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Can behavioral strategies increase physical activity and influence depressive symptoms and quality of life among children with epilepsy? Results of a randomized controlled trial

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ABSTRACT

Purpose: This study examined whether increasing physical activity (PA) through 6 months of behavioral counseling positively influenced depressive symptoms and quality of life (QoL) over 12 months among children with epilepsy (CWE).
Methods: A longitudinal multisite randomized controlled trial (RCT) was conducted with 8–14-year-old children with active epilepsy. Participants wore a pedometer to track daily PA and completed 3 measures at 4 time points to examine depressive symptoms and QoL. Stratified by site and activity level, participants were randomized to an intervention or control group. The 6-month intervention included 11 behavioral counseling sessions targeting self-regulation of PA. To assess the associations among PA, depression scores, and QoL, primary analysis involved mixed-effects models.
Results: We recruited 122 CWE, of whom 115 were randomized ($M_{age} = 11 \pm 2$; 50% female) and included in the analysis. The intervention did not increase PA in the treatment compared with the control group. No differences were found between groups over time during the subsequent 6 months, where PA decreased among all participants. Results did not show differences between the groups and over time for measures of depressive symptoms and QoL.
Significance: The intervention did not improve or sustain PA levels over 12 months. Both groups demonstrated declines in PA over one year, but there were no changes in depression scores or QoL. As most participants were already nearly reaching the Canadian average of step counts of children their age, with a baseline daily step count of over 9000, there may be a challenge for further increasing PA over a longer period.

1. Introduction

Physical activity (PA) is recognized to be beneficial for multiple health outcomes and quality of life (QoL) in individuals with epilepsy [1–3]. Logically, PA should also be beneficial for children with epilepsy (CWE); however, this population tends to hesitate participating in PA because of a host of factors including fear of injury, parental overprotection, and lack of knowledge regarding the benefits and risks associated with PA [4–6]. For this reason, CWE tend to achieve less than the recommended national guidelines of 60 min of moderate-to-vigorous PA per day [7–9], which may contribute to various, often long-term, comorbidities and poor functioning [1,10,11].

To date, there is no level I or II evidence on the impact of self-management programs in CWE [12,13], and no study has met the full Consolidated Standards of Reporting Trials (CONSORT) guidelines for nonpharmacological randomized controlled trials (RCTs) in this population [14]. Research is recommended to improve our understanding of the possible associations among self-management interventions, PA, depressive symptoms, and QoL for CWE and to support the design of

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interventions to promote positive health outcomes through self-managed PA participation [15]. Self-management is defined as "the individual's ability to manage the symptoms, treatment, physical and psychological consequences, and lifestyle changes inherent in living with a chronic condition. Self-management includes… [among others] engaging in activities that promote health and build physiological reserve, such as exercise, proper nutrition, social activation, and sleep" [16,p. 129–130].

We hypothesized that a self-management behavior intervention would increase PA and improve depressive symptoms and QoL outcomes among CWE. We used pedometers for this study, as they have acceptable validity and reliability for measuring step counts among children and youth [17] and are appropriate for obtaining an accurate depiction of PA in CWE [18]. In fact, youth and young adults with epilepsy have identified walking as their preferred mode of PA [19].

The current body of literature examining the relationships among PA, depressive symptoms, and QoL could be significantly improved by measuring PA directly among CWE, using pedometers. Pedometer-based interventions have been found to help maintain long-term PA adherence [20]. Meta-analyses have concluded that typically developing children who monitor daily step counts using a pedometer accrue more PA than children unable to do so [21,22]. Furthermore, research has shown that typically developing children who are offered performance-contingent rewards and receive PA counseling in addition to using a pedometer walk more steps on a daily basis than children monitoring step counts alone [23]. There is also a positive association between motivation and pedometer-based PA levels among typically-developing children [24]. These findings indicate that behavioral counseling that targets motivational and self-regulatory factors in combination with activity monitoring may be essential ingredients of interventions to promote adoption and maintenance of PA. Walking is generally a safe form of PA that may help to facilitate adherence to the intervention [25], particularly for children and parents who may have reservations about perceived higher-risk forms of PA. Engagement in low levels of PA may potentially limit opportunities to develop motivation and self-regulatory skills for PA. For these reasons, implementing behavioral counseling interventions among a population that stands to gain a wide range of benefits from regular PA participation appears to be a promising avenue.

This paper reports the results of an RCT designed to examine and quantify the associations among PA, depressive symptoms, and QoL in CWE. The primary purpose of this study was to examine whether a 6-month behavioral counseling program could increase PA levels and whether increasing PA would positively influence depressive symptom scores and QoL over one year. This study also aimed to determine whether PA levels established during the 6-month program would be sustained over a subsequent 6-month period.

2. Methods

2.1. Design

This trial conformed to the CONSORT 2017 guidelines for reporting nonpharmacological RCTs (see Supplementary Table 1 for checklist) [14]. Participants were randomly assigned to either the intervention group or a control group, and their PA levels were monitored daily over a 12-month period. To improve adherence for wearing the pedometer, participants from the McMaster site received a 25-cent (Canadian Dollar) incentive for each day of recorded steps. During this same 12-month period, all participants were asked to complete quarterly study reports to account for variations in seasonality, school time, and other factors possibly influencing outcomes.

2.2. Participants and research eligibility

Recruitment occurred between January 2012 and March 2017, primarily from two pediatric neurology clinics in Ontario with additional assistance from various local epilepsy organizations and independent neurologists. Eligibility criteria included the following: (i) aged 8–14 years; (ii) a diagnosis of epilepsy as confirmed by a neurologist, with at least one seizure in the previous 12 months; (iii) ambulatory; (iv) fluency in English or French; (v) intellectual functioning at grade ≥ 3 level as judged by parents; and (vi) access to a computer. Participants with additional diagnoses of psychogenic seizures or autism were not included. The study protocol was registered on ClinicalTrials.gov (NCT01550874).

2.3. Ethics, recruitment, and procedures

The study was approved by the Hamilton Integrated Research Ethics Board and the Children's Hospital of Eastern Ontario Research Ethics Board and included permission to recruit participants from outside organizations.

At both study sites, potentially eligible CWE were identified by the research nurse or neurologist. They were then approached during their clinic appointment by someone within their circle of care. If consent was given to be contacted by the research team, they met with a research assistant or the research coordinator to ascertain interest, to be given an information package containing a study timeline and consent form, and to obtain verbal consent to the release of personal health information to the study team. Those who agreed to the release of their personal health information met or spoke over the phone with the research coordinator to discuss the study in detail and to confirm eligibility, and then arranged their first study appointment.

