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Doctoral Thesis

Psychological Perspectives on Stigma and Self-Compassion in Adults with Epilepsy

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STIGMA AND SELF-COMPASSION IN EPILEPSY

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Thesis Abstract

Section 1 describes a systematic literature review examining quantitative correlates of stigma in adults with epilepsy living in Western countries. To identify relevant literature, four academic databases (PsycINFO, CINAHL, PubMed, and Scopus) were systematically searched using key terms related to stigma and epilepsy. The findings of the review suggested that stigma can be predicted by demographic, illness-related, and psychosocial factors; although associations were found to be highly culturally-specific. Detrimental effects of stigma included both physical health, including effective management of the condition, and psychological wellbeing, including difficulties such as depression and anxiety. These findings suggested that culturally-informed educational initiatives and therapeutic interventions which aim to address stigma in people with epilepsy (PWE) are needed.

Section 2 describes a research study examining the extent to which self-compassion can predict depression, anxiety, and resilience in PWE, when controlling for other important demographic and illness-related variables. Adults with epilepsy were invited to take part in a survey either online or in epilepsy or neurology clinics. Data were then analysed using hierarchical multiple regression models. In this sample of PWE, self-compassion was found to significantly predict lower depression and anxiety and higher resilience when other significant sociodemographic and illness-related variables had been taken into account. These findings indicated that self-compassion is an important factor in determining psychological outcomes for PWE, providing preliminary support for the use of compassion-focused approaches in this population.

Section 3 provides a critical appraisal of the thesis. This includes a summary of the main findings; a discussion of some of the key decisions, challenges, and professional issues

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identified during the research process; a consideration of potential future research arising from the findings; and personal reflections on the process of undertaking the work.

Declaration

This thesis records research undertaken for the Doctorate in Clinical Psychology course at the Division of Health Research at Lancaster University from January 2016 to May 2017. The work presented here is the author's own except where due reference is made. The work has not been submitted for the award of any higher degree elsewhere.

David Baker

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Section 1: Literature Review

Correlates of Stigma in Adults with Epilepsy: A Systematic Review of Quantitative Studies

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Formatted for submission to the journal "Epilepsy & Behavior"

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Highlights

- The present study examined correlates of stigma in people with epilepsy (PWE) in Western populations
- Thirty-three research papers reporting findings from 25 quantitative studies were identified
- Stigma was found to be associated with demographic, illness-related, and psychosocial factors
- Predictors of stigma were highly culturally-specific
- Negative outcomes of stigma included poorer physical health and psychological wellbeing, including greater depression and anxiety

Abstract**Objectives**

The aim of this review was to identify quantitative correlates, predictors, and outcomes of stigma in adults with epilepsy living in Western countries.

Methods

To identify relevant literature, four academic databases (PsycINFO, CINAHL, PubMed, and Scopus) were systematically searched using key terms related to stigma and epilepsy.

Results

Thirty-three research papers reporting findings from 25 quantitative studies of correlates of stigma in epilepsy were identified. The findings suggest that stigma can be predicted by demographic, illness-related, and psychosocial factors; although associations were found to be highly culturally-specific. Outcomes of stigma in people with epilepsy (PWE) were replicated more consistently across cultures and its impact was significant. Detrimental effects included both physical health, including effective management of the condition, and psychological wellbeing, including difficulties such as depression and anxiety.

Implications

Educational initiatives and therapeutic interventions which aim to address stigma in PWE are recommended; however, these need to be culturally-informed to ensure that they are valid and effective.

Keywords

Epilepsy; stigma; neurological conditions; chronic illness; mental health

1. Introduction

1.1 Stigma in chronic illness

Stigma has been defined as a phenomenon in which a person is discredited or rejected by society because of a particular attribute, in a way that spoils their normal identity [1]. Within this seminal definition, stigma is described as constituting a gap between a person's "virtual social identity", assumptions about how an individual ought to be, and their "actual social identity", the attributes an individual possesses in reality. Such discrepancies can be precipitated by "external deformations" such as physical disabilities and diseases, "deviations in personal traits", such as being unemployed or becoming addicted to drugs, and "tribal stigmas" based on, for example, ethnic group or nationality [1]. Various authors have since elaborated on, or provided alternatives to, Goffman's work to produce definitions of stigma that incorporate a range of salient factors. An influential definition by Jones et al. [2] developed Goffman's description of the relationship between "attributes and stereotypes" by defining stigma as a "mark" (attribute) that links a person to undesirable characteristics (stereotype). Crocker, Major, and Steele [3] similarly went on to describe stigma as the possession (or believed possession) of an attribute or characteristic that conveys a social identity that is devalued in a particular social context. In a more recent review of stigma conceptualisation [4], Link and Phelan argue that significant variations in stigma definitions have been apparent due to the varied circumstances in which the concept applies and the various disciplines involved in its study (e.g. psychology, sociology, anthropology). The authors of this paper go on to offer a more unified definition of stigma which derives elements from previous work, including Goffman and Jones, and incorporates novel elements including discrimination, stating that "stigma exists when elements of labelling, stereotyping, separating, status loss, and discrimination co-occur in a power situation that allows these processes to unfold" [4].

People with chronic illnesses or health conditions are often subjected to stigma that is enacted by others who do not have the condition through rejecting or discrediting behaviours, which can lead

to attempts at concealment [5-7]. Furthermore, even where stigma is not enacted externally, this may be “felt” internally [8]. A person’s beliefs about their own condition can help lead to a place of acceptance, or alternatively to self-stigmatising appraisals which affect self-esteem, self-efficacy, and coping; this has been studied most comprehensively in mental health populations [9-11].

1.2 Epilepsy

Epilepsy is a chronic neurological condition in which a person experiences recurrent episodes of abnormal electrical brain activity known as seizures [12]. Clinical manifestations of seizure activity are complex, depending on a wide range of underlying physical factors and affecting people with epilepsy (PWE) in a variety of ways; seizures can affect sensory, motor and autonomic function, consciousness, emotional state, memory, cognition, and behaviour [13]. Seizures can be broadly categorised as either “focal” (or partial), involving just one area of the brain, or “generalised”, involving all areas of the brain, with or without loss of consciousness [14], although different classification systems have been a matter of debate [15]. Seizures typically last a few seconds or minutes; some seizures involve convulsions, characterised by rhythmic jerking or shaking movements, whereas others can cause people to become unresponsive, vacant, or confused [16]. The condition can be life-threatening and there is a risk of sudden unexplained death in epilepsy (SUDEP), where a person with the condition dies without warning and with no obvious medical cause [17]. Seizures can happen at any time, including when a person is asleep [18], and can lead to physical injury or death [19]. Whilst awareness of such risks has improved, these are not always communicated to people with the condition [20]. There can be a number of possible causes of seizures including genetic influence, head trauma, brain conditions such as strokes or tumours, infectious diseases, prenatal injury, and developmental disorders; although epilepsy has no identifiable cause in about half of those with the condition [21].

Epilepsy affects millions of people globally. In England, between 362,000 and 415,000 people are estimated to have epilepsy, although 5-30% may have an incorrect diagnosis and two-thirds of

people with active epilepsy have the condition controlled effectively with anti-epileptic drugs [22]. In Europe, there are an estimated 2.5 million adults with active epilepsy, or 6-7 in every 1000 people, with around 20-30% having more than one seizure per month [23]. In the United States (US), around 2.4 million adults are currently diagnosed with the condition [24].

1.3 Stigma in epilepsy

Informed by the work of Goffmann [1], Scambler and Hopkins [25] described how stigma can manifest in PWE in their “Hidden Distress Model of Epilepsy”, which differentiated between “felt” and “enacted” stigma [26]. The model can be broadly operationalised into three areas: the sense of felt stigma that people experience when being confronted by a diagnosis and as a result feeling the need to conceal their illness; the impact of this concealment in relation to others being unaware of their epilepsy; and the disruption that this felt stigma can cause, which can be even greater than when stigma is enacted externally [27]. Examples of enacted stigma in relation to epilepsy include derogatory language being used to describe a person’s epilepsy or seizures, or a person being blamed for having epilepsy or seizures, or a person being avoided as a result of their condition. In contrast, PWE may experience felt stigma if they feel embarrassed about their condition or associated physical limitations, or if they feel left out of social events when there is no objective evidence to support this belief.

1.4 Historical context of epilepsy-related stigma

The cultural and epidemiological understanding of epilepsy, and therefore the stigma attached to it, has varied significantly over time. Some of the earliest evidence of a medical understanding of the condition emerged in ancient Greece; in 400 BC Hippocrates described epilepsy as a disease of the brain and argued that it should be treated with drugs and diet, rather than magic [28]. However, early Christian beliefs reverted to biblical notions of PWE being possessed, and historical Islamic remedies included the use of amulets and stones [29]. Such stigmatising beliefs continued for several hundred years; in the 15th century seizures were widely viewed as a characteristic of

witchcraft and seen as infectious [30]. However, during the period of Enlightenment in the 18th and 19th century, the Hippocratic concept was resurrected, with preeminent figures of the time such as John Hughlings Jackson (1835-1911) describing seizures as medical phenomenon that can “alter consciousness, sensation, and behaviour” [31]. Despite advancements, in the 20th Century the condition was treated predominantly as a dangerous and infectious disease, and PWE were commonly held in asylums or confined to discrete epilepsy communities [32].

1.5 Present context of epilepsy-related stigma

Public myths and misconceptions of epilepsy endure [33]. Misconceptions are often reinforced by the use of derogatory language and negative or erroneous media representations [34], and PWE continue to face social and legal barriers in the UK and other Western countries, underpinned by the longstanding stigma associated with the condition [35]. In the UK, it was illegal for PWE to marry until as late as 1970 [30]. To protect the rights of PWE in England, Scotland, and Wales, epilepsy has been included in the Equality Act [36], and in Northern Ireland in the Disability Discrimination Act [37]. However, despite legislative protections, PWE continue to be discriminated against in the UK, for example in regard to employment and driving [38].

Stigmatising negative attitudes towards epilepsy, underpinned by misconceptions of the condition and often enacted as discrimination, continue to impact on those living with the condition, although these have diminished over time [39,40]. This may be due in part to an increased understanding of the causes and nature of epilepsy and large-scale campaigns designed to raise awareness and understanding of epilepsy and to promote education and research. Such campaigns include the Global Campaign Against Epilepsy [41] and the Collaborative Research on Epilepsy Stigma Project [42], designed to inform the development of culturally appropriate approaches to reducing stigma and discrimination of epilepsy in the developing world.

A significant focus of these campaigns was on reducing stigma in developing countries, which reflects a cultural divide in terms of prevalence and strength of misconceptions of epilepsy

identified in research across Western and non-Western populations¹. For example, a relatively recent study of myths and misunderstandings about epilepsy in a rural community in Nigeria found that, of the people interviewed, only 12% attributed epilepsy to a brain disorder, with 81.4% attributing it to witchcraft, 49.8% to destiny, and 26.8% to demonic possession [43]. Similarly, in a survey of first-year medical students in Zambia, 80% said that they would not allow their children to marry someone with epilepsy; the majority viewed it as mental illness and some believed that PWE cannot have normal intelligence [44]. Such beliefs are commonplace in some cultures and are likely to be highly stigmatising to PWE in these communities.

In contrast, whilst misperceptions and misunderstanding continues to exist in the West [45-47], a broader acceptance of medical causes of illness, alongside public awareness campaigns such as those introduced by the US Epilepsy Foundation in 2001 [48], mean that such extreme and stigmatising beliefs are unlikely to be reflected by the majority of the population compared to those identified in research from non-Western samples. Despite this, misconceptions still exist in the West and research is needed to better understand stigma in this context [40].

1.6 Existing reviews of stigma and epilepsy

There has been significant interest in stigma, epilepsy, and factors relating to quality of life (QOL) in PWE over the last 15 years. In 2002, Morrell completed a narrative review of stigma and epilepsy in the US and Europe; she concluded that PWE frequently have to cope with stigma and that this was likely to continue until perceptions of the illness improved [49]. In the same year, a review of stigma and QOL in PWE concluded that those with the condition unquestionably face difficulties as a result of stigma and that for some this can lead to high levels of distress [38]. A further review in 2008 explored the frequency and nature of stigma towards epilepsy [50]; here, stigma was found to be associated with incomplete seizure control and poor psychosocial outcomes;

¹ Utilising definitions of “Western” and “non-Western” populations is pragmatic in research terms but flawed in real terms as it relies on arbitrary geographical and cultural distinctions. Further reference will be made to issues of cultural categorisation in the method and discussion sections.

the authors advocated further research to help understand the origins of stigma in epilepsy and how to decrease its impact. An updated review of illness-related stigma, the stigma experiences of PWE, and the beliefs and attitudes of other target groups was also completed by Jacoby [51]. This narrative review, incorporating literature from countries across the world, highlighted the importance of sociodemographic characteristics on negative attitudes; the author suggested that more research is required to better understand the nature of this relationship. Jacoby and colleagues have also discussed stigma and quality of life elsewhere [52]. More recently a systematic review was published synthesising the literature on misconceptions of epilepsy held by people without the condition in Western countries [40]; the authors concluded that misconceptions of the illness remain prevalent but that there is a limited literature on stigma reduction strategies in these settings. Despite the number of reviews exploring stigma, epilepsy, and QOL, these have typically provided narrative accounts of the available literature incorporating a range of research questions using mixed methods. However, to date no focused systematic review of quantitative studies examining correlates of stigma in epilepsy has been published.

1.7 Justification for a review

In summary, epilepsy is a common neurological condition that can affect people in many different ways. Whilst medical treatments for epilepsy have advanced, stigma around the condition has been shown to persist over time [53]. Perceptions of epilepsy may have improved in recent years, particularly in the West, as a result of health promotion campaigns. However, despite an increased awareness of the causes and effects of epilepsy, misconceptions that underpin stigma of the condition have not been eradicated, even in the Western world [40]. Previous reviews have described the frequency and nature of stigma towards epilepsy, examined misconceptions within the general population, and discussed issues related to stigma and QOL. However, in light of more recent public health initiatives which have aimed to shift social perceptions of the illness, an updated review is needed.

There are currently no systematic reviews that have explicitly examined the quantitative evidence of correlates of stigma in adults with epilepsy. An up-to-date account of the research in this area using systematic review principles will shed light on the factors associated with this important relationship. The review will add to existing research by identifying, synthesising, and appraising the available evidence of the current state of felt and enacted stigma experienced by adults with epilepsy. Given the disparity between Western and developing countries in relation to research, health promotion, and education, the review will focus on research from Western countries. Specifically, the review will identify predictors and outcomes associated with stigma for adults in this population. It is hoped that the findings will help to inform the future direction of interventions aimed at reducing the prevalence and impact of stigma in PWE.

2. Methods

2.1 Research aims

The primary aim of this review was to identify quantitative correlations, predictors, and outcomes of stigma in adults with epilepsy. A further aim of the review was to consider the implications of the findings and identify the need for further research.

2.2 Inclusion and exclusion criteria

As highlighted above, stigma in epilepsy is highly culturally-dependent [54]. Given the cultural sensitivity of the phenomenon, the focus of the review was limited to studies published in Western countries. As in previous research [40], this was defined as research from countries in North and South America, Europe, and Australia. Where countries could not easily be defined as either Eastern or Western, inclusion was considered on individual merit. This was underpinned by existing research into epilepsy perceptions; for example, studies from Turkey - a country which straddles continental Europe and Asia - were included in the review, as research has shown that, whilst discrimination against PWE exists in the country, there is generally a good understanding of the condition amongst the general population [55].

In order to understand the current status of stigma and epilepsy, the focus of the review was also narrowed to include only studies published after the year 2000, to coincide with the development of educational campaigns (e.g. [41,42]). The focus was also on correlates of stigma in adults; therefore studies looking at child and adolescent populations were excluded. In order to gain an empirical measure of the nature of the predictors and outcomes associated with stigma and epilepsy, the search was narrowed to focus only on studies that included quantitative measures of stigma and epilepsy, therefore qualitative studies were excluded from the review. The following inclusion and exclusion criteria were therefore developed to identify relevant published, peer-reviewed articles from database searches.

2.2.1 Inclusion criteria

- Studies that have quantitatively measured correlates of stigma in adults with epilepsy using (a) validated measure(s) of stigma
- Studies focusing on adult populations (ages ≥ 16 years)
- Studies published in Western countries (North America, South America, Europe, and Australia)
- Studies published after 2000
- Studies available in English

2.2.2 Exclusion criteria

- Studies using qualitative methods
- Studies examining misconceptions of epilepsy or perceptions of epilepsy stigma in the general population
- Studies including participants who have had seizures but do not have a diagnosis of epilepsy

These search parameters were chosen to provide a homogenous sample that would allow a clear picture to be obtained in relation to the current state of stigma in adults with epilepsy in a culturally specific context.

2.3 Description of systematic search process

In order to ensure that the search process was undertaken systematically, and to reduce the chance of missing relevant studies, an academic librarian was consulted to provide independent advice about the search strategy. To achieve a comprehensive search of the literature, four databases were identified: PsycINFO, CINAHL, PubMed, and Scopus. Search terms were developed to include the two main concepts under review: stigma and epilepsy. Two key search terms were used: “epilepsy” and “stigma”. Use of the truncation symbol in the context of “stigma*” to include suffixes such as “stigmatising” and “stigmatised” was discounted as it was felt that this would likely result in a more cumbersome search which would not yield additional relevant papers. Keyword searches including the terms “stigma”, “social stigma”, “labelling”, “stereotyped attitudes”, “stereotyping”, combined with the term “epilepsy”, were completed in databases where this functionality was available (e.g. Thesaurus in PsycINFO, CINAHL Headings, and Medical Subject Headings [MeSH] in PubMed). This was then combined with a free text search of the “abstract” or “title and abstract” fields to identify additional articles missed by index searches. The articles identified across databases were entered into the referencing software, Endnote, and duplications were removed. Articles were then filtered and excluded by title, abstract, or full-text according to their relevance to the research question, methodology, date and location of publication, and sample population. Reference lists of included papers were also searched for additional relevant articles. An overview of the search strategy, including the number of articles identified at each stage, is provided in Figure 1. A detailed summary of the results of searches by database is provided in Appendix A.

[Figure 1 here]

Once all relevant articles had been identified, the findings were compared and contrasted using a narrative synthesis. This approach was chosen as it allowed for a meaningful integration and discussion of the available evidence. Due to the heterogeneity of research identified in the review, which included a variety of measures and analyses used for different purposes and in different

populations, which would make it difficult to meaningfully synthesise findings numerically, a meta-analysis was not undertaken.

2.4 Appraisal of methodological quality

To assess the methodological quality of studies included in the review, a quality appraisal tool for observational studies adapted from the Agency for Healthcare Research and Quality was used [56]. This comprised an eight-point checklist of key methodological considerations which researchers should take into account and report in studies of this type, including issues relating to sample selection, measures, data handling, and analysis. Studies were rated on each item and assigned an overall score to indicate an appraisal of the methodological quality. To ensure the reliability and validity of appraisal ratings, a sub-sample of six papers was chosen at random and peer inter-rated; discrepancies were minor and final ratings were agreed by consensus.

3. Results

3.1 Synthesis of reviewed studies

An overview of the studies identified for inclusion in the review, including key elements of the design, sample, results, and authors' conclusions, is provided in Table 1. Correlation coefficients (Pearson's r) are also presented in Table 1, where available, as an accessible and widely used measure of effect size [57].

[Table 1 here]

3.2 Study characteristics

Following the search procedure described above, 33 research papers were identified, reporting findings from 25 quantitative studies of stigma in epilepsy. The total number of research participants across all of the studies included in the review was 16,942 adults with epilepsy. An additional 238 adults without a diagnosis of epilepsy were recruited as controls. Participant ages ranged from 16-98 years. Research was identified from countries in North and South America, Europe, and Australia. There were 12 papers from the US, five from Bulgaria, four from Turkey,

three from the UK, three from countries across Europe, two from Australia, one from the Netherlands, one from Croatia, one from Mexico, and one from Canada. Of the studies identified, 30 were cross-sectional in design and three incorporated longitudinal methods. Two studies compared findings to controls without epilepsy. Eight papers used only correlational analyses and 25 included regression analyses.

3.3 Measures

The papers identified in the review used 10 different standardised measures of stigma. Fifteen papers used the “Jacoby 3-Item Measure of Stigma” [8], which was the most widely used measure in the review. Twelve papers used the “Modified Parent Stigma Scale”, also referred to as the “Epilepsy Stigma Scale (ESS)” [58]. Of the remaining studies, individual papers used the “Felt Stigma Scale” [59], the “Perception of Stigma of Epilepsy Scale (PSE)” [60], the “Revised Stigma Scale” [61], the “Stigma Scale” [62], the “Stigma Scale for People with Intellectual Impairment” [63], and stigma items derived from the “Child Asthma Scale” [64].

3.4 Scope of the research

The identified studies examined correlations, predictors, and outcomes of stigma in adults with epilepsy. Statistical data regarding epilepsy epidemiology or stigma prevalence was not addressed in this review. Similarly, descriptive accounts of stigma experiences in PWE, which are typically the domain of qualitative research designs, were also beyond the scope of the review. Whilst the majority of research was cross-sectional in design, and therefore directionality of effect or causation could not be determined, researchers typically framed their findings in relation to what they viewed as predictors or outcomes of stigma within the target population.

3.5 Summary of quality appraisal

Overall, the methodological quality of studies in the review was satisfactory, with a mean score of 5.5 out of 8, although this ranged from 2.5 to 7 indicating variability of quality across studies. Most studies provided clear descriptions of participant samples, including details of inclusion/exclusion

criteria and how participants were recruited. Details of statistical analyses were generally provided and appropriate for the type of study. Consideration of confounding data was also widely taken into account, with the majority of studies using regression analyses to adjust for demographic or clinical factors likely to be correlated with outcomes. However, the appraisal revealed a number of common issues. Power calculations as a means of determining and justifying sample size were reported in only two studies. Validity of standardised measures was frequently referred to in relation to findings of previous studies; however reliability coefficients (e.g. Cronbach's alpha) were rarely calculated for present studies, therefore validity and reliability could not be fully assumed [65]. Details of missing data and how these were handled by researchers was also rarely reported; again this limits confidence that data was obtained and presented in a way which minimises bias. An overview of the outcomes of the methodological quality appraisal is provided in Table 2.

[Table 2 here]

3.6 Summary of main findings

3.6.1 Demographic, illness, and psychosocial correlates and predictors of stigma

Twenty studies examined correlations or predictors of stigma in PWE. Findings could be broadly categorised according to demographic, illness-related, and psychosocial variables found to be correlated with, or to predict, stigma.

3.6.1.1 Demographic variables

3.6.1.1.1 Socioeconomic factors

Several socioeconomic factors were identified as important. Yeni, Tulek, and Bebek identified a negative correlation between income and stigma [66]. Income was also found to predict lower stigma when other variables had been taken into account [67,68]. In a further regression study, Smith et al. found that people who were disabled or unemployed with greater seizure worry were more likely to report higher levels of stigma when adjusting for other variables (e.g. self-efficacy,

social support, and race) [69]. Yeni, Tulek, and Bebek also identified a negative correlation between education and stigma [66]. In correlational studies comparing patients from clinics in “low and high sociodemographic communities”, participants from low socioeconomic status backgrounds were found to report higher felt stigma [70,71]; although when psychosocial variables including QOL, depressive symptoms, and social support were entered into a regression model, these differences were found not to be significant [71]. These findings indicate that socioeconomic status may not in itself significantly affect stigma but that other related psychosocial variables may be of greater importance.

3.6.1.1.2 Cultural factors

The impact of cultural factors was also identified. In a large-scale continental study examining the relationship between stigma and health system performance across 10 European countries, including a sample of over 5,000 PWE, Baker et al. found country of origin to significantly contribute to variance in reported levels of stigma in regression analyses [54]. For example, Spanish participants reported significantly lower levels of stigma than participants in France. The authors suggested that cultural differences may be due to a range of factors, including sociocultural bias against epilepsy, cultural norms, the structure of the health system, and the existence of high profile public figures with the condition who may act as role models, although they suggested that more research is needed. Brigo et al., reporting on the same data, identified a trend towards negative correlation between stigma and overall health system performance and health expenditure per capita; however, this association was non-significant [72].

3.6.1.1.3 Personal factors

Personal factors were also identified as potentially contributing to variance in stigma. When taking into account other clinical and demographic variables using regression analyses, Baker et al. identified that being married significantly predicted lower levels of stigma, alongside six other important illness-related and psychosocial variables [54]. Bautista, Shapovalov, & Shoraka

replicated this finding [67]. Younger age was also found to be correlated with higher stigma in some studies [67,73,74]; this was found to independently predict lower levels of reported stigma when other variables had been taken into account in regression analyses [61]. In contrast, however, several studies using regression analyses did not find age to significantly predict stigma [66,68,71,75,76]. Gender was also found to be uncorrelated with stigma [68,71,75,77]. It has been suggested that such findings may be due in part to overarching negative social attitudes, particularly in developing countries, which can cause other factors to “recede into the background” [77].

3.6.1.2 Illness-related variables

3.6.1.2.1 Seizure type and severity

Eidhin and McLeavey found seizure type and severity to correlate significantly with stigma [78], although significant flaws were identified in their methodology. Baker also found seizure type (generalised seizures) to contribute to variance in stigma outcomes in regression analyses [79]; however, the authors of this paper stressed that the relevant contributions of these findings depended on the country of origin of those surveyed, highlighting the importance of cultural differences in determining the impact of illness-related variables on stigma. In regression analyses, Baker et al. found epilepsy-related injuries to significantly contribute to scores of stigma but not seizure type [54]. Viteva found no correlation between stigma and seizure severity [77].

3.6.1.2.2 Seizure frequency

Dilorio et al. found the number of seizures experienced during the past year to significantly predict stigma in regression analyses [68], and this was replicated in Croatian and UK studies using regression models which found number of seizures to date to significantly predict stigma [61,73]. Yeni et al. also identified positive correlations between seizure frequency and stigma [80]. Furthermore, Baker’s large-scale study in European countries found greater seizure frequency to be the most consistent cross-cultural predictor of higher levels of reported stigma in regression analyses [79]. However, these findings were partially in contrast to those of a large-scale study by

Baker et al., which found that whilst seizure frequency significantly correlated with measures of stigma, these variables did not predict significant variance in stigma when entered into a regression model alongside other variables [54]. Aydemir, Kaya, Yıldız, Öztura, and Baklan (2016) also found that number of seizures did not significantly predict stigma in regression analyses [75], and Viteva found no correlation at all between stigma and seizure frequency [77].

3.6.1.2.3 Epilepsy onset

The age of epilepsy onset (i.e. longer duration of epilepsy) was found to significantly correlate with stigma [80] and to contribute to higher scores of stigma in several regression studies[54,68,79].

However, cultural variations were again identified [54]. In another regression study, Smith et al. (2009) found that those with later seizure onset were more likely to report lower levels of stigma but only when they were experiencing a higher quality of care [69]. In contrast, Aydemir, Kaya, Yıldız, Öztura, and Baklan did not find duration of epilepsy to significantly predict stigma in regression analyses [75].

3.6.1.2.4 Epilepsy treatment

Aydemir, Kaya, Yıldız, Öztura, and Baklan found that taking a greater number of epilepsy medications was correlated with increased stigma [75]. Yeni et al. also identified positive associations between the use of epilepsy medication and stigma [80]. However, in contrast, Viteva found no correlation between stigma and prescribed treatment [77]. Observed associations may be due in part to iatrogenic effects of treatments. When taking into account other illness-related variables in regression analyses, adverse events and side effects relating to the use of anti-epileptic drugs were found to significantly predict stigma [61,81]. Aydemir, Özkara, Canbeyli, and Tekcan also examined the effects of epilepsy surgery by comparing participants who had already received surgery to those who were awaiting surgery using t-tests [82]. The authors found no significant differences in the pre- and post-surgery groups, which they argued might have been due to the long-term effect of being labelled as “epileptic”, even if epilepsy has gone into remission. It is also

possible that for some people stigma related to refractory epilepsy (e.g. seizures) was replaced by stigma related to surgery (e.g. visible scarring), although this was not included in analyses.

