

Month 6 Data



Study Pill Discontinuation

- 3 participants discontinued study pills (as of 10/15), but are still being followed
 - 2 participant decision
 - 1 for safety reasons (nephrolithiasis)

Physical Measures

	Baseline (n=677)	Month 3 (n=447)	Month 6 (n=230)
BMI	31.9	31.8	31.2
Systolic pressure	126.7	126.7	127.1
Diastolic pressure	76.6	77.4	77.4



Supplementation (self-reported)

	Baseline (n=672)	Month 3 (n=447)	Month 6 (n=231)
Vitamin D	272	316	295
Calcium	99	111	96



Glycemia

	Baseline (n=672)	Month 6 (N=221)
Glucose	108.5	107.0
HbA1c	5.92	5.85



Primary Outcome: Incident diabetes

- 2 participants have met the diabetes outcome by Central Laboratory criteria (both had to return for a repeat measure)
- 2 participants were started on metformin for diabetes prevention.
 - 1 came for an unscheduled/confirmatory (UNCO) visit prior to starting metformin; and did not meet the laboratory criteria for diabetes.
 - 1 started metformin prior to notifying the site. Records have been sent to the Clinical Outcomes Committee for adjudication.