ValidationInstitute

2024 Validation Report

Review for: Kaia Health

Validation Achieved: Program Validation

Valid through: May 2025

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Company Profile

Category:	**Musculoskeletal Management**
Website:	https://kaiahealth.com/
Public or Private:	Private
Year Established:	2016
President:	Konstantin Mehl
Company contact:	team@kaiahealth.com

Description Provided by the Company:

Kaia Health is the world's largest digital therapeutics company, creating accessible, evidence-based therapies for a range of conditions including musculoskeletal (MSK) pain and chronic obstructive pulmonary disease (COPD). Covering 60M million lives globally, our digital-first therapy programs are powered by motion analysis technology and guided by clinical experts. Patients only need a smartphone or tablet to access care 24/7, with no sensors, wearables, or other equipment needed. Headquartered in New York and Munich, **Kaia Health** partners with leading health plans and employers to deliver care that is proven to be as safe and effective as traditional care.

Validation Institute – Program Validation

Validation Institute is pleased to award Program Validation to Kaia Health's Digital Musculoskeletal Program. This validation recognizes the program for achieving better patient outcomes at lower costs. Since back pain is a common and costly condition, the program's impact is far reaching.

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.

Kaia Health conducted a randomized controlled trial which assigned primary care doctors to offer low back pain patients the Kaia digital low back pain program or to offer low back pain patients usual care. The results of the study concluded that the patients receiving the Kaia program had significantly more:

- Reduction in pain,
- Improvement on physical and mental health, and
- Improvement in physical function.

In addition, Kaia program users' total medical costs were significantly lower than the usual care (control) groups. Kaia's savings and outcomes reports are included below for reference.

Claim Assertion for Savings Validation

Patients with low back pain who were randomly assigned to Kaia Health's digital treatment program have significantly more improvement in pain (greater reduction) than patients receiving usual care. These patients also show significant reductions in total cost of care as compared to usual care across multiple service categories investigated. In addition, the intervention group's average benefit for time away from work decreased.

Since this study was a randomized controlled trial (RCT) in which enrollment was random rather than voluntary, the results are strong evidence that the program makes the difference.

Due to the clinical and health economic results of this study, German regulatory authorities may consider clinical guidelines to recommend use digital treatments such as Kaia.

Methods for Savings Validation

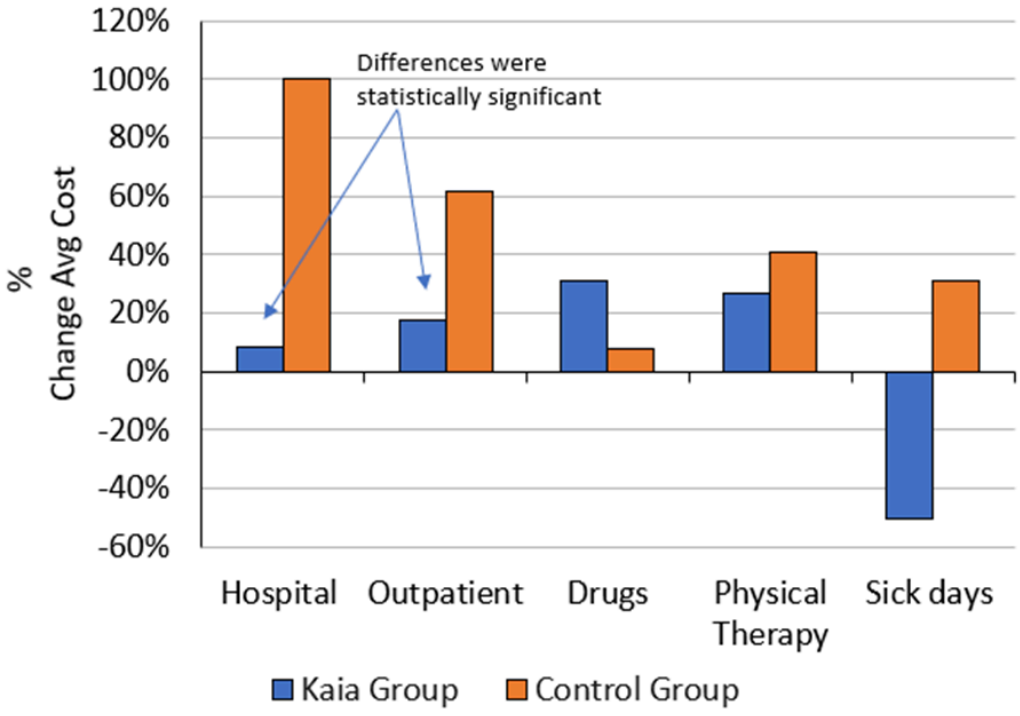
General Practitioners were randomly assigned to offer low back pain patients the Kaia Health digital program. A total of 933 Patients were included in the Kaia group. The staff was trained in the Kaia Health program and its support services. Similarly, 312 patients received usual care without restrictions - following the recommendations of the German National Care Guideline on treatment of non-specific back pain. These guidelines closely resemble United States national guidelines for non-specific back pain. The total patient sample was 1,245 participants.