3.6.1.3 Psychosocial variables

3.6.1.3.1 Psychological factors

Psychological and emotional factors which were found to predict higher levels of reported stigma in regression analyses included feelings about life and perceived impact of epilepsy [54], lower self-efficacy [68,69], lower patient satisfaction [68], feeling more socially restricted, and poor overall global QOL [61]. Social anxiety was also found to predict stigma in regression analyses, over and above depression and other types of anxiety [76]. Cognitive factors which were found to predict stigma variance in regression models included concerns related to social life and future occupation [75], negative outcome expectancies for seizures [68], and perception of the role of genetics in determining the condition [83]. Although previous research describes important differences between felt and enacted stigma [27], authors of the studies identified did not typically differentiate between the two; although in one study enacted stigma was found to predict felt stigma, with those experiencing discrimination, insults, threats or attacks reporting higher levels of the felt stigma [74]. Behavioural factors were also found to be important. After controlling for demographic and clinical variables including age, gender, duration of epilepsy, number of seizures, and number of medications using regression analyses, Aydemir, Kaya, Yıldız, Öztura, and Baklan found concealment of epilepsy to significantly predict felt stigma [75]. Similarly, the use of behavioural disengagement, a coping strategy whereby a person intentionally decreases the amount of effort needed to deal with a stressful situation, was also found in regression analyses to be independently associated with higher reported stigma [67].

3.6.1.3.2 Relational factors

Social support was found to be important. In a correlational study, participants with greater social support reported significantly lower stigma [66]. Furthermore, social support was found to

significantly predict lower stigma even when other sociodemographic variables had been taken into account in regression analyses [71]. To ascertain whether participants' social cognitive skills and their ability to understand the thoughts, intentions, beliefs, and emotions of others contributed to feelings of stigma, Noble, Robinson, and Marson compared "theory of mind" and stigma measures using regression analyses [84]; these were found to share little variance, regardless of participant seizure status, indicating that the model has little utility in understanding epilepsy stigma.

3.6.1.3.3 Knowledge and access to information

Access to understandable information was also found to be important. Correlational studies identified negative associations between knowledge and attitudes towards epilepsy (increased knowledge and more positive attitudes) and stigma [66,80]. After taking into account demographic and clinical variables using regression analyses, Baker also found knowledge of epilepsy to negatively predict stigma [79]. Similarly, difficulties in understanding written information, which may limit access to epilepsy knowledge, were found to predict higher levels of stigma in regression analyses [67].

3.6.2 Stigma as a predictor and correlate of wellbeing

Seventeen studies examined correlations between stigma and condition management, physical health or psychological wellbeing, with 11 studies then going on to use more complex models (e.g.. regression or mediation) where stigma was a predictor of physical and psychological wellbeing.

3.6.2.1 Physical wellbeing and condition management

Chesaniuk, Choi, Wicks, and Stadler found that higher perceived stigma was correlated with lower medication adherence; mediation analyses revealed this association to be explained largely by information, motivation, and behavioural skills [85]. Similarly, using path analysis Dilorio, Shafer, Letz, Henry, and Schomer found stigma to be indirectly related to medication self-management through its association with self-efficacy [86]. The association between stigma and lower self-efficacy was supported by a correlational study by Yeni et al., who found participants reporting

higher levels of stigma to be more likely to hide their condition from others and more likely to seek help from non-medical sources such as “mystics” [66]. In a regression study, Dilorio, Shafer, Letz, Henry, and Schomer found stigma to predict seizure severity [87], which they argued may be related to poor self-management or help-seeking behaviours; although it is possible that people who experience more seizures may be more likely to experience greater discrimination. Stigma was also found to be negatively correlated with social support [88] and epilepsy outcomes, including being identified as a significant predictor of “concerns about the social impact of epilepsy”, alongside seizure severity in regression analyses [62]. These findings may help to explain those identifying positive correlations between seizure severity and social support and stigma discussed above [69,78], and brings into question the causal direction of these relationships. In contrast to other studies, Elliott, Jacobson, and Seals did not find stigma to predict self-efficacy or epilepsy self-management in regression analyses [89]. The authors of this study identified age and ethnicity as the only predictors of these variables, highlighting the potential importance of demographic and cultural factors in determining health outcomes alongside stigma.

3.6.2.2 Psychological wellbeing and QOL

There was also evidence that stigma can affect psychological wellbeing and QOL. In several studies, stigma was positively correlated with depression and anxiety [66,70,71,77,86,87,88]. These findings were supported by a longitudinal study completed by Reisinger and Dilorio, in which stigma was found to be the third most important predictor of depression following employment status and social support, after controlling for demographic and seizure-related variables using regression analyses [90]. Similarly, in another regression study stigma was found to predict depression and anxiety when gender, age, and epilepsy-related variables had been controlled for [91]. Viteva also found that stigma correlated with affective and obsessive compulsive disorders (defined by the authors as “mental status impairment”) [77].

In addition to depression and anxiety, Viteva found stigma to negatively correlate with QOL [92]. Regression studies also found stigma to predict poor health-related quality of life (HRQOL), reduced psychosocial function, and lower “emotional wellbeing” when other variables had been accounted for [93,94]. Similarly, in regression analyses Suurmeijer, Reuvekamp, and Aldenkamp found perception of stigma to be the fourth strongest predictor of low QOL after psychological distress, loneliness, and adjustment and coping; this association was significant regardless of participants’ physical status [95]. Eidhin and McLeavey also found stigma to be significantly correlated with lower perceived acceptance of the condition, with participants with higher stigma feeling less cared for and less valued by others [78].

4. Discussion

4.1 Key findings

The findings of the review suggest that stigma is a complicated construct to understand in the context of PWE and is associated with a range of important factors. A number of demographic variables were found to be associated with stigma, although these findings were not replicated across all studies. Being married, higher income, and higher age were found to be associated with lower levels of stigma. These findings may be explained by the protective value that each of these variables has in relation to stigma. Being in a stable relationship may help to protect or mitigate against social rejection and the identification of an individual as “discredited” or having a “spoiled identity”, as per Goffman’s definition of stigma [1], through the social support offered by spouses [96]. This may help in part to explain why people who have stronger social relationships, including those that are married, have better health outcomes than those who are isolated or in relationships that are strained [97]. There is also evidence that those with access to greater financial resources and social support may be better able to cope with adversity [98,99]. Financial resources may be particularly relevant to PWE if it helps them to overcome limitations, for example paying for taxis may help to mitigate against the impact of being unable to drive and lead to feeling more included.

Older age has also been associated with increased resilience, which may be due to the development of coping skills and emotional regulation abilities [100]; this may again help to protect against the negative impact of externally-enacted stigma associated with the condition.

The review also highlighted differences in relation to illness-related variables. Findings in relation to seizure type and severity were mixed. Some studies found these factors to be associated with increased stigma whilst elsewhere the finding was not replicated. Regression analyses revealed that other illness-related variables such as age of epilepsy onset (lower age associated with higher stigma), number of seizures to date (greater number associated with higher stigma), and injuries associated with epilepsy, may be more important. Seizure frequency, whilst found to be associated with stigma, may also be less important in predicting stigma than the duration and impact of the condition. This fits in with wider health research which suggests that chronic illnesses can have a cumulative negative impact on psychological wellbeing [101], and can shift illness into the forefront of awareness [102]. For example, short-term illnesses may be easier to cope with than those experienced over a longer-period of time due to repeated exposure to negative health-related events, including experiences of discrimination by others. The cumulative number of seizures experienced may also increase the number of negative reactions from others (enacted stigma) and an increased perception of self as “externally deformed” (felt stigma), as per Goffman’s work [1] and Scambler’s Hidden Distress Model [26]. This longer-term exposure to seizures and negative reactions from others may also lead to an over-identification with the condition, exacerbated by negative language or labelling. The effect of labelling was demonstrated in an influential Brazilian study which reported experimental evidence that the term “epileptic” evoked more negative attitudes than the term "person with epilepsy" [103]. However, these findings have not been consistently replicated in other populations such as the UK and have been subject to criticism [104]. The findings of the review also suggested that the impact of illness-related variables on stigma can vary by country of origin, and therefore appeared to be, to a significant degree, culturally-specific.

Stigma in epilepsy is highly culturally-dependent [54] and this has been highlighted in previous research; for example, a recent cross-continental comparative study of PWE found Swedish participants to report significantly lower levels of stigma than PWE in Iran; the researchers argued that this was likely due to differences in medical treatment and educational exposure [105]. These cultural differences informed the rationale to narrow the focus the review on countries of Western origin, however there was still considerable heterogeneity identified across studies of different geographical origin.

One possible explanation relates to the impact of overall health system performance and health expenditure; the hypothesis being that higher expenditure will result in lower stigma as a result of greater understanding of the condition and better support systems. A PWE with greater seizure frequency and severity in a country where seizures are not well understood may be subject to greater stigma with lower support than someone experiencing the same level of seizure frequency and severity in a country where the condition is better understood. However, Brigo et al. found that, whilst there was a trend towards negative associations between expenditure and stigma, findings related to these variables were non-significant [72]. This suggests that general investments in public health systems do not necessarily lead to improvements in stigma-related epilepsy. To achieve this, the authors argue, funds need to be directed specifically towards epilepsy awareness and stigma-reduction programmes. Whilst public myths and misconceptions remain even in countries of higher socioeconomic status where educational campaigns have been launched [33,106], the negative impact of stigma on social identity in PWE can be greater in resource-poor countries [7]. Concealment of the condition in these countries is also likely to be higher [107], and issues of language and legality may increase the risks of stigma further [104]. It is therefore important that stigma reduction efforts are viewed as important and are culturally-informed [103]. Further variance in stigma can be explained by psychosocial factors. Knowledge of epilepsy, and the ability to access this, was universally found to be associated with lower stigma. Knowledge of

epilepsy is also an important factor in optimising control of seizures [108]; this may impact further on stigma and help to explain some of the geographical differences in stigma identified in different countries. Unsurprisingly, therefore, feelings of control and mastery over the condition were found to be negatively associated with perceptions of stigma. Where PWE reported lower feelings of self-efficacy or a deterministic view of the condition, or where they identified concerns about their ability to effectively manage their illness, to access support, or to cope in the future, stigma was higher. Such beliefs may also lead to maladaptive and avoidant coping strategies, such as concealment of the condition or behavioural disengagement with its management, which were found to increase stigma [67,75]. This could furthermore serve to reinforce a lack of social support, condition management, and perceived ability to cope, completing a vicious cycle that provides a fertile ground for perceived stigma in PWE. In this case, stigma may be seen as self-perpetuating, and again fits in with Scambler's "Hidden Distress Model of Epilepsy", in which a person feels stigmatised, conceals their condition from others, and feels increasingly distressed [26]. Therefore, in addition to wider societal educational campaigns, therapeutic interventions at an individual level are also likely to be important.

The findings associated with outcomes of stigma were more straightforward and perhaps less surprising. Higher levels of stigma were associated with a reduced sense of self-efficacy, lower motivation, and compromised condition management, characterised by lower medication adherence and poor epilepsy outcomes, including increased seizure severity. As previously identified, however, it was not possible to determine causal directions and it is likely that these relationships are strengthened in both directions. The psychological impact was also found to be significant. Stigma was found universally to be associated with or to predict depression and anxiety, even when other variables had been taken into account. This was in contrast to a review of earlier studies which found only one out of three studies to predict stigma [109], suggesting that the emotional impact of stigma may have changed over time. Stigma was also found to predict lower QOL and

was associated with other psychological difficulties including lower “emotional wellbeing” and perceived acceptance by others, and a greater incidence of obsessive compulsive disorders. Clearly, therefore, the impact of stigma on both physical and psychological wellbeing is significant, and warrants greater attention through research and targeted public health initiatives.

4.2 Implications and recommendations

The findings of the review suggest that, in addition to demographic and illness-related variables, psychosocial factors are likely to be particularly important in determining stigma. These are likely underpinned by knowledge about the condition, social support, and a perception that the care system, and in turn society, takes an understanding view of epilepsy and its management.

Insufficient awareness of epilepsy can result in a range of negative consequences, therefore public campaigns to address educational deficits have been advocated [48,110]. In the UK, this has been reflected by clinical guidelines that explicitly outline the responsibility of healthcare professionals to educate others about epilepsy as a means of reducing stigma [22], and a large number of awareness campaigns launched by charities [111,112]. Where such campaigns have been introduced, there has been some evidence of effectiveness [113]. However, there is some evidence that attitudes over the last 10 years may actually have worsened [114]. This may be explained in part by technological advances such as online social networking platforms like Twitter, where derogatory communications about epilepsy and seizures are common, and where stigma may be being fuelled by the propagation of negative attitudes towards the condition [115].

Societal values that can lead people to feel stigmatised and to conceal health conditions such as epilepsy can also extend to the law [116], therefore further research is needed to ensure that legal structures serve to protect, rather than stigmatise, people with the condition. In the current political climate, where division between different social and cultural groups is being made increasingly explicit, interventions which aim to reduce the stigma of people in minority health populations and increase compassion for those who are seen as “different” are now more important than ever. PWE

who feel stigmatised by others are more likely to feel depressed and anxious [e.g. 90]; they may also feel less accepted and valued by others [78]. Psychologists and other professionals working with PWE and their families should therefore help to give those they work with a voice, and to promote the view that epilepsy is a manageable, socially acceptable, condition that should not differentiate them negatively from others. Psychological therapies may also be beneficial in reducing perceived stigma. There is some evidence that psychological approaches such as acceptance and commitment therapy (ACT [117]) and compassion focused therapy (CFT; [118]) can help to increase psychological flexibility and reduce internalised health-related stigma [119]. Self-compassion has also been found to mediate the relationship between internalised self-stigma and depression; it has been suggested that self-compassion may provide a buffer against the negative impact of stigma that is experienced externally and then internalised [120]. Narrative therapy may also be beneficial in shedding light on alternative perspectives and helping PWE to develop new narratives about themselves [121]. In light of these recommendations, psychologists working in health settings arguably have a key role to play in tackling stigma at a wider societal level as part of their widening influence in public health initiatives [122].

4.3 Limitations and recommendations for further research

One of the most significant limitations of this review was that it relied heavily on cross-sectional surveys gathering data via self-report measures. The first limitation of this type of research is that it is not possible to determine causation [123]. For example, where higher seizure severity was found to be associated with greater stigma, severe seizures may have led to increased stigma or increased stigma may have led to more severe seizures, perhaps mediated by self-efficacy or condition management. Relationships in this context may therefore be bidirectional with one factor reinforcing another; from the research identified in the review it was possible to infer but not confirm this. Cross-sectional designs have also been criticised for assuming that variables remain stable over time and for therefore failing to address chronological variability, leading to biased

estimates and incorrect inferences [124]. Further research should aim to incorporate longitudinal methods to help determine causation and chronological variation. The second issue with this type of research is that, whilst an appropriate tool in this context, findings derived from self-report measures are open to bias [125]. They are also sensitive to culture [126], therefore the use of such measures in different countries requires careful consideration.

The specific tools used to measure stigma in the studies identified can also be brought into question. A large number of studies used a three-item measure of stigma originally used in a study of stroke patients [127], adapted for use in PWE by Jacoby [8]. Although this measure has been validated for use in this population [8,128], the measure is basic and may not detect subtle but important nuances such as “felt” versus “enacted” stigma. Further research should aim to use more detailed measurement tools and incorporate alternative sources of information such as clinical observations and case studies. A further limitation is that whilst much of the background literature on stigma in epilepsy differentiates between felt and enacted stigma as independent constructs, this was rarely discussed or addressed by researchers. This may be a significant omission as, for example, subtle differences in others’ language may be perceived as stigmatising by a person with epilepsy even where this is not intentionally or objectively enacted [129]. Current research fails to address this nuance of experience and this has implications for practice. For example, evidence of enacted stigma may point towards a need to direct change at public health level, whereas felt stigma may require support and interventions at an individual level.

A final limitation related to the challenges associated with determining inclusion and exclusion of studies on the basis of Western versus non-Western populations. Whilst the decision to differentiate was pragmatic and informed by an aim to address a defined research question, it is important to acknowledge that the “othering” - and potential stigmatising - of different social, cultural, and geographic groups may be perceived as in direct contrast to the spirit of this review. This is an

entirely unintended consequence of the limited scope of the work, which a further review or reviews in other populations would help to address.

4.4 Conclusions

The findings of this review suggest that stigma in PWE may be predicted by demographic, illness-related, and psychosocial factors, with the latter explaining a large degree of variance. However, findings varied significantly by country of origin. This suggests that stigma is, to a significant degree, culturally determined. As stigma is a social construct, this may be unsurprising; however it may present challenges to campaigners and legislators attempting to reduce stigma and its impact at an international level. What appears to be important, however, is fostering education and understanding of the condition, both in PWE and in the general population. The outcomes of stigma appear significant and more universal; its impact relates to both physical health, including management of the condition, and psychological wellbeing, including difficulties such as depression and anxiety. It is therefore important that healthcare providers, legislators, policy-makers, and citizens take steps to try and address these issues. Psychologists, who understand research and can influence others at individual and systemic levels, may be particularly well-placed to support these agendas. Whilst the evidence suggests that stigma of epilepsy remains prevalent, this is almost certainly to a significantly lesser degree in the West than in some developing areas of the world, particularly in rural areas where the condition is often still referred to in terms of demonic possession or a spiritual affliction. We may therefore already be able to see a positive influence of education and understanding. However, given the continued prevalence of stigma, perpetuated by historically and culturally-determined myths and misconceptions, and the impact it can have on PWE, we need to continue to invest in research and structures that can help to tackle stigma of epilepsy both now and in the future.

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Tables and figures

Figure 1. *Flow chart of search and inclusion/exclusion process*

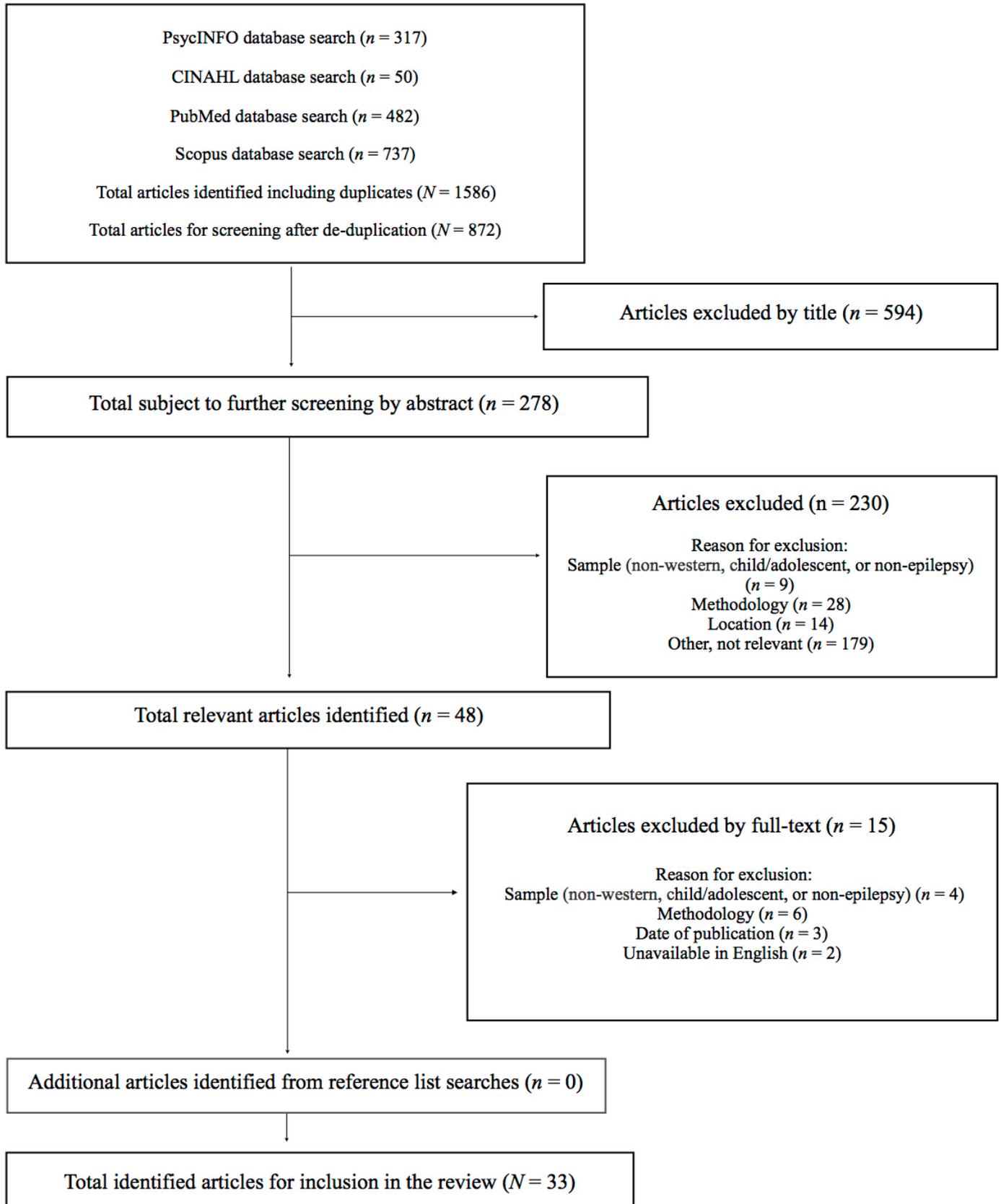


TABLE 1. CHARACTERISTICS OF QUANTITATIVE STUDIES OF EPILEPSY AND STIGMA IDENTIFIED IN THE REVIEW

<i>Study</i>	<i>Design</i>	<i>Country of Origin</i>	<i>Participants</i>	<i>Measures</i>	<i>Analysis</i>	<i>Effect size (Pearson's r)</i>	<i>Findings/Authors' Conclusions</i>
Aydemir, Özkara, Canbeyli, and Tekcan (2004)	Cross-sectional survey	Turkey	$n = 20$ patients awaiting epilepsy surgery and $n = 21$ who had already undergone surgery in Turkey ($N = 41$; mean age = 25.9 years)	Jacoby 3-item measure of stigma, the Perceived Impact of Epilepsy Scale, the Medical Outcomes Study Short Form-36 (SF-36), Beck Depression Inventory (BDI), State-Trait Anxiety Inventory (STAI)	T -test; Mann-Whitney U	Not reported	No significant difference was found relative to stigma levels between pre- and post-SAH groups ($p = .82$). In fact, a high level of stigma was observed in only 6 (14.7%) of the patients, suggesting that stigmatisation may be low among Turkish patients.
Aydemir, Kaya, Yıldız, Öztura, and Baklan (2016)	Cross-sectional survey	Turkey	$N = 200$ Turkish adults with epilepsy (age = 18-68 years, mean age = 31.68 years)	The Felt Stigma Scale, the Concealment of Epilepsy Scale, the Epilepsy Concern Scale, the Overprotection Scale	Correlation (r); hierarchical multiple regression	Stigma and overprotection ($r = .34$). Stigma and concealment ($r = .64$). Stigma and concerns related to future occupation ($r = .62$). Stigma and concerns related to social life ($r = .62$). Stigma and concerns related to marriage and having children ($r = .43$). Stigma and number of medications ($r = .21$).	Concealment of epilepsy ($\beta = .43, p < .001$), concerns related to social life ($\beta = .27, p < .001$), and concerns related to future occupation ($\beta = .26, p < .001$) were found as the predictors of felt stigma after controlling for demographics (age and gender), and clinical variables (duration of epilepsy, number of seizures, and number of medications).

<i>Study</i>	<i>Design</i>	<i>Country of Origin</i>	<i>Participants</i>	<i>Measures</i>	<i>Analysis</i>	<i>Effect size (Pearson's r)</i>	<i>Findings/Authors' Conclusions</i>
Baker, Brooks, Buck, and Jacoby (2000)	Cross-sectional survey	10 European countries including France, UK, Germany, and the Netherlands	$N = 5211$ adult epilepsy patients living in 15 European countries (69% from France, UK, Germany, and the Netherlands) (age = 16+ years, mean age = 35 years)	Jacoby 3-item measure of stigma, Perceived Impact of Epilepsy Scale, Extent of Worry over Epilepsy, the Medical Outcomes Study Short Form 36 (SF-36), Terrible-Delighted Faces Scale	Correlation (r); multiple regression analysis	Not reported	A multivariate analysis identified impact of epilepsy ($\beta = .43, p < .0001$), age of onset ($\beta = .09, p < .0001$), country of origin, feelings about life ($\beta = .05, p < .001$), and injuries associated with epilepsy ($\beta = .05, p < .01$) as significant contributors on scores on the stigma scale. Whereas seizure type and frequency were significantly correlated with scores on the stigma scale, results of the multiple regression showed that neither seizure frequency nor seizure type accounted for a significant amount of the variance on scores on the stigma scale.
Brigo, Igwe, Ausserer, Tezzon, Nardone, and Otte (2015)	Cross-sectional survey	10 European countries including France, UK, Germany, and the Netherlands	$N = 5211$ adult epilepsy patients from 10 European countries (age = 16-98 years, mean age = 37 years)	Percentages of people with epilepsy with epilepsy-related stigma obtained from Baker et al.'s (2000) study (which used the Jacoby 3-item measure of stigma), data on overall health system performance in 1997, data on health expenditure per capita in international dollars in 1997*	Correlation (r)	Stigma percentage and health system performance ($r = -.16$). Stigma and health expenditure per capita ($r = -.24$). Stigma and quality of life ($r = -.33$).	We found a nonsignificant trend towards negative correlation between the epilepsy-related stigma percentage and the overall health system performance ($r = -0.16$; $p = 0.57$), the health expenditure per capita in international dollars ($r = -0.24$; $p = 0.4$), and the Economist Intelligence Unit's quality-of-life index ($r = -0.33$; $p = 0.91$).

**Used the same sample as Baker et al. (2000)*

<i>Study</i>	Design	Country of Origin	Participants	Measures	Analysis	Effect size (Pearson's <i>r</i>)	Findings/Authors' Conclusions
Baker (2002)	Cross-sectional survey	European countries including France, UK, Germany, and the Netherlands	<i>N</i> = 6156 adult epilepsy patients from 10 European countries (age = 16-98 years, mean age = 37 years)	Jacoby 3-item measure of stigma, the Epilepsy Knowledge Questionnaire, the Impact of Epilepsy Questionnaire, and the Acceptance of Illness Scale	ANOVA ; stepwise multiple regression analysis	Not reported	After taking into account demographic and clinical variables, a number of factors were predictive of stigma, including seizure frequency, knowledge of epilepsy, duration of epilepsy, and seizure type. The relative contributions of these factors varied depending on the country of origin of those surveyed.
Bautista, Shapovalov, and Shoraka (2015)	Cross-sectional survey	USA	<i>N</i> = 182 adults with epilepsy at US epilepsy centres (mean age = 43 years)	The Epilepsy Stigma Scale (ESS), the Quality of Life in Epilepsy-10 (QOLIE-10), the Beliefs about Medicine Questionnaire (BMQ), the Short Test of Functional Health Literacy in Adults (STOHFLA), the Brief-COPE	Correlation (<i>r</i>); ANOVA ; multiple linear regression analysis	Stigma and age ($r = -.164$). Stigma and QOL ($r = .36$). Stigma and use of denial ($r = .15$). Stigma and behavioural disengagement ($r = .33$). Stigma and venting ($r = .2$).	Using multiple linear regression, marital status (being single) ($\beta = -4.027$, $p = .01$), being poorer, indicated by higher QOLIE-10 scores ($\beta = .45$, $p < .01$), difficulties understanding written information ($\beta = -2.19$, $p = .03$), and the use of behavioural disengagement ($\beta = 2$, $p = .01$) were independently associated with poorer scores on the Epilepsy Stigma Scale.

