Bazedoxifene plus conjugated estrogen to treat menopausal depression – a pilot study

Jayashri Kulkarni^{1,2}, Eveline Mu^{1,2}, Qi Li^{1,2}, Marta Malicka^{1,2}, Emorfia Gavrilidis^{1,2}, Anthony de Castella^{1,2}, Caroline Gurvich^{1,2}

¹Multidisciplinary Alfred Psychiatry Research Centre, Alfred Brain, Alfred Health; ²HER Centre Australia, School of Translational Medicine, Monash University

BACKGROUND

- Gonadal hormone fluctuations in the menopausal transition, particularly the decline in brain estrogen levels, significantly contribute to menopausal depression^{1,2}
- Although menopause hormone therapy (MHT) effectively manages physical symptoms,³ it is not routinely used for mental health disturbances
- Concerns about the long-term safety of estrogen and progestins have prompted the exploration of alternative hormone therapies
- Bazedoxifene, a selective estrogen receptor modulator, in combination with conjugated estrogens, is a newer, safe option for physical menopause symptoms⁴

AIMS & HYPOTHESIS

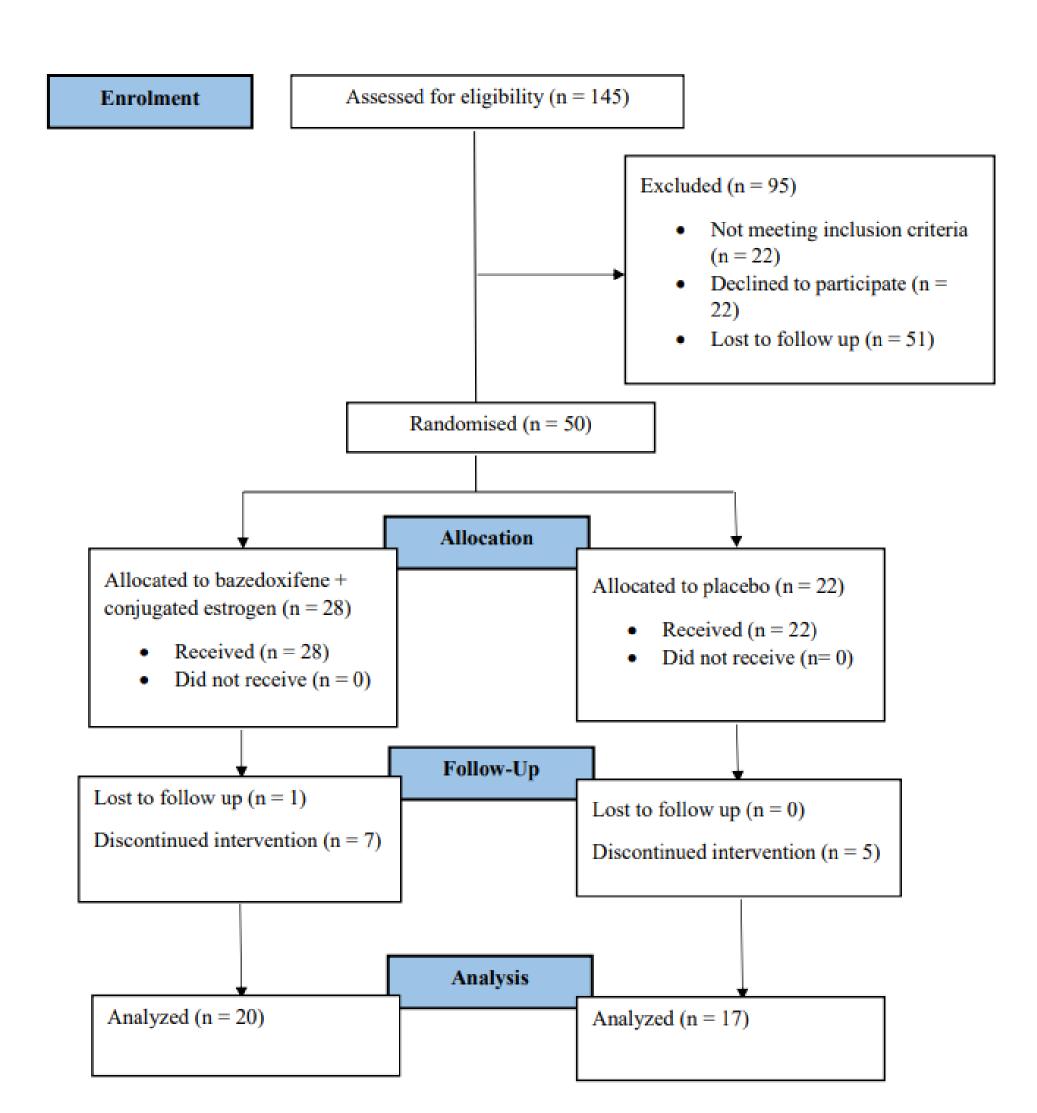
To investigate the effectiveness of bazedoxifene plus conjugated estrogen vs placebo in treating depressive symptoms in menopausal women.