The Kaia and the control groups were compared on demographic traits to ensure that they were similar to one another. They were compared on gender (% female), age, height/weight, education, employment, use of pain killers, risk of chronic pain, and how they were referred for care.

The percent change in average hospital, outpatient, drug, and physical therapy cost per patient were calculated for the Kaia and control groups. from the 12-month period before the intervention began to the 12 months following. For the same time periods, average per person sick day benefit was also calculated; sick day benefits are a percentage of the person's regular salary and begin after the person has lost six weeks of work. The percent change in average per user sick day benefits was calculated, and then compared between the two groups (Difference in differences). The significance of the differences between the two groups was also calculated (p values).

Findings for Savings Validation

Graph 1 summarizes how much each group's average per person costs changed as a percentage of the baseline costs from the pre- to the post-period. The average medical costs for hospital and outpatient services were significantly different between the two groups: the Kaia group's increase in costs was statistically lower than the increase for the control group. The other components reviewed differed between the two groups, but not significantly so.



Graph 1

Claim Assertion for Outcomes Validation

Patients with low back pain who were randomly assigned to Kaia Health's digital treatment program have significantly more improvement in pain (greater reduction) and improvement in function than patients receiving usual care.

Since this study was a randomized controlled trial (RCT) in which enrollment was random rather than voluntary, the results are strong evidence that the program makes the difference.

Methods for Outcomes Validation

General Practitioners were randomly assigned to offer low back pain patients the Kaia Health digital program. A total of 933 Patients were included in the intervention group. The staff was trained in the Kaia Health program and its support services. Similarly, 312 patients received usual care without restrictions - following the recommendations of the German National Care Guideline on treatment of non-specific back pain. These guidelines closely resemble United States national guidelines for non-specific back pain. The total patient sample was 1,245 participants.

The Kaia and the control groups were compared on demographic traits to ensure that they were similar to one another. They were compared on gender (% female), age, height/weight, education, employment, use of pain killers, risk of chronic pain, and how they were referred for care.

Pain scores for the Kaia Health and the control groups were measured and averaged at the start of care (baseline) and three months later. Patients were followed for 12 months, however, with additional data forthcoming. The Numerical Rating Scale (NRS) was used for pain measurement; it is a validated instrument for this purpose.

In addition to pain assessment, patients also responded to the questionnaires listed below. (Note: all survey tools are validated, which means they are reliable and credible data sources.)

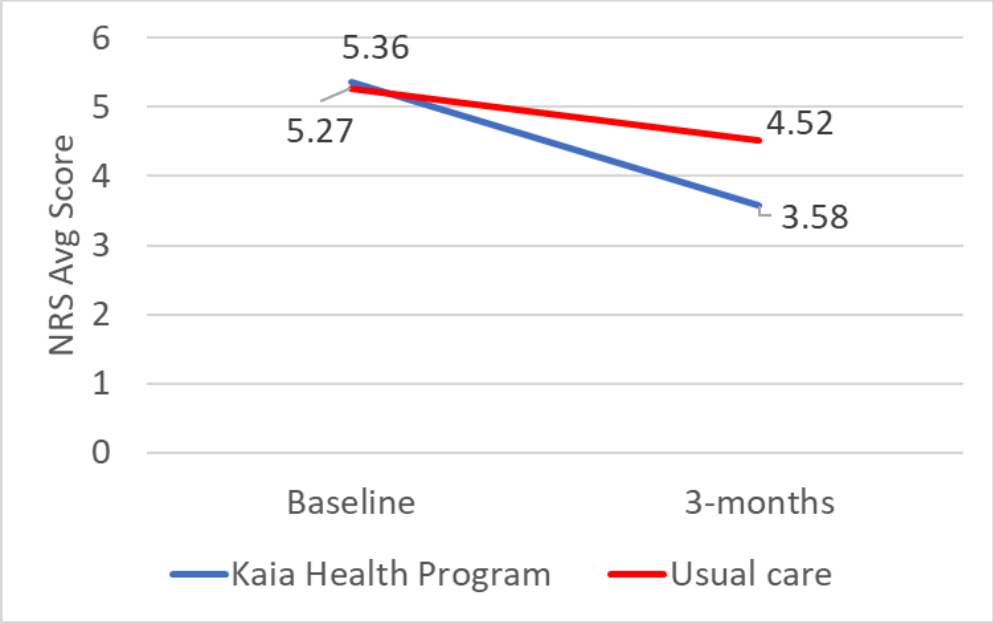
- Quality of life regarding physical and mental health (Veterans Rand 12)
- Depression, anxiety, and stress (Depression, Anxiety, Stress Scale or DASS)
- Functional capacity (Hannover Functional Ability Questionnaire)

