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Systematic review

Is self-management effective for improving the quality of life in adult epileptics? A systematic review and meta-analysis of randomized controlled trials

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ABSTRACT

Introduction: Epilepsy is a chronic brain disorder with high morbidity and mortality. Self-management for epileptic patients is a complex and targeted process requiring taking medication, tracking seizures, ensuring medication adherence, managing negative events, adapting to the environment, keeping healthy lifestyle and maintaining good relationship with family and friends. An increasing number of studies have reported that self-management has become an important adjuvant for controlling epilepsy. However there have been no systematic reviews carried out to evaluate the effectiveness of self-management to improve the quality of life in adult epileptics.

Methods: Randomized controlled trials on self-management for adult epilepsy were included. Web of Science, PubMed, Science Direct, Cochrane Library, CNKI, VIP and Wanfang databases were searched. Reporting quality of trials was assessed by two reviewers independently using the Cochrane Risk of Bias Tool. The study was registered on PROSPERO registration number CRD42017078356.

Results: Eleven trials involving 1217 participants were identified. Meta-analysis showed that self-management interventions could improve quality of life (SMD 0.69, 95% CI [0.26, 1.11]; $I^2 = 90\%$), reduce depression (SMD −0.31, 95% CI [−0.60, −0.01]; $I^2 = 78\%$), increase self-efficacy (SMD 0.52, 95% CI [0.34, 0.69]; $I^2 = 44\%$) and self-management (MD 3.35, 95% CI [0.33, 6.37]; $I^2 = 87\%$), and improve medical adherence (MD 0.21, 95% CI [0.06, 0.36]; $I^2 = 0\%$) for adult epileptics, but had no effect on seizure frequency (MD −0.73, 95% CI [−5.63, 4.16]; $I^2 = 54\%$) and negative health events (MD −2.30, 95% CI [−8.31, 3.27]; $I^2 = 71\%$). Reporting and methodological quality was limited for all included trials.

Conclusion: Self-management may be effective in improving for quality of life in adult epileptics. However, these findings should be interpreted with caution due to the methodological quality of included trials. Furthermore, strict trials with precise methodological design and rigorous reporting on clinical efficacy and adverse events controlling self-management for epilepsy may be promising.

1. Introduction

Epilepsy is a chronic brain disorder resulting in high morbidity and mortality [1]. Epilepsy causes seizures, and types of seizure vary. There are 70 million people with epilepsy, with more than 90% living in developing countries [2]. Morbidity rate for people with epilepsy ranges between or is approximately 0.4–0.9% [3] and there were more than 9,000,000 epileptic patients in China by the end of 2017 [4]. The peak age for the onset of epilepsy is 18 years, and will affect quality of life without proper treatment. Though mortality in epilepsy generally has been reduced due to the development of medicine (0.36% with uncomplicated epilepsy cases), the number of individuals with underlying neurological disability caused by epilepsy is huge (7.43 per 1000) [1]. Epilepsy can impair patients cognition (one study reported that

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30–40% epileptics suffered from cognition impairment, mainly in attention, memory and judgment) [5], and it can also bring a heavy financial burden to the family and society [6]. Antiepileptic drugs (ADs) are effective for epilepsy, but 33.5% epilepsy patients suffer from adverse effects caused by antiepileptic drugs. In addition, 25.3% adult epileptics turned to intractable epilepsy caused by drug resistance (the condition in which an organism can resist after drug treatments) and long term treatment of epilepsy [7]. More than 40% adults epileptic report seizure consequences including control of fits, job loss, and even death because of failure to adhere to doctors' advice [8–10].

People with epilepsy report negative health events including accidents, low life quality and even death due to poor epilepsy control [11,12]. Poor epilepsy control may be because of medication non-adherence, lack of medication education, poor social support, and also psychiatric comorbidities including anxiety and depression [13]. Epileptic patients and their families need to understand epilepsy and why seizures occur, how to control them, and how to adapt to the environment. Sufficient knowledge about medication chosen and adherence, what should do during recovering, and how to deal with the negative mood like depression should be taught to epilepsy patients by professionals [14,15].

Self-management interventions for epileptic patients could help these problems, but it is a complex process which needs to target: taking medication, monitoring seizures, adhering to medication (whether patients take their medications as prescribed), managing negative events, adjusting to surroundings, keeping good lifestyle and maintaining good relationship with family and friends [16], which need more effort by the patients themselves rather than medical workers. Obviously, epileptic patients cannot be monitored in the continuously, so self-management is critical in ensuring patients' behavior change and helping them to acquire knowledge about epilepsy and the psychosocial consequences of the disease [17]. Compared with antiepileptic drugs (ADs) therapy, self-management interventions could not only improve the quality of life in epileptic and increase the effectiveness of treatments, but also reduce the occurrence of adverse events [18,19]. Recurrent epileptic attacks are hard to predict, but always occurs after negative emotion [20]. Self-management also helps patients to adjust to their surroundings and improve daily mood, which is an advantage compared to other interventions commonly used in the clinical activities.

