

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

Plain English Summary

The study compared mulberry leaf extract with a placebo taken twice daily for 12 weeks in 100 adults with overweight. Results were analysed for 85 participants who completed the study: 44 taking the extract and 41 taking placebo.

After a standard breakfast, the blood sugar rise during the first hour was 30% smaller at week 1 and 39% smaller at week 12 in the extract group. The maximum rise in blood sugar was also 21% and 24% smaller, respectively. These differences were statistically significant. Blood sugar responses during the second hour did not differ significantly between groups.

Participants taking the extract reported less hunger at weeks 1, 6 and 12, and less desire to eat at weeks 1 and 12. At week 12, they also reported that they felt able to eat less food. Feelings of fullness did not differ significantly between groups.

Additional analyses at week 12 found lower fasting blood sugar and lower levels of C-reactive protein, a marker of inflammation, in the extract group. At week 12, estimated insulin resistance was lower in the extract group than in the placebo group. No statistically significant differences were reported for average blood sugar over the preceding months (HbA1c), fasting insulin, blood pressure, blood fats or the other inflammation and hormone markers measured.

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

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