Original article

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The Effect of the Paleolithic Ketogenic Diet (PKD) on Metabolic Parameters, Fatigue, and Sleep

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Abstract

***Background*:** The authors of this study have been using the so-called paleolithic ketogenic diet (PKD), an animal meat-fat-based diet, to treat various chronic diseases since 2012. Here, we present a descriptive cohort study of our patients who followed the PKD for various health reasons.

***Methods*:** The present study aimed to systematically analyze blood glucose, ketones, body weight, BMI, systolic and diastolic blood pressure, fatigue, and sleep in 274 patients participating in our online medical program, with a 2-week follow-up during which patients were placed on the PKD. Our aim was to create a homogeneous sample; only adult patients without medications were included.

***Results*:** Over the 14 days, there were significant changes in blood glucose, blood pressure, weight, and BMI. Fatigue and poor sleep improved significantly.

***Conclusions*:** We conclude that the PKD is associated with positive health changes.

Keywords: Ketogenic diet, low-carb diets, glucose, ketosis, blood pressure

Introduction

The paleolithic ketogenic diet (PKD) is an animal meat-fat-based diet similar to that originally proposed and used by gastroenterologist Voegtlin in 1975. (1) The authors of the current paper have developed and used the PKD to treat chronic diseases since 2012. We have published case studies, including patients with epilepsy, (2,3) type 1 diabetes, (4,5) metabolic syndrome, (6) Gilbert's syndrome, (7) Crohn's disease, (8) colorectal cancer, (9) soft palate cancer, (10) cervical intraepithelial neoplasia, (11) and glioblastoma. (12) In a previous group study with 100 patients, we showed that C-peptide level, which is an insulin marker and overall health marker, remains low in PKD. (13) In another study with 50 patients, we showed that despite the apparent low magnesium content of the PKD, serum magnesium levels remain normal. (14)

The PKD differs from the classical ketogenic diet, the paleo diet, and the carnivore diet. Key differences between these diets are highlighted in **Table 1**.

The ketogenic diet has been historically used in the treatment of epilepsy for the last 100 years. Beyond epilepsy, a large body of studies has documented benefits in a variety of neurological and metabolic conditions. Limitations and disadvantages of the ketogenic diet have also been characterised. (15) Over the years, different versions of the ketogenic diet have been introduced to mitigate side effects and improve sustainability and palatability. In the literature, the terms "ketogenic diet" and "classical ketogenic diet" are used interchangeably. Given that

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all previous versions of the ketogenic diet are based on plant foods and dairy, in the present study, we collectively refer to these diets as the "classical ketogenic diet".

The PKD is fundamentally different from the classical ketogenic diet, as it is based on meat and animal fat but excludes dairy. Therefore, the disadvantages of the classical ketogenic diet do not apply to the PKD. In our observation, if properly applied, side-effects from the classical ketogenic diet do not apply to the PKD.

The paleo diet, which gained popularity in the early 2000s, is based on whole, unprocessed foods, including vegetables, fruits, meat, fish, and eggs, but lacks clear guidance on their proportions. (16)

The carnivore diet, as defined, is based on animal foods while excluding all plant foods. Although it has gained substantial popularity, only two studies have statistically examined laboratory parameters, (17,18) with one also evaluating weight and BMI on the carnivore diet. (17) Both studies relied on social media surveys, which limits the strength of their conclusions. Since a typical carnivore diet does not induce ketosis, it differs from the PKD, and therefore, the findings from these diets have limited applicability to the PKD.

The PKD is defined by rules shaped by patient feedback, tracked symptoms, and laboratory blood work since 2012.

In this study, we monitored and analyzed blood glucose, ketones, body weight, BMI, systolic and diastolic blood pressure, fatigue, and sleep over 14 days in patients following the PKD. The data came from participants in our online program with a 2-week follow-up.

Our aim was to provide robust data to demonstrate the effects of PKD on health parameters. To ensure a consistent dataset, we included only patients who were not taking any medications or supplements and who were not undergoing radiotherapy or chemotherapy at the time of the program.

Methods

Patients

We retrospectively analyzed data from our patients between February 2021 and July 2025. To create a robust sample, we selected patients based on the following criteria:

Inclusion Criteria:

- Participating in the full online medical program, including an initial consultation and a two-week follow-up;
- Providing home measurements for at least 14 consecutive days after the initial consultation;
- Age 18 or older.

Exclusion Criteria:

- Diagnosis of type 1 diabetes or LADA (Latent Autoimmune Diabetes in Adults);
- Taking medications during the program;
- Receiving chemotherapy or radiotherapy during the program.

