



2023 Q1 CLINICAL UPDATE

From the desk of the Chief Medical Officer • Katie Hill MD

June 1, 2023

Executive Summary:

Nudj Health delivers evidence-based Lifestyle Medicine: update on clinical outcomes

Medicare patients enrolled in the Lifestyle Medicine program experienced clinically significant improvements in all of Lifestyle Medicine's pillars of health including stress management, sleep, nutrition, physical activity, social connectedness, and risky behaviors. The evidence-based treatment Nudj Health uses to deliver this treatment is adapted from the industry-leading Collaborative Care Method.

- Improved stress management: 2,238 patients have been screened for depression symptoms and 1,555 patients were screened for anxiety symptoms. Of those with clinically significant symptoms, depression and anxiety decreased by 52% within 12 weeks of initiating treatment.
- Improved sleep: 547 patients were screened for insomnia symptoms. By 12 weeks of treatment, insomnia decreased by 34-41%.
- Improved nutrition: the new Comprehensive Nutrition program is a 16-week program that began in January 2023. Initial results are promising with 42% of the first cohort achieving a clinically significant weight loss of 5-10% and other patients achieving improvement in cardiometabolic variables such as lipid measurements and waist circumference. We look forward to reporting on the complete outcomes of the Nudj Comprehensive Nutrition program in future clinical updates.
- Improved physical activity: 135 patients have been treated in the physical activity pathway. They increased the days per week they have intentional physical activity by 54%, increased the minutes per days with intentional physical activity by 90%, and improved their lower extremity strength and balance and functional movement by 20% as measured by the 5x Sit-to-Stand test.
- Improved social connectedness: 84 patients were screened for social isolation and those who were flagged as at risk improved their social connectedness by 24%.
- Decreased risky behaviors: since the initiation of the program in January 2023, three patients have participated to quit smoking. One patient experience is highlighted. We plan on expanding our tobacco cessation offering this summer with a combination of individual coaching and group classes to foster community and support.

We remain committed to delivering efficient and highly effective clinical care with the aim of improving health and well-being.

Sincerely,

Katie Hill MD

Katie Hill, MD

Introduction:

I'm pleased to report the clinical outcomes for patients treated in Nudj Health's Collaborative Care Lifestyle Medicine program. This data represents routine care delivered from the initial rollout of our technology registry in September of 2021 until April 2023 and will be focused on our behavioral health outcomes. Our treatment aims to reduce risk factors for and chronic disease itself via lifestyle change and improved psychological health. We use evidence-based behavioral health treatment via the collaborative care method in the six pillars of lifestyle medicine including stress management, sleep, social isolation, nutrition, fitness, and avoidance of risky behaviors.

Evidence-based Treatment: Collaborative Care Method Meets Lifestyle Medicine

Nudj Health's treatment is based on the collaborative care model, as pioneered by the University of Washington AIMS Center, a patient-centered, team-based approach to managing chronic medical and mental health conditions. This approach involves the coordination of care between primary care providers, specialists, and behavioral health providers, with the goal of improving patient outcomes and reducing healthcare costs (1). Nudj Health uses this evidence-based treatment model to deliver Lifestyle Medicine, a branch of medicine that aims to prevent, manage, treat, and even cure chronic disease with lifestyle change.

The collaborative care method utilizes a care manager, typically a nurse or a social worker, who acts as a liaison between the patient, primary care provider, and specialist. The care manager is responsible for monitoring the patient's progress, providing education, support, time-limited psychotherapy, health coaching, and coordinating care across different healthcare providers. Additionally, the care manager is responsible for identifying and addressing any barriers to care, such as lack of transportation or lack of understanding of the patient's condition (1). Nudj Health also adds health coaches to the care team to support the patient.

