

ISRCTN89882877: Clinical trial to evaluate Reducose® mulberry leaf extract as a functional food ingredient to improve metabolic health: Results

Participant flow

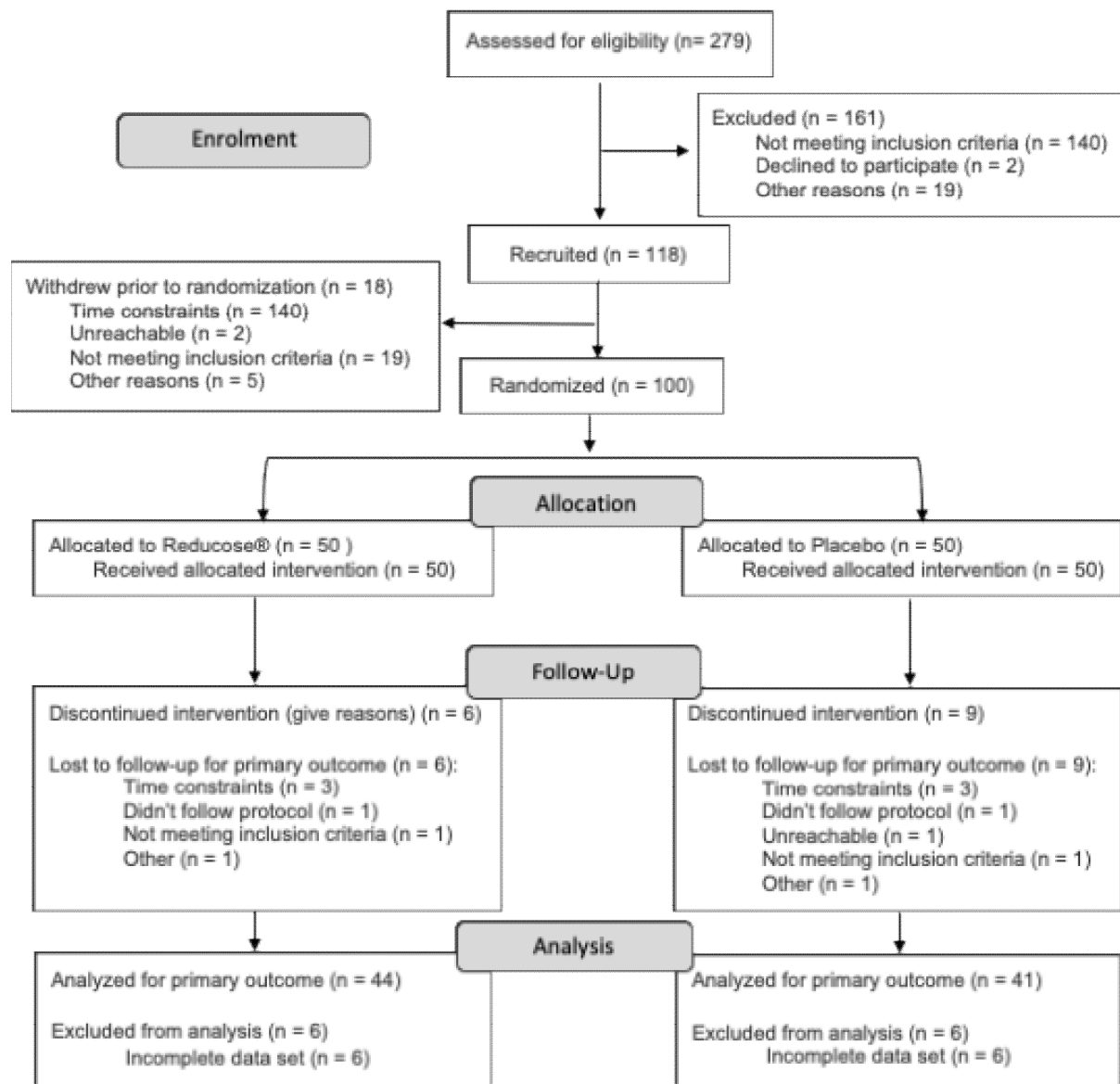


Figure 1: Consort flow diagram (2025)

