

**After the storm: How do partners of those receiving an implantable cardioverter  
defibrillator (ICD) experience episodes of electrical storm, which have resulted  
from ICD activation (shocks)?**

**An exploration using Interpretative Phenomenological Analysis**

Thesis submitted to the University of Leicester  
Faculty of Medicine & Biological Sciences, School of Psychology  
for the partial fulfilment of Doctorate in Clinical Psychology

**By**  
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**2017**

### **Declaration**

I confirm that I am responsible for the current thesis. Worked contained herein is original and has not been submitted for any other academic award. I confirm that I have checked the current thesis is complete prior to submission.

**After the storm: How do partners of those receiving an implantable cardioverter defibrillator (ICD) experience episodes of electrical storm, which have resulted from ICD activation (shocks)?**

**An exploration using Interpretative Phenomenological Analysis**

**Carl Rideout**

**Thesis abstract**

**Literature review**

Atrial fibrillation (AF) has been associated with reduced psychosocial functioning, and such reductions may be influenced by illness perceptions. Although one published review has explored the relationships between illness perceptions and emotional wellbeing in AF patients, it had a narrow focus and lacked robust quality appraisal. Thus, the aims of the current review were to systematically review relationships between illness perceptions and broader psychosocial outcomes in AF patients, and to quality appraise the available literature. Thirteen studies were elicited. Although findings were equivocal, studies identified that particular illness perceptions were related to and, in some cases, appeared to predict poorer psychosocial functioning in terms of reduced emotional wellbeing, poorer quality of life (QOL) and health-related quality of life (HRQOL), adjustment, and treatment seeking delay. It is recommended that the illness perceptions of AF patients are assessed, and modified where indicated. Further research is warranted and suggestions are provided.

**Empirical Study**

Implantable cardioverter defibrillators (ICDs) are potentially life-saving devices. However, ICD recipients and their partners may experience negative psychosocial consequences following implantation and any isolated device activations. Furthermore, ICDs may activate multiple times, with three or more activations within 24 hours being classed as an electrical storm (ES). Although ESs have been shown to cause psychological difficulties for ICD recipients, no studies have investigated the impact of ESs on partners. Semi-structured interviews were conducted with six participants who had witnessed their partner suffering an ES. The data were analysed using Interpretative Phenomenological Analysis (IPA) and four superordinate themes were identified: 'Feeling overwhelmed during the ES (all at sea)', 'Challenges in post-ES adjustment', 'Trying to cope (not being becalmed)', and 'Living and growing'. There is a need for professionals to engage with partners and support them prior to, and following ESs. Further research is warranted and suggestions are provided.

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\*Excluding contents page, mandatory appendices, references, tables and diagrams.

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### **List of abbreviations**

ACS:	Acute coronary syndrome.
ACT:	Acceptance and Commitment Therapy.
AF:	Atrial fibrillation.
AFEQT:	Atrial Fibrillation Effect on Quality of Life.
AFSS:	Atrial Fibrillation Severity Scale.
ANCOVA:	Analysis of covariance.
ANOVA:	Analysis of variance.
ATSSS:	Atrial Tachyarrhythmia Symptom Severity Scale.
BDI-I:	Beck Depression Inventory-I.
BDI-SF-13:	Beck Depression Inventory-Short form-13.
BMI:	Body Mass Index.
CAD:	Coronary artery disease.
CBT:	Cognitive Behavioural Therapy.
CCS-SAF:	Canadian Cardiovascular Society Severity of Atrial Fibrillation Scale.
CES-D:	Centre for Epidemiologic Studies Depression Scale.
CHD:	Chronic heart disease.
CSM:	Common Sense Model of Self-regulation.
CVD:	Cardiovascular disease.
DSM-IV:	Diagnostic and Statistical Manual of Mental Disorders 4 <sup>th</sup> ed.
DSM-V:	Diagnostic and Statistical Manual of Mental Disorders 5 <sup>th</sup> ed.
ECV:	Electrical cardioversion.
ES:	Electrical storm.
HADS:	Hospital Anxiety and Depression Scale.
HADS-A:	Hospital Anxiety and Depression Scale: Anxiety subscale.
HF:	Heart failure.
HRA:	Health Research Authority.
HRQOL:	Health-related quality of life.
ICD:	Implantable cardioverter defibrillator.
IES-R:	Impact of Event Scale-Revised.
IMQ:	Illness Management Questionnaire.
IPA:	Interpretative Phenomenological Analysis.
IPQ:	Illness Perception Questionnaire.
IPQ-R:	Illness Perception Questionnaire-Revised.
MI:	Myocardial infarction.
MS:	Multiple sclerosis.
MUIS-C:	Mishel Uncertainty in Illness Scale-Community Form.
NHS:	National Health Service.
PAIS-SR:	Psychosocial Adjustment to Illness Scale.
PHQ-9:	Patient Health Questionnaire-9.
POMS:	Profile of Mood States.
POMS-TMD:	Profile of Mood States – Total Mood Disturbance.
PSM:	Psychological Stress Measure.
PSS:	Perceived Stress Scale.
PTSD:	Posttraumatic stress disorder.
QOL:	Quality of life.
RCT:	Randomised control trial.
REC:	Research Ethics Committee.

