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Coping with Stress: A pilot study of a self-help stress management intervention for patients with epileptic or psychogenic non-epileptic seizures

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Abstract

Purpose: Many patients with epilepsy or psychogenic non-epileptic seizures (PNES) experience high levels of stress. Although psychological interventions have been developed for seizure disorders, few patients can currently access them. We aimed to assess the acceptability and feasibility of a self-help intervention targeting stress in patients with seizures, and to provide preliminary evidence for its effectiveness.

Method: Patients were recruited from outpatient neurology clinics and randomised to an immediate intervention group ($n=39$), who received the intervention at baseline, or a delayed intervention group ($n=43$), who received the intervention one month post-baseline. Participants completed self-report questionnaires measuring stress (SSSI), anxiety (GAD-7), depression (NDDI-E), quality of life (EQ-5D), seizure severity and frequency (LSSS-3) at baseline, and at one- and two-month follow-up. Participants also provided telephone feedback. The intervention consisted of a self-help stress management workbook based on an integrative stress model framework.

Results: Although the rate of participants failing to return follow-up information at two months was approximately 50%, those who completed the trial found the intervention acceptable; with the majority rating it as helpful (63.6%) and that they would recommend it to others with seizures (88.1%). A significant reduction in self-reported stress ($p = 0.01$) with a medium effect size ($d_z = 0.51$) was observed one-month post-intervention. There were no significant changes in any other measures.

Conclusion: The intervention was perceived to be acceptable, safe and helpful by participants. It could be a useful complementary treatment option for reducing stress experienced by patients living with seizure disorders. Further evaluation in a larger trial is warranted.

Keywords: epilepsy; psychogenic non-epileptic seizures; stress; self-help intervention; self-affirmation

1. Introduction

Many patients with epilepsy or psychogenic non-epileptic seizures (PNES) experience high levels of stress, comorbid psychiatric conditions [1, 2], and stigma associated with these disorders [3, 4]. All of this has a negative impact on quality of life (QoL) [5]. In addition, stress is one of the most commonly self-reported triggers of epileptic seizures [6-8]. For some patients with PNES, their events can be best understood as an intrinsic stress defence response to internal or external stimuli. In addition, long-term stress in PNES has been associated with factors that may perpetuate the condition, such as hypervigilance to information perceived as threatening [9].

The psychosocial problems associated with both epilepsy and PNES suggest that patients could benefit from complementary psychological interventions. Indeed, the United Kingdom National Institute for Health and Care Excellence (NICE) guidelines for the management of epilepsy recommend the use of supplementary psychological therapies [10], and there is growing evidence of the benefits of psychological and self-management interventions in improving QoL [11]. Furthermore, there is at least some evidence that non-pharmacological interventions for epilepsy can reduce seizures in some patients [12]. Psychological treatment is accepted as the treatment of choice for PNES [13-15].

Although a number of psychological interventions for epilepsy and PNES have been described, only a minority of patients currently gain access to targeted psychological therapies due to the limited availability of such interventions, providers' practical concerns about offering psychological treatment to patients who may have seizures, and patients' lack of motivation to engage [14, 16, 17]. Few of the programmes shown to be effective in research studies have been put into general use, perhaps because perceived economic constraints and staffing implications associated with these interventions outweigh expectations of patient benefit [16].

Self-help interventions offer a possibly more cost-effective, accessible and acceptable mode of treatment delivery. Such interventions typically involve the active use of brief written materials in the form of books, booklets or leaflets as well as computerised resources, containing information about the given condition and exercises to help patients manage symptoms, designed to be practiced independently, with varying degrees of assistance from a healthcare professional [18, 19]. These interventions have been used as an alternative or an adjunct to standard face-to-face treatments in a range of mental health conditions and are a key part of some stepped-care models [20-22].

A number of meta-analyses provide support for the efficacy of written self-help in the management of symptoms of depression, anxiety, insomnia, binge eating, PTSD, and psychosocial problems such as stress [18, 19, 23-25]. This mode of delivery can also be helpful in managing psychological distress associated with a range of long-term health conditions [26], with stress-management interventions and those based on a therapeutic model such as cognitive-behavioural therapy (CBT) showing largest effect sizes [27].

A theory-based, empirically tested self-help intervention for people with seizures to manage the stress they experience (in the context of epilepsy or PNES) would be relatively easy to implement in neurological or non-specialist health care settings and could have positive

effects on how stressed patients feel, the frequency of their seizures and their overall QoL. However, to our knowledge, such a targeted self-help stress management intervention has not been systematically evaluated in people with seizures. We therefore developed such an intervention, in accordance with the UK Medical Research Council (MRC) framework [28], combining a range of self-help stress management techniques, applicable to both people with epilepsy and PNES.