The combination therapy of bazedoxifene plus conjugated estrogen is hypothesised to provide greater benefits in managing menopausal depression compared to placebo due to the unique pharmacological profile of bazedoxifene and the mood-stabilising effects of conjugated estrogen

METHOD

Study design: A 12-week randomised double-blinded placebo-controlled pilot trial

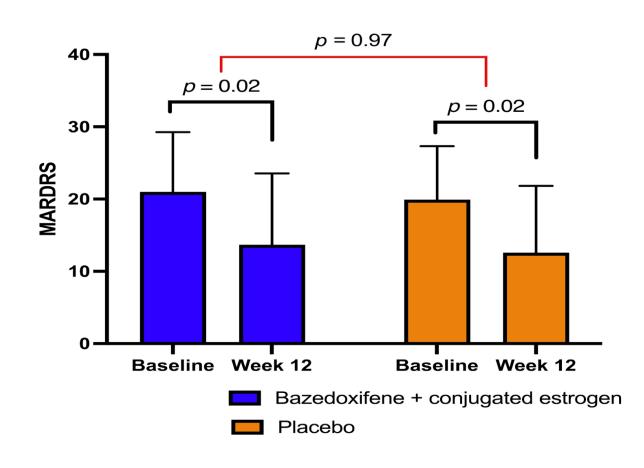
Intervention: (1) Oral bazedoxifene plus conjugated estrogen (20mg/0.45mg) (Duavive) or (2) an oral placebo



RESULTS

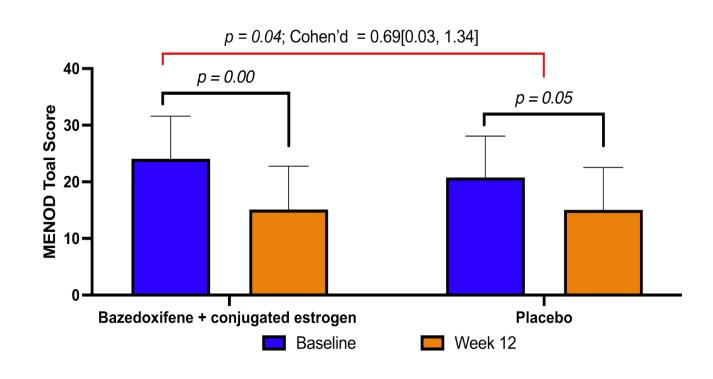
Primary outcome measure: Montgomery-Asberg Depression Rating Scale (MADRS; standard depression scale)⁵

 No sig. difference between bazedoxifene + conjugates estrogen and placebo groups

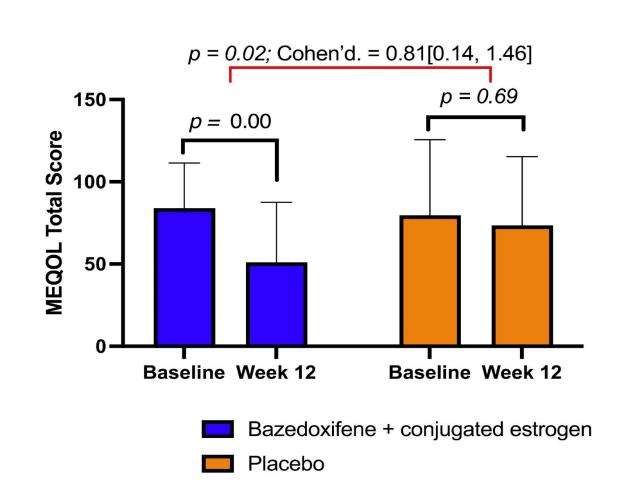


Secondary outcome measure: (1) Meno-D (menopausal depression specific scale)⁶

 Total Meno-D score was sig. lower in the bazedoxifene + conjugated estrogen group cf. placebo



- (2) Menopause-Specific Quality of Life (MENQOL)⁷
- MENQOL was sig. lower in the bazedoxifene + conjugated estrogen group cf. placebo



CONCLUSION

- The first study globally to investigate the effectiveness of bazedoxifene + conjugated estrogen in reducing depressive symptoms in menopausal women with a diagnosis of major depression
- It is important for clinicians and researchers to understand and measure menopause mental ill health differently from standard depression, especially in using menopause specific measures
- Support the use of MHT to treat menopausal depression

