

# Social correlates of health status, quality of life, and mood states in patients treated with cannabidiol for epilepsy



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## ARTICLE INFO

### Article history:

Accepted 12 December 2016

Available online 21 February 2017

### Keywords:

Cannabidiol

Epilepsy

Social determinants of health

Health disparity

Patient-centered outcomes

Quality of life

## ABSTRACT

Social characteristics, such as socioeconomic status and race/ethnicity, play a role in the treatment and outcomes of patients with epilepsy (PWE), but little is known about how these factors affect patients receiving cannabidiol (CBD) to treat seizures. This exploratory study examined the sociodemographic profile of patients treated with CBD ( $n = 80$ ) and associations between social factors and patient-centered outcomes – overall health status, Quality of Life in Epilepsy-89 (QOLIE-89), and Profile of Mood States (POMS) – in this population. Associations were examined using Pearson correlations and multiple ordinary-least-squares regression ( $\alpha = 0.1$ ). The sample was predominantly white (96%) and non-Hispanic/Latino (96%); 76% of patients had family incomes of \$40,000+/year. Some patients/families reported experiencing food scarcity (13%), not being able to make ends meet (6%), or not being able to afford antiepileptic medications (8%). The patients' health ratings declined with age and income ( $p \leq 0.014$ ), and there was a statistically significant interaction ( $p < 0.055$ ) between these variables: for example, a higher-income 10-year-old had a predicted health rating of 3 (“very good”), followed by a higher-income 40-year-old with a rating of 2 (“good”), a low-income 10-year-old with a rating of 1 (“fair”), and a low-income 40-year-old with a rating of 0 (“poor”). This is the first study reporting the social profile of patients taking pharmaceutical grade CBD for the treatment of epilepsy. The results suggest that despite free access to this treatment some patients may not be accessing CBD because of their socioeconomic situation or race/ethnicity. Larger, diverse samples and longitudinal data are needed to more accurately model social factors and patient-centered outcomes in PWE receiving CBD.

**This article is part of a Special Issue entitled “Cannabinoids and Epilepsy”.**

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## 1. Introduction

How individuals fare in sickness and in health depends on their social position. Social characteristics, such as socioeconomic status (SES) and race/ethnicity, play an important role in the treatment and outcomes of patients with epilepsy (PWE) [1], but little is known about how these factors affect patients receiving cannabidiol (CBD) therapy to treat seizures. This exploratory study examined the sociodemographic profile of patients being treated with CBD oil and the association between social factors and patient-centered outcomes – overall health status, Quality of Life in Epilepsy-89 (QOLIE-89) [2], and Profile of Mood States (POMS) [3] – in this population. This paper also provides an introductory conceptual framework for future investigations of social factors and patient-centered outcomes in cannabis-based therapies to treat epilepsy and other disorders.

### 1.1. CBD treatment for epilepsy in Alabama

In 2016, Carly Chandler of Birmingham, Alabama was 5 years old and had CDKL5, a rare neurological disorder that has no cure or treatment [4]. For most of her life, Carly has experienced 200–300 seizures a day lasting up to 20–30 min; she has not been able to talk or walk. In 2014, Dustin Chandler, Carly's father, approached the Alabama state legislature about legalizing CBD oil for treatment of seizures. Despite initial resistance, he went “door-to-door” showing the lawmakers videos of his convulsing child, and ultimately convinced them of the importance of compassionate access to CBD as a treatment for epilepsy. In April of 2014, Alabama passed legislation titled Carly's Law, which authorized the use of CBD oil as part of a clinical study conducted at the University of Alabama at Birmingham.