Nudj Health partners with referring physicians as an extension of his/her clinic staff. Our treatment is fully remote with telephone and video visits with patients (2). In addition to the behavioral services described above, patients are offered remote patient monitoring (RPM) services and are sent a blood pressure cuff and/or weight scale that transmits measurements automatically to their physician. They are also offered Nudj Academy group classes that are informational or activity-based such as group exercise classes and foster community and engagement. The key goal of care is creation of a personalized plan that includes creating sustainable behavior and lifestyle changes, assessment score changes, laboratory or blood pressure changes, and appropriate medication regimens.

The evidence base for the collaborative care model is strong, with numerous randomized controlled trials and observational studies showing positive results for a variety of chronic medical conditions. For more details on the evidence base of collaborative care in treating comorbid mental health and chronic physical health conditions please see Appendix A. Overall, the collaborative care model has been shown to be an effective approach for managing chronic medical conditions, improving patient outcomes and reducing healthcare costs.

At Nudj, we have found that combining Collaborative Care methods with Lifestyle Medicine principles leads to effective and efficient treatment for a variety of chronic medical and mental health conditions.

Patient and Partnering Practice Demographics

Patients are represented from multiple areas of the country including California and Texas. They live in both urban and rural areas and have a broad variety of socioeconomic backgrounds and cultures. Average age of patients was 72 years old. Fifty-three percent of patients were female and 43% were male.

Partnering entities include large healthcare systems, academic groups, private practice groups, and solo-practitioners from the specialties of primary care, cardiology, and oncology.

Stress Management Pathway and Sleep Pathway

Nudj Health's team screened a total of 2,238 patients for depression symptoms using the Patient Health Questionnaire-9 (PHQ-9) assessment between August 2021 and April 2023. A total of 1,555 patients were screened for anxiety symptoms using the Generalized Anxiety Disorder-7 (GAD-7) assessment. A total of 547 patients were screened for insomnia symptoms using the Insomnia Severity Index (ISI). While all patients are typically assessed via the PHQ-9 and GAD-7, only those patients who report difficulty with sleep on the PHQ-9 are then assessed with an ISI. All three assessments are clinically validated tools that are widely accepted and used in the industry.

Of those screened, 799 patients had clinically relevant symptoms of depression, 605 had symptoms of anxiety, and 422 had symptoms of insomnia.

Table 1 - Total number of patients assessed data from October 2021 to last week in Apr 2023

Assessment	N, Total	N, Positive Symptoms*
PHQ-9	2,238	799
GAD-7	1,555	605
ISI	547	422

* PHQ-9 score 5+, GAD-7 score 5+, ISI score 8+

After initial screening, patients select a treatment pathway and are reassessed periodically. Patients with at least one measurement post initial screening at any time during treatment show decreases in symptoms from 22-35% (see Tables 2-4). This group also includes patients who are new to treatment and mid treatment. Improvements are seen regardless of the severity of symptoms at treatment onset, with even those patients reporting severe depression, anxiety, and insomnia appreciating reduced symptom burden.

Table 2 - Change in PHQ-9 score

Starting Score of 5+				
Starting Score	Starting Average	Ending Average	N	Average Change
5 to 9	6.54	5.09	520	-23%
10 to 14	11.53	8.31	179	-28%
15 to 19	16.58	11.68	76	-30%
20 to 24	21.05	14.16	19	-33%
25	27.60	21.00	5	-24%

* Includes patients with at least one measurement post-initial screening.

Table 3 - Change in GAD-7 score

Starting Score of 5+				
Starting Score	Starting Average	Ending Average	N	Average Change
5 to 9	6.21	4.76	386	-23%
10 to 14	11.34	7.43	150	-34%
15	17.26	12.38	69	-28%

* Includes patients with at least one measurement post-initial screening.

Table 4 - Change in ISI score

Starting Score of 5+				
Starting Score	Starting Average	Ending Average	N	Average Change
8 to 14	10.85	9.20	236	-15%
15 to 21	17.44	13.49	148	-23%
22 to 28	24.29	15.87	38	-35%

* Includes patients with at least one measurement post-initial screening.