Our primary aim was to assess the acceptability and feasibility of the intervention and observe recruitment and retention rates. As a secondary aim, we sought to examine the efficacy of the intervention and provide preliminary effect size estimates to inform a future definitive randomised controlled trial (RCT) determining the effectiveness of the intervention on stress, quality of life and seizures.

2. Methodology

2.1 Participants

Consecutive patients were recruited from Neurology Outpatient Clinic and Specialist Epilepsy Nurse Clinics at the Royal Hallamshire Hospital, Sheffield, United Kingdom, between December 2014 and April 2015. Adult patients with a clinical diagnosis of epilepsy or PNES were approached to participate in the study. Interested patients were screened for suitability, based on the following exclusion criteria: inability to complete the study measures unaided, no seizures within the last 12 months, uncertain diagnosis, and stress not perceived to be relevant by the potential participant. All diagnoses were formulated by fully trained and experienced epileptologists on the basis of available data. Informed consent was obtained from all eligible participants.

2.2 Self-help intervention

The intervention was an unguided self-help intervention in the form of a brief A5 booklet. The booklet also included a CD with recordings of a guided muscle relaxation taken from the Non-epileptic Attacks website, with the permission of the authors (<http://nonepilepticattacks.info>). The intervention had several different components; the structure of the intervention is detailed in Table 1. In the booklet introduction, participants were encouraged to go through the initial psychoeducational information and subsequently try out the different strategies and continue using those that were most helpful to them.

The overall framework for the structure of the intervention was based on the integrative model of stress [29], according to which the experience of 'stress' comprises interactions between environmental demands; appraisal of demands and adaptive capacities; the resulting perceived stress; and the associated emotional, cognitive, behavioural and physiological stress responses. The intervention therefore included techniques targeting each of these components: strategies aimed at identifying stressors, a section addressing the appraisal of the stressors and coping skills, and a range of techniques targeting the different stress responses, including strategies for tackling negative thoughts, relaxation and breathing techniques, and strategies for overcoming maladaptive stress-related behaviours. The intervention suggested two approaches to coping with stressors on the basis of their controllability: problem-focused coping approaches were recommended for more controllable stressors, and emotion-focused coping for stressors that are outside of the individual's control [30].

2.2.1 Psycho-education

Psycho-education is a recognised treatment option for a range of mental health problems, based on improving patients' understanding and self-management of their condition through education. Psycho-educational approaches have previously been described as beneficial for patients with epilepsy [31, 32], and PNES [33]. A brief psycho-educational section about stress and seizures was therefore included in the current intervention.

2.2.2 Core cognitive-behavioural techniques

The specific techniques included were selected on the basis of a review of literature about the design of self-help and stress management interventions [20, 27, 34-41]. The core strategies were based on the cognitive-behavioural approach, which is at present the most empirically-grounded approach for the management of stress and anxiety [22, 40, 42]. Cognitive-behavioural techniques typically involve cognitive restructuring by learning to identify and challenge maladaptive thinking patterns, and behaviour modifications to reinforce adaptive behaviours and reduce levels of arousal. These techniques are practical, as they can be broken down into easy steps [40].

2.2.3 Self-affirmation

Self-affirmation is a psychological technique in which individuals are guided to reflect upon important personal attributes and values. It was shown to have positive effects on both acute and chronic psychological and physiological stress responses as well as other health-related behaviours [43-46]. The possible mechanism of action could be two-fold. Firstly, reflecting on valued domains may put the person's stressors in a different perspective and thereby alter stress appraisal by changing its perceived significance and reducing any additional concerns that may exacerbate the stress experience [44]. Secondly, as an alternative mechanism of restoring one's sense of self-integrity (i.e., perception of oneself as adaptively and morally adequate) when faced with new information that threatens pre-existing beliefs, self-affirmation has been shown to decrease defensiveness and increase openness towards threatening information [46, 47]. Therefore, it may make patients more receptive to, and accepting of, the advice presented in the booklet. The self-affirmation exercise included in the intervention drew upon values-based self-affirmation techniques and consisted of identifying and writing about most important personal values [45, 48].

2.2.4 Implementation intentions

Implementation intentions are simple, goal-oriented 'if-then' plans, designed to increase behavioural change by encouraging people to mentally link critical situations with desired behavioural responses, for example, "*If situation X arises, then I will perform goal-directed behaviour Y!*" [49, 50]. A wealth of studies shows that people's goals and intentions do not easily translate into action [51]. The theory behind implementation intentions is that forming an implementation intention plan, which specifies when, where and how the goal-directed behaviour will be initiated, will lead to the relevant behaviour being elicited automatically when the critical situation is encountered in real life [49].

