

The Reality of Reversal: Inside The Revolution in Type 2 Diabetes Treatment



“When I was diagnosed with diabetes, my world came crashing down. The nurse told me I would have diabetes for the rest of my life, and it felt like a life sentence.”



Lester, diagnosed with type 2 diabetes in 2012

Unfortunately, Lester’s experience reflects the norm for approaching diabetes. It’s a life sentence. You’ll never get better. You might only slow down the progression of the disease. But does that have to be the case? Is reversal or even remission possible?

Setting the Stage: What’s at Stake?

More than half of the adult population in the U.S. suffers from diabetes or prediabetes. Some estimates say that more than \$327 billion healthcare dollars in the U.S.¹ are spent on diagnosed diabetes. That number only grows if you factor in the 1 in 4 Americans living with type 2 who don’t know they have it. The scale of the problem simply can’t be overstated.

Type 2 diabetes is characterized by insulin resistance that manifests as carbohydrate intolerance, leading to elevations in blood sugar (hyperglycemia). Hyperglycemia that persists over long periods of time is a major factor in developing complications of diabetes, and is even linked to premature death.²

Potential Complications of Type 2 Diabetes



Eye issues



Foot issues



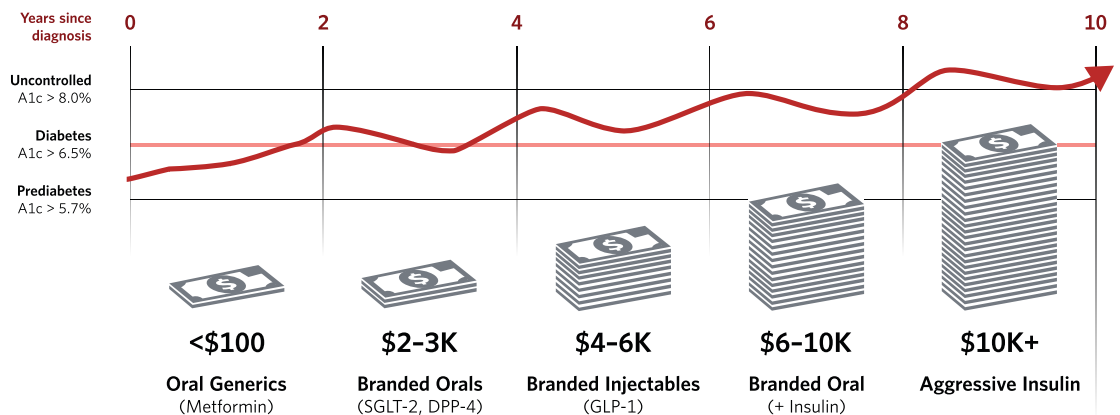
Increased risk of heart disease

Diabetes has always been considered a chronic, progressive condition. Getting worse over time was accepted as the norm. Traditional management of the disease usually means artificially adding more insulin or other drugs, aiming to bring blood sugar back down to normal or near normal levels. But adding more insulin, and other diabetes drugs, is not actually addressing the root problem. It may slow down the progression, but the underlying issue remains untreated.

The side effects of medications can also be debilitating, and to manage blood sugar levels over time and slow the disease progression, more and more medications are often needed. The costs for the individual patients (and payers) continue to stack up as quality of life often gradually gets worse. That’s the status quo in diabetes management—add more drugs that cost more money as patients get sicker.

The Cost of Diabetes Management

Chart intended to illustrate an example patient journey on diabetes management. Informed by numerous patient experiences. Drug cost data informed by GoodRx Research: Nguyen A et al. The Staggering True Cost of Diabetes (GoodRx Research), April 2020



There's a Better Way— Diabetes Treatment is Undergoing a Revolution

Diabetes reversal, and even remission, is possible.

Remission of type 2 diabetes wasn't common in the broader scientific lexicon until 2009, when the American Diabetes Association (ADA) defined three types of remission. As time went on, more and more evidence to support the possibility of remission emerged and a consensus evolved. In 2021, a group of experts, including representatives from the American Diabetes Association® (ADA), the Endocrine Society, the European Association for the Study of Diabetes (EASD), and Diabetes UK., [released a groundbreaking consensus statement](#) defining diabetes remission as sustaining normal blood glucose (sugar) levels for three months or more.