Baseline characteristics

Baseline characteristics of study participants

Characteristics	Placebo	MLE	Total	p-value ^a
Number of participants	41	44	85	
Sex (M/F)	14/27	13/31	27/58	0.412
Age (years)	42.2 ± 2.0	40.0 ± 2.0	41.0 ± 1.4	0.418
BMI (Kg/m ²)	27.2 ± 0.2	27.1 ± 0.2	27.1 ± 0.14	0.274
HbA1c (%)	5.61 ± 0.04	5.51 ± 0.04	5.56 ± 0.03	0.073
Fasting glucose, FBG (mmol/L)	5.72 ± 0.2	5.75 ± 0.1	5.73 ± 0.09	0.867
Fasting Insulin, FPI (IU/mL)	9.1 ± 1.0	12.7 ± 2.4	10.9 ± 1.3	0.090
Body Fat, BF (%)	31.9 ± 0.9	31.5 ± 0.9	31.7 ± 0.6	0.750
Free Fat Mass, FFM (%)	51.6 ± 1.7	51.6 ± 1.6	51.6 ± 1.2	0.992

Data presented as mean ± Standard error of the mean (SEM), ^a, Pearson Chi-Square for Group × Gender, while all other baseline variables were compared using independent-samples t-test.

Outcome measures

Postprandial Glucose Outcomes at Weeks 1 and 12

Outcome	Week 1		Week 12	
	Result	p value	Result	p value
Glucose iAUC 0–60 min	30.3% lower with MLE $\beta = -16.53$ (–28.17 to –4.89)	< 0.01	39.4% lower with MLE $\beta = -17.86$ (–30.49 to –5.23)	< 0.01
Glucose iAUC 60–120 min	39.6% higher with MLE $\beta = 7.78$ (–3.79 to 19.35)	n.s.	32.7% higher with MLE $\beta = 8.35$ (–4.13 to 20.83)	n.s.
Incremental peak glucose (iCmax, mmol/L)	Placebo: 2.017 ± 0.15 MLE: 1.589 ± 0.12 21.2% lower with MLE	< 0.05	Placebo: 1.725 ± 0.14 MLE: 1.306 ± 0.12 24.3% lower with MLE	< 0.05
Glucose curve Time effect	F = 45.14	< 0.0001	F = 26.68	< 0.0001
Glucose curve Treatment effect	F = 0.284	n.s.	F = 1.098	n.s.
Time × treatment interaction	F = 4.286	< 0.01	F = 7.793	< 0.0001
Between-group glucose differences by timepoint	30 min	< 0.05	30 min	< 0.05
	45 min	< 0.005	45 min	< 0.005
	120 min	< 0.05	90, 105 and 120 min	< 0.001
Week 1 vs week 12 within MLE group	—	—	Time × week: F = 2.703	< 0.05
			Time effect: F = 22.65	< 0.0001
			45 min: $\beta = -0.4581$ (–0.8071 to –0.1091)	< 0.01

Values in parentheses are 95% confidence intervals for β . Percentage differences are MLE relative to placebo. iAUC, incremental area under the curve; iCmax, incremental peak glucose; CI, confidence interval; n.s., not statistically significant.

Unadjusted and Adjusted Percentage Change from Baseline in Inflammatory and Adipokine Biomarkers at 6 and 12 Weeks

Parameters	Unadjusted Mean Diff, (β , [95% CI]) ^a		Adjusted Mean Diff, (β , [95% CI]) ^b	
	6 weeks	12 weeks	6 weeks	12 weeks
TNF-α	-0.037 (-0.536, +0.461)	+0.026 (-0.472, +0.525)	-0.025 (-0.539, +0.490)	+0.047 (-0.470, +0.564)
IL-6	+0.080 (-0.585, +0.744)	-0.028 (-0.561, +0.505)	+0.057 (-0.633, +0.747)	+0.008 (-0.539, +0.555)
Leptin	+0.290 (-0.167, +0.746)	+0.175 (-0.160, +0.511)	+0.283 (-0.063, +0.628)	+0.172 (-0.076, +0.420)
Adiponectin	+0.451 (-0.075, +0.998)	+0.015 (-0.491, +0.522)	+0.461 (-0.075, +0.998)	+0.015 (-0.491, +0.522)

Data presented as β coefficients (MLE minus Placebo) with 95% confidence intervals (CI). ^aUnadjusted β coefficients. ^bAdjusted β coefficients controlling for age, sex, baseline BMI, baseline body fat percentage, and baseline biomarker value.

