



2022 Q4 CLINICAL UPDATE

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

January 30, 2023

EXECUTIVE SUMMARY

Nudj Health announces clinical outcomes in a Medicaid cohort.

Medicaid patients enrolled in the Nudj program by their cardiology provider experienced clinically significant reductions in blood pressures and improvements in measures of depression, anxiety, and insomnia.

- **Reduced Hypertension:** Patients with initial blood pressures greater than 140/90 mm Hg achieved clinically significant reductions in systolic and diastolic blood pressures even in the initial four months of treatment.
- **Immediate mental health treatment access and improved depression, anxiety, and insomnia:** The integrated care delivery model provided immediate access to mental health services for patients suffering from depression, anxiety, and insomnia. Treatment with Nudj Health allowed 43% of depressed patients to experience a decrease of 50% or greater relative to their initial score when starting the Nudj program. For anxiety and insomnia patients, 35% and 27%, respectively, achieved a decrease in scores of 50% or greater.
- **Rapid improvement:** median time to achieve a 50% decrease in scores was 3 months, significantly better than the 21 months that research suggests is time for reduction or remission in typical outpatient treatment settings. This allowed patients to focus on additional lifestyle treatment areas such as nutrition and exercise interventions.
- **Social determinants of health:** Many of the cohort experience acute health related-social needs including daily food, living, and financial insecurity. Forty-eight percent of the patients are Spanish-speaking only.

Introduction:

I am pleased to report the clinical outcomes for Nudj Health's initial rollout with Medicaid patients within a cardiology outpatient setting. This cohort of patients in Southern California resides in the urban and rural desert area colloquially known as the Inland Empire, famous for Palm Springs and the concert Coachella, all within Riverside and San Bernardino counties. Resources in the Inland Empire for specialty medical treatment are very limited despite local high needs. The Medicaid cohort we describe here is similar to the Medicare population we described in prior clinical updates with common cardiac conditions such as hypertension, atrial fibrillation, coronary artery disease, etc. However, Medicaid typically covers individuals of lower socioeconomic status that suffer from an increased incidence and worse outcomes from cardiovascular and other chronic diseases¹. Our treatment aims to reduce cardiovascular disease risk factors as we address psychological health and poor lifestyle choices. Our treatment also satisfies recent American Heart Association recommendations for screening and referral for mental health treatment from within cardiology^{2,3}. The outcomes presented in this report represent patients enrolled between August to November 2022 and receiving treatment up until Dec 31, 2022. Treatment and data collection in this cohort is ongoing. Please refer to the table below for demographic information.

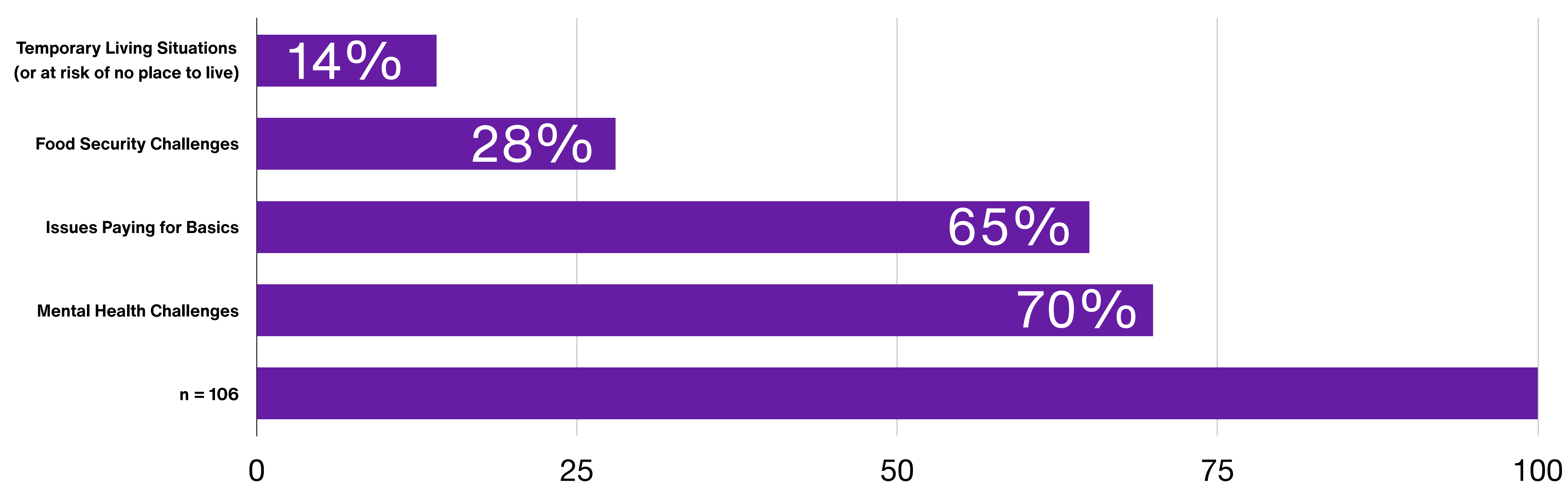
Treatment Summary and Patient Demographics:

Nudj Health's Collaborative Care treatment pathway consists of 6 treatment arms addressing the American College of Lifestyle Medicine's 6 essential pillars to improve and maintain cardiovascular health: nutrition, sleep, physical fitness, stress management, social isolation, and avoidance of risky behaviors such as alcohol and tobacco consumption. Partnering physicians also have the option of prescribing Remote Patient Monitoring (RPM) additionally or exclusively, which allows them to closely monitor physical and objective signs of cardiovascular disease.

The cardiology provider partnered with Nudj Health to treat 158 patients, 64 of whom participated in a lifestyle pathway and RPM, and 94 of whom participated in RPM only. 106 patients were screened for health-related social needs using the Centers for Medicare & Medicaid Services Center for Medicare and Medicaid Innovation's Accountable Health Communities Health-Related Social Needs (HRSN) Screening Tool. This HRSN Screening tool revealed 28% of the cohort had food security challenges, 65% had issues paying for basics, 70% had mental health challenges, and 14% either had temporary living situations or were at risk of not having a place to live in the days to come. For more information about the population, please refer to the figure below.

Demographics for patients with >1 month in Nudj Programming (including SDOH)

	Overall (N=106 out of total 158)
Age	
Mean (SD)	58.2 (13.3)
Median [Min, Max]	58.0 [23.0, 93.0]
Gender	
Female	71 (44.9%)
Male	87 (55.1%)
Total Months	
0	0 (0%)
1	33 (20.9%)
2	34 (21.5%)
3	44 (27.8%)
4	47 (29.7%)



Blood Pressure:

To analyze blood pressures (BP), we used linear mixed effect modeling to predict expected change in BP over time resulting from treatment with Nudj Health. This statistical modeling allows us to account for the relatively short time period recorded, the rolling enrollment process, and still make predictions about future outcomes. Patients with initial BP greater than 140/90 mm Hg (49 patients) experienced a mean decrease in systolic BP of 1.32 mm Hg per month in the program, and a mean diastolic BP decrease of 0.58 mm Hg per month. In other words, the average patient with Stage 2 Hypertension enrolled in August of 2022 had experienced a decrease in mean BP of 5.28 mm Hg systolic and 2.32 mm Hg diastolic by December 2022.

Medicaid Predicted Monthly Blood Pressure Change via Linear Mixed Effect Modeling

	Change/month (mm Hg)	95% Confidence Interval
Systolic	-1.32	0.14, 1.00
Diastolic	-0.58	0.54, 2.17

N = 49 patients with initial BP \geq 140/90

Furthermore, when those patients who participated in a lifestyle pathway + RPM are compared to the RPM-only group, statistically significant larger changes in BP were achieved. Systolic BP decreased by 6.98 mm Hg (95% CI -2.6, -11.34, $p=0.002$) and diastolic BP decreased 3.87 mm Hg (95% CI -1.4, -6.3, $p=0.002$). This suggests that our behavioral health treatment contributes to greater decreases in BP and, therefore, greater cardiovascular risk reduction relative to those patients who received only RPM support. Based on the modeling, we expect to see on-going improvements in blood pressure as the cohort continues treatment with Nudj over the course of 12 months.