The implementation intention technique has previously been found to enhance the effectiveness of self-help interventions [52] and has been successfully used in conjunction with the self-affirmation technique [53]. Implementation intentions have also been used to

increase medication adherence in patients with epilepsy [54]. An implementation intention plan was therefore included in the present intervention.

The lead author can be contacted to obtain additional details about the intervention booklet.

Insert Table 1 here

2.3 Design and Procedure

The study was a pilot of a prospective RCT. Participants were randomised to two groups, (1) an immediate intervention group who received the self-help intervention immediately after completion of a baseline assessment and (2) a delayed intervention group who received the intervention at one-month follow-up and served as a control group in the initial period, from baseline to one month. Participants in both groups were assessed at baseline and subsequently followed up after one and after two months by a set of self-report questionnaires.

At baseline, participants allocated to the immediate intervention group completed the questionnaire measures and were provided with the intervention booklet and encouraged to work through the booklet over the following week. Patients allocated to the delayed intervention group completed the questionnaires only. The self-help booklet was sent to them by post as part of the one-month follow-up assessment. One- and two-month follow-up questionnaires were sent to all participants by post.

2.4 Outcome Measures

2.4.1 Self-report questionnaires

Participants were asked to complete a set of questionnaires comprising demographic questions and five validated self-report measures.

Liverpool Seizure Severity Scale (LSSS-3)

The LSSS-3 is a 12-item inventory designed to quantify the severity of patient's seizures [55]. Scores ranged from 0- 100 with a higher score reflecting greater symptoms. It provides a single-unit weighted scale that measures the severity of the most severe seizures the patient has experienced during the past 4 weeks. Reliability and validity of the scale has been demonstrated [55].

Smith Stress Symptom Inventory – generalised (SSSI)

The SSSI is a 35-item measure of stress symptoms using a four-point scale over the past month, comprising symptom categories including worry/negative emotion, attentional deficits, striated muscle tension, autonomic arousal, depression, and interpersonal conflict [56]. Scores were averaged giving a possible score of 1 – 4; a higher score indicating greater stress symptomatology. Internal consistency reliability ranges from 0.76 to 0.89; validity has also been demonstrated [57].

Neurological Disorders Depression Inventory for Epilepsy (NDDI-E)

The NDDI-E is a 6-item screening tool developed to detect major depression in patients with epilepsy [58]. The inventory was found to have internal consistency reliability of 0.85 and

test-retest reliability between 0.78 and 0.82 [58, 59]. A score of ≥ 15 on the NDDI-E had 90% specificity, 81% sensitivity and a predictive value of 0.62 for a diagnosis of major depression.

Generalised Anxiety Disorder 7-item Scale (GAD-7)

The GAD-7 assesses anxiety symptoms experienced over the course of the previous two weeks [60]. Overall, a score of 5-9 suggests mild, 10-14 moderate and ≥ 15 severe symptoms of anxiety. The GAD-7 has been validated by significant positive correlations with a number of anxiety measures and has excellent internal consistency reliability [60-62]. The scale has previously been used as a screening tool in epilepsy [63].

European Quality of Life – 5 Dimensions Scale (EQ-5D)

The EQ-5D is a standardised, generic measure of quality of life applicable to a range of health conditions, consisting of five descriptive items and a visual analogue scale [64]. The scoring is based on obtaining a unique health state by combining one level from each of the descriptive items, which can be converted into a single index value between 0 (poor health) and 1 (perfect health). The scale has been validated in diverse patient populations [65, 66].

2.4.2 Telephone feedback questionnaire

Patients were contacted by telephone one week after receiving the intervention and interviewed using a questionnaire designed to assess compliance with the instructions and to collect feedback on the booklet. The questionnaire included four questions assessing (1) the overall helpfulness of the booklet (rated on a five-point scale from 'Not at all helpful' to 'Very helpful'), (2) whether or not the participant went through each of the nine sections ('Yes' or 'No') and if so, the usefulness of each of the sections ('Not at all useful' to 'Very useful'), (3) the participant's likelihood of using at least one of the techniques introduced in the booklet in the future ('Very unlikely' to 'Very likely'), and (4) how much they would recommend the booklet to other people with seizures ('Definitely not recommend' to 'Definitely recommend'). Three additional open-ended questions assessed (1) what the participant liked the most about the booklet, (2) what they liked the least, and (3) which particular coping technique they liked the most. In addition, participants were given an opportunity to provide any further comments about the booklet.