SCL:	Symptom Checklist.
SCLs:	Symptom Checklist-Severity.
SDQL:	Scale of Disease and Quality of Life.
SF-36:	Short Form Health Survey-36.
SF-36 MCS:	Short Form Health Survey-36 – Mental Component Summary.
SF-36 PCS:	Short Form Health Survey-36 – Physical Component Summary.
STAI:	State-Trait Anxiety Inventory.
TF-CBT:	Trauma Focused Cognitive Behavioural Therapy.
UK:	United Kingdom.
USA:	United States of America.
UT-AFSS:	University of Toronto Atrial Fibrillation Severity Scale.



## **PART 1: Systematic Literature Review**

### **Associations between illness perceptions and psychosocial functioning in atrial fibrillation: A systematic review**

(Author guidelines for the intended journal can be found in Appendix A)

## **Abstract**

**Background:** Atrial fibrillation (AF) has been associated with increased psychological morbidity, which may be influenced by illness perceptions. There appears to be only one published review exploring relationships between illness perceptions and psychosocial functioning in AF. However, its focus on anxiety and depression neglected wider psychosocial outcomes, and it lacked quality appraisal. The aims of the current review were to synthesise and evaluate published literature investigating relationships between illness perceptions and broader psychosocial outcomes.

**Method:** Systematic searches of Cochrane, PsycINFO, PubMed, Scopus and CINAHL were conducted in July 2016 and March 2017. The elicited studies were quality appraised and synthesised.

**Results:** Thirteen studies met the eligibility criteria. Although studies identified relationships between perceptions and poorer psychosocial functioning, findings were equivocal. Most commonly, poorer emotional wellbeing was related to perceptions of: AF being caused by psychological or psychosocial factors, poorer illness understanding, greater uncertainty and appraising uncertainty as threatening, more severe and frequent symptoms, greater illness consequences, and symptom preoccupation. Poorer quality of life (QOL)/health-related quality of life (HRQOL) was related to perceptions of: AF being caused by psychological stress or exercise, greater symptom severity and frequency, and symptom preoccupation. Furthermore, perceptions regarding symptom number attributable to AF, and severity of illness consequences were related to changes in HRQOL over time. Poorer adjustment was related to perceptions of greater symptom number attributable to AF and more severe illness consequences, and treatment-seeking delay was related to perceptions concerning symptom interpretation.

**Conclusions:** Illness perceptions were associated with, and in some cases appeared to predict, poorer psychosocial functioning in AF populations beyond those noted in a previous review. It is recommended that professionals assess and, where indicated, support the modification of illness perceptions. Furthermore, as there was a dearth of literature and findings were unequivocal, it is recommended that further research is undertaken.

## **1. Introduction**

### **1.1. Atrial fibrillation (see Appendix B for a glossary of terms)**

Atrial fibrillation (AF) is one of the most common forms of cardiac arrhythmia, occurring when chaotic electrical activity develops in the atrial walls, overriding the sinus node. This disrupts the normal rhythm of these upper chambers and they contract in an irregular and uncoordinated fashion. AF disrupts ventricle function, causing them to beat faster and irregularly.<sup>1</sup> AF can be defined as paroxysmal (irregular episodes often ceasing within 48 hours without treatment), persistent (each episode lasts for over seven days, or less with treatment) or permanent (AF is constantly present).<sup>2</sup>

Although underlying causes for AF are not always identifiable, there are noted risk factors: age (particularly over 65 years), hypertension, male gender, diabetes mellitus, hyperthyroidism, heart failure (HF), heart valve disease, coronary artery disease (CAD), obesity (especially in combination with sleep apnoea), excessive alcohol consumption and smoking.<sup>3</sup> Some individuals may be asymptomatic, but symptoms of AF can include palpitations, shortness of breath, dizziness, fatigue, and/or chest discomfort.<sup>4</sup>

The prevalence of AF has increased over the last two decades with an estimated 33.5 million individuals diagnosed globally during 2010.<sup>5</sup> Indeed, during 2013/14 approximately 1.36 million people in England were identified as in AF (approximately 2.4% prevalence), with more males and those over 65 years old having the condition.<sup>6</sup> The prevalence of AF is predicted to rise, such that by 2030 there will be up to 17 million individuals living with AF in Europe (a rise from an estimated 10 million in 2014) with an incident rate of 120,000-215,000.<sup>6</sup>

Those with AF report greater anxiety than those with other heart rhythm conditions,<sup>7</sup> more severe depression,<sup>8-10</sup> particularly for persistent AF,<sup>11</sup> and reduced quality of life (QOL).<sup>8,12</sup> Such psychosocial difficulties may also contribute to increasing healthcare costs as AF patients may present at services for support in managing their condition and/or psychological status. During 2008 it was estimated that AF, as a lone diagnosis and a precursor to secondary problems (e.g. AF-related stroke and AF-related HF), was costing the NHS nearly £2.2 billion per year.<sup>1</sup> Moreover, AF has been considered a significant contributor to increasing healthcare costs in Western countries.<sup>6</sup>

## **1.2. Illness perceptions**

Psychosocial impacts of AF, as with other health conditions, are not only affected by biomedical factors but also how individuals perceive their condition. Psychological theories including Lazarus and Folkman's Theory of Coping,<sup>13</sup> Mishel's Uncertainty in Illness Theory,<sup>14</sup> and models of cognitive biases,<sup>15</sup> to name a few, have offered frameworks for understanding relationships between illness perceptions and psychosocial functioning. Of the models emerging over the last three decades, the Common Sense Model of Self-regulation (CSM),<sup>16</sup> offers a more comprehensive account of illness perceptions. This model suggests that when individuals experience ill-health they form inter-related cognitive representations, ascribing meaning to the illness, shaped by past experiences of illness and associated consequences. These representations (or illness perceptions) encompass: i) cause of illness, ii) consequences of illness, iii) ability to control illness (personal or treatment control), iv) timeline (expected duration or time pattern of illness), and v) identity (symptoms or labels defining the illness).<sup>16</sup>

