

Menopause Treatment Tool

Study summary

1. Study Title:

Development of a Menopausal Treatment Tool to help clinicians evaluate the benefit/risk of Menopause Hormonal Therapy in symptomatic menopausal women: Results from an international study.

2. Study Sponsor:

Theramex Ltd, 5th Floor 50 Broadway, London, SW1H 0BL

3. Study Objective(s):

To develop and test the practicality and usefulness of the Menopause Treatment Tool in real-world clinical settings across Europe (United Kingdom, Germany, Italy, Poland, Spain, Switzerland and U.S.

4. Study Design:

- Study type: Non-interventional mixed method research collected the feedback through:
 - a) questionnaires and interviews with Health Care Professionals (MTT-HCPs)
 - b) questionnaires with menopausal women (MTT-MW)
- Methods for the study included literature review, qualitative research, and expert committee involvement throughout by testing 2 types of questionnaires

5. Study Population:

- 41 gynecologists
- 8 primary care physicians
used MTT-HCP or MTT-W questionnaires with:
 - a. 172 suspected menopause women (age range: 45-60).
- Total: 227 participants

6. Methodology:

- Literature search identified 74 articles and 25 apps/trackers, on menopausal symptoms and menopause hormonal treatment risk factors were reviewed .
- Creation of two types of questionnaires:
 - a. one for HCP use during consultations (Menopause Treatment Tool – Health Care Professional (MTT- HCP)
 - b. one for women (MTT-Woman (MTT-W)) to complete in-office or prior to the consultation.
- Cognitive debriefing of the revised MTT with 18 HCPs (MTT-HCP) and 48 MW (MTT-W) from 7 countries to assess its content validity (relevance, HCP and MW comprehension, and preferences for different versions.
- MTT-HCP and MTT-W assessment for feasibility and content validity with clinicians (8/country) willing to test both MTTs with at least three potentially menopausal women/clinician in their practice. Clinicians were recruited through QualWorld and Theramex Ltd networks.

7. Study Locations:

- United Kingdom, Switzerland, Germany, Italy, Poland, Spain and US

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8. Regulatory Information:

- The study protocol was approved on 24 March 2023 by WCG IRB, located at 1019 39th Ave SE #120, Puyallup, WA 98374, United States.
- Study Number: 1350580

9. Results Summary:

- Eight primary care physicians (UK, US only) and 41 gynaecologists (all countries, except UK), with an average of 13 years of practice, participated. Menopausal women (n=172) were between 45 and 61 years (mean: 52 years).
- Based on feedback questionnaires (160 clinician's and 156 menopausal women's)
 - a. Most (>85%) clinicians and women reported both tools to be convenient and valuable for discussing symptoms and treatment options.
 - b. Most clinicians (>55%) and women (>70%) reported improved interactions and confidence in treatment decisions.
- Menopausal women were positive about MTT-HCP use in their consultation. They reported the MTT-HCP was:
 - a. easily understood (93%)
 - b. asked about relevant symptoms (96%)
 - c. provided clear and structured conversations with their HCPs (93%)
 - d. reassured (89%) and increased confidence (82%) in their treatment options
- Clinicians acknowledged the shift towards electronic tools in implementation phase, considered diverse formats (paper, app, tablet) and linkage to medical records.

10. Safety and Adverse Events:

- No safety concerns or adverse events reported during the study.

11. Conclusions:

- Both types of questionnaires: MTT-HCP and MTT-W are valid and efficient tools for clinical practice, facilitating discussions between physicians and women to streamline and optimise menopausal diagnosis and treatment.
- Both tools were refined based on study feedback and steering committee discussions, ensuring clinicians can use the MTT version that best meets the needs of their practice setting
- Objectives of the study were met.

12. Publication Plans:

- The study results are published in peer-reviewed journal (*Maturitas*); results available under the link:
<https://url.uk.m.mimecastprotect.com/s/NdbtCvQJPH73A8qUXhkSQLizN?domain=kwnsfk27.r.eu-west-1.awstrack.me>
- Planned publication: results focused on General Practitioners feedback only excluding gynecologists is planned in 2025

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13. Contact Information:

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