2.5 Statistical Analyses

For our primary aim of assessing the feasibility of the intervention, the focus was on descriptive statistics presenting recruitment and retention rates and baseline self-report measures. Where group comparisons were made, Chi-square analyses were used for categorical variables and *t*-tests for continuous variables.

For the secondary aim, due to the modest number of patients recruited to the intervention overall, pre- and post-intervention outcome measures from the two intervention groups were combined and compared. This approach was taken to maximise the sample size and report a more informed estimate of effect size. The effects are reported both with and without Bonferroni correction for multiple tests. Cohen's d_z measure of effect size was calculated using a power analysis software G*Power [67].

All statistical analyses were conducted using SPSS (Version 22 for Mac; SPSS Inc., Chicago, IL, U.S.A.). P-values of < 0.05 were considered statistically significant.

3. Results

3.1 Participants

3.1.1 Recruitment and retention rates

A total of 429 patients were approached and screened for eligibility. After identifying those interested in participating and applying the eligibility criteria, 82 gave informed consent and were randomised. Three of these patients were subsequently removed from further analyses because of uncertainty about their diagnosis (Figure 1).

Of the 36 participants randomised to the immediate intervention group who completed baseline measures, 14 participants (38.9%) returned one-month follow-up and 12 participants (33.3%) returned both one- and two-month follow-up questionnaires. Of the 38 participants randomised to the delayed intervention group who completed all baseline measures, one-month follow-up was completed by 26 (68.4%) and both one- and two-month follow-ups by 20 (52.6%) participants.

Insert Figure 1 here

3.1.2 Baseline measures

Baseline measures in the two intervention groups

There were no baseline demographic or clinical differences between the immediate and the delayed intervention groups (see Table 2).

Insert Table 2 here

Baseline measures in completers versus non-completers

The baseline characteristics were also compared between those participants who completed both follow-ups ('completers'; $N = 29$) and those who dropped out or withdrew from the study ('non-completers'; $N = 42$, see Table 3 for results). Participants who completed the study were older than those who did not complete it; there were no other significant differences between the groups.

Insert Table 3 here

3.2 Participant Feedback

Forty-four patients provided telephone feedback on the booklet (20 in the immediate intervention group, 24 in the delayed group). Overall, those who had worked through the booklet and responded to the self-report questionnaires were positive, with most participants finding the booklet helpful and informative. As can be seen from Figure 2, most patients rated the intervention as helpful or very helpful, were likely or very likely to use some of the coping techniques from the booklet in the future, and to recommend it to other people with seizures. Approximately 36% of patients were 'neutral' or found the booklet 'unhelpful', however, 12% were indifferent about recommending it to others. This suggests

that while some individuals may not have necessarily found the booklet helpful at that time, they viewed it as potentially beneficial for others. Patient's responses were not followed up therefore the reason for this is unclear, however, it is possible that the booklet may not have been that relevant to their experiences of stress.

Insert Figure 2 here

Table 4 summarises the numbers of participants who reported reading through each of the different sections of the booklet and their ratings of the perceived usefulness of the relevant booklet sections.

Insert Table 4 here

The aspects people appreciated the most included the material being explained in a way that was easy to understand and written in an informal, 'friendly' language ($N = 8$), the way the intervention enabled them to self-assess their stressors and thoughts and to respond in a proactive, constructive way rather than getting overwhelmed ($N = 8$). People also felt that the intervention increased their understanding of stress and the links between stress and seizures ($N = 6$), introduced new information and gave them a new perspective ($N = 5$), and included useful resources ($N = 5$). Others commented on the intervention being comprehensive, relevant to people with seizures, practical, and interactive.

With regard to the least liked aspects, most people said that there was nothing particular they disliked about the intervention ($N = 29$). However, some thought the intervention was too detailed and complex ($N = 8$) and a few felt the booklet covered material they were already familiar with ($N = 3$). Two participants suggested it would have been helpful to have someone guide them through it.

3.3 Preliminary Evaluation of Effectiveness

A preliminary test of the effectiveness of the intervention was conducted as a secondary aim of the study, by combining data from the two intervention groups and comparing pre- and post-intervention measures. Due to low numbers of patients with PNES, it was not possible to perform meaningful sub-group comparisons of the two patient groups.

3.3.1 Spontaneous changes in the delayed intervention group

A series of paired-samples *t*-tests on the baseline versus one-month self-report measures revealed no significant differences in the delayed intervention group, indicating that there were no significant spontaneous changes in these measures during the no-intervention period. The associated effect sizes were small, suggesting this was not an issue of statistical power.