Such illness perceptions appear influential in determining coping and psychological morbidity for numerous disease processes,<sup>17</sup> including cardiac conditions. In coronary heart disease, perceiving the condition to be chronic, with a greater number of symptoms and more negative consequences, has been associated with poorer QOL;<sup>18</sup> and perceiving poorer understanding and control of the illness, and more negative illness consequences has been associated with greater anxiety and depression.<sup>18</sup> HF patients reporting poorer understanding of their illness and greater negative emotional impact expressed less confidence in self-care;<sup>19</sup> and perceptions of cardiac illness as chronic and cyclical, and conferring more severe consequences predicted higher levels of disability and poorer physical functioning three months post-cardiac surgery.<sup>20</sup> Moreover, after myocardial infarction (MI), perceptions of more severe illness consequences were related to poorer coping,<sup>21</sup> and perceptions of greater illness severity were related to difficulties in social functioning, recreational activity and sexual dysfunction. By contrast, perceptions of short illness duration and less severe consequences were associated with quicker return to work.<sup>22</sup>

The importance of illness perceptions can also be gauged by the impact of the interventions which endeavour to modify them. Techniques such as cognitive

restructuring to promote more positive, adaptive and coherent illness perceptions have been associated with improved psychosocial functioning across long-term conditions.<sup>23-</sup>

<sup>26</sup> However, despite growing evidence regarding the role of illness perceptions in psychosocial outcomes for long-term conditions generally, and cardiac conditions specifically, their role appears far less examined in outcomes for arrhythmic disorders, particularly AF. There appears to be only one published review exploring relationships between illness perceptions and psychosocial functioning in AF populations, investigating links between illness perceptions and anxiety and depression.<sup>27</sup> However, other important indices of outcomes, notably QOL, treatment-seeking behaviour, adjustment and wider measures of psychological wellbeing/distress were not included in this review, and it lacked robust quality appraisal.

### **1.3. Aims**

The aims of the current review are thus to: elicit, synthesise and evaluate the published empirical literature investigating relationships between illness perceptions and broader psychosocial outcomes (including emotional wellbeing, QOL and HRQOL (health-related quality of life), adjustment to AF and treatment-seeking behaviour) in AF patients, and to provide recommendations for clinical practice and further research.

## **2. Method**

### **2.1. Search strategy**

Systematic searches of five databases (Cochrane, PsycINFO, PubMed, Scopus and CINAHL) were conducted in July 2016 and again in March 2017. The searches were conducted by combining the search term ‘atrial fibrillation’ with the search term ‘illness perception’ and its variants (see Appendix C). These searches were supplemented by searches of grey literature and hand searching the reference lists of included articles. Search terms were identified by consulting the key terms of relevant articles and by identifying synonyms of the words ‘perception’ and ‘appraisal’. To reduce the risk of relevant articles being overlooked, the term ‘psychosocial functioning’ and terms related to specific areas of psychosocial functioning were *not* included in the searches. Instead, the adopted strategy was to remain broad by screening all articles exploring illness perceptions and AF, and then manually remove unsuitable articles.

### **2.2. Eligibility criteria**

Studies were eligible for inclusion if they:

- were original research articles;
- reported samples comprising adults (>18 years) with diagnosed AF;
- examined associations between participants’ perceptions of their AF and their psychosocial functioning.

Studies were excluded if they:

- were not reported in English;
- adopted a qualitative methodology;
- were reviews or editorials;
- used a sample which did not report discernible data on AF populations.

### **2.3. Data extraction**

Full text articles meeting eligibility criteria went through a standardised process of data extraction using a Cochrane Collaboration data extraction tool.<sup>28</sup> The standardised tool guided the extraction of information regarding: (i) participant recruitment and sample

characteristics, (ii) definition and measurement of variables, (iii) methods of statistical analysis, and (iv) potential study biases.

#### **2.4. Quality appraisal**

Study quality was appraised using the QualSyst (version for quantitative studies),<sup>29</sup> comprising 14 items assessing methodological quality across important areas, including: appropriateness of study design and analysis, sample numbers and characteristics, and sufficiency of reporting. For each item, a score of 2 was awarded if criteria were fully met, 1 if the criteria were partially met, and a score of 0 if the criteria were not met. Items not relevant to the studies were not scored and marked as 'N/A' (not applicable).

Each article was ascribed a total score by summing its item scores, and the maximum score that the article could achieve was determined. Then, for each article the total score was converted into a percentage score of the maximum score. Based on previous reviews,<sup>29,30</sup> a score of >80% was considered to indicate strong methodological quality, a score of 60-79% good methodological quality, a score of 50-59% adequate methodological quality, and a score of <50% poor methodological quality.

Eight of the thirteen articles were randomly selected and second rated by the researcher's supervisor. Inter-rater reliability calculations of the total scores ascribed by the researcher and the supervisor were performed using the Kappa statistic. Such calculations identified an 'almost perfect'<sup>31</sup> agreement between the two independent raters ( $\kappa=.913$ , 95% CI: 0.817–1.00,  $p<0.01$ ).