On a population level, this magnitude of change in blood pressure is highly significant: the seminal Intersalt study⁴ still considered relevant today demonstrated that each decrease of 2 mm Hg difference in systolic pressure correlated to a decrease in mortality of 4% for coronary deaths, 6% in stroke mortality, and 3% in all cause deaths per year. If blood pressure was lowered by 5 mm Hg, the study showed potential lives saved were even higher with decreases of 9% for cardiac-related deaths, 14% decreased stroke-related deaths, and 7% decrease in deaths of all causes (see the table below). Thus, despite lower income and other negative social determinants of health that worsen health outcomes, the cohort of Inland Health Empire's patients receiving Nudj treatment significantly decreased their mortality risk.

Intersalt Study: Potential for Lowering Mortality with Lower Average Population Systolic BP

Decrease in Systolic BP	Coronary Deaths	Stroke Deaths	All Deaths	Potential # Saved Lives/Year*
2 mm Hg	-4%	-6%	-3%	12,000
3 mm Hg	-5%	-8%	-4%	16,000
5mm Hg	-9%	-14%	-7%	28,000

*Based on the number of US deaths in 1985 from all causes for men and women ages 45-64 years old.

Prior to initiating treatment with Nudj, 16 patients reported being hospitalized and/or visiting the emergency room in the prior 12 months. Since initiating treatment with Nudj, only 3 of those patients reported being hospitalized and/or visiting the emergency room again. We find this promising and worthy of future and more formal investigation, as data was acquired directly from the patient and has not been verified against historical or current claims data.

Mental Health Access and Treatment Outcomes:

The integrated care delivery model received by patients treated with RPM and a Lifestyle Medicine pathway (74 patients) provided immediate access to mental health services for patients suffering from depression, anxiety, and insomnia. All outcome measures decreased in tandem with blood pressure. To assess depression, anxiety, and insomnia we use the following clinical assessment tools: Patient Health Questionnaire-9 (PHQ-9), General Anxiety Disorder-7 (GAD-7), and Insomnia Severity Index (ISI). Please see the appendix for more information on the scoring of each assessment. In behavioral health, industry-wide accepted treatment targets are defined as a 50% reduction in scores or reaching remission of disease. However, the literature suggests real-world clinical outcomes are slightly slower with rural and low-income populations such as our Medicaid cohort described here ^{6,7}. Treatment with Nudj Health allowed 43% of depressed patients to experience a decrease of 50% or greater relative to their initial score when starting the Nudj program. For anxiety and insomnia patients, 35% and 27%, respectively, achieved a decrease in scores of 50% or greater. Median time to a 50% decrease was 3 months, which is consistent with results obtained in our Medicare population and is much more efficient than the 21 months needed for a 50% reduction in scores in a typical outpatient treatment setting ⁵. All decreases in symptoms described are clinically meaningful and result in improved quality of life, relationships, activities, and unlocked emotions and experiences many described feeling denied to them such as joy, well-being, and vitality.

Outcomes All Patients

	PHQ-9 (N=74)	GAD-7 (N=74)	ISI (N=22)
Initial Score			
Mean (SD)	8.00 (6.07)	7.36 (5.31)	16.3 (5.74)
Median [Min, Max]	7.00 [0, 25]	6.00 [0, 20.5]	17.0 [6, 26]
Most Recent Score			
Mean (SD)	5.50 (5.57)	5.31 (5.27)	11.7 (6.75)
Median [Min, Max]	4.00 [0, 23]	4.00 [0, 21]	9.50 [1, 22]
Percent with ≥ 50% decrease in score	43.24%	35.14%	27.27%

* Median time to a decrease of ≥50% is 3 months.

Depression Outcomes:

Further analysis of patients with depression symptoms showed those with mild depression scores (21 patients) experienced an average decrease of 41%. Those with moderate depression (11 patients) experienced a 38% reduction in scores, and those with moderately severe depression (8 patients) experienced a reduction of 51% in scores. Severely depressed individuals (5 patients) also experienced improvement in symptoms, by 14% (see below).

