Reversal of Type 2 Diabetes Mellitus Disease Burden Through a Patented Non-Pharmaceutical Program

Short Title: Revert to Non-Clinical Diabetes with Diabetes Reversal Group®

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Abstract

Type 2 diabetes mellitus (T2DM) affects over 34.2 million Americans—approximately 10.5% of the population—and continues to grow at epidemic proportions. Despite widespread pharmaceutical management, outcomes remain suboptimal for many patients. The Diabetes Reversal Group® (DRG®) program is a patented, non-pharmacological intervention designed to achieve full clinical reversal of T2DM, defined as a reduction in HbA1c to 5.9% or below with complete elimination of anti-diabetic medications, including metformin and insulin.

This consecutive case series evaluated 137 adult Americans diagnosed with T2DM who enrolled in the DRG® program between 2013 and 2021. The intervention combined supervised dietary modification, lifestyle coaching, medication monitoring in coordination with participants' primary physicians, and proprietary nutritional supplementation. Baseline and post-program data were collected for HbA1c, fasting plasma glucose (FPG), weight, body mass index (BMI), blood pressure, and medication dosages.

Mean HbA1c decreased from 7.65% (±1.57) to 6.04% (±0.68), a mean reduction of 1.62% (-18.57%; statistically significant). Mean FPG declined by 41.32 mg/dL (-20.09%). Participants lost an average of 20.4 lbs (-9.4% body weight). Systolic blood pressure decreased by 11.34 mmHg (-6.80%). Among participants taking metformin (n=97), doses were reduced by an average of 52.12%; among those on insulin (n=40), doses decreased by 85.00%. Full clinical reversal—meeting both HbA1c and medication elimination criteria—was achieved in 36 participants (26.28%). An additional 25 participants (18.25%) achieved target HbA1c but were categorized as clinically controlled rather than reversed due to continued reliance on anti-glycemic medications.

These findings suggest the DRG® non-pharmaceutical program produces clinically and statistically significant improvements across key T2DM metrics in a real-world adult population. Further investigation through randomized controlled trials is warranted to validate efficacy and assess long-term durability of outcomes.

Keywords: type 2 diabetes reversal, non-pharmacological diabetes management, HbA1c, glycemic control, consecutive case series, metformin elimination, insulin reduction, lifestyle intervention

Introduction

Type 2 diabetes mellitus (T2DM) represents one of the most significant public health burdens in the United States. The Centers for Disease Control and Prevention (CDC) National Diabetes Statistics Report estimated 34.2 million Americans—approximately 10.5% of the population—were living with diabetes as of 2020, an increase from 9.4% reported in 2017 [1].

Having emerged at epidemic proportions in the 20th century, T2DM remains largely uncontrolled well into the 21st century [2].

The core pathology of T2DM is chronic hyperglycemia arising from insulin resistance and progressive impairment of insulin secretion. Left uncontrolled, hyperglycemia drives a cascade of microvascular complications (retinopathy, nephropathy, neuropathy) and macrovascular complications (coronary artery disease, peripheral arterial disease, cerebrovascular disease) [3]. In 2016, diabetes accounted for over 16 million emergency room visits and 7.8 million hospitalizations in the United States. By 2017, total annual costs of diagnosed diabetes reached $327 billion in direct and indirect costs [1].

Current standard-of-care management for T2DM relies heavily on pharmaceutical intervention—primarily metformin and insulin analogs—with adjunctive lifestyle guidance. While these approaches can control symptoms, they do not reverse the underlying metabolic dysfunction for most patients. The American Diabetes Association acknowledges that T2DM management must encompass behavioral change, dietary modification, self-monitoring, and comprehensive education, yet pharmaceutical-only approaches remain dominant in practice [4].

The Diabetes Reversal Group® (DRG®) program is a patented, non-pharmacological intervention that targets full clinical reversal of T2DM—defined as achieving HbA1c ≤5.9% with complete elimination of anti-diabetic medications, including metformin [5]. Founded on the evidence base for lifestyle-driven metabolic improvement, the program combines individualized dietary plans, lifestyle coaching, medication dose monitoring in coordination with participants' primary physicians, proprietary nutritional supplementation, and structured diabetes education. This study reports preliminary findings from a consecutive case series of 137 participants enrolled in the DRG® program between 2013 and 2021, evaluating clinical effectivity across glycemic, anthropometric, and pharmacological parameters.