The QualSyst was selected as it aims to address the lack of non-randomised control trial (RCT) quality appraisal tools (none of the reviewed studies adopted RCT designs), difficulties in appraising diverse study designs, and limitations to operational utility observed in more generic quality appraisal tools. Furthermore, the QualSyst was developed with consideration to previously published quality appraisal tools and has demonstrated good inter-rater reliability.<sup>29</sup>

### **3. Results**

#### **3.1. Study selection**

Systematic searches of the literature yielded 20,015 papers, of which 9,802 remained following the removal of duplicates. The titles and then abstracts of these 9,802 papers were screened by the researcher with 9,764 felt not to be relevant for the review. Studies were most commonly excluded because they researched medical matters without exploring illness perceptions (e.g. the thoughts and perceptions of professionals). Furthermore, a number of studies were excluded as they explored illness perceptions but not their association with psychosocial outcomes, or explored wider perceptions (e.g. perceptions of medical treatment options and outcomes). The researcher and supervisor more thoroughly considered the remaining 38 articles and 13 met the eligibility criteria. See Figure 1 for a flowchart depicting the process of article identification and selection.



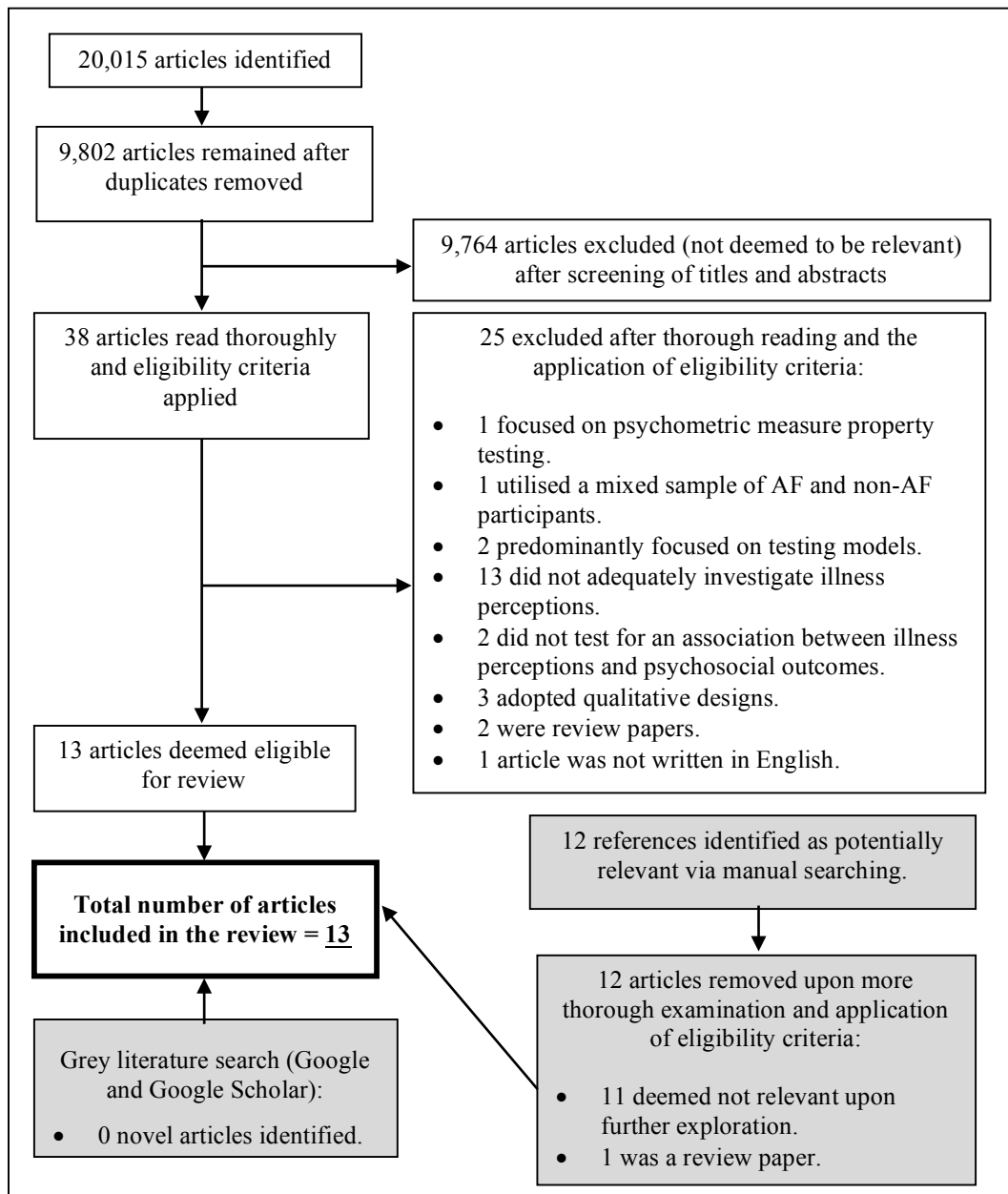


Figure 1: Article identification and selection.

### 3.2. Study characteristics

Thirteen studies met the inclusion criteria and were included in the current review.<sup>32-44</sup> Seven of these papers were included in Patel et al.'s<sup>27</sup> review,<sup>32,33,36,38,40,42,44</sup> and two pairs of studies utilised the same participant samples but reported investigation of different variables: Kang<sup>33</sup> and Kang and Bahler,<sup>34</sup> and McCabe and Barnason<sup>37</sup> and McCabe et al.<sup>38</sup> Relevant information regarding the included studies is provided in Table 1.