Although self-management interventions show some effectiveness for epilepsy, there has been no systematic review focusing on self-management and the quality of life in epileptics. This article systematically reviewed the evidence for self-management interventions for adult epilepsy in order to evaluate its efficacy focused on quality of life, self-efficacy, self-management, medication adherence and safety (measured by negative health events), and also to inform future research and clinical practice.

2. Methods

This systematic review is reported following the Preferred Reporting Item for Systematic Reviews and Meta-Analysis (PRISMA) [21].

2.1. Data sources and search terms

Databases including Web of Science, PubMed, Science Direct, Cochrane Library, Embase, PsycINFO, China National Knowledge Infrastructure (CNKI), VIP and Wanfang were searched from inception to October 2018. There was no restriction on publication language. The search strategy followed the guidance of Cochrane Review Handbook, please refer to the attached file 1.

2.2. Inclusion and exclusion criteria

2.2.1. Types of studies

Randomized controlled trials (RCTs) evaluating quality of life and other related results for epilepsy (i.e. epilepsy self-efficacy scale, epilepsy self-management scale, medication adherence scale, seizure frequency, hospital anxiety and depression scale) from inception to October 2018 were included in this study, regardless of language, blinding, and publication region.

2.2.2. Types of participants

Study participants were included if they had a confirmed diagnosis of any type of epilepsy. This was irrespective of age, gender, ethnicity restrictions, type of epilepsy, or disease duration.

2.2.3. Types of interventions

Trials of intervention on self-management were included in this study. Comparisons: Trials comparing self-management versus no stimulation/ waitlist/ usual care (UC); trials evaluating self-management plus ADs or other treatments (i.e. Tai chi, yoga, Chinese medicine, nerve stimulation including transcutaneous electrical nerve stimulation (TENS) and transcranial electrical stimulation (TES)) versus ADs or other treatments.

2.2.4. Types of outcome measures

The primary outcome was life quality as measured by the Quality of Life in Epilepsy (QOLIE, higher scores indicated better quality of life), and the secondary outcomes include self-efficacy assessed by the Epilepsy Self-Efficacy Scale (ESES, higher scores indicated better self-efficacy), self-management assessed by the Epilepsy Self-Management Scale (ESMS, higher scores indicated better self-management), adherence tested by Medication Adherence Scale (MAS, higher scores reflected greater adherence), seizure frequency, negative moods assessed by Psychiatric Scale (PS, higher scores reflected worse symptoms), and negative health events (higher scores reflected more negative events).

2.3. Data extraction

Clinical characteristics extraction included: study ID, sample size, age, interventions in treatment and control groups, outcome measures, period of follow-up, assessment of safety, adverse events and reporting quality.

2.4. Risk of bias and reporting quality of selected studies

Two independent reviewers (WZJ, ZY) assessed the reporting quality and methodology quality (risk and bias) by using Cochrane Review Handbook. Low, unclear, or high risk of bias was judged in seven domains for every included trial following those tools. The third reviewer (HXY) gave advice in the case of no consensus.

The Jadad scale [22] was used to judge the risk of bias of including trials: scores between 1–3 indicated high risk, while 4–7 indicated low risk (low risk bias recorded 1 point, while unclear and high risk bias recorded zero). CONSORT [23] was used to assess the quality of included trials (positive percent $\geq$70% indicating high quality, otherwise, low quality). Grades of Recommendations Assessment, Development and Evaluation (GRADE) [24] were used to assess the evidence level of including trials.

2.5. Data synthesis and analysis

Meta-analysis was analyzed by Review Manager 5.3 software (The Nordic Cochrane Centre, The Cochrane Collaboration, 2014). Mean difference (MD) or std. Mean difference (SMD) with 95% confidence intervals (CI) was calculated for dichotomous and continuous data, and presented the continuous variables of outcomes in this study. The I^2 statistics test was used to assess statistical heterogeneity and to choose the effect model. When $I^2 > 50\%$ and the P-value of the Chi^2 was less than 0.1, it was considered as high heterogeneity, than a random-effects

model was conducted; otherwise a fixed-effects model was performed to obtain a pooled estimate of effect. The heterogeneity of participants in terms of their age, different comparison groups, outcome measures employed and follow-ups was assessed.

2.6. Subgroup analysis

Subgroup analysis was conducted for different comparisons, and outcome measures that might influence the effect of self-management intervention. Data from each subgroup was synthesized and evaluated independently. If a meta-analysis could not be executed because of small number studies in subgroup, then a narrative description was reported. If there were sufficient trials available, then funnel plot was applied to assess the publication bias.

3. Results

A total of 815 possibly relevant papers were identified. After excluding 316 duplicate trials, a further 452 were excluded by screening titles or abstracts. The remaining 47 studies were retrieved and full texts were read. Finally, 11 trials which met the inclusion criteria remained (Fig. 1).