3.3.2 Pre- versus post-intervention outcomes

Table 5 summarises the pre- and post-intervention outcome measures from patients in both intervention groups combined (i.e., the baseline versus the one-month follow-up measures in the immediate intervention group, and the one-month versus the two-month follow-up measures in the delayed intervention group).

There was a significant reduction in self-reported stress from pre- to post-intervention, $t(28) = 2.74, p = 0.011$. Applying Bonferroni correction for the five tests would lead to an adjusted significance level of 0.01 (0.05/5), which means that this effect would still approach significance. This effect would still approach significance with Bonferroni corrected alpha = 0.01. The associated effect size was $d_z = 0.51$, indicating a medium effect size [68]. There were no significant improvements in the other measures.

Insert Table 5 here

3.4 Sample Size Calculation for a Future RCT

In order to determine the sample size that would be needed for an appropriately powered randomised controlled trial of the intervention, a preliminary sample-size calculation was performed. One way of analysing the data would be to perform a series of 2 x 2 analyses of covariance (ANCOVAs) for mixed designs. The G*Power software was used to calculate the sample size required to achieve sufficient power using a series of ANCOVAs. Using a Bonferroni-corrected significance level of 0.01 and assuming a small to medium effect size, the total sample size needed to achieve 80% power would be $N = 191$. This means approximately 96 participants in each intervention group. However, taking into account the dropout rate observed in the present study, future studies should expect dropout rates of at least 50%. In order to allow for such level of attrition, the sample recruited into the RCT would need to be at least $N = 382$ (i.e., 191 participants in each intervention group).

4. Discussion

This study investigated the acceptability and feasibility of a self-help stress-management intervention for individuals living with a seizure disorder. The fact that one in five of those approached considered stress relevant to their seizures and were sufficiently motivated to participate indicates that stress is an important issue for many patients. Participant feedback suggested that the booklet was acceptable, with more than half of the participants rating the booklet as 'helpful' or 'very helpful'. Furthermore, over 80% reported that they intended to continue using the booklet and nearly 90% would recommend it to others.

A secondary aim of the study was to explore the preliminary effectiveness of the intervention. A significant reduction in self-reported stress was found, demonstrating a medium effect size one-month post-intervention.

Despite strict screening criteria and an attempt to recruit motivated individuals, a relatively high dropout rate was observed. Other than finding that older patients were more likely to complete the study, we did not identify any baseline differences between those who completed and those who failed to complete the study. The reason for age having an effect on the likelihood of study completion is unclear but has been found elsewhere [38, 69, 70]. It could be that older adults had more time available to participate; however, it may also be that given the increased risk of psychosocial difficulties in later life, this age group find it difficult to manage stress associated with their seizures and exhibit a greater need [71].

Overall, a considerable dropout rate of approximately 50 – 70% was reported. While we examined opinions on the booklet in those who completed the study, we did not explore the experiences of those who dropped out. As such, we are not able to determine whether the attrition was due to the process of engaging in a clinical trial or the intervention itself. For example, patients may have found the booklet difficult to engage with or too upsetting to focus on their stress without support from a healthcare professional. In a future RCT it would be helpful to explore the experiences of non-completers in an attempt to rule out the possibility of causing any harm with the intervention with greater certainty. Having said that, the rate of non-completers observed in our study is comparable to studies of self-help interventions for affective disorders [38, 69, 72]. This level of dropout also seems to reflect the engagement with psychological treatments in patients with epilepsy [16] and PNES. For example, a feasibility study of a psycho-educational intervention for patients with PNES reported a 45% completion rate [33]. In contrast, a somewhat higher completion rate of 72% was found in an RCT of an online CBT-based intervention for depression in patients with epilepsy [73]. This could be explained by the recruitment for that study, from epilepsy-specific online forums, potentially capturing proactive individuals motivated to participate. Nevertheless, given that participants in the present study were not offered any additional or interactive advice tailored to their specific needs, it is promising that our rates are comparable.

There was an interesting difference in attrition between the two intervention groups. Whereas only one third of patients (33.3%) in the immediate intervention group completed the whole study, more than half of the patients (52.6%) in the delayed intervention group did. One reason for this could be that the anticipation of receiving and benefiting from the intervention served as an incentive for participants in the delayed intervention group to stay in the study and respond to the first follow-up. It is also conceivable that a higher proportion of patients in the immediate intervention group dropped out early on due to the initial demands of having to complete the baseline assessment, work through the intervention and provide feedback within the first week of the study. Differences in drop-out during the initial phases were observed in another self-help treatment programme, for post-traumatic stress disorder [70]. Differential attrition can pose a problem for the internal validity of the study; therefore, the demands on participants and subsequent effects on retention should be considered in a definitive RCT.