The studies were conducted across five countries: USA (8) (including both pairs of repeated samples), UK (2), Netherlands (1), Italy (1) and Japan (1). Sample sizes ranged from  $n=62-378$  (median=118). The median age of participants was 64.2 years (range=57.9-71.4), with only one study reporting a mean age of under 60 years old.<sup>42</sup> Studies recruited more male than female participants (male median=64%, range=44%-70%), with only two studies having a greater proportion of females than males.<sup>39,44</sup> Proportions of participants with symptomatic, asymptomatic, paroxysmal, persistent and permanent AF varied across studies, as did time between AF diagnosis and data collection. Furthermore, some studies did not report on these factors (see Table 1).

### **3.3. Study methodologies**

One article utilised a longitudinal, experimental (uncontrolled) design but only observational, cross-sectional data explored the association between illness perceptions and psychosocial functioning. The remaining 12 articles adopted observational designs: 10 were cross-sectional, one used a prospective cohort design, and one primarily used a cross-sectional design with a prospective cohort design nested sub-study. Ten studies recruited participants from outpatient settings (including one pair of the repeated samples), one study recruited participants from an inpatient setting, and two studies, utilising the same sample, recruited participants from both inpatient and outpatient settings (see Table 1).

### **3.4. Measurement of illness perceptions**

Two studies assessed the five illness perception domains reported in the CSM.<sup>36,41</sup> Three studies assessed perceptions of illness coherence and emotional representations of the illness in addition to the five illness perceptions incorporated within the CSM.<sup>37,38,44</sup> McCabe et al.<sup>39</sup> developed a bespoke measure of illness perceptions, informed by the CSM, and Suzuki and Kasanuki<sup>42</sup> administered a bespoke measure of perceived severity of AF attack symptoms and an untitled measure of perceived psychosocial inducers of AF attack, which they had previously developed (see Table 1).

More circumscribed illness perceptions were evidenced in studies examining participants' perceptions of: symptom severity and/or symptom frequency,<sup>32,34,35,37,43</sup> symptom preoccupation,<sup>40</sup> and a combination of perceptions including: illness severity,

uncertainty regarding the condition, and tendency to appraise uncertainty as danger or opportunity<sup>33</sup> (see Table 1).

Although most studies noted previously established validity and reliability of measures, quality of reporting varied with some authors failing to include information regarding the following measures: AFSS and CCS-SAF,<sup>32</sup> ATSSS,<sup>35</sup> and the IPQ-R.<sup>44</sup> Furthermore, many studies reported that administered measures reached acceptable (or greater) levels of reliability in their current administration, but this information was not included for the AFEQT and CCS-SAF,<sup>32</sup> AFSS,<sup>32,43</sup> ATSSS,<sup>35</sup> IMQ,<sup>40</sup> both untitled measures administered by Suzuki and Kasanuki<sup>42</sup> and the IPQ-R.<sup>44</sup> Although McCabe et al.'s<sup>39</sup> measure of treatment-seeking delay was not suitable for internal consistency testing, content validity was established.

### **3.5. Areas of psychosocial functioning investigated**

Seven studies focused solely on relationships between illness perceptions and emotional wellbeing. Kupper et al.<sup>35</sup> explored depression, anxiety and perceived stress, Gehi et al.<sup>32</sup> and Thompson et al.<sup>43</sup> both explored depression and anxiety, Kang<sup>33</sup> explored depression, Trovato et al.<sup>44</sup> investigated perceived stress, and McCabe and Barnason<sup>37</sup> and McCabe et al.<sup>38</sup> both investigated psychological distress more generally. Three studies explored associations between illness perceptions and both emotional wellbeing and HRQOL or QOL: Lane et al.<sup>36</sup> explored depression, anxiety and HRQOL, Ong et al.<sup>40</sup> explored QOL and psychological distress, and Suzuki and Kasanuki<sup>42</sup> investigated QOL and anxiety (symptoms of agoraphobia). One study investigated associations between illness perceptions and HRQOL only.<sup>34</sup> Lastly, two studies explored broader domains of psychosocial functioning; McCabe et al.<sup>39</sup> explored treatment-seeking delay and Steed et al.<sup>41</sup> explored adjustment to AF (see Table 1).

Reporting of previously established psychometric properties for the utilised outcome measures varied across studies, with the PHQ-9 and HADS-A,<sup>32</sup> STAI and SF-36,<sup>36</sup> and PSS<sup>35</sup> failing to be documented. Furthermore, few studies reported on the psychometric properties of the measures when administered in the current studies. Information was lacking for the: BDI-I and STAI,<sup>35</sup> BDI-SF-13 and SF-36,<sup>36</sup> SF-36 and HADS,<sup>40</sup> PAIS-SR,<sup>41</sup> SDQL,<sup>42</sup> HADS-A and PHQ-9,<sup>32,43</sup> and the PSM.<sup>44</sup> For the remaining studies,

authors noted that administered measures reached acceptable (or greater) levels of reliability during their current administration.