274 patients were identified as meeting the above criteria. Among the included patients, there were 129 males and 145 females. The mean (±SD) age was 47.9 years (±12.8), with an age range of 20–80 years. At the time of starting the program, patients had been following various diets, with most having already been on a low-carb, ketogenic, or carnivore diet. Some had already been following the PKD to the best of their knowledge. In this analysis, we included only patients who had not received medication, chemotherapy, or radiotherapy, as these treatments may affect the measured parameters. Because nutritional intervention is the primary therapeutic modality in our practice, patients who never took medication for chronic conditions, or discontinued it, may be overrepresented in our sample compared with the general patient population. Although the PKD allows eggs, poultry, fish, and seafood, we advise against these foods in the initial phase of the diet. Therefore, the data reported here reflect a version of the diet that excludes these foods. Certain plant-based foods may be allowed in limited amounts later in the PKD. In the initial phase of the diet, these foods are not allowed. The study was conducted in accordance with the principles outlined in the Declaration of Helsinki. The study was approved by the local Research Ethics Committee (approval number: 3/ 2019.08.30.).

Paleolithic ketogenic diet

The idea of an animal meat-fat-based diet as an evolutionary adaptation for humans was first proposed by gastroenterologist Voegtlin. (1) The PKD is a diet focused on four-legged animals, with a specific meat-to-fat ratio, and includes organ meats. The PKD excludes milk and dairy products. Animals in the diet should be properly fed: grass-fed for ruminant animals, and a natural omnivore diet

for pork. In the program, the PKD is followed in its strictest form, meaning it excludes plant-based foods. During the initial phase of the PKD, patients are also advised to avoid poultry, eggs, fish, and seafood. Due to patients' diverse backgrounds, there has been variation in the primary meat source, with some relying more on beef versus pork. Patients from the US and Western Europe mainly consumed beef, while those from Central and Eastern Europe ate more pork. Typically, patients had two meals per day. They were advised to stop all supplements.

The online medical program

The program starts with an initial medical consultation and includes a two-week follow-up period to provide ongoing support. During this time, patients are monitored using our patient-tracking platform. On the platform, patients are asked to record daily measurements, upload photos of their food, and communicate in writing. Patients receive recommendations regarding the meat-to-fat ratio and overall food quantities. These recommendations are designed to help achieve and maintain a glucose level between 3.5 and 4.5 mmol/l, as well as ketone levels in the 2–3.5 mmol/l range. The target ranges were determined based on our previous observations, which indicated that the best overall results were associated with these ranges.

Measurements

During follow-up, patients record daily home measurements and symptom severity scores. From these measurements, we included glucose, ketones, body weight, and systolic and diastolic blood pressure. BMI was calculated using the standard formula: BMI = weight (kg) / height (m)^2. Blood glucose and ketones were measured from a blood drop with glucose and ketone meters. Patients were instructed to take measurements before their second meal. When entering glucose and weight data, patients can choose between unit systems, and the platform converts the data. For this analysis, we used SI units. During the initial consultation, the patient's symptoms were identified and entered into the platform, allowing us to monitor them throughout follow-up. Symptoms of fatigue and poor sleep were included by default. Patients rated their symptoms on a 0–10 scale, where 0 means no symptom, and 10 indicates the worst severity.

Statistical tests

For each day, averages were calculated for the measured parameters. To further analyze the data, we created subgroups based on the 0–25th, 25th–75th, and 75th–100th percentiles, using the measurements from the first day. These categories are referred to as the "lower," “middle two," and “upper” quartiles. We also calculated averages for each day within these subgroups. Paired t-tests compared Day 1 and Day 14 within each group. Since not all data were available for every patient, the number of data points is also listed. Because poor sleep and fatigue are categorical variables, we created 10 subgroups based on Day 1 scores and then statistically compared Day 1 and Day 14 scores using paired t-tests and the Wilcoxon signed-rank test as a sensitivity analysis. In addition, we created a whole-cohort mixed-effects model to assess how symptoms changed over the 14 days.

Results

Glucose level

Glucose levels decreased significantly from Day 1 to Day 14 in the overall analysis and within the upper and middle two quartiles. The decrease in average glucose was greatest in the upper quartile, dropping from 5.89 mmol/l to 4.76 mmol/l. In the upper quartile, 61 of 63 patients decreased their blood glucose from Day 1 to Day 14. In contrast, glucose in the lower quartile increased significantly, averaging from 3.63 mmol/l to 4.06 mmol/l. On Day 1, only 111 patients were within the glucose target range (3.5–4.5 mmol/l), which increased to 156 by Day 14. The standard deviation (SD) for glucose gradually decreased over the 14 days (**Table 2**, **Table 3**, **Figure 1**, **Figure 2**).

Ketone level

Ketone levels increased significantly from Day 1 to Day 14 in the overall analysis and in the lower and middle two quartiles. Ketones decreased significantly in the upper quartile. The greatest increase in ketones was observed in the lower quartile, rising from 0.33 mmol/l to 2.7 mmol/l. On Day 1, only 78 patients were within the ketone target range, increasing to 147 on Day 14. The standard deviation (SD) for ketones gradually decreased over the 14 days (**Table 2**, **Table 3**, **Figure 1**, **Figure 2**).