Carly is now one of the participants in the study, which is testing the safety and tolerability of the oil for patients with treatment-resistant seizures. She currently has only 3–4 seizures per day, often very short in duration, and she has several days at a time without any seizures. Her cognitive ability has reportedly improved, and she has taken her

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first steps. Dustin Chandler hopes that the oil can help treat other people: “[T]his was just the beginning to allow more people to get help. It was never about my daughter (...) if it didn’t help her, if it could help one other child or adult, it made it all worth it” (p. 95) [4]. Although Dustin Chandler called for expanding access to CBD oil, and the UAB study does not charge patients for the drug, it is unclear if access to this treatment is open to individuals of any social standing. As we explain below, there are disparities in epilepsy and epilepsy treatment by SES and other social characteristics, which may prevent some PWE from taking advantage of this treatment.

### 1.2. Social determinants of health

The key social factors that affect health are referred to as social determinants of health (SDH), which are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems (e.g., social norms, economic and health systems) that shape the conditions of daily life [5]. Social determinants of health also interact with biological factors in shaping individual and population-level outcomes and are the main driver of health inequalities [6,7]. Individual-level SDH most often studied include SES, race/ethnicity, age, and gender.

Socioeconomic status refers to a person’s social position and life chances based on educational attainment, income, and occupational status. Socioeconomic status of children and youth is typically assessed by using parental or family SES. The SES–health link is well established: the higher the SES, the higher the health status of an individual or group. Most evidence points to the causal mechanism in which SES affects health, but a reverse process has also been demonstrated – with poor health or illness state leading to lower SES and fewer economic resources. Research shows that socioeconomic deprivation increases the incidence and prevalence of epilepsy, that PWE have lower education, household income, and health status compared with the healthy population, and that finding employment is difficult for PWE [8,9]. Other research has shown associations between poor medication adherence and lower SES and insufficient insurance among PWE [8,9]. Housing, school/employment situation, and nutrition are examples of material factors potentially mediating the relationship between SDH, care, and outcomes in epilepsy [1]. Financial and material assets provide people with stability and allow them to reside in places characterized by higher standards of living and better access to and quality of health care. These conditions, in turn, are conducive to better outcomes [9,10].

Racial and ethnic disparities in health are also prevalent. African American PWE have higher rates of hospitalizations and ER visits, lower rates of surgery, and more deaths after surgery than their white counterparts [8,11–13]. In a recent national study, white and privately insured patients were found to be more likely to have surgery than their respective minority and publicly-insured counterparts [14]. Because whites are more likely than minority patients to have private insurance, access and financial considerations are potential barriers to advanced epilepsy treatments for minority and low-SES PWE.

Age and gender are both demographic and social variables. Epilepsy tends to affect the young and the older groups, and males have higher rates of epilepsy than females. However, membership in a specific age and gender group is also associated with a social position characterized by a certain level of SES and material and other resources, which, in turn, determine health status and quality of life. For example, resources tend to shrink in older ages, and women have on average lower SES and access to resources than men.

### 1.3. Patient-centered outcomes

Outcomes researchers have concluded that patients are often the best source of information regarding their condition [15]. Medical technology allows assessments of physical, physiological or biochemical data of the patient, but these data are limited and cannot provide the complete picture of the patient’s condition or treatment. Some

information can be obtained only directly from the patient [16]. Patient-centered outcomes research (PCOR) has become a gold standard as a strategy to assess success of medical treatments. The goal of PCOR is to emphasize research that examines choices and clinical outcomes that are meaningful to patients. This research takes into account patients’ views, values, and preferences.

Patient-reported outcomes (PROs) are any reports of the status of a patient’s health condition (his/her feelings, function, well-being, symptoms, or life satisfaction) that come directly from the patient, without interpretation of the patient’s response by a clinician or anyone else [17]. Sometimes a self-report is provided by a proxy respondent (e.g., parent reporting for a child) [18]. For example, patients or proxies might be asked to assess their general health, ability to complete various activities, mood, level of fatigue, and pain. Health-related quality of life (HRQOL) assessments are especially valuable. In contrast to a symptom assessment which is unidimensional, HRQOL represents the patient’s general perception of the effect of illness and treatment on various aspects of life such as physical, psychological, and social well-being. While the primary objective of treatment is to have a direct effect on symptoms, HRQOL is often described as an indirect outcome of disease state or treatment. Patient-reported outcomes provide unique information about impact of disease on the patient, help to empower patients/families, allow the determination of efficacy of treatment, and create a rapport between the patient/family and clinician, all of which contribute to useful interpretation of clinical outcomes and treatment decision making [16,19].

