosed with personality disorder, despite evidence to suggest the condition is relatively common amongst older people with mental health problems. Untreated personality disorders are thought by some researchers to be responsible for poor treatment response to depression in older people.

Our aim is to recruit 10 individuals who will participate in the study. If we do not believe that MBT is indicated in the treatment of your condition, then we will not ask you to participate in the study. Instead, we will refer you to another service within Manchester Later Life services. This may include another psychological therapy, such as Structured Clinical Management or Radically Open Dialectical Behaviour Therapy. If these alternatives are not appropriate we will discuss suitable alternatives with you and your care team.

What would taking part involve?

Attendance

MBT is an intensive, long term, psychological therapy. The treatment phase, involves two appointments per week, one of which is a group. It lasts for 18 months. This could represent a significant impact to your routine, and is a substantial commitment.

Recording and data management

We plan to use two questionnaires to determine whether the treatment is effective. In order to make sure we get enough data to understand if MBT is effective, we will ask you to fill out these questionnaires each week. Typically, this takes around 2-5 minutes. Most people do not find the questionnaires distressing or upsetting to complete, but filling them out does take a 2-5 minutes of your time.

At the start of your treatment, and at the end of your time in the study, you will be asked to participate in a short interview. This will help us understand your views on MBT, including how suitable you think it is as a treatment.

In order to ensure our research is done to a good standard, we will video record all appointments relevant to the study. This is to ensure that the study design is followed, and to ensure that the therapists are applying the treatment correctly. The recordings made are deleted after 100 days automatically, and are shared only with the MBT team, and the team's supervisor, who will rate the recordings to determine if they are adherent to the treatment manual.

If you do not wish to be video recorded, then we will work with you to support you with your concerns. Unfortunately, if you do not want your appointments to be recorded, you will be unable to participate in the study.

Consent

We will ask you to consent to being part of the study. This means that you agree to participate in various aspects of the study. You can withdraw this agreement at any time, up until the study has been completed. Principally, we will ask you to consent to

1) Participating in the therapy for the full duration of the treatment.
2) Allowing us to record the data your provide to us when filling out the questionnaires on a secure database. When your data is recorded you will be given a pseudonym, or participant number, which will mean that you will not be identifiable.
3) To allow us to take a record your demographic information, including your age and ethnicity. This will be anonymised and will not be used to identify you.
4) To allow us to review your medical records to take data about the amount of contact you have had with A and E, hospitals, mental health services, as well as any incidents of self-harm or suicide. This data will be anonymised and will not be used to identify you.
5) To allow the therapy team to video record your appointments, and share these videos with the team's MBT supervisor. These videos will be deleted after 100 days.

6) For the research team to publish the results of the study in an academic journal. You will not be identifiable in the publication.
7) For the treatment team to liaise with other professionals involved in your care

What elements of the study are additional to standard MBT treatment?

If you decide not to participate in the research, you will still be able to access MBT. Outside of the study, participating in MBT as part of standard care would still involve the same number of sessions, participation in a group, and video recording of all sessions.

The elements to the study that are additional to the standard level of care offered in the MBT service include

- Weekly completion of questionnaires.
- A higher level of supervision provided to the therapists.
- Completion of monthly questionnaires for 6 months following treatment
- Waiting for a randomised period of 4-8 weeks following the introductory group.
- Assessment and diagnosis of personality disorder
- Being involved in some interviews to understand what you think about MBT

Screening and exclusion

Participants will be eligible for the study if they meet the criteria for the diagnosis of personality disorder. If a participant has difficulties which are 'sub threshold' to the diagnosis of personality disorder (1 point below the threshold for diagnosis) they will also be included in the study. If a participant has autism, they will also be allowed to participate in the study.

Participants will not be able to participate in the study if they are

- Violent towards others
- Have mild cognitive impairment or dementia
- Have a primary psychotic illness
- Would be unable to commit to the duration of the study
- Lacks capacity to give informed consent to the study

Involvement of other services and professionals

As part of standard care, we ask that individuals taking part in MBT consent to the treatment team contacting your GP, mental health care team, and any other relevant professional involved in your care. This is to ensure that your medical needs are met, and that relevant information pertaining to your treatment and safety is shared appropriately.

Practically speaking, this means that the treatment team will seek consent to contact your GP, and your mental health team, to let them know that you are participating in the study. If there is any reason to suggest that you or someone else is at risk, then other professionals may be contacted in line with local safeguarding policies.

What are the possible benefits of taking part?

Participants of the study will gain all of the benefits that individuals who access MBT in standard care currently receive. Outcome data suggests that older people who have received MBT in the service to date have experienced significant improvement in their mental health. A large scale randomised controlled trial into MBT found that it significantly improved mental health outcomes for adults of working age.

