Study Summary

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 non-interventional study.

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

Status
Completed.

Objectives
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.).

Study Type
Non-interventional, prospective, observational, mixed method research collected the feedback through:

- Feedback forms and interviews with Health Care Professionals (MTT-HCPs).
- Feedback forms with menopausal women (MTT-MW).

Study Population
- 41 gynaecologists.
- 8 primary care physicians.
- Used MTT-HCP or MTT-W questionnaires with 172 menopausal women (age range: 45-61).
  Total: 227 participants.

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:

- One for HCP use during consultations (Menopause Treatment Tool – Health Care Professional (MTT- HCP)
- 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.

Data Analysis
The study's sample sizes were determined to meet qualitative research standards, with 8–12 participants recommended for robust results (interview a minimum of eight HCPs per country to assess feasibility). For quantitative feedback questionnaire analysis, a minimum of 150 MW's responses was considered adequate.

Study Location
UK, Switzerland, Germany, Italy, Poland, Spain and US.

Ethics approval
The study protocol was approved on 24 March 2023 by WCG IRB, located at 1019 39th Ave SE #120, Puyallup, WA 98374, United States (IRB Tracking Number: 20231107).

Summary of Results
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 forms responses: (160 clinician's and 156 menopausal women's).

- Most (>85%) clinicians and women reported both tools to be convenient and valuable for discussing symptoms and treatment options.
- 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:

- Easily understood (93%).
- Asked about relevant symptoms (96%).
- Provided clear and structured conversations with their HCPs (93%).
- 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.

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.

Limitations

- The study aimed to enlist less experienced physicians (<10 years in practice), but faced recruitment challenges, leading to inclusion of more experienced HCPs, which may have led to some biases against use of the measure.
- Challenges in recruiting Primary Care Physicians (PCPs) in the UK were noted, and while PCPs were included in the US cohort, gathering more feedback from PCPs in a qualitative study is warranted. No gynaecologists were recruited in the UK, because PCPs are primarily responsible for menopause treatment in UK.
- The majority of women included in this study were Caucasian and the socio-economic status of the women was not collected. Given potential differences in the menopause experience and/or prescribing practices by race/ethnicity and/or socioeconomic status it would be beneficial to test the usefulness of the tool with non-Caucasian women, immigrant women, and/or those from less affluent socio-economic backgrounds.

Reference

The study results published in peer-reviewed journal: Stute P, Binkowska M, Briggs P, Palacios S, Abetz-Webb L, Law V, Zablotna-Pociupany R, Boolell M, et al. Development, content validation and feasibility of a decision aid tool for the treatment of women with menopausal symptoms. Maturitas. 194 (2025). https://doi.org/10.1016/j.maturitas.2025.108195