### 1.4. Study aims and hypotheses

Because of limited current knowledge, this study aimed to describe the sociodemographic profile of PWE receiving CBD in a clinical research program and to examine the association between social factors and several patient-centered outcomes – overall health status, quality of life, and mood states – in this population. Considering the general health inequalities and disparities in epilepsy, we hypothesized that patients taking CBD for the treatment of epilepsy would be predominantly white, non-Hispanic, and high-SES, and experience few financial strains. We further hypothesized that age would be negatively associated with socioeconomic measures and outcomes (i.e., older ages would be associated with lower socioeconomic resources/higher financial strains and worse health outcomes). We also expected that patient outcomes would be associated with patient/family incomes and levels of financial constraints. That is, higher income levels would be associated with higher overall health status and quality of life and fewer mood problems. Conversely, financial difficulties would be associated with lower overall health status and quality of life and greater mood problems. We also hypothesized potential interactions between age, gender, and socioeconomic measures, with higher ages and female patients having, compared to younger and male patients, lower socioeconomic resources and thus worse outcomes.

## 2. Material and methods

### 2.1. Data

Baseline social and outcomes data were collected from patients with treatment-resistant epilepsy enrolled in the University of Alabama at Birmingham CBD Program between 4/1/2015 and 3/30/2016 using standardized questionnaires. All patients with treatment-resistant epilepsy were referred to the study by their neurologist by submitting information packets containing treatment histories, laboratory testing results, medication lists, a report of video-electroencephalogram (VEEG) confirming the diagnosis of epilepsy, and a seizure calendar documenting at least 4 seizures per month averaged over the preceding 3 months. Complete packets were reviewed by a committee for approval. Neurologists submitting incomplete packets were notified of the missing

information and given the opportunity to resubmit. Exclusion criteria included having Lennox–Gastaut Syndrome (LGS), Dravet Syndrome, not having enough seizures to qualify, or not fulfilling any of the other inclusion criteria. All study procedures were approved by IRB, and the study was FDA-approved and registered with [www.clinicaltrials.gov](http://www.clinicaltrials.gov) under the numbers NCT02695537 (pediatric arm) and NCT02700412 (adult arm).

The first approved patient's initial visit was 4/1/2015. Between 2/18/2015 and 3/30/2016, 59 adult and 90 pediatric patient packets were submitted for consideration. Of the adults who submitted packets, 3 were incomplete and 15 were not approved because they did not meet the study criteria. Of the pediatric packets submitted, 5 were incomplete and 33 were not approved because they did not meet the study inclusion criteria. Parents of 2 pediatric patients declined participation after being approved for participation. A total of 42 pediatric and 39 adult patients were admitted to the study before 3/30/16 and completed the SDH interview (data on one adult patient were not available for analyses). Of the remaining packets submitted prior to 3/31/16, 3 adult and 2 pediatric patients were pending approval.

The SDH interview schedule was administered face-to-face by a trained interviewer (BH or MS) at the patient's initial visit and included items that assessed patient's sociodemographic background, socioeconomic status, overall health status, and other social/psychosocial factors. The interview schedule consisted of 27 structured items (some with open-ended follow-up probes). The items were adapted from measures previously validated in other health surveys/studies. Four versions of the interview schedule were developed and used, each containing items and wording appropriate for self-reporting (1) and caregiver-reporting (2) for adult patients ( $\geq 15$  years of age) and self-reporting (3) and caregiver-reporting (4) for pediatric patients ( $< 15$  years of age). A caregiver report was used if the patient was too young or unable (due to cognitive or seizure status) to report for him/herself. The average interview lasted 20 min.