Materials and Methods

Study Design

This is a retrospective consecutive case series evaluating the effectiveness of the DRG® program in adults with T2DM. Data were collected from participant charts spanning 2013 to 2021 across at least four DRG® clinical sites and a network of remote virtual consult providers operating in more than 25 US cities.

Study Population

The target population comprised adult Americans (age ≥18) with a confirmed T2DM diagnosis per American Diabetes Association (ADA) criteria who had enrolled in and paid for the DRG® program. The study was not interventional; it retrospectively analyzed program outcomes from existing participant records.

Inclusion Criteria

- Confirmed T2DM diagnosis by at least one ADA criterion at time of program enrollment: FPG ≥126 mg/dL; HbA1c ≥6.5%; 2-hour OGTT plasma glucose ≥200 mg/dL; or random plasma glucose ≥200 mg/dL with classic hyperglycemic symptoms
- Age 18 years or older
- US resident
- Complete baseline and post-program clinical parameters (anthropometrics, laboratory results, medication dosages)

Exclusion Criteria

- Non-diabetic per ADA criteria at time of enrollment
- Diagnosis of type 1 diabetes mellitus
- Incomplete baseline or post-program data
- Age under 18 years

Intervention: The DRG® Program

The DRG® program is a structured, non-pharmacological T2DM reversal protocol. Upon enrollment, participants underwent a Wellness Consultation to collect baseline data and assign a proprietary Diabetes Score—derived from baseline HbA1c, anti-diabetic medication burden, total daily medications, body weight, and age—which determined program length: 2-month (5–9 points), 4-month (10–18 points), or 6-month plan (19–25 points).

Program components included: (1) individualized, low-carbohydrate dietary meal plans with access to over 240 recipes; (2) proprietary DRG® nutritional supplements; (3) a 30-day DRG® Gentle Cleanse; (4) weekly physical activity guidance; (5) unlimited 1-on-1 support via phone or video call with Wellness Coordinators and Support Doctors, available seven days per week; (6) weekly group sessions covering diabetes management topics; and (7) ongoing medication dose monitoring in coordination with participants' primary physicians. No medication changes were made without the agreement of the participant's own primary physician.

Outcome Measures

The primary outcome was full clinical T2DM reversal, defined as achieving HbA1c ≤5.9% and complete elimination of all anti-diabetic medications (including metformin and insulin analogs) at the end of the program.

Secondary outcomes included: mean percent-change in HbA1c; mean percent-change in FPG; mean percent-change in body weight and BMI; mean percent-change in systolic and diastolic blood pressure; mean percent-change in medication dosages (metformin, insulin, other antiglycemics, antihypertensives, anticholesteremics); and proportion of participants achieving clinical T2DM control (HbA1c ≤5.9% without full medication elimination).

HbA1c was measured using a DCA Vantage® Analyzer at baseline and program completion. FPG and other laboratory parameters were submitted by participants from their own physicians' labs. Blood pressure and anthropometrics were self-reported and recorded by DRG® staff during Wellness Consultations.

Statistical Analysis

Descriptive statistics were computed for all clinical parameters at baseline and post-intervention. Mean values, standard deviations (SD), and percent-change were calculated. Statistical significance of percent-changes was evaluated using standard error (SE) with 95% confidence intervals; a change was deemed statistically significant if both the upper and lower confidence bounds were the same sign (i.e., the interval did not cross zero). A clinically significant reduction in HbA1c was defined as ≥0.5% per NCBI/NICE guidelines [6, 7]. A clinically significant reduction in systolic blood pressure was defined as ≥5 mmHg [8]. All analyses were performed using Microsoft Excel.

Sample size: A minimum of 96 participants was required to achieve 95% confidence with a 5.0% margin of error, assuming a population of >20,000 eligible T2DM patients. The study enrolled 137 participants, yielding a margin of error of approximately 4.37.

Ethics, Consent, and Data Governance

This study was conducted in full accordance with all applicable Diabetes Reversal Group® policies, state and federal regulations, and the Good Clinical Practice (GCP) Consolidated Guideline approved by the International Conference on Harmonization (ICH). All participants provided informed consent prior to enrollment. Consent was collected in the form of a signed Consent Form at the time of program enrollment. Participants unable to complete a Consent Form due to disability or cognitive impairment were represented by informed assent from legal guardians or first-degree relatives, with cognitive status assessed using a Montreal Cognitive Assessment (MoCA) where applicable.