The 2021 Consensus Statement on Remission



Remission should be defined as a return of HbA1c to <6.5% that occurs spontaneously or following an intervention and persists for >3 months in the absence of glucose-lowering pharmacology.



HbA1c, or hemoglobin A1c, is a measure of blood glucose (sugar) levels. Type 2 diabetes is diagnosed when HbA1c is greater than 6.5%.

Support for remission as a realistic option for type 2 diabetes started to gain more support when Virta Health published their first peer-reviewed paper in 2017 with ten week outcomes, and then again in 2018 with one year data from their clinical trial. The one-year clinical trial data showed type 2 diabetes can, indeed, be “reversed” to pre-diagnostic criteria (without surgery) while reducing or eliminating the use of diabetes-specific medications.

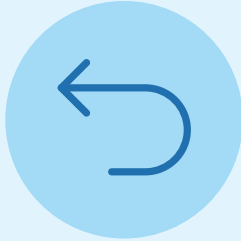
60% of patients completing one year on the Virta treatment reversed their diabetes³, or achieved an HbA1c below 6.5% and eliminated all diabetes-specific meds (or were only on metformin.) In other words, if you looked at people's labs, you wouldn't know they had diabetes at all. This was done through a virtual care model, using personalized nutrition therapy based on the science of carbohydrate restriction, and guided by a team of health coaches and medical providers.

In only four months on the Virta treatment, I lost almost 50 pounds, went from a size 38 waist to 34, and at my last check-up, had dropped my A1c down to 5.4%—below the threshold for type 2 diabetes and prediabetes! It is as if I have hit the reset button on my health!

Greg, Virta Health Patient

The 2021 consensus statement also defined reversal. Though slightly different from Virta's reversal target, the acknowledgement of reversal is a huge step forward for the treatment of type 2 diabetes and the lives impacted by the condition once thought chronic and progressive.

The 2021 Consensus Statement on Reversal



The term **reversal** is used to describe the process of returning to glucose levels below those diagnostic of diabetes.

The Virta treatment's reversal target is defined as: **"Achieving HbA1c <6.5% without the use of diabetes medications, or only metformin."**

**Metformin is excluded because it is not diabetes-specific and is indicated for other conditions, like prediabetes and polycystic ovarian syndrome (PCOS).*

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Check for updates

Consensus Report: Definition and Interpretation of Remission in Type 2 Diabetes

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A consensus report of a particular topic contains a comprehensive examination and is authored by an expert panel (i.e., consensus panel) and represents the panel's collective analysis, evaluation, and opinion. The need for a consensus report arises when clinicians, scientists, regulators, and/

Improvement of glucose levels into the normal range can occur in some people living with diabetes, either spontaneously or after medical interventions, and in some cases can persist after withdrawal of glucose-lowering pharmacotherapy. Such sustained improvement may now be occurring more often due to newer forms of treatment. However, terminology for describing this process and objective measures for defining it are not well established, and the long-term risks versus benefits of its attainment are not well understood. To update prior discussions of this issue, an international expert group was convened by the American Diabetes Association to propose nomenclature and principles for data collection and analysis, with the goal of establishing a base of information to support future clinical guidance. This group proposed "remission" as the most appropriate descriptive term, and HbA_{1c} < 6.5% (48 mmol/mol) measured at least 3 months after cessation of glucose-lowering pharmacotherapy as the usual diagnostic criterion. The group also made suggestions for active observation of individuals experiencing a remission and discussed further questions and unmet needs regarding predictors and outcomes of remission.