**Table 1: Summary of study characteristics**

<b>Authors</b>	<b>Source of participants</b>	<b>Study design</b>	<b>Illness perception (measurement tool/s)</b>	<b>Psychosocial factor/s investigated (measurement tool/s)</b>	<b>Participant <i>n</i> Mean age years (SD) % male</b>	<b>AF details provided by authors</b>
Gehi et al. <sup>32</sup>	Outpatient, USA	Observational, cross-sectional	AF symptom severity (UT-AFSS, AFEQT and CCS-SAF)	Depression (PHQ-9)  Anxiety (HADS – anxiety subscale)	300 61.7 (13.5) 66%	58% persistent 42% paroxysmal
Kang <sup>33,a</sup>	Outpatient, USA	Observational, cross-sectional	Symptom severity (SCLs)  Uncertainty in illness (MUIS-C)  Appraisal (Appraisal scale - derived from the Ways of Coping Checklist)	Depression (CES-D)	81 67.3 (12.05) 51%	AF type not reported  Time since diagnosis: 82% <3 months 18% >3 months to <6 months
Kang and Bahler <sup>34,a</sup>	Outpatient, USA	Observational, cross-sectional	Symptom frequency and severity (SCL)	HRQOL (SF-36)	81 67.3 (12.05) 51%	AF type not reported  Time since diagnosis: 82% <3 months 18% >3 months to <6 months
Kupper et al. <sup>35</sup>	Outpatient, Netherlands	Observational, cross-sectional, with a prospective cohort sub-study	Number and frequency of symptoms (ATSSS)	Depression (BDI-I)  Anxiety (STAI – state subscale)  Perceived stress (PSS)	118 68 (9.4) 62%  4 weeks post ECV follow-up analysis: 52	100% persistent  Time since diagnosis: mean 3.8yrs (+/- 4.6)
Lane et al. <sup>36</sup>	Outpatient, UK	Observational, prospective cohort	Illness perceptions (IPQ)	Depression (BDI-SF-13)  Anxiety (STAI)  HRQOL (SF-36)	70 71.4 (9.1) 64%	54% persistent 46% permanent Lone AF  Newly referred (<4 weeks)

**Table 1: Summary of study characteristics continued**

<b>Authors</b>	<b>Source of participants</b>	<b>Study design</b>	<b>Illness perception (measurement tool/s)</b>	<b>Psychosocial factor/s investigated (measurement tool/s)</b>	<b>Participant <i>n</i> Mean age years (<i>SD</i>) % male</b>	<b>AF details provided by authors</b>
McCabe and Barnason <sup>37, b</sup>	Inpatient and outpatient, USA	Observational, cross-sectional	Illness perceptions (IPQ-R)  Symptom Frequency and severity (SCL)	Psychological distress (POMS)	207 64.2 (12.3) 56%	36% persistent 64% paroxysmal Recurrent symptomatic AF  Time since diagnosis: mean 63.4 months (+/- 66.4)
McCabe et al. <sup>48, b</sup>	Inpatient and outpatient, USA	Observational, cross-sectional	Illness perceptions (IPQ-R)	Emotional responses (IPQ-R - emotion representation subscale)	207 64.2 (12.3) 56%	36% persistent 64% paroxysmal Recurrent symptomatic  Time since diagnosis: mean 63.35 months (+/- 66.44)
McCabe et al. <sup>39</sup>	Inpatient, USA	Observational, cross-sectional	Factors associated with treatment-seeking delay (bespoke measure, including questions regarding illness perceptions)	Treatment-seeking delay (no delay = <1 week / delay = >1 week)	150 66.5 (11.1) 49%	AF type not reported  Time since diagnosis: Recruited during hospitalisation for first detected AF= 31% 1 to <3 months= 37% >3 to <6 months= 18% >6 to <9 months= 6% >9 to 12 months= 8%

**Table 1: Summary of study characteristics continued**

<b>Authors</b>	<b>Source of participants</b>	<b>Study design</b>	<b>Illness perception (measurement tool/s)</b>	<b>Psychosocial factor/s investigated (measurement tool/s)</b>	<b>Participant <i>n</i> Mean age years (SD) % male</b>	<b>AF details provided by authors</b>
Ong et al. <sup>40</sup>	Outpatient, Canada	Observational, cross-sectional	Symptom preoccupation (IMQ – Focusing on symptoms factor)	QOL (SF-36)  Psychological distress (HADS)	93 61.9 (12.04) 66%	41% permanent/ persistent. 59% paroxysmal 44% lone AF 56% concurrent CVD  Illness duration: mean 7.45yrs (+/- 6.22)  AF episodes: >1 per week= 21% >1 per week to <1 per month= 16% <1 per month= 32%
Steed et al. <sup>41</sup>	Outpatient, UK	Observational, cross-sectional	Illness perception (IPQ)	Psychosocial adjustment to AF (PAIS-SR)	62 68 (11) 66%	Symptomatic (64%) and asymptomatic (36%). Within symptomatic defined as paroxysmal or chronic AF <sup>c</sup>  Illness duration: mean 5.6yrs (+/- 10)
Suzuki and Kasanuki <sup>42</sup>	Outpatient, Japan	Observational, cross-sectional	Subjective symptoms of AF attack: frequency, duration and distress (bespoke measure)  Perceived psychological inducers of attack (no title provided but previously developed by the authors)	Anxiety symptoms: agoraphobic symptoms (DSM-IV)  QOL (SDQL)	240 57.9 (13.78) 70%	100% paroxysmal  Illness duration: mean 8.05yrs (+/- 4.95)

**Table 1: Summary of study characteristics continued**

Authors	Source of participants	Study design	Illness perception (measurement tool/s)	Psychosocial factor/s investigated (measurement tool/s)	Participant <i>n</i> Mean age years (SD) % male	AF details provided by authors
Thompson et al. <sup>43</sup>	Outpatient, USA	Experimental (uncontrolled), longitudinal <sup>d</sup>	Symptom and frequency severity (AFSS)	Anxiety severity (HADS – anxiety subscale)  Depression severity (PHQ-9)	378 61.7 (13.3) 66%	58% persistent. 42% paroxysmal Symptomatic and asymptomatic AF
Trovato et al. <sup>44</sup>	Outpatient, Italy	Observational, cross-sectional	Illness perception (IPQ-R)	Psychological stress (PSM)	80 60.5 (13.97) 44%	100% permanent

<sup>a</sup> Utilised the same participant sample.

