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PARTICIPANT INFORMATION SHEET – PETRUSHKA Trial

This is the patient information sheet for the trial called PETRUSHKA, which stands for: Personalise antidEpressant Treatment foR Unipolar depreSsion combining individual cHoices, risKs and big datA.

Invitation

You are being invited to take part in a research study. Before you decide if you want to take part in the study or not, it is important to understand why the research is being done and what it will involve. Please read the following information and take your time to consider if this is the right study for you.

What is the purpose of the study?

Antidepressants are one of the available treatments for depression. There are many antidepressants that are licensed in the UK and any of them can be prescribed to you by your doctor. Matching antidepressant treatment to specific patients, however, is too often a matter of trial and error, with many factors influencing whether a treatment is suited to an individual. These factors may include clinical and demographic characteristics, how a person has responded to other treatments in the past, how severe their condition is and whether they have any other conditions they are being treated for.

By using routinely collected NHS data and clinical trial data, we have developed a tool (called PETRUSHKA tool) to personalise treatment for people with depression and predict which antidepressant works best for each individual, based on their characteristics (for instance, age, sex assigned at birth, severity of symptoms) and their preferences about side effects. In this study, we will test the PETRUSHKA tool in adults with depression who are seen by their General Practitioner (GP) and compare this personalised approach with usual care in the NHS (i.e., standard care).

What are the aims of this study?

The study aims to personalise treatment for people with depression. It uses a web-based decision support tool to predict which antidepressant works best for each individual patient,

in comparison to usual care (i.e., when clinicians choose the antidepressant to prescribe based on their experience and clinical judgement). The study lasts 24 weeks in total, but after 8 weeks we will see how many participants are still taking the allocated treatment. This measure will tell us how acceptable and well tolerated a treatment is. If an antidepressant is better suited to an individual, it is likely that they will benefit from the medication, experience less undesirable side effects and are therefore more likely to continue taking the medication.

The study also aims to evaluate whether using the PETRUSHKA tool results in a greater reduction in the severity of depressive symptoms for patients and an improvement in their quality of life, when compared with standard care. This will be measured by administering questionnaires that assess mood-related symptoms, side effects and quality of life at the beginning of the trial and at set time points throughout the study.

How many people will take part?

This is a study which will be offered to patients seen by their GP. We aim to recruit 504 participants in total across the UK.

Why have I been invited?

You have been invited to take part because you are;

- Aged between 18 – 74 years inclusive and diagnosed with a depressive disorder
- Willing to take an antidepressant, but have not been treated with antidepressants in the previous 4 weeks (this is because for some antidepressants, such as fluoxetine, it can take up to 4 weeks to eliminate any traces of the medicine from the body)

Do I have to take part?

No. It is important that you understand that participation in this study is entirely voluntary, and it is up to you to decide whether to take part. You have the right to withdraw from the study at any point, without giving a reason. Your medical care and legal rights will not be affected. Not taking part will not impact on the usual treatment that you will receive.

What will happen to me if I decide to take part?

- If you do decide to take part, you will be invited for a baseline visit where you will be asked to complete and sign an e consent form. This form will be stored in a confidential manner, and you will be securely emailed an electronic copy.
- After successfully completing the consent form, you will then be asked some questions to confirm your eligibility. As part of this first visit you will also be asked some questions about yourself which will include your demographics and medical history. This will take approximately 10 minutes.
    - Additionally, you will be asked to complete some questionnaires. Some of these questionnaires will be administered by the clinician and some will be completed by you independently. This will take approximately 30 minutes.
    - Once the questionnaires are completed, you will be allocated to either the group receiving standard care or to the group using the PETRUSHKA tool. This

allocation will be randomly assigned (i.e., by chance), using a computerised system and cannot be decided by you or your GP.
    - If you are assigned to the PETRUSHKA tool, you will be asked to express your preferences about some side effects and rank them based on how troublesome you would find them. At the end of the process, the PETRUSHKA tool will show you and your GP the three antidepressants that are most recommended for you (in ranking order), and you and your GP will be guided in the selection of the antidepressant to prescribe.
- Throughout the study, you will be required to complete questionnaires (using a smart phone, tablet, computer or any other electronic device) at set time points, summarised in the table below. Paper versions can be made available if necessary. Please note that questionnaire responses will not be reviewed by the clinical team at specific time points but will only be analysed at the end of the study, as part of study measures.
- If you become upset when completing the questionnaire, you can stop at any time and if necessary please contact your GP.
- You will be contacted by the central study team at weeks 8 and 24 to complete over the phone three short questionnaires about your symptoms. These are the same questionnaires that the clinician used at the baseline visit.
- Whichever group you are allocated to, we anticipate that you will be required to see the GP (either in person or remotely) up to 4 times during the study (baseline visit, week 4, week 8 and week 24).
- For all participants of the PETRUSHKA trial, standard care assessments will be available as per NICE guidelines (i.e. at weeks 4 and 8)