The preliminary analysis of effectiveness indicated significant reductions in self-reported stress; however, no changes were found in depression, anxiety or quality of life. The reasons for this could be the lack of statistical power to detect changes in these measures, group differences between PNES and epilepsy (unfortunately, due to the number of patients with PNES in the present sample we were unable to perform any meaningful sub-group comparisons) or the fact that anxiety and depression were not specifically targeted by the intervention. There were also no improvements in seizure frequency, at least in the short-term. One reason for this may be the relatively low baseline seizure frequency of the participants in the current study. Having said that, a number of studies emphasised that the psychosocial problems associated with having a seizure disorder are often more disabling than the seizures themselves and it is therefore important to develop treatments targeting all the different difficulties associated with the disorders [74-76]. Additionally, there may be a sub-group of patients in whom stress does directly trigger seizures [8, 77]. While the

present study was not powered to explore sub-groups of patients, this is something that could be further investigated in future studies.

Based on the findings of this pilot study, a definite RCT of the intervention would require a considerably larger sample size and would need to account for a high dropout rate of at least 50% or more. To ensure the generalizability of the findings of a definitive future effectiveness study, modifications to the administration of the intervention should be considered. A few participants in the present study expressed an interest in receiving more guidance on the intervention and some trials of self-help interventions for affective disorders indeed report contact with a therapist as a potential moderator of the relationship between the intervention and outcomes [19, 20]. A face-to-face meeting with a clinician to go through the booklet could therefore be included, perhaps enhanced by at least one follow-up contact. Future research should also assess the cost-effectiveness of the intervention and include an extended follow-up period, in order to assess long-term benefits of the intervention. It may also be desirable to monitor compliance and examine the relationship between the degree of adherence and treatment outcomes. It would also be interesting to explore the mechanisms of change and possible moderators of improvement, for example, individual resilience factors, which may help to make the intervention more tailored.

4.1 Limitations

One of the main limitations was the low retention rate. The resulting small sample size and the lack of statistical power mean that, although the results seem promising, they cannot be confidently generalised at this stage.

There are inherent limitations associated with self-help interventions. In addition to the risk of a high proportion of patients not finishing the treatment, there is a lack of professional assessment and a limited opportunity to monitor patients' adherence. This means that patients may not complete the intervention or may apply the treatment inappropriately. Apart from asking patients which sections of the booklet they read through, adherence was not formally assessed in this pilot study. It is therefore unclear how patients used the content of the intervention. One way of assessing adherence would be to convert the booklet into an online intervention and electronically monitor how many sections people accessed and completed.

The feedback provided by patients was only assessed by one researcher (BN) who was not blinded to the intervention group or the identity of the patients. While every effort was made to transcribe and evaluate the responses as objectively as possible, there may, nevertheless, have been a degree of bias. Moreover, asking patients their experiences of the booklet over the phone may have resulted in more socially acceptable answers being collected compared to, for example, using anonymised questionnaires.

Finally, this study relied on self-report measures. Although a selection of standardised, well-established measures was used, self-report questionnaires are prone to a number of recall and response biases. This is particularly relevant for the current patient group as, for example, Myers et al., found that approximately one-third of patients with epilepsy or PNES demonstrate alexithymia [78, 79].

5. Conclusions

Despite these limitations, this pilot study provided evidence of the acceptability and perceived helpfulness of a theory-based intervention specifically targeting stress in patients with seizures. The preliminary results of the study suggest that this simple intervention may have potential beneficial effects on the reduction of perceived stress. While an appropriately powered RCT of the intervention is needed to provide definitive evidence for its effectiveness and cost-effectiveness, our pilot study suggests that in motivated individuals who perceive stress to be a factor contributing to their seizures, this self-help intervention could offer a useful tool to help them manage their stress better.

6. Declarations of Interest

None.