<i>Study</i>	<i>Design</i>	<i>Country of Origin</i>	<i>Participants</i>	<i>Measures</i>	<i>Analysis</i>	<i>Effect size (Pearson's r)</i>	<i>Findings/Authors' Conclusions</i>
Begley, Shegog, Iyagba, Chen, Talluri, Dubinsky, ... and Friedman (2010)	Cross-sectional survey	USA	$n = 167$ US patients from "high socioeconomic status" epilepsy clinic and $n = 71$ from "low socioeconomic status" clinic ($N = 238$; age = 18+ years, mean age = 40.9 years)	Modified Parent Stigma Scale, Epilepsy Self-Management Scale, Epilepsy Knowledge Scale, Epilepsy Self-Efficacy Scale, Treatment Outcome scale, Shared control portion of the Multidimensional Desire for Control Scale, Personal Resource Questionnaire 85, Part 2 (PRQ85-2), Center for Epidemiologic Studies Depression Scale (CES-D), Patient Satisfaction Questionnaire III	T -test; correlation (r); multivariate regression analysis	Stigma and self management ($r = .077$).	Stigma, along with self-efficacy, depression, social support, desire for control, and outcome expectations, was higher for those of high socio-economic status ($P < 0.01$).

<i>Study</i>	<i>Design</i>	<i>Country of Origin</i>	<i>Participants</i>	<i>Measures</i>	<i>Analysis</i>	<i>Effect size (Pearson's r)</i>	<i>Findings/Authors' Conclusions</i>
Leaffer, Hesdorffer, and Begley (2014) <i>*Used the same sample as Begley et al. (2010)</i>	Cross-sectional survey	USA	$n = 167$ US patients from "high socioeconomic status" epilepsy clinic and $n = 71$ from "low socioeconomic status" clinic ($N = 238$; age = 18+ years, mean age = 40.9 years)	Modified Parent Stigma Scale, Epilepsy Self-Management Scale, Epilepsy Knowledge Scale, Epilepsy Self-Efficacy Scale, Treatment Outcome scale, Shared control portion of the Multidimensional Desire for Control Scale, Personal Resource Questionnaire 85, Part 2 (PRQ85-2), Center for Epidemiologic Studies Depression Scale (CES-D), Patient Satisfaction Questionnaire III	T -test; correlation (r); linear regression analysis	Stigma and QOL ($r = .41$) Stigma and social support ($r = -.39$). Stigma and self-efficacy ($r = -.21$).	Reported levels of stigma were higher in low SES than in high SES ($p < 0.0001$), and all psychosocial variables were associated with stigma, including depression severity ($p < 0.0001$), knowledge of epilepsy ($p = 0.006$), quality of life ($p < 0.0001$), social support ($p < 0.0001$), and self-efficacy ($p = 0.0009$). Stigma was statistically significantly associated with quality of life in the low SES group and with depression severity and social support in the high SES group.
Bielen, Friedrich, Sruk, Prvan, Hajnšek, Petelin, ... and Jacoby (2014)	Cross-sectional survey	Croatia	$N = 298$ Croatian epilepsy outpatients (age = 17-82 years, mean age = 45 years)	Revised version of the Jacoby 3-item measure of stigma, translated into Croatian.	ANOVA; Multiple stepwise regression (B)	Not reported	Feelings of stigma were significantly associated with age ≤ 50 years, younger age of epilepsy onset, more than 50 seizures to date, generalised tonic-clonic seizures, and a shorter seizure-free period. Multiple stepwise regression showed number of seizures to date as a significant variable ($B = 0.246$).

<i>Study</i>	<i>Design</i>	<i>Country of Origin</i>	<i>Participants</i>	<i>Measures</i>	<i>Analysis</i>	<i>Effect size (Pearson's r)</i>	<i>Findings/Authors' Conclusions</i>
Chesaniuk, Choi, Wicks, and Stadler (2014)	Cross-sectional survey	USA	<i>N</i> = 140 PWE in the US (age = 20-65 years, mean age = 38.51 years)	The Epilepsy Stigma Scale, Knobel Brief Adherence Questionnaire, adapted scale of adherence information, motivation and behavioural skills	Correlation (r); mediation analysis	Stigma and medication adherence ($r = -.18$). Stigma and levels of information ($r = -.28$). Stigma and motivation ($r = -.55$). Stigma and behavioural skills ($r = -.41$).	Higher perceived epilepsy-related stigma was associated with lower medication adherence ($r = -.18$, $p = .05$). Higher stigma was associated with lower levels of information ($r = -.28$, $p = .05$), motivation ($r = -.55$, $p = .05$), and behavioural skills ($r = -.41$, $p = .05$). Adherence information, motivation, and behavioural skills explained nearly all of the association between perceived stigma and adherence: the total effect of perceived stigma on adherence ($c = -.18$, $p = .05$) was reduced to a direct effect near zero ($c = 0.06$, $p = .48$) when accounting for the indirect effects through information, motivation, and behavioural skills.
Chong, Drake, Atkinson, Ouellette, and Labiner (2012)	Cross-sectional survey	USA	<i>N</i> = 50 Hispanic epilepsy clinic patients of Mexican descent (age = 18+ years, mean age = 38.6 years)	Edited version of the Parent Stigma Scale, the Epilepsy Self-Efficacy Scale, the Interpersonal Support Evaluation List (ISEL), the Family Emotional Involvement and Criticism Scale (FEICS), the Patient Health Questionnaire 9 (PHQ-9), the Acculturation Rating Scale for Mexican Americans II (ARSMA-II)	Correlation (r); Principal components analysis (PCA)	Stigma and depression ($r = .39$). Stigma and social support ($r = -.65$).	Stigma was positively correlated with depression ($r = 0.39$, $p < 0.01$) and negatively associated with social support ($r = -0.65$, $p < 0.001$). Stigma was not significantly correlated with perceived criticism, emotional involvement, self-efficacy, or national orientation.

<i>Study</i>	<i>Design</i>	<i>Country of Origin</i>	<i>Participants</i>	<i>Measures</i>	<i>Analysis</i>	<i>Effect size (Pearson's r)</i>	<i>Findings/Authors' Conclusions</i>
Dilorio, Osborne Shafer, Letz, Henry, Schomer, and Yeager (2003)	Cross-sectional survey	USA	<i>N</i> = 314 adult men and women with epilepsy in the US recruited from "Project EASE" (age = 19 to 75 years, mean age = 43 years)	The Parent Stigma Scale modified for use to measure stigma in adults, the Epilepsy Self-Efficacy Scale, the Epilepsy Self-Management Scale, the Self-Reported Medication-Taking Scale, the Patient Satisfaction Questionnaire—III, Multidimensional Desire for Control scale	ANOVA ; Correlation (<i>r</i>); hierarchical regression analysis	Stigma and self-efficacy to manage epilepsy (<i>r</i> = -.431). Stigma and outcome expectancies related to treatment (<i>r</i> = -.213) and seizures (<i>r</i> = .652). Stigma and medication management (<i>r</i> = -.200). Stigma and patient satisfaction (<i>r</i> = -.190 to -.350). Stigma and expectancies related to information management (<i>r</i> = .159).	Participants who reported higher levels of perceived stigma also reported lower levels of self-efficacy to manage epilepsy (<i>r</i> = -0.431); more negative outcome expectancies related to treatment (<i>r</i> = -0.213) and seizures (<i>r</i> = 0.652); and lower levels of medication management (<i>r</i> = -0.200), medication adherence (<i>r</i> = 0.202), and patient satisfaction (<i>r</i> = -0.190 to -0.350). However, they reported more positive outcome expectancies related to information management (<i>r</i> = 0.159). In regression analysis, income, age at first seizure, seizures during the past year, lower self-efficacy, negative outcome expectancies for seizures, and less patient satisfaction explained 54% of the variance in perceived stigma.

<i>Study</i>	<i>Design</i>	<i>Country of Origin</i>	<i>Participants</i>	<i>Measures</i>	<i>Analysis</i>	<i>Effect size (Pearson's r)</i>	<i>Findings/Authors' Conclusions</i>
Dilorio, Shafer, Letz, Henry, and Schomer (2004) <i>*Used the same sample as Dilorio et al. (2003)</i>	Cross-sectional survey	USA	<i>N</i> = 317 PWE in the US recruited from "Project EASE" (age = 19-75 years, mean age = 43.3 years)	Modified version of The Parent Stigma Scale (expanded to 10 items), Epilepsy Self-Efficacy Scale, Epilepsy Self-Efficacy Scale, Epilepsy Regimen-Specific Support Scale, Personal Resource Questionnaire 85 Part 2 (PRQ85-2), Center for Epidemiologic Studies Depression Scale (CES-D), Patient Satisfaction Questionnaire-III, Multidimensional Desire for Control Scale	Path analysis	Not reported	Stigma was directly related to self-efficacy and depressive symptoms. Stigma was indirectly related to medication self-management through its association with self-efficacy. These results suggest that those who feel highly stigmatised because of their epilepsy are less efficacious in taking their medications.

<i>Study</i>	<i>Design</i>	<i>Country of Origin</i>	<i>Participants</i>	<i>Measures</i>	<i>Analysis</i>	<i>Effect size (Pearson's r)</i>	<i>Findings/Authors' Conclusions</i>
Dilorio, Shafer, Letz, Henry, and Schomer, (2006)	Longitudinal survey	USA	<i>N</i> = 272 PWE in the US recruited from "Project EASE" (age = 19-74 years, mean age = 43.7 years)	The Epilepsy Stigma Scale, The Epilepsy Self-Efficacy Scale, The Epilepsy Management Scale, The Personal Resource Questionnaire 85 Part 2 (PRQ85-2), The Epilepsy Regimen Specific Support Scale, The Patient Satisfaction Questionnaire-III (PSQ), The Center for Epidemiologic Studies Depression Scale (CES-D)	Hierarchical regression	Not reported	Stigma was a "potentially significant predictor" of self-efficacy ($F=3.643$, $p<0.057$) but this was less important than self-management, depressive symptoms and seizure severity. The inverse relationship found between perceived stigma and self-efficacy in this study suggests that those who harbour negative thoughts about epilepsy also feel less confident in their ability to manage epilepsy.
<i>*Used the same sample as Dilorio, Osborne Shafer, Letz, Henry, Schomer, & Yeager (2003)</i>							
Reisinger and Dilorio (2009)	Longitudinal survey	USA	<i>N</i> = 319 PWE in the US recruited from "Project EASE" (age = 19-75 years, mean age = 43.3 years)	Epilepsy Stigma Scale, Center for Epidemiologic Studies Depression Scale (CES-D), Epilepsy Self-Management Scale (ESMS), Epilepsy Self-Efficacy Scale (ESES), Self-Reported Medication-Taking Scale, Personal Resource Questionnaire 85 Part 2 (PRQ85-2), Patient Satisfaction Questionnaire	ANOVA ; Correlation (r); stepwise multiple regression (B)	Stigma and depression at baseline, 3 and 6-month follow-up ($r=.425$, $.343$ and $.371$, respectively).	Stigma was correlated with depression at baseline, 3- and 6-month follow-up ($r=.425$, $.343$ and $.371$, respectively, $p<.001$). The three major factors that predicted depressive symptoms at each time point (when controlling for demographic and seizure-related variables) were employment status, social support, and stigma. The third main predictor of depressive symptoms in the study was epilepsy-related stigma.

<i>Study</i>	<i>Design</i>	<i>Country of Origin</i>	<i>Participants</i>	<i>Measures</i>	<i>Analysis</i>	<i>Effect size (Pearson's r)</i>	<i>Findings/Authors' Conclusions</i>
Whatley, Dilorio, and Yeager (2010) <i>*Used a subset of the same sample as Dilorio et al. (2003)</i>	Longitudinal study	USA	<i>N</i> = 147 US adults with epilepsy recruited from "Project EASE" (age = 19-75 years, mean age = 45 years)	10-item scale adapted from the Parent Stigma Scale, 31-item Quality of Life in Epilepsy (QOLIE-31) scale, adapted from the more comprehensive 89-item scale, Center for Epidemiologic Studies Depression Scale (CES-D), Personal Resource Questionnaire (PRQ85-part 2)	Correlation (<i>r</i>); multiple linear regression	Stigma and QOL (<i>r</i> = -.513).	Correlational analyses revealed statistically significant negative correlations between depressive symptoms, stigma and sometimes regimen-specific support and QOL. Psychosocial variables measured 3 months prior to QOL were entered into a hierarchical multiple linear regression model, revealing that depressive symptoms, stigma and social support can be used to predict QOL at a later time.
Elliott, Jacobson, and Seals (2006)	Cross-sectional survey	USA	<i>N</i> = 94 epilepsy patients in the US (age = 19-78 years, mean age = 45 years)	The Liverpool Stigma Scale (LSS), the Osteoporosis Knowledge Test (OKT), the Osteoporosis Health Belief Scale (OHBS), the Osteoporosis Self-Efficacy Scale (OSES), the Quality of Life in Epilepsy (QOLIE-31) scale, and the Epilepsy Self-Efficacy Scale (ESES)	ANOVA; Multivariate regression analysis (B)	Not reported	The Liverpool Stigma Scale did not predict any of the dependent variables (self-efficacy for calcium, exercise, and epilepsy self-management).

<i>Study</i>	<i>Design</i>	<i>Country of Origin</i>	<i>Participants</i>	<i>Measures</i>	<i>Analysis</i>	<i>Effect size (Pearson's r)</i>	<i>Findings/Authors' Conclusions</i>
Heersink, Kocovski, MacKenzie, Denomme, and Macrodimitris (2015)	Cross-sectional survey	Canada	<i>N</i> = 101 PWE in Canada (age = 18-65 years, mean age = 37.51 years)	Jacoby 3-item measure of stigma, the Social Phobia Inventory (SPIN), the Hospital Anxiety and Depression Scale (HADS), the Epilepsy Knowledge Questionnaire (EKQ), the Liverpool Seizure Severity Scale (LSSS), the Impact of Epilepsy scale, the Disclosure Management Scale, Brief Fear of Negative Evaluation (BFNE) scale, Acceptance and Action Epilepsy Questionnaire (AAEpQ)	Correlation (r); hierarchical regression analysis; ANCOVA	Stigma and social anxiety ($r = .48$).	Social anxiety positively correlated with felt stigma ($r = .48, p < .001$). This relationship remained significant after controlling for depression ($p < .001$). Social anxiety significantly predicted the variance in stigma above and beyond age, anxiety, impact of epilepsy, seizure frequency, and depression ($\beta = .33, p < .001$).
McLaughlin, Pachana, and McFarland (2008)	Cross-sectional study	Australia	Epilepsy group <i>N</i> = 64 older adults with epilepsy in Australia (age = 60+ years, mean age = 67.59 years). Control group <i>N</i> = 60 adults recruited from the general community (age 60+ years, mean age = 66.50 years).	3-Item Stigma scale, Mini mental state exam (MMSE), Washington Psychosocial Seizure Inventory (WPSI), Quality of life in epilepsy (QOLIE-31), Seizure frequency	MANOVA; multiple regression analysis	Not reported	In the HRQOL regression, stigma contributed significantly to prediction of HRQOL ($sr^2 = .21$). A greater perception of stigma was strongly related to poor quality of life and reduced psychosocial function. Less stigma and lower frequency of seizures uniquely contributed to the overall prediction of better health-related quality of life. Overall, the predictors of stigma and seizure frequency together accounted for 54% of the variability in health-related quality of life.

<i>Study</i>	<i>Design</i>	<i>Country of Origin</i>	<i>Participants</i>	<i>Measures</i>	<i>Analysis</i>	<i>Effect size (Pearson's r)</i>	<i>Findings/Authors' Conclusions</i>
Eidhin and McLeavey (2001)	Cross-sectional survey	Northern Ireland	$N = 52$ people with a diagnosis of epilepsy attending an outpatient clinic in Northern Ireland (age = years, mean age = years)	Jacoby 3-item measure of stigma; Perceived Severity of Epilepsy Scale; Perceived Acceptance Scale; Questions relating to epilepsy and seizure type and frequency	Correlation (r)	Stigma and seizure severity ($r = .37$). Stigma and perceived acceptance ($r = -.35$).	Seizure severity was significantly correlated with perception of stigma ($r = .37$, $p < .01$). A significant negative correlation were found between perceived stigma and perceived acceptance ($r = -.35$, $p < .05$).
Noble, Robinson, and Marson (2016)	Cross-sectional study	UK and Republic of Ireland	$N = 503$ PWE in the UK and Republic of Ireland (age = 18-79 years, median age = 37 years)	Jacoby 3-item measure of stigma, the Faux Pas Task-Short Version (FPT), the Reading the Mind in the Eyes Test (RMET)	Correlation (r); multiple regression analysis	Stigma and theory of mind performance ($r = -.02$ on the RMET and $r = -.05$ on the FPT).	Feelings of stigma held a negligible, negative, and nonsignificant association with ToM performance ($r = -.02$ and $-.05$). The ToM model for understanding epilepsy stigma has limited utility.
Peterson, Walker, and Shears (2014)	Cross-sectional survey	Australia	$N = 300$ PWE in Australia completing the 2010 Australian Epilepsy Longitudinal Survey to register participants on the Australian Epilepsy Research Register (AERR) (age = 18+ years)	Stigma scale emerging from factor analysis of items principally derived from the Child Asthma scale (including social scale and personal scale subscales), the Hospital Anxiety and Depression Scale (HADS)	Correlation (r); Multiple regression analysis (B)	Not reported	Pearson correlations identified significant correlations between anxiety and depression and social and personal aspects of stigma. Social aspects of stigma significantly predicted depression and anxiety ($B = .34$ and $.32$, respectively, $p < .01$) when gender, age and epilepsy-related variables had been controlled for. Social aspects of stigma had the strongest effect on anxiety, followed by the effectiveness of current control on seizures. Those who take more epilepsy drugs experienced greater stigma as a result and, therefore, had higher rates of depression and anxiety.

<i>Study</i>	<i>Design</i>	<i>Country of Origin</i>	<i>Participants</i>	<i>Measures</i>	<i>Analysis</i>	<i>Effect size (Pearson's r)</i>	<i>Findings/Authors' Conclusions</i>
Sabatello, Phelan, Hesdorffer, Shostak, Goldsmith, Sorge,... and Ottman (2015)	Cross-sectional survey	USA	$n = 181$ PWE and $n = 178$ biologic relatives without epilepsy in the US ($N = 359$; mean age = 52 years)	Epilepsy Stigma Scale (ESS), Family Epilepsy Stigma Scale (FESS), three questions related to genetic causal attribution	T -test; Correlation (r); multivariate analyses using generalized estimating equations (GEE) models	Not reported	Felt stigma was higher among individuals who were aged ≥ 60 years, were unemployed, reported epilepsy-related discrimination, or had seizures within the last year or >100 seizures in their lifetime. Adjusting for other variables, ESS scores in people with epilepsy were significantly higher among those who perceived genetics played a "medium" or "big" role in causing epilepsy in the family than in others (3.4 vs. 2.7, $p = 0.025$).
Smith, Ferguson, Saunders, Wagner, Wannamaker, and Selassie (2009)	Cross-sectional survey	USA	$N = 244$ adults with epilepsy in the US (age = 18+ years)	The Stigma Scale (8 questions modified from the scale developed by Dilorio), the Epilepsy Self-Efficacy Scale (ESES),	Kruskal-Wallis test; multiple linear regression	Not reported	After adjustment for the other variables in the final model, only three combinations were significantly related to perceived stigma. Reported levels of stigma were associated with interactions of seizure worry and employment status (disabled or unemployed with higher seizure worry=higher stigma), self-efficacy and social support (higher scores=lower stigma), and quality of care and age at seizure onset (higher quality of care and over 40=lower stigma).

<i>Study</i>	<i>Design</i>	<i>Country of Origin</i>	<i>Participants</i>	<i>Measures</i>	<i>Analysis</i>	<i>Effect size (Pearson's r)</i>	<i>Findings/Authors' Conclusions</i>
Suurmeijer, Reuvekamp, and Aldenkamp (2001)	Cross-sectional survey	The Netherlands	<i>N</i> = 210 PWE attending outpatient clinics in The Netherlands (age = 18-65 years, mean age = 38 years)	Perception of stigma of epilepsy (PSE), Perception of epilepsy seizures (PES), Health perceptions (HP), Life-fulfillment questionnaire (LFQ), Loneliness scale (LS), General adjustment to epilepsy (GATE), Self-esteem (RSE), Mastery (MAS), Mental health (MH), Psychological distress (GHQ), Visual Analogue Scale (VAS-DT)	Correlation (<i>r</i>); Hierarchical multiple regression analysis (<i>B</i>)	Stigma and QOL (<i>r</i> =0.17).	Perception of stigma in epilepsy was negatively correlated with QOL (<i>r</i> =0.17, <i>p</i> <.01). In decreasing order of importance, psychological distress, loneliness, adjustment and coping, and stigma perception (<i>B</i> =.17, <i>p</i> =.4) appeared to contribute most significantly to the outcome QoL as judged by the patients themselves, regardless of their physical status.

<i>Study</i>	<i>Design</i>	<i>Country of Origin</i>	<i>Participants</i>	<i>Measures</i>	<i>Analysis</i>	<i>Effect size (Pearson's r)</i>	<i>Findings/Authors' Conclusions</i>
Taylor, Baker, and Jacoby (2011)	Cross-sectional survey	UK	$N = 1566$ adults with epilepsy in the UK (mean age = 40 years)	The Revised Stigma Scale, the Newly Diagnosed Epilepsy Quality of Life (NEWQOL) battery	Correlation (r); Kruskal–Wallis test; χ^2 test; stepwise multiple regression	Stigma and anxiety ($r = .41$). Stigma and depression ($r = .41$). Stigma and mastery ($r = -.41$). Stigma and cognitive effects of anti-epileptic drugs ($r = .43$). Stigma and adverse events ($r = .45$).	Those who felt highly stigmatised were significantly younger than those who did not report feeling stigmatised; they were also more likely to have a previous or current neurological disorder (25.0% vs 14.1%), less likely to be married (47.9% vs 60.2%), more likely to have already experienced four or more seizures (86.5% vs 60.7%), more likely to have no formal educational qualifications on leaving school (52.7% vs 37.1%), and more likely to be unemployed (69.0% vs 47.6%). Gender, seizure type, presence of a neurological deficit, and social class were not associated with degree of felt stigma. A multivariate linear regression demonstrated that scores on the AEP, mastery scale, and ABNAS, poor overall global QOL, age < 50 years, more than four seizures at baseline, and feeling more socially restricted were significant predictors of the revised stigma score.
Viteva (2012)	Cross-sectional survey	Bulgaria	$n = 94$ patients with refractory epilepsy (RE) and $n = 70$ patients with pharmacoresistant epilepsies (PSE) in Bulgaria ($N = 164$; age = 18-65 years, mean age = 41.72 years)	Jacoby 3-item measure of stigma, the Beck Depression Inventory (BDI-II), the Hamilton Anxiety Scale (HAS), the Liverpool Seizure Severity Scale (LSSS), and	Correlation (r)	Stigma and depression ($r = .40$). Stigma and mental status impairment ($r = .19$).	No correlation was found between stigma and age and gender, education, marital status, employment, seizure frequency and severity, prescribed treatment, or anxiety ($P > 0.05$). A moderate correlation was found between depression and stigmatisation frequency and severity ($r = .40$, $P < .01$). A mild correlation was found between mental status impairment and stigmatisation. Mental status impairment was associated with a more frequent and more severe stigmatisation ($r = .19$, $P < .05$).

Study	Design	Country of Origin	Participants	Measures	Analysis	Effect size (Pearson's r)	Findings/Authors' Conclusions
Viteva (2013) <i>*Used the same sample as Viteva (2012)</i>	Cross-sectional survey	Bulgaria	<i>N</i> = 140 PWE (70 patients with refractory epilepsy and 70 patients with pharmacoresistant epilepsy) in Bulgaria (age = 18-65 years, mean age = 41.7 years)	Jacoby 3-item measure of stigma, the Health Related Quality of Life measure (QOLIE-89)	Correlation (r)	Stigma and QOL ($r = -.6$).	Perceived stigma had a negative impact on QOL (<i>T</i> -score 47.8), including all sub-scales of QOLIE-89, with the exception of "change in health" and "sexual relations". Patients with refractory epilepsy reporting stigmatisation most commonly had very low and low scores on the sub-scales "health perceptions" (82.9%), "emotional well-being" (71.5%), "memory" (63.4%) and "health discouragement" (62.5%). There was a negative correlation of all QOLIE-89 sub-scales with perceived stigma severity.
Viteva (2014)	Cross-sectional survey	Bulgaria	<i>N</i> = 64 patients with refractory epilepsy and intellectual impairment in Bulgaria (age = 18-65 years, mean age = 44.88 years)	The stigma scale, the Glasgow Depression Scale for people with a Learning Disability (GDS-LD), ⁴ the Glasgow Anxiety Scale for people with Intellectual Disability (GAS-ID), The Liverpool Seizure Severity Scale (LSSS), The Glasgow Epilepsy Outcome Scale (GEOS-35), the carer supplement of the GDS-LD (GDS-CD)	Correlation (r); multivariate regression analysis	Stigma and health-related QOL ($r = .43$).	GEOS-35 total scores were associated with seizure frequency and severity, stigma, depression, and anxiety. On multivariate regression analysis predictors of the GEOS-35 total score were anxiety, seizure severity, and stigma $p < 0.001$ ($F = 14.66$). Regarding GEOS-35 sub-scales, on multivariate regression analysis seizure severity and stigma were predictors of "concerns about social impact" $p < 0.001$ ($F = 18.31$).

Study	Design	Country of Origin	Participants	Measures	Analysis	Effect size (Pearson's r)	Findings/Authors' Conclusions
Viteva and Semerdjiva (2015) <i>*Used the same sample as Viteva (2014)</i>	Cross-sectional survey	Bulgaria	N = 64 patients with refractory epilepsy and intellectual impairment in Bulgaria (age = 18-65 years, mean age = 44.88 years)	The stigma scale for people with intellectual impairment (10-item), Evaluation rapide des fonctions cognitives (ERFC), interview about enacted stigma comprising four statements about a real experience of discrimination	Correlation (r); multiple regression analysis	Stigma and discrimination (r=.71). Stigma and experienced insults and threats and/or attacks (r=.43)	The experience of insults and/or threats and attacks because of participants' health problems was more frequent in cases with moderate intellectual impairment ($\chi^2 = 5.17, P < 0.05$). Participants who gave a greater number of positive answers about experienced discrimination or insults and/or threats and attacks reported a more pronounced perceived stigma (F=19.30, P<0.001 and F=12.91, P<0.001, respectively). Perceived stigma and the experience of insults and/or threats and attacks proved to be predictors of discrimination on multivariate regression analysis (F=40.54, P<0.001).
Viteva (2016)	Cross-sectional survey	Bulgaria	N = 153 patients with epilepsy in Bulgaria (age = 18-65 years, mean age = 39.34 years)	Jacoby 3-item measure of stigma, the Liverpool Adverse Events Profile (LAEP)	Correlation (r); multiple regression analysis	Stigma and the presence of neurological and psychiatric adverse events (r=.60). Stigma and the presence of non-neurological adverse events (r=.20).	Perceived stigma was observed in 64.71% of the study participants. There was a significant association between perceived stigma and the total LAEP score (p < 0.05, F = 13.71). Patients who reported AEs had an increased risk of perceiving stigma compared to those who did not experience AEs. A significant correlation between perceived stigma and the presence of neurological and psychiatric AEs (p < 0.001, r = +0.60) and a mild correlation between perceived stigma and the presence of nonneurological AEs (p < 0.01, r = +0.20) were verified. In a multivariate regression analysis the only predictors of perceived stigma were AED polytherapy and the presence of neurological and psychiatric AEs.