During the first study appointment at the clinic, informed consent and assent were obtained, and participants were given a Fitbit® Wireless Activity Tracker (see Study measures) along with instructions on how to use the device and set up the software at home. Next, the research staff collected anthropometric data (i.e., height, weight, waist and hip circumference), and the participant's parent(s) or caregiver completed a demographic questionnaire and epilepsy report. Participants also completed a battery of patient-reported outcome measures assessing QoL, health-related QoL, and depressive symptoms (see Primary outcomes). These measures were repeated at 16, 28, and 52 weeks. Following the first study appointment, participants had their number of daily steps monitored for a 2-week baseline period.

2.4. Intervention

The control group received instruction to continue wearing the pedometer with weekly charging and syncing of data but received no information from the study team through the device and did not have access to the Fitbit step tracking website interface. Aside from reminders to sync, charge, or replace the Fitbit and schedule study visits, the control group was not contacted or provided any type of support throughout the entirety of the study. The intervention group participated in PA behavior-change counseling conducted by a trained research assistant (McMaster site) or the study research coordinator (Ottawa site). Content of the counseling activities was drawn from theory and past research (see Table 1) [26]. Counseling sessions were 15 min long and occurred weekly for weeks 1–4, bi-weekly for weeks 6–12, and monthly (booster sessions) for weeks 16–24. Sessions were scheduled at a convenient time for the participant to ensure each session was completed. The aims of these sessions were to develop motivation as well as to learn and implement self-regulatory skills to support behavior change. All participants were given the goal to reach a level of PA consistent with the number of steps associated with meeting Canadian PA guideline recommendations by the end of the 6-month period [27]. To reach this goal, participants were asked on a weekly basis to increase their average step count of the previous week by 10%, but only if the previous week's target was met. If the target was not met, the goal from the previous week was prescribed again. For these participants, the research assistant or research coordinator spent extra time brainstorming ways the participant could modify their behavior

Table 1
Coaching call schedule, call descriptions, and behavior change techniques.

Schedule	Description	Behavior change techniques
1st week	Develop rapport; discuss benefits of PA; assess PA history, available activity equipment and motivation for change; identify ways to take more steps	Information/knowledge sharing, consciousness-raising, self-monitoring
2nd week	Discuss PA guidelines and potential benefits of PA most important to participant; introduce self-monitoring using Fitbit® and weekly step count goals; discuss FITT (i.e., frequency, intensity, type and time) principles of exercise goal setting and basic goal-setting	Information/knowledge sharing; decide target standard of behavior; self-monitoring; goal-setting; social support (emotional)
3rd week	Review self-monitoring; assess performance towards basic goal; discuss facilitators and barriers to meeting goals; detailed goal setting based on FITT principles; introduce action planning; set weekly step goal (increase steps by 10% from previous week)	Self-monitoring; goal review; performance feedback; goal setting; facilitator and barrier identification; action planning; social support (emotional)
4th week	Assess performance towards detailed goal and weekly step goal; review action planning; identify barriers and brainstorm solutions to overcome barriers to PA goals; set weekly step goal	Goal review; performance feedback; action planning; barrier identification; coping planning; social support (emotional)
6th week	Discuss current PA levels, learn how to use Fitbit® website to track PA, assess performance feedback towards goals, self-monitoring; set weekly step goal	Consciousness-raising; information/knowledge sharing; self-monitoring, goal review; performance feedback; social support (emotional)
8th week	Review PA tracking on Fitbit® website; assess performance towards goals, review action planning, discuss barriers and solutions to overcome barriers to PA, discuss what has helped them achieve success/steps, establish walking routes and buddy systems; set weekly step goal	Self-monitoring; information/knowledge sharing; social support, monitoring; goal review; performance feedback; facilitator and barrier identification; action planning; coping planning; social support (instrumental); social support (emotional)
10th week	Assess performance towards goals; direct control of planning and thinking to participant by presenting their progress and which techniques have positively contributed to their success; set weekly step goal	Goal review; performance feedback; self-monitoring; social support (emotional)
12th week	Assess performance towards goals; direct control of planning and thinking to participant by presenting their progress and which techniques have positively contributed to their success; set weekly step goal	Goal review; performance feedback; self-monitoring; social support (emotional)
16th week	Booster session: assess performance towards goals; direct control of planning and thinking to participant by presenting their progress and which techniques have positively contributed to their success; set weekly step goal	Goal review; performance feedback; self-monitoring; social support (emotional)
20th week	Booster session: assess performance towards goals; direct control of planning and thinking to participant by presenting their progress and which techniques have positively contributed to their success; set weekly step goal	Goal review; performance feedback; self-monitoring; social support (emotional)
24th week	Booster session: assess performance towards goals; direct control of planning and thinking to participant by presenting their progress and which techniques have positively contributed to their success; set weekly step goal	Goal review; performance feedback; self-monitoring; social support (emotional)

to reach their weekly goal. All participants in the intervention group completed the counseling sessions and the 6-month self-monitoring phase of the study. Reminders to sync data and charge the pedometer were given if required.

2.5. Study measures

Measures were identified based on concepts and definitions of functioning, disability, health, and QoL [28,29]. All measures were completed at each study visit except for the baseline demographic information completed by the parent/caregiver. Study visits took roughly 2 h.

2.5.1. Demographic questionnaire and epilepsy report

At the first visit, the participant's parent(s) or caregiver completed a demographic information questionnaire. Research staff interviewed the participant and parent(s)/caregiver for information pertaining to seizure history, antiepileptic medications, and health care utilization. A healthcare professional confirmed diagnosis of epilepsy through chart review.

2.5.2. Anthropometric measures

Anthropometric data (height and weight) were obtained using a calibrated weight scale and stadiometer to calculate body mass index (BMI) (mass(kg) / height(m)^2). Waist (i.e., superior border of iliac crest) and hip circumference (i.e., widest portion of the buttocks) were estimated as a mean of three measures taken with a nonplastic tape measure and recorded to the nearest 0.1 cm.