## 2.2. Measurement

### 2.2.1. Dependent variables

The patient-centered outcomes included self/caregiver-reported overall health status, QOLIE-89, and POMS Total Mood Disturbance (TMD) [2,3,20–22]. The overall health status item was administered to both pediatric and adult patients. The QOLIE-89 and POMS were administered only to adult patients.

Overall health status was assessed with a question asked of the patient/caregiver: "In general, would you say, your (patient's) health is excellent, very good, good, fair, or poor?" This single-item measure of general health status has been shown to be a valid and reliable indicator of individual health in various populations, and it correlates with many objective measures of health such as physician's assessments and mortality [22–24]. Some researchers argue that this measure is superior to objective measures because it takes into account many different dimensions of health such as physical health and functioning, acute and chronic conditions, general feelings such as fatigue or headaches, and psychological, spiritual, and emotional well-being [25,26]. For bivariate and multivariable analyses, to simplify the interpretation of results, we treated the health status variable as continuous and coded it from 0 ("poor") to 4 ("excellent").

The QOLIE-89 is the most widely used and most comprehensive instrument specifically developed for evaluation of HRQOL in patients with seizures [2,20]. Higher scores indicate better HRQOL. The instrument can be completed in about 15 min. One patient had data missing on this variable and was excluded from analyses that included this variable.

The POMS is a 65-item, self-administered questionnaire that measures six theorized mood states: depression/dejection, tension/anxiety, anger/hostility, vigor/activity, fatigue/inertia, and confusion/bewilderment [3,21]. POMS can be completed in about 20 min. Higher

scores point to worse mood problems, except for the vigor/activity scale, in which the relation is reversed. The TMD score was calculated from POMS by summing the scores across all six factors (weighting vigor negatively). The TMD is thought to be a highly reliable and clinically relevant measure of overall mood and mood problems because of the inter-correlations among the six primary POMS factors.

### 2.2.2. Predictor variables

Socioeconomic factors were assessed with family income and financial strains. Family income was assessed with the item: "Can you tell me which category on this card best represents your total combined family income in the last 12 months?" Twenty-one response categories were possible from "<\$5000" to "\$200,000 and more." We dichotomized the variable into "<\$40,000/year" and "\$40,000+/year" (reference category). Two missing values on family income were replaced with a modal category (\$70,000 to \$79,999).

Financial strains in terms of money situation and problems with food availability and paying for epilepsy medications were assessed by using 3 items: 1) "How would you describe the money situation in your household right now?" The response categories were: "comfortable with extra," "enough but no extra," "have to cut back," and "cannot make ends meet." To simplify the interpretation of results, we treated this variable as continuous and coded it 0 ("comfortable with extra") to 3 ("cannot make ends meet"). 2) "In the past 12 months, how often has the following statement been true in your household: *The food we bought ran out and we didn't have money to get more.*" 3) "In the past 12 months, how often have you had problems covering the cost of your epilepsy medications?" The response categories for items 2 and 3 were: "never true," "sometimes true," and "often true." We dichotomized these responses into "never true" (reference category) and "sometimes true." A singular response of "often true" on the food scarcity variable was recoded as "sometimes true." There were no cases for "often true" on the medication scarcity variable. Four cases had missing values on each of the financial strains variables, as the pediatric patients responding for themselves were not asked these questions. Because of the exploratory nature of the study, a simple method of mean replacement was used to preserve the full sample size.

Race was self/caregiver-reported according to the following categories: white, black or African American, American Indian or Alaska Native, Asian, and Native Hawaiian or other Pacific Islander. Biracial participants were included in the minority race category (e.g., white and black/African American was coded as black/African American). The patients in the sample were either white or black/African American. Hispanic/Latino origin was indicated as yes/no. Age was measured in years. Gender/sex was binary (male/female).