All data were de-identified prior to analysis; individual participant records were assigned study ID numbers and no directly identifiable information was used in statistical analysis or reporting. Data were stored in encrypted, password-protected electronic formats accessible only to investigators, research associates, and reviewers, each of whom signed a non-disclosure agreement (NDA). This study does not involve a regulated pharmaceutical intervention. Risk to participants was minimal, as no changes to medications or care plans were enacted without agreement from participants' primary physicians.

This study is classified as observational research on retrospective program data. The study protocol was designed in accordance with DRG® institutional policy and applicable federal and state law. No research grant or external funding was received; the study was funded internally by Diabetes Reversal Group®.

Results

Participant Characteristics

A total of 137 participants were included in this consecutive case series. The cohort was predominantly male (72.26%; n=99) with a mean age of 65.50 years (±9.64). Mean BMI at baseline was 31.46 (±5.79), consistent with obesity. Mean duration of T2DM diagnosis was 11.89 years (±10.76). Most participants (86.86%; n=119) presented with uncontrolled hyperglycemia (HbA1c ≥5.9%) at baseline; 64.23% (n=88) reported active diabetic symptoms. Comorbidities included hypertension (62.20%; n=79) and dyslipidemia (50.39%; n=64).

Pharmaceutical history at baseline: 70.80% were on metformin, 29.20% on insulin, 54.01% on other oral antiglycemic agents, 55.47% on antihypertensives, and 37.96% on anticholesteremics (Table 1).

Table 1. Baseline Descriptive Clinical Features (N=137)

Clinical Feature	Value (N=137)
Age (mean years ± SD)	65.50 ± 9.64
Sex (% male)	72.26% (n=99)
Height (mean inches ± SD)	68.2 ± 4.4
Weight (mean lbs ± SD)	208.8 ± 46.4
BMI (mean ± SD)	31.46 ± 5.79
T2DM diagnosis duration (mean years ± SD)	11.89 ± 10.76

Newly diagnosed T2DM (%)	5.69% (n=7)
Uncontrolled hyperglycemia (%)	86.86% (n=119)
Symptomatic (%)	64.23% (n=88)
Hypertension (%)	62.20% (n=79)
Dyslipidemia (%)	50.39% (n=64)
On Metformin (%)	70.80% (n=97)
On Insulin (%)	29.20% (n=40)
On other antiglycemic drugs (%)	54.01% (n=74)
On antihypertensives (%)	55.47% (n=76)
On anticholesteremics (%)	37.96% (n=52)
Family history of T2DM (%)	23.20% (n=29)

Program allocation: 19.71% (n=27) were enrolled in the 2-month plan, 16.06% (n=22) in the 3-month plan, 49.64% (n=68) in the 4-month plan, and 6.57% (n=9) in the 6-month plan. Program completion status: 80.29% (n=110) fully completed, 15.33% (n=21) withdrew early, and 4.38% (n=6) had incomplete data. Mean participant stay was 136 days (±78 days; approximately 5 months).

Glycemic Outcomes

Mean HbA1c decreased from 7.65% (±1.57) at baseline to 6.04% (±0.68) at program completion, a mean reduction of 1.62% (percent-change: -18.57%). This change was statistically significant (SE=1.27; 95% CI: -16.09% to -21.06%). Mean FPG declined from 154.44 mg/dL (±53.60) to 113.19 mg/dL (±18.94), a mean reduction of 41.32 mg/dL (-20.09%), also statistically significant (Table 2).

Table 2. Baseline Clinical Data and Post-Intervention Changes

Parameter	Pre-Intervention	Post-Intervention	Mean Change	% Change
HbA1c (% ± SD)	7.65 ± 1.57	6.04 ± 0.68	-1.62 ± 1.63	-18.57%
FPG (mg/dL ± SD)	154.44 ± 53.60	113.19 ± 18.94	-41.32 ± 55.02	-20.09%
Weight (lbs ± SD)	208.8 ± 46.4	191.3 ± 41.9	-20.4 ± 12.4	-9.4%
BMI (kg/m² ± SD)	31.46 ± 5.79	28.75 ± 5.36	-3.1 ± 1.9	-9.4%
Systolic BP (mmHg ± SD)	135.42 ± 24.75	124.74 ± 13.89	-11.34 ± 21.74	-6.80%
Diastolic BP (mmHg ± SD)	78.49 ± 13.89	75.95 ± 9.29	-5.68 ± 13.73	-5.45%
Total Cholesterol (mg/dL ± SD)	159.91 ± 36.59	151.21 ± 36.85	-12.26 ± 31.74	-5.88%

Anthropometric and Secondary Clinical Outcomes

Participants lost an average of 20.4 lbs (±12.4 lbs), representing a 9.4% decrease in body weight and a reduction in mean BMI from 31.46 to 28.75 kg/m² (-9.4%). Mean systolic blood pressure decreased by 11.34 mmHg (-6.80%) and diastolic blood pressure by 5.68 mmHg (-5.45%). Mean total serum cholesterol decreased by 12.26 mg/dL (-5.88%). All anthropometric and blood pressure changes were statistically significant (Table 3).