Weight

Weight decreased significantly in the overall analysis and across all three subgroups. On average, the greatest weight loss was seen in the upper quartile, dropping from 86.7 kg to 83.2 kg. In the upper quartile, 67 of 68 patients decreased their weight from Day 1 to Day 14 (**Table 2**, **Table 3**, **Figure 1**, **Figure 2**).

BMI

BMI decreased in the overall analysis and across all three subgroups. The largest decrease was seen in the upper quartile, dropping from 28 to 26.8 kg (**Table 2**, **Table 3**, **Figure 1**, **Figure 2**).

Systolic blood pressure

Systolic blood pressure decreased in the overall analysis, the upper quartile, and the middle two quartiles. The greatest decrease occurred in the upper quartile, dropping from 134.5 to 126.1 mmHg on average. In the upper quartile, 39 of 50 patients decreased their systolic blood pressure from Day 1 to Day 14. Systolic blood pressure in the lower quartile did not change significantly (**Table 2**, **Table 3**, **Figure 1**, **Figure 2**).

Diastolic blood pressure

Diastolic blood pressure decreased significantly in the overall analysis and within the upper quartile and the two middle quartiles. The greatest decrease was observed in the upper quartile, dropping from 88.7 to 80.7 mmHg on average. In the upper quartile, 41 of 44 patients decreased their diastolic blood pressure from Day 1 to Day 14. Conversely, diastolic blood pressure rose significantly in the lower quartile, increasing from 63 to 65.9 mmHg on average (**Table 2**, **Table 3**, **Figure 1**, **Figure 2**).

Fatigue

There has been a gradual improvement in the reported fatigue score over the 14 days. The improvement in sleep was more pronounced among those with higher initial poor sleep scores. The fatigue score decreased significantly in the subgroups with initial scores of 4, 5, 6, 7, and 8. In the additional sensitivity analysis, the fatigue score decreased significantly in the 4, 5, 6, 7, 8, 9, and 10 subgroups. The significant increase in the 0 subgroup is a statistical artifact known as ”regression to the mean” and, as such, should therefore be ignored (**Table 4A**, **Figure 3A**). A linear mixed-effects model fitted to all available fatigue scores showed that fatigue scores decreased significantly over time. On average, the change was -0.070 points per day (β = -0.070, SE = 0.010, 95% CI = -0.090 to -0.050, t value = -7.00, p value < 0.001). Because regression to the mean was a potential concern, we performed a sensitivity analysis where patients who started with a score of 0 or 10 were excluded. After that, the fatigue model used 191 participants. Fatigue still dropped in a clear way with β = −0.097, 95% CI −0.117 to −0.076, and p value < 0.001.

Poor sleep

There has been a gradual improvement in the reported sleep score over the 14 days. The improvement was more pronounced among those with higher initial poor sleep scores. The poor sleep score significantly decreased in the subgroups with initial scores of 2, 3, 4, 5, 6, and 8. In the additional sensitivity analysis, the poor sleep score decreased significantly in the 2, 3, 4, 5, 6, 8, 9, and 10 subgroups. The significant increase in the 0 subgroup is a statistical artifact known as ”regression to the mean” and should therefore be ignored (**Table 4B**, **Figure 3B**). The linear mixed-effects model showed that poor sleep scores significantly decreased over time. Every additional day was associated with a mean score decrease of 0.055 points (β = −0.055, SE = 0.009, 95% CI −0.073 to −0.036, t value −5.81, p value < 0.001. To account for the regression to the mean, in a sensitivity analysis, patients who started with a score of 0 or 10 were excluded. After that, the fatigue model used 160 patients. This analysis still showed a significant decrease in poor sleep score (β = −0.099, 95% CI −0.119 to −0.078, p < .001).

Discussion

Over the past few decades, numerous studies have demonstrated that carbohydrate-restricted diets positively influence metabolic parameters and various health outcomes. Most of these studies focus on plant-based diets. Given the fundamental differences between plant-based and animal-based diets, the effects observed in plant-based diets cannot be directly applied to animal-based diets, which have recently gained popularity.

So far, only three group studies have reported on meat-based diets. (17–19) These studies reported on weight loss, improvements in metabolic parameters, and symptom relief. However, conclusions from these studies are limited by data heterogeneity and

by the reliance on self-reported data from patients who self-applied the carnivore diet.

To our knowledge, this is the first group study to use firsthand patient data from clinicians treating patients with a meat-based diet. Unlike previous carnivore studies, we employed the PKD, a well-formulated meat-fat-based diet with predefined glucose and ketone targets, which distinguishes it from a generic carnivore diet.

In our study, glucose levels were generally low. Those with initially high glucose levels typically had their glucose levels lowered within a few days. On the last day of the program, the average glucose was 4.37 mmol/l. This is a significant difference from the carnivore diet, in which, in our observations, blood glucose often remains elevated. In the study by Klement et al., (18) glucose remained at 4.8 mmol/l, unchanged after the carnivore diet was started. The other two carnivore studies did not report glucose data. (17,19) In our study, those with very low blood glucose levels significantly increased their levels as intended.