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Tables

Table 1. *Structure of the self-help booklet*

Booklet section	Rationale/Aims of section	Techniques and strategies
Section 1 'Step 1: Understand stress'	Psychoeducational information aimed at increasing the understanding of stress, its effects and its interactions with seizures	<ul style="list-style-type: none"> • Information about what is stress • Information about what causes stress • Information about the symptoms of stress • Information about how stress is related to seizures • The vicious cycle of stress diagram
Section 2 'Step 2: Spot the stressors in your life'	A section based on the idea that patients may find it difficult to identify the sources of stress in their lives, aimed at increasing awareness of the degree of stress experienced and helping to identify and tackle stressors	<ul style="list-style-type: none"> • Life events checklist with ratings of stressfulness • Writing down minor everyday stressors and hassles
Section 3 'Step 3: Clarify your values and priorities'	A value-based self-affirmation exercise aimed at clarifying and reflecting on valued life domains in order to put stressors into perspective and reduce defensiveness	<ul style="list-style-type: none"> • Drawing a value diagram • Identifying and writing down the most important value • Writing a few sentences about the identified value
Section 4 'Step 4: Cope more effectively'	An explanation of two different ways of appraising and coping with stressors, depending on whether or not it is possible to change, control or avoid the sources of stress	<ul style="list-style-type: none"> • For stressors that can be controlled or avoided, a problem-focused coping approach is recommended • For stressors that are not possible to control or avoid, an acceptance based, emotion-focused coping approach is recommended
Ways of coping	Goal/action-oriented, problem-focused coping strategies based on the CBT approach	<ul style="list-style-type: none"> • Problem-solving exercise based on identifying the problem, listing all possible solutions, choosing the best one and breaking it down into steps • Time-management exercise to give shape to one's day • Practicing to say 'No'
Coping with stressful thoughts	CBT based techniques for cognitive restructuring by identifying and challenging stress-related negative cognitions	<ul style="list-style-type: none"> • Learning to spot stressful thoughts using a checklist of common cognitive errors • Challenging thoughts • Taking control of worries
Coping with stressful feelings	CBT and relaxation based techniques to reduce physiological arousal, negative emotions, and prevent impending seizures.	<ul style="list-style-type: none"> • Learning to relax using a progressive muscle relaxation with guided audio instructions • Controlled breathing technique • Taking time out • Sensory grounding exercise • Taking a break and engaging in enjoyable activities • Connecting with others and seeking social support
Coping with a stressful lifestyle	Basic advice and information about life hygiene aimed at encouraging a healthy lifestyle and reducing maladaptive stress related behaviour	<ul style="list-style-type: none"> • Techniques for improving sleep • Techniques for improving diet and reducing alcohol consumption • Engaging in safe levels of exercise
Section 5 'Step 5: Take action'	Implementation intention based goal plan aimed at encouraging patients to translate the coping techniques into action	<ul style="list-style-type: none"> • Selecting the most helpful coping strategy from a list of the coping techniques introduced in the booklet • Forming a goal plan ('If I feel stressed, tensed or worried, then I will use my X technique to help me cope!')
Section 6 'Step 6: Getting more help'	A list of additional resources and contact details for relevant support services	<ul style="list-style-type: none"> • Books and CDs • Online resources • Useful contacts

Table 2. *Baseline demographic and clinical characteristics of the two intervention groups*

Characteristic	Immediate Group (<i>N</i> = 35) Mean (<i>SD</i>)	Delayed Group (<i>N</i> = 36) Mean (<i>SD</i>)	Both Groups Combined (<i>N</i> = 71) Mean (<i>SD</i>)	<i>P</i> - value
Age	40.49 (12.59)	43.22 (13.99)	41.87 (13.29)	.390
Gender (<i>N</i> female (%))	23 females (65.7%)	27 females (75.0%)	50 females (70.4%)	.391
Years in education	13.66 (2.84)	13.88 (2.43)	13.77 (2.62)	.735
Economically active (<i>N</i> active (%))	19 active (54.3%)	17 active (47.2%)	36 active (50.7%)	.552
Diagnosis (<i>N</i> (%))				.747
Epilepsy	26 (74.3%)	31 (86.1%)	57 (80.3%)	
Idiopathic generalised epilepsy	7	5	12	
Focal epilepsy	18	22	40	
Unclassifiable epilepsy	1	4	5	
PNES	7 (20.0%)	5 (13.9%)	12 (16.9%)	
Mixed epilepsy and PNES	2 (5.7%)	0	2 (2.8%)	
Seizure disorder duration (years)	17.88 (16.84)	16.25 (13.51)	17.06 (15.16)	.654
Median seizure frequency (seizures/month)	3.00 (16.00)	2.00 (4.00)	2.50 (6.75)	.492
Seizure severity	55.20 (21.65)	56.72 (18.14)	55.96 (19.83)	.757
AED use (<i>N</i> (%))				.199
None	5 (15.2%)	1 (2.9%)	6 (8.8%)	
AED Monotherapy	15 (45.5%)	19 (54.3%)	34 (50.0%)	
AED Polytherapy	13 (39.4%)	15 (42.9%)	28 (41.2%)	
EQ-5D index value	0.69 (0.23)	0.64 (0.30)	0.66 (0.27)	.448
SSSI	2.47 (0.66)	2.37 (0.64)	2.42 (0.65)	.530
GAD-7	9.74 (6.29)	9.25 (6.26)	9.49 (6.23)	.747
NDDI-E	15.23 (3.66)	15.08 (4.22)	15.30 (3.94)	.639

