Real World Testing of an Artificial Intelligence-enabled App as an Early Intervention and Support Tool in the Mental Health Referral Care Pathway

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Methods

Randomisation – sequence generation

Demographic data was collected from all patients immediately after completion of the informed consent process, over the phone. Together with data from the IAPT referral, this information was used in the randomisation algorithm to ensure that the intervention and control arms were balanced on key variables (gender, age, ethnicity, self-reported antidepressant use, and severity of depression).

Randomisation – allocation concealment mechanism

Consenting participants were inputted into a masked computer randomisation algorithm and the outcome was recorded in an electronic record to conceal treatment allocation from study researchers. Participants were sent an automatic email to inform them of their group assignment, and participants in the intervention arm will receive the link to download Wysa.

Randomisation – implementation

Psychology assistants recruited specifically for the trial and covering the three London Community Living Well Service sites enrolled participants in the study. A computer generated the random allocation sequence assigned participants to interventions, with a ration of 2:1 randomization to the intervention group.

Blinding

Due to the nature of the intervention, no blinding of participants was possible in the study, as all participants knew whether they were using the app. Clinical treatment teams were not blinded as they knew through the electronic patient record if a participant has received the intervention. The evaluation team will be blinded to treatment using the randomisation algorithm.

Statistical methods

Descriptive statistics was used to assess baseline comparability and the distributions of the primary and secondary outcomes. Visualisations via density and box plots supplemented the tabulations. Linear regression was used to carry out comparative analysis of the primary outcome PHQ9, and secondary outcome GAD7, to compare the two treatment arms. For the primary outcome, PHQ9, the study was powered to detect a clinical meaningful difference of 2 points, with 80% power and a Type 1 error rate of 0.05. Additional post hoc regression was carried out for individuals who had a PHQ2<5 and PHQ2<4 at baseline.