

Supplementary

Table S1 Univariate logistic regression to assess social determinants and diet-related factors contributing to the improvement of seizures improvement of seizures in the participants

Independent variables	Reference category	Univariate logistic regression model		
		P value	Crude OR #	95% CI of OR
Mother's age (years)	–	0.484	0.963	0.867–1.070
Father's age (years)	–	0.421	0.959	0.867–1.061
Mother's education level				
Intermediate school	Primary school	1.000	0.000	0.000
High school	Primary school	1.000	1.000	0.041–24.547
Bachelor's degree	Primary school	0.949	0.909	0.050–16.540
Father's education level				
Intermediate school	Primary school	0.858	1.333	0.057–31.121
High school	Primary school	0.846	0.750	0.041–13.677
Bachelor	Primary school	0.283	0.367	0.059–2.292
Income level	–	0.196	1.000	1.000–1.000
Health insurance	No	0.283	0.367	0.059–2.292
Marital status of parents				
Divorced	Married	0.510	2.333	0.188–29.036
Work status of mother	Unemployed	0.855	1.182	0.197–7.082
Father's occupation				
Worker	Unemployed	1.000	1.000	0.034–29.807
Employee	Unemployed	0.999	0.000	0.000
Military	Unemployed	0.355	4.000	0.211–75.659
Professional	Unemployed	0.819	0.750	0.064–8.834
Family history of epilepsy	No	0.886	1.167	0.142–9.586
Diet ratio				
2:1	1:1	0.999	0.000	0.000
3:1	1:1	0.896	0.967	0.580–1.610
4.5:1	1:1	0.706	0.867	0.412–1.821

#, adjusted for the other variables in the table; *, P value is statistically significant at <0.05. CI, confidence interval; OR, odds ratio.

Table S2 Univariate logistic regression analysis to assess parents-related factors contributing to the improvement of seizures in the participants

Independent variables		Seizure outcomes		Univariate logistic regression		
		Not improved	Improved	P value	Crude OR	95% CI of OR
Social status of parents (n=30)	Married	14 (53.8%)	12 (46.2%)		Reference category	
	Divorced	1 (33.3%)	2 (66.7%)	0.510	2.333	0.188–29.036
	Widow	1 (100.0%)	0 (0.0%)	1.000	0.000	0.000
Income level	Mean ± SD	12.7±4.9	16.5±8.5	0.196	1.000	1.000–1.000
	Min - Max	4.9–22.0	7.0–35.0			
Mother's age (years)	Mean ± SD	38.4±7.3	36.6±7.0	0.484	0.963	0.867–1.070
	Min - Max	29.0–54.0	26.0–47.0			
Father's age (years)	Mean ± SD	43.9±7.6	41.6±7.5	0.421	0.959	0.867–1.061
	Min - Max	31.0–56.0	31.0–52.0			
Mother's education level (n=30)	Primary school	1 (50.0%)	1 (50.0%)		Reference category	
	Intermediate school	1 (100.0%)	0 (0.0%)	1.000	0.000	0.000
	High school	3 (50.0%)	3 (50.0%)	1.000	1.000	0.041–24.547
	Bachelor	11 (52.4%)	10 (47.6%)	0.949	0.909	0.050–16.540
Father's education level (n=30)	Primary school	1 (50.0%)	1 (50.0%)		Reference category	
	High school	3 (42.9%)	4 (57.1%)	0.858	1.333	0.057–31.121
	Bachelor	12 (57.1%)	9 (42.9%)	0.846	0.750	0.041–13.677
Health insurance (n=30)	Yes	5 (71.4%)	2 (28.6%)	0.283	0.367	0.059–2.292
	No	11 (47.8%)	12 (52.2%)		Reference category	
Mothers employed (n=30)	No	13 (54.2%)	11 (45.8%)		Reference category	
	Yes	3 (50.0%)	3 (50.0%)	0.855	1.182	0.197–7.082
Fathers employed (n=21)	No	2 (50.0%)	2 (50.0%)		Reference category	
	Worker	1 (50.0%)	1 (50.0%)	1.000	1.000	0.034–29.807
	Employee	3 (100.0%)	0 (0.0%)	0.999	0.000	0.000
	Military	1 (20.0%)	4 (80.0%)	0.355	4.000	0.211–75.659
	Professional	4 (57.1%)	3 (42.9%)	0.819	0.750	0.064–8.834

P value is significant at P<0.05. CI, confidence interval; OR, odds ratio; Max, maximum; Min, minimum; SD, standard deviation.

Appendix 1 Telephone Consent

Study Title: Effect of a Ketogenic Diet on Decrease of Seizures in Refractory Epilepsy among Children (Infancy to 14 Years Old) in Saudi Arabia: A Cross-sectional Study.