When patient scores are followed over time, we see more dramatic decreases in symptoms with subsequent weeks of treatment. Patients who remain in treatment and are reassessed at weeks 4 or 5 experience, on average, a decrease in depression symptoms of 43%, while those that remain in treatment for 10-12 weeks experience, on average, a 52% decrease in symptoms. Anxiety symptoms decrease 47-52% over the course of 4-12 weeks. Insomnia symptoms decrease 34-41% over the course 4-12 weeks (Tables 5-7).

Table 5 - Change in PHQ-9 scores over time compared to initial assessment at Week 0

Starting Score of 5+				
Time Frame	Patients	Starting Ave. (Week 0)	Ending Average	Average Change
Week 4-5	119	10.30	5.90	-43%
Week 8-9	114	9.87	6.22	-37%
Week 10-12	40	10.88	5.18	-52%

Table 6 - Change in GAD-7 scores over time compared to initial assessment at Week 0

Starting Score of 5+				
Time Frame	Patients	Starting Ave. (Week 0)	Ending Average	Average Change
Week 4-5	101	10.06	5.37	-47%
Week 8-9	85	9.38	4.94	-47%
Week 10-12	29	10.10	4.83	-52%

Table 7 - Change in ISI score

Starting Score of 5+				
Time Frame	Patients	Starting Ave. (Week 0)	Ending Average	Average Change
Week 4-5	67	14.82	8.95	-40%
Week 8-9	62	13.44	7.92	-41%
Week 10-12	17	14.94	9.88	-34%

As we scale and increase the number of patients served, we continue to maintain high quality treatment with outcomes that meet or exceed national collaborative care standards with rapid decreases in symptom burden.

Nutrition Pathway

The Nudj Nutrition Program was revised at the end of 2022 with aim of improving patient outcomes to reduce cardiovascular disease. The 16-week new Nudj Health Comprehensive Nutrition program enrolled its first cohort of patients in January 2023. This comprehensive program added a group educational experience, changed the focus to creating sustainable healthy eating, and will collect data such as laboratory values and waist circumference in addition to the prior blood pressure and weight monitoring. The curriculum is focused around building sustainable and healthy eating habits that gradually move toward a more plant-based and whole-foods predominant diet.

The first cohort recently finished the 16-week program and final laboratory values are being collected. We will report on those outcomes in a future clinical update.

Social Isolation Pathway

The Social Isolation Pathway was initiated at Nudj in February of 2022 as an independent pathway to improve social support and engagement for socially isolated patients. While all patients are typically assessed via the PHQ-9 and GAD-7, only those patients who report few social contacts are then assessed. The Care Manager then worked with the patient to address barriers to social engagement and apply behavioral therapies to support the patient to increase social connection.

The Lubben Social Network-6 (LSN-6) assessment is a clinically validated tool used to identify people at risk for social isolation. Patients with social isolation have higher risk of multiple poor health outcomes, including depression and anxiety. The LSN-6 scoring range is 0-30, with scores between 12-30 indicating mild to no risk and 0-11 indicating patients at a higher risk of social isolation.

To date, Nudj has screened 84 patients for social isolation. Of those, 25 were flagged as being at risk and experienced a 24% improvement in scores during treatment.

Table 8 - Change in Lubben Social Network - 6

Assessment	N	Starting Average	Ending Average	Average Change
LSN-6 Any Score	84	15.30	15.80	3%
LSN-6 Score 0-11	25	6.80	8.40	-24%

* Scoring range 0-30. Scores 0-11 at risk of social isolation, 12-30 mild or no risk.

Fitness Pathway

The fitness pathway demonstrates excellent clinical outcomes and includes patients treated from initiation of treatment in January 2022 to April 2023. The program consists of a mix of strength training, balance training, and aerobic activities, which meets U.S. nationally recommended physical activity guidelines for older adults with multiple chronic health conditions (5). Patients were in treatment for an average of 15.53 weeks and experienced an improvement in the 5x Sit-to-Stand test of 20%. The 5x Sit-to-Stand test is an industry-accepted measure of lower extremity strength and balance and lower scores predict decreasing fall risk (6). Patients also increased their days per week with exercise by 54% and increased their minutes per day of exercise by 90%.

