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Primary care screening to identify symptomatic menopausal women

Submission date
02/02/2021

Recruitment status
No longer recruiting

Registration date
13/08/2021

Overall study status
Completed

Last Edited
12/04/2024

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The menopause represents a normal physiological change that occurs on average occurs in women aged 50. Though not strictly an illness, the low levels of oestrogen associated with the menopause commonly results in vasomotor 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.
Menopausal symptoms can be easily managed with hormone replacement therapy (HRT) however the potential increased risk of breast and other cancers, although very slight, has led to concerns among many women so that uptake of HRT is relatively low and women remain symptomatic.
The purpose of the present study is to make use of a validated screening tool to identify women eligible for treatment with HRT and who, according to the screening tool, experience moderate to severe menopausal symptoms. These women will be offered an appointment with a practice pharmacist to discuss the benefits and any possible risks from using HRT to enable them to make an informed choice on whether they wish to manage their symptoms with treatment.
We are interested in exploring the proportion of eligible symptomatic women who subsequently decide to use HRT and the extent to which the symptom burden is reduced by treatment.

Who can participate?
All women between the ages of 47 and 53 who are currently not prescribed any form of hormone replacement therapy and who have no medical reason not to use the treatment.

What does the study involve?
After giving informed consent participants 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 they have moderate to severe symptoms, they will be invited to have a discussion with their practice pharmacist about using HRT to manage symptoms, this consultation will take place online. The pharmacist will provide information on the benefits and any risks associated with using HRT, to allow participants to make an informed decision. If they want to try using HRT, the pharmacist will discuss the various treatment options and participants will have a follow-up online appointment with the pharmacist after three months to assess whether or not the treatment is working.

What are the possible benefits and risks of participating?
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.

Where is the study run from?
Rotherham, Doncaster, and South Humber NHS Foundation Trust (RDaSH) (UK)

When is the study starting and how long is it expected to run for?
January 2019 to December 2021

Who is funding the study?
Besins Healthcare (UK) Limited

Who is the main contact?
Miss Jeannie McKie, j.mckie@nhs.net
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
265355

Protocol serial number
CPMS 44336, IRAS 265355

Study information

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

Study objectives
Providing women with moderate to severe menopausal symptoms with educational support from their practice pharmacist will support them to make informed treatment choices and reduce symptom severity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/03/2020, North West - Greater Manchester Central Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 1048 007; gmcentral.rec@hra.nhs.uk), ref: 19/NW/0745

Study design
Interventional non-randomized

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Primary care screening to identify symptomatic menopausal women

Interventions

This will be an uncontrolled before and after intervention study with participants recruited from primary care. The intervention consists of the use of the menopause rating scale (MRS) combined with the educational input from the practice pharmacists.

Recruitment/Data collection

1. Practice databases will be searched to identify women aged 47 to 53 not currently/previously prescribed any form of HRT. Patients identified from the search will be sent (from the practice) a letter of invite to the study, an information leaflet, consent form and copies of the MRS/MenQol scales and asked to return the completed forms (consent, MRS, MenQol) to the practice. Non-responders will be sent a follow-up two weeks after the initial letter has been sent.
2. The practice (administrative staff) will collate the completed MRS/MenQol forms and invite those with a score ≥8 (on the MRS) for an appointment with the practice pharmacist to discuss use of HRT.
3. Eligible participants willing to use HRT will be invited back for a follow-up appointment after 3 months to review the impact of HRT on MRS and MenQol scores
4. Practices will be asked to record the number of patients identified in the database search /current treatments/No of non-responders/refusals
5. Participant demographics & current treatment will be transcribed onto an anonymised data collection form
6. Participants opting for a trial of HRT will be asked to return to the practice after 3 months for a treatment review and asked to complete a second menopausal rating scale and QOL questionnaire.
7. Any known adverse effects reported by women will be documented in the medical notes and new or unrecognised effects will be reported using the yellow card scheme.

Pharmacist training

To ensure that all participating clinical pharmacists are prepared to participate in the study, we will produce a bespoke training pack that will cover background information on the menopause, symptomology and any national guidance around treatment recommendations and information to help complete the study paperwork.

Data Analysis

Both demographics and current treatments used by women will be analysed descriptively. Means and standard deviations will be used for normally distributed continuous variables, medians and interquartile ranges will be used for non-normally distributed continuous variable, and counts and percentages will be used to describe categorical
variables.
Changes in total MRS/MenQol scores will be assessed using paired t-tests if the data are normally distributed or nonparametric equivalents if the data are skewed.

Intervention Type

Behavioural

Primary outcome(s)

Menopause symptom severity measures using the MRS and MenQol scales at 3 months

Key secondary outcome(s))

Uptake of HRT measured using self report at 3 months

Completion date

31/12/2021

Eligibility

Key inclusion criteria
All women between the ages of 47 and 53 years who are currently not prescribed any form of hormone replacement therapy and who have no recorded contra-indications to using the treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
47 years

Upper age limit
53 years

Sex
Female

Total final enrolment
63

Key exclusion criteria
1. Current, past or suspected breast cancer
2. Known or suspected oestrogen-sensitive cancer
3. Undiagnosed vaginal bleeding
4. Untreated endometrial hyperplasia
5. Previous idiopathic or current deep vein thrombosis or pulmonary embolism unless on anticoagulant therapy.
6. Active or recent arterial thromboembolic disease (e.g. angina, myocardial infarction)
7. Untreated hypertension
8. Active liver disease with abnormal liver function tests
9. Porphyria cutanea tarda
10. Pregnancy

Date of first enrolment
06/02/2021

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Clifton Medical Centre
Doncaster Gate
Rotherham
United Kingdom
S65 1DA

Study participating centre
Mayford House Surgery
Boroughbridge Rd
Northallerton
United Kingdom
DL7 8AW

Study participating centre
The Scott Practice
Greenfield Lane
Balby
Doncaster
United Kingdom
DN4 0TG

Sponsor information

Organisation
Rotherham, Doncaster, and South Humber NHS Foundation Trust (RDaSH)

Funder(s)

Funder type
Industry

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the small size of the trial.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article			19/03/2024	Yes	No
HRA research summary			28/06/2023	No	No
Other unpublished results			23/11/2023	No	No
Participant information sheet	version 1.4	17/08/2020	10/08/2021	No	Yes
Plain English results			12/04/2024	No	Yes
Protocol file	version 1.5	17/08/2020	30/12/2021	No	No