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A randomized controlled trial of a manual-based Psychosocial group Intervention for young people with Epilepsy [PIE]

Liam Dorris*^{1,2}, Helen Broome^{1,2}, Margaret Wilson², Cathy Grant³, David Young⁴, Gus Baker⁵, Selina Balloo⁶, Susan Bruce⁷, Jo Campbell⁸, Bernie Concannon⁶, Nadia Conway⁷, Lisa Cook⁹, Cheryl Davis⁹, Bruce Downey⁸, Jon Evans¹, Diane Flower¹⁰, Jack Garlovsky⁹, Shauna Kearney⁶, Susan Lewis¹¹, Victoria Stephens¹⁰, Stuart Turton¹¹, & Ingram Wright¹⁰.

1. Institute of Mental Health & Wellbeing, University of Glasgow, Glasgow G12 OXH, Scotland, UK
2. Paediatric Neurosciences Research Group, Royal Hospital for Children, Glasgow G51 4TF, Scotland, UK
3. University Hospitals Leicester NHS Trust, Leicester, UK
4. University of Strathclyde, Glasgow, UK
5. Neuroscience Group, University of Liverpool, UK
6. Birmingham Children's Hospital NHS Foundation Trust, Birmingham, UK
7. Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle, UK
8. Royal Aberdeen Children's Hospital, NHS Grampian, UK
9. Sheffield Children's Hospital NHS Foundation Trust, Sheffield, UK
10. University Hospitals Bristol NHS Foundation Trust, Bristol, UK
11. County Durham and Darlington NHS Foundation Trust, Durham, UK

*Corresponding author at: 2nd Floor Office Block, South Glasgow University Hospitals Campus, 1345 Govan Road, Glasgow G51 4TF, Scotland, UK. Tel: +44 141 451 6554. Email address: liam.dorris@ggc.scot.nhs.uk.

Abstract

We conducted an exploratory RCT to examine feasibility and preliminary efficacy for a manual-based psychosocial group intervention aimed at improving epilepsy knowledge, self-management skills, and quality of life in young people with epilepsy.

Method: Eighty-three participants (33:50 m/f; age range 12-17 years) were randomized to either the treatment or control group in seven tertiary pediatric neuroscience centers in the UK, using a wait-list control design. Participants were excluded if they reported suicidal ideation and/or scored above the cut off on mental health screening measures, or if they had a learning disability or other neurological disorder. The intervention consisted of six weekly 2-hour sessions using guided discussion, group exercises and role-plays facilitated by an epilepsy nurse and a clinical psychologist. **Results:** At three month follow up the treatment group (n=40) was compared with a wait-list control group (n=43) on a range of standardized measures. There was a significant increase in epilepsy knowledge in the treatment group ($p = 0.02$). Participants receiving the intervention were also significantly more confident in speaking to others about their epilepsy ($p = 0.04$). Quality of life measures did not show significant change. Participants reported the greatest value of attending the group was: Learning about their epilepsy (46%); Learning to cope with difficult feelings (29%); and Meeting others with epilepsy (22%). Caregiver and facilitator feedback was positive, and 92% of participants would recommend the group to others. **Conclusion:** This brief psychosocial group intervention was effective in increasing participants' knowledge of epilepsy and improved confidence in discussing their epilepsy with others. We discuss the qualitative feedback, feasibility, strengths and limitations of the PIE trial.

Keywords: Pediatric epilepsy, randomized controlled trial, psychosocial, group intervention, epilepsy knowledge, adolescents.

1. Introduction

Epilepsy is the most common serious childhood neurological disorder, and requires a young person to make substantial psychological and behavioural adjustments in order to manage seizures and to maintain a good quality of life [1]. Despite this, there has been little research on the use of effective interventions to support these adjustments or focus on addressing the psychosocial well-being of young people with epilepsy (YPWE) [2].

It is well documented that young people with epilepsy are at significantly increased risk for psychopathology [3, 4, 5]. Baker et al. [6] found higher levels of depression, lower levels of self-esteem and higher levels of social anxiety. Interestingly, these authors also found that low levels of epilepsy knowledge were associated with higher levels of psychopathology. Adolescents with epilepsy have also been found to have poorer quality of life compared to those with chronic conditions such as diabetes [7], and asthma [8]. Moreover, compared to a healthy control group, YPWE were found to have a significantly higher incidence of attention deficit hyperactivity disorder, generalised anxiety disorder, major depression, separation anxiety, social phobia, tics and oppositional defiant disorder [9].

The documented poor educational and social outcomes [10, 11] experienced by many people with epilepsy, and the high health and social care costs [12] indicate that the consequences of epilepsy for the individual and for society are very significant. Therefore, developing early interventions aimed at improving the psychosocial well-being of YPWE would seem important.

A few previous studies have suggested group interventions may be a useful means to provide psychosocial care for YPWE [2]. There is some evidence that psychological therapeutic groups focused on changing young people's cognitions and illness appraisals, as well as enhancing their coping skills, may be an effective treatment for psychosocial difficulties associated with paediatric epilepsy [13-15]. Funderburk, McCormick and Austin [16] also found that YPWE who have a more positive attitude towards having epilepsy are less likely to have poor self-concept and behaviour problems. Furthermore, previous research has shown that children's perceptions of their quality of life can be significantly related to the social impact of

their epilepsy, including problems with peer acceptance, academic difficulties, fear of having seizures, and taking medication [17, 18]. Fayed et al. [19] reported that social and mental health support appears to have a positive relationship with the child's quality of life. The implications of this research and previous studies with other chronic illness groups, suggest that group interventions may be a feasible and effective means to provide psychosocial care for YPWE.

The current intervention, a manual-based Psychosocial Intervention for young people with Epilepsy (abbreviated to PIE), was developed following a series of focus groups studies with children and adolescents with epilepsy [17, 18]. Therefore, the content of the PIE intervention was informed and derived directly from issues raised by young people with epilepsy. Following a pilot study, the intervention was refined through discussion and review by two expert reference group meetings consisting of epilepsy specialist nurses, clinical psychologists and paediatric neurologists held in London and Glasgow. This established a UK network of paediatric clinical psychologists and epilepsy nurses who were trained in the intervention and facilitated the trial in seven paediatric neurosciences centres across the UK.

Using an exploratory RCT design, the central aims of this study were to explore the feasibility and preliminary efficacy of a manual-based psychosocial group intervention for young people with epilepsy. Our two primary hypotheses were that relative to controls, participants receiving the intervention would firstly, show significantly increased knowledge of epilepsy; and secondly, demonstrate improvements in self-management skills. We also set a secondary hypothesis that participants would demonstrate improvements in quality of life. Whilst the PIE intervention was not a mental health treatment per se, we also aimed to monitor the psychological health of participants during the conduct of the trial.