2.6. Primary outcomes

2.6.1. Physical activity

Physical activity was monitored daily using the Fitbit® Ultra Wireless Activity Tracker, later replaced by the Fitbit® One Wireless Activity Tracker, an upgraded model. This advanced three-dimensional pedometer provides valid and reliable measurements of steps [30]. At the McMaster site, some participants repeatedly lost their pedometers over a short period of time and were offered the Fitbit® Flex Wireless Activity Tracker. This tracker is worn around the wrist rather than clipped to a waistband or pocket. For analysis purposes, weekly averages for PA were calculated. A week of PA was included in the analysis if participants achieved 3 or more days of ≥500 steps. Because of the large fluctuations in week-to-week PA data, a 3-week moving average was applied to smooth the data as recommended by Streiner [31].

2.6.2. Quality of life

Quality of life was measured at each assessment using the 25-item Childhood Epilepsy Quality of Life scale (CHEQOL) [32]. The CHEQOL has established validity and reliability [32]. It consists of five specific QoL subscales including interpersonal/social, intrapersonal/emotional, keeping epilepsy a secret, quest for normality, and worries and concerns, with each subscale having 5 questions. Each item in this Harter-formatted scale contained one positive and one negative description of a specific aspect of QoL, for which participants selected the statement that better describes them and whether that statement is "really true for me" or "sort of true for me." Responses were coded so that higher scores reflected greater QoL. Internal consistencies were acceptable for each scale at each administration (Cronbach's $\alpha = 0.65–0.83$).

2.6.3. Health-related quality of life

Health-related QoL was measured at each assessment using the KIDSCREEN-27 [33], which has strong psychometric properties [34]. The KIDSCREEN-27 has 5 subscales including physical well-being (5 items), psychological well-being (7 items), autonomy and parents (7 items), peers and social support (4 items), and school environment (4 items). Participants respond to 27 questions on a 5-point Likert-type scale ranging from 1 "never or not at all" to 5 "always or extremely".

Negatively oriented items are reverse scored before computing subscale scores so that higher values reflect greater QoL. Internal consistencies were acceptable for each scale at each administration (Cronbach's $\alpha = 0.78–0.90$).

2.6.4. Depressive symptoms

The Children's Depression Inventory — Short (CDI-S) was used to measure depressed mood in children at each assessment [35]. The CDI has strong psychometric properties [36]. Participants respond to 10 items on a 3-point scale ranging from 0 "not true" to 2 "very true" with higher scores indicating greater depressive symptoms. Internal consistency was acceptable at each administration (Cronbach's $\alpha = 0.77–1.00$).

2.7. Sample size

To determine sample size, a mean between-group difference of 5 points was targeted for the measures of health and QoL. Fixing the probability of type-I error at 5%, a sample size of 64 patients per group provided a power of 80% to detect such a difference. This difference represents an effect size of Cohen's $d = 0.5$, which is considered a medium effect size as per Cohen [37].

2.8. Randomization and blinding

After the 2-week baseline period, participants were randomly assigned to the control or intervention group. Participants were stratified, first by site to account for any site differences in patient population, and then into two activity level groups: those currently achieving ≥5000 steps/day (Group 1: 'relatively active') and those achieving <5000 steps/day (Group 2: 'sedentary'). This cut-point was determined by an earlier pilot study [18] and is in keeping with literature of step counts of children with chronic health conditions [38,39]. Separate balanced block randomization schemes were established for each activity group, and an allocation ratio of 1:1 was used to maximize the likelihood that each treatment arm (i.e., intervention vs. control)

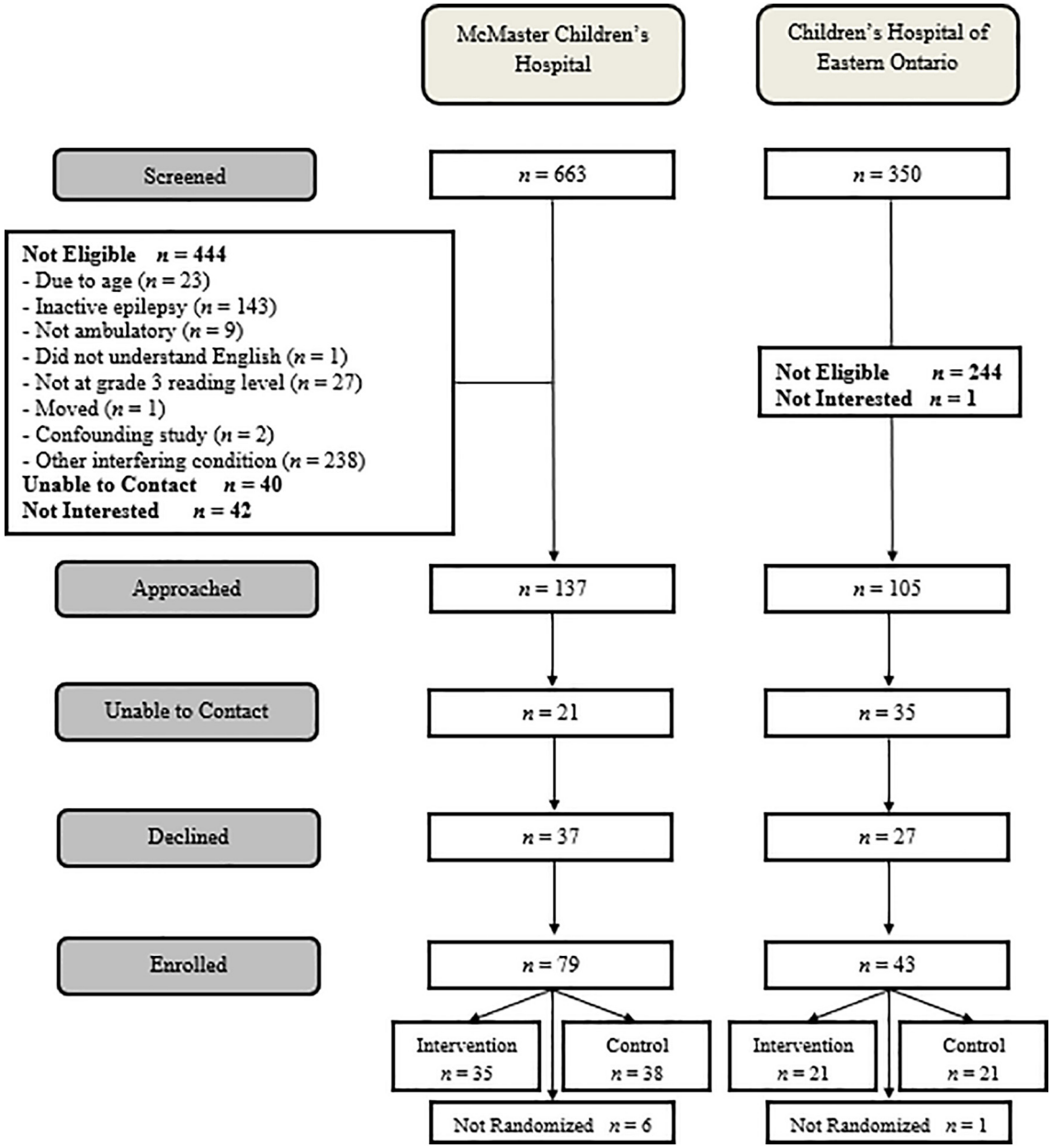

Fig. 1. Participating sites with recruitment data flow chart.

