Using an AI-based Voice Assistant to Manage Insulin in Diabetes: a Randomized-Control Trial

NCT05081011

February 2, 2021

Power and sample size calculation

Sample size was determined to be 32 participants for 80% power and a 2-sided alpha of 0.05 to detect a treatment difference of 84% for the voice AI group vs 40% for the standard of care group for the proportion that achieve glycemic control. We decided to use our secondary outcome of glycemic control as the basis of our power calculation because it has been used in prior studies.

The treatment difference of 84% vs 40% was based on a similar study which found a 2:1 (60% vs 30%) treatment difference for their digital intervention. Given that this similar study supported titration of more complicated insulin regimens and did not utilize voice, we felt that an increased projected treatment effect of 84% for our intervention was reasonable. We also requested and received approval to recruit up to 50 participants to account for drop out.