2. Methods

2.1 Study design

The study employed a randomized controlled trial (RCT) design using a wait list control group as recommended for the development and evaluation of complex health interventions [20]. The design was implemented across seven tertiary paediatric neuroscience centers in the UK. The West of Scotland NHS Research

Ethics Committee 3 approved this study and all relevant NHS health boards obtained local ethical approvals.

2.2 PIE protocol

The PIE intervention ran over six weeks and consisted of weekly group sessions lasting 120 minutes; with the first and last sessions lasting 150 minutes to allow time for the completion of measures. The groups were facilitated by an epilepsy nurse and a clinical psychologist. Each week a separate theme was focused on and delivered using a mixture of facilitator led didactic psycho-education along with open group discussion, paired work, role plays, and educational videos/audio clips. There were homework tasks for participants on most weeks, providing further skill learning and resources. Caregivers were invited to wait in a separate room and given work sheets for the corresponding group session. Participants were sent reminder appointment letters in between group sessions.

The first three sessions of the PIE intervention focused on; sharing experiences of having epilepsy, increasing epilepsy knowledge, and improving self-management of the condition. For example, 'self-management' covered medication adherence, managing medical appointments, improving sleep, discussing the ketogenic diet, and considering issues such as driving. Sessions 4-6 focused on increasing resilience and developing coping strategies for anxiety or low mood through strategies such as problem solving, and techniques based on cognitive behavioral therapy (CBT) [21] and mindfulness [22].

2.3 Participants

This was an exploratory trial and the sample size was not based on a power calculation. Using incidence and prevalence data obtained from the Scottish Paediatric Epilepsy Network (SPEN) audit [23] of General Practice, we aimed to recruit 20 participants per research site (initially 10 across the UK). Unfortunately, due to staffing and logistical problems, three sites withdrew from the study prior to recruitment. In line with research recommendations the authors aimed to recruit between 6 and 10 participants per group to ensure that there are enough verbal participants [18]. Therefore, this study aimed to recruit a total of 84-140 participants across seven research sites. The size of each group varied between 4-7, and were

not combined across centres. The children were randomised using two age categories, mental health support and gender.

2.4 Inclusion and exclusion criteria

Young people were recruited if they a) had the ability to give written informed consent, b) had a diagnosis of epilepsy (controlled or refractory) of at least six months duration, c) were aged between 12-17 years old, d) had a level of expressive and receptive English language abilities judged to be sufficient to enable them to fully participate and contribute to the group process, and e) attended mainstream schooling. Participants were excluded if they a) had a formal diagnosis of Learning Disability or attendance at a school for children with Special Educational Needs, b) if, during the screening protocol, they reported suicidal ideation and/or scored ≥ 40 on the Beck Depression Inventory for Youth (BDI-Y) and Beck Anxiety Inventory for Youth (BAI-Y) [24], c) had a diagnosis of non-epileptic seizures in the absence of epileptic seizures, or d) epilepsies occurring in the context of: i) postnatally acquired structural lesions (e.g. brain injury or neuro-oncological conditions), ii) immune mediated disorders (e.g. limbic or anti-NMDAR encephalopathy) or iii) metabolic disorders (e.g. GLUT1 deficiency).

2.5 Screening, recruitment and consent

Participants were selected from the caseload of regional paediatric neurosciences centres, and subsequently informed about the study by their medical consultant or epilepsy nurse when attending the epilepsy clinic or via telephone/post. Age-appropriate information sheets explaining the nature and purpose of the research were provided to both young people and their caregivers. Recruitment took place over a four-month period from April to July 2015.

If interested in taking part, the participant and caregiver arranged to meet with the clinical psychologist or epilepsy nurse. During this session, they were given a further opportunity to ask questions about the group. Participants were asked to sign the consent form if they wanted to take part in the study. Caregivers and participants were then asked to complete the participant and caregiver questionnaires.

Participants were screened for mental health difficulties and/or suicidal ideation

using the BDI-Y and BAI-Y. Alternative therapeutic support by the clinical psychologist was available for participants not meeting the inclusion criteria.

2.6 Randomization and blinding

Participants were randomly allocated to the intervention or control conditions using a stratified (block) randomisation protocol based on age, gender and type of mental health support. The participants were divided by age (2 levels: ages 12-14, ages 15-17), gender (2 levels: female, male) and type of mental health support (2 levels: receiving support, no support). Participants were then assigned to either the treatment or control condition using an Excel random number generator. Study participants and the interventionists delivering PIE could not be blinded; however, the second author inputting the data remained blinded until study completion.

2.7 Data collection

Data was collected at seven time points. Data collection (DC) 1 represents baseline data which was collected from all participants prior to the first intervention group. DC 2 occurred immediately after the last group session, with control participants completing their measures at home and returning via post. DC 3 occurred three months after the first intervention; all participants completed their measures at home and returned them via post. The treatment group completed postal measures again at 6 months follow up (DC 5). The control group attended the PIE intervention after the 3 month follow up data was collected. For this group, DC 3 represents their baseline measures prior to them receiving the PIE intervention. Data collected at time points 4 (end of intervention), 6 (3 months follow up) and 7 (6 months follow up) were completed only by the control group. Qualitative data regarding participant and caregiver feedback data was collated from all participants at the end of both interventions.

For the RCT statistical analyses the quantitative data from the intervention group and wait list control groups were compared using the data taken at baseline (DC 1), immediately following the intervention (DC 2), and three months after the intervention (DC 3). Data collection points and the RCT design are outlined in Figure 1.

Insert Figure 1 here

2.8 Intervention fidelity

As previously discussed the PIE manual was developed and informed from previous focus groups [17, 18]. One day training sessions were provided by the first and second authors who are both experienced clinical psychologists. The training focused on developing expertise with the content of the manual and the theoretical approaches used within the intervention. Weekly supervision sessions were also provided by the first and second authors when required. Audio recordings of each session were also sent to the second author to be checked for fidelity ratings.

2.9 Intervention feasibility

To assess the feasibility of running a psychosocial group intervention we measured participant attrition rates, reasons for withdrawal, completion of outcome measures and attendance/completion of sessions. Participants were classified as completing the group intervention if they attended at least two out of three sessions from the first and last three group sessions. To assess 'acceptability' we asked participants, caregivers and facilitators to complete evaluation forms.

