



ValidationInstitute

2023 Validation Report

Review for: Virta Health
Validation Achieved: Outcomes
Valid through: September 2024

Company Profile



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

Description Provided by the Company:

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.



Claim Assertion for 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.





Method / Calculation / Examples

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 & 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.

Limitations

The statistical methods used in both studies sought to adjust for baseline differences between Virta Health program participants and usual care participants, but the groups may vary in ways that cannot be measured.



Validation and Credibility Guarantee

Virta Health's Continuous remote care intervention achieved validation for **Outcomes**. Validation Institute is willing to provide up to a \$25,000 guarantee as part of their Credibility Guarantee Program. To learn more, visit <https://validationinstitute.com/credibility-guarantee/>.

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 2024

CERTIFICATE OF VALIDATION

Applicant:

Virta Health

501 Folsom St.

San Francisco, California, 94105

Product:

Continuous remote care intervention

Claim:

Improvement in outcomes for those who use the continuous remote care intervention program

Validation Achieved:

Validated for Outcomes

Al Lewis

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Validation Institute

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Validation Institute



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.