



ValidationInstitute

2022 Validation Report

Review for: Virta Health

Validation Achieved: Program Validation

Valid through: September 2023

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Company Profile



Category:	Disease Management
Website:	www.virtahealth.com
Public or Private:	Private
Year Established:	2014
President:	Sami Inkinen
Company contact:	support@virtahealth.com
Description:	

Virta Health is the first clinically-proven treatment to safely and sustainably reverse type 2 diabetes and other chronic metabolic diseases without the use of medications or surgery. **Virta Health's** innovations in nutritional biochemistry, data science and digital tools combined with clinical expertise are shifting the diabetes treatment paradigm from management to reversal. **Virta Health's** mission is to reverse type 2 diabetes in 100 million people by 2025.

Validation Institute – Program Validation

Validation Institute is pleased to award Program Validation to Virta's Diabetes Reversal program. This validation recognizes the program for achieving better patient outcomes at lower costs, specifically using one or more of the methodologies described here.

Program Validation is reserved for programs that have strong evidence of significant impact on both patient outcomes and on medical costs. Evidence is assessed based upon the certainty it provides that the result is due to the program and not to other factors, such as recruiting people who are most likely to succeed. When people or groups are assigned randomly to the program or to usual care, we can be more certain that differences in outcomes or use of medical care are due to the program.

While no study is without limitations, the two Virta studies (parallel assignment at Indiana University and a wait-list control at the Veterans Health Administration) are limited mostly by sample size, whereas other diabetes vendors use study designs that by themselves have limitations (and also sometimes limited sample sizes, and limited durations as well).



Claim Assertion for Savings Validation

Virta Health delivers diabetes prescription drug cost savings of \$186 PMPM in year 1 and \$280 PMPM in year 2.



Methods for Savings Validation

Virta Health offers a treatment for type 2 diabetes reversal that utilizes a combination of nutritional therapy based on carbohydrate restriction, as well as a novel telemedicine approach called “continuous remote care.” Multiple peer-reviewed studies have shown that patients receiving this treatment see significant improvements in HbA1c while simultaneously reducing or eliminating the need for glucose-lowering diabetes drugs.

Virta Health partnered with Indiana University Health on a parallel arm, outpatient clinical trial, with 262 patients enrolled in Virta Health receiving continuous care intervention, and 87 receiving usual care[1]. Primary outcomes were retention, glycemic outcomes, and weight changes over 2 years. Retention over two years was 78% in the Usual Care group and 74% in the Virta Health intervention (Table 1). This is considered by the Validation Institute to be comparable.

Participants were recruited from two clinics. One offered enrollment in Virta Health and one offered enrollment in usual care, where patients could select to participate or not, while all are included in the outcomes other than those lost to follow up. All signed informed consent to participate. One can consider this trial design as similar to a two-site cluster randomized trial, which is viewed as a “Gold Standard” by the Validation Institute. An example of another valid study done as a cluster randomization is here.

Methods for Savings Validation

	Baseline	1-year	2-year
Virta Health intervention			
n	262	218	194
Retention		83%	74%
Usual Care (UC)			
n	87	78	68
Retention		90%	78%

Table 1. Study Size and Retention Rate over Two Years

The number of patients on each diabetes drug class was measured at baseline, at one year, and at two years in each group. For example, at baseline, approximately 57% of the cluster offered Virta Health were on glucose-lowering diabetes drugs (excluding metformin), compared to 67% of patients in the cluster that consented but was offered Usual Care. Among those who completed two years of the trial, only 27% of Virta Health patients were on diabetes drugs other than metformin, compared to 79% of Usual Care patients (Table 2). As mentioned above, retention over two years was 78% in the Usual Care group and 74% in the Virta Health intervention. (This difference is considered negligible and aligns with the expectation that the Virta Health treatment requires more commitment than usual care).