	Mild (5-9)	Moderate (10-14)	Moderately Severe (15-19)	Severe (20-27)
Initial score	n=21	n=11	n=8	n=5
Mean (SD)	7.62 (1.43)	12.09 (1.45)	15.88 (0.99)	21.70 (1.99)
Median [Min, Max]	8.00 [5, 9]	12.00 [10, 14]	15.50 [15, 17]	21.00 [20, 25]
Most recent score				
Mean (SD)	4.33 (3.94)	7.27 (4.67)	7.75 (5.31)	18.70 (3.46)
Median [Min, Max]	4.00 [0, 15]	7.00 [2, 18.0]	6.00 [2, 15.0]	19.00 [15, 23]
Percent change	-41.0%	-42%	-51.2%	-13.8%

Anxiety Outcomes:

A subset analysis of patients with anxiety symptoms in the mild category (21 patients) had a 23% reduction in scores. Those patients in the moderate anxiety category (18 patients) showed a 38% reduction in scores, while those patients experiencing severe anxiety (8 patients) experienced a 19% reduction in symptoms (see below).

	Mild (5-9)	Moderate (10-14)	Severe (15-21)
Initial score	n=21	n=18	n=8
Mean (SD)	6.83 (1.56)	11.86 (1.21)	17.81 (1.78)
Median [Min, Max]	6.00 [5, 9]	12.00 [10, 13]	17.5 [15, 20.5]
Most recent score			
Mean (SD)	5.24 (3.03)	7.33 (4.46)	14.42 (5.91)
Median [Min, Max]	6.00 [0, 11]	6.5 [0, 17]	15.5 [4, 21.0]
Percent change	-23.3%	-38.2%	-19.1%

Insomnia Outcomes:

Of the patients complaining of insomnia symptoms, patients with mild insomnia (N=6) had a 32% reduction in scores. Those patients with moderate insomnia (10 patients) experienced a 29% reduction in scores, while those patients experiencing severe insomnia (4 patients) experienced a 22% reduction in symptoms (see below).

	Mild (8-14)	Moderate (15-21)	Moderately Severe (22-28)
Initial score	n=6	n=10	n=4
Mean (SD)	11.50 (2.35)	17.90 (1.79)	24.50 (1.73)
Median [Min, Max]	11.5 [8, 14]	11.5 [8, 14]	25.0 [22, 26]
Most recent score			
Mean (SD)	7.83 (4.58)	12.70 (6.34)	19.00 (3.56)
Median [Min, Max]	7.00 [1, 15]	12.5 [2, 22]	20.00 [14, 22]
Percent change	-31.9%	-29.1%	-22.45%

Conclusion:

Overall, our outcomes in this rural Southern California Medicaid cohort after only 4 months of follow-up suggest that treatment with Nudj Health had significant and clinically positive effects. Of the patients experiencing depression, 43% achieved response or remission of symptoms in 3 months. Of the patients experiencing anxiety and insomnia symptoms, 35% and 27%, respectively, achieved response or remission in 3 months. Outcomes also suggest that treatment with Nudj Health lowers risk of hospitalization, and we hope to examine this more formally in the future.

Physiologic outcomes showed treatment with Nudj Health's Lifestyle + RPM program lowered blood pressure by 6.98/3.87 mm Hg after 4 months of follow-up, which change was statistically significant when compared to the group receiving RPM treatment only. Based on the modeling results, we expect further decreases in blood pressure as this cohort continues treatment with us in the coming months.

In sum, treatment with Nudj Health rapidly decreased cardiac morbidity and mortality risk for this Medicaid cohort. We remain committed to delivering innovative, efficient, and highly effective clinical care with the aim of improving health and well-being. We look forward to continuing treatment with the individuals in this cohort and working alongside them to achieve their health goals.

Sincerely,

Katie Hill MD

Katie Hill, MD
CMO

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Appendix:

Depression PHQ9, Anxiety GAD7, Insomnia ISI scoring

DEPRESSION (PHQ-9)		ANXIETY (GAD-7)		INSOMNIA (ISI)	
0-4	Minimal depression	0-4	Minimal anxiety symptoms	0-7	No clinically significant insomnia
5-9	Mild depression	5-9	Mild anxiety symptoms	8-14	Mild, sub threshold insomnia
10-14	Moderate depression	10-14	Moderate anxiety symptoms	15-21	Moderate, clinical insomnia
15-19	Moderately Severe Depression	15-21	Severe anxiety symptoms	22-28	Severe, clinical insomnia
20-27	Severe Depression				