2.10 Study outcome measures assessing efficacy

The efficacy of the intervention was evaluated using a range of standardized and bespoke measures:

Quality of Life measures:

- Paediatric Quality of Life Inventory PedsQL™ version 4.0 [25]

The multidimensional PedsQL™ 4.0 Generic Core Scales encompass the essential core domains for paediatric health-related quality of life measurement: 1) Physical Functioning (8 items), 2) Emotional Functioning (5 items), 3) Social Functioning (5 items), and 4) School Functioning (5 items). A higher score reflects greater quality of life. The instrument takes approximately 5 minutes to complete and internal consistency reliability is high (> 0.90).

- Glasgow Epilepsy Outcome Scale for Young Persons (GEOS-YP) [26]

The GEOS-YP is a UK norm referenced, 45 item self-report questionnaire that provides a direct measure of how adolescents perceive epilepsy impacts their quality

of life. A higher score reflects greater quality of life. The GEOS-YP has sound psychometric properties and provides a relatively brief and potentially useful clinical outcome tool.

Epilepsy self-knowledge and self-management:

- The Epilepsy Knowledge Profile-General (EKP-G) [27]

EKP-G is a 55-item questionnaire consisting of true and false items; 34 items are about medical knowledge and 21 items cover social knowledge. The questionnaire takes about 10 minutes to complete. The scale has been shown to have both good internal and test–retest reliability [29]. In terms of accessibility, evidence indicates that the scale is "user friendly" and that EKP–G scores are sensitive to differences in patient knowledge [29]. The results can be analysed in terms of total scores or replies to specific items. A higher score indicates greater knowledge of epilepsy.

- Seizure Self Efficacy Scale for Children (SSEC-C) [28]

The SSEC-C [25] is a 15-item scale that measures the degree of self-efficacy related to the management of the seizure disorder. Children rate each statement on a 5-point scale of 1 (*I'm very unsure I can do that*) to 5 (*I'm very sure I can do that*). Sample items include "I can manage my seizure condition even if I am at a friend's, on vacation, or on a school trip." "I can talk to the doctor or nurse if I have questions about my seizure condition." Summing across all items and dividing by the number of items obtains a mean score. A higher score reflects greater self-efficacy. Support for reliability and validity has been found [25].

- Brief - Illness Representations Questionnaire (B-IPQ) [29]

The B-IPQ measures Leventhal's eight components of illness representations; consequences of illness, expected duration of illness, ability to personally control symptoms, ability of treatment to control symptoms, influence of illness on personal identity, concern about illness, understanding illness, and emotional response to illness. Specific items are scored on a 0-10 Likert scale ranging from 'no affect at all' to 'severely affects my life'. A higher score reflects that the individual perceives their illness as more of a threat than benign. The B-IPQ has been shown to have good test-retest reliability and concurrent validity with similar measures. It has also been

shown to have good predictive validity with individual items being related to mental and physical functioning at 3 months' follow up [29]. The B-IPQ has been used with adolescents, and validated in populations with diabetes and asthma [30, 31].

Psychological Adjustment:

- Paediatric Index of Emotional Distress (PI-ED) [32]

Given the importance of screening for suicidal ideation in youth with epilepsy, the BDI-2, which has an item assessing suicidal ideation was chosen for the screening protocol. The PIED normative data was, however, felt to be more appropriate for the current sample (i.e., youth with a chronic illness who do not have a clinical diagnoses of depression). The PI-ED is a self-rating scale used as an early screening tool of psychological symptoms. It is based on the Hospital Anxiety and Depression Scale (HADS). The PI-ED comprises of 14 questions exploring the young person's symptoms of anxiety and depression. A higher score reflects moderate to severe mental health difficulties. It uses appropriate language and concepts for use with young people. It has been shown to have predictive validity and can differentiate between symptoms of emotional distress and those of physical illness. Therefore, it can be used with children who have a physical illness, as it will not confound physical symptoms of distress with those of a physical condition. A cut-off score identifies those that require further clinical assessment and intervention.

Subjective measure of quality of life, social functioning and seizure control:

- Participant questionnaire.

Participants completed a tailor-made questionnaire at baseline, following the last group session, and at 3 and 6-month follow-up. The questionnaire assessed the impact of the intervention on the participants social functioning (e.g. spending time with friends, confidence talking to others about their epilepsy), quality of life, and changes in seizure activity, and self-management skills of their epilepsy.

- Caregiver questionnaire

Caregivers also completed a tailor-made questionnaire at baseline, following the last group session, and at 3 and 6 month follow up. The questionnaire explored whether

the caregiver observed any changes in their child's quality of life, social activities and seizure activity.

2.11 Study outcome measures assessing feasibility

The following outcome measures were completed at the end of the first and second PIE intervention:

Experience of service use and quality:

- Commission for Health Improvement-Experience of Service Questionnaire (CHI-ESQ) -Caregiver and young person self-report versions, [33].

The CHI-ESQ consists of 12 items and three free text sections for the client to write about what they like about a service, what they think needs improving and any other comments. CHI-ESQ was devised from focus groups by the Care Quality Commission to determine client satisfaction with services. It has been piloted with carers and children and has been found to have high face validity.

- Service evaluation form

A tailor-made evaluation form provided feedback from participants about their experience of being part of the group intervention and invited suggestions for improvements to the group content or set up.

- Facilitator feedback

In addition to reporting on participant attendance and reasons for withdrawal, facilitators were also asked to complete a PIE evaluation questionnaire. This questionnaire explored whether PIE was practical to run for clinicians and invited thoughts on how delivery of the intervention might be improved.

2.12 Statistical methods

Descriptive statistics are presented as frequencies or means \pm standard deviation (SD). Intention-to-treat analysis is reported. At six weeks (end of intervention) and three months' post-intervention the treatment group was compared with a wait-list control group on a range of standardized measures. Total scores for continuous data

were analysed using two-sample t-tests to compare the treatment and control groups at end of intervention and 3 months follow up. Data not meeting requirements for parametric analysis were analysed using Mann-Whitney tests and McNemar's test was used for analysis of binary data. For continuous data the results will be summarised as means and p values. Ordinal data will be summarised as differences between the change in the median and p values.

To assess effect sizes for continuous data, we used Cohen's effect size d , with $d \geq 0.2$ being classified as small, $d \geq 0.5$ as medium, and $d \geq 0.8$ as a large effect [34].

Data missing at all time points after baseline, where baseline measures were available, were replaced by the group median value at that time point. Those without any baseline were not included in the analysis.