Note. *SD* = standard deviation; *AED* = anti-epileptic drugs; *EQ-5D* = European Quality of Life-5 Dimension; *SSSI* = Smith Stress Symptom Inventory; *GAD-7* = Generalised Anxiety Disorders 7-item Scale, *NDDI-E* = Neurological Disorders Depression Inventory for Epilepsy. The *p*-value refers to comparisons between the immediate and delayed groups.

Table 3. *Baseline demographic and clinical characteristics of completers and non-completers*

Characteristic	Completers (N = 29) Mean (SD)	Non-completers (N = 42) Mean (SD)	P- value
Age	47.00 (13.76)	38.00 (11.88)	.006
Gender (N female (%))	23 females (79.3%)	27 females (64.3%)	.173
Years in education	14.15 (2.60)	13.50 (2.64)	.330
Economically active (N active (%))	12 active (41.4%)	24 active (57.1%)	.192
Diagnosis (N (%))			.694
Epilepsy	23 (79.3%)	34 (81.0%)	
PNES	4 (13.8%)	8 (19.0%)	
Mixed epilepsy and PNES	2 (6.9%)	0	
Seizure disorder duration (years)	19.16 (15.80)	15.61 (14.71)	.335
Median seizure frequency (seizures/month)	3.00 (14.00)	2.00 (4.50)	.224
Seizure severity	50.38 (22.08)	59.59 (17.57)	.065
AED use (N (%))			.854
None	2 (7.1%)	4 (10.0%)	
AED Monotherapy	15 (53.6%)	19 (47.5%)	
AED Polytherapy	11 (39.3%)	17 (42.5%)	
EQ-5D index value	0.69 (0.28)	0.64 (0.26)	.474
SSSI	2.39 (0.61)	2.44 (0.68)	.732
GAD-7	9.61 (6.10)	9.41 (6.41)	.895
NDDI-E	15.11 (3.79)	15.43 (4.10)	.740

Table 4. *Usefulness ratings of the different parts of the intervention*

Booklet Section	<i>N</i> read	Usefulness rating <i>M (SD)</i>	<i>N</i> (%) useful (rated 4 or 5)	<i>N</i> (%) neutral (rated 3)	<i>N</i> (%) not useful (rated 1 or 2)
Section 1 Understand stress	39	4.03 (1.04)	28 (71.8%)	8 (20.5%)	3 (7.7%)
Section 2 Spot the stressors	40	4.20 (0.85)	31 (77.5%)	8 (20.0%)	1 (2.5%)
Section 3 Clarify your values	37	3.86 (1.00)	23 (62.2%)	12 (32.4%)	2 (5.4%)
Section 4 Cope more effectively					
4.1 Ways of coping	38	3.71 (1.10)	21 (55.26%)	11 (28.9%)	6 (15.8%)
4.2 Coping with thoughts	38	4.00 (0.96)	25 (65.8%)	11 (28.9%)	2 (5.3%)
4.3 Coping with feelings	37	3.95 (0.97)	27 (73.0%)	6 (16.2%)	4 (10.8%)
4.4 Coping with lifestyle	35	3.91 (0.85)	25 (71.4%)	8 (22.9%)	2 (5.7%)
Section 5 Take action	27	3.96 (0.90)	18 (66.7%)	8 (29.6%)	1 (3.7%)
Section 6 Getting more help	24	4.29 (0.81)	19 (79.2%)	5 (20.8%)	0 (0%)

Table 5. Mean pre- and post-intervention outcome measures and associated effect sizes

Outcome Measure	<i>N</i>	Pre-intervention Mean (<i>SD</i>)	Post-intervention Mean (<i>SD</i>)	<i>P</i> -value	Cohen's <i>d_z</i>
EQ-5D index value	29	0.72 (0.24)	0.71 (0.21)	.767	0.056
SSSI	29	2.32 (0.65)	2.12 (0.59)	.011	0.509
GAD-7	30	9.10 (6.43)	8.30 (4.87)	.334	0.179
NDDI-E	30	15.00 (3.95)	15.20 (3.23)	.659	0.082
Seizure frequency	31	18.81 (51.10)	13.58 (25.34)	.302	0.188

Note. Variation in sample sizes indicates missing data for certain measures.