Principle Investigator: Dr Leena Baghdadi

Hello, my name is Dr. Renad Alhomaiddi, from King Saud University. We are asking you to volunteer to take part in a phone interview as part of a research study about the ketogenic diet impact on infants and children up to 14 with refractory epilepsy attending a King Fahad Medical City. The interview will take approximately 2 minutes of your time. Your participation in this survey is completely voluntary. This means you do not have to participate if you don't want to. If you agree to participate, you have the right to only answer the questions you choose to answer. This phone interview is being conducted to determine your socioeconomic state. The phone interview will consist of questions pertaining to your socioeconomic state including age, social status, income level, educational level, occupation, living area, health insurance, access to government or private hospital, availability of the ketogenic diet and family history of epilepsy. The potential risks of this research are minimal and confidentiality of private health information that you share with us will be maintained to the highest level. You have the right to stop participation at any point during the interview if you choose so. If you have questions or concerns regarding this research, you can contact the PI Dr Leena Baghdadi at 0501235269 the IRB, the committee that works to protect your rights and welfare at King Saud University”

“Do you have any questions?”

“Do you agree to voluntarily participate in this survey process?”

[]	Yes	If Yes.....	Continue
[]	No	If No.....	Good-bye.

Follow with list of specific questions you will be asking. You can only collect information provided in the script, so be specific and thorough. The last page is your record of your telephone/oral consent. This must be kept, just as a written Informed Consent would be kept.

(Title) Telephone Consent

VERBAL CONSENT DOCUMENTATION FOR PARTICIPATION.

Subject: **The ketogenic diet impact on infants and children up to 14 with refractory epilepsy attending a King Fahad Medical City (KFMC) in Saudi Arabia: A cross sectional study.**

This consent serves as documentation that the required elements of informed consent have been presented orally to the participant or the participant's legally authorized representative.

Verbal consent to participate in this telephone survey has been obtained by the participant's willingness to continue with the telephone survey by providing answers to a series of questions related to **socioeconomic state**.

Surveyor's Name (Printed)

Surveyor's Witness's Name (Printed)

Surveyor's Signature

Surveyor's Witness's Signature

Date

Date

Appendix 2. Ketogenic diet protocol

The ketogenic diet is initiated in the inpatient setting according to the following protocol-based on John Hopkins over 3-4 days as per the following table:

1. Inpatient initiation of KD:
 - ❖ Calculate KD prescription
 - ❖ Calculate KD meals (10 to 30 meals start with)
 - ❖ Incorporate diet modification and restriction into food selections (for calculations)
 - ❖ Determine appropriate ultimate KD ratio for age/condition
 - ❖ Calculate fluid needs
 - ❖ Instruct/demonstrate to caregiver:
 - ♦ food preparation
 - ♦ use of gram scale including calibration
 - ♦ vitamin/mineral supplementation and schedule
 - ♦ fluid management
 - ♦ signs & symptoms of hypoglycemia + treatment
 - ♦ signs & symptoms of excess ketosis + treatment
 - ♦ sick day guidelines
 - ♦ constipation prevention and treatment
 - adjust diet during hospitalization for optimal tolerance
 - advance diet to final goal of full strength
 - coordinate KD formula procurement with home health agencies
 - coordinate KD discharge readiness with neurology and nursing

Ketogenic diet protocol pathways

	Critical pathways Day 1	Day 2	Day 3
Monitor serum	Labs baselines surveillance (if not done previously) <ul style="list-style-type: none"> ❖ CBC, chemistry panel, lipids, electrolytes ❖ Carnitine (total, free, acyl) ❖ AED levels 	Dexi check at bedside; <ul style="list-style-type: none"> ❖ Q2 hours if <1 year ❖ Q4 hours if >1 year If no hypoglycemic events in past 24 hours, may increase ratio to 2:1	Dexi check at bedside; <ul style="list-style-type: none"> ❖ Q2 hours if <1 year ❖ Q4 hours if >1 year If no hypoglycemic events in past 24 hours, may increase ratio to 3:1
	Dexi check at bedside; <ul style="list-style-type: none"> ❖ Q2 hours if <1 year ❖ Q4 hours if >1 year If glucose below 50mg/dl give 15cc apple juice and dexi re-check in 1 hour. If NPO, give 50cc D5W and call physician.	Dexi check in 2 hours. if below 50mg/dl give 15cc apple juice and re-check dexi in 1 hour. If NPO, give 50cc D5W and call physician	Dexi check in 2 hours. if below 50mg/dl give 15cc apple juice and re-check Dexi in 1 hour. If NPO, give 50cc D5W and call physician
Urine	Urine acetone q void Urine specific gravity q void If >1.020 encourage fluid compliance	Urine acetone q void Urine specific gravity q void If >1.030 past 24 hours, consider IVF (no dextrose) bolus	Urine acetone q void urine specific gravity q void If >1.030 past 24 hours, consider IVF (no dextrose) bolus
Weight	Daily weight	Daily weight	Daily weight
Vital	Vital signs q shift	Vital signs q shift	Vital signs q shift