

Testosterone Therapy on Gender Dysphoria, Depression, and Suicidality in Transgender and Gender Diverse Individuals Seeking Masculinisation: A Randomised Controlled Trial

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Background: Testosterone treatment is a necessary component of management for some transgender (trans) and gender diverse individuals. Observational studies have demonstrated improvements in gender dysphoria and depression following commencement of gender-affirming hormone therapy but there is a lack of randomised controlled trial data.

Objectives: To assess the impact of testosterone therapy compared to no treatment on gender dysphoria, depression, and suicidality in trans people seeking masculinisation.

Methods: Three-month open-label randomised controlled trial of 64 trans individuals seeking initiation of testosterone therapy comparing immediate testosterone commencement (intervention group) with no treatment (standard care waiting list of 3 months prior to commencement). This design ensured no individuals would be waiting longer than standard care. Primary outcome was gender dysphoria, as measured by the Gender Preoccupation and Stability Questionnaire (GPSQ). Secondary outcomes included the Patient Health Questionnaire-9 (PHQ-9) to assess depression and the Suicidal Ideation Attributes Scale (SIDAS) to assess suicidality. Questionnaires were undertaken at 0 and 3 months. ANCOVA was used to compare mean differences between groups.

Results: Compared to standard care, the intervention group had a decrease in gender dysphoria [mean difference -7.2 points (95% CI (-8.3, -6.1), $p < 0.001$], a clinically significant decrease in PHQ-9 [mean difference -5.6 points (-6.8, -4.4), $p < 0.001$], and a decrease in SIDAS [mean difference -6.5 points (-8.2, -4.8), $p < 0.001$]. Resolution of suicidality assessed by PHQ-9 item 9 occurred in 11 (52%) individuals with immediate testosterone commencement compared to 1 (5%) in standard care ($p = 0.002$).

Conclusions: This randomised controlled trial supports the use of testosterone therapy to significantly reduce gender dysphoria, depression, and suicidality in trans and gender diverse individuals desiring testosterone therapy.

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