Data collection time points	Study assessments							
	Informed consent	**Allocation to study arm**	**Demographics**	**Medical History**	**Mood & Anxiety questionnaires**	**Medication adherence questionnaire**	**Side effect questionnaire**	**Quality of life questionnaires**
Screening & Baseline	**x**							
		x	**x**	**x**	**x**			**x**
Week 2					**x**	**x**	**x**	
Week 4					**x**	**x**	**x**	**x**
Week 6					**x**		**x**	
Week 8					**x**	**x**	**x**	**x**
Week 12					**x**	**x**	**x**	**x**
Week 16					**x**		**x**	
Week 20					**x**		**x**	
Week 24					**x**	**x**	**x**	**x**

What should I consider?

Before deciding whether you would like to take part, please consider the following requirements:

- Being willing and able to provide informed consent.

- Being willing and able to complete the study procedures as specified in this document.

Please be aware of the following, which may prevent you from participating in this study:

- History of other significant mental health problems.
- Previous limited response to two or more antidepressant drugs.
- Certain heart problems.
- You requiring urgent mental care or hospital admission (including for suicidal intent or plans).
- Being currently enrolled in another interventional trial about depression;
- Being currently pregnant, planning pregnancy or currently breast-feeding

Are there any possible disadvantages or risks from taking part?

No, we do not expect there to be any disadvantages or increased risk in taking part in this study. All the antidepressant medications that are prescribed are approved and routinely used as part of standard care in the NHS.

What are the possible benefits of taking part?

By taking part in the PETRUSHKA trial participants will receive a treatment which may produce a reduction in depressive symptoms and an improvement in quality of life. However, this cannot be guaranteed for all or any of the patients on this trial. By entering this trial, you will be contributing to research which will help increase our knowledge of how depression treatment may be personalised, which may help improve future treatment of patients with depression.

Will my taking part in the study be kept confidential?

You will be assigned a unique participant ID which will be used throughout the study and your personal identity will not be identifiable from this number. All information, which is collected about you during the trial will be treated as strictly confidential. Delegated individuals from the University of Oxford may look at your medical and research records to check the accuracy of the research study. Information collected about you for the research purposes will be held securely and confidentially at the University of Oxford. The people who analyse the study data will not be able to identify you and will not be able to find out your name, NHS number or contact details.

What should I do if I become unwell during the study?

In the event you experience a worsening of symptoms or are worried about any side effects whilst participating in the study, we encourage participants to:

- Contact your General Practitioner for further advice
- Contact the study team via petrushka.trial@psych.ox.ac.uk
- Dial “999” if you feel this is necessary

What will happen to my data?

UK Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is ‘a task in the public interest.’ The

University of Oxford, based in the United Kingdom, is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you in order to undertake this study and will use the minimum personally identifiable information possible. We will keep identifiable information about you for 1 year after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 5 years after the end of the study.

The [local study team] will use your [name, NHS number, home address, and contact details], to [contact you about the research study,]. They will keep identifiable information about you from this study in keeping with local policy for retention of medical notes.

UK Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting the study team at (petrushka.trial@psych.ox.ac.uk).

What will happen to the results of this study?

At the end of the study the information collected will be analysed for publication in an international scientific peer-reviewed journal and presented in an aggregated format. However, other methods of communication such as social media platforms will be used to disseminate results to the wider public. Your GP will be informed of any publications as well. We will be able to supply a copy of these publications to you on request. The identity of the patients who took part in the study will remain confidential i.e. you will not be able to be identified individually via these publications.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment that is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact the Chief Investigator, Professor Andrea Cipriani (andrea.cipriani@psych.ox.ac.uk), or you may contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) office on 01865 616480 or email ctrg@admin.ox.ac.uk.

How have patients and the public been involved in this study?

In designing and planning this study, we have worked closely with people with lived experience of depression and other mental health issues and benefitted from their feedback. Their opinions about the PETRUSHKA tool, the frequency of participant visits, the duration of

the trial and the assessments that we will carry out have been incorporated. Potential participants were involved in reviewing the Participant Information Sheet and the Consent Form.

Who is organising and funding the study?

The PETRUSHKA trial has been funded by the National Institute of Health Research (and is sponsored by the University of Oxford.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by the South Central-Hampshire B Research Ethics Committee.

Further information and contact details:

If you have any question, please contact the study team at petrushka.trial@psych.ox.ac.uk.

Thank you for considering taking part.