Methods for Savings Validation

	Baseline		1-year		2-year	
	Virta Health	Usual Care	Virta Health	Usual Care	Virta Health	Usual Care
Any diabetes drug, excluding Metformin	57%	67%	28%	76%	27%	79%
Sulfonylurea	24%	24%	0%	26%	0%	29%
Insulin	30%	46%	15%	51%	11%	55%
Thiazolidinedione	2%	1%	1%	1%	3%	7%
SGLT-2	10%	15%	1%	17%	3%	14%
DPP-4	10%	8%	6%	12%	7%	9%
GLP-1	13%	16%	15%	21%	11%	28%
Metformin	71%	61%	64%	60%	64%	64%

Table 2. Percentage of Population Segment Utilizing Diabetes Drugs

Methods for Savings Validation

To estimate the cost of diabetes drugs, we studied market data from a variety of sources[2] and made assumptions for a typical commercial payor's allowed cost of a one-month supply for each diabetes medication class as illustrated in Table 3 below. We also constructed a dynamic model that allows users to enter their own negotiated price for drugs, if needed, and as required by the Validation Institute.

Diabetes Drug	Allowed Cost for 1 Month Supply
Sulfonylurea	\$15
Insulin	\$420
Thiazolidinedione	\$15
SGLT-2	\$330
DPP-4	\$340
GLP-1	\$480
Metformin	\$10

Table 3. Allowed Cost of Drugs to Payer for One Month Supply

Methods for Savings Validation

We constructed a difference-in-differences savings estimate to compare the per member per month (PMPM) costs between Virta Health patients and Usual Care patients at 1 year and at 2 years (Table 4). This analysis utilized both the drug utilization data as well as the cost per drug data to determine average monthly costs for each cohort, compared to the baseline values on a PMPM basis (Table 5). The cost per drug was trended at 8.8% annually to reflect the approximate increase of diabetic drug costs over time. The annual trend of 8.8% is derived from the total health care cost of diabetes patients published by the ADA from 2012 to 2017, in Economic Costs of Diabetes in the U.S. in 2017. (Changes in the assumption of annual trend would not materially change the savings estimate.)

	Usual Care			Virta Health			Difference		
	Baseline	1-year	2-year	Baseline	1-year	2-year	Baseline	1-year	2-year
Sulfonylurea	\$3.62	\$4.18	\$5.20	\$3.56	\$0.00	\$0.00	(\$0.06)	(\$4.18)	(\$5.20)
Insulin	\$193.20	\$234.42	\$274.44	\$125.16	\$67.17	\$56.18	(\$68.04)	(\$167.25)	(\$218.26)
Thiazolidinedione	\$0.18	\$0.21	\$1.23	\$0.23	\$0.08	\$0.46	\$0.05	(\$0.13)	(\$0.76)
SGLT-2	\$49.17	\$59.96	\$53.91	\$33.99	\$3.23	\$12.11	(\$15.18)	(\$56.73)	(\$41.80)
DPP-4	\$27.54	\$42.54	\$34.61	\$33.66	\$23.67	\$26.97	\$6.12	(\$18.87)	(\$7.65)
GLP-1	\$77.28	\$107.06	\$156.82	\$64.32	\$78.86	\$61.37	(\$12.96)	(\$28.20)	(\$95.46)
Metformin	\$6.09	\$6.56	\$7.55	\$7.14	\$6.98	\$7.56	\$1.05	\$0.42	\$0.01
Grand Total	\$357.08	\$454.93	\$533.76	\$268.05	\$180.00	\$164.65	(\$89.03)	(\$274.93)	(\$369.12)

Table 4. Difference in Diabetes Drug Cost Between Virta Health and Usual Care at Baseline, 1 Year, 2 Years

Methods for Savings Validation

Year 1	Year 2
\$185.90 PMPM	\$280.09 PMPM
= 1 year difference - Baseline difference	= 2 year difference - Baseline difference
= \$274.93 - \$89.03	= \$369.12 - \$89.03

Table 5. Estimated PMPM Savings of Virta Health intervention, Utilizing a Difference-in-Differences Calculation

Multiple additional studies of Virta Health have been reported, including among Virta Health’s commercial book of business—validating “real world” outcomes—as well as among a population of veterans treated at the Veterans Health Administration[3]. The VHA study, which employed a quasi-experimental waitlist design, found a medication reduction of 34.5% after over 5 months. (These data points are added as support for the valid study results. The VHA study’s waitlist control would be considered a Gold Standard if the power is high enough, but the more typical and practical and ERISA-compliant commercial participants-vs-non-participants study design can overstate savings.)

Findings for Savings Validation

Virta Health's intervention showed diabetes drug cost savings of \$185.90 PMPM in year 1 and \$280.09 PMPM in year 2. Other potential sources of savings for Virta Health—e.g., related to medical cost savings stemming from improved A1c or weight loss—were beyond the scope of this analysis.