Medication Outcomes

Among the 97 participants on metformin, mean dose decreased from 1,452.20 mg (±575.75) to 726.63 mg (±770.59), a 52.12% reduction (statistically significant; 95% CI: -44.20% to -60.05%). Among the 40 participants on insulin, mean dose decreased from 35.38 IU (±20.39) to 6.38 IU (±12.48), an 85.00% reduction (statistically significant; 95% CI: -80.63% to -89.37%). Other antiglycemic agents were reduced by 76.89% across 74 participants. Antihypertensives were reduced by 30.71% across 76 participants. Anticholesteremics showed a 22.58% reduction across 52 participants (Table 3).

Table 3. Baseline Medication Doses and Post-Intervention Changes

Medication	Pre-Intervention	Post-Intervention	% Change
Metformin (mg ± SD; n=97)	1452.20 ± 575.75	726.63 ± 770.59	-52.12%
Insulin (IU ± SD; n=40)	35.38 ± 20.39	6.38 ± 12.48	-85.00%
Other Antiglycemics (n=74)	N/A	N/A	-76.89%
Antihypertensives (n=76)	N/A	N/A	-30.71%
Anticholesteremics (n=52)	N/A	N/A	-22.58%

T2DM Reversal and Clinical Control Outcomes

Of 137 participants, 82.48% (n=113) achieved some reduction in HbA1c. A total of 61 participants (44.53%) reached the target HbA1c ≤5.9%. Of those, 36 participants (26.28% of the total cohort) achieved full clinical T2DM reversal—meeting both the HbA1c target and complete elimination of all anti-diabetic medications. An additional 25 participants (18.25%) achieved target HbA1c but were classified as clinically controlled due to continued anti-glycemic medication use.

Among participants on insulin, 60.00% (n=24) fully eliminated insulin by program completion. Among participants on metformin, 38.14% (n=37) fully eliminated metformin. Among those on other antiglycemic agents, 64.86% (n=48) were fully discontinued (Table 4).

Notably, among participants who did not achieve clinical reversal, 99% failed to adhere to the program's core compliance requirements: weekly check-ins, daily food log submission, and program protocol adherence.

Table 4. T2DM Reversal and Clinical Control Outcomes

Outcome Parameter	Result
Any HbA1c reduction (N=137)	82.48% (n=113)
Reached target HbA1c ≤5.9%	44.53% (n=61)
Full T2DM reversal (HbA1c + medication elimination)	26.28% (n=36)
Clinical control only (HbA1c target, not fully off meds)	18.25% (n=25)
Insulin eliminated (of insulin users; n=40)	60.00% (n=24)
Metformin eliminated (of metformin users; n=97)	38.14% (n=37)
Other antiglycemics eliminated (n=74)	64.86% (n=48)

Statistical Significance Summary

Table 5. Statistical Significance of Key Outcomes at 95% Confidence Interval

Parameter	Δ	% Δ	SD	SE	% Δ UB	% Δ LB	Sig.
HbA1c	-1.62	-18.57%	14.48	1.27	-16.09%	-21.06%	Significant
FPG	-41.32	-20.09%	23.69	2.02	-39.30%	-43.34%	Significant
Weight	-20.4	-9.4%	5.1	0.43	-8.50%	-10.20%	Significant
BMI	-3.1	-9.38%	5.25	0.45	-8.50%	-10.26%	Significant
Metformin dose	-660.47	-52.12%	47.32	4.04	-44.20%	-60.05%	Significant
Insulin dose	-29.13	-85.00%	26.07	2.23	-80.63%	-89.37%	Significant

Discussion

This consecutive case series provides objective, real-world evidence that the DRG® non-pharmacological program produces clinically and statistically significant improvements in key T2DM metrics, including HbA1c, FPG, body weight, blood pressure, and medication burden. A mean HbA1c reduction of 1.62% far exceeds the 0.5% threshold considered clinically significant per NCBI and NICE guidelines [6, 7]. The 85.00% reduction in insulin dose among insulin-dependent participants is particularly notable, given the clinical and economic burden of insulin dependency in T2DM management.