3.1. Study characteristics

Study characteristics are presented in Table 1. 1217 participants (ranged from 22 to 404) from eleven trials, six [25–27,31,32,35] were conducted in USA, two in China [28,29], one in Iran [30], one in UK [33], and one in the Netherlands [34]. Six [25,28–31,33] of the included trials carried out self-management intervention by face-to-face education groups only, one [27] used WebEase software learning and collected information, three made telephone communications [26,32] or computer self-testing [34] followed by face-to-face groups, and one [35] performed a three stage intervention: face-to-face learning groups, following computer self-testing, and then following telephone communications. Of the control groups, eight performed usual care, and three put the patients on a waitlist. All included trials had a follow up period (1 to 12 months) and two trials [33–35] reported adverse events measure the safety.

3.2. Quality of reporting

Generally speaking, the reporting quality of including trials was moderate. According to CONSORT, nine including trials [25–27,30–35] were evaluated high quality of reporting because the positive percent were >70%, while two trials [28,29] had low quality with positive percents of67.6% and 64.9%. (Table S1)

3.3. Risk of bias in included trials

Methodological quality of the included trials was limited (Fig. 2). Nine included trials reported random sequence generation methods, eight [25,28–32,35] (88.88%) used random number tables, one [33] (11.11%) used online system. Three (27.27%) trials [25,33–35] used sealed envelopes, which indicated low risk of bias. Two (18.18%) reported blinding information, one [33] reported blinding to follow-up

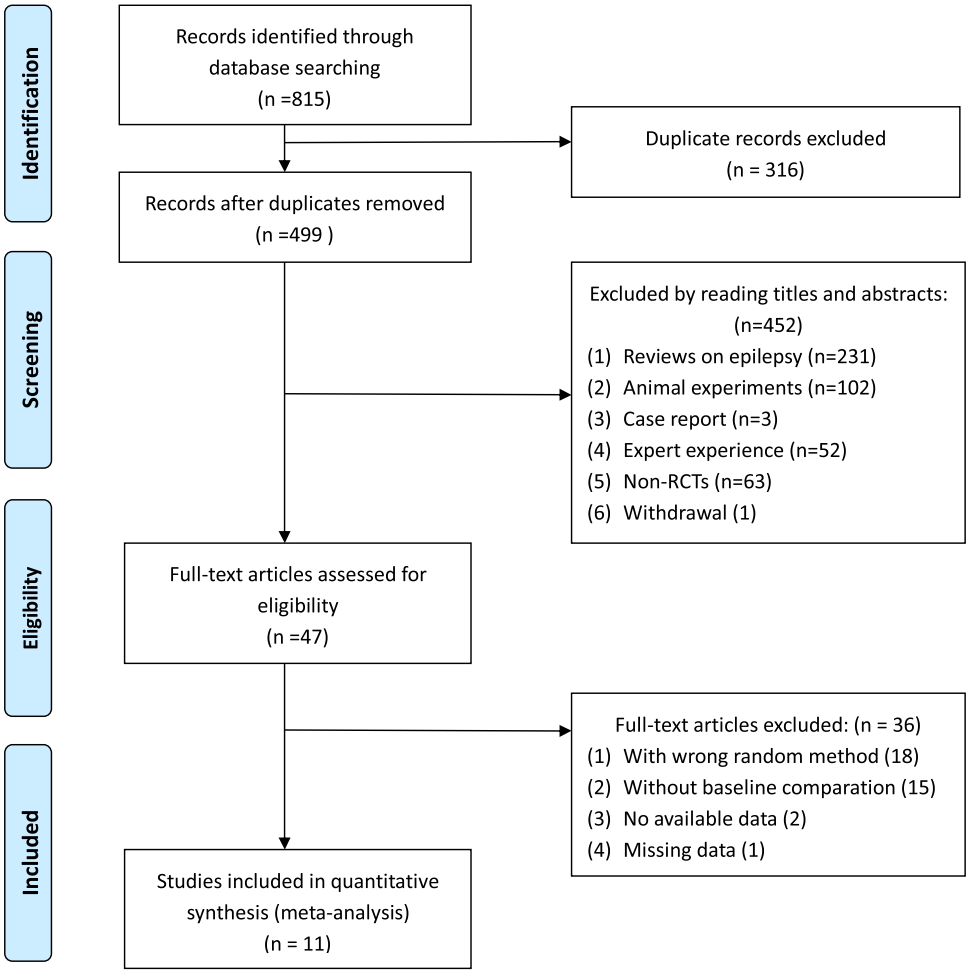


Fig. 1. Literature screening process and results.

Table 1
Summary of the including trials.