The natural history of type 2 diabetes (T2D) is better understood now than previously. It is clearly heterogeneous, with both genetic and environmental factors contributing to its pathogenesis and evolution. Typically, a genetic predisposition is present at birth but the hyperglycemia that defines diabetes appears only gradually and reaches diagnostic levels in adulthood. Environmental factors modulating expression of T2D include availability of various foods, opportunity for and participation in physical activity, stress related to family, work, or other influences; exposure to pollutants and toxins; and access to public health and medical resources. Two common but transitory events can lead to earlier emergence of hyperglycemia in susceptible individuals: pregnancy or short-term therapy with glucocorticoids. Accordingly, people may develop "gestational diabetes" or "steroid diabetes" as conditions that are distinct but nevertheless related to typical T2D (1,2). In these settings, hyperglycemia is provoked by insulin resistance but may not persist, as responses to insulin improve when the baby is delivered or glucocorticoid therapy ceases. Glucose levels can return to normal after the pregnancy, yet an increased risk of later T2D remains (3). Acute illness or other stressful experiences can also provoke temporary hyperglycemia, sometimes called "stress hyperglycemia," in vulnerable individuals. T2D that has developed gradually and independent of these stimuli, but most often accompanying weight gain in midlife, can become easier to control or appear to remit following weight loss in some cases. Moreover, individuals with T2D can unintentionally lose weight due to illness, emotional distress, or unavailability of food related to serious social dislocation. Either voluntary or

CONSENSUS REPORT

Key Takeaways



Diabetes reversal is an accepted term



Diabetes reversal can be sustained



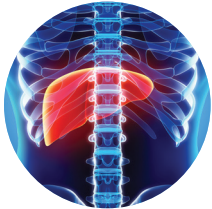
Remission is defined as returning to sub-diabetic A1c without drug therapy for 3+ months



Three Methods for Achieving Diabetes Remission

There are three methods that demonstrate the possibility of type 2 diabetes reversal and remission: metabolic or bariatric surgery, very low calorie diets, and low carbohydrate nutrition therapy. In a national survey, we asked patients with type 2 diabetes how they felt about each of these methods, and here's what we found:

Bariatric Surgery



Some studies suggest that bariatric surgery results in a wide range of diabetes remission rates from 19⁴–63⁵% 1 to 5 years following the procedure

This method can be the most extreme option—it's expensive, and as with any surgery, can carry risks for complications.

Only 13% of surveyed patients find this method appealing.⁶

Very Low Calorie Diet



Low calorie diets implemented in a medical, scientific, and real world setting have resulted in remission rates as high as 46% at one year⁷.

Longer-term, low-calorie diets seem to fall short of maintaining remission—in one study, only 7% achieved remission after 4 years of an initial low calorie formula diet replacement, followed by a calorie and fat-restricted nutrition therapy with physical activity.⁸ At 5 years, a low calorie Mediterranean diet implemented in those with newly diagnosed type 2 diabetes demonstrated 5.6% remission.⁹

35% of surveyed patients find this method appealing.⁶

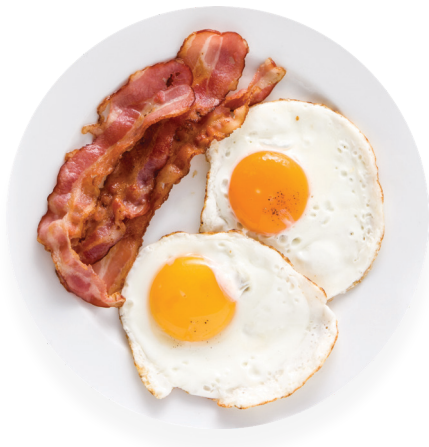
Very Low Carbohydrate Diet



Very low carbohydrate nutrition therapy interventions can result in lower blood sugar, less reliance on diabetes medications, weight loss, and reduce hunger.¹⁰ And they can work quickly. In one study, patients following a very low carbohydrate diet achieved an A1c reduction of 0.5 and a 40% reduction in meds after 2 weeks¹¹. Another study shows long-term impact of a low carb diet with 25% of patients achieving remission after 2 years.¹²

56% of surveyed patients find this method appealing.⁶

Very low carbohydrate diets are the only method patients find more appealing than unappealing.⁶