Methods for Outcomes Validation

Scores on these questionnaires were taken at the start of care and three months later. Patients were followed for 12 months total with additional data forthcoming. Each patient's change in score was then averaged, and the average change in scores was compared between the group receiving the Kaia program and the group receiving usual care.

Findings for Outcomes Validation

The Kaia group and the intervention group had nearly identical average pain scores at the start of treatment. The graph below shows the Kaia Health group and control group's baseline and three-month average pain score, as measured by the NRS tool. The Kaia patients' pain score declined 33.3% which can be considered a clinically meaningful improvement, and the control group's pain score declined 14.3%. The Kaia patients had statistically significantly more pain reduction than the usual care patients. In fact, Kaia patients saw more than double the pain improvement of the control group.

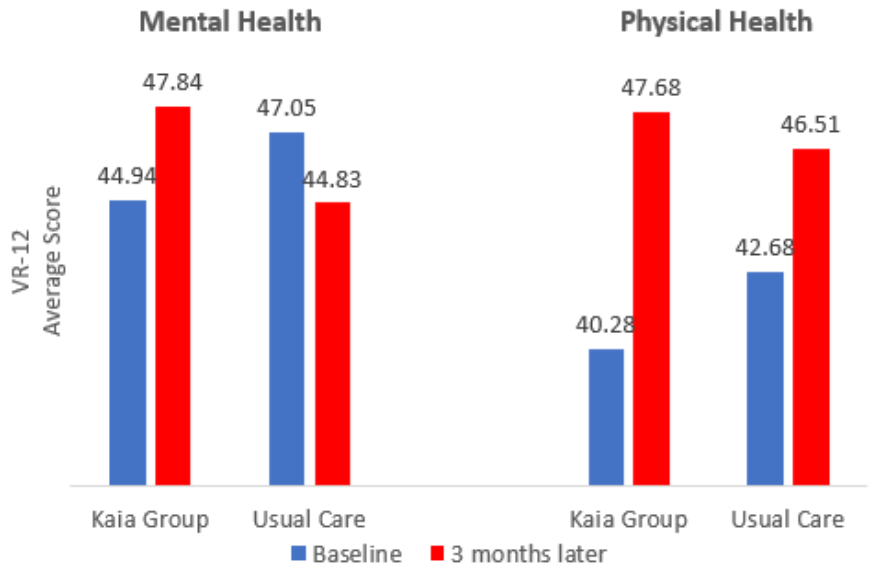


Graph 1: Average Pain Scores

The subset of the Kaia user population who scored at a higher acuity level (as measured by the StaRT Back tool) showed a greater than average pain improvement of 43%. (Note: StarT Back scores were not analyzed here)