Pre-program, our patients' level of activity was low enough to be considered sedentary. Post-program, they are stronger and average 90 minutes of exercise per week, which significantly decreases their risk of all-cause mortality, heart disease, stroke, hypertension, cancer, type 2 diabetes mellitus, obesity, etc.

Table 9 - Change in seconds of 5x Sit-to-Stand for patients from beginning to end of fitness pathway.

Assessment type	Starting Average	Ending Average	Patients	Average Change
5x Sit-to-Stand	15.86	12.72	98	-20%

* Average weeks in treatment is 15.53 weeks.

Table 10 - Change in self reported assessments for patients from beginning to end of fitness pathway

Assessment Type	Starting Average	Ending Average	Patients	Average Change
Days per Week with Exercise	2.32	3.57	121	54%
Minutes per Week with Exercise	13.48	25.66	135	90%

* Average weeks in treatment is 15.53 weeks.

Risky Behaviors Pathway

The Nudj Risky Behaviors Pathway was rolled out in January 2023. While we've had several patients participate in this pathway so far, I'd like to highlight the story of one individual to give readers a sense of the magnitude of change our patients experience with high quality, evidence-based treatment. Identifying information has been removed to protect his privacy. This individual is in his late 50s and was a two-pack-per-day smoker for more than 30 years. He had one successful period of abstinence about 15 years ago but when he relapsed, he immediately returned to his two pack per day habit. He was motivated to quit smoking after his cardiologist told him he was only a short time away from a major heart attack.

The patient initiated treatment in January of 2023 with behavioral coaching. Evidence-based pharmacotherapy was added in March and he quit entirely on April 22nd. He has remained tobacco free since then and has eliminated his consumption of high sugar energy drinks as a result of his decreased need for caffeine. He tells his team he's particularly enjoyed getting his ability to smell back and feels more energetic and healthier than he has in years. He is weaning off of the pharmacotherapy that supported his cessation and has not experienced a return of cravings. He says, "My wife is thrilled and I'm never going back to cigarettes."

We plan on expanding our tobacco cessation offering this summer with a combination of individual coaching and group classes to foster community and support and new outreach efforts to identify patients who are motivated to change.

Conclusion

Patients receiving Nudj Health's multi-disciplinary and evidence-based treatment access immediate mental health care and chronic disease monitoring and modification. Patients also benefit from improved psychological health, improved sleep, increased levels of physical activity, strength, and balance, and improved social connectedness. In the next several months we look forward to expanding treatment to patients in Nebraska and Michigan and expect to introduce our unique lifestyle medicine obstetrics program.

Appendix A: Evidence Supporting Collaborative Care's Efficacy in Treating Co-morbid Mental Health and Physical Chronic Conditions

A randomized controlled trial published in the New England Journal of Medicine in 2010 found that patients with cardiovascular disease or diabetes and co-existing depression had significant improved control of medical disease and depression compared with usual care (7). Another study, published in the Archives of General Psychiatry in 2012 found that multi-condition collaborative care for individuals with depression and poorly controlled diabetes or coronary heart disease produced cost-effective improvements in quality-adjusted life-years based on improvements in systolic blood pressure, HbA1C, and LDL-C (8). A third study, a meta-analysis published in JAMA Network Open in 2021 showed that interprofessional collaborative practice was significantly associated with reductions in HbA1c and systolic and diastolic blood pressures with greater effect sizes found for those with more severe disease at onset of treatment (9).

There is also one study that showed positive evidence for chronic disease remission. COMPASS (Care of Mental, Physical and Substance-use Syndromes) evaluated the dissemination of a three-year, multi-site initiative that used the collaborative care model for patients with diabetes and/or cardiovascular disease and co-occurring depression among 18 medical groups and 172 clinics spread across eight states. Outcomes from the COMPASS initiative found that 40% of patients with previously uncontrolled diabetes achieved remission or response, 23% achieved glycemic control, and 58% achieved blood pressure control (10).

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