Table 2
Demographic data (continuous) at recruitment (N = 122) and upon randomization (N = 115).

Variable	Total sample M (SD)	Missing (%)	INT M (SD) ($n = 56$)	Missing	CTRL M (SD) ($n = 59$)	Missing	p
Age (years)	11.37 (1.91)	1 (0.8)	11.54 (1.93)	1	11.20 (1.86)	0	0.62
Epilepsy age of onset (years)	7.20 (3.18)	3 (2.5)	7.74 (3.32)	1	7.04 (3.00)	1	0.42
Duration of epilepsy (years)	4.22 (3.24)	4 (3.3)	3.80 (3.20)	3	4.22 (2.79)	3	0.42
Epilepsy-related emergency room visits, previous year	0.99 (1.49)	3 (2.5)	1.15 (1.92)	2	0.91 (1.03)	1	0.17
Height (m)	1.50 (0.15)	28 (23.0)	1.52 (0.15)	12	1.48 (0.15)	16	0.79
Weight (kg)	47.93 (18.33)	27 (22.1)	48.49 (19.16)	12	46.80 (18.69)	15	0.71
BMI (weight/height^2)	20.73 (5.36)	28 (23.0)	20.38 (5.24)	12	20.65 (5.35)	16	0.78
Waist (cm)	72.17 (14.62)	33 (27.0)	72.79 (15.57)	15	71.17 (14.36)	18	0.75
Hip (cm)	84.15 (13.62)	35 (28.7)	84.84 (14.33)	16	83.38 (13.92)	19	0.90
Waist-to-hip ratio (waist/hip)	0.85 (0.07)	35 (28.7)	0.85 (0.07)	16	0.85 (0.07)	19	0.44
Current grade at school	5.79 (1.91)	2 (1.6)	6.07 (1.87)	1	5.48 (1.89)	1	0.77
Number of siblings	1.58 (1.20)	2 (1.6)	1.51 (0.90)	1	1.52 (1.33)	1	0.17
Pedometer step count, 2-week baseline (daily average)	9035.25 (3144.55)	7 (5.7)	8519.98 (3058.71)	0	9524.32 (3172.38)	0	0.90

Note. INT = Intervention condition; CTRL = Control condition; M = Mean; SD = Standard deviation.

would contain an equivalent number of participants [40]. The research coordinator at the McMaster study site conducted this process for all participants at both sites, and treatment allocation was concealed from the study team.

2.9. Statistical analysis

All data were analyzed on an intention-to-treat basis. To test the adequacy of randomization and the comparability of sites, between-group analyses of baseline characteristics were conducted using independent samples t-tests for continuous variables and χ^2 tests for dichotomous variables. An independent samples t-test was computed to test for differences between groups for PA tracker adherence. To test our primary hypothesis, mixed-effects linear growth curves were used to analyze the 0–6, 7–12, and 0–12-month step data between groups, with participants nested within site and time nested within participant, to account for any baseline differences between sites. This approach used full information maximum likelihood, which allowed participants with missing data to be included in the analysis. Variables known or theorized to affect the outcome (i.e., age, sex, BMI) and baseline step count were included as covariates. All statistical analyses were performed using IBM SPSS version 20.

3. Results

Fig. 1 outlines the recruitment data for the participating sites. In both sites combined, 1013 patients were screened as potential participants, and 242 (23.9%) were eligible and approached by their circle of care and then a study team member during their clinic visit. Of the 242, 56 (23.1%) could not be reached after initial contact, and 64 (26.4%) declined to participate. In total, 122 CWE enrolled in the study, and 115 were randomized (94.3%). Demographic and epilepsy-related data are shown in Tables 2 through 4. Separate t-tests computed on baseline data for each of the continuous variables revealed that the groups were balanced across all measures (all $ps \geq 0.11$). Chi-squared tests showed that the groups did not differ on any dichotomous variable (all $ps \geq 0.15$).

3.1. Primary outcomes

Parameter estimates (i.e., beta-coefficients, standard errors, t-values, p-values, and 95% confidence intervals) for time, group, and the group by time interaction for each of the primary outcome variables are displayed in Table 5.

3.1.1. Physical activity

Separate t-tests for PA tracker adherence (defined as ≥500 steps on ≥3 days in a week) revealed no differences between the groups during the 6-month intervention period (Intervention group: $M = 77.9\% \pm 27.0$; Control group: $M = 69.1\% \pm 30.1$) and the subsequent 6-month follow-up period (Intervention group: $M = 60.8\% \pm 37.1$; Control group: $M = 51.4\% \pm 34.0$) (all $ps > 0.25$). Overall, results of the mixed-effects model for PA across the 12-month study period (see Fig. 2) failed to show a significant main effect of group ($p = 0.67$) or group by time interaction ($p = 0.87$); however, PA levels significantly decreased over time for both groups ($p < 0.001$). Mixed-effects model analysis for PA during the 6-month intervention period revealed no differences between groups, over time, or a group by time interaction (all $ps \geq 0.16$). During the 6-month post-intervention period, a mixed-effects model for PA did not show a significant main effect of group or group by time interaction (all $ps \geq 0.17$); however, PA significantly decreased for both groups over time ($p < 0.001$).

Table 3
Demographic data (categorical) at recruitment.