Study ID	Sample size (n)		Age (year)	Interventions		Outcomes	Follow-up (month)	Adverse Jadad events scale
	T	C		T	C			
Pramuka (2007) [25]	31	24	50 ± 14.5	SM	UC	(1)(2)(3)	10	NR L
Dilorio (2009) [26]	11	11	43 ± 13.51	SM	UC	(2)(6)	3	NR L
Dilorio (2011) [27]	70	78	40.87 ± 13.32	SM	waitlist	(2)(4)(5)(3)	3	NR L
Wang (2012) [28]	50	50	35.03 ± 13.97	SM	UC	(1)	6	NR H
Liu (2014) [29]	35	35	39.09 ± 4.43	SM	UC	(1)	3	NR L
Yadegary (2015) [30]	30	30	18–65	SM	UC	(1)	1	NR H
Fraser (2015) [31]	46	46	45.2 ± 12.5	SM	waitlist	(1)(2)(4)(5)(3)	6	NR H
Sajatovic (2016) [32]	22	22	48.25 ± 11.82	SM	UC	(1)(3)(6)	4	NR L
Ridsdale (2018) [33]	205	199	41.7 ± 14.1	SM	UC/waitlist	(1)(3)(5)(6)	12	HR H
Leenen (2018) [34]	52	50	41.7 ± 14.7	SM	UC	(1)(2)(3)(4)(5)(7)	6	HR H
Sajatovic (2018) [35]	60	60	41.3 ± 11.8	SM	waitlist	(1)(2)(3)(4)	6	NR L

T: treatment group; C: control group; SM: Self-management program; UC: usual care; NR: not reported; HR: has reported; L: low reporting quality; H: high reporting quality; (1) Quality of life in epilepsy (QOLIE); (2) Epilepsy self-efficacy scale (ESES); (3) Psychiatric scale (PS); (4) Epilepsy self-management scale (ESMS); (5) Medication adherence scale (MAS); (6) Seizure frequency; (7) Negative health events.

assessments and the patients healthcare providers, and one [25] reported no blinding. Four included trials [25,32,33,35] (36.36%) reported details on withdrawals, dropping out but without any reasons being given except for Ridsdale's study [33], so there is a high potential risk of bias. Two trials [26,29] 18.18% did not report ethical committee information.

According to the Jadad scale score, five included trials [28,30,31,33,34] (45.45%) were considered high quality, while the other six [25–27,29,32–35] (54.54%) were low quality.

3.4. Evidence level based on GRADE

Outcomes including quality of life, self-efficacy, depression level, self-management, medication adherence, seizure frequency and negative health events were evaluated by GRADEprofiler 3.6.1. The results showed that evidence of quality of life and medication adherence was moderate quality, self-efficacy and depression level was low quality, while self-management, seizure frequency and negative health events was very low quality (Fig. S1).

3.5. Effect estimation

3.5.1. Quality of life in epilepsy

Quality of life in epilepsy (QOLIE) was measured by QOLIE-10 (score 1–10, higher score indicates better quality of life) or QOLIE-31 (score 31–170, higher score indicates better quality of life) in this study.

Nine included trials [25,28–35] reported QOLIE as a main outcome (seven used QOLIE-31, and two used QOLIE-10) and showed a statistically significant pooled improvements between self-management intervention and controls when combining all trials (SMD 0.69, 95% CI [0.26, 1.11]; I^2 = 90%; 9 trials; n = 1036) (Fig. 3A).

3.5.1.1. Subgroup analysis. Because of the high heterogeneity of the results of QOLIE (P < 0.0001, I^2 = 90%), subgroup analysis was carried out according to different scales and different patient ages. Based on different scales, the results showed that self-management improved quality of life better than the control group (MD 4.38, 95% CI [2.34, 6.41]), and the heterogeneity was high (P < 0.0001, I^2 = 95%). Seven trials evaluated quality of life by QOLIE-31 showing self-management could improve quality of life in epilepsy (MD 6.53, 95% CI [1.57, 11.50]; I^2 = 94%; 7 trials; n = 883); and when restricting the analysis to QOLIE-10, the results also showed a positive effect (MD 0.45, 95% CI [0.16, 0.74]; I^2 = 0%; 2 trials; n = 153) (Fig. 3B); Based on different ages, the results showed that self-management improved quality of life better than the control group no matter the ages (SMD 0.68, 95% CI [0.22, 1.51]), but because of the heterogeneity (P < 0.0001, I^2 = 91%),subgroup analysis was conducted. When restricting the analysis to the age under 40 years, self-management intervention showed a beneficial effect (SMD 1.85, 95% CI [0.13, 3.56]; I^2 = 95%; 2 trials; n = 170), and the same result showed the analysis to the age of 50 years or older (SMD 0.84, 95% CI [0.29, 1.40]; 1 trial; n = 55); but when restricting the analysis to the age between 40 and 50, the results showed no different between self-management intervention and the control interventions (SMD 0.21, 95% CI [−0.01, 0.42]; I^2 = 43%;5 trials; n = 751) (Fig. 3C).

3.5.2. Epilepsy self-efficacy scale

Epilepsy Self-Efficacy Scale (ESES) was a questionnaire about self-efficacy for epilepsy patients [36]. Two types of questionnaire were used in this study: one was scored 1–10, and another was 33–330.

