Introduction: Twin Precision Treatment (TPT): a novel whole-body digital twin enabled precision nutrition that utilizes 174 health markers and 3000 daily data points from blood tests and connected devices that measure weight, physical activity, sleep and sensor glucose values, for achieving remission. Methods: Contemporary consensus statement defines remission as a return of hemoglobin A1c (HbA1c) to <6.5% and persists for at least three months in the absence of diabetes medication. Estimated HbA1c (eA1C) <6.5% or fasting plasma glucose (FPG) <126 mg/dl can be used as an alternative tool in determining remission when HbA1C<6.5% is not a reliable marker. The concordance in remission by the different criteria was obtained and Kappa agreement was calculated. We evaluated the data of the multicenter RCT that is based on the patented Whole-Body Digital Twin (WBDT) enabled precision treatment for reversing diabetes. The trial was approved by an independent ethics committee, the Medisys Ethics committee (MCERB/2020/07). Trial registration: Clinical Trials Registry India (CTRI) (CTRI/2020/08/027072). SPSS Version 28.0 was used for the statistical analysis. Results: We analyzed the dataset of 199 patients. The mean age was 43.3 years (±8.7); diabetes duration was 3.7 years (±2.7). The mean baseline HbA1c (%) of 9 (±1.8) reduced to 5.7 (±0.5) (p<0.001). The mean baseline eA1C (%) of 8.1(±2.3) reduced to 4.9 (±0.6) (p<0.001). The mean baseline FPG of 170.2(±59.9) (mg/dl) reduced to 95.9 (±18.2) (mg/dl) (p<0.001). 167(83.9%) achieved remission by HbA1c criteria. 166 (83.4%) achieved eA1C<6.5%. 161 (80.9%) achieved remission for FPG<126 mg/dl. 167 (83.9%) achieved remission by either FPG<126 mg/dl or eA1C<6.5%. For every person achieving remission based on HbA1c criteria there were equivalent number achieving remission by eA1C criteria (1: 1) and proportionally the same by FPG criteria (1: 0.96). Concordance of rate of remission by eA1c and HbA1c was 97.5%, and their kappa agreement was 0.91 (95% CI 0.83 to 0.99, p<0.001) (almost perfect agreement). Concordance of rate of remission by FPG and HbA1c criteria was 94%, kappa 0.79 (95% CI 0.68-0.90, p<0.001) (moderate agreement). By either FPG or eA1C criteria, the concordance rate was 97%, kappa 0.89 (95% CI 0.80 to 0.98, p<0.001) (strong agreement). We benchmarked eA1C and FPG against HbA1c for achieving remission. Sensitivity (%), specificity (%), and kappa agreement for eA1C and FPG was 98.2, 93.8, 0.91 and 94.6, 90.6, 0.79, respectively. Conclusion: There was high concordance irrespective of the criteria used to evaluate remission. This homogeneity in the criteria may positively affect, assessing remission by the independent yet flexible choice of markers of remission. Using patient-level data in RCT would be an important step in putting the remission guidelines to utility in the real world. It appears that HbA1c, eA1C and FPG are comparable and reliable markers for assessing remission of T2D.

Presentation: Sunday, June 12, 2022 12:30 p.m. - 2:30 p.m.