A repeated-measures ANOVA was performed for each outcome measure in the treatment group across the three time points; 6 weeks, 3 months and 6 months, to analyze if changes had been sustained. Pairwise comparisons were completed between baseline and three months, baseline and 6 months and three months to 6 months. Bonferroni correction was applied to the multiple comparisons.

Feasibility data from bespoke measures (using open, closed and likert scale questions) from sixty-four participants, fifty-two caregivers and all facilitators are summarized in the results sections 3.5 to 3.8 and in tables 5 and 6. Similar responses to open-questions were grouped in to the same category. Only data from the free text sections on the CHI-ESQ are reported.

3. Results

3.1 Recruitment and characteristics of the sample

A total of 85 participants were screened for eligibility. Two participants withdrew before randomization. Therefore, 83 participants across seven research sites were randomized to either the control (43 participants) or intervention (40 participants) group. Frequency of missing data are highlighted in Figure 2, which presents the CONSORT participant flow diagram.

Insert Figure 2 here

Demographics for all participants that provided data at baseline are summarized in Table 1. Differences between the control and intervention group were minimal and well-balanced. The mean/median age of participants was 14 years; however, the full age range across 12-17 years was represented. The most common diagnosis was genetic generalized epilepsy and the most common type of seizure reported was generalized tonic-clonic. No participants had a diagnosis of non-epileptic attack disorder. Ninety-eight percent of participants were taking anti-epilepsy drugs (AEDs). Approximately 1/3 of the sample was receiving additional support in mainstream education.

Insert Table 1 here

There was a low incidence of mental health difficulties reported by participants at screening using the BDI-Y and BAI-Y, and during the conduct of the trial using the PIED. The PI-ED has a clinical cut-off score of 20 [35], therefore all participants in this sample were classified as being in the 'non clinical' range, with their scores remaining stable post intervention and at 3-month follow-up. BDI-Y and BAI-Y scores from the screening data were compared to normative scores in the manual [22]. The current sample was found to be twice as likely to be in the 'extremely elevated' range for anxiety (8%) compared to the normative sample (4%). There were no differences found between the test norms and the current sample for low mood (as measured by the BDI-Y).

3.2 Main outcome measures

There was a significant increase in epilepsy knowledge in the treatment group at 6 weeks ($p = 0.04$, $d=0.25$), with an increased effect size at 3 months' follow-up ($p = 0.02$, $d=0.58$). There was a positive trend found on the GEOS-YP, BIPQ, PI-ED and SSEC in the intervention group, however these differences were not statistically significant at post-intervention or at 3-month follow-up (see Table 2).

Insert Table 2 here

3.3 Caregiver and participant questionnaires

Using baseline data obtained at the screening interview prior to completion of main outcome measures, there were no significant differences were found between the intervention and control group on frequency or severity of seizures, parental concern, child quality of life, or the child's social activities as reported by the caregivers (see Table 3).

Insert Table 3 here

When analyzing the young person's questionnaire responses (see Table 4), it was found that after attending the PIE group, the participants in the intervention group were found to be significantly more 'confident in talking about their epilepsy' compared to participants in the control group at 6 weeks ($p=0.04$) and this was sustained at 3 months ($p=0.04$).

Insert Table 4 here

3.4 Follow-up data for control and treatment groups

Further analysis was conducted to investigate if the significant findings on the EKP-G and 'confidence talking to peers' in the intervention group were sustained at 6 month follow up. The original analysis (see Table 2 and 4) looked at change over time for the intervention group relative to the control group. However, for the 6 month follow up analysis there was no control comparison because the participants from the control group attended the PIE group after the 3-month data collection. Therefore, a repeated measures ANOVA was performed for the EKP-G across the three time points in the intervention group only. Pairwise comparisons were then conducted between baseline and 3 months, baseline and 6 months and 3 months to 6 months. Bonferroni correction was applied to the multiple comparisons. A significant difference was found between all three time points ($p<0.001$). There was also a

significant increase from baseline to three months ($p < 0.001$) which was sustained to 6 months. Hence, participants' knowledge on epilepsy continued to increase following the PIE intervention and was maintained 6 months' post-intervention.

In relation to 'confidence talking to others about my epilepsy' only 15% of participants were 'very confident' in talking about their epilepsy at baseline, rising to 41% after the intervention and remaining at 35% at 6 month FU. It is also of note that whilst 18% were 'not confident' in discussing their epilepsy at baseline, this reduced to 0% at 6 months follow up (FU).

3.5 Feasibility data

The intervention group had an attendance rate of 83% ($n=33$), with a lower attendance rate (65%, $n=28$) in the control group. This may be explained by the fact that the control participants were enrolled into the study five months before receiving the intervention, and many had made other commitments. The postal return rate at 3 months was positive, with 73% ($n=29$) of the intervention group and 81% ($n=35$) of controls returning data. However, this decreased at 6 months to 50% in the intervention group. Reasons for missing data were known in 16 cases. Three withdrew as they no longer thought the intervention was needed (due to being seizure free), whilst 13 withdrew due to life events (such as illness) or transport difficulties.

64 participants completed evaluation forms. All of the participants stated that the group was well organized (100%) with excellent materials provided (85.9% $n=55$). Most participants also reported enjoying the activities in the group (95.3% $n=61$) in addition to rating the facilitator's performance as good (17.1% $n=11$) or excellent (76.6% $n=49$).

3.6 Qualitative Feedback – Participants

Nearly all participants stated they would recommend the PIE group to others with epilepsy (94%, $n=60$). The most common responses regarding the greatest value of attending PIE was 1) Learning more about their epilepsy (46%, $n=31$), 2) How to manage difficult feelings (29%, $n=20$) and 3) Meeting other young people with epilepsy (22%, $n=15$).

The tailor-made questionnaires provided an 'additional comments' section for young people and caregivers to respond with anything they wanted to feedback about the PIE group. It is clear from these comments that PIE helped the young people feel less isolated, learn more about their epilepsy and improved their confidence (see Table 5).

Insert Table 5 here

3.7 Qualitative Feedback – Caregivers

Most caregivers stated that the PIE group had helped their child and thought that the facilitators running the group were helpful.

Insert Table 6 here

As demonstrated by the comments in Table 6, caregivers felt the PIE group helped their child to not only learn more about their epilepsy, but also encouraged them to express their feelings and develop confidence to take part in new activities. These comments also illustrate how a child talking about their epilepsy to their peers can help reduce stigma and isolation.

3.8 Qualitative Feedback – Facilitators

Facilitators commented that they enjoyed delivering the different therapeutic sessions in PIE such as thought challenging, problem-solving and mindfulness strategies. Facilitators' most popular component of PIE was the relaxation/mindfulness session and the session on psycho-education of epilepsy/seizures.