Six included trials [25–27,31,34,35] reported ESES as an outcome and showed a statistically significant pooled improvements between self-management intervention and controls when combining all trials (SMD 0.52, 95% CI [0.34, 0.69]; I^2 = 44%; 6 trials; n = 539); or when restricting the analysis to scoring 33–330, the results showed self-management intervention could improve self-efficacy (SMD 0.53, 95% CI [0.34, 0.73]; I^2 = 63%; 4 trials; n = 425); and the same result showed when restricting the analysis to scoring 1–10 (MD 0.46, 95% CI [0.09, 0.83]; I^2 = 0%; 2 trials; n = 114) (Fig. 4).

3.5.3. Psychiatric scale

Seven included trials [25,27,31–35] measured depression level of epileptic by psychiatric scale. The analysis showed that there was difference between self-management intervention and control groups in improving depression (SMD −0.31, 95% CI [−0.60, −0.01]; I^2 = 78%; 7 trials; n = 965) (Fig. 5).

3.5.4. Epilepsy self-management scale

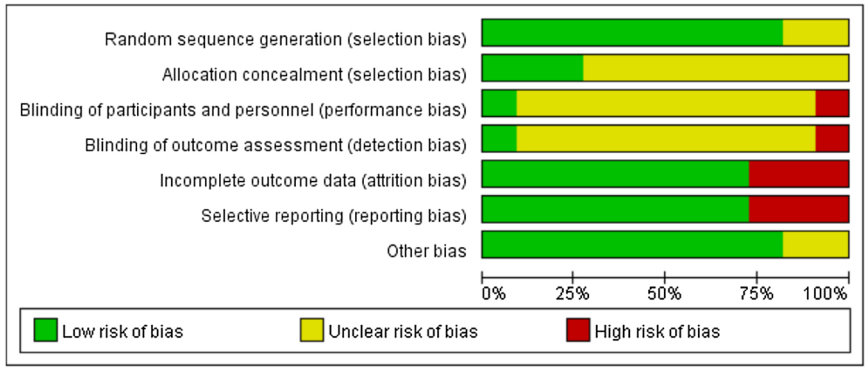
Four included trials [27,31,34,35] reported Epilepsy Self-Management Scale (ESMS) as an outcome and showed there was a difference between self-management intervention and control groups (MD 3.35, 95% CI [0.33, 6.37]; I^2 = 87%; 4 trials; n = 462) (Fig. 6).

3.5.5. Medication adherence scale

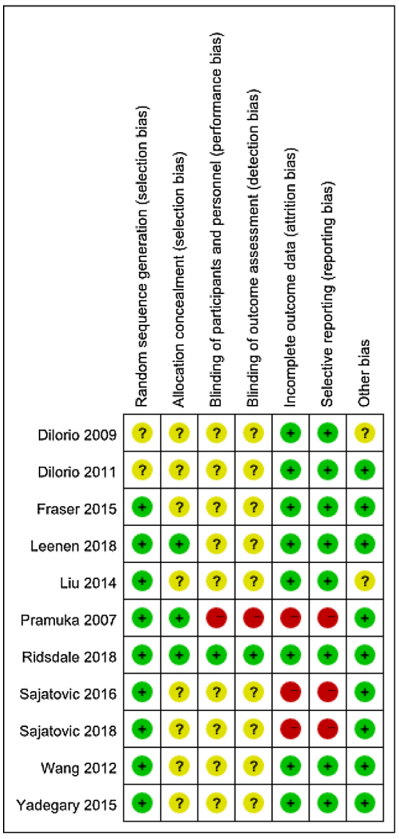
Four included trials [27,31,33,34] reported medication adherence scale to measure medical adherence in epileptic patients. Statistically pooled improvements between self-management intervention and controls were shown in this study (MD 0.21, 95% CI [0.06, 0.36]; I^2 = 0%; 4 trials; n = 746) (Fig. 7).

3.5.6. Seizure frequency

Three included trials [27,32,33] reported seizure frequency and



a Risk of bias graph



b Risk of bias summary

Fig. 2. Risk of bias a. Risk of bias graph b. Risk of bias summary.

there was no statistical difference between self-management intervention and control groups (MD -0.73, 95% CI [−5.63, 4.16]; I^2 = 54%; 3 trials; n = 470) (Fig. 8).

3.5.7. Negative health events

Two included trials [33,34] measured negative health events occurred during interventions with no statistical difference between self-management intervention and control groups (MD −2.30, 95% CI [−8.31, 3.27]; I^2 = 71%; 2 trials; n = 506).