Characteristic	Total sample ($N = 122$)	%	INT ($n = 56$)	CTRL ($n = 59$)	χ^2
Sex					
Male	58	47.5	27	28	0.93
Female	62	50.8	28	30	
Missing	2	1.6	1	1	
Primary language spoken					
English	108	88.5	52	50	0.30
French	5	4.1	2	4	
Other	7	5.7	1	4	
Missing	2	1.6			
School class placement					
Regular class	95	77.9	41	48	0.29
Regular class with help	25	20.5	14	10	
Special class	0	0			
Missing	2	1.6			
Family structure					
Biological two-parent family	94	77.0	43	45	0.53
One-parent family	7	5.8	4	2	
Separated/divorced	11	9.0	4	7	
Reconstituted two-parent family	6	4.9	4	2	
Extended family	2	1.6	0	2	
Missing	2	1.6			
Household income					
<$20,000	6	4.9	1	0	0.23
$20,000–$29,000	5	4.1	2	2	
$30,000–$39,000	5	4.1	3	2	
$40,000–$49,000	6	4.9	2	2	
$50,000–$59,000	6	4.9	0	6	
$60,000+	92	75.4	44	45	
Missing	2	1.6			

Table 4
Epilepsy and seizure characteristics (categorical) at recruitment.

Characteristic	Total sample ($N = 122$)	%	INT ($n = 56$)	CTRL ($n = 59$)	χ^2
Seizure types per patient					
Single type	70	57.4	29	37	0.37
Two types	43	35.2	23	19	
Three or more types	6	4.9	4	2	
Missing	3	2.5	0	0	
Seizure type distribution, past 12 months[a]					
Simple partial seizures	15	12.3	6	9	0.15
Complex partial seizures	28	23.0	17	11	0.66
Generalized tonic–clonic seizures	52	42.6	21	28	0.66
Absence seizures	48	39.3	23	24	0.44
Myoclonic seizures	6	4.9	4	1	0.17
Atonic seizures	0	0.0	0	0	–
Missing	5	4.1	0	0	
Seizure severity[b]					
Low severity	50	41.0	23	25	0.98
High severity	67	54.9	30	33	
Missing	5	4.1	0	0	
Number of current antiepileptic drugs					
None	12	9.8	5	7	0.72
One	74	60.7	36	33	
Two	27	22.1	10	15	
Three or more	6	4.9	3	3	
Missing	3	2.5	0	0	
Common antiseizure medication					
Carbamazepine/oxcarbazepine	36	29.5	14	19	0.39
Levetiracetam	33	27.0	17	14	0.42
Ethosuximide	19	15.6	8	10	0.70
Valproate	20	16.4	10	7	0.36
Lamotrigine	13	10.7	5	5	0.93
Other[c]	23	18.9	7	11	0.37

[a] Because of dual classification, numbers may add up to more than 100%.
[b] As per Cramer et al. [52]: In the past 12 months, Low = 1–20 simple partial seizures, 1–4 complex partial seizures, 1 generalized tonic–clonic seizure, 1–20 absence or myoclonic seizures; High = >20 simple partial seizures, >4 complex partial seizures, >1 generalized tonic–clonic seizure, >20 absence or myoclonic seizures.
[c] Clobazam ($n = 8$), topiramate ($n = 7$), lacosamide ($n = 2$), clonazepam ($n = 1$), phenobarbital ($n = 1$), phenytoin ($n = 1$), diazepam ($n = 1$), perampanel ($n = 1$), and stiripentol ($n = 1$).

3.1.2. Condition specific quality of life

The numbers of CHEQOL assessments recorded at each visit were 107 at Visit 1, 97 at Visit 2, 92 at Visit 3, and 84 at Visit 4. Results from the separate mixed-effects models indicated no differences between groups, over time, or group by time interaction for child interpersonal and social, child intrapersonal and emotional, child secrecy, child normalcy, child present concerns, and child total (all $ps \geq 0.07$).

3.1.3. Health-related quality of life

The numbers of KIDSCREEN-27 assessments recorded at each visit were 107 at Visit 1, 93 at Visit 2, 94 at Visit 3, and 89 at Visit 4 except for the subscale "School and Learning", which had 101 at Visit 1, 90 at Visit 2, 88 at Visit 3, and 82 at Visit 4. Separate mixed-effects models did not demonstrate significant main effects of group and time as well as a group by time interaction for PA and health, general mood and feelings, family and free time, friends, and school and learning (all $ps \geq 0.15$).

3.1.4. Depressive symptoms

The numbers of CDI-S assessments recorded at each visit were 109 at Visit 1, 97 at Visit 2, 92 at Visit 3, and 83 at Visit 4. Results of the mixed-effects model for depressive symptoms did not show a significant main effect of group, time, or group by time interaction, (all $ps \geq 0.07$).

Table 5
Parameter estimates from mixed effects models for physical activity, depressive symptoms and quality of life.