All 14 facilitators completed the feedback forms. Overall, facilitators reported that the content of PIE was helpful to the young people and that it was a good use of clinical resources. When asked, 'do you feel PIE represents a good use of clinical time?', 84% responded saying 'yes', 8% responded saying 'yes, if more young people were able to attend' and 8% stated 'possibly, if it's run as a workshop over one or two days'.

The majority of facilitators (70%) reported that the group should be run again, with 26% stating they would run the group, but with modifications such as more flexible group discussion, using one therapeutic modality and making sure at least 6 participants were able to attend the group. Two facilitators (4%) stated they would run the group again, but as a workshop as opposed to six weekly sessions.

3.9 Qualitative Feedback – What could be improved?

Most young people attending the intervention felt nothing needed improving (54.7%, n=35), however others suggested that in the future having follow-up sessions, using more music or videos and having larger groups would be better.

Facilitators and caregivers reported that additional follow up sessions would be helpful to the young people to encourage the development of new friendships and further reduce their feelings of isolation. Facilitators also thought that a parent group, which ran alongside PIE, may be helpful in alleviating some of the caregivers' anxieties in addition to providing professional advice specific to their child's difficulties. Other suggestions included running PIE as a workshop over two days, using one psychological modality in the last three sessions, and introducing short mindfulness exercises at the start of each group session. Two caregivers were concerned that some of the young people were negative about having epilepsy. However, the most common response was that nothing was needed to improve PIE (82.7%, n=43).

4 Discussion

The PIE intervention was found to be effective in increasing epilepsy knowledge; a factor previously linked to better mental wellbeing [6], and noted to significantly improve young people's confidence when talking about epilepsy to their peers. This could be an important factor in improving friendship quality and participation in group activities. Many young people with epilepsy report feeling isolated from peers [6, 14] and this can have an important developmental cost during adolescence - a period where young people typically engage as a group in behaviours associated with a level of risk as they navigate the increased levels of autonomy and independence available to them. The importance of participation in 'normal' group learning

experiences and activities during adolescence offers key opportunities for personal growth, and social exclusion may be linked to later negative outcomes such as poorer quality of life (QoL) [36]. Another significant finding from the trial was that participants became self-guided learners and ‘discoverers’ about their own condition after the intervention was completed, as they continued to evidence increased knowledge about epilepsy at 3 and 6-month follow-up.

There was a low incidence of mental health difficulties amongst our participants at screening and, therefore, PIE had no effect on improving mental health (as assessed with standardized clinical measures). The PIE intervention was designed as a brief psychosocial, multi-component intervention and not as a high-intensity mental health intervention. The signals from the self and parent reported qualitative data indicated improvements in participants’ sense of confidence and inclusion, and may indicate that group therapies such as PIE may be important in preventing or moderating the development of more serious later mental health disorders.

Whilst we did find improvements in epilepsy knowledge and confidence, we did not find any significant improvement on participant’s health-related QoL immediately following the groups, or at 3 and 6-month follow-up. This somewhat disappointing result may indicate that increases in subjective QoL require major changes in social relationships, health status, or participation in new activities to alter self-perception of one’s life having significantly improved. We note that one study found improvements in aspects of QoL, such as social exclusion, using a group intervention for CYPE [14]. It is, therefore, important to consider what type of intervention is likely to improve particular aspects of self-rated QoL, as health related QoL is a multi-faceted complex construct. A few studies have suggested that some families alter the pattern of their activities with more time spent at home following an epilepsy diagnosis [37], which is consistent with our clinical experience. Indeed, one of the major roles of the epilepsy nurse is to advise on maintaining activities, and getting the balance right between this and recommending adequate safety measures, while also normalizing the anxiety that both young people and their carers may experience regarding participation in community and holiday based activities. These dimensions of care were discussed within the PIE groups and would hopefully lead to further discussion during future individual clinic appointments. Another factor often cited in studies

looking at QoL trajectories in pediatric epilepsy concerns 'AED side effects', often reported as memory and attention problems or fatigue. Again, a brief intervention such as PIE might not remove these concerns, but can instill more awareness and confidence in discussing these issues with the epilepsy care team.

The trial facilitators were keen to continue using the intervention, and PIE could, with modification, become part of the standard care pathway for young people with epilepsy. A further benefit expressed by the PIE interventionists was that joint working between clinical psychologists and specialist epilepsy nurses subsequently improved the routine care provided for YPWE within neurosciences centres; including more efficient discussion of patients, and in defining psychosocial and mental health care pathways

The feasibility data collected suggests the intervention was highly acceptable; with young people reportedly feeling less isolated, more confident and more able to manage difficult thoughts and feelings. Moreover, carers reported that young people were more confident in talking about their epilepsy and in trying new activities, such as swimming and attending 'sleepovers' with friends.

Limitations and lessons learned

The PIE trial required that participants completed extensive questionnaire packs at 6 time points, often via post. The length of time required to complete questionnaires was an issue for participants, and the logistical challenges of gathering extensive follow-up data was also a significant challenge for the investigators. It may be beneficial for future studies to provide a voucher system or monetary reward for participants on completion of follow-up measures (this was not approved by the ethics committee for the present study).

An important concern within any trial is whether there is a systematic bias inherent in patterns of missing data, which happens if data are not missing at random. For example, if missing data are more likely to occur in participants with high v low seizure severity, and if difference in outcome measures is expected between these groups, then a simple imputation strategy using group medians to replace missing data would potentially not represent the missing data effectively. However, given the

nature of the data and the low variability in the scores for this fairly uniform sample of participants, with a lack of any clear difference between those with missing data and those without, we felt a simple data imputation strategy using group medians was justified. However, we acknowledge that the choice of imputation strategy can influence the obtained results.

We did not find improvements on measures of quality of life, in contrast to the consistent positive signals obtained from the young people's qualitative feedback. In obtaining funding for trials such as PIE there can be a bias for studies using standardized outcome measures; however, these can be insensitive to the changes that occur within an intervention such as PIE. Future studies should consider the optimal ways in which to measure and describe more sensitively the changes that may be expected given the intervention content. This trial had its developmental origins in the use of qualitative focus group methods, and perhaps post-intervention interviews or other enriched qualitative approaches would be more useful in assessing the value and outcomes of future interventions.