In addition to this benefit, participants will be provided therapy to an adherent level. Extra steps have been taken to ensure that the therapists conducting the trial are providing MBT to the highest standard possible. Therapists in the trial have to have a proportion of their therapy sessions rated to adherence, which does not happen in standard care. This means that the therapy is more likely to be adherent than treatment provided in standard care.

Beyond these benefits, there are no other expected benefits, other than being part of a study that aims to improve our understanding of what may help older people. Our hope is that the study may raise awareness as to the importance of older adult mental health, and provide some guidance on how to effectively support individuals with complex emotional needs.

What are the possible disadvantages of taking part?

The service providing MBT as part of the research trial has reported no adverse events associated with being part of the therapy. In the randomised controlled trial that was conducted on working age adults, no adverse events associated with the therapy were reported.

Some disadvantages to being part of the study may include

- Spending 2-5 minutes per week filling out a questionnaire may provide some inconvenience to the participant
- The typical wait between the introductory group and the treatment phase is 4-6 weeks. In the study you may wait for up to 8 weeks, or may be asked to join the treatment after only 4 weeks of waiting. This may inconvenience the participant, but is unlikely to affect the efficacy of the treatment.
- Your responses to the questionnaires will be securely recorded. Some participants may not be comfortable with their data being secured in this manner.

- Generally speaking, MBT is an intensive and long term psychotherapy. It requires a commitment over a long period of time, which constitutes a significant change to routine.

How we will process participants data in line with General Data Protection Regulation (GDPR)

How will we use information about you?

We will need to use information from you and from your medical records for regular care. This information will include your NHS number, name, and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

For research purposes, we will collect data for age, gender, marital status, and level of education, but these demographic details will not be used to identify you.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. This extends the treatment team. Your therapist and group therapists will not be able to see the data you have recorded in your questionnaires.

We will keep all information about you safe and secure. Any written information you supply will be stored under lock and key at an NHS site. Digital information will be securely stored on an NHS server, in a secure database that only members of the research team, or Greater Manchester NHS Foundation Trust research office will be able to access. All information will be destroyed following the end of the study.

You can find out more about our GDPR policy by visiting:

https://www.gmmh.nhs.uk/gdpr-in-research

At the end of the study the results of the study will be sent to members of the research team at Tilburg University in the Netherlands. They will not receive any participant identifiable information and they must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. Your data will be deleted when the study ends. 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.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your GMMH record. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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/information-about-patients/, by asking one of the research team.

Further supporting information (full guidance covering further supporting information)

Sometimes people with mental health issues may experience an episode of crisis, which is where their mental health deteriorates significantly. If this happens to you, then we will involve your care team to ensure that you are fully supported. You can also call the below numbers for additional support

GMMH Crisis Line - 0800 953 0285
Samaritans – 116 123
Campaign against living miserable (CALM) – 0800 58 58 58

What will happen if I don't want to carry on with the study?
If you do not wish to carry on with the study you can withdraw your consent at any time by talking to one of the research team. If you feel like dropping out of therapy, as per the treatment, the therapy team will attempt to work with you to ensure that you make an informed decision about leaving treatment.

How will information be kept confidential?
Information gained from your questionnaires will be securely stored on a database, which is not accessible by the treatment team. Your data will be assigned a participant number, so nobody will be able to know which data belongs to you.

Your medical information will be recorded on the local NHS system, known as PARIS. This system stores information which is relevant to your care and treatment.

What will happen to the results of this study?
At the end of the study the results will be prepared for a peer reviewed journal. The research team aims to publish the results of the study.

Who is organising and funding this study?
The study is funded by Greater Manchester Mental Health. It is being organised jointly by Greater Manchester Mental Health, and Tilburg University – a university in the Netherlands.

How have patients and the public been involved in this study?
Manchester Later Life's expert by experience group was consulted when forming the study design. They gave comments on how the research study could mitigate some of the inconveniences and discomfort that parts of the study may cause.

Who has reviewed this study?
This study has been reviewed by Greater Manchester Mental Health's research department, who have agreed to sponsor the study. It has also been reviewed by Professor Arjan Videler and Dr Machteld Owens, who are providing academic oversight and support to the project.

Further information and contact details
Luke Jordan – Chief Investigator luke.jordan@gmmh.nhs.uk

What to expect during the consent process
A member of the research team will contact you over the phone to go through the information on this form. Following this initial contact, you will be given a period of

time (7 days) to consider whether you would like to be part of the study. If you would like to participate, you will be invited to attend a face to face appointment with a member of the team who will ask you consent to the various aspects of the study. If you are happy to consent, then at that stage you will be provided with a consent form which we will ask you sign. The consent form will be securely stored for the duration of the study.

What if relevant new information becomes available?

If any new information becomes available which is relevant to the study, we will inform you of this information at the earliest opportunity.

What if I have a complaint about the research study?

You can make a complaint about this study by contacting

Call: 0161 358 0600

Email: complaints@gmmh.nhs.uk

You can also contact the GMMH research office:

Email: researchoffice@gmmh.nhs.uk

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