Measure	β (SE)	*t*-Value, *p*-Value	95% confidence interval
PA 0–6 months			
Group	−69.69 (532.22)	−0.13, 0.90	−1129 to 990
Time	−28.54 (19.06)	−1.50, 0.14	−67 to 9
Group * Time	18.16 (27.12)	0.67, 0.51	−36 to 72
PA 6–12 months			
Group	1560.12 (1111.78)	1.40, 0.17	692 to 3812
Time	−40.24 (26.40)	−2.27, 0.029	−76 to −4
Group * Time	−34.48 (26.40)	−1.31, 0.20	−87.89 to 18.93
PA 0–12 months			
Group	201.01 (467.38)	0.43, 0.67	−729 to 1131
Time	−26.47 (8.56)	−3.09, 0.003	−44 to 9
Group * Time	1.96 (12.19)	0.16, 0.87	−22.0.40 to 26.32
CHEQOL interpersonal			
Group	−0.97 (0.78)	−1.25, 0.21	−2.51 to 0.56
Time	0.31 (0.25)	1.23, 0.22	−0.19 to 0.81
Group * Time	0.31 (0.35)	0.90, 0.37	−0.37 to 1.00
CHEQOL intrapersonal			
Group	−0.62 (0.90)	−0.70, 0.49	−2.38 to 1.14
Time	0.18 (0.27)	0.68, 0.50	−0.35 to 0.72
Group * Time	0.57 (0.37)	1.54, 0.13	−0.16 to 1.30
CHEQOL secrecy			
Group	−0.66 (0.85)	−0.77, 0.44	−2.34 to 1.03
Time	0.24 (0.25)	0.96, 0.34	−0.25 to 0.72
Group * Time	0.33 (0.34)	0.97, 0.33	−0.34 to 0.99
CHEQOL normalcy			
Group	−0.76 (0.89)	−0.85, 0.40	−2.51 to 1.00
Time	0.02 (0.27)	0.07, 0.95	−0.51 to 0.55
Group * Time	0.46 (0.37)	1.25, 0.21	−0.27 to 1.18
CHEQOL present			
Group	−0.94 (0.93)	−1.02, 0.31	−2.77 to 0.89
Time	0.10 (0.28)	0.35, 0.73	−0.45 to 0.64
Group * Time	0.50 (0.38)	1.31, 0.19	−0.25 to 1.25
CHEQOL total			
Group	−4.36 (2.34)	−1.87, 0.07	−9.99 to 0.27
Time	0.93 (0.81)	1.14, 0.26	−0.68 to 2.53
Group * Time	2.02 (1.11)	1.82, 0.07	−0.18 to 4.23
KIDSCREEN PA/health			
Group	−0.09 (0.2.60)	−0.03, 0.97	−5.24 to 5.06
Time	1.04 (0.81)	1.29, 0.20	−0.56 to 2.65
Group * Time	−1.18 (1.11)	−1.06, 0.29	−3.39 to 1.03
KIDSCREEN mood			
Group	−3.38 (2.51)	−1.35, 0.18	−8.36 to 1.59
Time	−1.04 (0.72)	−1.46, 0.15	−2.46 to 0.37
Group * Time	0.96 (0.98)	0.98, 0.33	−0.98 to 2.91
KIDSCREEN family			
Group	0.57 (2.71)	0.21, 0.83	−4.81 to 5.94
Time	−0.59 (0.82)	−0.72, 0.47	−2.21 to 1.03
Group * Time	0.14 (1.12)	0.13, 0.90	−2.08 to 2.36
KIDSCREEN friends			
Group	0.58 (3.31)	−0.18, 0.86	−7.13 to 5.97
Time	−1.46 (0.1.01)	−1.44, 0.15	−3.48 to 0.55
Group * Time	−0.74 (1.40)	0.53, 0.60	−2.03 to 3.50
KIDSCREEN school			
Group	−1.01 (2.38)	−0.42, 0.67	−5.74 to 3.72
Time	0.54 (0.80)	0.68, 0.50	−1.05 to 2.13
Group * Time	−1.10 (1.11)	−1.00, 0.32	−3.30 to 1.10
Depression scores			
Group	0.85 (1.51)	0.56, 0.58	−2.14 to 3.84
Time	−0.38 (0.58)	−0.66, 0.51	−1.53 to 0.76
Group * Time	−0.34 (0.78)	−0.43, 0.67	−1.89 to 1.21

Note. Scores reflect Control group in reference in Intervention group. Estimates are derived from linear mixed-effects model that adjusts for Baseline score, age, gender, and BMI. *p* values are from *t*-tests for null hypotheses that parameter estimates were set to zero.

4. Discussion

The purpose of the current study was to examine whether a behavioral counseling program targeting self-regulatory factors in combination with self-monitoring could increase PA levels among CWE, and in turn, positively influence mental health and QoL over one year. Contrary

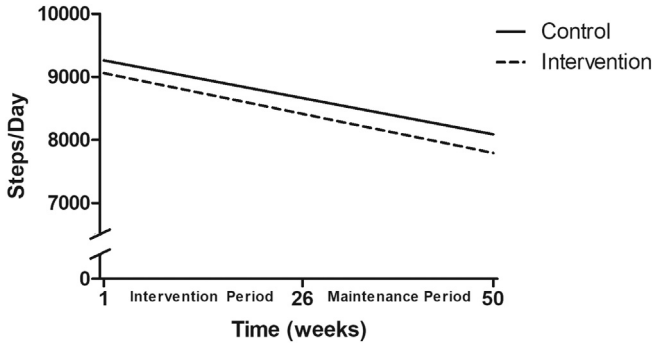

Fig. 2. Model predicted physical activity over time by group controlling for age, gender, BMI, and baseline step count.

to our predictions, the counseling program was unsuccessful in increasing PA to levels above those found in the control group. Measures of mental health and QoL also showed no differences between conditions over the one-year period. In fact, PA levels decreased among both groups following the 6-month intervention period; however, reductions in PA were not associated with declines in depressive symptoms and QoL.

The current study aimed to address a major gap in the literature by utilizing PA trackers to obtain objective measurements of PA to examine the relationship between PA, mental health, and QoL among CWE. Despite the 11-session counseling intervention rooted in evidence-based behavior change techniques, PA levels did not differ between the intervention and control groups. One possible reason why the intervention may have been unsuccessful is that the levels of PA were close to the age-matched Canadian average among participants at baseline [41]. Prior to randomization, participants were stratified based on higher or lower baseline PA levels as per our earlier feasibility study [18]. Unfortunately, only 7 participants were considered sedentary whereas 108 participants exceeded this cut-point.

These results suggest that our sample was skewed and that sedentary CWE may have been less interested in participating in the study. This characteristic of the sample poses a major challenge for understanding the relationship between PA, mental health, and QoL as sedentary CWE potentially stand to gain the most from increasing PA. Relatively active CWE may have established schedules, routines, or habits that already include PA in their own or families' lifestyles. They also may already have some self-management skills such as goal setting, action planning, and coping with barriers that enable them to regulate PA behavior, which could have limited the potential benefits of an additional intervention targeting skills for maintaining and enhancing PA participation. Further, they may have strong familial or peer support networks that facilitate and reinforce PA, as these may be influential determinants of PA that were not targeted in this intervention. Moving forward, it would be worthwhile to determine whether implementing this intervention among sedentary CWE could demonstrate more pronounced effects for PA behavior and impart positive downstream effects on mental health and QoL. If results in further studies appear promising, the behavioral counseling intervention employed in the current study could be an effective template for research concerning PA interventions and health outcomes in other populations with childhood-onset disabilities that are also significantly underdeveloped.

During the 6-month follow-up period, both groups demonstrated reductions in PA; however, no such changes were seen in the measures of mental health and QoL. It is worth noting that, despite this decline, PA levels were still within the "relatively active" range. Given that PA provides an excellent setting for social support [42], and that social support is one of the most robust predictors of QoL among CWE [43], it is not surprising that mental health and QoL were maintained throughout the study. Research has also shown that the novelty of using a PA tracker dissipates gradually over time, with one-third of people stopped using their device after 6 months [44]. Thus, participants may have worn their pedometer on a less consistent basis over time, and voluntary removal of the self-monitoring stimulus could explain why we observed decreases in PA levels across both groups despite no changes in mental health and QoL.