We used both CBT and mindfulness approaches within the intervention and in future would consider using only one therapeutic modality such as mindfulness, or ACT given its emerging evidence base for adolescents and people with epilepsy [38, 39]. Whilst we had a low incidence of mental health disorder in this study, there is a clear need for highly specified mental health interventions for CYPE, potentially using group based delivery.

The use of a manual-based intervention can also make discussion feel less flexible, e.g. therapists might feel they must move on from important conversations prematurely to cover the content for each session. However, they do provide a standardized and practical approach to delivering interventions and assessing effectiveness between service providers.

Several facilitators suggested running PIE over a two-day workshop, which although might reduce attrition, probably would not allow time for friendships to grow between participants or caregivers; neither would it allow time for enough home tasks to be completed or for participants to practice new coping strategies. Given that the

completion rate was relatively high we recommend running PIE over six weeks to maintain the efficacy of the intervention. Participants stated it was helpful to have travel expenses reimbursed and to receive reminder appointment letters in between group sessions. We also recommend offering families informal monthly ‘top-up’ sessions to maintain newly developed friendships, and support new learning and adaptation.

Future Research

We are currently refining the intervention content and intend to set this up as a treatment option for use by paediatric epilepsy centres. It could also be a potential intervention to be used against other paediatric epilepsy interventions in future trials.

Although the PIE intervention has been developed for use with YPWE, the model of using focus groups/qualitative methods to develop ‘bottom-up’ approaches alongside modified evidence based psychological therapies to developing interventions, could also be adapted for use with other chronic paediatric illness groups. Finally, there is also a need to develop interventions for the parents/carers of YPWE supporting family coping and adjustment.

Summary

The PIE group intervention offers significant potential to improve the clinical care and longer-term outcomes of young people with epilepsy. We have demonstrated using quantitative and qualitative methods that a brief intervention delivered by existing trained staff can increase both knowledge and confidence amongst YPWE, alongside improved mental wellbeing. We believe group-based early interventions such as PIE have the potential to offer effective, holistic care and could serve as a model for other paediatric chronic illness groups.

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Conflict of interest

The authors declare that they have no competing interests.

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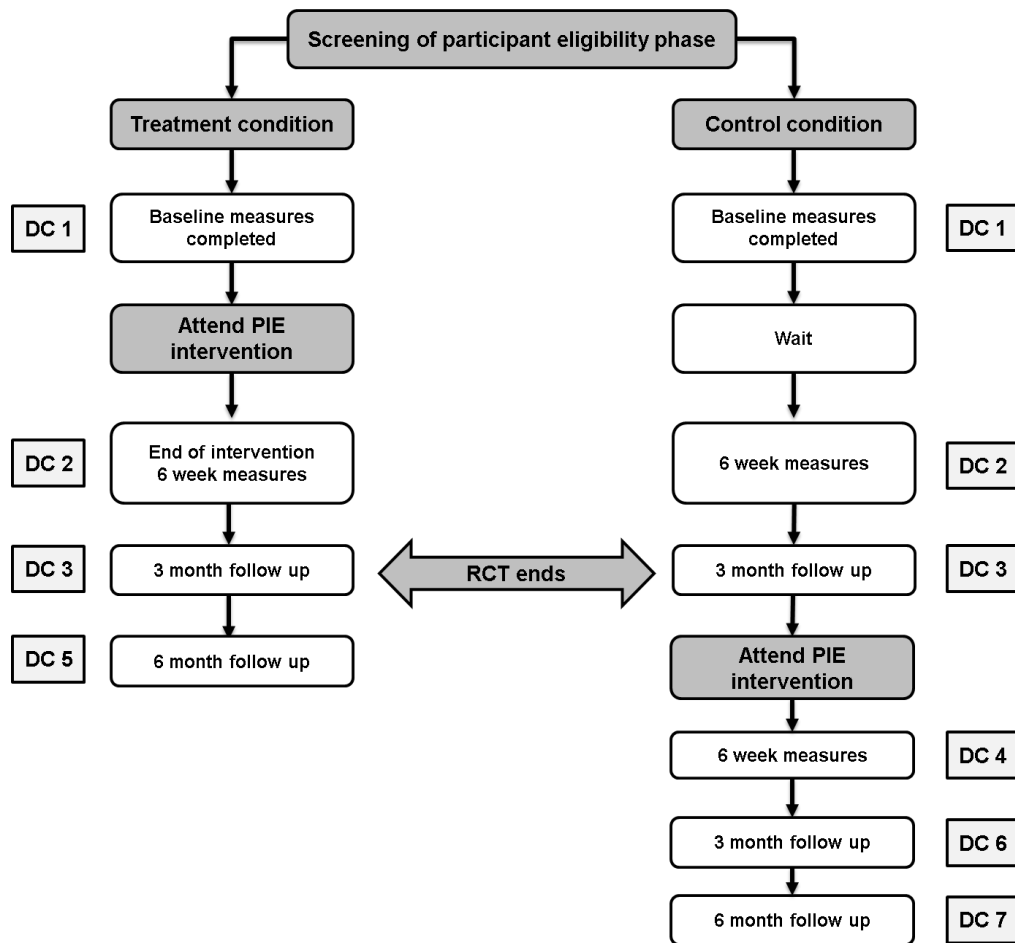


Figure 1. Study flow chart and data collection (DC) time points for intervention and wait list control groups.

Figure 2. CONSORT participant diagram.