<i>Study</i>	<i>Design</i>	<i>Country of Origin</i>	<i>Participants</i>	<i>Measures</i>	<i>Analysis</i>	<i>Effect size (Pearson's r)</i>	<i>Findings/Authors' Conclusions</i>
Yeni, Tulek, Bebek, Dede, Gurses, Baykan, and Gokyigit (2016)	Cross-sectional survey	Turkey	<i>N</i> = 70 Turkish patients with epilepsy (age = 18-70 years, mean age = 31.7 years)	Jacoby 3-item measure of stigma, The Epilepsy Attitude Scale, the Epilepsy Knowledge Scale, Rotter's Locus of Control Scale, the Hospital Anxiety and Depression Scale (HADS), the Quality of Life in Epilepsy Inventory-10 (QOLIE-10-P)	Mann-Whitney U test; Kruskal-Wallis test; correlation (r)	Stigma and attitude towards epilepsy (r=-.267). Stigma and anxiety (r=.283). Stigma and depression, r=.282). Stigma and QOL epilepsy effects (r=-.255). Stigma and QOL role functioning (r=-.336).	Significant correlations were obtained between stigma and attitude towards epilepsy (r=-.267, p=.026), anxiety and depression (r=.283, p=.018, r=.282, p=.018), QOL epilepsy effects (r=-.255, p=.033), and QOL role functioning (r=-.336, p=.004).
Yeni, Tulek, and Bebek (2016)	Cross-sectional survey	Turkey	<i>N</i> = 194 Turkish patients with epilepsy (age = 18-80 years, mean age = 31.4 years)	Jacoby 3-item measure of stigma, the Multidimensional Scale of Perceived Social Support (MSPSS), the Social Support Scale, the General Self-Efficacy Scale, the Epilepsy Knowledge Questionnaire, and the Epilepsy Attitude Scale	Mann-Whitney U test; Kruskal-Wallis test; correlation (r)	Stigma and social support (r=-.3) Stigma and knowledge of epilepsy (r=-.18). Stigma and attitudes towards epilepsy (r=-.152). Stigma and self-efficacy (r=-.185).	Education ($\chi^2=8.23$, p=.016), income ($\chi^2=9.735$, p=.008), age at onset (r=-0.183, p=.01), seizure frequency in previous year ($\chi^2=9.26$, p=.01), social support (r=-.3, p=.001), and knowledge and attitudes towards epilepsy (r=-.18, p=.012, r=-.152, p=.034) were significant factors determining scores on the stigma scale. It was also determined that stigma was associated with seeking non-medical help ($Z=3.60$, p=.001), disclosure of the diagnosis ($Z=2.59$, p=.01), and self-efficacy (r=-.185, p=.01).

TABLE 2. RATINGS OF METHODOLOGICAL QUALITY APPRAISAL

<i>Study</i>	Quality Rating (out of 8)
Aydemir, Özkara, Canbeyli, & Tekcan (2004)	4.5
Aydemir, Kaya, Yıldız, Öztura, & Baklan (2016)	6
Baker, Brooks, Buck, & Jacoby (2000)	5
Brigo, Igwe, Ausserer, Tezzon, Nardone, & Otte (2015)	
Baker (2002)	5
Bautista, Shapovalov, & Shoraka (2015)	6
Begley et al. (2010)	5
Leaffer, Hesdorffer, & Begley (2014)	
Bielen et al. (2014)	7
Chesaniuk, Choi, Wicks, & Stadler (2014)	7
Chong, Drake, Atkinson, Ouellette, & Labiner (2012)	5
Dilorio, Osborne Shafer, Letz, Henry, Schomer, & Yeager (2003)	7
Dilorio, Shafer, Letz, Henry, & Schomer (2004)	
Dilorio, Shafer, Letz, Henry, & Schomer, (2006)	
Reisinger & Dilorio (2009)	
Whatley, DiIorio, & Yeager (2010)	
Elliott, Jacobson, & Seals (2006)	6.5
Heersink, Kocovski, MacKenzie, Denomme, & Macrodimitris (2015)	4
McLaughlin, Pachana, & McFarland (2008)	5.5
Ni Eidhin & McLeavey (2001)	2.5
Noble, Robinson, & Marson (2016)	7
Peterson, Walker, Shears (2014)	4.5
Sabatello et al. (2015)	6
Smith et al. (2009)	6
Suurmeijer, Reuvekamp, & Aldenkamp (2001)	7
Taylor, Baker, & Jacoby (2011)	6.5
Viteva (2012)	5
Viteva (2013)	

TABLE 2. RATINGS OF METHODOLOGICAL QUALITY APPRAISAL

<i>Study</i>	Quality Rating (out of 8)
Viteva (2014)	5
Viteva & Semerdjieva (2015)	
Viteva (2016)	5.5
Yeni et al. (2016)	4
Yeni, Tulek, & Bebek (2016)	4

Appendices**Appendix A. Literature review database search history****PsycINFO**

Search terms: “epilepsy”, “stigma” (abstract field)

Thesaurus terms: “Stigma”, “Labelling”, “Stereotyped attitudes”, “Epilepsy”

Combined Thesaurus and free text search completed on 10/11/2016 - 391 results

Limited to papers since 2000 - 350 results

Limited to academic journals - 317 results

CINAHL

Search terms: “epilepsy”, “stigma” (abstract field)

CINAHL Headings: “Stigma”, “Labelling”, “Stereotyped attitudes”, “Epilepsy”

Combined CINAHL Headings and free text search completed on 10/11/2016 - 77 results

Limited to papers since 2000 - 70 results

Limited to academic journals - 50 results

Pubmed

Search terms: “epilepsy” and “stigma” (title/abstract field)

Medical Subject Headings [MeSH]: “Epilepsy” and “Social Stigma”

Combined Mesh and free text search completed on 10/11/2016 - 527 results

Limited to papers since 2000 - 482 results

Scopus

Search completed: 11/11/16

Search terms: “epilepsy” and “stigma” (title/abstract field)

Free text search completed on 08/11/2016 - 834 results

Limited to papers since 2000 - 737 results

Total = 1,586

Total Endnote de-duplicated = 1,280

Total hand de-duplicated = 872

Total excluded by title = 594

Total screened by abstract = 278

Articles excluded by abstract = 230

Excluded by relevance = 179

Excluded by methodology = 28 (34)

Excluded by sample = 9 (13)

Excluded by location = 14

Articles excluded by full-text = 15

Sample (non-Western, child/adolescent, or non-epilepsy) = 4

Methodology = 6

Date of publication = 3

Excluded by unavailable in English = 2

Additional articles identified from reference list searches = 0

Articles examining “outcomes” = 13

Articles examining “predictors” = 20

Total articles identified for inclusion in the review = 33

Appendix B - Copy of notes to contributors for selected journal: Epilepsy & Behaviour

Article structure

Subdivision - numbered sections

Divide your article into clearly defined and numbered sections. Subsections should be numbered 1.1 (then 1.1.1, 1.1.2, ...), 1.2, etc. (the abstract is not included in section numbering). Use this numbering also for internal cross-referencing: do not just refer to 'the text'. Any subsection may be given a brief heading. Each heading should appear on its own separate line.

Introduction

State the objectives of the work and provide an adequate background, avoiding a detailed literature survey or a summary of the results.

Material and methods

Provide sufficient detail to allow the work to be reproduced. Methods already published should be indicated by a reference: only relevant modifications should be described.

Results

Results should be clear and concise.

Discussion

The **Discussion** section should explore the significance of the results of the work, not repeat them.

Results and **Discussion** should be separate and may be organized into subheadings. Avoid extensive citations and discussion of published literature.

Conclusions

The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion or Results and Discussion section.

Essential title page information

- **Title.** Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.
- **Author names and affiliations.** Please clearly indicate the given name(s) and family name(s) of each author and check that all names are accurately spelled. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lower-case superscript letter immediately after the author's name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name and, if available, the e-mail address of each author.
- **Corresponding author.** Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication. **Ensure that the e-mail address is given and that contact details are kept up to date by the corresponding author.**

• ***Present/permanent address.*** If an author has moved since the work described in the article was done, or was visiting at the time, a 'Present address' (or 'Permanent address') may be indicated as a footnote to that author's name. The address at which the author actually did the work must be retained as the main, affiliation address. Superscript Arabic numerals are used for such footnotes.

Please note that proprietary names for drugs should *not* be used in the article title.

Abstract

A concise and factual abstract is required. The abstract should state briefly the purpose of the research, the principal results and major conclusions. An abstract is often presented separately from the article, so it must be able to stand alone. For this reason, References should be avoided, but if essential, then cite the author(s) and year(s). Also, non-standard or uncommon abbreviations should be avoided, but if essential they must be defined at their first mention in the abstract itself.

Graphical abstract

Although a graphical abstract is optional, its use is encouraged as it draws more attention to the online article. The graphical abstract should summarize the contents of the article in a concise, pictorial form designed to capture the attention of a wide readership. Graphical abstracts should be submitted as a separate file in the online submission system. Image size: Please provide an image with a minimum of 531 × 1328 pixels (h × w) or proportionally more. The image should be readable at a size of 5 × 13 cm using a regular screen resolution of 96 dpi. Preferred file types: TIFF, EPS, PDF or MS Office files. You can view Example Graphical Abstracts on our information site.

Authors can make use of Elsevier's Illustration and Enhancement service to ensure the best presentation of their images and in accordance with all technical requirements: Illustration Service.

Highlights

Highlights are a short collection of bullet points that convey the core findings of the article. Highlights are optional and should be submitted in a separate editable file in the online submission system. Please use 'Highlights' in the file name and include 3 to 5 bullet points (maximum 85 characters, including spaces, per bullet point). You can view example Highlights on our information site.

Highlights are mandatory for Original Reports and Reviews only. They are optional but encouraged for all other article types.

Keywords

Immediately after the abstract, provide a maximum of 6 keywords, using American spelling and avoiding general and plural terms and multiple concepts (avoid, for example, 'and', 'of'). Be sparing with abbreviations: only abbreviations firmly established in the field may be eligible. These keywords will be used for indexing purposes.

Abbreviations

Define abbreviations that are not standard in this field in a footnote to be placed on the first page of the article. Such abbreviations that are unavoidable in the abstract must be defined at their first mention there, as well as in the footnote. Ensure consistency of abbreviations throughout the article.

Acknowledgements

Collate acknowledgements in a separate section at the end of the article before the references and do not, therefore, include them on the title page, as a footnote to the title or otherwise. List here those individuals who provided help during the research (e.g., providing language help, writing assistance or proof reading the article, etc.).

Formatting of funding sources

List funding sources in this standard way to facilitate compliance to funder's requirements:

Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

It is not necessary to include detailed descriptions on the program or type of grants and awards.

When funding is from a block grant or other resources available to a university, college, or other research institution, submit the name of the institute or organization that provided the funding.

If no funding has been provided for the research, please include the following sentence:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Units

Follow internationally accepted rules and conventions: use the international system of units (SI). If other units are mentioned, please give their equivalent in SI.

Math formulae

Please submit math equations as editable text and not as images. Present simple formulae in line with normal text where possible and use the solidus (/) instead of a horizontal line for small fractional terms, e.g., X/Y. In principle, variables are to be presented in italics. Powers of e are often more conveniently denoted by exp. Number consecutively any equations that have to be displayed separately from the text (if referred to explicitly in the text).

Footnotes

Footnotes should be used sparingly. Number them consecutively throughout the article. Many word processors can build footnotes into the text, and this feature may be used. Otherwise, please indicate the position of footnotes in the text and list the footnotes themselves separately at the end of the article. Do not include footnotes in the Reference list.

Artwork***Electronic artwork******General points***

- Make sure you use uniform lettering and sizing of your original artwork.
- Embed the used fonts if the application provides that option.
- Aim to use the following fonts in your illustrations: Arial, Courier, Times New Roman, Symbol, or use fonts that look similar.
- Number the illustrations according to their sequence in the text.
- Use a logical naming convention for your artwork files.
- Provide captions to illustrations separately.
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Doctorate in
Clinical Psychology

Lancaster
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Section 2: Research Paper

Title: What is the Relationship Between Self-Compassion and Depression, Anxiety, and Resilience
in Adults with Epilepsy?

Word Count – 5,771 excluding abstract, tables, figures, and references

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Highlights

- The present study examined the relationship between self-compassion and depression, anxiety, and resilience in people with epilepsy (PWE)
- Higher self-compassion was found to predict lower depression and anxiety and higher resilience
- These findings highlight the importance of self-compassion in improving psychological wellbeing in PWE
- The study provides support for clinical interventions that target self-compassion in this population

Abstract**Background**

Research suggests that people with epilepsy (PWE) have a poorer quality of life and are more likely to experience depression and anxiety than the general population. Given the adversity faced by people with the condition, resilience may be an important psychological resource. However, to date resilience has been largely overlooked in the epilepsy literature. Self-compassion, and therapies designed to promote it, have been widely associated with improved psychological wellbeing and, to a lesser extent, resilience. However, the impact of self-compassion on depression, anxiety, and resilience in PWE has not been examined.

Objectives

Using a quantitative cross-sectional survey design, the aim of the present study was to address this gap in the research by examining the extent to which self-compassion predicted depression, anxiety, and resilience when controlling for other important demographic and illness-related variables.

Methods

Adults with epilepsy were invited to take part in a survey online or in epilepsy or neurology clinics. Two-hundred and seventy participants completed the survey and data were analysed using hierarchical multiple regression models.

Results

In this sample of PWE, self-compassion significantly predicted lower depression and anxiety and higher resilience when other significant sociodemographic and illness-related variables had been taken into account.

Conclusions

The findings of the present study indicate that self-compassion is an important factor in determining psychological outcomes for adults with epilepsy. This study offers an important first step in the development of compassion-focused approaches to help improve psychological outcomes for PWE.

Keywords

Epilepsy; Self-Compassion; Depression; Anxiety; Resilience

1. Introduction

Epilepsy is a chronic neurological condition characterised by recurrent episodes of abnormal electrical brain activity known as seizures which can affect sensory, motor and autonomic function, consciousness, emotional state, memory, cognition, and behaviour [1,2]. In England, epilepsy affects between 362,000 and 415,000 [3]; in Europe, the number of adults with active epilepsy is estimated to be 2.5 million [4]; and in the United States (US) the number of adults currently diagnosed with the condition is around 2.4 million [5].

1.1 Epilepsy and psychological wellbeing

As a result of difficulties associated with the condition, people with epilepsy (PWE) have poorer quality of life (QOL) than the general population [6-10]. Depression and anxiety are also prevalent and contribute significantly to poorer QOL in this population [11]. Furthermore, in PWE depression and anxiety have been shown to significantly impair social functioning [12], and have been associated with poor sleep quality and suicidal ideation [13]. However, despite an increasing body of evidence supporting the link between epilepsy and poor psychological outcomes including depression and anxiety, trajectories of psychological wellbeing in PWE often do not follow the clinical course of the condition. Instead, psychological wellbeing and QOL may be affected by a wide range of psychosocial factors including discrimination, difficulties of adjustment, personal and social capital, and social support [14]. Coping and engagement strategies, perceived social support, stress, and self-efficacy have also been identified as important [15].

Depression is highly prevalent in PWE [16]. It has been suggested that this high prevalence may be related to the frequency of seizures and the potentially depressogenic effects of some epilepsy medications [17]. In contrast, a 2015 review by Lacey, Salzberg, and D'Souza [18] found that, whilst epilepsy illness-related factors are important in predicting depression, sociodemographic factors including age, gender, education, employment and income predict this more consistently, and psychological factors including emotional aspects of recovery from seizures; social concerns

such as fear of injury, activity restriction, and embarrassment; and a past history of depression, anxiety and perceived stress were also important.

Anxiety is also highly prevalent in PWE [19]. Perhaps unintuitively, the prevalence of anxiety in people whose epilepsy is well controlled does not appear to be lower than those with refractory epilepsy [20]. Such a high prevalence is often underestimated and it has been suggested that anxiety and epilepsy may share common neurobiological correlates, meaning that anxiety may both follow and precede epilepsy, although the evidence for this is largely derived from animal studies and further research is needed [21]. This perspective also fails to take into account psychological and social factors associated with epilepsy and anxiety, such as those identified by a recent study of adult epilepsy outpatients which found that a combination of psychosocial factors, including the use of coping strategies involving escape-avoidance and accepting greater responsibility, lower self-efficacy, and greater self-illness enmeshment, were associated with anxiety [22]. Other social factors such as workplace discrimination have also been highlighted as important predictors of anxiety, alongside seizure control and the use of epilepsy medication [23].

1.2 Shame in epilepsy

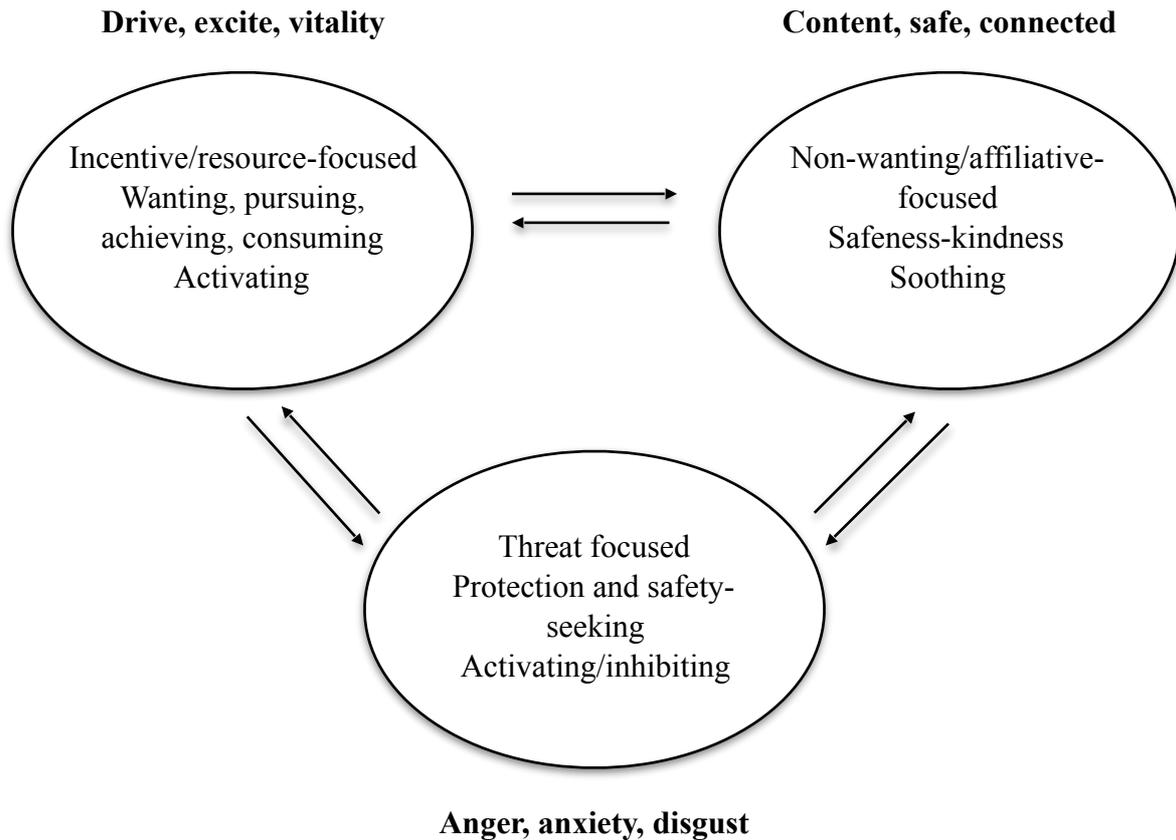
An important predictor for depression and anxiety in general population is shame [24,25]. Shame can be viewed as a self-focused and self-evaluative experience of being flawed or inadequate [26,27], or of negative aspects of the self being exposed [28,29]. In addition to self-evaluation, shame may relate to how we believe we exist in the minds of others or result from a process of internalising the “external shame” (e.g. criticism or ridicule) expressed by others [30]. Shame may furthermore represent a perception of self as being close to an undesired and unattractive self, rather than simply failing to meet ideal standards [31-33].

Although the relationship between depression, anxiety, and shame has not been investigated directly in PWE, it is likely to be highly relevant to this population. Shame has been identified in qualitative research into self-evaluating emotions in PWE, with participants describing the

condition as shameful, not wanting others to know about their diagnosis, and feeling bad about themselves as a result of having the condition [34]. In another study 56% of participants reported feelings of shame associated with their epilepsy [35]. Similar findings have been identified in research into children with epilepsy, with researchers observing an implicit reluctance for children to accept epilepsy as a part of their identity and displaying associated feelings of shame [36].

1.3 Self-compassion and psychological wellbeing

The psychological impact of shame in PWE has not been well evidenced. However, in the general population shame has been linked closely to self-criticism and depression in both adults and children [37-39]. However, there is an increasing body of evidence to suggest that self-compassion can help to protect against shame and lead to better mental health outcomes [40,41,42]. Self-compassion has been defined as the act of being kind and understanding towards oneself in the face of difficult experiences, recognising one's own experiences as part of the shared human condition rather than viewing them as isolating, and sitting mindfully with painful thoughts or feelings rather than over-identifying with them [43]. This conceptualisation is underpinned by Paul Gilbert's evolutionary model of emotional regulation [44], which comprises three interacting neurophysiological systems:



In Gilbert's model, individuals who are high in shame inhabit an over-activation of the drive and threat-based systems, whilst the soothing system is comparatively inaccessible. In contrast, individuals who are higher in self-compassion are able to achieve calmness and relieve distress more easily through the activation of the self-soothing system [45]. In the general population, self-compassion has been shown to predict improved psychological wellbeing including lower depression and anxiety, even when other variables have been accounted for [46-48]. In PWE, as highlighted above, if one views their condition as meaning that they are inadequate, or believe that others view them in this way, then they are more likely to experience feelings of shame which can precipitate (or be precipitated by) experiences of depression or low mood. In contrast, those who are high in self-compassion should, according to Gilbert's model and subsequent research, experience better psychological wellbeing.

1.4 Resilience

In addition to reducing depression and anxiety, self-compassion has also been associated with resilience [49-51], although few studies have measured this directly and the empirical evidence to support this claim is currently limited. In recent years, the concept of resilience has received increasing interest in the psychological literature. Resilience has been defined simply as “an outcome of successful adaptation to adversity” [52]. Within this definition, two elements are seen as important: recovery, or how people “bounce back” from a stressful event [53]; and sustainability, or the capacity to continue forward in the face of adversity [54]. Resilience has been demonstrated as an important personal resource which is associated with improved physical and psychological wellbeing [55], and has been examined in a wide range of health populations including adults with cancer [56], diabetes, [57], and chronic pain [58]. To date, however, resilience has been largely overlooked in the epilepsy literature, where the focus has been on risk factors for negative psychological outcomes such as depression and anxiety [59]. Given the potentially significant psychosocial impact of the condition identified, resilience is arguably an important psychological resource to consider in this population.

1.5 Rationale for the present study

In summary, the currently available evidence for predictors of depression and anxiety in PWE suggests that a combination of psychosocial, illness-related, and sociodemographic factors are likely to be important. However, existing research does not adequately account for variations in psychological outcomes, and it is possible that other factors which have not yet been investigated may be important. In the general population, self-compassion has been posited as a potential antidote to feelings of shame and has been linked to improved psychological outcomes and resilience. However, self-compassion as a predictor of reduced depression and anxiety and increased resilience in PWE has not been examined. If self-compassion can help to promote resilience and protect against illness-related factors and shame for people with this condition, then this may lead to reductions in depression and anxiety. The findings of this research may therefore

have potentially significant clinical implications for the psychological care of PWE, for example by providing evidence for interventions such as CFT as a means of increasing resilience and improving psychological wellbeing.

1.6 Research aims and hypotheses

Using a quantitative design, the aim of the study was to identify whether self-compassion predicted additional variance in measures of depression, anxiety, and resilience when other known predictors of wellbeing including socio-demographic and illness-related variables had been accounted for. It was hypothesised that self-compassion would be negatively associated with depression and anxiety and positively associated with resilience, even when other known influencing variables had been accounted for.

2. Method

2.1 Design

The study used a quantitative cross-sectional survey design to examine predictors of depression, anxiety, and resilience in PWE. Feedback on the design was obtained from a panel of service user representatives from the charity Epilepsy Action (the Epilepsy Action Research Network; EARN) and suggested changes were incorporated into the final design.

2.2 Participants

A predictive power calculation for a linear multiple regression with six predictors suggested that to achieve power of .8 with a medium effect size of .2 (as indicated in other studies of self-compassion [e.g. 60]) at a probability level of $p = .05$ required 75 participants. Epilepsy Action supported recruitment by advertising the study on their website, newsletter, and social media channels. A total of 327 participants consented to take part in the study; 305 were recruited online through Facebook support groups and Twitter, and 22 were recruited from local NHS epilepsy services. Of these, 270 provided responses that could be utilised in the final study.

2.2.1 Inclusion and exclusion criteria

To be eligible for inclusion participants were required to self-report a diagnosis of epilepsy, to be at least 18 years old, and to be able to understand English and complete a survey. People who had experienced seizures but did not have an epilepsy diagnosis were excluded. The questionnaires used were not all validated in other languages, therefore non-English speakers were not able to take part.

2.3 Procedure

2.3.1 Online recruitment

Participants were recruited online and from local NHS epilepsy services. Online recruitment took place between October 2016 and January 2017. The study was posted on the Lancaster University Doctorate in Clinical Psychology research page (http://www.lancaster.ac.uk/shm/study/doctoral_study/dclinpsy/research). The research page included the participant information sheet (PIS) and a link to the consent form and Qualtrics survey. An invitation and link to the research page were also posted on Twitter and Facebook, and on Epilepsy Action's website and newsletter. Participants were asked to provide consent by reading the PIS and completing the consent form at the beginning of the survey. The survey took participants approximately 10-15 minutes to complete. Following this a debrief sheet including information about support organisations was displayed.

2.3.2 Clinic recruitment

A secondary recruitment avenue took place in local epilepsy clinics. From October to December 2016 the primary researcher attended epilepsy and neuropsychology clinics and asked patients if they would be willing to complete a short paper-based or online survey. The survey was prefaced with a participant information sheet (PIS) containing a description of the study, its purpose, the inclusion and exclusion criteria, and how the data would be used. Patients were given the option to complete the survey on paper in clinic or later online (via a web link provided) to give them sufficient time (> 24 hours) to read the information before deciding whether to take part.

Participants were asked to provide consent by completing a consent form provided and a debrief sheet was provided at the end of the survey. Copies of the PIS, consent form, and debrief sheet are provided in the Research Ethics section.

2.3.3 Data collection and measures

Data were collected via a survey comprising questions about demographic and clinical information alongside standardised measures of seizure severity, self-compassion, depression, anxiety, and resilience. The survey comprised electronic and paper versions of the following standardised measures: The Liverpool Seizure Severity Scale 2.0 (LSSS) [61]; The Neff Self-Compassion Scale (SCS) [62]; The Hospital Anxiety and Depression Scale (HADS) [63]; and The Brief Resilience Scale (BRS) [64]. In addition to standardised measures, data were collected about sociodemographic and illness related variables. Details about the measures and survey questions, including Cronbach's alpha coefficients reported in previous research, are provided in Appendix A. Electronic versions were administered using the Qualtrics platform, a web-based survey and data collection software licensed for use by Lancaster University staff and students.

2.4 Analysis

Statistical analyses were completed using IBM SPSS, Version 22. Correlation analyses were completed for all of the main variables. Those that were found to be significantly associated with the outcome variables were then entered into a hierarchical regression model, followed by self-compassion as the main predictor variable of interest. In order to input non-binary categorical variables into the regression model (i.e. employment status, level of education, and relationship status), these were recoded into binary categorical variables in SPSS (i.e. employed/unemployed, higher education/below higher education, in a relationship/not in a relationship). The predictor variables were entered into the model in three steps: 1) Sociodemographic variables, 2) Illness-related variables, and 3) Self-compassion (SCS). The outcome variables were: 1) Depression (HADS), 2) Anxiety (HADS), and 3) Resilience (BRS).

2.5 Ethical Considerations

It was not anticipated that this study would result in risks to participants or raise significant ethical issues. Participant wellbeing was considered carefully, as per the study procedure outlined above. Data protection was also carefully considered. For the majority of participants, anonymous, non-identifiable, quantitative demographic and research questionnaire data was collected only. No personal identifiable data was routinely collected and all data was stored securely and used only for the intended and advertised purpose. Throughout the course of the study ethical considerations were discussed with the external supervisor, an expert working in the field of epilepsy. Ethical and research governance approval to complete the research and recruit from the hospital was provided by an independent NHS Research Ethics Committee (REC) and the relevant Research and Development (R&D) department via the Health Research Authority (HRA) integrated system.