Claim Assertion for Outcomes Validation

Virta Health offers a continuous remote care intervention to people living with type 2 diabetes. Participants adhere to a carbohydrate-restricted nutritional protocol, and, via a mobile app, receive daily monitoring and supervision by a health coach as well as a board-certified physician. The interaction with the program – daily or more often in the early stages – ensures that medical management is continuous, and as participants' metabolism changes, the physicians quickly deprescribe medications.

Two non-randomized clinical trials were reviewed: Hallberg et al, Effectiveness and Safety of a Novel Care Model for the Management of Type 2 Diabetes at 1 Year: An Open-Label, Non-Randomized, Controlled Study, *Diabetes Therapy* (2018) 9:583 – 612; and Athinarayanan et al, Long-Term Effects of a Novel Continuous Remote Care Intervention Including Nutritional Ketosis for the Management of Type 2 Diabetes: A 2-Year Non-randomized Clinical Trial, *Frontiers in Endocrinology* (2019) 10:348. These studies focused upon changes in various laboratory tests, ranging from weight and blood glucose to blood cholesterol and liver enzymes.

Methods for Outcomes Validation

Participants were recruited and voluntarily enrolled in the **Virta Health** program or the comparison group, which consisted of patients referred to a diabetes education program by their physician. Patients' data were assigned to their original group, even if they dropped out. Both groups had lab values assessed at baseline, at one year and at two years. Intent-to-treat analyses with methods for handling missing data, as well as completers analyses, were performed. Statistical adjustments were made to account for differences between the two groups' baseline characteristics.

Findings for Outcomes Validation

The table below lists selected measures and the amount of improvement that program participants achieved. Data is not shown for the Usual Care comparison group because no significant change was observed.

Measure	Participants' Improvement vs. Baseline [^]	
	At One Year	At Two Years
HbA1c	-1.3	-0.9
Weight (kg)	-14.29	-11.94
Weight (%)	-11.80%	-10.40%
T2D medication excl metformin (% of pts)	Decrease from 56.9% to 29.7%	Decrease from 56.9% to 26.8%

[^] Point estimate difference; see study for ranges.

Validation and Credibility Guarantee

Virta Health's Diabetes Reversal program achieved Program Validation. Validation Institute is willing to provide up to a \$50,000 guarantee as part of their Credibility Guarantee Program. To learn more, visit <https://validationinstitute.com/credibility-guarantee/>

Program Validation

Program has strong evidence of significant impact on both patient outcomes and on medical costs. Evidence is assessed based upon the certainty it provides that the result is due to the program and not to other factors, such as recruiting people to participate in the program who are most likely to succeed.

Savings

Can reduce health care spending per case/participant or for the plan/purchaser overall.

Outcomes

Product/solution has measurably improved an outcome (risk, hba1c, events, employee retention, etc.) of importance.

Metrics

Credible sources and valid assumptions create a reasonable estimate of a program's impact.

Contractual Integrity

Vendor is willing to put a part of their fees "at risk" as a guarantee.



Validation Expiration: September 2023

CERTIFICATE OF VALIDATION

Applicant:

Virta Health

501 Folsom St.

San Francisco, California, 94105

Product:

Virta Health's Diabetes Reversal program

Claim:

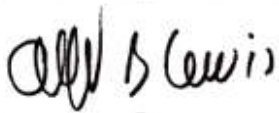
This validation recognizes Virta Health's diabetes reversal program for achieving better patient outcomes at lower costs.

Validation Achieved:

Program Validation

Validation Award Date:

September 2022



Al Lewis

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About Validation Institute

Validation Institute is a professional community that advocates for organizations and approaches that deliver better health value - stronger health outcomes at lower cost. We connect, train, and certify health care purchasers, and we validate and connect providers delivering superior results. Founded in 2014, the mission of the organization has consistently been to help provide transparency to buyers of health care.

Validation Review Process

Validation Institute has a team of epidemiologists and statisticians who review each program. The team focuses on three components:

- Evidence from published literature that a similar intervention had similar results.
- The reliability and credibility of the data sources.
- The rigor of the approach to calculating results.

To achieve validation, the program has to satisfy each of these components. VI's team then summarizes the review into a report which is publicly available. Details of VI's review are available with the program's permission.