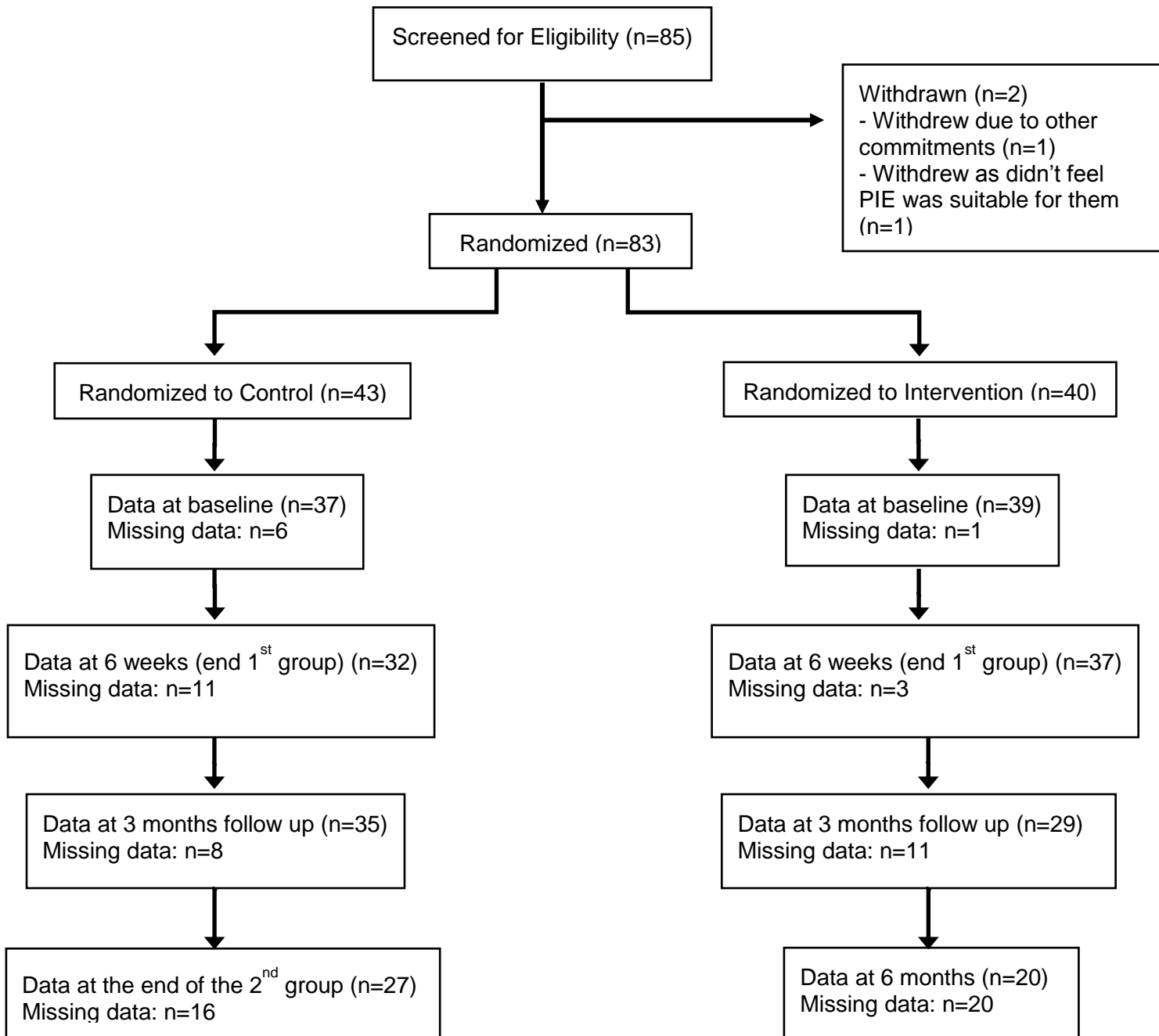


Table 1. Participant characteristics. Values shown as means (SD) or *N* (%).

Characteristic	Intervention (n = 40)	Control (n = 43)
Gender, female <i>N</i> (%)	26 (65.4)	24 (66.7)
Age (years), mean \pm SD (range)	14.4 \pm 1.5 (12-17)	14.3 \pm 1.4 (12-17)
Type of epilepsy		
Genetic generalised epilepsies (including JME, JAE & CAE)	20 (50%)	21 (48.8%)
Focal (unspecified)	15 (37.5%)	18 (41.9%)
Benign rolandic epilepsy	3 (7.5%)	3 (7%)
Unknown	2 (5%)	1 (2.3%)
Type of seizures*, <i>N</i> (%)		
Generalised clonic/tonic-clonic	25 (43.1)	29 (40.8)
Focal	12 (20.7)	19 (26.8)
Absences	16 (27.6)	16 (22.5)
Myoclonic	4 (6.9)	5 (7.1)
Status epilepticus	1 (1.7)	1 (1.4)
Tonic	0 (0)	1 (1.4)
Duration of epilepsy (years), mean \pm SD (range)	7.4 \pm 3.9 (2-16)	5.6 \pm 3.5 (1-16)
Number of AED, <i>N</i> (%)		
0	2 (5)	0 (0)
1	21 (52.5)	30 (69.8)
2	13 (32.5)	11 (25.6)
3	4 (10)	2 (4.6)
Type of medication*, <i>N</i> (%)		
Levetiracetam	17 (29.8)	14 (25)
Lamotrigine	15 (26.3)	8 (14.3)
Sodium Valporate	8 (14)	13 (23.2)
Carbamazepine	3 (5.3)	10 (17.9)
Topiramate	4 (7)	3 (5.35)
Clobazam	1 (1.75)	3 (5.35)
Oxcarbazepine	1 (1.75)	2 (3.6)
Ethosuximide	3 (5.3)	0 (0)
Sultiame	2 (3.5)	0 (0)
Phenytoin	1 (1.75)	1 (1.8)
Perampanel	0 (0)	1 (1.8)
Lacosamide	1 (1.75)	0 (0)
Midazolam	1 (1.75)	0 (0)
Zonisamide	0 (0)	1 (1.8)
Educational Support, <i>N</i> (%)	15 (37.5)	16 (37.2)
Mental health support, <i>N</i> (%)		
No support	34 (85)	35 (81.4)
School counsellor	2 (5)	2 (4.7)
CAMHS	3 (7.5)	4 (9.2)
Tier 4 Specialist Service	1 (2.5)	2 (4.7)
BAI-Y, mean \pm SD (range)	51.8 \pm 11 (31-77)	49.5 \pm 10.4 (33-77)
BDI-Y, mean \pm SD (range)	51.2 \pm 10.3 (34-76)	47.8 \pm 9.7 (34-73)
PI-ED, mean \pm SD (range)	13.6 \pm 6.2 (3-30)	12.8 \pm 7.8 (0-28)

Note. SD, standard deviation; JME, Juvenile myoclonic epilepsy; JAE, Juvenile absence epilepsy; CAE, Childhood absence epilepsy; AED, Anti-epilepsy drugs; CAMHS, Child and adolescent mental health service; BAI-Y, Beck Anxiety Inventory-Youth Version; BDI-Y, Beck Depression Inventory-Youth Version; PIED, Paediatric Index of Emotional Distress.

*Participants could answer more than one item.

Table 2. Means, standard deviations, and difference of change between intervention and control group for all continuous outcome measures at baseline, post-intervention and at 3 month follow up.