Most of our patients were already in ketosis when they started the program, with an average ketone level of 1.9 mmol/l on the first day. Overall, patients increased their ketone levels. However, patients with very high initial ketone levels had their levels decreased to reach the target range. Based on our experience, the carnivore diet usually does not lead to ketosis. In the three carnivore studies, no ketone levels were reported.

Weight loss was significant and consistent, with a 3.49 kg reduction in the upper quartile and with 2.22 kg in the overall analysis.

Overall, systolic and diastolic blood pressure decreased significantly. However, those with the lowest diastolic blood pressure significantly increased it, alongside a reduction in initially elevated ketone levels.

Decreases in blood glucose, body weight, and blood pressure align with expectations. However, the increase in diastolic blood pressure in the lowest diastolic blood pressure group indicates that PKD also increases blood pressure when needed.

In our study, both fatigue and sleep improved. The improvement was gradual over the 14 days and was observed across subgroups with different initial symptom scores. We believe that consistent improvements in fatigue and sleep result not only from the diet composition but also from the specific glucose and ketone target ranges of the PKD. This is supported by the fact that symptom improvement over the 14 days paralleled the movement of glucose and ketone levels into the target range.

Although our analysis is retrospective, when working with patients, we intentionally guided them rather than simply monitoring their progress. This guidance involved providing day-to-day feedback, education, communication, identifying potential mistakes, and adjusting the amounts of meat, fat, and organ meat in the diet.

We are not aware of any carnivore study as specific and systematic as ours. However, based on available data from carnivore research and our observations of patients following a carnivore diet, we conclude that results with the PKD surpass those with the carnivore diet. In our experience, patients on the carnivore diet initially report improvements in fatigue, but it later worsens due to the limitations of a generic carnivore approach. This sharply contrasts with the PKD, where fatigue tends to improve over time.

The carnivore diet, by definition, excludes all plant foods. However, the diet can vary significantly in the amount of food recommended and whether it includes dairy or organ meats. Unlike the generally suggested “ad libitum” food intake of the carnivore diet, the PKD aims to limit food consumption to physiological needs.

The present study provides robust evidence that the PKD offers significant health benefits in the studied parameters. A major strength of the study design is that, by excluding patients on medication and supplements, we could control for drug effects and obtain more robust findings. Adherence levels were also higher than in most other diet intervention studies.

As regards further use of the data, it can serve as a baseline for patients with PKD who are taking medications or tapering them. This is important because most patients seek care for conditions involving medications that require medical guidance beyond diet advice. Most medications are known to affect glucose and fat metabolism and, therefore, usually elevate blood glucose levels, as do beta-blockers (20), diuretics, and corticosteroids. (21) Conversely, other medications, such as ACE inhibitors, may lower blood glucose, (22) a phenomenon rarely seen in clinical settings because it is masked by high blood glucose in patients with metabolic syndrome. Multiple conditions treated with several medications can create a complex situation that may become nearly impossible to manage without understanding the baseline

dynamics of glucose, ketones, weight, and blood pressure.

The study's results are strong but do not show the full effect size of PKD, as most patients had already been on a low-carb or meat-based diet. About half of them were already in ketosis at the start of follow-up. However, the study shows that upgrading from a less-defined diet to the PKD and progressing toward a well-executed PKD provides additional metabolic and symptomatic benefits beyond those seen with a less-defined diet.

The strengths of the study design include the use of first-hand data, high adherence due to daily communication and tracking, a large sample size (n=274), and a sample free of drug effects. The study also offers insights into the transition toward an ideal glucose and ketone range and the associated metabolic and symptomatic benefits, with daily data collected over 14 days.

Based on our experience, we believe that high adherence to the PKD, defined by specific glucose and ketone levels, is essential to maximize health benefits, reduce recovery time, and avoid unnecessary trial-and-error cycles that often occur when patients impose a less clear diet on themselves.

Conflict of interest

The authors declare no conflict of interest.

Table 1. Comparison between the classical ketogenic diet, the paleo diet, the carnivore diet, and the PKD

	Classical Ketogenic Diet	**Paleo diet**	**Carnivore Diet**	**PKD**
Definition	Ensuring ketosis	Excluding food items not available in the Paleolithic era	Excluding plant food	Meat-fat-based diet based on 4-legged animals, with a specific meat:fat ratio, including organ meats
Food groups	Fat sources: plant oils, dairy (butter, cream), moderate protein (meat, fish, eggs), low-carb vegetables; limited fruits	Whole, unprocessed food items, low-carb vegetables, fruits, fish, meat, eggs	Meat (beef, lamb, pork, poultry, fish), eggs, animal fats; dairy varies	Meat, fat, organ meat from 4-legged animals
Excluded food groups	None specifically, only the amount is limited to an extent that ensures ketosis	Grains, cereals, milk, dairy, vegetable oils, nightshades, legumes	Plant foods	Grains, cereals, milk, dairy, plant oils, oilseeds, nightshades, legumes, sweets, artificial sweeteners
Macronutrient ratio (in grams)	4:1 fat:protein, carbohydrates 20g/day max	Undefined	Varies, typically 3:1 protein:fat, zero carbs	2:1 fat:protein ratio, may vary between and within individuals
Supplements	Many and mandatory	Varies	Varies, but typically yes	No