Full T2DM reversal—achieving HbA1c ≤5.9% with complete elimination of all anti-diabetic medications—was achieved in 26.28% of participants over an average of approximately 5 months. This reversal timeline compares favorably to published outcomes from other intensive lifestyle intervention programs. The finding that 99% of non-reversal participants failed to meet core program compliance requirements (weekly check-ins, food log submission, and protocol adherence) underscores the critical role of participant engagement in program efficacy and aligns with established evidence that behavioral adherence is the strongest predictor of outcomes in lifestyle-based diabetes interventions [4, 9].

The concurrent reductions in antihypertensive medications (30.71%) and anticholesteremic medications (22.58%) suggest broad cardiometabolic benefit beyond glycemic control alone.

Reductions in systolic blood pressure (11.34 mmHg) and body weight (20.4 lbs average) are consistent with the established positive effects of dietary modification and weight loss on cardiovascular risk in T2DM [3, 4].

Limitations

This study carries inherent limitations of a retrospective, single-arm case series design. The absence of a control group precludes definitive causal attribution. Self-reported anthropometrics and externally collected laboratory results introduce potential measurement variability. The requirement for complete baseline and post-program data introduced a selection effect, potentially excluding participants with the poorest outcomes or least engagement. Confounders including age, sex, ethnicity, and family history of T2DM were acknowledged but not controlled in the primary analysis. The study population was predominantly male (72.26%) and older (mean 65.50 years), which may limit generalizability. Data on long-term durability of T2DM reversal beyond program completion were not available in this dataset.

The participant pool was drawn from a self-selecting population that voluntarily enrolled in and paid for the DRG® program, which may introduce motivation bias. Future studies should include randomized controlled designs, longer follow-up periods, and standardized laboratory collection protocols to provide higher-level evidence for the efficacy of this intervention.

Conclusions

The DRG® non-pharmacological T2DM reversal program produced clinically and statistically significant reductions in HbA1c, FPG, body weight, blood pressure, and anti-diabetic medication dosages across a real-world cohort of 137 adult Americans over an average of approximately five months. Full clinical T2DM reversal—defined as HbA1c ≤5.9% with complete elimination of anti-diabetic medications—was achieved in 26.28% of participants. Outcomes were strongly associated with program compliance. These findings support the potential of structured non-pharmacological intervention as a viable, evidence-based approach to T2DM reversal in a motivated adult population. Prospective randomized controlled trials are warranted to confirm these findings and assess the long-term durability of reversal outcomes.

Author Contributions

All authors have reviewed and approved the final manuscript.

Author	Contribution
Vincent Sean D. Ribaya, MD, MBA (V&E Research Solutions)	Conception and design of the study, data collection oversight, data analysis, manuscript drafting, and critical revision.
Elizabeth Laurize A. Alejandro-Ribaya, MD (V&E Research Solutions)	Conception and design of the study, data collection oversight, clinical interpretation of findings, and critical revision of the manuscript.
Kristine Burke, MD (Contributing Reviewer)	Critical appraisal of clinical methodology, review of adverse event protocols, and final manuscript review. Board Certified in Integrative Medicine, Family Medicine, and Sports Medicine; Certified Functional Medicine Practitioner.

Diabetes Reversal Group® (Study Sponsor)	Provided participant data, program infrastructure, and funded the study. DRG® personnel contributed to data collection (Wellness Coordinators, Support Doctors).

Conflicts of Interest

The Diabetes Reversal Group® (DRG®) is the sponsor and funder of this study. The principal investigators (V.S.D. Ribaya, E.L.A. Alejandro-Ribaya) conducted this study under contract with DRG®. Jeffrey Hockings is the Founder and CEO of Diabetes Reversal Group®, holder of the patented DRG® T2DM Reversal System, and has a direct commercial interest in the program evaluated herein. Kristine Burke, MD declares no competing financial interests. These relationships are disclosed in full; readers should consider them in evaluating the findings of this study.

Funding

This study was funded internally by Diabetes Reversal Group®. No external grants or public funding were received. The funder provided participant data and program infrastructure but was not involved in statistical analysis or interpretation beyond the scope described in the Author Contributions section.

Ethics Statement

All participants provided written informed consent prior to enrollment. Data were de-identified for analysis. The study was conducted in accordance with all applicable DRG® institutional policies, federal and state regulations, and the ICH GCP Consolidated Guideline. No pharmaceutical interventions were administered; all medication adjustments required concurrent approval by participants' primary physicians. Risk to participants was classified as minimal.

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