Outcome	Mean (SD)						Difference of change between intervention and control group (95% CI)	
	Intervention			Control			Baseline - Post	Baseline - 3 month FU
	Baseline (n=39)	Post (n=39)	3 month FU (n=39)	Baseline (n=37)	Post (n=37)	3 month FU (n=37)		
PI-ED	14.49 (6.61)	14.95 (6.39)	13.72 (5.86)	12.76 (7.84)	13.39 (6.69)	13.95 (7.76)	0.2, (-3.03, 2.64) ns	1.8, (-4.32, 0.67) ns
EKP-G	39.15 (5.28)	41.36 (5.05)	43.36 (3.24)	39.87 (4.69)	40.29 (3.75)	41.10 (4.41)	2, (-0.00, 3.99) p = 0.04 ^{†a}	3, (0.00, 5.00) p = 0.02 ^{†b}
GEOS-YP	62.61 (14.85)	63.82 (14.43)	65.83 (11.62)	66.20 (13.95)	66.83 (11.85)	66.16 (12.13)	0.5, (-3.75, 4.77) ns	2.1, (-2.43, 6.68) ns
PedsQL	70.93 (15.41)	67.61 (14.10)	67.79 (11.74)	69.36 (19.42)	66.93 (17.28)	69.19 (17.79)	0.9, (-7.18, 5.40) ns	3.6, (-9.76, 2.49) ns
BIPQ	36.26 (12.32)	36.38 (12.77)	35.72 (12.00)	34.47 (13.54)	34.87 (12.75)	34.95 (13.33)	0.1, (-4.97, 4.70) ns	1, (-6.45, 4.54) ns
SSEC	57.15 (14.72)	60.23 (10.34)	60.69 (8.23)	59.26 (12.80)	60.84 (9.91)	60.55 (10.45)	1, (-4.00, 6.99) [†] ns	0, (-3.99, 5.01) [†] ns

† indicates nonparametric test

^acohen's d = 0.25

^bcohen's d = 0.58

Note. ns, not significant; SD, standard deviation; CI, confidence interval; FU, follow-up; PIED, Paediatric Index of Emotional Distress; EKP-G, The Epilepsy Knowledge Profile-General; GEOS-YP, Glasgow Epilepsy Outcome Scale for Young Persons; PedsQL, Paediatric Quality of Life Inventory PedsQL™ version 4.0; BIPQ, Brief - Illness Representations Questionnaire; SSEC, Seizure Self Efficacy Scale for Children.

Table 3. Difference of change in median between intervention and control group for all categorical outcome measures completed by caregivers between baseline and post-intervention, and between baseline and 3 month follow up.

Outcome	Difference of change in median between intervention and control group					
	Baseline – post		P value (95% CI)	Baseline - 3 month FU		P value (95% CI)
	Intervention (n=39)	Control (n=37)		Intervention (n=39)	Control (n=37)	
Frequency of seizures	0	0	0.3355 (-0.9997, 0.0000)	-1	0	0.1348 (- 0.9998,- 0.0003)
Severity of seizures	0	0	0.9041 (0.0002, 0.0001)	0	+0.5	0.6192 (-0.0001, 0.0002)
Parental concern	-0.5	0	0.5385 (-1.0001, 0.0000)	0	0	0.5385 (-1.0001, 0.0000)
Epilepsy prevented young person from socializing	0	0	0.9175 (-0.0001, 0.0000)	0	0	0.9175 (-0.0001, 0.0000)
Parental view of child's quality of life	-1	+1	0.1177 (- 0.9999,- 0.0000)	0	+1	0.1992 (-0.9998, 0.0002)

Note. FU, follow-up; CI, confidence interval.

Table 4. Difference of change in median between intervention and control group for all categorical outcome measures completed by young person between baseline and post-intervention, and between baseline and 3 month follow up.

Outcome	Difference of change in median between intervention and control group					
	Baseline – post		P value (95% CI)	Baseline - 3 month FU		P value (95% CI)
	Intervention (n=40)	Control (n=43)		Intervention (n=40)	Control (n=43)	
Young person's quality of life	0	0	0.5770 (0.0001, 0.9998)	0	0	0.7297 (0.0001, 1.0001)
Confidence talking to peers about their epilepsy	0	0	0.0424 (-0.0000, 1.0002)	+1	0	0.0459 (-0.0001, 0.9999)
Worry about seizures	0	+1	0.7698 (-1.0001, -0.0001)	0	0	0.8128 (-1.001, 1.000)
Epilepsy prevented young person from socializing	+1	-1	0.7586 (-0.000, 1.000)	0	-1	0.7020 (-1.000, -0.000)
Confidence managing epilepsy	0	0	0.7102 (0.0001, 0.0001)	0	0	0.7102 (0.0001, 0.0001)

Note. FU, follow-up; CI, confidence interval; ns, not significant.

Table 5. Selected illustrative quotes from young people on their experience of attending PIE.

Comment

"It was lovely to get the chance to meet people with similar experiences to myself, it made me feel less alone, more understood and happier". (F, 15).

"I enjoyed my time and learned a lot about my condition. I also met others like me!" (F, 16).

"I will miss the people. It was great because I made new friends". (M, 14).

"It helped me correct rumours about epilepsy and learnt more about it". (F, 16).

"I feel less alone with my epilepsy. It was a relaxed environment to talk about epilepsy". (F, 16).

"Everyone has been kind and helpful and it's boosted my confidence about my epilepsy". (M, 14).

Table 6. Selected illustrative quotes from caregivers on their experience of their child attending PIE.

Comment

“By attending these meetings my child has opened up about their condition. She’s also learnt more about her condition and has more confidence asking questions in clinic”.(Child = F, 17).

“It hasn't changed anything with my child's seizures but it has definitely helped my child's confidence! Previous to this course none of his peers knew of his seizures but after only 2 sessions he had confidence to tell some of them. It has helped him see that he isn't the only one with seizures and he can share how he feels. He has made friends he will keep in contact with and this course has been incredibly valuable and we are very grateful of being involved”. (Child = M, 13).

“I was treated with respect and was given sufficient information about what each session was about. It was a good chance to speak to other parents about their feelings and emotions about our children”.(Child = F, 14).

“The PIE group has been good for him to interact with other teenagers going through similar worries to his. He's even signed up for swimming lessons and looks forward to getting out more”. (Child = M, 12).

“It has been a great help and support to my child and myself – to have the opportunity to discuss epilepsy with other parents in a similar situation. My child is very sad the group has finished and I feel she would really benefit from it continuing every 3-4 months”. (Child = F, 14).

“I'm very pleased with this service I wish there was something like this earlier when my child was first diagnosed. The sessions have helped my son understand his condition and also meeting other teenagers in same situation has been an eye opener. My child appears to be more content and able to talk about feelings and what may be playing on his mind, whereas he wouldn't have before. Overall these sessions have been of benefit to him thank you for the opportunity to take part”.(Child = M, 16).