3. Results

A total of 327 participants consented to take part in the study. Of these, 305 were recruited online and 22 from epilepsy clinics. Independent *t*-Tests were carried out to compare the variable means of the clinical and online samples; no significant differences were identified between the two groups in relation to all of the main variables ($p > .01$), with the exception of level of education, which was found to be higher in the online sample ($t = 3.141, p = .004$). Of the 327 survey responses, 59 contained missing data. Fifty-seven were excluded from statistical analyses due to missing data on three or more main variables. Many of these participants did not complete demographic questions, therefore it was not possible to compare those with missing data to those who completed the survey. In the remaining two cases, data was imputed for missing BRS responses using mean substitution. This provided a total of 270 responses that were included in statistical analyses.

3.1 Sample characteristics

An overview of the socio-demographic and clinical characteristics of the sample are provided in Table 1. Approximately 76% of the sample were female, which may not be representative of the general population in which females are thought to have a marginally lower risk of developing epilepsy than males [65]. The sample covered an age range from 18-71+, although only 8.1% of participants were aged over 60, which again may not fully represent the general population in which the incidence of epilepsy is thought to be higher in older adults [66]; although the mode categorical age (31-50 years) was comparable to means of other studies [67,68]. Considering ethnicity, 73% of participants identified as White British, therefore other ethnic backgrounds were comparatively under-represented. Approximately 40% of participants were educated to degree level or above, however only 6% reported having no qualifications, which suggests that people with lower levels of education were also comparatively under-represented in the sample.

[Table 1 here]

Descriptive statistics and Cronbach's α coefficients for the standardised questionnaires are presented in Table 2. The mean seizure severity score of the sample was 32.93 out of 100, which was marginally lower than other similar studies of epilepsy populations [69,70]. However, for participants who had not experienced a seizure in the last four weeks, a score of zero was indicated on the Liverpool Seizure Severity Scale, as per the authors' guidelines [61]. This applied to 41% of the sample, lowering the overall average score of seizure severity. The mean depression score of 7.94 placed this above the recommended clinical cut-off score of ≥ 7 for depression in an epilepsy population [71]; this was higher than other similar studies [72,73]. The mean anxiety score was higher still at 11.01, placing this in the moderate clinical range and well above the recommended cut-off score of ≥ 8 in an epilepsy population [71]; this was again higher than other similar studies [72,73]. The α coefficients for responses observed in the present study indicated high internal consistency. Alpha values ranged from 0.83 to 0.94, which were in line with those reported in previous research (see Appendix A).

[Table 2 here]

3.2 Correlational analyses

Normality of the distributions were checked by examining the skew and kurtosis of data. The Liverpool Seizure Severity Scale was not normally distributed (see Table 3), therefore non-parametric tests of correlation were used.

[Table 3 here]

Spearman's rho correlations between all demographic, illness, and outcome variables are provided in Table 4.

[Table 4 here]

Several demographic variables were found to correlate with the outcome variables. Employment status was correlated with depression (being employed was associated with lower depression; $\rho = -.183, p < .005$), and resilience (being employed was associated with higher resilience; $\rho = .158, p < .01$), but not anxiety. Age was positively correlated with resilience ($\rho = .138, p < .05$), and negatively correlated with anxiety ($\rho = -.197, p = .001$), but not depression. Gender, level of education, and relationship status were not correlated with any of the main outcome variables. Illness-related variables were found to be significant. Seizure severity was positively correlated with depression ($\rho = .255, p < .001$) and anxiety ($\rho = .202, p = .001$), and negatively correlated with resilience ($\rho = -.208, p = .001$). Seizure type also correlated with anxiety (generalised seizures were positively associated with anxiety; $\rho = .142, p < .05$), but not depression or resilience. Medication use was not associated with any of the main outcome variables. Self-compassion was significantly negatively correlated with depression ($\rho = -.585, p < .001$) and anxiety ($\rho = -.608, p < .001$), and positively correlated with resilience ($\rho = .595, p < .001$). Self-compassion and seizure severity were not significantly correlated ($p = .466$).

3.3 Multiple hierarchical regression analyses

Variables which were found to be significantly correlated with the outcome variables depression, anxiety, and resilience were entered as predictor variables into the regression model.

Sociodemographic variables were entered into the first stage of the model, followed by illness-related variables in the second stage, and self-compassion in the third and final stage as the main variable of interest. The regression model was therefore structured as follows:

- 1) Sociodemographic variables: age, employment status
- 2) Illness-related variables: seizure severity (LSSS), seizure type
- 3) Self-compassion (SCS)

The results of the multiple hierarchical regression analyses are provided in Table 5 (a-c).

[Tables 5 a-c here]

The data were checked in SPSS to ensure that the main assumptions of multiple regression were met. Dependent and independent variables were linearly related (indicated by scatterplots of predictor and dependent variables, residual terms were uncorrelated (using the Durbin-Watson test as a measure of autocorrelation), residuals at each level of the predictor had similar variance (homoscedasticity; indicated by scatterplots of residual and predictor variables), errors were normally distributed (indicated by histogram and P-P-Plots of residuals), and no multicollinearity was present (indicated by variance inflation factor (VIF) and tolerance statistics) [74]. Data were also checked for outliers; none were identified.

The regression analyses for depression indicated that Steps 1 and 2 of the model accounted for 9.4% of the variance in the outcome. Self-compassion was found to increase the explanatory power of the final model to 43.5%. Self-compassion therefore explained 34.1% of the variance in depression, and the overall model was significant ($F = 39.942, p < .001$). In the final model, the variables that were found to be significant were seizure severity ($\beta = .252, p < .001$), employment status ($\beta = -.115, p < .01$) and self-compassion ($\beta = -.596, p < .001$).

The regression analyses for anxiety indicated that Steps 1 and 2 of the model accounted for 9.5% of the variance in the outcome. Self-compassion was found to increase the explanatory power of the final model to 41.7%. Self-compassion therefore explained 32.2% of the variance in anxiety, and the overall model was significant ($F = 37.127, p < .001$). In the final model, the variables that were found to be significant were seizure severity ($\beta = .182, p < .001$), seizure type ($\beta = .102, p < .01$) and self-compassion ($\beta = -.579, p < .001$).

Finally, regression analyses for resilience indicated that Steps 1 and 2 of the model accounted for 7.3% of the variance in the outcome. Self-compassion was found to increase the explanatory power of the final model to 41%. Self-compassion therefore explained 33.7% of the variance in resilience, and the final model was again significant ($F = 36.150, p < .001$). In the final model, the variables that were found to be significant were seizure severity ($\beta = -.176, p < .001$) and self-compassion ($\beta = .593, p < .001$).

4. Discussion

The present study examined the relationship between self-compassion and depression, anxiety, and resilience in people with epilepsy (PWE), using a cross-sectional survey design. Regression analyses of the data revealed higher self-compassion to predict lower depression and anxiety and higher resilience, supporting the initial study hypotheses.

4.1 Self-compassion and psychological wellbeing in epilepsy

Self-compassion is a concept that has received increasing interest in the psychological world in recent years. Self-compassion is a multifaceted term which incorporates self-kindness, mindfulness, and a sense of common humanity as an alternative to negative states of self-criticism, isolation, and over-identification with painful emotions [43]. These are likely to be important for PWE due to the adversity associated with the condition. Unsurprisingly, a common reaction to adversity and negative life experiences such as chronic illness is depression [75,76]. This is particularly relevant for PWE who often face difficulties which are complex and may persist even

when the condition is well-managed, including compromised physical health, cognitive impairment, isolation, uncertainty, fear, and discrimination [19,77,78]. Epilepsy has therefore also been associated with anxiety [19]. In contrast, people with higher resilience may be able to cope better with the adversity due to their increased capacity to bounce back from experiences of adversity [52]. Self-compassion may therefore be particularly important for helping alleviate depression and anxiety and increasing resilience for PWE.

The findings of the present study suggest that, despite the complex nature of epilepsy and its impact on psychological wellbeing and QOL, for some PWE self-compassion may be associated with better psychological outcomes. These findings may be explained in part by the known influence of self-compassion on self-criticism and shame [41], which many PWE experience as a result of their condition [79]. Similarly, in the general population events that are perceived to have been inflicted on the self (known as self-adversity), as opposed to those which are inflicted on others (other-orientated adversity), have been shown to be more strongly associated with depression [80]. It has been suggested that epilepsy is often associated with self-blame, shame, and anger [81]. Therefore, if PWE have a low capacity for self-compassion and blame themselves for their condition, then they may possess a greater sense of self-adversity, which may lead to higher levels of depression. This is in line with previous epilepsy research into the negative impact of self-blame on depression and QOL [82,83]. The impact of self-compassion on depression may also be explained in part by the effect of rumination, which has been found to mediate this relationship in the general population [84]. In contrast, if PWE are able to adopt a more compassionate view towards themselves and their condition, in a way which is non-blaming and avoids over-identifying with the adversity of their situation, then this may help to protect against feelings of depression. Although the current study is cross-sectional so causality cannot be ascertained, the findings suggest that this is a plausible hypothesis.

The findings also indicate that higher levels of self-compassion are associated with lower levels of anxiety in this population. This partially replicates previous findings from a study of people diagnosed with social anxiety, where self-compassion was found to be lower in those with a clinical diagnosis of social anxiety disorder; lower self-compassion was also associated with greater fear of evaluation from others [85]. These findings may be explained in part by the impact of self-compassion on cognitive processing. In the general population, the relationship between self-compassion and anxiety has been shown to be mediated by positive and negative automatic thoughts [86]. Worry and rumination have similarly been found to mediate this relationship [84]. The impact of self-compassion on worry and catastrophic thinking may therefore help to explain the findings of the present study. For example, PWE who make more positive, self-compassionate, appraisals of their condition may feel less anxious than those who worry or make negative or catastrophic appraisals in relation to their condition.

A further important finding of this study was that self-compassion predicted increased resilience. As previously highlighted, despite some evidence of this relationship in the general population [49-51], the literature to support the association between self-compassion and resilience is currently limited. The present study offers a significant novel finding as it provides preliminary evidence of a relationship between self-compassion and resilience in PWE – a population who typically face high levels of adversity and for whom resilience is likely to be valuable to protect against feelings of depression and anxiety often associated with the condition. It has been suggested that increased resilience in other populations may be explained by self-compassion acting as an adaptive emotional regulation strategy which protects against the activation of negative schemas triggered by adverse experiences [87]. Self-compassionate thoughts may also promote an acceptance of suffering as something that is universal, and people may therefore be less likely to feel guilty or attend to the negative aspects of their situation; they may instead be better able to control negative reactions to experiences which cause discomfort [88]. Self-compassion has also been shown to

reduce the tendency for harsh self-criticism [89], and to increase the capacity for optimism and feelings of self-efficacy [51,90,91]. Given this is a cross-sectional study, such mechanisms can only be tentatively suggested, however they may help to explain the findings of the present study in relation to higher self-compassion predicting greater resilience in this sample of PWE.

4.2 Implications

The findings of this study have potentially significant implications in relation to psychological care and public health strategies for PWE. At a clinical level, the most significant indicator arising from this study is that it highlights a possible link between self-compassion and better psychological outcomes in PWE. Although causation cannot be determined from the present study, these findings suggest that researching CFT for this population would be a useful next step in informing care for PWE who are less resilient or at risk of experiencing depression or anxiety. The observed link between self-compassion and affect regulation systems required to feel reassured, safe, and well is the basis on which CFT is predicated [45]. In contrast, in people with higher levels of shame and self-criticism these regulation systems are less accessible; in these cases self-compassionate approaches have been shown to help to reduce shame and predict improved mood [92-94].

Importantly, the present study extends the findings of previous research into self-compassion to an adult epilepsy population. While it is acknowledged that the current findings are cross-sectional and therefore do not provide an indication of causation, they suggest that interventions which directly target self-compassion may be helpful to consider in PWE. Given that seizure severity and self-compassion were found not to be correlated, the study suggests furthermore that it is possible to be self-compassionate even when actively experiencing epilepsy-related symptoms. PWE are likely to require resilience in order to cope with the difficulties associated with the condition. Currently the only psychological interventions which are recommended in clinical guidelines in the UK are relaxation, cognitive behavioural therapy (CBT), and biofeedback [3]. However, given the observed association between self-compassion and resilience, the present research suggests that it

may also be helpful to consider compassion-focused approaches such as CFT in the psychological care of PWE presenting to clinical health services. Further research into the use of CFT in this population is needed to determine its benefits.

The finding that self-compassion predicts lower depression and anxiety may also be due to social perceptions of epilepsy, which can cause people to feel bad about themselves and conceal their condition from others [34], leading to poor psychosocial outcomes [79,95,96]. Therefore, at a public health level, more may need to be done to tackle the negative societal judgement of the visible aspects of epilepsy (i.e. uncontrolled seizures), and to foster a compassionate view of the condition by both people with and without the condition. This could be achieved through the development of campaigns that model a compassionate view of the condition; this may include literature or advertisements that describe or explain epilepsy and seizures in compassionate language, via avenues that are accessible to a wide range of people such as online social media platforms, combatting negative misinformation that currently exists in these arenas [97].

4.3 Further research

The findings of this study highlight a number of areas of further research that would be beneficial in advancing our understanding of psychological care for this population. The present study provides evidence of the predictive capacity of self-compassion in regards to resilience, depression, and anxiety in PWE. This suggests that increasing self-compassion in this population could have beneficial effects on wellbeing and therefore it would be useful to examine CFT in this population in further research. This could be best achieved through experimental designs such as randomised controlled trials (RCTs) which offer a rigorous method of determining the effectiveness of clinical interventions [98]. Secondly, it would be useful to better understand how self-compassion is experienced in PWE (i.e. what makes some people in this population more likely to engage in acts of self-kindness than others and how can this be developed in the real world). This may be explored initially through qualitative research involving samples of PWE identified as being either

high or low in self-compassion; interpretative phenomenological analysis (IPA) is an approach well suited to this type of health research [99]. This could be followed up with further quantitative research to examine predictors of self-compassion in PWE, incorporating longitudinal methods which would allow researchers to examine causal relationships between these variables [100]. Additional research in these areas would help us to identify how self-compassion can be fostered and developed in PWE as a means of improving psychological wellbeing in this population in a preventative, rather than purely reactive way (i.e. by increasing resilience).

4.4 Strengths and limitations

The present study used a cross-sectional survey to gather data pertaining to variables of interest. This design presents a number of known limitations, including failing to address chronological variability [101]. The use of self-report measures is open to bias [102] and is sensitive to culture [103], further compromising the reliability of findings. There were also limitations in the variables examined. For example, duration of diagnosis was not included in analyses, therefore it was not possible to determine the potential impact of epilepsy diagnosis duration on key variables measured within the study (e.g. whether people who are diagnosed at a younger age or who have been diagnosed for longer are likely to be higher or lower in self-compassion, depression, anxiety, or resilience). In previous research, duration of epilepsy diagnosis has not been reliably associated with depression and anxiety [104], however it is possible that inclusion of such a variable may have reduced the variance attributed to self-compassion in this sample. Furthermore, whilst participants were recruited through epilepsy clinics, the majority of the sample was recruited online. These samples were found to be comparable on key variables, however it was not possible to verify with certainty who the respondents to the survey were and if the sample was truly valid (i.e. that all respondents met the inclusion criteria). Additionally, whilst the study was open internationally, the majority of participants were White British and female. Online recruitment may also have inadvertently excluded people who were not computer literate or did not have access to the

technology necessary to access the study, which may have included older adults or those who were less educated; therefore the findings may not be generalisable to these populations. Despite these limitations, the online recruitment also provided some of the study's main strengths. The benefits of online methodology in psychology has been recognised as it offers an effective means expanding the scale and scope of research [105]; this approach allowed a large sample to be recruited, therefore analyses were highly powered. The use of social networking sites also provided an inclusive means of giving voice to a wide range of people, regardless of their ability to attend research clinics or even to speak to a researcher on the telephone.

4.5 Conclusions

The findings of the present study suggest that self-compassion may be an important factor in determining psychological outcomes for adults with epilepsy. Whilst socio-demographic and illness-related variables have been demonstrated here and elsewhere to contribute to the wellbeing of people in this population, these findings suggest that other factors may also be important. The present study suggests that higher self-compassion may be associated with improved psychological outcomes such as lower depression and anxiety, and higher resilience. Therefore, if self-compassion can be fostered and developed through means such as formalised clinical interventions (e.g. CFT), personal self-care strategies, public health interventions, or community support approaches, then this may be beneficial to PWE. Further research which examines the acceptability and effectiveness of such approaches is needed. However, this study offers an important first step in highlighting the potential importance of investigating and developing compassion-focused approaches to help improve psychological outcomes for PWE.

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Tables

Table 1
Sociodemographic and Clinical Information (%)

Age	
18-25	14.4
26-30	15.6
31-40	21.1
41-50	22.6
51-60	18.1
61-70	7.4
71 or over	0.7
Gender	
Male	23.8
Female	76.2
Relationship Status	
Single	33.1
Married or cohabiting	58.0
Other	8.9
Highest level of Education	
Degree or above	40.7
A-Level, trade or other higher education	31.3
GCSE or NVQ	18.7
Other, level unknown	3.3
No qualifications	6.0
Employment status	
Employed	45.0
Unemployed	27.9
Other	27.1
Medication	
Yes	95.2
No	4.8
Most common seizure type	
Focal (partial)	45.1
Generalised	54.9

Table 1
Sociodemographic and Clinical Information (%)

Nationality	
English	55.2
Welsh	1.5
Scottish	4.4
Northern Irish	1.5
British	14.8
Irish	12.6
Other	9.7
Ethnicity	
White - English/Welsh/Scottish/Northern Irish/British	72.8
White - Irish	13.8
Any other White background	7.1
White and Black Caribbean	1.5
White and Black African	.4
Any other Mixed/Multiple ethnic background	1.5
Indian	.4
Pakistani	1.1
Chinese	.4
Any other ethnic group	1.1

Table 2
Descriptive Statistics - Reliability Values, Means, and Standard Deviations of Main Variables

	α	M	SD
1. Seizure severity	0.86	32.93	32.10
2. Self-compassion	0.94	2.61	0.68
3. Depression	0.84	7.94	4.70
4. Anxiety	0.83	11.01	4.60
5. Resilience	0.87	2.74	0.86

Table 3
Descriptive Statistics - Distributions of Main Variables

		Statistic	Std. Error
1. Seizure severity	Skew	.245	.148
	Kurtosis	-1.534	.295
2. Self-compassion	Skew	.406	.148
	Kurtosis	.186	.295
3. Depression	Skew	.307	.148
	Kurtosis	-.602	.295
4. Anxiety	Skew	-.146	.148
	Kurtosis	-.653	.295
5. Resilience	Skew	.400	.148
	Kurtosis	-.077	.295

Table 4
Spearman's Rho Correlations Between Variables

	1	2	3	4	5	6	7	8	9	10	11	12
12. Seizure type												-

* ** $p \leq .01$

* $p \leq .05$

Table 5a
Results of Hierarchical Multiple Regression for Depression

	<i>B</i>	<i>SE</i>	<i>Beta</i>	<i>t</i>	<i>p</i>	<i>R</i> ²	<i>Adj.</i> <i>R</i> ²	<i>F</i>
Step 1						.043	.035	5.572*
Socio-demographic variables								
Age	-.166	.191	-.054	-.868	.386			
Employment status	-2.053	.643	-.197	-3.192	.002			
Step 2						.108	.094	7.546**
Illness-related variables								
Age	-.157	.185	-.051	-.847	.398			
Employment status	-1.476	.638	-.142	-2.313	.022			
Seizure severity	.038	.009	.263	4.277	.000			
Seizure type	.292	.563	.031	.519	.604			
Step 3						.446	.435	39.942**
Self-compassion								
Age	.212	.149	.069	1.419	.157			
Employment status	-1.200	.504	-.115	-2.379	.018			
Seizure severity	.037	.007	.252	5.186	.000			
Seizure type	-.040	.445	-.004	-.089	.929			
Self-compassion	4.231	.344	-.596	-12.30	.000			

* $p < .01$

** $p < .001$

Table 5b
Results of Hierarchical Multiple Regression for Anxiety

	<i>B</i>	<i>SE</i>	<i>Beta</i>	<i>t</i>	<i>p</i>	<i>R</i> ²	<i>Adj.</i> <i>R</i> ²	<i>F</i>
Step 1 Socio-demographic variables						.059	.052	7.901**
Age	-.652	.183	-.218	-3.561	.000			
Employment status	-1.012	.616	-.101	-1.642	.102			
Step 2 Illness-related variables						.109	.095	7.606**
Age	-.632	.179	-.211	-3.529	.000			
Employment status	-.575	.616	-.057	-.933	.352			
Seizure severity	.027	.009	.193	3.144	.002			
Seizure type	1.233	.543	.136	2.269	.024			
Step 3 Self-compassion						.428	.417	37.127**
Age	-.285	.147	-.095	-1.945	.053			
Employment status	-.316	.495	-.031	-.638	.524			
Seizure severity	.026	.007	.182	3.696	.000			
Seizure type	.921	.437	.102	2.108	.036			
Self-compassion	-3.974	.338	-.579	-11.765	.000			

** $p < .001$

Table 5c
Results of Hierarchical Multiple Regression for Resilience

	<i>B</i>	SE	<i>Beta</i>	<i>t</i>	<i>p</i>	<i>R</i> ²	Adj. <i>R</i> ²	<i>F</i>
Step 1						.052	.044	6.847**
Socio-demographic variables								
Age	.095	.035	.169	2.751	.006			
Employment status	.277	.117	.146	2.378	.018			
Step 2						.087	.073	5.952**
Illness-related variables								
Age	.093	.034	.165	2.729	.007			
Employment status	.201	.118	.106	1.706	.089			
Seizure severity	-.005	.002	-.187	-3.008	.003			
Seizure type	-.111	.104	.065	-1.069	.286			
Step 3						.422	.410	36.150**
Self-compassion								
Age	.026	.028	.047	.947	.345			
Employment status	.151	.094	.079	1.604	.110			
Seizure severity	-.005	.001	-.176	-3.546	.000			
Seizure type	-.051	.083	-.030	-.612	.541			
Self-compassion	.767	.064	.593	11.972	.000			

** $p \leq .001$

Appendices

Appendix A. Details of Measures and Questions Included in the Survey

Appendix A.

Details of Measures and Questions Included in the Survey

Scale	Reference	Number of Items	Internal Reliability (Cronbach's alpha) Reported in Previous Research	Previous Use in Epilepsy Research
Liverpool Seizure Severity Scale 2.0 (LSSS)	Scott-Lennox, J. Bryant-Comstock, L., Lennox, R. & Baker, G. A. (2001). Reliability, validity and responsiveness of a revised scoring system for the Liverpool Seizure Severity Scale. (2001). <i>Epilepsy Research</i> , 44(1), 53–63. doi:10.1016/S0920-1211(01)00186-3	13	$\alpha = .66 - .87$	E.g. Viteva, E. I. (2014). Seizure frequency and severity: How really important are they for the quality of life of patients with refractory epilepsy. <i>Annals Of Indian Academy Of Neurology</i> , 17(1), 35-42. doi: 10.4103/0972-2327.128544
Neff Self-Compassion Scale	Neff, K. D. (2003). Development and validation of a scale to measure self-compassion. <i>Self and Identity</i> , 2, 223–250.	26	$\alpha = .92$	No research has been identified into self-compassion in people with epilepsy (PWE), therefore no precedent set for use of measures.
Hospital Anxiety and Depression Scale (HADS)	Zigmond, A.S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. <i>Acta Psychiatrica Scandinavica</i> 67 (6): 361–370. doi:10.1111/j.1600-0447.1983.tb09716.x. PMID 6880820.	14	$\alpha = .67 - .93$	Kwong, K. L., Lam, D., Tsui, S., Ngan, M., Tsang, B., Lai, T. S., & Lam, S. M. (2016). Anxiety and depression in adolescents with epilepsy. <i>Journal Of Child Neurology</i> , 31(2), 203-210. doi: 10.1177/0883073815587942

Appendix A.

Details of Measures and Questions Included in the Survey

Scale	Reference	Number of Items	Internal Reliability (Cronbach's alpha) Reported in Previous Research	Previous Use in Epilepsy Research
Brief Resilience Scale (BRS)	Smith, B. W., Dalen, J., Wiggins, K., Tooley, E., Christopher, P., & Bernard, J. (2008). The brief resilience scale: assessing the ability to bounce back. <i>International journal of behavioral medicine</i> , 15(3), 194-200.	6	$\alpha = .80 - .91$ (One of the highest rated scales from a recent review: Windle et al. (2011). A methodological review of resilience measurement scales. <i>Health and Quality of Life Outcomes</i> , 9(8).	There is a drought of research into resilience in epilepsy (Ring, A., Jacoby, A., Baker, G. A., Marson, A., & Whitehead, M. M. (2016). Does the concept of resilience contribute to understanding good quality of life in the context of epilepsy?. <i>Epilepsy & Behavior</i> , 56153-164. doi:10.1016/j.yebeh.2016.01.002), therefore no precedent set for use of measures.
Demographic information (age, gender, relationship status, highest level of education, employment status)	N/A	5	N/A	N/A
Illness-related variables (epilepsy medication, most common seizure type)	N/A	2	N/A	N/A

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Divide your article into clearly defined and numbered sections. Subsections should be numbered 1.1 (then 1.1.1, 1.1.2, ...), 1.2, etc. (the abstract is not included in section numbering). Use this numbering also for internal cross-referencing: do not just refer to 'the text'. Any subsection may be given a brief heading. Each heading should appear on its own separate line.

Introduction

State the objectives of the work and provide an adequate background, avoiding a detailed literature survey or a summary of the results.

Material and methods

Provide sufficient detail to allow the work to be reproduced. Methods already published should be indicated by a reference: only relevant modifications should be described.

Results

Results should be clear and concise.

Discussion

The **Discussion** section should explore the significance of the results of the work, not repeat them. **Results** and **Discussion** should be separate and may be organized into subheadings. Avoid extensive citations and discussion of published literature.

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The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion or Results and Discussion section.

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List funding sources in this standard way to facilitate compliance to funder's requirements:

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[1] Van der Geer J, Hanraads JAJ, Lupton RA. The art of writing a scientific article. *J Sci Commun* 2010;163:51–9.

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[dataset] [5] Oguro M, Imahiro S, Saito S, Nakashizuka T. Mortality data for Japanese oak wilt disease and surrounding forest compositions, Mendeley Data, v1; 2015. <https://doi.org/10.17632/xwj98nb39r.1>. Note shortened form for last page number. e.g., 51–9, and that for more than 6 authors the first 6 should be listed followed by 'et al.' For further details you are referred to 'Uniform Requirements for Manuscripts submitted to Biomedical Journals'

Section 3: Critical Appraisal

Psychological Perspectives on Stigma and Self-Compassion in Adults with Epilepsy

Word Count - 3,564 excluding references

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1. Main findings

1.1 Literature review

The systematic literature review of correlates of stigma in people with epilepsy (PWE) identified, appraised, and synthesised a large body of empirical evidence from 33 papers reporting findings from 25 quantitative research studies. The findings suggested a complicated combination of potential predictors and outcomes. Predictors were found to be influenced by country of origin and included demographic, illness-related, and psychosocial variables. Being married, higher income, and higher age were found to predict lower levels of stigma. In contrast, being diagnosed younger, having a greater number or more frequent seizures, and sustaining greater injuries from seizures were found to predict higher stigma. Higher stigma was also predicted by psychological factors including lower self-efficacy, social anxiety, future concerns or negative expectations about the condition, and beliefs that the condition is genetically determined. Avoidant coping strategies such as concealing the condition from others, or disengaging from managing it, were also associated with higher stigma. Stigma was also higher when PWE did not have access to understandable information about the condition. Social support, in contrast, was found to predict lower stigma. Outcomes from stigma were more uniform; those who felt stigmatised reported lower self-efficacy and motivation, and unsurprisingly reported poorer physical wellbeing and condition management, characterised by lower medication adherence and increased seizure severity. Poorer psychological outcomes were also identified for those with higher stigma, including higher depression and anxiety and lower quality of life.