4.1. Strengths and limitations

Although the current study was unable to increase PA levels, there were several strengths that should be taken into consideration in the planning of future studies. First, this study had a strong design, using a longitudinal rather than cross-sectional approach to examine whether engaging in PA had benefits for mental health and QoL over time among CWE, a population that has received limited attention regarding exercise for health. Second, the study examined autonomous PA behavior within a naturalistic setting. Most studies investigating the effects of PA on health and/or QoL among people with epilepsy have been conducted in laboratory-based settings where participants are guided through an exercise protocol [45–47]. Such studies fail to account for the self-management skills necessary for initiating and maintaining PA behavior outside of the laboratory. Third, using an objective measure of PA improved the accuracy of PA measurement compared with self-reported PA measures [48]. Finally, the PA behavior change intervention was rooted in evidence-based behavior change techniques that have shown potential to improve PA participation in several healthy and clinical populations [49].

Despite numerous strengths that aimed to address gaps within the literature, several limitations must be acknowledged. The study sample was heavily skewed towards relatively active CWE, who may already possess self-management skills that enable them to achieve higher PA levels and therefore have less room to gain from a behavioral counseling intervention targeting self-regulation of PA. A second sampling limitation relates to the high socioeconomic status of the participants. A recent review [50] highlighted the lack of participation of families of lower socioeconomic status in studies examining QoL. Moving forward, studies including participants from a range of socioeconomic statuses may provide a better understanding of the influence of this factor on QoL among people with epilepsy. Another limitation is that there was a potential for both favorable outcomes and limited generalizability of the findings because we included children who functioned at, or above, a grade 3 level, estimated to constitute about 80% in pediatric epilepsy [51]. Lastly, the novelty of receiving a Fitbit® and having access to current daily step counts provided behavioral feedback to self-monitor PA which may have influenced PA levels among the control condition. Prior research has shown that activity trackers are an effective motivational tool that positively influences PA levels, particularly among children [21], therefore, future studies should disable feedback information on PA trackers for control conditions in order to maximize the reliability and validity of using direct measures of PA while limiting the potentially confounding effect of self-monitoring.

In conclusion, the present study did not determine whether increasing PA positively influences mental health and QoL among CWE. Several strengths and limitations provide insight regarding how to address gaps in the literature in the future. Researchers are encouraged to conduct longitudinal investigations examining whether PA self-management interventions may be effective for improving mental health and QoL among low active CWE.

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Contributors

GR involved in all aspects of study and paper. PR, BT, SB, DS, and DP were involved in study design and critical review of manuscript. NM assisted in study design and writing manuscript. DP was the site responsible researcher for CHEO. SH assisted in study design and intervention delivery. DB involved in data analysis, writing manuscript, and intervention delivery. MF advised on data analysis and was involved in critical review of this manuscript. DS advised data analysis.

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Disclosure

None of the authors has any conflict of interest to disclose.

Patient consent

Obtained.