Table 2. Grand mean averages, standard deviations (SD), and number of data points (n) for glucose, ketones, weight, BMI, systolic blood pressure, diastolic blood pressure, fatigue, and poor sleep

Day		1	2	3	4	5	6	7	8	9	10	11	12	13	14
Glucose (mmol/l)	Mean	4.65	4.53	4.39	4.31	4.31	4.30	4.33	4.32	4.29	4.32	4.28	4.29	4.28	4.37
	SD	1.01	1.01	0.88	0.85	0.80	0.71	0.67	0.67	0.70	0.73	0.69	0.66	0.60	0.78
	n	274	274	273	274	273	273	273	274	274	271	268	271	268	260
Ketones (mmol/l)	Mean	1.89	2.16	2.26	2.53	2.68	2.81	2.67	2.81	2.87	2.87	2.87	2.88	2.95	2.87
	SD	1.51	1.57	1.38	1.41	1.30	1.28	1.20	1.25	1.17	1.17	1.10	1.14	1.12	1.02
	n	266	268	268	270	271	272	271	270	271	267	268	269	266	258
Weight (kg)	Mean	66.45	66.13	65.81	65.50	65.39	65.11	64.95	64.83	64.65	64.49	64.37	64.34	64.14	64.23
	SD	15.14	15.00	14.98	14.89	14.77	14.72	14.58	14.52	14.42	14.41	14.37	14.35	14.30	14.37
	n	269	269	269	267	266	266	268	267	269	267	268	264	265	255
BMI	Mean	22.25	22.14	22.03	21.92	21.87	21.78	21.75	21.71	21.65	21.60	21.56	21.55	21.48	21.51
	SD	4.18	4.14	4.12	4.10	4.07	4.05	4.01	3.99	3.97	3.97	3.96	3.95	3.94	3.97
	n	269	269	269	267	266	266	268	267	269	267	268	264	265	255
Systolic BP (mm/Hg)	Mean	115.38	114.88	113.77	114.00	114.24	113.85	113.01	112.51	112.03	113.04	111.30	111.58	110.73	110.08
	SD	14.90	15.98	15.20	17.08	15.94	15.42	15.19	15.41	15.80	15.53	15.39	15.08	15.21	15.25
	n	214	214	213	212	213	213	211	211	211	212	213	213	210	205
Diastolic BP (mm/Hg)	Mean	75.22	74.91	74.84	74.64	74.85	74.30	73.62	73.70	73.13	73.70	72.97	73.08	72.82	72.47
	SD	10.00	10.27	10.47	11.49	10.45	9.94	9.13	9.74	9.15	10.01	9.83	9.83	9.55	9.46
	n	215	213	214	214	214	214	212	212	212	213	214	213	210	205
Fatigue	Mean	3.22	3.28	3.11	3.11	3.00	2.94	2.81	2.67	2.58	2.59	2.51	2.43	2.51	2.46
	SD	2.76	2.84	2.84	2.87	2.73	2.71	2.64	2.58	2.67	2.58	2.54	2.42	2.60	2.61
	n	274	274	274	274	274	274	274	274	274	273	273	272	270	261
Poor sleep	Mean	2.60	2.59	2.44	2.51	2.49	2.39	2.22	2.08	2.15	2.08	2.01	2.04	1.94	2.07
	SD	2.80	2.81	2.77	2.66	2.71	2.52	2.58	2.35	2.55	2.54	2.44	2.44	2.40	2.54
	n	274	274	274	274	274	274	274	274	274	273	273	272	270	261

Legend: Note the decreasing trend in the metabolic parameters over the 14 days. Also, note that the SDs for glucose and ketones tended to decrease during the 14 days.