1.2 Research paper

The empirical research paper was underpinned by the theory that self-compassion, and therapies which promote growth in people's individual capacity to be self-compassionate, can aid self-soothing in the face of adversity, and therefore improve psychological wellbeing [1,2]. The existing self-compassion research across populations has primarily focused on outcomes of depression and

anxiety [3-5], and to a lesser extent resilience [6]. The aim of the study was to take the established phenomenon and apply it to a specific health population, namely PWE, to ascertain whether these concepts are transferable to people with a complex neurological condition. In a quantitative study of a sample of adults with epilepsy, the findings of the study indicated that self-compassion can play a significant role in predicting improved psychological outcomes in this population - specifically lower depression and anxiety and increased resilience. The most significant implication of these findings was providing preliminary evidence that compassion-focused interventions such as compassion focused therapy (CFT) may be beneficial in the psychological care of PWE.

2. Research decisions, challenges, and professional issues

Throughout the course of the thesis a large number of important decisions were presented by the development of both the literature review and empirical research study. These decisions fundamentally shaped the thesis content, process, and outcomes. They also underpinned the relative strengths and limitations of the research in terms of its methodology and value in the wider psychological literature. Some of the key decisions, challenges, and professional issues are discussed here, with reference to strengths and limitations they precipitated in the thesis.

2.1 Literature review

2.1.1 Scope

An important consideration early on in the thesis was the focus of the literature review. I had already decided what the focus of the empirical paper would be, therefore in the literature review I was initially interested in examining the main research variable, self-compassion, more closely. I was specifically interested in the relationship between self-compassion and shame, as this is something that I had come across in the literature [7,8]. However, through initial scoping searches it became apparent that the research was heterogenous and it would be difficult to create a meaningful and focused narrative. This brought me closer to the subject of stigma in epilepsy, which had already come up literature searches and was highly applicable to my research study. In

consultation with my research supervisor I decided to look at correlates of stigma in epilepsy. This produced a large number of results which seemed unmanageable, and again too heterogenous, to easily draw together. I was therefore required to narrow the search to focus my research aims. During this process, I had to make decisions about cut-off criteria, for example deciding whether or not to include Western and Non-Western research, older and newer studies, and child and adult populations. Overall, I feel that focusing only on Western, adult populations, published since the year 2000 provided a focused review of current literature. However, despite limiting the cultural and geographical scope of the review, the sample was less homogenous than I had envisaged, and there were significant differences identified across countries. This highlights the complex nature of stigma in PWE and warrants further research. However, the sample was also still arguably less heterogeneous than if non-Western populations had been included; again this warrants a separate review.

I also had to carefully consider alternative search terms, for example terms associated with stigma, such as “shame” and “misconceptions”, and truncated words such as “*”, to include terms such as stigmatising and stigmatised. These iterations were rejected in the final list of search terms, which was kept relatively simple in order to ensure that the search remained focused. These decisions were made pragmatically and with the knowledge that no search is perfect. In order to produce a focused and robust search strategy, I liaised with the academic librarian for guidance who made a number of suggestions, such as using thesaurus search terms in databases; I believe that these steps led to a comprehensive review of the literature and represented a strength of the research.

2.1.2 Methodological appraisal

Once I had completed my searches and identified relevant studies, a further key decision was how best to critically appraise the methodological quality of the papers included in the literature review. Having had previous experience of using quality appraisal tools, I have learned that the process can be time-consuming, subjective, and can seem like an unhelpful process. I have previously used

long checklists such as the STROBE [9]; however, this has been criticised for inappropriate use as a methodological quality assessment tool [10]. For the thesis, I was keen to use a shorter tool that focused on the main issues of reporting and methodology. I therefore considered a range of different options before deciding to use the quality appraisal tool for observational studies adapted from the Agency for Healthcare Research and Quality [11]. This tool was chosen as the items were highly relevant to the cross-sectional survey design used in the majority of research papers in the review. Peer inter-rating helped to ensure that the process was as objective as possible and to identify areas of error or bias.

2.2 Research paper

2.2.1 Measurement and survey design

In the early development of the empirical study, one of the most important decisions was which standardised variable measures to use. There were several choices for measures of depression, anxiety, resilience, and self-compassion, and each presented compromises. These decisions were informed largely by previous studies in the field. For example, the Hospital Anxiety and Depression Scale (HADS [12]) is widely used in epilepsy populations as it is designed for clinical samples due to fewer somatic items than some other measures of depression and anxiety [13].

Whilst epilepsy specific measures of depression exist, I was advised by my field supervisor that these were less well established than the HADS, therefore these were avoided. Another important consideration was the demand that the survey may place on participants. Whilst it was desirable to gain a comprehensive dataset that would allow for nuanced and meaningful analyses, it was important to balance this with the time and demand placed on participants; it was also possible that longer questionnaires would lead to higher attrition rates. I decided that as the main variable of interest it was important to have a comprehensive measure of self-compassion, therefore the 26-item Neff Self Compassion Scale (SCS; [14]) was used. However, to ensure that the survey did not

become too long, shorter measures, such as the six-item Brief Resilience Scale (BRS; [15]), were used to measure other variables in the study.

Despite the careful consideration given to measures, there was evidence that some aspects of the survey may have been challenging or undesirable to participants, and this may represent a limitation of the study design. The data suggests that some participants discontinued their responses when presented with questions from the SCS. Although missing data in questionnaire surveys is inevitable [16], some participants in the clinic appeared to find some of the more convoluted questions difficult to answer, which may help to explain some of the attrition identified in the online sample. The SCS has come under increasing scrutiny for its psychometric properties [17,18], although it has been validated as a measure of self-compassion [19] and is presently the most widely relied upon tool for this purpose [20]. The measure was therefore considered to be the best available at the time of the undertaking the research study.

Once the variable measures had been chosen, there were decisions to make around how the survey would operate using the Qualtrics software. One such example was whether or not to force responses so that a question cannot be answered until responses have been given to all previous questions. The dilemma in this issue was that forcing responses would lead to complete datasets but would likely result in higher levels of attrition and would not give participants the option to skip difficult or emotive questions, however not forcing responses would likely result in missing data, which would present further difficulty later in managing data analysis. I decided that it was more important to give participants the option to complete only the questions they felt able to, as this was ethically more desirable and would likely result in more participants completing the survey as a whole, albeit perhaps with some missing data. The outcome of this appeared generally favourable: the majority of participants completed all or the majority of questions and the fraction of missing data was small.

2.2.2 Recruitment and data collection

Ethical issues in relation to recruitment and data collection were also identified. An important ethical challenge identified during the recruitment phase was that of identifying potential participants in clinic in an ethical and practical way. In consultation with my supervisors, I considered a number of different approaches including obtaining patient names from clinic staff, sending out participant information sheet by post in advance, and opportunistically approaching patients in the waiting room. A further related issue was that of informed consent. Whilst recruiting in clinic it was pragmatic for patients to be approached and asked if they would be interested and willing to take part in the study. However, the recommended norm is to give potential participants in excess of 24 hours to decide whether or not to take part [21], therefore it was unclear whether they could reasonably complete a paper copy of the survey on the day they were approached in clinic. In order to ascertain the best approach to addressing these issues, I consulted HRA guidance, spoke to my supervisors, and then contacted the REC who had provided approval for the study. I was advised that it is acceptable and pragmatic to give people the option to complete the study survey on the day of clinic, as long as they have the option to take it away and think if needed; this was supported by up-to-date research guidance [22]. Given this advice, I decided to ask nurses and consultants if they could identify participants at the end of consultations and direct them to me if they were interested in hearing about the study and potentially taking part. This was in line with my approved ethics application, was non-intrusive, did not put much work onto clinical staff, and was practically effective.

2.2.3 Sample

Despite the careful consideration given to recruitment, a limitation of the study was clearly identifying a sample of adults with a diagnosis of epilepsy. I was advised by my field supervisor early on in the research process that some people may believe that they have epilepsy when they have not in fact received a medical diagnosis. Whilst we could establish for certain that participants recruited from outpatient clinics had received a diagnosis, this was not possible for those recruited

online; this was open to anyone who stated that they had received a diagnosis. However, there was no way to confirm that this was accurate. Furthermore, the manager of the video telemetry (VT) clinic advised that even some patients who have received a diagnosis of epilepsy may not actually have the condition. Part of the work of this clinic is identifying the nature of seizure activity, and it is possible that some seizures may be better accounted for by the psychiatric diagnosis of non-epileptic attack disorder (NEAD). In order to provide an indication of this possible bias, the clinical and online samples were compared using a series of t-tests; these were found to be largely comparable. The sample was also unintentionally homogenous, with a disproportionately high number of White British females, under the age of 60; although the ethnic make-up was reasonably typical of the UK population [23]. This was likely due largely to the fact that the study was primarily advertised on online social media sites, including Facebook support groups and Twitter, supported by a UK epilepsy charity. This limited the generalisability of the study and prevents us from making assertions that apply beyond this. For example, it is possible that self-compassion is a culturally dependent construct in this context, however this was beyond the scope of the present study.

3. Future research

Given the significance of the finding that self-compassion can significantly predict higher resilience and lower depression and anxiety in PWE, it would be valuable to understand more about the role of self-compassion in other areas of health. It would be particularly valuable to extend these findings to other long-term neurological health conditions in order to gain a greater understanding of how broad-reaching the benefits of self-compassion may be and if there are any negative effects of utilising approaches such as CFT in neurological populations. Potentially valuable research could be carried out in areas such as Parkinson's disease, multiple sclerosis, Huntington's disease, and motor neurone disease, amongst others. This would allow us to better understand whether these findings are generalisable or whether there are certain factors specific to an epilepsy population

which make this a particularly important psychological construct. One such example is stigma, which was identified in the literature review as particularly important for PWE. The findings may also be relevant to some other neurological populations; for example there has been preliminary evidence for the use of CFT in people suffering from acquired brain injury [24].

A further area of potential future research is to extend the scope of research into self-compassion in PWE to different populations. As noted above, the sample obtained in the study was homogenous and findings were particularly applicable to a White British population; future studies could therefore examine self-compassion in PWE in other specific countries or cultures to determine whether or not findings could be replicated and generalised.

4. Personal reflections

Prior to undertaking this research, I understood logically that PWE can face a range of difficulties on a day-to-day basis, and that self-compassion may be able to help protect against some of these. The findings of the thesis supported these hypotheses. However, over-and-above the findings obtained from the review and empirical study, my understanding of the importance of these areas was enhanced through personal reflection and engagement with the research area throughout the thesis process. Through researching stigma whilst completing the systematic literature review, and through speaking to PWE (and people who care for PWE) during the design and data collection of the empirical study, I feel that I gained a much greater understanding of just how challenging the condition and its impact can be.

During the course of the study, I became immersed in the interesting, and to me previously largely unknown, world of epilepsy. This exposure helped me to better understand the difficulties faced by people with this condition and the resilience that they demonstrate publicly to others. This was particularly true of the welcome into the epilepsy community I was fortunate to be given online. For example, in order to recruit participants on Twitter I “followed” a number of epilepsy charities and groups, and for several months my Twitter feed was filled with information about the condition

and the experiences of those diagnosed with it. This provided illuminating insights into the types of issues faced by PWE on a daily basis. Similarly, I also had the opportunity to attend an epilepsy surgery meeting where clinical decisions are made about patients' condition and their suitability for surgical or medical interventions. This helped me to gain an appreciation of the medical nature of epilepsy, the difficult decisions that some patients face, and the impact that this might have psychologically and socially. I feel that these experiences were valuable; they complemented the research I was doing and helped me, as a researcher, to better understand the subject and ground my findings in a wider body of knowledge.

This connection to the research material was particularly important to me. I initially undertook the study due to a personal connection with the subject; I do not have a diagnosis of epilepsy, however I have experienced two isolated seizures, ten years apart from one another, the most recent of which was in 2014, immediately prior to starting my clinical psychology doctorate. This experience gave me an insight into what it might be like to live with seizures over a longer period of time, and the impact that this could have on the lives of people with the condition. I experienced feelings of anxiety, uncertainty, and powerlessness as a result of these, relatively minor, isolated but uncontrollable events. I was unable to drive for six months, which impacted my work and social life. I was also faced with questions about how these events arose and what they meant, and was left with some sense of felt, if not enacted, stigma. Revisiting the subject two years later felt empowering as it allowed me to better understand the psychological and social processes involved, and to approach the area in a more positive way. It also motivated me to do something to help people who have to live with epilepsy on a daily basis. Since I last experienced a seizure, I have become much more familiar with third wave cognitive behavioural therapy (CBT) approaches such as mindfulness and CFT, both personally and professionally. To apply this knowledge to a condition to which I felt some affiliation felt like a valuable and humbling pursuit. Whilst my personal experiences were by no means essential to completing the work, I believe that they

provided motivation and, I hope, allowed me to approach the study with the compassion I was attempting to measure in those who agreed to participate.

5. Conclusions

Overall, I feel that this thesis was successful in gaining valuable insights in relation to the psychological nature of epilepsy, including improving our understanding of the impact of the condition, and identifying ways in which some people are able to cope with the adversity associated with it. The systematic literature review highlighted and examined an important challenge faced by this population - stigma - and the empirical research study a specific psychological attribute - self-compassion - which was found to predict increased resilience to such challenges. I believe that these two individual papers therefore complimented each other to provide a cohesive and well-balanced narrative of important psychological factors in this population. The findings could be summarised very broadly as this: PWE face significant challenges as a result of their condition and the perceptions of themselves and others in relation to it; however, it appears that approaching the challenges in a kind, understanding, and empathic way may help in some way to protect PWE against this adversity, and perhaps resolve some of it altogether.

In addition to identifying negative outcomes of physical health conditions, clinical psychologists' role includes identifying protective factors and approaches that support or promote positive psychological outcomes as part of the development of comprehensive clinical formulations [25]. I therefore feel that it was important to consider resilience as an outcome in the study as well as examining depression and anxiety. I believe that findings from the study in relation to resilience were some of the most unique and interesting in advancing our understanding of how PWE may be able to cope with the adversity associated with living with the condition. These findings, along with those of the rest of the thesis, may be particularly relevant to PWE, their carers, and the services involved in their care; however, they may apply more broadly beyond this population and condition. Stigma and self-compassion are arguably concepts that are important to us all, and

further research will help us to determine the extent of their relative significance. However I hope, and believe, that this thesis has provided a small yet significant contribution to our growing understanding of these psychological phenomena in a specific population by examining the nature of stigma and self-compassion in the context of epilepsy.

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Section 4: Ethics Section

Title: What is the Relationship Between Self-Compassion and Depression, Anxiety, and Resilience
in Adults with Epilepsy?

Word Count - 5,201 excluding appendices

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LA1 4YG

IRAS Form

Reference:

IRAS Version 5.3.2

16/LO/1554

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Self-Compassion, Depression, Anxiety, and Resilience in Epilepsy

1. Is your project research?

Yes No

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Basic science study involving procedures with human participants
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:

Other study

2a. Please answer the following question(s):

- a) Does the study involve the use of any ionising radiation? Yes No
- b) Will you be taking new human tissue samples (or other human biological samples)? Yes No
- c) Will you be using existing human tissue samples (or other human biological samples)? Yes No

3. In which countries of the UK will the research sites be located? (Tick all that apply)

- England
- Scotland

Full Set of Project Data

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- Wales
 Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- England
 Scotland
 Wales
 Northern Ireland
 This study does not involve the NHS

4. Which applications do you require?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

- IRAS Form
 Confidentiality Advisory Group (CAG)
 National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

- Yes No

5. Will any research sites in this study be NHS organisations?

- Yes No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative in all study sites?

Please see information button for further details.

- Yes No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

- Yes No

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The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

Yes No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

Yes No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

Yes No

9. Is the study or any part of it being undertaken as an educational project?

Yes No

Please describe briefly the involvement of the student(s):

The study will be undertaken as part of a doctoral thesis for a clinical psychology training programme (DClinPsy).

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

Yes No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

Yes No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

Yes No

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Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting [Help](#).

Please define any terms or acronyms that might not be familiar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
 Self-Compassion, Depression, Anxiety, and Resilience in Epilepsy

PART A: Core study information
1. ADMINISTRATIVE DETAILS
A1. Full title of the research:

What is the Relationship Between Self-Compassion and Depression, Anxiety, and Resilience in Adults with Epilepsy?

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Mr	David	Baker
Address	Doctorate in Clinical Psychology, Furness College Faculty of Health and Medicine Lancaster University, Lancaster		
Post Code	LA1 4YG		
E-mail	d.baker1@lancaster.ac.uk		
Telephone	07870410021		
Fax			

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
 Doctorate in Clinical Psychology (DClinPsy)

Name of educational establishment:
 Lancaster University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Dr	Fiona	Eccles

Full Set of Project Data

IRAS Version 5.4.2

Address	C37 Furness College Doctorate in Clinical Psychology, Lancaster University Lancaster, Lancashire
Post Code	LA1 4YG
E-mail	f.eccles@lancaster.ac.uk
Telephone	01524592807
Fax	

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Mr David Baker	<input checked="" type="checkbox"/> Dr Fiona Eccles

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- Student
 Academic supervisor
 Other

A3-1. Chief Investigator:

	Title Forename/Initials Surname
	Mr David Baker
Post	Trainee Clinical Psychologist
Qualifications	BSc, MSc, PGDip
ORCID ID	
Employer	Lancashire Care NHS Foundation Trust
Work Address	Doctorate in Clinical Psychology, Furness College Faculty of Health and Medicine Lancaster University, Lancaster
Post Code	LA1 4YG
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* Personal E-mail	d.baker1@lancaster.ac.uk
Work Telephone	07870410021
* Personal Telephone/Mobile	07870410021
Fax	

* This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.

A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?

This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

Full Set of Project Data

IRAS Version 5.4.2

	Title Forename/Initials Surname
	Dr Diane Hopkins
Address	Research Services Room B14, Furness College Lancaster University
Post Code	LA1 4YT
E-mail	ethics@lancaster.ac.uk
Telephone	01524592838
Fax	

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):

Sponsor's/protocol number:

Protocol Version:

1

Protocol Date:

25/07/2016

Funder's reference number:

Project website:

http://www.lancaster.ac.uk/shm/study/doctoral_study/dclinpsy/research/

Additional reference number(s):

Ref.Number	Description	Reference Number
	The project will also be on Epilepsy Action's website	

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

Yes No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

This will be a quantitative study examining self-compassion as a predictor of depression, anxiety, and resilience in people with epilepsy (PWE). The study will use a cross-sectional survey design targeting adults with epilepsy recruited through local NHS services and online avenues. Data will be collected via a survey comprising questions about demographic information alongside standardised measures of seizure severity, self-compassion, depression, anxiety, resilience, and stigma. We will use a hierarchical regression model to control for known predictors of depression and then add in self-compassion as the variable of interest to ascertain whether this is a significant additional predictor. It is hypothesised that self-compassion will be negatively associated with depression and anxiety, and positively associated with resilience, even when other known variables are accounted for, as this may help in some way to protect against the effects of illness-related factors and shame and stigma associated with epilepsy.

Full Set of Project Data

IRAS Version 5.4.2

A6-2. Summary of main issues. Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

It is anticipated that issues relating to this study are likely to be minimal. Participants will be required to provide informed consent before taking part. The study will be supervised by clinical psychologists with expertise in the field of epilepsy and clinical research. The study will also be completed in consultation with the charity Epilepsy Action who have been involved in the design of the research. At the end of the survey a debrief sheet will be provided to participants with information about organisations they can contact for additional support if needed.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. Please tick all that apply:

- Case series/ case note review
- Case control
- Cohort observation
- Controlled trial without randomisation
- Cross-sectional study
- Database analysis
- Epidemiology
- Feasibility/ pilot study
- Laboratory study
- Metanalysis
- Qualitative research
- Questionnaire, interview or observation study
- Randomised controlled trial
- Other (please specify)

A10. What is the principal research question/objective? Please put this in language comprehensible to a lay person.

Using a quantitative design, the study will aim to address the following research question:

Does self-compassion predict reduced depression and anxiety and increased resilience when other known predictors of wellbeing including socio-demographic variables (age, gender, relationship status, education, and employment) and illness-related variables (seizure frequency, seizure severity, time since diagnosis) have been accounted for?

A11. What are the secondary research questions/objectives if applicable? Please put this in language comprehensible to a lay person.

As a secondary research question, we are also interested in whether epilepsy-related stigma is linked to self-compassion.

A12. What is the scientific justification for the research? Please put this in language comprehensible to a lay person.

Research suggests that people with epilepsy (PWE) have poorer quality of life (QOL) and higher levels of depression and anxiety than the general population. The currently available evidence for predictors of QOL and depression in PWE

Full Set of Project Data

IRAS Version 5.4.2

suggests that a combination of psychosocial, illness-related, and socio-demographic factors are likely to be important. Existing research, however, does not adequately account for variations in psychological outcomes, and it is possible that other factors which have not yet been investigated may also be of importance.

Self-compassion is the act of being kind and understanding towards oneself in the face of difficult experiences; recognising ones own experiences as part of the shared human condition rather than viewing them as isolating; and sitting mindfully with painful thoughts or feelings rather than over-identifying with them. Even when other variables have been accounted for, self-compassion has been shown to predict improved psychological health including lower levels of depression. Self-compassion has also been associated with resilience.

In PWE, depression, anxiety, and poor QOL may be linked to self-criticism resulting from shame and stigma associated with the condition. However, self-compassion as a predictor of depression, anxiety, and resilience in people with epilepsy has not been explored.

It is hypothesised that self-compassion will be negatively associated with depression and anxiety and positively associated with resilience even when other known variables are accounted for, as this may help in some way to protect against the effects of illness-related factors and shame and stigma associated with epilepsy.

The findings of this research may have potentially significant clinical implications for the psychological care of people with epilepsy, for example by providing evidence for treatment approaches such as Compassion Focused Therapy (CFT) in improving psychological resilience and mood-related outcomes.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Participants will be recruited from local NHS epilepsy services and via an online survey. The chief investigator or clinic staff will provide information about the study to patients in epilepsy clinics to consider if they would like to take part. Patients will be provided with a participant information sheet (PIS) outlining the study, its purpose, and how the data will be used. They will be able to take this information away to consider whether they would like to participate before providing informed consent by completing a consent form and completing the survey. Participants will be able to complete the survey electronically or on paper in the clinic or online. A debrief sheet with a list of support organisations will be provided at the end of the survey.

A secondary recruitment avenue will use online platforms including social media and the Epilepsy Action website. An invitation to the study will be posted online with a link to the participant information sheet (PIS), consent form, and the Qualtrics survey. This will be contained within the Lancaster University Doctorate in Clinical Psychology website.

Data will be collected via a survey comprising questions about demographic information alongside standardised measures of seizure severity, self-compassion, anxiety, depression, resilience, and stigma. We will also ask for participants to provide their nationality and ethnicity, although this will not be included as a variable in regression analyses. The survey will take around 15 minutes to complete.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- Design of the research
- Management of the research
- Undertaking the research
- Analysis of results
- Dissemination of findings
- None of the above

Give details of involvement, or if none please justify the absence of involvement.

The design of the study was developed in consultation with a panel of service users from the Epilepsy Action Research Network (EARN). Epilepsy Action have also provided consultation on the PIS to make this more reader-friendly for a lay audience. The findings of the study will be disseminated to service users via the charity.

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RESEARCH PARTICIPANTS**A15. What is the sample group or cohort to be studied in this research?**

Select all that apply:

- Blood
- Cancer
- Cardiovascular
- Congenital Disorders
- Dementias and Neurodegenerative Diseases
- Diabetes
- Ear
- Eye
- Generic Health Relevance
- Infection
- Inflammatory and Immune System
- Injuries and Accidents
- Mental Health
- Metabolic and Endocrine
- Musculoskeletal
- Neurological
- Oral and Gastrointestinal
- Paediatrics
- Renal and Urogenital
- Reproductive Health and Childbirth
- Respiratory
- Skin
- Stroke

Gender: Male and female participants

Lower age limit: 18 Years

Upper age limit: No upper age limit

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Participants must have a diagnosis of epilepsy, be at least 18 years old, and be able to understand English.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

People with no diagnosis of epilepsy, even if they have experienced seizures. People who are unable to complete a survey e.g. non-English speakers.

RESEARCH PROCEDURES, RISKS AND BENEFITS

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A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. These include seeking consent, interviews, non-clinical observations and use of questionnaires.

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Provide informed consent. Participants will be given information about the study and asked to tick a box to indicate consent.	1		5	Written information will be provided at the start of the survey in the form of the participant information sheet (PIS). Consent will be obtained in paper or electronic form by a member of the research team present in an epilepsy clinic or accessed independently by participants online.
Complete survey	1		15	The survey will be provided to participants to complete independently, either in an epilepsy clinic or online.

A21. How long do you expect each participant to be in the study in total?

Each participant will be asked to read the participant information sheet (PIS) and to complete a short survey which will take approximately 15 minutes.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

The risks of taking part in this study are minimal. Participants will be asked to answer questions about their epilepsy, symptoms of depression and anxiety, and factors associated with resilience, stigma, and self-compassion. We will not be targeting a clinical mental health population and it is not anticipated that participants are likely to be in a state of distress when taking part in the study.

Participants will be asked to complete a short survey only and the information requested is not of a sensitive nature. Participants will be given an information sheet outlining the nature of the study before being asked to provide informed consent by completing the consent form. They will be given time to consider whether or not they want to take part in the study. A list of support organisations will be provided to participants in a debrief sheet at the end of the survey.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

Yes No

A24. What is the potential for benefit to research participants?

Participants are unlikely to benefit directly. However, they will be informing our understanding of self-compassion in people with epilepsy (PWE).

A26. What are the potential risks for the researchers themselves? (if any)

None identified.

RECRUITMENT AND INFORMED CONSENT

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In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? For example, identification may involve a disease register, computerised search of social care or GP records, or review of medical records. Indicate whether this will be done by the direct care team or by researchers acting under arrangements with the responsible care organisation(s).

Potential participants will be identified in two ways:

- 1) Patients in local NHS epilepsy or neurology/neuropsychology clinics will be approached and asked if they would be willing to take part by completing a short survey either on paper or electronically using equipment provided, or independently online.
- 2) The survey will be advertised online via Epilepsy Action, Twitter, Facebook, and the Lancaster University website. A link will be provided to complete the survey electronically.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

Yes No

Please give details below:

No patient records or other identifiable information will be accessed and identification of the sample will be opportunistic.

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

Yes No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

The study will be advertised online through social media and the Epilepsy Action and Lancaster University websites.

A29. How and by whom will potential participants first be approached?

Potential participants online will be able to click on a link which provides information about the study via the participant information sheet (PIS). They will then be given a link to the consent form which will require them to provide consent via ticking the relevant boxes, following which they will be taken to the survey itself.

Potential participants in epilepsy clinics will be given the participant information sheet (PIS) and offered the opportunity to take part. Participants will be able to take the study information away to decide whether or not they want to take part. No participants will be asked to come into clinic to complete the survey - only those already in attendance will be approached.

A30-1. Will you obtain informed consent from or on behalf of research participants?

Yes No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

A description of the purpose and nature of the study will be provided to potential participants to read in the form of the participant information sheet (PIS). Participants will be directed to the consent form to complete either in electronic or paper form and asked to indicate that they consent to taking part by ticking the relevant boxes.

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If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

Yes No

A31. How long will you allow potential participants to decide whether or not to take part?

Participants can take as long as they want within the duration of the recruitment phase of study to decide whether or not to take part. A link to the survey will remain available online for the duration of the recruitment phase of the study.

Participants approached in clinic will be able to take the study information away before completing the survey in the clinic or online via a webpage link provided.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?(e.g. translation, use of interpreters)

The questionnaires being used are not necessarily validated in other languages therefore non-English speakers will not be invited to take part in the study. People with communication or learning difficulties which would make it difficult to complete a survey will also be excluded from the study for practical reasons. It is not anticipated that this should significantly limit the scope of the research.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? Tick one option only.