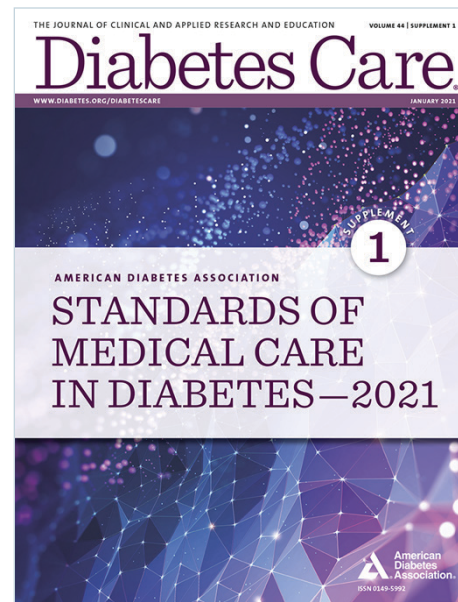
Carbohydrate Restriction for Treating Type 2 Diabetes Gains Widespread Support

In 2019, a consensus report on nutrition therapy for type 2 diabetes stated that:

“Low-carbohydrate eating patterns, especially very-low carbohydrate eating patterns, have been shown to reduce A1c and the need for antihyperglycemic medications. These eating patterns are among the most studied eating patterns for type 2 diabetes.”¹³

The 2021 ADA Standards of Medical Care said that:

“Reducing overall carbohydrate intake for individuals with diabetes has demonstrated the most evidence for improving glycemia and may be applied in a variety of eating patterns that meet individual needs and preferences.”¹⁴



Virta Health's nutrition protocols are cited in ADA's clinical standards of care (2019, 2020, and 2021) and recommended as a first line therapy for type 2 diabetes.

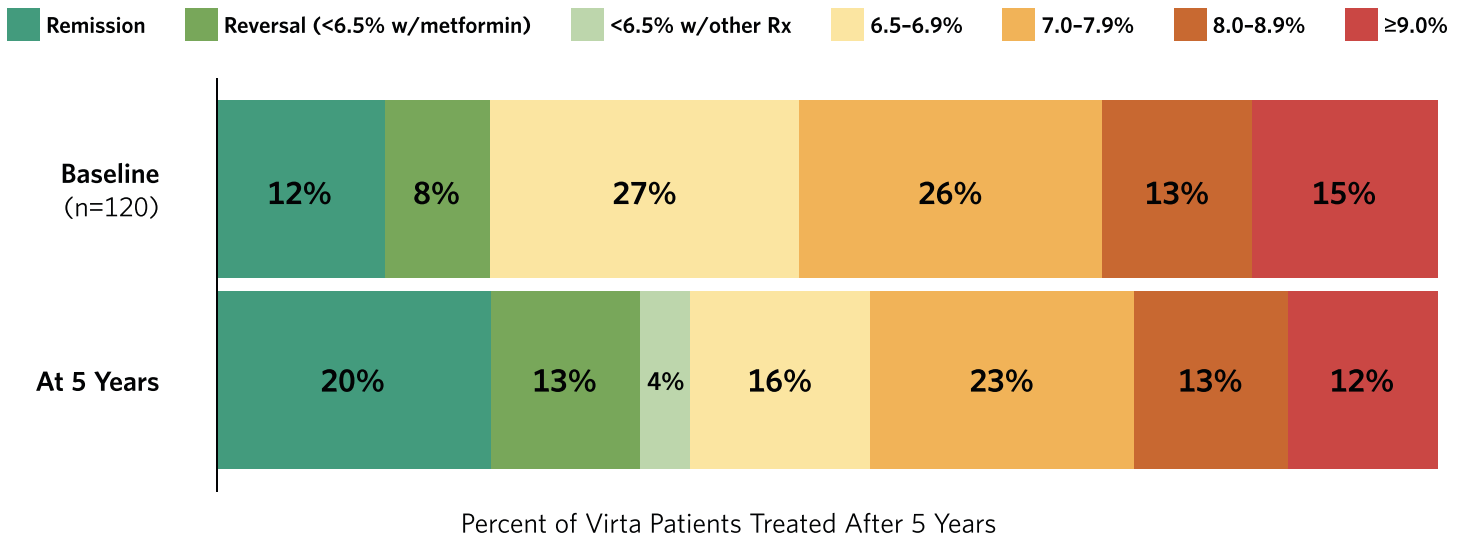
Very Low Carbohydrate Diets—With an Added Ingredient—Can Lead to Lasting Results

A major question when it comes to achieving reversal or full remission using very low carbohydrate (or any lifestyle) intervention is long-term sustainability.