## 2.3. Analysis

The analysis was conducted using IBM SPSS Statistics software, Version 22 (IBM Corporation 2013). The analysis included descriptive analyses (percentage distributions for categorical variables and mean/median and standard deviation for continuous variables), Pearson correlations, and ordinary-least-squares regression ( $\alpha = 0.1$ ). Only variables having significant correlations with each other were selected for the regression analysis. The main effects model of each outcome was tested, followed by a model with interaction terms (e.g., age\*family income), if deemed appropriate (i.e., significant main effects present).

## 3. Results

The full sample ( $n = 80$ ; 38 adults, 42 children) was 51% male, 96% white, and 96% non-Hispanic (Table 1). Mean age was 19 years ( $\pm 12.9$ ;  $29 \pm 11.4$  for adults). A total of 23% had income <\$40,000/year, and some experienced financial strains – 18% money, 13% food, and 8% medication related. The health status, QOLIE-89, and POMS means

**Table 1**  
Sociodemographic, socioeconomic, and health profile of patients in the UAB CBD program (n = 80).

	%	Mean	SD	Min	Max
Age (years)		19	12.9	1	62
Sex					
Male	48.8				
Female	51.2				
Race					
White	96.3				
Black or African American	3.8				
Hispanic/Latino origin					
No	96.3				
Yes	3.8				
Family income					
<\$40 K	22.5				
\$40 K+	77.5				
Financial strain: money situation					
Comfortable with extra	42.5				
Enough but no extra	40.0				
Have to cut back	11.3				
Cannot make ends meet	6.3				
Financial strain: food scarcity					
Never	87.5				
Sometimes	11.3				
Often	1.3				
Financial strain: can't afford AEDs					
Never	92.5				
Sometimes	7.5				
Often	0.0				
Pediatric or adult patient					
Pediatric	52.5				
Adult	47.5				
Self/caregiver-reported health status					
Poor	7.5				
Fair	16.3				
Good	30.0				
Very good	27.5				
Excellent	18.8				
QOLIE-89 total score <sup>a</sup>		50.0	16.9	6	77
POMS total mood disturbance (TMD) <sup>b</sup>		49.4	35.2	9	156

<sup>a</sup> n = 37.

<sup>b</sup> n = 38.

were 2.3 (± 1.2), 50.0 (± 16.9), and 49.4 (± 35.2), respectively. Bivariate associations (Table 2) showed health ratings decreasing with age (p = 0.008) and income <\$40,000/year (p = 0.039); QOLIE-89

decreasing with money strain (p = 0.097); and, income <\$40,000 being associated with money (p < 0.001), food (p = 0.026), and medication (p = 0.001) related strains. The POMS TMD had a negative correlation with QOLIE-89 (p = 0.097).

Based on the results of the bivariate analyses, we explored several regression models predicting health status and QOLIE-89. In the sample limited to adults, no significant results were found in regression models predicting QOLIE-89. The final regression model predicting health status showed main effects of age (p = 0.003) and income <\$40,000/year (p = 0.014) and their interaction (p = 0.055; R-square = 0.159; Table 3). Using these results, predicted values of health status based on specific ages and income levels can be computed. For example, a higher-income 10-year-old had a predicted health rating of 3 (“very good”), followed by a higher-income 40-year-old with a rating of 2 (“good”), a low-income 10-year-old with a rating of 1 (“fair”), and a low-income 40-year-old with a rating of 0 (“poor”; Fig. 1).

These results support our hypotheses regarding the socioeconomic and racial/ethnic distribution of the sample. Evidence for the other hypotheses was mixed. We found negative associations between age, family income, and health status. However, we did not find significant associations between the social variables and quality of life or mood states, or associations among gender, family income, and outcome variables.