<sup>b</sup> Utilised the same participant sample.

<sup>c</sup> Proportions not fully documented but study found no difference between chronic and paroxysmal AF patients.

<sup>d</sup> As longitudinal investigations did not explore the relationship between illness perceptions and psychosocial functioning, only baseline data is reported.

**List of abbreviations:**

**AF:** Atrial fibrillation.

**CVD:** Cardiovascular Disease.

**ECV:** Electrical cardioversion.

**HRQOL:** Health-related quality of life.

**QOL:** Quality of life.

**AFEQT:** Atrial Fibrillation Effect on Quality of Life.

**AFSS:** Atrial Fibrillation Severity Scale.

**ATSSS:** Atrial Tachyarrhythmia Symptom Severity Scale.

**BDI-I:** Beck Depression Inventory-I.

**BDI-SF-13:** Beck Depression Inventory-Short form-13.

**CES-D:** Centre for Epidemiologic Studies Depression Scale.

**DSM-IV:** Diagnostic and Statistical Manual of Mental Disorders 4<sup>th</sup> ed..

**HADS:** Hospital Anxiety and Depression Scale.

**IMQ:** Illness Management Questionnaire.

**IPQ:** Illness Perception Questionnaire.

**IPQ-R:** Illness Perception Questionnaire-Revised.

**MUIS-C:** Mishel Uncertainty in Illness Scale-Community Form.

**PAIS-SR:** Psychosocial Adjustment to Illness Scale

**PHQ-9:** Patient Health Questionnaire-9.

**POMS:** Profile of Mood States.

**PSM:** Psychological Stress Measure.

**PSS:** Perceived Stress Scale.

**SCL:** Symptom Checklist.

**SCLSSs:** Symptom Checklist-Severity.

**SDQL:** Scale of Disease and Quality of Life.

**SF-36:** Short Form Health Survey-36.

**STAI:** State-Trait Anxiety Inventory.

**UT-AFSS:** University of Toronto Atrial Fibrillation Severity Scale.



### **3.6. Main findings of the reviewed articles (see Table 2 for a summary)**

As the purpose of the current review was to explore relationships between illness perceptions and psychosocial functioning, the reporting of study findings has been restricted to these relationships. Examined are associations between illness perceptions and: i) emotional wellbeing, ii) QOL/HRQOL, and iii) broader areas of psychosocial functioning as these associations emerged from the reviewed papers.