4. Discussion

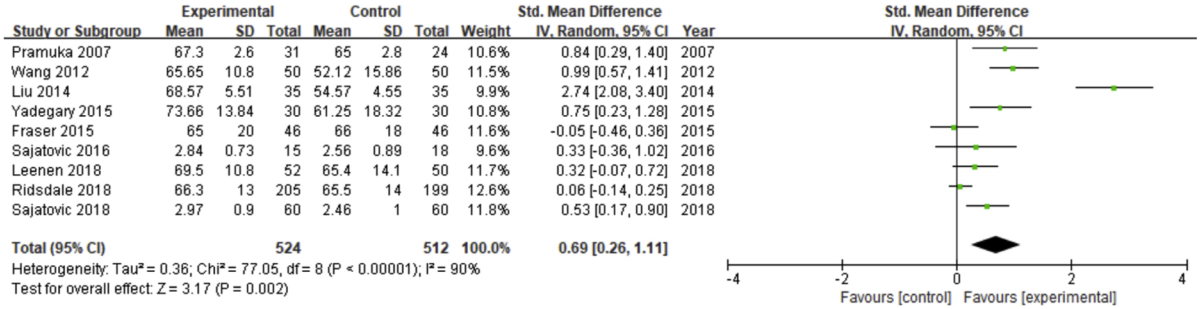
This systematic review focused on evaluating self-management intervention for quality of life in adult epileptics. Though there are limitations, this systematic review and meta-analysis still provides promising evidence for the clinical efficacy of self-management as a part of the treatment regimen for epileptic control.

4.1. Summary of main results

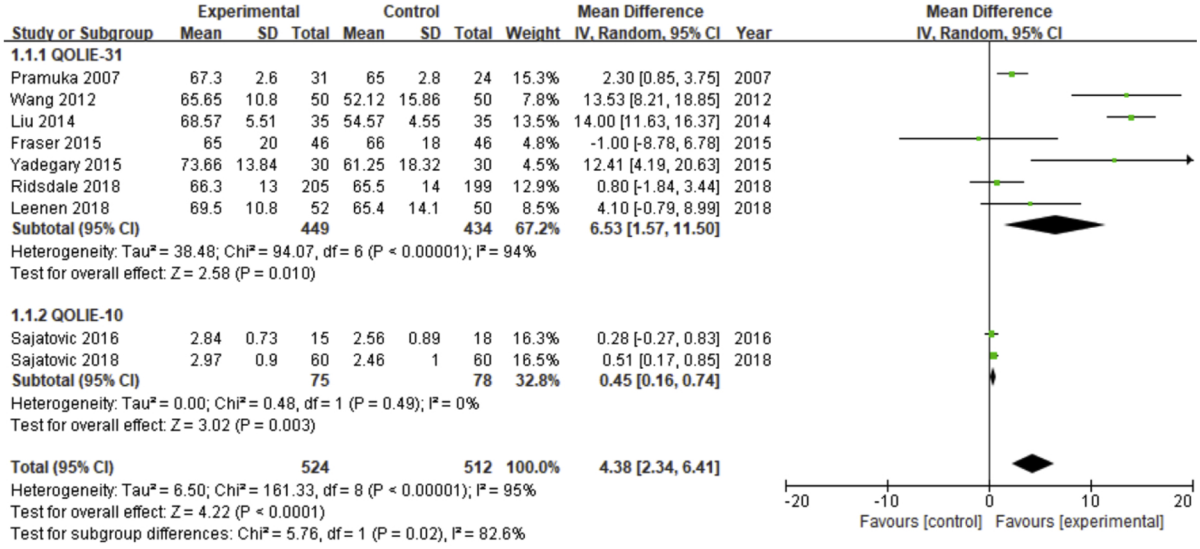
Eleven trials were eligible for this systematic review and meta-analysis. After combining included RCTs, the results showed that self-management intervention may improve the quality of life, reduce depression level, increase self-efficacy and self-management, and improve medical adherence in adult epileptic. While, self-management interventions did not seem to reduce seizure frequency and negative health events.

In view of our results, self-management intervention may have effect on improving life quality. The high heterogeneity in some results may because of small number of including trials, or different scales used for the same item. And education level, employment status, comorbidities or ages of including participants also could be the reasons of high heterogeneity. Hence more rigorous trials with robust methodological design and strict reporting are required in future clinical studies. Also it should focus on using the specific outcome measures to determine the effect of self-management intervention for epilepsy.