In June of 2022, Virta Health reported preliminary findings from a 5-year clinical trial (the longest of its kind in digital health) at the American Diabetes Association 82nd Scientific Sessions. The results: long-term reversal and remission are possible without surgery or extreme calorie restriction.

What makes the Virta study unique is not only the personalized nutrition therapy centered around a very low carbohydrate diet, but also how the care is delivered. The Virta treatment leverages “continuous remote care”—meaning the treatment is all done virtually through an app, and that the care team and physicians can monitor key inputs like biomarkers in real time. Machine learning also enables the system to flag key inflection points for patients in the program to identify when they may be vulnerable to lapsing in their treatment.

After 5 Years of Treatment, 33% of Virta patients achieve diabetes reversal target or drug-free remission



33% of patients completing the trial at 5 years achieved either reversal or full remission of their diabetes.¹⁵ And while sustained remission and reversal are fantastic outcomes, they aren't always realistic for every patient. The study also revealed that a very low carbohydrate diet can produce other health benefits, even among those who don't reverse or go into remission. Participants who completed 5 years showed:

- Clinically significant weight loss of 7.6%
- A 60% reduction in medication
- Improvements in cardiovascular health, and markers of kidney and liver function
- Increased perception of control over eating

In a nutshell, the study shows that people with type 2 diabetes can get better. They don't have to accept their diagnosis as a life sentence.

“What means the most to me is just how great I feel, and how much happier I am. My 7-year-old daughter and I try to go to a bike track at least 3 days a week to race and spend time together. Even in my wildest dreams, I never thought I would be able to do this again at 49 years old.”



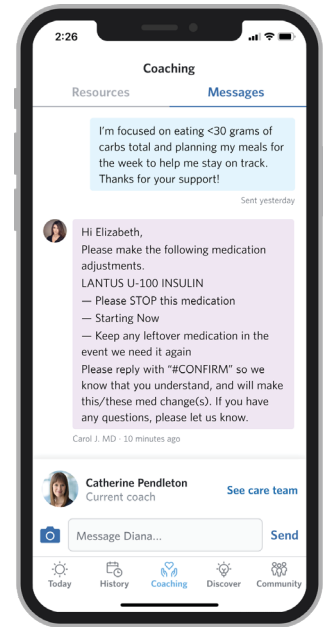
Chris, reversed his diabetes

Technology Enables Safe, Sustainable Diabetes Reversal

Patients often need to make several decisions related to their type 2 diabetes every day. It's a complex condition, with a lot of variables at play. Most traditional management options and even lifestyle interventions geared at reversal or remission don't take this need for ongoing support into account.

That's why it's historically been difficult to sustain any improvements or achieve diabetes reversal—because the level of support and interaction with patients just wasn't there. This is changing as technology-enabled virtual care starts to gain momentum.

For example, the Virta treatment's model allows patients to interact with a clinician-led care team at their many decision points, or whenever they need it.



How Virta Works



Sustained Reversal Can Lead to Other Positive Outcomes

Sustained reversal can also result in massive financial savings for patients (and payers)—the cost of diabetes medications have become out of range for most, and for those without insurance, it can be impossible. A new study shows that a [staggering 4 out of 5 Americans](#) who have diabetes, or care for someone who does, have gone into credit card debt to cover the cost of insulin. With reversal, easing the financial burden comes not only from the elimination of medications, but also from avoiding the terrible and costly side-effects that diabetes can have if it progresses—amputation, blindness, kidney failure, to name a few.