- The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- The participant would continue to be included in the study.
- Not applicable – informed consent will not be sought from any participants in this research.
- Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?(Tick as appropriate)

- Access to medical records by those outside the direct healthcare team
- Access to social care records by those outside the direct social care team

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- Electronic transfer by magnetic or optical media, email or computer networks
- Sharing of personal data with other organisations
- Export of personal data outside the EEA
- Use of personal addresses, postcodes, faxes, emails or telephone numbers
- Publication of direct quotations from respondents
- Publication of data that might allow identification of individuals
- Use of audio/visual recording devices
- Storage of personal data on any of the following:
 - Manual files (includes paper or film)
 - NHS computers
 - Social Care Service computers
 - Home or other personal computers
 - University computers
 - Private company computers
 - Laptop computers

Further details:

Personal identifiable data will not be collected from participants. Anonymous, non-identifiable, quantitative demographic and research questionnaire data will be collected only, other than in the circumstance described below.

Personal addresses, postcodes, faxes, emails or telephone numbers will only be used if participants request paper copies of study information (e.g. surveys) to be sent out to them. Once sent out, this data will be deleted and will not be held or used for any other purpose. Personal data will not be linked to anonymous survey responses.

A37. Please describe the physical security arrangements for storage of personal data during the study?

Data will be stored electronically on the Qualtrics web based survey and data collection tool licensed for use by Lancaster University. Paper copies of surveys will be inputted into the electronic Qualtrics system and then immediately securely destroyed. If required, personal data may be held for a short period of time on the secure and encrypted server system used by Lancaster University. This will be destroyed as soon as the relevant information has been sent out to potential participants.

A38. How will you ensure the confidentiality of personal data? Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.

No personal data will be routinely gathered from participants, other than in the circumstances outlined above.

A40. Who will have access to participants' personal data during the study? Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.

No personal data will be routinely obtained. Where potential participants provide contact information in requests for paper copies of survey information this will be accessible only by the research team.

Storage and use of data after the end of the study**A41. Where will the data generated by the study be analysed and by whom?**

Data will be analysed by the Chief Investigator under supervision of the Academic Supervisor. Analysis will be completed at the home of the Chief Investigator and at Lancaster University.

A42. Who will have control of and act as the custodian for the data generated by the study?

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	Title Forename/Initials Surname
	Prof Bill Sellwood
Post	Programme Director, Lancaster University Doctorate in Clinical Psychology
Qualifications	
Work Address	Doctorate in Clinical Psychology, Furness College Faculty of Health and Medicine Lancaster University, Lancaster
Post Code	LA1 4YG
Work Email	b.sellwood@lancaster.ac.uk
Work Telephone	01524593998
Fax	

A43. How long will personal data be stored or accessed after the study has ended?

- Less than 3 months
 3 – 6 months
 6 – 12 months
 12 months – 3 years
 Over 3 years

A44. For how long will you store research data generated by the study?

Years: 10

Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended. Say where data will be stored, who will have access and the arrangements to ensure security.

Data will be stored by the Lancaster Doctorate in Clinical Psychology on the secure Lancaster University network (or other location deemed by the university to meet the same security standards) and will be accessible to the PI, supervisors, data custodian, research or programme director or administrative staff on the programme.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

- Yes No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

- Yes No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g.

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financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

Yes No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

Yes No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50-1. Will the research be registered on a public database?

Yes No

Please give details, or justify if not registering the research.

The research will be listed as trainee research on the Lancaster University website at http://www.lancaster.ac.uk/shm/study/doctoral_study/dclinpsy/research/

The study will also be listed on the Epilepsy Action website.

Registration of research studies is encouraged wherever possible.

You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? Tick as appropriate:

- Peer reviewed scientific journals
- Internal report
- Conference presentation
- Publication on website
- Other publication
- Submission to regulatory authorities
- Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- No plans to report or disseminate the results
- Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

N/A

A53. Will you inform participants of the results?

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Yes No

Please give details of how you will inform participants or justify if not doing so.

Participants will not be informed of the results directly. However, it is hoped that findings will be made available via Epilepsy Action publications which are freely available and accessible within the epilepsy community. Participants will be directed to the Lancaster University Research website and Epilepsy Action website for updates on the findings of the study.

5. Scientific and Statistical Review

A54-1. How has the scientific quality of the research been assessed? Tick as appropriate:

- Independent external review
- Review within a company
- Review within a multi-centre research group
- Review within the Chief Investigator's institution or host organisation
- Review within the research team
- Review by educational supervisor
- Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

The research has been developed by the Chief Investigator as part of a doctoral thesis for the Doctorate in Clinical Psychology (DClinPsy) at Lancaster University. As such, the project is supervised by an experienced researcher (Academic Supervisor) and a practising clinical neuropsychologist in the field of epilepsy (External/Field Supervisor).

A research proposal was developed and approved by the Chair of the Exam Board on behalf of the DClinPsy programme. Throughout the project, the research team will liaise regularly to discuss the process in order to maintain high levels of scientific standards in line with doctorate level academic research. Consultation on the design of the study has also been provided by the charity Epilepsy Action.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? Tick as appropriate:

- Review by independent statistician commissioned by funder or sponsor
- Other review by independent statistician
- Review by company statistician
- Review by a statistician within the Chief Investigator's institution
- Review by a statistician within the research team or multi-centre group
- Review by educational supervisor
- Other review by individual with relevant statistical expertise
- No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

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	Title Forename/Initials Surname
Department	Doctorate in Clinical Psychology, Faculty of Health and Medicine
Institution	Lancaster University
Work Address	C37 Furness College Doctorate in Clinical Psychology, Lancaster University Lancaster, Lancashire
Post Code	LA1 4YG
Telephone	
Fax	
Mobile	
E-mail	

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

The Hospital Anxiety and Depression Scale (HADS) as a measure of depression and anxiety (Zigmond, A.S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica* 67 (6): 361–370. doi:10.1111/j.1600-0447.1983.tb09716.x. PMID 6880820); and the Brief Resilience Scale (BRS) as a measure of resilience (Smith, B. W., Dalen, J., Wiggins, K., Tooley, E., Christopher, P., & Bernard, J. (2008). The brief resilience scale: assessing the ability to bounce back. *International journal of behavioral medicine*, 15(3), 194-200).

A58. What are the secondary outcome measures?(if any)

We may conduct further regression analyses to measure the effect of felt or enacted stigma on self-compassion. To measure stigma we will use The Stigma Scale for Chronic Illnesses 8-item version (SSCI-8) (Molina, Y., Choi, S., Cella, D., & Rao, D. (2013). The Stigma Scale for Chronic Illnesses 8-Item Version (SSCI-8): Development, Validation and Use Across Neurological Conditions. *International Journal Of Behavioral Medicine*, 20(3), 450-460. doi:10.1007/s12529-012-9243-4).

A59. What is the sample size for the research? How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.

Total UK sample size: 75
Total international sample size (including UK): 75
Total in European Economic Area: 75

Further details:

This figure is an estimate of the minimum number of participants needed to address the research question using the proposed form of analysis.

A60. How was the sample size decided upon? If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.

A predictive power calculation for a linear multiple regression with 6 predictors suggests that to achieve power of .8 with a medium effect size of .2 (as indicated in other studies of self-compassion e.g. Soysa, C. K., & Wilcomb, C. J. (2015). Mindfulness, self-compassion, self-efficacy, and gender as predictors of depression, anxiety, stress, and well-being. *Mindfulness*, 6(2), 217-226.) at a probability level of $p = .05$ requires 75 participants. We will therefore aim to recruit approximately 75-100 participants.

A61-1. Will participants be allocated to groups at random?

Yes No

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A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

We will use a hierarchical regression model to control for known predictors of depression and anxiety and then add in self-compassion as the variable of interest to ascertain whether this is a significant additional predictor. The following variables will be used:

Predictor variables:

1. Socio-demographic variables: age, gender, relationship status, education, employment
2. Illness-related variables: seizure frequency and severity (LSSS), time since diagnosis
3. Self-compassion (Neff Self-Compassion Scale)

Outcome variables:

1. Depression (HADS)
2. Anxiety (HADS)
3. Resilience (BRS)

As a secondary research question, we may use a similar regression model to measure the effect of stigma on self-compassion, as stigma has been highlighted as potentially important in the literature.

Demographic data and outcomes of correlational and regression analyses will be provided in tables, and findings will be discussed.

Where data is missing and surveys are only partially completed, available data may still be included e.g. if there are complete sets of some but not all predictor or dependent variables.

6. MANAGEMENT OF THE RESEARCH**A63. Other key investigators/collaborators.** Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.

	Title	Forename/Initials	Surname
	Dr	Helen	Caswell
Post	Consultant Clinical Neuropsychologist		
Qualifications	Chartered Clinical Psychologist		
Employer	Salford Royal NHS Foundation Trust		
Work Address	Dept of Neuropsychology		
	Clinical Science Building, Salford Royal Hospital		
	Stott Lane, Salford		
Post Code	M6 8HD		
Telephone	01612062029		
Fax			
Mobile			
Work Email	helen.caswell@srft.nhs.uk		

A64. Details of research sponsor(s)**A64-1. Sponsor**

Lead Sponsor

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Status: <input type="radio"/> NHS or HSC care organisation <input checked="" type="radio"/> Academic <input type="radio"/> Pharmaceutical industry <input type="radio"/> Medical device industry <input type="radio"/> Local Authority <input type="radio"/> Other social care provider (including voluntary sector or private organisation) <input type="radio"/> Other <i>If Other, please specify:</i>	Commercial status: Non-Commercial
<p>Contact person</p> <p>Name of organisation Lancaster University, Research Services</p> <p>Given name Diane</p> <p>Family name Hopkins</p> <p>Address Room B14 Furness College, Lancaster University</p> <p>Town/city Lancaster</p> <p>Post code LA1 4YT</p> <p>Country UNITED KINGDOM</p> <p>Telephone 01524592838</p> <p>Fax</p> <p>E-mail ethics@lancaster.ac.uk</p>	
<p>Is the sponsor based outside the UK?</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p><i>Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.</i></p>	

A65. Has external funding for the research been secured?

- Funding secured from one or more funders
- External funding application to one or more funders in progress
- No application for external funding will be made

What type of research project is this?

- Standalone project
- Project that is part of a programme grant
- Project that is part of a Centre grant
- Project that is part of a fellowship/ personal award/ research training award
- Other

Other – please state:

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A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? Please give details of subcontractors if applicable.

Yes No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

Yes No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title Forename/Initials Surname
	Ms Natalie Garratt
Organisation	Research and Development
Address	Salford Royal NHS Foundation Trust
	Stott Lane
	Salford
Post Code	M6 8HD
Work Email	Natalie.garratt@manchester.ac.uk
Telephone	01612065203
Fax	
Mobile	

Details can be obtained from the NHS R&D Forum website: <http://www.rdforum.nhs.uk>

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/08/2016

Planned end date: 28/02/2017

Total duration:

Years: 0 Months: 6 Days: 28

A71-1. Is this study?

Single centre
 Multicentre

A71-2. Where will the research take place? (Tick as appropriate)

England
 Scotland
 Wales
 Northern Ireland
 Other countries in European Economic Area

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Total UK sites in study 1

Does this trial involve countries outside the EU? Yes No USA Other international (please specify)

The research will take place in England. The study will be advertised online, therefore whilst we anticipate the majority of participants to be UK residents, the scope of the research is international.

A72. Which organisations in the UK will host the research? Please indicate the type of organisation by ticking the box and give approximate numbers if known:

 NHS organisations in England 1 NHS organisations in Wales NHS organisations in Scotland HSC organisations in Northern Ireland GP practices in England GP practices in Wales GP practices in Scotland GP practices in Northern Ireland Joint health and social care agencies (eg community mental health teams) Local authorities Phase 1 trial units Prison establishments Probation areas Independent (private or voluntary sector) organisations Educational establishments 1 Independent research units Other (give details)

Total UK sites in study: 2

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

 Yes No

A73-2. If yes, will any of these organisations be NHS organisations?

 Yes No

If yes, details should be given in Part C.

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The Chief Investigator will complete the research under the supervision of the Academic Supervisor at Lancaster

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University and the External Supervisor who is an expert in epilepsy research and working in the field. Regular supervision meetings will take place to ensure that the research is completed to a high standard.

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? Please tick box(es) as applicable.

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- NHS indemnity scheme will apply (NHS sponsors only)
 Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? Please tick box(es) as applicable.

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- NHS indemnity scheme will apply (protocol authors with NHS contracts only)
 Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
 Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

- Yes No Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. For further information please refer to guidance.

Investigator identifier	Research site	Investigator Name
IN1	<input checked="" type="radio"/> NHS site <input type="radio"/> Non-NHS site Country: England Organisation name Address Post Code	Forename David Middle name Andrew Family name Baker Email d.baker1@lancaster.ac.uk Qualification (MD...) BSc, MSc, PGDip Country UNITED KINGDOM

DRAFT

2. Research protocol

Doctorate in
Clinical Psychology



Research Protocol

Version number: 1

Date: 25/07/16

IRAS ID: 205444

Title: What is the Relationship Between Self-Compassion and Depression, Anxiety, and Resilience
in Adults with Epilepsy?

Applicant: David Baker

Lancaster University, Doctorate in Clinical Psychology

Research Supervisor: Dr Fiona Eccles

Field Supervisor: Dr Helen Caswell

Introduction

Background

People with epilepsy (PWE) have poorer quality of life (QOL) than the general population (Strine, Kobau, Chapman, Thurman, Price & Balluz, 2002; Tellez-Zenteno, Matijevic & Wiebe, 2005; Wiebe, Bellhouse, Fallahay & Eliasziw, 1999; Kobau, Zahran, Grant, Thurman, Price & Zack, 2003; Santhouse, Carrier, Arya, Fowler & Duncan, 2007). Epilepsy is also significantly associated with depression (Fiest et al., 2013), and depression predicts poor QOL (Boylan, Flint, Labovitz, Jackson, Starner & Devinsky, 2004). Anxiety is also highly prevalent in this population (Beyenberg, Mitchell, Schmidt, Elger, & Reuber, 2005).

QOL trajectories in PWE often do not follow the clinical course of epilepsy, but instead may be affected by a wide range of psychosocial factors including experienced stigma and discrimination, difficulties of adjustment, personal and social capital, and social support (Jacoby & Baker, 2008). Coping and engagement strategies, perceived social support, stress, and self-efficacy have also been identified as important (Gandy, Sharpe & Perry, 2012). In a recent review by Lacey, Salzberg & D'Souza (2015), epilepsy illness-related factors including seizure frequency, and to a lesser extent seizure recency, were found to predict depression in PWE. However, sociodemographic factors including age, gender, education, employment and income were found to predict depression more consistently; and psychological factors including emotional aspects of recovery from seizures; social concerns such as fear of injury, activity restriction, and embarrassment; and a past history of depression, anxiety, perceived stress, and stigma were also found to be important.

The currently available evidence for predictors of QOL and depression in PWE suggests that a combination of psychosocial, illness-related, and socio-demographic factors are likely to be influential. Existing research, however, does not adequately account for variations in psychological outcomes, and it is possible that other factors which have not yet been investigated may also be

important. Stigma has been highlighted as a potentially significant factor in precipitating or exacerbating poor QOL in PWE (Antonak & Livneh, 1992; Jacoby, 2002; Baker, Jacoby, Buck, Stalgis, & Monnet, 1997; Beyenburg et al., 2005; Hesdorffer and Lee, 2009; Lambert & Robertson, 1999; Marsh & Rao, 2002). There is also evidence that even where stigma is not enacted externally, this may be 'felt' by PWE (Jacobi & Austin, 2007), and some may feel less valuable, adaptable, dependable, mature, stable, able to cope, successful and well-adjusted than people without the condition (Collings, 1990). Health-related stigma, including stigma in epilepsy, has been related to shame (Scambler, 2009). In the general population, shame has been linked to self-criticism and depression (Gilbert & Miles, 2000). In contrast, there is an increasing body of evidence to suggest that across a range of contexts, self-compassion may protect against shame and lead to better mental health outcomes (Johnson & O'Brien, 2013; Ferreira, Pinto-Gouveia, & Duarte, 2013; Leary, Tate, & Adams et al., 2007).

Self-compassion is the act of being kind and understanding towards oneself in the face of difficult experiences; recognising one's own experiences as part of the shared human condition rather than viewing them as isolating; and sitting mindfully with painful thoughts or feelings rather than over-identifying with them (Neff, 2003). Even when other variables have been accounted for, self-compassion has been shown to predict improved psychological health including lower levels of depression and anxiety (Neff & Faso, 2015; Soysa & Wilcomb, 2015; Van Dam, Sheppard, Forsyth & Earleywine, 2011). Self-compassion has also been associated with resilience (Kemper, Mo & Khayat, 2015; Neff & McGehee, 2010; Smeets, Neff, Alberts & Peters, 2014), although few studies have measured this directly. Resilience may help to protect against illness-related factors affecting mood and QOL. It is possible that in PWE, depression and anxiety (and thus poor QOL) may be linked to self-criticism resulting from shame and stigma associated with the condition. However, self-compassion as a predictor of psychological wellbeing and resilience in people with epilepsy has not been examined.

It is hypothesised that self-compassion will be negatively associated with depression and anxiety and positively associated with resilience even when other known variables are accounted for. The findings of this research may have potentially significant clinical implications for the psychological care of people with epilepsy, for example by providing evidence for treatment approaches such as Compassion Focused Therapy (CFT) in improving psychological wellbeing and resilience.

Research Aims

Using a quantitative design, the study will aim to address the following research question: Does self-compassion predict reduced depression and anxiety and increased resilience when other known predictors of wellbeing including socio-demographic variables (age, gender, relationship status, education, and employment) and illness-related variables (seizure frequency, seizure severity) have been accounted for? As a secondary research question, we are also interested in whether epilepsy-related stigma is linked to self-compassion.

Method

Design

The study will use a quantitative cross-sectional survey design to examine predictors of depression, anxiety, and resilience in people with epilepsy. The design was developed in consultation with research and external supervisors with relevant expertise. Feedback was also obtained from a panel of service user representatives from the Epilepsy Action Research Network (EARN) and suggested changes were incorporated into the final design. Epilepsy Action also commented on the participant information sheet to make this more readable for a lay audience.

Participants

A predictive power calculation for a linear multiple regression with 6 predictors suggests that to achieve power of .8 with a medium effect size of .2 (as indicated in other studies of self-compassion e.g. Soysa & Wilcomb, 2015) at a probability level of $p = .05$ requires 75 participants.

We will therefore aim to recruit approximately 75-100 participants through local NHS epilepsy services and online avenues including social media including Facebook support groups and Twitter using #epilepsy. It is hoped that the charity, Epilepsy Action will also support recruitment. This may include advertising on their website, forum (Forum4e, an online community of people with epilepsy and carers), social media (Facebook and Twitter), publications (Epilepsy Today and Epilepsy Professional), local branches, groups and events.

Inclusion criteria:

To be eligible for inclusion, participants must:

- Have a diagnosis of epilepsy
- Be at least 18 years old
- Be able to understand English

Exclusion criteria:

Participants will be excluded if they:

- Do not have a diagnosis of epilepsy (even if they have experienced seizures)
- Are unable to complete a survey e.g. non-English speakers

Materials

Electronic and paper versions of the following standardised measures will be used in the survey: Liverpool Seizure Severity Scale 2.0 (LSSS) (Scott-Lennox, Bryant-Comstock, Lennox, & Baker, 2001); Neff Self-Compassion Scale (Neff, 2003); Hospital Anxiety and Depression Scale (Zigmond, & Snaith, 1983); Brief Resilience Scale (BRS) (Smith, Dalen, Wiggins, Tooley, Christopher, & Bernard, 2008); and The Stigma Scale for Chronic Illnesses 8-item version (SSCI-8) (Molina, Choi, Cella, & Rao, 2013). Further information about measures is provided in Appendix 1. Electronic versions will be delivered using Qualtrics web-based survey and data collection software licensed for use by Lancaster University staff and students. If participants wish to complete the survey electronically in the epilepsy clinic, computer equipment will be provided.

Procedure

Recruitment. Participants will be recruited from local NHS epilepsy services and online. The primary researcher will attend clinics and ask patients if they would be willing to complete a short survey either on a computer tablet or on paper. The survey will be prefaced with a participant information sheet (PIS) containing a description of the study, its purpose, and how the data will be used. Patients approached in clinic will be able to take the study information away before completing the survey in the clinic or online via a webpage link provided. Patients will be asked to provide consent by completing a consent form provided (again this could be electronic or on paper). The survey will take a total of approximately 15 minutes to complete. A secondary recruitment avenue will use online platforms including social media and the Epilepsy Action website. An invitation to the study will be posted on the Lancaster University Doctorate in Clinical Psychology research page (http://www.lancaster.ac.uk/shm/study/doctoral_study/dclinpsy/research) with a link to the participant information sheet (PIS), the consent form, and the Qualtrics survey.

Data Collection. Data will be collected via a survey comprising questions about demographic information (age, gender, nationality, ethnicity, relationship status, highest level of education, employment hours per week, therapy offered/received) and illness-related information (age at epilepsy onset/diagnosis, seizure type (if known), medication) alongside standardised measures of seizure severity, self-compassion, depression, anxiety, resilience, and stigma.

Personal identifiable data will not routinely be collected from participants. Anonymous, non-identifiable, quantitative demographic and research questionnaire data will be collected only. Personal addresses, postcodes, faxes, emails or telephone numbers will only be used if participants request paper copies of study information (e.g. surveys) to be sent out to them. If required, personal data may be held for a short period of time on the secure and encrypted server system used by Lancaster University. This data will be destroyed as soon as the relevant information has been sent out to potential participants and will not be used for any other purpose. Personal data will not be

linked to anonymous survey responses. Data will be stored electronically on the Qualtrics web based survey and data collection tool licensed for use by Lancaster University. Paper copies of surveys will be inputted into the electronic Qualtrics system and then immediately securely destroyed. Anonymous survey data will be held securely for a period of 10 years in line with university procedures and then destroyed.

Analysis

We will use a hierarchical regression model to control for known predictors of depression and anxiety and then add in self-compassion as the variable of interest to ascertain whether this is a significant additional predictor. The following variables will be used:

Predictor variables:

1. Socio-demographic variables: age, gender, relationship status, education, employment
2. Illness-related variables: seizure severity (LSSS), time since diagnosis
3. Self-compassion (Neff Self-Compassion Scale)

Outcome variables:

1. Depression (HADS)
2. Anxiety (HADS)
3. Resilience (BRS)

As a secondary analysis we intend to use a similar regression model to assess whether felt or enacted stigma predicts self-compassion when other variables have been controlled for.

Dissemination

It is anticipated that findings will be submitted for publication in a relevant peer reviewed academic journal. It is hoped that findings will also be disseminated to the epilepsy community through Epilepsy Action publications.

Practical Issues

Costs

Licenses for all measures have been obtained as necessary and associated costs have been covered by Lancaster University.

Potential Limitations

The study will use a quantitative survey design and as such we will not be able to gain detailed qualitative information from participants about their experiences. Given the proposed sample size and analysis it will not be possible to determine mediating or moderating effects. The sample will be obtained in part from local NHS services, therefore this may represent a limited demographic and findings may not be generalisable more widely.

Ethical considerations

It is not anticipated that this study will result in significant risks to participants or raise significant ethical issues. Participants will be free to withdraw from the study at any time. At the beginning of the study participants will be provided with a brief outline of the study in the form of the participant information sheet (PIS). At the end of the survey participants will be presented with a list of available resources/organisations to contact should they require any additional support. Any ethical issues arising during the course of the study will be discussed with the Field Supervisor who is a Consultant Clinical Neuropsychologist with significant expertise working in the field of epilepsy. Ethical approval will be sought from a Research Ethics Committee (REC) and research governance approval from Trust Research and Development (R&D) departments via the Integrated Research Application System (IRAS) prior to commencing data collection.

Service-user involvement

The design of the study and materials were developed in consultation with a panel of service user representatives from the Epilepsy Action charity's research network (EARN).

Estimated Timescale

August 2016

Start data collection

December 2016

End data collection

January-March 2017

Analyse and write-up data

April-May 2017

Complete final version of research paper

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Appendix 1

Details of Measures Chosen for the Survey

Scale	Reference	Number of Items	Internal Reliability (Cronbach's alpha)	Previous Use in Epilepsy Research
Liverpool Seizure Severity Scale 2.0 (LSSS)	Scott-Lennox, J. Bryant-Comstock, L., Lennox, R. & Baker, G. A. (2001). Reliability, validity and responsiveness of a revised scoring system for the Liverpool Seizure Severity Scale. (2001). <i>Epilepsy Research</i> , 44(1), 53–63. doi: 10.1016/S0920-1211(01)00186-3	13	$\alpha=0.66-0.87$	E.g. Viteva, E. I. (2014). Seizure frequency and severity: How really important are they for the quality of life of patients with refractory epilepsy. <i>Annals Of Indian Academy Of Neurology</i> , 17(1), 35-42. doi: 10.4103/0972-2327.128544
Neff Self-Compassion Scale	Neff, K. D. (2003). Development and validation of a scale to measure self-compassion. <i>Self and Identity</i> , 2, 223–250.	26	$\alpha=0.92$	No research has been identified into self-compassion in people with epilepsy (PWE), therefore no precedent set for use of measures.

Appendix 1

Details of Measures Chosen for the Survey

Scale	Reference	Number of Items	Internal Reliability (Cronbach's alpha)	Previous Use in Epilepsy Research
Hospital Anxiety and Depression Scale (HADS)	Zigmond, A.S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. <i>Acta Psychiatrica Scandinavica</i> 67 (6): 361–370. doi:10.1111/j.1600-0447.1983.tb09716.x. PMID 6880820.	14	$\alpha=.67-.93$	Kwong, K. L., Lam, D., Tsui, S., Ngan, M., Tsang, B., Lai, T. S., & Lam, S. M. (2016). Anxiety and depression in adolescents with epilepsy. <i>Journal Of Child Neurology</i> , 31(2), 203-210. doi: 10.1177/08830738155587942
Brief Resilience Scale (BRS)	Smith, B. W., Dalen, J., Wiggins, K., Tooley, E., Christopher, P., & Bernard, J. (2008). The brief resilience scale: assessing the ability to bounce back. <i>International journal of behavioral medicine</i> , 15(3), 194-200.	6	$\alpha=0.80- 0.91$ (One of the highest rated scales from a recent review: Windle et al. (2011). A methodological review of resilience measurement scales. <i>Health and Quality of Life Outcomes</i> , 9(8).	There is a drought of research into resilience in epilepsy (Ring, A., Jacoby, A., Baker, G. A., Marson, A., & Whitehead, M. M. (2016). Does the concept of resilience contribute to understanding good quality of life in the context of epilepsy?. <i>Epilepsy & Behavior</i> , 56153-164. doi: 10.1016/j.yebeh.2016.01.002), therefore no precedent set for use of measures.