**4. Discussion**

This study is the first to describe the social characteristics and patient-centered outcomes in patients with epilepsy at the time of enrollment in a pharmaceutical grade CBD treatment program. We found this cohort to be predominantly white, non-Hispanic, with a large proportion of the patients reporting economic security and few financial strains related to money situation or food or medication scarcity. This finding suggests that racial and ethnic minorities and patients with lower incomes or limited other resources (e.g., insurance) are underrepresented in this study. In a 2004 review of epilepsy clinical trials reported in high-impact journals, it was noted that only 6.6% of the 318 reviewed studies reported the race or ethnicity of study participants and 71% of those few did not analyze possible differences between racial groups [27]. Considering federal mandates regarding the inclusion of minorities in clinical research and studies documenting higher rates of epilepsy among blacks and lower levels of SES among PWE [1,11,12,28], more members of minority groups should be found in a clinical CBD program. Special efforts should be made in the future

**Table 2**  
Bivariate correlations among the social and outcome variables<sup>a</sup>.

		Health status	QOLIE-89 total score	POMS TMD	Age	Male	Income <\$40 K	Financial strain: money	Financial strain: food	Financial strain: meds
Health status	Pearson correlation	1.000	<b>0.293</b>	−0.072	− <b>0.295</b>	−0.018	− <b>0.232</b>	−0.184	−0.109	−0.122
	Sig. (2-tailed)		<b>0.078</b>	0.666	<b>0.008</b>	0.875	<b>0.039</b>	0.103	0.337	0.279
QOLIE-89 total score	Pearson correlation		1.000	− <b>0.277</b>	<b>0.305</b>	0.212	−0.010	− <b>0.277</b>	−0.198	0.129
	Sig. (2-tailed)			<b>0.097</b>	<b>0.066</b>	0.207	0.955	<b>0.097</b>	0.239	0.445
POMS TMD	Pearson correlation			1.000	0.098	0.096	0.016	−0.147	−0.242	0.055
	Sig. (2-tailed)				0.559	0.566	0.923	0.377	0.144	0.743
Age	Pearson correlation				1.000	0.010	<b>0.209</b>	−0.075	0.011	0.077
	Sig. (2-tailed)					0.927	<b>0.063</b>	0.507	0.920	0.498
Male	Pearson correlation					1.000	−0.013	0.049	0.142	−0.007
	Sig. (2-tailed)						0.906	0.668	0.210	0.950
Income <\$40 K	Pearson Correlation						1.000	<b>0.462</b>	<b>0.249</b>	<b>0.301</b>
	Sig. (2-tailed)							<b>&lt;0.001</b>	<b>0.026</b>	<b>0.007</b>
Financial strain: money	Pearson correlation							1.000	<b>0.561</b>	<b>0.335</b>
	Sig. (2-tailed)								<b>&lt;0.001</b>	<b>0.002</b>
Financial strain: food	Pearson correlation								1.000	<b>0.323</b>
	Sig. (2-tailed)									<b>0.003</b>
Financial strain: meds	Pearson correlation									1.000
	Sig. (2-tailed)									

Note. Significant (p < 0.1) correlations and p-values are noted in bold.

<sup>a</sup> n = 80 except for correlations that included QOLIE-89 total score (n = 37) and POMS Total Mood Disturbance (TMD; n = 38).

**Table 3**  
Multiple regression results: age and family income as predictors of health status.

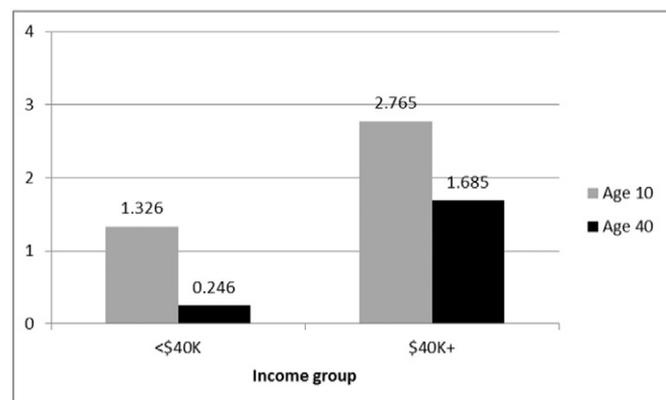
	Model 1			Model 2			
	b	SE	p-value	b	SE	p-value	p-Value
(Constant)	2.904	0.228	0.000	3.125	0.251	0.000	
Age	−0.024	0.010	0.021	−0.036	0.012	0.003	
Income <\$40 K	−0.499	0.307	0.108	−1.439	0.569	0.014	
Age * Income < \$40 K				0.042	0.022	0.055	
R-square	0.117			0.159			
Adj. R-square	0.094			0.126			
R-square change				0.042			
Sig. F change							0.055