Medication Savings with Diabetes Reversal

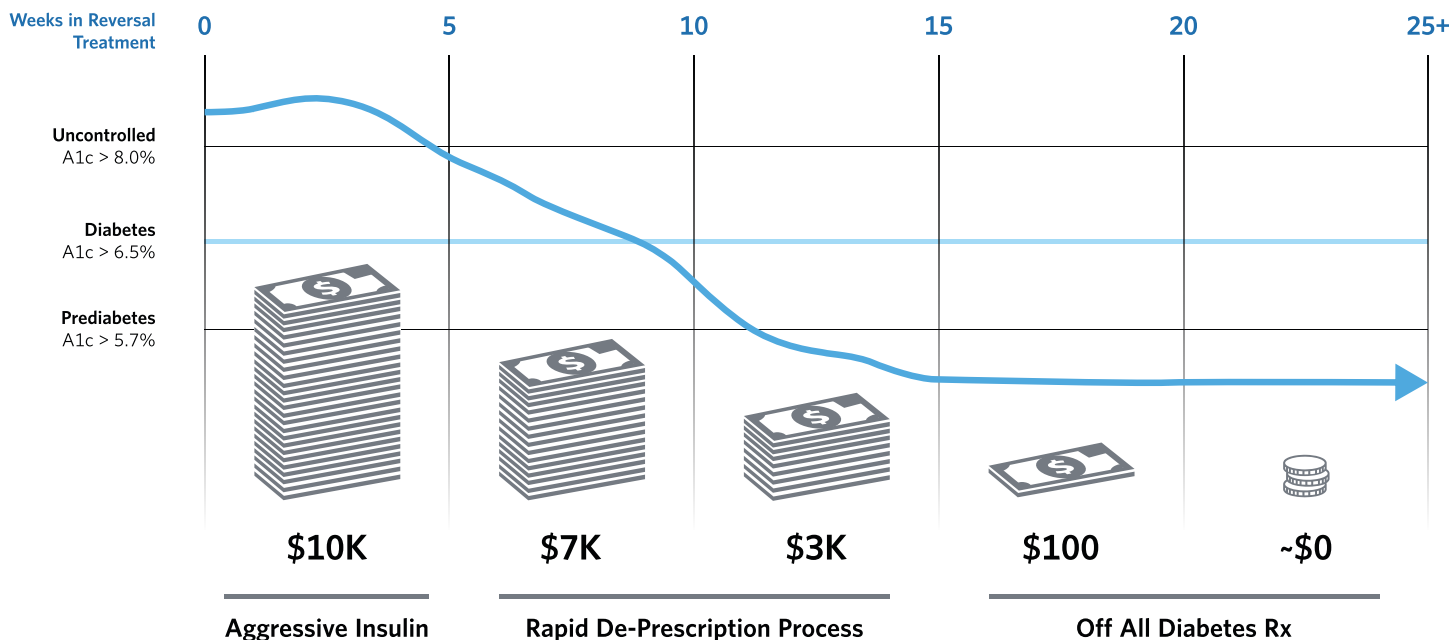


Chart intended to illustrate an example patient journey on diabetes management. Informed by numerous patient experiences. Drug cost data informed by GoodRx Research: Nguyen Aet al. The Staggering True Cost of Diabetes (GoodRx Research), April 2020

But despite international consensus on remission and reversal, and mounting scientific evidence, patients are largely unaware that there is an alternative to traditional diabetes management. In a national survey, 78% of people with type 2 diabetes say they were unaware of reversal, or knew very little about it. But when made aware, **87% say they want to make the pursuit of reversal a personal goal.**⁶

In Closing

There is growing consensus around the possibility of diabetes remission and reversal in the scientific and medical communities. The evidence behind lifestyle interventions for treating, reversing, and even putting type 2 diabetes into remission means that we now have alternatives to traditional management.

People living with type 2 diabetes deserve to know that reversal, and even remission, is an option.

The biggest barrier to achieving this is simply a lack of knowledge—62% of patients say they just don't know enough about reversal to make it a goal⁶.

People deserve to know that improving their health without drugs or surgery is a real possibility. And it doesn't have to include calorie counting or following a very low calorie diet. It can mean enjoying food while also improving blood sugar, getting off of medications, and losing weight.



[Contact us](#) to learn more about the Virta treatment

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