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Table 3. Means and statistical comparisons between Day 1 and Day 14 for glucose, ketones, weight, BMI, systolic and diastolic blood pressure

				Day 1						Day 14	
Measure	n	Grand mean	0–25th percentile mean	25–75th percentile mean	75–100th percentile mean		n	Grand mean	0–25th percentile mean	25–75th percentile mean	75–100th percentile mean
Glucose (mmol/l)	274	4.65	3.63	4.54	5.89		260	4.37	4.06	4.34	4.76
Ketones (mmol/l)	266	1.89	0.33	1.59	4.02		251	2.87	2.70	2.73	3.32
Weight (kg)	269	66.45	50.45	64.18	86.68		255	64.23	48.89	61.77	83.19
BMI	269	22.25	18.02	21.49	27.99		255	21.51	17.55	20.66	26.82
Systolic	214	115.38	97.98	114.71	134.47		205	110.08	98.92	107.88	126.06
Diastolic	215	75.22	63.02	75.47	88.67		205	72.47	65.94	72.13	80.69
			Change (Day 14 - Day 1)							P-value	
		Grand mean	0–25th percentile mean	25–75th percentile mean	75–100th percentile mean			Grand mean	0–25th percentile mean	25–75th percentile mean	75–100th percentile mean
Glucose (mmol/l)		-0.28	0.44	-0.21	-1.12			< 0.0001	< 0.001	< 0.001	< 0.0001
Ketones (mmol/l)		0.99	2.37	1.14	-0.70			< 0.0001	< 0.0001	< 0.0001	< 0.001
Weight (kg)		-2.22	-1.56	-2.41	-3.49			< 0.0001	< 0.0001	< 0.0001	< 0.0001
BMI		-0.74	-0.47	-0.84	-1.17			< 0.0001	< 0.0001	< 0.0001	< 0.0001
Systolic		-5.30	0.94	-6.84	-8.41			< 0.0001	0.58	< 0.0001	< 0.0001
Diastolic		-2.75	2.92	-3.34	-7.99			< 0.0001	< 0.01	< 0.0001	< 0.0001

Legend: n: number of patients for whom the variable was available. P-values correspond to the paired t-test to assess Day 14 - Day 1 changes.

Table 4. Fatigue (A) and poor sleep (B) scores on Day 1 and Day 14

A

Fatigue					
Day 1	Day 14	n	D14-D1 change	P-value t-test	P-value Wilcoxon test
0	0.79	73	0.79	<0.001	<0.001
1	1.57	7	0.57	0.413	0.572
2	1.94	32	-0.06	0.870	0.255
3	2.62	37	-0.38	0.262	0.187
4	2.96	28	-1.04	0.012	0.018
5	2.70	27	-2.30	<0.001	<0.001
6	3.13	15	-2.87	0.003	0.01
7	4.52	23	-2.48	<0.001	0.01
8	5.50	12	-2.50	0.006	0.009
9	6.50	2	-2.50	0.500	0.004
10	5.60	5	-4.40	0.130	0.004

B

Poor sleep					
Day 1	Day 14	n	D14-D1 change	P-value t-test	P-value Wilcoxon test
0	0.82	104	0.82	0.00	<0.001
1	1.42	12	0.42	0.58	0.824
2	1.14	28	-0.86	0.00	0.003
3	2.15	27	-0.85	0.04	0.027
4	2.74	23	-1.26	0.01	0.018
5	2.79	19	-2.21	0.00	0.001
6	3.71	14	-2.29	0.00	0.009
7	5.23	13	-1.77	0.06	0.081
8	4.86	14	-3.14	0.00	0.004
9	5.00	4	-4.00	0.05	0.004
10	8.00	3	-2.00	0.07	0.004

Legend: number of data points (N); Mean change from Day 1 to Day 14; p-value for the respective paired t-test and the Wilcoxon signed-rank test as a sensitivity analysis. Subsamples 0–10 were determined based on Day 1 scores.

Figure 1. Number of patients below, in, and above the target range during the 14-day follow-up for glucose (A) and ketones (B)

