Efficacy and safety of **G**luco**L**o Plus in Typ**e** 2 Diab**e**tes manageme**n**t (GLEEN study): a double-blind, randomised, placebo-controlled, parallel-group, multicenter trial.

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Abstract (300 word limit)

Introduction: Diabetes is a chronic disease associated with many comorbidities and a higher risk of mortality. Patients are constantly in the lookout for Complementary and Alternative Medicines that are safe and efficacious for type 2 diabetes management. Objectives: The primary outcome was to evaluate the effect of GlucoLo Plus on HbA1c and the secondary outcome was to assess the effect on bodyweight and it's innocuity. Methodology: This double-blind randomised placebo-controlled trial evaluated the effects of daily GlucoLo Plus, a newly formulated all natural supplement for diabetes type 2 management. Results: Of 64 individuals assessed for eligibility, 61 (mean HbA1c 6.98% [52.8 mmol/mol], mean age 67.3 years [SD 9·5], 26 [43%] women, mean diabetes duration 3.2 years, and mean body-mass index 27·9 kg/m^2) were randomly assigned to GlucoLo Plus (n=32 [53%]), or placebo (n=28 [47%]). 1 participant was lost to follow up. At 12 weeks, GlucoLo Plus decreased HBa1c by 0.83% (P=0.0131) while placebo reduced it by 0.12% (p = 0.6151). The GlucoLo Plus arm had a mean 1.84 lbs weight loss while the placebo arm had a 0.21 lbs weight gain. The most frequent adverse events with GlucoLo Plus were mild and transient gastrointestinal events including nausea (9.3% vs 3.5%) and dyspepsia (15.6% vs 10.7%). Conclusion: GlucoLo Plus significantly lowered the HbA1c, had a positive effect on bodyweight and had a minimal side effect profile. These results suggest that GlucoLo Plus could be an alternative and adjunct to type 2 diabetes in people who are reluctant to initiate or add new antidiabetic agents.



Biography (150 word limit)

Deanna Mulvihill has her expertise in evaluation and passion in improving the health and wellbeing. Her open and contextual evaluation model based on responsive constructivists creates new pathways for improving healthcare. She has built this model after years of experience in research, evaluation, teaching and administration both in hospital and education institutions. The foundation is based on fourth generation evaluation (Guba& Lincoln, 1989) which is a methodology that utilizes the previous generations of evaluation: measurement, description and judgment. It allows for value-pluralism. This approach is responsive to all stakeholders and has a different way of focusing.

Alexandro Zarruk has been practicing in the West Island, Vaudreuil and Hudson since 2012. He is associated with the Lakeshore General Hospital. His practice is in the field of metabolic medicine. He is the founder and president of Groupe Nature Pharma which specializes in all natural supplements for the management of chronic diseases.

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