Note. Model 1 is the main effects model. Model 2 includes the age \* income interaction. Model 2 coefficients and model fit statistics are significant at  $p < 0.1$ .

to reach out to disadvantaged patients with treatment-resistant epilepsy, so that they also have better access to CBD and other novel therapies.

At the same time, the observed disparities within the study sample should not be overlooked. A fifth of patients reporting lower levels of income, and some patients reporting financial strains, especially in terms of medication access, are not insignificant. Greater levels of support within the community and the health care system could improve outcomes among PWE, which are likely dependent on socioeconomic status and material resources. The epilepsy community has been calling for interventions to reduce disparities and to improve quality of life in epilepsy [28]. For example, according to the CDC's Behavioral Risk Factor Surveillance System (BRFSS), which gathers epilepsy prevalence data across 19 states, almost 24% of PWE reported they could not afford to visit a doctor in the previous 12 months with 17% having no insurance coverage. Nearly 41% of patients' annual incomes were <\$25,000. Of the 2207 PWE monitored, 12% were 65 years of age or older. The authors of the report indicated a need for additional analytical studies of epilepsy occurrence in more diverse communities and called for increased community-based strategies to link PWE to health-care providers as well as social, mental health, and employment services in order to improve quality of life. Transportation services, in particular, were identified as a significant need. Other interventions that focus on increasing awareness of epilepsy through the implementation of educational programs for schools, employers, health-care providers, and the public in general might reduce the stigma associated with epilepsy and cannabis-based treatments and also improve quality of life for PWE [29,30].

This study had several limitations. First, the sample was relatively small, especially for the analyses of quality-of-life and mood outcomes in the adult patients. It is likely that some associations were found non-significant due to the modest sample size. Second, the measures of socioeconomic status and resources were also limited. Third, the study was cross-sectional and, hence, constrained in its ability to determine causal associations between social factors and patient outcomes.



**Fig. 1.** Health rating (0–4) by age and income group ( $p = 0.055$ ).

Despite these limitations, this study provides an initial insight into the sociodemographic and socioeconomic profile of PWE on CBD as well as associations between social statuses and patient-centered outcomes in this population. The paper also lays out some directions for future research.

## 5. Conclusions

Higher age and low income are associated with lower health ratings among patients receiving CBD to treat epilepsy. Older patients tend to be poorer and have lower perceived health than younger patients, suggesting potentially detrimental effects of epilepsy on patient/family socioeconomic circumstances and patient's perceived health over time. This finding is consistent with prior literature showing financial and treatment access struggles among adult patients with epilepsy, but more research regarding access and utilization of CBD therapies is needed. In particular, we call for systematic inclusion of social and patient-centered outcome variables in studies of patients on CBD. Larger and diverse samples and longitudinal data are needed to establish long-term effects of social statuses on outcomes in this patient population. The current paper provides a framework for similar future investigations.

## Conflicts of interest

EMB and JPS are PIs of the UAB CBD Program and receive salary support; BH receives salary support. CBD (Epidiolex®) is provided by GW Pharmaceuticals, Inc. free of charge to the patients. MS reports no conflicts of interest.

## Acknowledgements

The study was funded, in part, by the State of Alabama in support of implementation and research of medical use of CBD (Carly's Law). We thank M. Brooke Thompson for assistance with study management and data collection.

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