Findings for Outcomes Validation

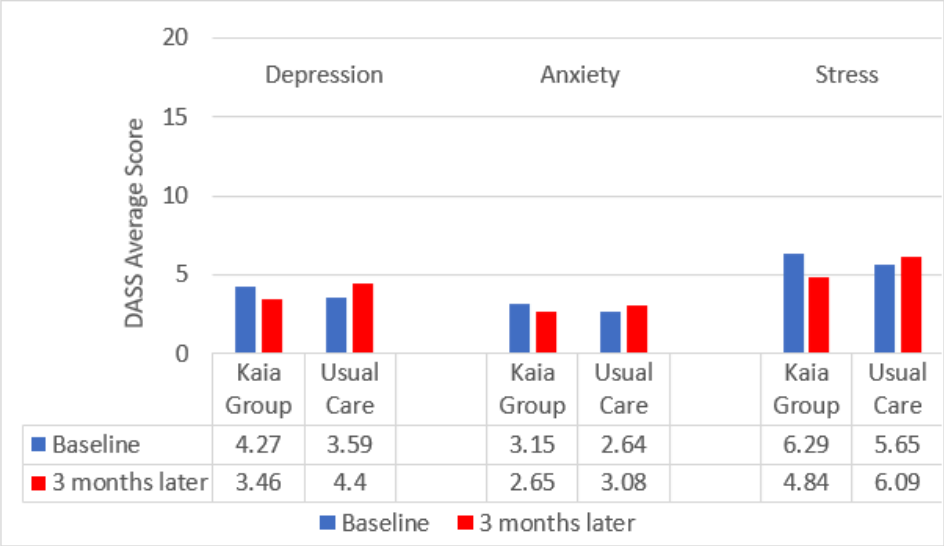
Further, Kaia participants used the program on average approximately 1 out of every 3 days during the period of the study.
The graph below shows the quality-of-life (VR-12) scores for both groups. The Kaia group improved its scores in both mental and physical health; the control group worsened in mental health on average. In both mental and physical health, Kaia program users significantly outperformed the control group; this means their change in average scores was statistically different than the change for the control group. In physical health, Kaia program users' average change was large enough to mark a clinically-meaningful change in health status (minimum clinically important difference).



Graph 2: Quality of Life VR-12 Average Scores

Findings for Outcomes Validation

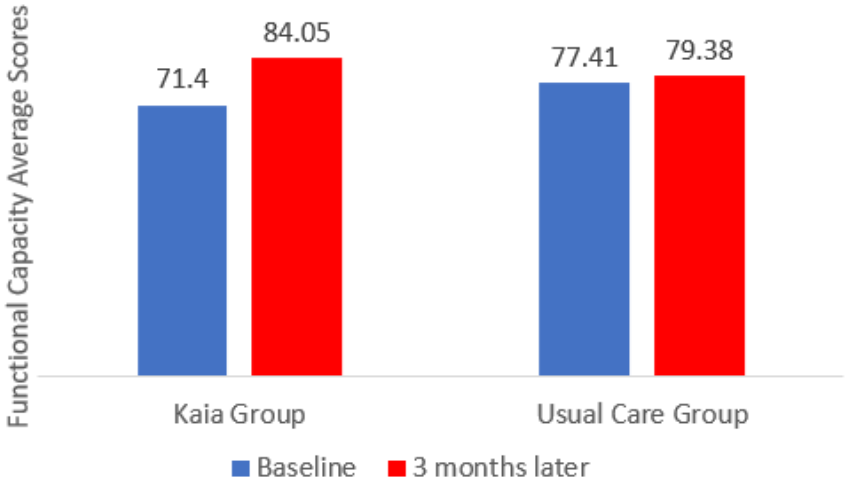
The graph below shows the depression, anxiety, and stress scores (DASS) scores for both groups. The control group on average had an increase in their scores, denoting a worsening of depression, anxiety, and stress. The Kaia group improved significantly on all three. In addition, the Kaia group's average change in scores for each section was statistically different from the control group's average.



Graph 3: Depression, Anxiety, Stress Average Scores

Findings for Outcomes Validation

The graph below shows the average scores in functional capacity, as measured by the Hannover Functional Ability Questionnaire. Both groups improved, but the Kaia group's improvement was statistically significantly higher.



Graph 4: Functional Capacity Average Scores

Validation and Credibility Guarantee

Kaia Health's Digital Musculoskeletal Program achieved **Program Validation**. Validation Institute is willing to provide up to a $100,000 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 INSTITUTE
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Validation Expiration: May 2025

CERTIFICATE OF VALIDATION

Applicant:	**Kaia Health** 99 Wall Street #5880, New York, NY 10005
Product:	Kaia Health's Digital Musculoskeletal Program
Claim:	This validation recognizes Kaia Health's Digital Musculoskeletal Program for achieving better patient outcomes at lower costs.
Validation Achieved:	**Program Validation**
Validation Award Date:	July 2022

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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.