The use of a screening tool in primary care to identify menopausal and perimenopausal women who could benefit from hormone replacement therapy.

IRAS Number: 265355

PATIENT INFORMATION SHEET

You are invited to take part in a study to determine if you have menopausal symptoms that might be relieved with hormone replacement therapy

You are invited to take part in a research study. Before you decide to take part, it is important that you understand why the research is being done and what it will involve. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

What is the purpose of the study?

The menopause represents a normal physiological change that occurs on average occurs in women age 50. Though not strictly an illness, the low levels of oestrogen associated with the menopause commonly results in symptoms such as hot flushes and night sweats. In addition, some also experience sleep disturbance, depression, mood changes, musculoskeletal pain, vaginal dryness and low libido. Hormone replacement therapy (HRT) is an effective treatment for menopausal symptoms but media reports of an increased risk of cancers have led to a decrease in the number of women using HRT despite the fact that symptoms can have a large and negative effect on quality of life. Participating in the study could involve a prescription of HRT, which is licensed for this purpose, as well as an assessment of the impact of this therapy using the two questionnaires.

Why have I been invited?

You have been identified as someone within the age range of women who are likely to experience menopausal symptoms.

Do I have to take part?

No. It is up to you to decide whether or not to take part. Taking part in the study, will involve having a discussion with a pharmacist, and taking HRT if this is advised, should the responses to the questionnaires indicate the presence of menopausal symptoms is optional. If you are considering taking part, please read this information sheet and, when you feel ready, sign the online consent form (Version 1.4 Date: 17/08/2020). Participation is entirely voluntarily. If you do agree to take part, you are still free to withdraw at any time and without giving a reason. You are welcome to discuss your participation in the study with your Pharmacist and can contact the research team for further information.

What will happen to me if I take part?

After you read this information sheet, consent you will complete the menopausal symptom rating (MRS) scale and a quality of life questionnaire (Men QoL) online, both should take less than 5 to 10 minutes to complete. If the result from the rating scale shows that you have moderate to severe

symptoms, you will be invited to have a discussion with the practice pharmacist about using HRT to manage your symptoms, this consultation will take place online. The pharmacist will provide you with more information on the benefits and any risks associated with using HRT, to allow you to make an informed decision. If you feel that this is something you would like to use, they will discuss the various treatment options with you and we ask that you have a follow-up online appointment with the pharmacist after three months so that we can assess whether or not the treatment is working. You will not be under any pressure to try HRT, the study is looking at the possible benefit of providing women with more information.

Will my taking part in this study be kept confidential?

Yes, we will respect your confidentiality throughout the study but ask that you let us inform your GP of your participation in the study. A member of staff at the surgery will have searched the database in the practice to identify you. They will create a unique identifier for you and collect basic information, for example, date of birth, how long you have had symptoms and your current treatments. All of this anonymised information will be sent to the research team for analysis and will not be shared with anyone outside the research team.

Data Protection and GDPR

Rotherham Doncaster and South Humber NHS Foundation Trust (RDaSH) is the sponsor for this study based in England. The sponsor will be using anonymous information from your medical records in order to undertake this study and will act as the data controller for this study. This means that RDaSH are responsible for looking after your information and using it properly. RDaSH will keep identifiable information about you 12 months after the study has finished.

Your rights to access, change or move your information are limited, as RDaSH will need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, RDaSH will keep the information about you that RDaSH have already obtained. To safeguard your rights, RDaSH will use the minimum personally identifiable information possible. All identifiable and confidential information will be kept in locked storage at the sponsor location.

How will we use information about you?

We will need to use information from you from your medical records and your GP for this research project. This information will include your initials/ NHS number/ name/ contact details/ Medication history (current and past medical history).

Examination results (Men QoL and MRS)

People will use this information to do the research or to check your records to make sure that the research is being done properly.

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.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. 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.
- Follow up data will be collected after withdrawal: If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records or your GP. 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
- by sending an email to [**rdash.groundedresearch@nhs.net**], or
- by ringing us on [**01302 798456**].

You can find out more about how we use your information on our webpage;
https://www.rdash.nhs.uk/about-us/grounded-research/

Are there any expenses or payments with regards to my participation in the study?
No. It is not expected that you will incur any additional costs, all consultations will take place online.

What are the possible benefits of taking part?
We hope that if you are identified as someone with moderate to severe menopausal symptoms that you will receive the appropriate therapy and that this will help control those symptoms. You will also be helping to evaluate whether this type of screening service should become routine for pharmacists working within GP practices.

What are the possible disadvantages and risks of taking part?
Hormone replacement therapy is indicated for the relief of menopausal symptoms although it is associated with some risks including blood clots, stroke, endometrial cancer, breast cancer and ovarian cancer. However, these risks are small. For example, over a 5-year period, 5 women aged between 50 and 59 can expect to have a blood clot. Using HRT for 5 years increases this risk to 7 (i.e. an extra 2 cases per 1,000 women). Guidance to doctors suggests that the benefits of short-term HRT outweigh the risks in the majority of women. The pharmacists will discuss the benefits and risks from using the treatment with you.
If you experience any problems or unclear about the study, please contact the pharmacist at the surgery who can hopefully answer any of your questions. Further queries regarding the risks and benefits of taking the prescription should also be discussed with your GP.

Who is organising and funding the research?
This study is being funded by a grant from Besins Healthcare (UK) limited, a company that manufactures HRT products. The research is being carried out by a team from Grounded Research Rotherham Doncaster & South Humber NHS Trust. However, Besins Healthcare (UK) limited has not been involved in the design of the study and there is no requirement that Besins Healthcare products are used for the study. They will receive a copy of the study results, but this will not include any information about individual participants. Any prescriptions given as an outcome of the results

and pharmacy consultation will be prescribed locally from your GP, Besins Healthcare is not the sole manufacturers of the product but are the funders of the study.

Who has reviewed the study?
This study has been reviewed by an NHS ethics committee and the Health Research Authority to ensure that it complies with all relevant regulations.

What if I have a complaint?
If you have a complaint about the way you have been approached or treated during this study, please feel free to contact Dr Rod Tucker (contact details below). Alternatively, if you want to talk with someone independent about the research, you can contact PALs telephone on 0800 015 and email: rdash.pals@nhs.net

Where can I get further information about the study?
If you have any questions about this study, please contact either of the following individuals:

Dr Rod Tucker
Principal Researcher
Rotherham Doncaster & South Humber NHS Trust
Tickhill Road Site
Doncaster DN4 8SQN
Email: rodtucker.tucker@gmail.com
Mobile 07969 155658