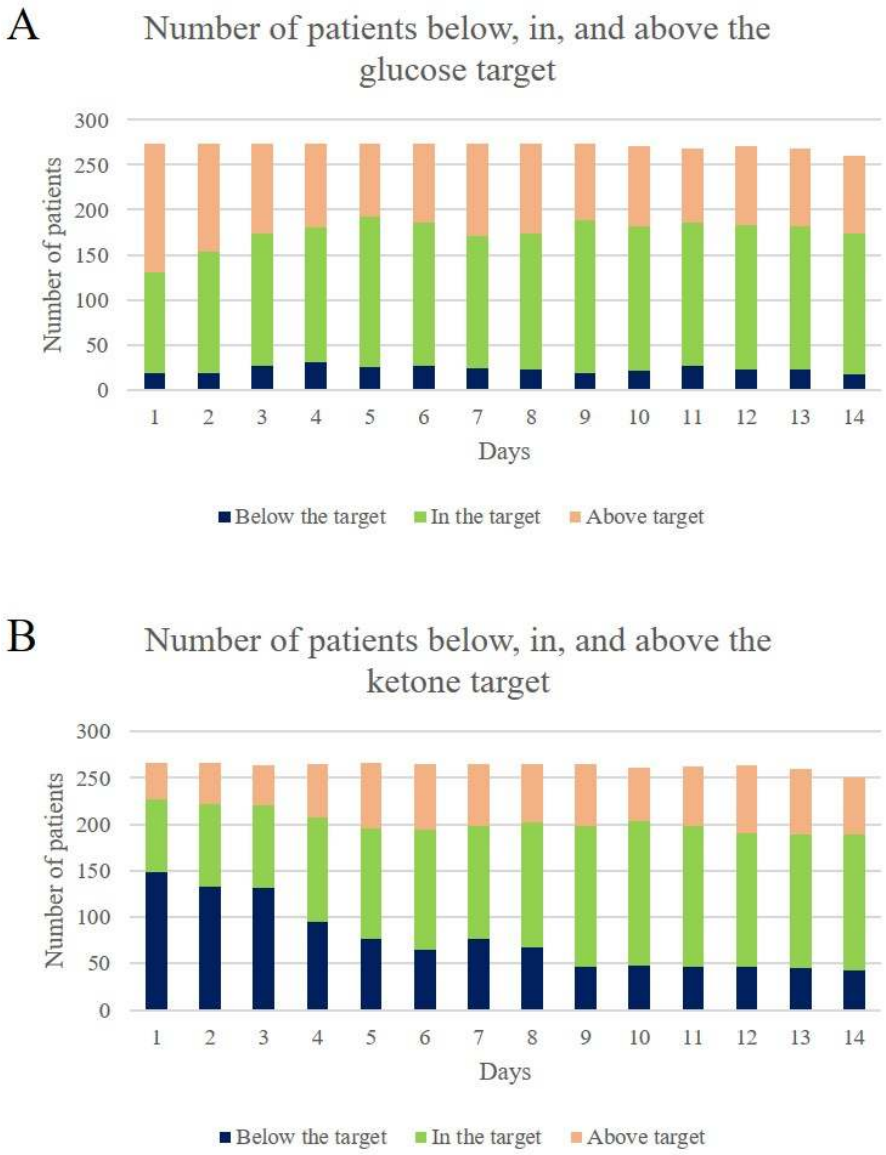
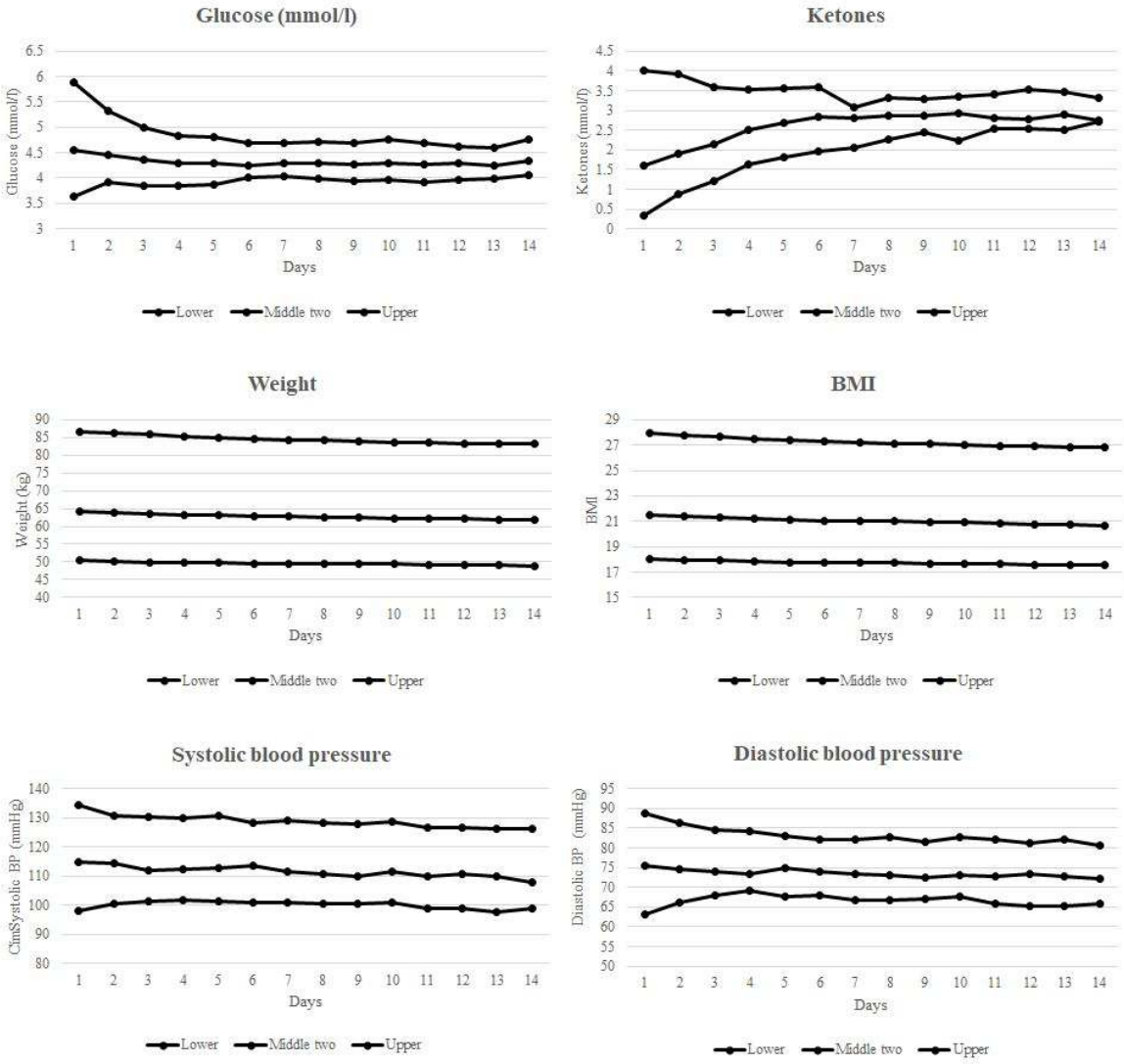
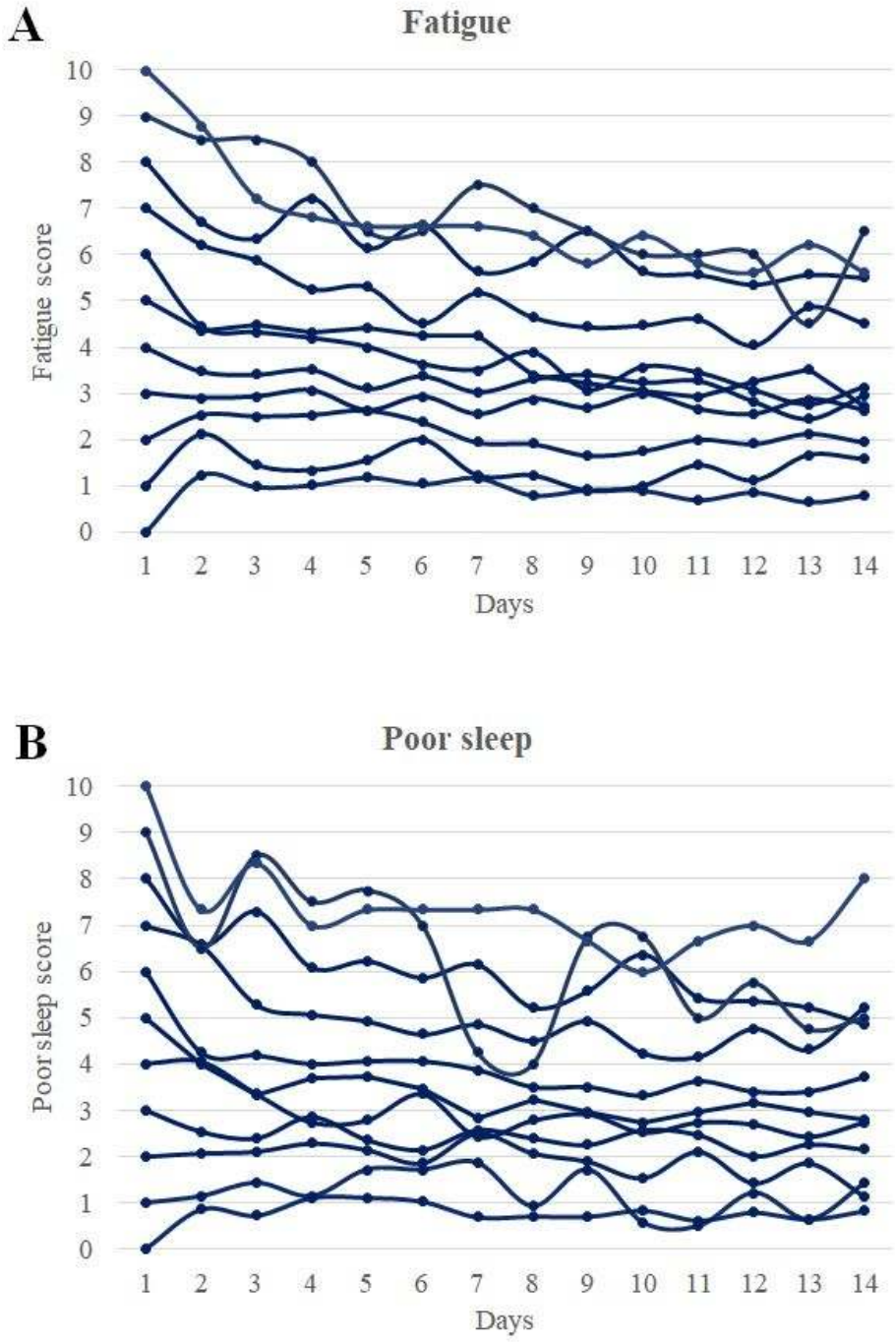


Figure 2. Glucose, ketones, weight, BMI, systolic, and diastolic blood pressure averages over the 14 follow-up days in the upper, middle two, and lower quartiles



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Figure 3. Averages of fatigue (A) and poor sleep score (B) across the 10 subgroups over 14 days



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