3A QOLIE



3B QOLIE according to different scales



3C QOLIE according to different ages

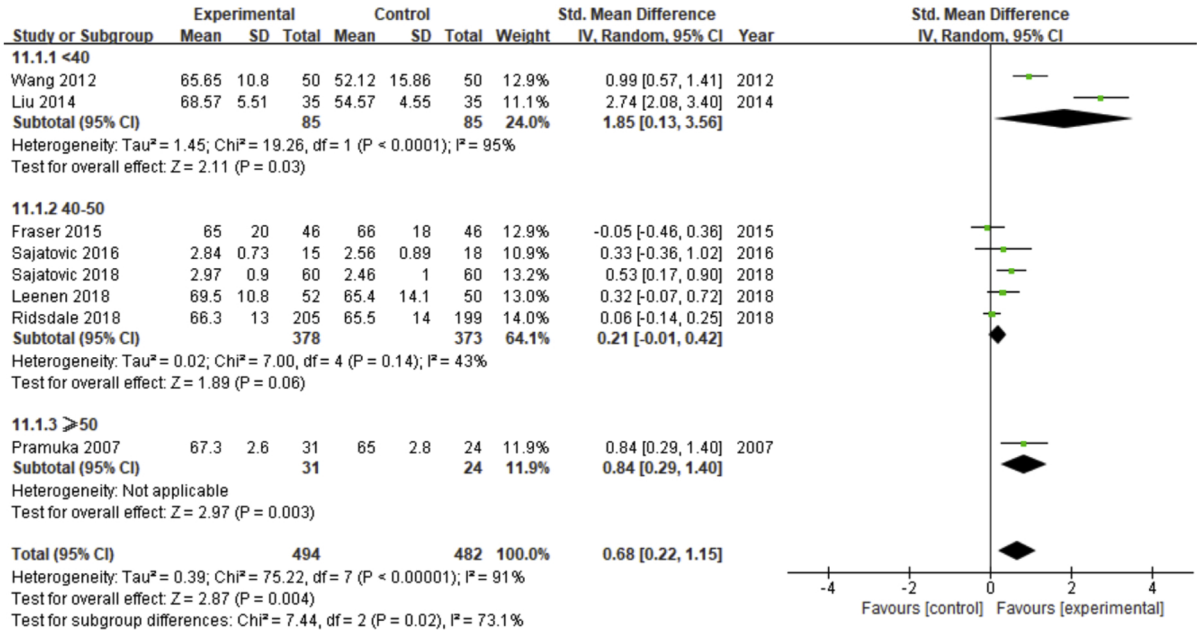


Fig. 3. Results of QOLIE A. QOLIE B. QOLIE according to different scales C. QOLIE according to different ages.

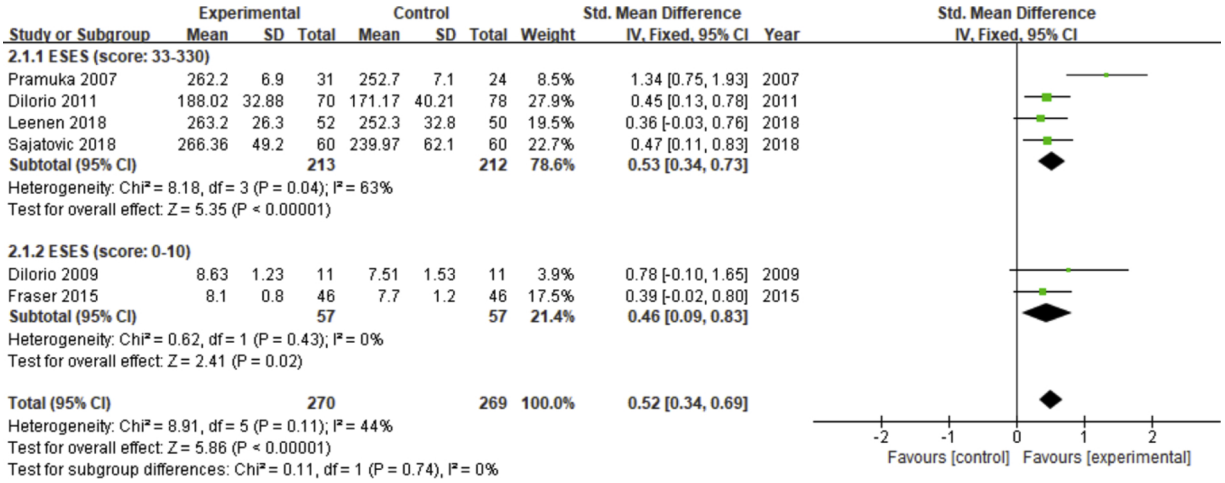


Fig. 4. Epilepsy self-efficacy scale.

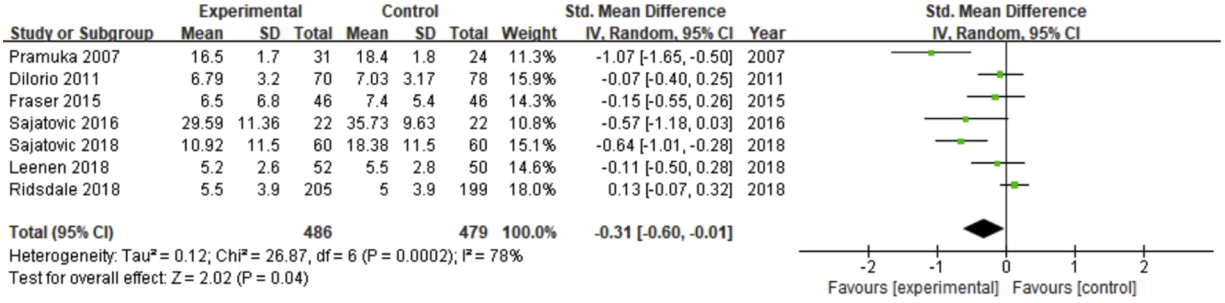


Fig. 5. Psychiatric scale.