Adjusted Appetite AUC (Breakfast + Lunch) at Weeks 1, 6, and 12

Appetite Dimension	Time Point	Placebo group	MLE group	Treatment difference (β , [95% CI])	p-value
Hunger	Week1	25054.37 (1088.69)	21835.71 (1076.49)	-3218.66 [-6301.66, -135.66]	0.041*
	Week 6	24847.89 (1275.71)	21059.18 (1218.58)	-3788.71 [-7349.61, -227.81]	0.037*
	Week 12	23139.47 (1160.58)	17855.36 (1106.66)	-5284.12 [-8510.52, -2057.71]	0.002*
Fullness	Week1	22626.27 (1108.07)	23864.36 (1095.65)	1238.09 [-1899.79, 4375.96]	0.435
	Week 6	24036.37 (1094.77)	25296.28 (1045.74)	1259.91 [-1795.92, 4315.73]	0.415
	Week 12	24368.70 (1103.14)	22922.91 (1051.89)	-1445.80 [-4512.54, 1620.94]	0.351
Desire to eat	Week1	25679.88 (1080.65)	22588.79 (1068.54)	-3091.09 [-6151.30, -30.88]	0.048*
	Week 6	24867.74 (1233.79)	21454.30 (1178.53)	-3413.44 [-6857.32, 30.44]	0.052
	Week 12	23340.14 (1145.25)	18390.56 (1092.04)	-4949.58 [-8133.36, -1765.80]	0.003*
Prospective Consumption	Week1	25789.42 (1126.22)	22620.83 (1113.60)	-3168.59 [-6357.86, 20.68]	0.051
	Week 6	24378.07 (1204.30)	22103.17 (1150.36)	-2274.90 [-5636.47, 1086.67]	0.182
	Week 12	23274.97 (1121.13)	19123.01 (1069.04)	-4151.96 [-7268.70, -1035.21]	0.01*

Data presented as adjusted mean $\pm$ standard error (SE). Models adjusted for age, sex, screening body weight, and screening HbA1c. Treatment differences are reported as adjusted mean differences (MLE minus placebo) with 95% confidence intervals (CI) and two-sided p-values.* $p < 0.05$.

Unadjusted and Adjusted Percentage Change from Baseline in Blood Pressure and Blood Lipids at 6 and 12 Weeks

Parameters	Unadjusted Mean Diff, 95% CI ^a		Adjusted Mean Diff, 95% CI ^b	
	6 weeks	12 weeks	6 weeks	12 weeks
TC (mg/dL)	+0.007 (+2.560, -2.546)	+0.233 (+2.540, -2.074)	-0.367 (+2.337, -3.071)	+0.126 (+2.569, -2.317)
HDL(mg/dL)	-1.718 (+1.339, -4.775)	-3.283 (-0.272, -6.294)	-2.217 (+1.848, -6.062)	-3.857 (-0.771, -6.883)
LDL(mg/dL)	-1.780 (+2.643, -6.203)	-1.620 (+2.736, -5.976)	-1.697 (+2.832, -6.226)	-1.526 (+2.913, -5.967)
TG (mg/dL)	+0.930 (+18.999, -17.139)	+17.472 (+35.016, -0.072)	+0.762 (+17.999, -16.475)	+17.110 (+34.872, -0.652)
SBP (mmHg)	+0.211* (-1.590, +2.013)	+0.213* (-1.589, +2.015)	+0.274 (-1.519, +2.066)	+0.258* (-1.538, +2.053)
DBP (mmHg)	-0.114 (-2.173, +1.945)	-0.200 (-2.259, +1.860)	+0.338 (-1.663, +2.339)	+0.229 (-1.764, +2.222)

Data presented as β coefficients (MLE minus Placebo) with 95% confidence intervals (CI). ^aUnadjusted β coefficients. ^bAdjusted β coefficients controlling for age, sex, baseline BMI, baseline body fat percentage, and baseline biomarker value. * p , 0.05

Anthropometric, microbiome and microbial metabolite data remain under analysis. The registry results will be updated to include these outcomes when the analyses are complete.

Adverse events

Two participants in the placebo group reported constipation or nausea. No adverse events were reported in the extract group.