Ethics

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

References

[1] Arida RM, Cavalheiro EA, da Silva AC, Scorza FA. Physical activity and epilepsy. Sports Med 2008;38:607–15.
[2] Arida RM, Scorza FA, da Silva SG, Schachter SC, Cavalheiro EA. The potential role of physical exercise in the treatment of epilepsy. Epilepsy Behav 2010;17:432–5.
[3] Fountain NB, May AC. Epilepsy and athletics. Clin Sports Med 2003;22:605–16.
[4] Brna PM, Gordon KE, Woolridge E, Dooley JM, Wood E. Perceived need for restrictions on activity for children with epilepsy. Epilepsy Behav 2017;73:236–9.
[5] Howard GM, Radloff M, Sevier TL. Epilepsy and sports participation. Curr Sports Med Rep 2004;3(1):15–9.
[6] Pimentel J, Tojal R, Morgado J. Epilepsy and physical exercise. Seizure 2015;25:87–94.
[7] Tremblay MS, Carson V, Chaput JP, Connor Gorber S, Dinh T, Duggan M, et al. Canadian 24-hour movement guidelines for children and youth: an integration of physical activity, sedentary behaviour, and sleep. Appl Physiol Nutr Metab 2016;41:S311–27.
[8] Wong J, Wirrell E. Physical activity in children/teens with epilepsy compared with that in their siblings without epilepsy. Epilepsia 2006;47:631–9.
[9] Ronen GM, Janssen IA. Canadian youth with epilepsy: time spent on physical activity, sedentary screen-time and sleep during 24 hours. Abstract accepted for child neurology society meeting; 2018.
[10] Jalava M, Sillanpaa M. Physical activity, heath-related fitness, and health experience in adults with childhood-onset epilepsy: a controlled study. Epilepsia 1997;38:424–9.
[11] Yu CG, Lee A, Wirrell E, EMS Sherman, Hamiwka L. Health behavior in teens with epilepsy: how do they compare with controls? Epilepsy Behav 2008;13(1):90–5.
[12] Fleeman N, Bradley PM. Care delivery and self-management strategies for children with epilepsy. Cochrane Database Syst Rev 2018;3:CD006245.
[13] Wagner JL, Modi AC, Johnson EK, Shegog R, Escoffery C, Bamps Y, et al. Self-management interventions in pediatric epilepsy: what is the level of evidence? Epilepsia 2017;58:743–54.
[14] Boutron I, Altman DG, Moher D, Schulz KF, Ravaud P, CONSORT NPT Group. CONSORT statement for randomized trials of nonpharmacologic treatments: a 2017 update and a CONSORT extension for nonpharmacologic trial abstracts. Ann Intern Med 2017;167:40–7.
[15] Vella SA, Magee CA, Cliff DP. Trajectories and predictors of health-related quality of life during childhood. J Pediatr 2015;167:422–7.
[16] Ahmed S, Andrich D. ISOQOL dictionary of quality of life and health outcomes measurement. International Society for Quality of Life Research (ISOQOL); 2015.
[17] McNamara E, Hudson Z, Taylor SJ. Measuring activity levels of young people: the validity of pedometers. Br Med Bull 2010;95:121–37.
[18] Whitney R, Bhan H, Persadie N, Streiner D, Bray S, Timmons B, et al. Feasibility of pedometer use to assess physical activity and its relationship with quality of life in children with epilepsy: a pilot study. Pediatr Neurol 2013;49:370–3.
[19] Gordon KE, Dooley JM, Brna PM. Epilepsy and activity—a population-based study. Epilepsia 2010;51:2254–9.
[20] Fitzsimons CF, Baker G, Wright A, Nimmo MA, Ward Thompson C, Lowry R, et al. The 'Walking for Wellbeing in the West' randomised controlled trial of a pedometer-based walking programme in combination with physical activity consultation with 12 month follow-up: rationale and study design. BMC Public Health 2008;8:259.
[21] Kang M, Marshall SJ, Barreira TV, Lee JO. Effect of pedometer-based physical activity interventions: a meta-analysis. Res Q Exerc Sport 2009;80:648–55.
[22] Lubans DR, Morgan PJ, Tudor-Locke C. A systematic review of studies using pedometers to promote physical activity among youth. Prev Med 2009;48:307–15.
[23] Horne PJ, Hardman CA, Lowe CF, Rowlands AV. Increasing children's physical activity: a peer modelling, rewards and pedometer-based intervention. Eur J Clin Nutr 2009;63:191–8.
[24] Rutten C, Boen F, Seghers J. How school social and physical environments relate to autonomous motivation in physical education: the mediating role of need satisfaction. J Teach Phys Educ 2012;31:216–30.
[25] Pons-Villanueva J, Seguí-Gómez M, Martínez-González MA. Risk of injury according to participation in specific physical activities: a 6-year follow-up of 14 356 participants of the SUN cohort. Int J Epidemiol 2009;39:580–7.
[26] Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med 2013;46:81–95.
[27] Colley RC, Janssen IA, Tremblay MS. Daily step target to measure adherence to physical activity guidelines in children. Med Sci Sports Exerc 2012;44:977–82.
[28] World Health Organization. International classification of functioning, disability and health: ICF. Geneva: World Health Organization; 2001.
[29] WHOQoL Group. Study protocol for the World Health Organization project to develop a quality of life assessment instrument (WHOQOL). Qual Life Res 1993;2:153–9.
[30] Takacs J, Pollock CL, Guenther JR, Bahar M, Napier C, Hunt MA. Validation of the Fitbit One activity monitor device during treadmill walking. J Sci Med Sport 2014;17:496–500.
[31] Streiner DL. Speaking graphically: an introduction to some newer graphing techniques. Can J Psychiatry 1997;42:388–94.
[32] Ronen GM, Streiner DL, Rosenbaum P. Health-related quality of life in children with epilepsy: development and validation of self-report and parent proxy measures. Epilepsia 2003;44:598–612.
[33] Ravens-Sieberer U, Auquier P, Erhart M, Gosch A, Rajmil L, Bruil J, et al. The KIDSCREEN-27 quality of life measure for children and adolescents: psychometric results from a cross-cultural survey in 13 European countries. Qual Life Res 2007;16:1347–56.
[34] Robitail S, Ravens-Sieberer U, Simeoni MC, Rajmil L, Bruil J, Power M, et al. Testing the structural and cross-cultural validity of the KIDSCREEN-27 quality of life questionnaire. Qual Life Res 2007;16:1335–45.
[35] Kovacs M. The Children's Depression Inventory (CDI). Psychopharmacol Bull 1985;21:995–8.
[36] Smucker MR, Craighead WE, Craighead LW, Green BJ. Normative and reliability data for the Children's Depression Inventory. J Abnorm Child Psychol 1986;14(1):25–39.
[37] Cohen J. Statistical power analysis for the behavioral sciences. 2nd ed. New York (NY): Academic Press; 1998.
[38] Baerg S, Cairney J, Hay J, Rempel L, Mahlberg N, Faught BE. Evaluating physical activity using accelerometry in children at risk of developmental coordination disorder in the presence of attention deficit hyperactivity disorder. Res Dev Disabil 2011;32:1343–50.
[39] Tudor-Locke CE, Myers AM. Methodological considerations for researchers and practitioners using pedometers to measure physical (ambulatory) activity. Res Q Exerc Sport 2001;72(1):1–12.
[40] Efird J. Blocked randomization with randomly selected block sizes. Int J Environ Res Public Health 2010;8:15–20.
[41] Colley RC, Garriguet D, Janssen I, Craig CL, Clarke J, Tremblay MS. Physical activity of Canadian children and youth: accelerometer results from the 2007 to 2009 Canadian Health Measures Survey. Health Rep 2011;22:15.
[42] Bloemen MA, Backx FJ, Takken T, Wittink H, Benner J, Mollema J, et al. Factors associated with physical activity in children and adolescents with a physical disability: a systematic review. Dev Med Child Neurol 2015;57:137–48.
[43] Ferro MA, Avery L, Fayed N, Streiner DL, Cunningham CE, Boyle MH, et al. Child- and parent-reported quality of life trajectories in children with epilepsy: a prospective cohort study. Epilepsia 2017;58:1277–86.
[44] Ledger D, McCaffrey D. Inside wearables: how the science of human behavior change offers the secret to long-term engagement. Endeavour Partners 2014;200(93):1.
[45] Eom S, Lee MK, Park JH, Jeon JY, Kang HC, Lee JS, et al. The impact of an exercise therapy on psychosocial health of children with benign epilepsy: a pilot study. Epilepsy Behav 2014;37:151–6.
[46] Eom S, Lee MK, Park JH, Lee D, Kang HC, Lee JS, et al. The impact of a 35-week long-term exercise therapy on psychosocial health of children with benign epilepsy. J Child Neurol 2016;31:985–90.
[47] Nakken KO, Bjørholt PG, Johannessen SI, Løyning T, Lind E. Effect of physical training on aerobic capacity, seizure occurrence, and serum level of antiepileptic drugs in adults with epilepsy. Epilepsia 1990;31:88–94.

[48] Prince SA, Adamo KB, Hamel ME, Hardt J, Connor Gorber S, Tremblay M. A comparison of direct versus self-report measures for assessing physical activity in adults: a systematic review. Int J Behav Nutr Phys Act 2008;5:56.
[49] Heath GW, Parra DC, Sarmiento OL, Andersen LB, Owen N, Goenka S, et al. Evidence-based intervention in physical activity: lessons from around the world. Lancet 2012; 380:272–81.
[50] Ronen GM, Rosenbaum PL, Boyle MH, Streiner DL. Patient-reported quality of life and biopsychosocial health outcomes in pediatric epilepsy: an update for healthcare providers. Epilepsy Behav 2018;86:19–24.
[51] Berg AT, Langfitt JT, Testa FM, Levy SR, DiMario F, Westerveld M, et al. Global cognitive function in children with epilepsy: a community-based study. Epilepsia 2008; 49:608–14.
[52] Cramer JA, Westbrook LE, Devinsky O, Perrine K, Glassman MB, Camfield C. Development of the quality of life in epilepsy inventory for adolescents: the QOLIE-AD-48. Epilepsia 1999;40:1114–21.