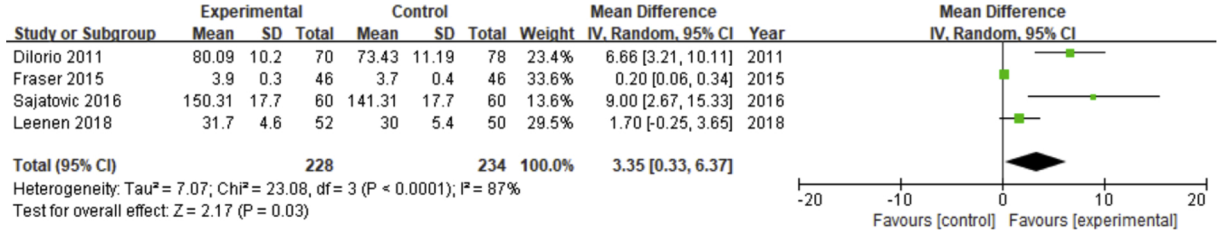


Fig. 6. Epilepsy self-management scale.

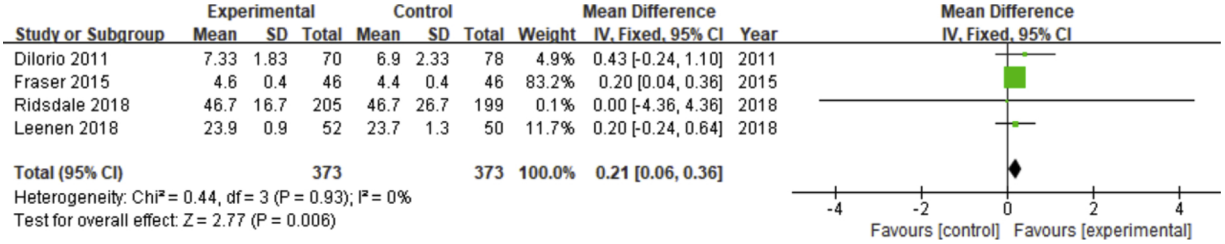


Fig. 7. Medication adherence scale.

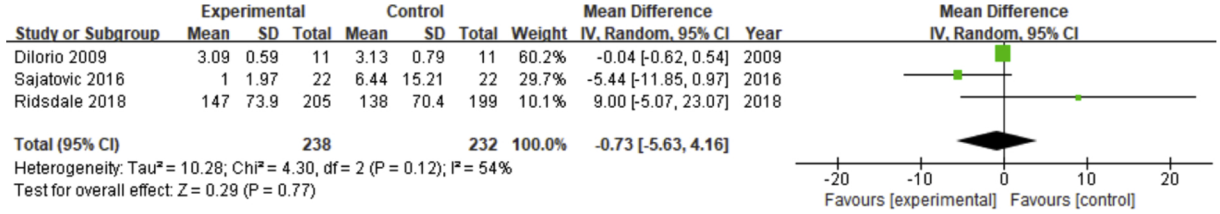


Fig. 8. Seizure frequency.

4.2. Limitations

Firstly, the most important limitations of this study were that not all the included trials were judged to have high methodological quality. There was high potential performance bias as only one trial reported double-blinding, but given that self-management interventions should be carried out by direct communication between specialists and patients, this makes it difficult to report blinding in the included trials. Secondly, only two included trials reported negative health events but there were no observed differences between self-management and control groups. Therefore, the safety of self-management for epilepsy could not be estimated. Thirdly, because of the limitation of searching databases, only eleven trials conducted in five regions were included in this study. Conclusion on whether self-management interventions can improve quality of life in adult epileptics all over the world remains unclear. Lastly, no subgroups analysis could be conducted by educational level, which may be a significant influencing factor for epileptic self-management.

5. Conclusion

There is limited but some evidence that self-management intervention could improve quality of life, reduce the level of depression, increase self-efficacy and self-management, and improve medical adherence in adult epileptic. However, the findings should be interpreted with caution due to the limitation of the methodological quality of the included trials. Furthermore, strict trials with precise methodological design and rigorous reporting on clinical efficacy and adverse events controlling self-management for epilepsy should be promising.

Funding

None.

Author's contribution

WZJ and ZY contributed equally to this work. This review was drafted by WZJ and ZY, and revised by XY, GX and ZLX. The search strategy was addressed by HXY, GW and ZLX, and updated by WZJ. WZJ and MH screened potential trials, extracted data, and completed the data synthesis independently. ZLX and GW assessed the risk of bias. GX arbitrated in cases of disagreement and ensured the absence of errors. All authors gave final approval for the version to be published.

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.

Declaration of Competing Interest

The authors declare that they have no conflicts of interest to declare.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.eujim.2019.100926.

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