Appendix 1

Details of Measures Chosen for the Survey

Scale	Reference	Number of Items	Internal Reliability (Cronbach's alpha)	Previous Use in Epilepsy Research
The Stigma Scale for Chronic Illnesses 8-item version (SSCI-8)	Molina, Y., Choi, S., Cella, D., & Rao, D. (2013). The Stigma Scale for Chronic Illnesses 8-Item Version (SSCI-8): Development, Validation and Use Across Neurological Conditions. <i>International Journal Of Behavioral Medicine</i> , 20(3), 450-460. doi: 10.1007/s12529-012-9243-4	8	$\alpha=0.89$	As this is a relatively new area of research, there has been little use of this scale in epilepsy studies. One paper has used the scale to measure stigma in epilepsy as a comparison to migraines: Young, W. B., Park, J. E., Tian, I. X., & Kempner, J. (2013). The Stigma of Migraine. <i>Plos ONE</i> , 8(1), 1-8. doi:10.1371/journal.pone.0054074

Appendix 1
Details of Measures Chosen for the Survey

Scale	Reference	Number of Items	Internal Reliability (Cronbach's alpha)	Previous Use in Epilepsy Research
Demographic Information (age, gender, nationality, ethnicity, relationship status, highest level of education, employment hours per week, therapy offered/received)	N/A	8	N/A	N/A
Illness-related information (age at epilepsy onset/diagnosis, seizure type (if known), medication)	N/A	3	N/A	N/A

Total number of items: 78

Doctorate in
Clinical Psychology

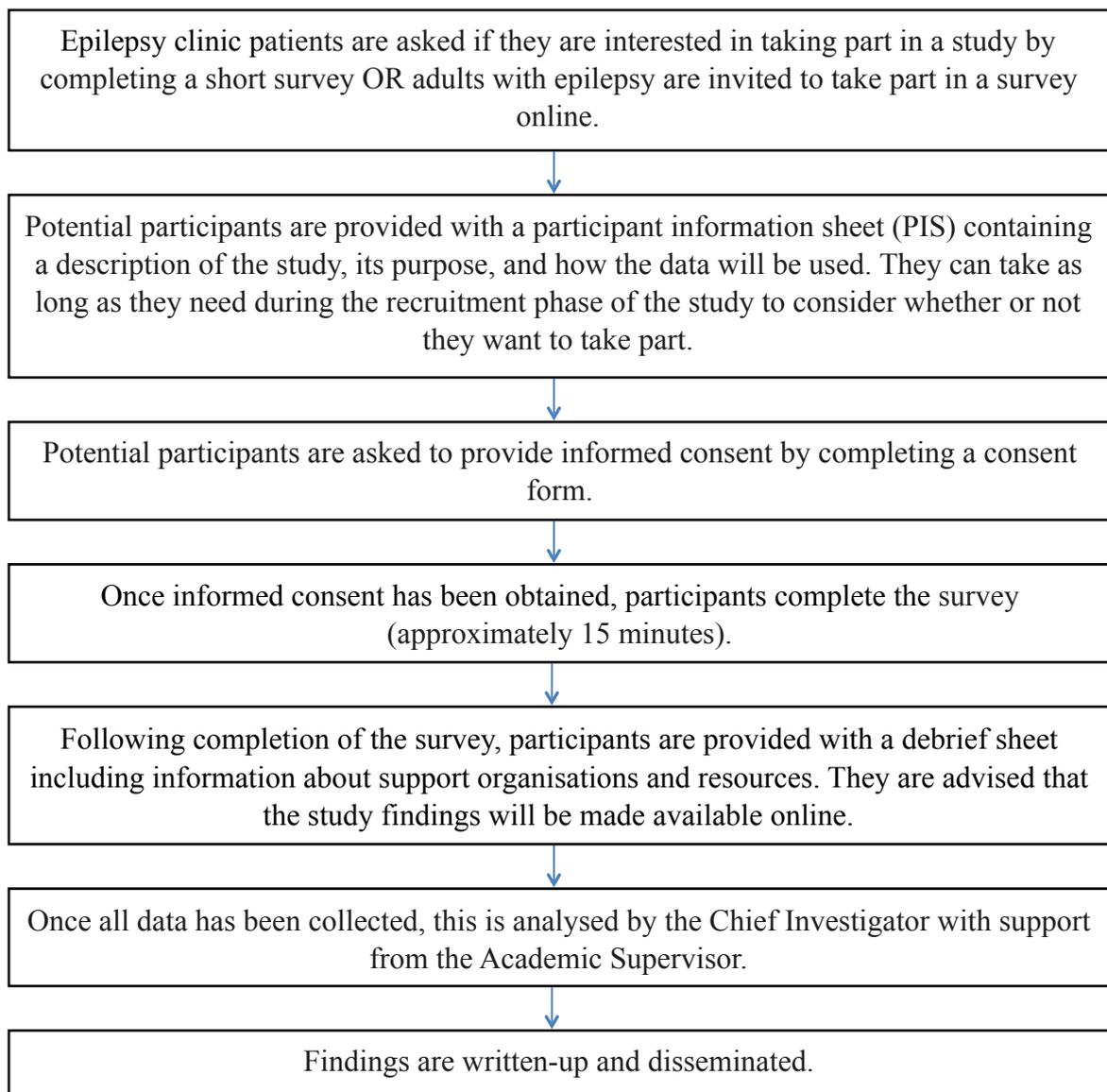


Flow Chart of Thesis Research Protocol

Version number: 1

Date: 25/07/16

IRAS ID: 205444





Health Research Authority
London - Stanmore Research Ethics Committee

Ground Floor
NRES/HRA
80 London Road
London
SE1 6LH

Telephone: 020 7972 2554

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

07 September 2016

Mr David Baker
Doctorate in Clinical Psychology, Furness College
Faculty of Health and Medicine
Lancaster University, Lancaster
LA1 4YG

Dear Mr Baker

Study title: What is the Relationship Between Self-Compassion and Depression, Anxiety, and Resilience in Adults with Epilepsy?
REC reference: 16/LO/1554
IRAS project ID: 205444

Thank you for your letter of 7th September 2016, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact

the REC Manager Ms Julie Kidd, nrescommittee.london-stanmore@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

1. *Add a version number and date to the consent form.*

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” above).

Approved documents

The documents reviewed and approved by the Committee are:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Social media advertising posts]	1	25 July 2016
Covering letter on headed paper [Covering letter on headed paper]	1	25 July 2016
Covering letter on headed paper		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Lancaster university professional indemnity insurance]	1	25 July 2016
IRAS Application Form [IRAS_Form_04082016]		04 August 2016
IRAS Application Form XML file [IRAS_Form_04082016]		04 August 2016
IRAS Checklist XML [Checklist_04082016]		04 August 2016
Letter from sponsor [Lancaster university sponsorship letter]	1	25 July 2016
Other [Liverpool Seizure Severity Scale]		
Other [Participant debrief sheet]	1	25 July 2016
Other [Lancaster university public liability insurance]	1	25 July 2016
Other [Lancaster university employers liability insurance]	1	25 July 2016
Other [Zurich]		
Participant consent form		
Participant consent form [Participant consent form]	1	25 July 2016
Participant information sheet (PIS) [Participant information sheet (PIS)]	1	25 July 2016
Research protocol or project proposal [Research protocol]	1	25 July 2016

Summary CV for Chief Investigator (CI) [CV for chief investigator]	1	25 July 2016
Summary CV for supervisor (student research) [CV for academic supervisor]	1	25 July 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Research protocol flow chart]	1	25 July 2016
Validated questionnaire [Hospital anxiety and depression scale (HADS)]	1	25 July 2016
Validated questionnaire [Neff self compassion scale]	1	25 July 2016
Validated questionnaire [Brief resilience scale]	1	25 July 2016
Validated questionnaire [Liverpool seizure severity scale]	1	25 July 2016
Validated questionnaire [Stigma scale for chronic illnesses 8 item]	1	25 July 2016

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance>

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

16/LO/1554

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely
PP

A handwritten signature in cursive script that reads "J. Kidd."

Mrs Rosemary Hill
Chair

Email: nrescommittee.london-stanmore@nhs.net

Enclosures: *"After ethical review – guidance for researchers"*
Copy to: *Dr Diane Hopkins*





Health Research Authority
London - Stanmore Research Ethics Committee

Ground Floor
NRES/HRA
80 London Road
London
SE1 6LH

Telephone: 020 7972 2554

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

08 September 2016

Mr David Baker
Doctorate in Clinical Psychology, Furness College
Faculty of Health and Medicine
Lancaster University, Lancaster
LA1 4YG

Dear Mr Baker

Study title: What is the Relationship Between Self-Compassion and Depression, Anxiety, and Resilience in Adults with Epilepsy?
REC reference: 16/LO/1554
IRAS project ID: 205444

Thank you for your email of the 7th September. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 07 September 2016.

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Other [Participant de brief sheet]	1	13 July 2016
Participant consent form	2	01 September 2016

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Social media advertising posts]	1	25 July 2016
Covering letter on headed paper [Covering letter on headed paper]	1	25 July 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Lancaster university professional indemnity insurance]	1	25 July 2016
IRAS Application Form [IRAS_Form_04082016]		04 August 2016
IRAS Application Form XML file [IRAS_Form_04082016]		04 August 2016
IRAS Checklist XML [Checklist_04082016]		04 August 2016
Letter from sponsor [Lancaster university sponsorship letter]	1	25 July 2016
Other [Liverpool Seizure Severity Scale]		
Other [Lancaster university public liability insurance]	1	25 July 2016
Other [Lancaster university employers liability insurance]	1	25 July 2016
Other [Zurich]		
Other [Participant de brief sheet]	1	13 July 2016
Participant consent form	2	01 September 2016
Participant information sheet (PIS) [Participant information sheet (PIS)]	1	25 July 2016
Research protocol or project proposal [Research protocol]	1	25 July 2016
Summary CV for Chief Investigator (CI) [CV for chief investigator]	1	25 July 2016
Summary CV for supervisor (student research) [CV for academic supervisor]	1	25 July 2016
Summary, synopsis or diagram (flowchart) of protocol in non-technical language [Research protocol flow chart]	1	25 July 2016
Validated questionnaire [Hospital anxiety and depression scale (HADS)]	1	25 July 2016
Validated questionnaire [Neff self-compassion scale]	1	25 July 2016
Validated questionnaire [Brief resilience scale]	1	25 July 2016
Validated questionnaire [Liverpool seizure severity scale]	1	25 July 2016
Validated questionnaire [Stigma scale for chronic illnesses 8 item]	1	25 July 2016

You should ensure that the sponsor has a copy of the final documentation for the study. It is

the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

16/LO/1554

Please quote this number on all correspondence

Yours sincerely

A handwritten signature in cursive script that reads "Julie Kidd".

Julie Kidd
REC Manager

E-mail: nrescommittee.london-stanmore@nhs.net

Copy to: *Dr Diane Hopkins*
[REDACTED], *Research and Development*



Applicant name: David Baker
Division: DHR

25 July 2016

Dear David,

Re: What is the Relationship Between Self-Compassion and Depression, Anxiety, and Resilience in Adults with Epilepsy?

The University of Lancaster undertakes to perform the role of sponsor in the matter of the work described in the accompanying grant application. As sponsor we assume responsibility for monitoring and enforcement of research governance. As principal investigator you will confirm that the institution's obligations are met by ensuring that, before the research commences and during the full term of the grant, all the necessary legal and regulatory requirements are met in order to conduct the research, and all the necessary licenses and approvals have been obtained. The Institution has in place formal procedures for managing the process for obtaining any necessary or appropriate ethical approval for this grant. Full ethical approval must be in place before the research commences and should be reviewed at all relevant times during the grant.

Yours sincerely,

A handwritten signature in black ink that reads "Diane Hopkins". The signature is written in a cursive style.

PP Professor Roger Pickup
Associate Dean for Research
Chair Faculty of Health and Medicine Research Ethics Committee.

CC Dr Diane Hopkins, Secretary to FHMREC

Mr David Baker
Doctorate in Clinical Psychology, Furness College
Faculty of Health and Medicine
Lancaster University, Lancaster
LA1 4YG

Email: hra.approval@nhs.net

23 September 2016

Dear Mr Baker,

Letter of HRA Approval

Study title:	What is the Relationship Between Self-Compassion and Depression, Anxiety, and Resilience in Adults with Epilepsy?
IRAS project ID:	205444
REC reference:	16/LO/1554
Sponsor	Lancaster University, Research Services

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details

IRAS project ID	205444
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and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document “*After Ethical Review – guidance for sponsors and investigators*”, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the [HRA website](http://www.hra.nhs.uk), and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the [HRA website](http://www.hra.nhs.uk).

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at <http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/>.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

Your IRAS project ID is **205444**. Please quote this on all correspondence.

Yours sincerely

Miss Lauren Allen
Assessor

Email: hra.approval@nhs.net

Copy to: *Dr Diane Hopkins (Sponsor contact)*
, *Research and Development (Lead NHS R&D contact)*

Participating NHS organisations in England

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Social media advertising posts]	1	25 July 2016
Covering letter on headed paper [Covering letter on headed paper]	1	25 July 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Lancaster university professional indemnity insurance]	1	25 July 2016
IRAS Application Form [IRAS_Form_04082016]		04 August 2016
Letter from sponsor [Lancaster university sponsorship letter]	1	25 July 2016
Other [Liverpool Seizure Severity Scale]		
Other [Lancaster university public liability insurance]	1	25 July 2016
Other [Lancaster university employers liability insurance]	1	25 July 2016
Other [Zurich]		
Other [Participant de brief sheet]	1	13 July 2016
Other [Statement of Activities]	1	23 September 2016
Other [Schedule of Events]	1	23 September 2016
Participant consent form	2	01 September 2016
Participant information sheet (PIS) [Participant information sheet (PIS)]	1	25 July 2016
Research protocol or project proposal [Research protocol]	1	25 July 2016
Summary CV for Chief Investigator (CI) [CV for chief investigator]	1	25 July 2016
Summary CV for supervisor (student research) [CV for academic supervisor]	1	25 July 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Research protocol flow chart]	1	25 July 2016
Validated questionnaire [Hospital anxiety and depression scale (HADS)]	1	25 July 2016
Validated questionnaire [Neff self compassion scale]	1	25 July 2016
Validated questionnaire [Brief resilience scale]	1	25 July 2016
Validated questionnaire [Liverpool seizure severity scale]	1	25 July 2016
Validated questionnaire [Stigma scale for chronic illnesses 8 item]	1	25 July 2016

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability and Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study: Dr Diane Hopkins (ethics@lancaster.ac.uk, 01524592838).

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The Statement of Activities and Schedule of Events will act as the agreement between the sponsor and the participating NHS organisation.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	No funding will be provided to the participating NHS organisation.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Yes	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

There is one site type. Local clinic staff will be required to assist with the identification of participants. Participants can complete the survey in clinic or online.

Some participants may also be recruited outside the NHS. HRA Approval does not cover activity outside the NHS. Before recruiting outside the NHS the research team must follow the procedures and governance arrangements of responsible organisations.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

Participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research.**

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capability will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix.
- The [Assessing, Arranging, and Confirming](#) document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).

A Local collaborator will be required at the participating NHS organisation to facilitate access arrangements for the research team where needed.

GCP training is not a generic training expectation, in line with the [HRA statement on training expectations](#).

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken

Members of the research team who do not have a contractual relationship with the participating NHS organisation will require a Letter of Access to conduct study activity on NHS premises. Disclosure and Barring Service and Occupational Health checks will be required where a Letter of Access is

needed.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.

- The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Dear Mr Baker

RE: IRAS Confirmation of Capacity and Capability at ■ Trust

Full Study Title: What is the Relationship Between Self-Compassion and Depression, Anxiety, and Resilience in Adults with Epilepsy?

REC: 16/LO/1554

This email confirms that ■ Trust has the capacity and capability to deliver the above referenced study.

We agree to start this study on 1st October 2016 as per the Statement of Activities and the first participant should be recruited into this study by no later than **2nd December 2016**. If there are difficulties in meeting this target, please do not hesitate to contact us at ■ where we can offer advice and support.

If you wish to discuss further, please do not hesitate to contact me.

Kind regards

■ Trust

R&D Lead

Doctorate in
Clinical Psychology

Lancaster
University



Participant Information Sheet

Version number: 1

Date: 25/07/16

IRAS ID: 205444

Study Title: What is the Relationship Between Self-Compassion and Depression, Anxiety, and Resilience in Adults with Epilepsy?

My name is David Baker. I am conducting this research as part of a doctoral programme in clinical psychology at Lancaster University.

What is the purpose of the study?

Research suggests that some people with epilepsy may experience depression and anxiety as a result of their condition.

We would like to ask adults with epilepsy to complete a short survey about epilepsy, self-compassion, depression, anxiety, resilience and stigma. We want to find out whether self-compassion (the act of being kind to oneself) can:

- Help to reduce depression and anxiety in people with epilepsy
- Increase resilience in people with epilepsy

We are also interested in whether epilepsy-related stigma is linked to self-compassion. We hope that this will help to improve psychological care for people with epilepsy in the future.

Can I take part?

We would like to invite you to take part if you:

- Are aged 18 or above
- Have been diagnosed with epilepsy
- Are able to understand English

Do I have to take part?

No. Your involvement in this study is entirely voluntary. You are free to withdraw at any time up until you complete the survey. Once you have completed the survey it will not be possible to withdraw your answers, because they will be anonymous.

What will happen if I decide to take part?

At the beginning of the survey, we will ask you to give your consent to take part. We will then ask you to answer some questions about epilepsy, self-compassion, depression, anxiety, resilience and stigma. All your answers will be anonymous, and it should take around 15 minutes to complete.

How do I take part?

You can access the survey via the link at the bottom of this page. You may ask a family member, friend or carer to help you to complete the survey if needed.

Alternatively, to receive a paper copy of the survey and a pre-paid return envelope, please contact David Baker:

Email: d.baker1@lancaster.ac.uk

Tel: on 07xxxxxxxx (insert research phone number once known)

Will my data be confidential?

All data provided by you will entirely anonymous. Nobody will have access to any personal information that identifies you.

Lancaster University will store the electronic survey data securely for up to 10 years. We will input the answers from paper surveys on to our electronic survey software and destroy the paper copies immediately.

What will happen to my data?

We will analyse the survey data you provide. The results will be written up and submitted as part of a thesis within the Lancaster Doctorate in Clinical Psychology programme.

Our findings will be shared with the charity Epilepsy Action to ensure that they are accessible to people with epilepsy. We also hope that the findings will be written up into a brief paper for submission in a relevant academic journal.

What are the possible benefits or risks of taking part?

We cannot guarantee any direct benefits of taking part. However, completing our survey may help you to reflect on your experiences. You will also be helping to inform our understanding of psychological care for people with epilepsy in the future.

We do not anticipate any risks in taking part in this study. However, if you experience any distress, during or after your involvement in the research, you

should contact someone for support. Information on available resources can be found at the end of the survey.

What if I have a complaint?

If you have any complaints about this research, please contact the primary researcher, David Baker:

Tel: 07xxxxxxxxxx

Email: d.baker1@lancaster.ac.uk

Alternatively, to make a complaint to Lancaster University, you can contact:

Dr Bill Sellwood, the Research Director:

Tel: 01524 593 998

Or

Prof Bruce Hollingsworth, the Head of Division:

Tel: 01524 594 154.

For independent advice, please contact:

Prof Roger Pickup, Associate Dean for Research:

Tel: 01524 593 746

Email: r.pickup@lancaster.ac.uk

Who is involved in this research?

The study will be undertaken by the Primary Researcher, David Baker (Trainee Clinical Psychologist, Doctorate in Clinical Psychology, Lancaster University, Tel: 07xxxxxxxxxx).

The study will be supervised by the Academic Supervisor, Dr Fiona Eccles (Lecturer in Research Methods, Lancaster Doctorate in Clinical Psychology, Tel: 01524 592807), and the Field Supervisor, Dr Helen Caswell (Consultant Clinical Neuropsychologist, Department of Clinical Neuropsychology, Salford Royal NHS Foundation Trust, Tel: 0161 206 2029).

Thank you for taking the time to consider taking part in our study.

If you would like to take part, please click on the link below to provide consent and take the survey:

(LINK TO CONSENT FORM)

CONSENT FORM

Version number: 2

Date: 01/09/16

IRAS ID: 205444

Title of Project: What is the Relationship Between Self Compassion and Depression, Anxiety, and Resilience in Adults with Epilepsy?

We are asking if you would like to take part in a research project about self compassion and depression, anxiety and resilience in epilepsy. We are also interested in stigma in people with epilepsy.

Before you consent to participating in the study we ask that you read the participant information sheet and mark each box below with your initials if you agree. If you have any questions or queries before signing the consent form please speak to the principal investigator, David Baker.

Please tick all boxes

1. I confirm that I have read the information sheet and fully understand what is expected of me within this study.
2. I confirm that I have had the opportunity to ask any questions and to have them answered.
3. I understand that my participation is entirely voluntary and I am free to withdraw at any time up until I complete the survey, without my medical care or legal rights being affected. I understand that once I have completed the survey it will not be possible to withdraw my data.
4. I understand that my responses to the survey will be anonymous and I consent for this data to be used for the purposes of research outlined in the participant information sheet.
5. I consent to take part in the above study.

Name of Participant Date Signature

Name of Researcher Date Signature



Participant Debrief Sheet

Version number: 1
Date: 13/07/16
IRAS ID: 205444

Thank you for taking the time to complete our survey.

The findings of this study will be available on the Lancaster University Research website and on the Epilepsy Action website.

If you feel you would benefit from any support, the following services may be able to help you:

- For information about NHS therapy and counselling, or details of private therapy and charities, visit [nhs.uk/conditions/stress-anxiety-depression/pages/free-therapy-or-counselling.aspx](https://www.nhs.uk/conditions/stress-anxiety-depression/pages/free-therapy-or-counselling.aspx)
- To speak to someone at any time, the Samaritans helpline is available 24 hours a day, 365 days a year:
Tel: 08457 90 90 90
Website: [samaritans.org](https://www.samaritans.org)
- For information and support around mental health, contact Mind:
Tel: 0300 123 3393 (9am to 6pm, Monday to Friday (except for bank holidays))
Website: [mind.org.uk](https://www.mind.org.uk)
- For advice and information about epilepsy contact Epilepsy Action:
Freephone: 0808 800 5050
Website: [epilepsy.org.uk](https://www.epilepsy.org.uk)

If, at any time, you experience suicidal thoughts or thoughts of wanting to harm yourself or someone else, visit your GP or attend A&E.

HOW I TYPICALLY ACT TOWARDS MYSELF IN DIFFICULT TIMES

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

- | Almost
never | | | | | Almost
always |
|-------------------------|----------|----------|----------|----------|---|
| 1 | 2 | 3 | 4 | 5 | |
| _____ | | | | | 1. I'm disapproving and judgmental about my own flaws and inadequacies. |
| _____ | | | | | 2. When I'm feeling down I tend to obsess and fixate on everything that's wrong. |
| _____ | | | | | 3. When things are going badly for me, I see the difficulties as part of life that everyone goes through. |
| _____ | | | | | 4. When I think about my inadequacies, it tends to make me feel more separate and cut off from the rest of the world. |
| _____ | | | | | 5. I try to be loving towards myself when I'm feeling emotional pain. |
| _____ | | | | | 6. When I fail at something important to me I become consumed by feelings of inadequacy. |
| _____ | | | | | 7. When I'm down and out, I remind myself that there are lots of other people in the world feeling like I am. |
| _____ | | | | | 8. When times are really difficult, I tend to be tough on myself. |
| _____ | | | | | 9. When something upsets me I try to keep my emotions in balance. |
| _____ | | | | | 10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people. |
| _____ | | | | | 11. I'm intolerant and impatient towards those aspects of my personality I don't like. |
| _____ | | | | | 12. When I'm going through a very hard time, I give myself the caring and tenderness I need. |
| _____ | | | | | 13. When I'm feeling down, I tend to feel like most other people are probably happier than I am. |
| _____ | | | | | 14. When something painful happens I try to take a balanced view of the situation. |
| _____ | | | | | 15. I try to see my failings as part of the human condition. |
| _____ | | | | | 16. When I see aspects of myself that I don't like, I get down on myself. |
| _____ | | | | | 17. When I fail at something important to me I try to keep things in perspective. |

- _____ 18. When I'm really struggling, I tend to feel like other people must be having an easier time of it.
- _____ 19. I'm kind to myself when I'm experiencing suffering.
- _____ 20. When something upsets me I get carried away with my feelings.
- _____ 21. I can be a bit cold-hearted towards myself when I'm experiencing suffering.
- _____ 22. When I'm feeling down I try to approach my feelings with curiosity and openness.
- _____ 23. I'm tolerant of my own flaws and inadequacies.
- _____ 24. When something painful happens I tend to blow the incident out of proportion.
- _____ 25. When I fail at something that's important to me, I tend to feel alone in my failure.
- _____ 26. I try to be understanding and patient towards those aspects of my personality I don't like.

Brief Resilience Scale (BRS)

Please respond to each item by marking <u>one box per row</u>		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
BRS 1	I tend to bounce back quickly after hard times	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
BRS 2	I have a hard time making it through stressful events.	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
BRS 3	It does not take me long to recover from a stressful event.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
BRS 4	It is hard for me to snap back when something bad happens.	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
BRS 5	I usually come through difficult times with little trouble.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
BRS 6	I tend to take a long time to get over set-backs in my life.	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1

Scoring: Add the responses varying from 1-5 for all six items giving a range from 6-30. Divide the total sum by the total number of questions answered.

My score: _____ item average / 6

Smith, B. W., Dalen, J., Wiggins, K., Tooley, E., Christopher, P., & Bernard, J. (2008). The brief resilience scale: assessing the ability to bounce back. *International journal of behavioral medicine*, 15(3), 194-200.

These findings support the validity and reliability of using a most severe seizure scoring for data collected with the original LSSS (a version that collects data on major and minor seizures). To replicate the recommended scoring procedure, researchers must ask patients to report the number of major and minor seizures experienced during each recall period so that patients without seizures can be assigned a severity of 0 for their LSSS seizure severity scores.

In conclusion, our findings indicate that measurement of seizure severity is an important endpoint in the clinical study of epilepsy. We propose a modification of the LSSS and a revised scoring system that assesses the most severe seizures that the patient experienced during a recall period without specifically differentiating between major

and minor seizures. Use of the revised LSSS ‘most severe seizure’ promises to provide reliable and responsive assessments of the impact of antiepileptic pharmacotherapy on seizure severity.

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Appendix A

Liverpool Seizure Severity Scale 2.0

So we can better understand the severity of your seizures, please complete the following questionnaire thinking about the *most severe seizure* you experienced during the past 4 weeks. (This may be different for each individual, but is based on your most severe seizures over the past 4 weeks.) Your responses are a very important part of this study and will be kept strictly CONFIDENTIAL. No one but the research staff will see your responses. If results of this study are published, only aggregate data will be used; names and any other identifying information will not be reported.

How many seizures have you experienced during the past 4 weeks? _____ seizures

Note: Please enter ‘0’ if you have not experienced any seizures in the last 4 weeks and do not complete the remainder of the questionnaire. If you cannot remember the exact number of seizures you’ve experienced, please estimate based on the number you usually had during a single day or week.

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Please answer each question based on the most severe seizure you have experienced in the past 4 weeks. Circle only one answer for each question.

1. I feel that my most severe seizures have mostly been:	Very severe	0	Severe	1	Mild	2	Very Mild	3				
2. Most commonly when I blank out/lose consciousness:	I blank out for less than 1 minute	1	I blank out for between 1 and 2 minutes	2	I blank out for between 3 and 5 minutes	3	I blank out for more than 5 minutes	4	I never blank out/lose consciousness	0		
3. When I have my most severe seizures, I smack my lips, fidget, or behave in an unusual way:	Always	0	Usually	1	Sometimes	2	Never	3				
4. After my most severe seizures:	I feel very confused	0	I feel fairly confused	1	I feel slightly confused	2	I do not feel confused at all	3				
5. After my most severe seizures my confusion lasts for:	Less than 1 minute	1	Between 1 and 5 minutes	2	Between 6 minutes and 1 hour	3	1 to 2 hours	4	More than 2 hours	5	I never feel confused	0
6. When I have my most severe seizures:	I always fall to the ground	0	I usually fall to the ground	1	I sometimes fall to the ground	2	I never fall to the ground	3				
7. After my most severe seizures:	I always have a headache	0	I usually have a headache	1	I sometimes have a headache	2	I never have a headache	3				
8. After my most severe seizures:	I always feel sleepy	0	I usually feel sleepy	1	I sometimes feel sleepy	2	I never feel sleepy	3				
9. After my most severe seizures:	I always find that I have wet myself	0	I usually find that I have wet myself	1	I sometimes find that I have wet myself	2	I never find that I have wet myself	3				
10. After my most severe seizures:	I always find that I have bitten my tongue	0	I usually find that I have bitten my tongue	1	I sometimes find that I have bitten my tongue	2	I never find that I have bitten my tongue	3				
11. After my most severe seizures:	I always find that I have injured myself (other than biting my tongue)	0	I usually find that I have injured myself (other than biting my tongue)	1	I sometimes find that I have injured myself (other than biting my tongue)	2	I never find that I have injured myself (other than biting my tongue)	3				
12. After my most severe seizures I can usually return to what I am doing in:	Less than 1 minute	0	Between 1 and 5 minutes	1	Between 6 minutes and 1 hour	2	1 to 2 hours	3	More than 2 hours	4		

*The Hospital Anxiety and Depression Scale has not been included here as this is a licensed product.