**Table 2: Summary of study findings**

Authors	Analysis	Statistical controls	Associations between illness perceptions and psychosocial functioning	Main conclusions
Gehi et al. <sup>32</sup>	ANCOVA	Age, gender, ethnicity, employment status, education level, congestive HF and smoking	<p><b>PHQ-9 descriptor and UT-AFSS (<math>p&lt;0.001</math>):</b> No/minimal (AFSS mean: 10.2); Mild/moderate (AFSS mean: 14.2); Severe (AFSS mean: 20.2)</p> <p><b>PHQ-9 descriptor and AFEQT (<math>p&lt;0.001</math>):</b> No/minimal (AFEQT mean: 72.3); Mild/moderate (AFEQT mean: 59.8); Severe (AFEQT mean: 39.2)</p> <p><b>PHQ-9 descriptor and CCS-SAF (<math>p&lt;0.001</math>):</b> No/minimal (CCS-SAF mean: 2.2); Mild/moderate (CCS-SAF mean: 2.5); Severe (CCS-SAF mean: 3.1)</p> <p><b>HADS-A descriptor and UT-AFSS (<math>p&lt;0.001</math>):</b> Normal (UT-AFSS mean: 12.5); Possible (UT-AFSS mean: 15.5); Probable (UT-AFSS mean: 20.6)</p> <p><b>HADS-A descriptor and AFEQT (<math>p&lt;0.001</math>):</b> Normal (AFEQT mean: 65.1); Possible (AFEQT mean: 46.1); Probable (AFEQT mean: 42.2)</p>	More severe depression and anxiety associated with perceptions of greater symptom severity, largely regardless of the scale used (relationship between anxiety and perceptions of symptom severity was not significant).
Kang <sup>33,a</sup>	Correlation Regressions Path analysis	Length of time since diagnosis (<3 months and >3 months) and healthcare provider/research site	<p><b>Correlations:</b></p> <p>MUIS-C and appraisal: danger (<math>r=0.53</math>, <math>p&lt;0.01</math>); Appraisal: danger and CES-D (<math>r=0.64</math>, <math>p&lt;0.01</math>); Appraisal: opportunity and CES-D (<math>r=-0.22</math>, <math>p&lt;0.05</math>)</p> <p><b>Regressions (path analysis – fully recursive model):</b></p> <p>SCLs explaining MUIS-C (<math>R^2_{adj}=0.21</math>, <math>\beta=0.34</math>, <math>p&lt;0.01</math>) and CES-D (<math>R^2_{adj}=0.45</math>, <math>\beta=0.18</math>, <math>p&lt;0.05</math>); MUIS-C explaining appraisal: danger (<math>R^2_{adj}=0.31</math>, <math>\beta=0.44</math>, <math>p&lt;0.01</math>) and CES-D (<math>R^2_{adj}=0.45</math>, <math>\beta=0.18</math>, <math>p&lt;0.01</math>); Appraisal: danger explaining CES-D (<math>R^2_{adj}=0.45</math>, <math>\beta=0.47</math>, <math>p&lt;0.01</math>)</p>	Greater perceived symptom severity predicted more uncertainty. Uncertainty correlated with, and predicted, appraisal of uncertainty as danger (positive direction). Greater appraisal of uncertainty as danger associated with, and predicted, greater depression. Greater appraisal of uncertainty as opportunity associated with decreased depression. Perceived symptom severity and uncertainty predicted depression.
Kang and Bahler <sup>34,a</sup>	Pearson correlation	None reported	<p><b>Main correlations:</b></p> <p>SF-36: physical health and SCL: frequency (<math>r=-0.390</math>, <math>p&lt;0.01</math>); SF-36: physical health and SCL: severity (<math>r=-0.406</math>, <math>p&lt;0.01</math>); SF-36 mental health and SCL: frequency (<math>r=-0.410</math>, <math>p&lt;0.01</math>); SF-36 mental health and SCL: severity (<math>r=-0.302</math>, <math>p&lt;0.01</math>)</p> <p><b>Correlations between SCL: Symptom frequency (SF) and symptom severity (SS) with SF-36: sub-dimensions:</b></p> <p>Physical functioning (SF: <math>r=-0.423</math>, SS: <math>r=-0.435</math>); Role limitations due to physical health problems (SF: <math>r=-0.350</math>, SS: <math>r=-0.297</math>); General health perceptions (SF: <math>r=-0.428</math>, SS: <math>r=-0.397</math>); Vitality, energy or fatigue (SF: <math>r=-0.575</math>, SS: <math>r=-0.481</math>); Social functioning (SF: <math>r=-0.374</math>, SS: <math>r=-0.291</math>); General mental health (including psychological distress and well-being) (SF: <math>r=-0.510</math>, SS: <math>r=-0.463</math>); Bodily pain (SF: <math>r=-0.354</math>, SS: <math>r=-0.377</math>): all <math>p&lt;0.01</math>. Role limitations due to emotional problems (SF: <math>r=-0.284</math>, <math>p&lt;0.05</math>)</p>	Perceptions of symptom severity and frequency negatively correlated with HRQOL (mental and physical) and all HRQOL subdomains apart from ‘role limitations due to emotional problems’, which correlated with symptom frequency but not severity.

**Table 2: Summary of study findings continued**

Authors	Analysis	Statistical controls	Associations between illness perceptions and psychosocial functioning	Main conclusions
Kupper et al. <sup>35</sup>	Pearson correlation  Regression  Linear mixed modelling	Age, gender, BMI, engagement in physical activity, concomitant CVDs: CAD and Congestive HF	<p><b>During AF episode:</b> Correlations: BDI-I and ATSSS: number (<math>r=0.53</math>) (<math>p&lt;0.001</math>); BDI-I and ATSSS: frequency (<math>r=0.55</math>) (<math>p&lt;0.001</math>); STAI (state subscale) and ATSSS: number (<math>r=0.30</math>) (<math>p&lt;0.01</math>); STAI (state subscale) and ATSSS: frequency (<math>r=0.26</math>) (<math>p&lt;0.01</math>); PSS and ATSSS: number (<math>r=0.37</math>, <math>p&lt;0.001</math>); PSS and ATSSS: frequency (<math>r=0.29</math>, <math>p&lt;0.01</math>)</p> <p>Linear regression (no covariates): BDI-I and ATSSS: number (<math>\beta=0.58</math>, <math>p&lt;0.001</math>); BDI-I and ATSSS: frequency (<math>\beta=0.52</math>, <math>p&lt;0.001</math>); STAI (state subscale) and ATSSS: number (<math>\beta=0.35</math>, <math>p=0.002</math>); STAI (state subscale) and ATSSS: frequency (<math>\beta=0.28</math>, <math>p=0.008</math>); PSS and ATSSS: number (<math>\beta=0.41</math>, <math>p&lt;0.001</math>); PSS and ATSSS: frequency (<math>\beta=0.32</math>, <math>p=0.003</math>)</p> <p>Multivariable regression (with covariates): BDI-I and ATSSS: number (<math>\beta=0.45</math>) and ATSSS: frequency (<math>\beta=0.54</math>), both <math>p&lt;0.0005</math></p> <p><b>Linear mixed modelling (with covariates):</b> Change of BDI-I in relation to changes in ATSSS: number (estimate: 0.30) and ATSSS: frequency (estimate: 0.74), both <math>p&lt;0.0005</math></p>	<p>During AF episode depression, anxiety and perceived stress positively associated with perceptions of symptom number and frequency.</p> <p>Without covariates depression, anxiety and perceived stress predicted (positive direction) perceived symptom number and frequency.</p> <p>With covariates only depression continued to predict perceived symptom number and frequency. Change in depression between baseline and 4 week follow-up (post-ECV) associated with changes in perceived number and frequency of symptoms (positive direction).</p>
Lane et al. <sup>36</sup>	Pearson product-moment correlation  Linear hierarchical multiple regression	Age, gender and AF type	<p><b>Correlations between baseline IPQ and 12 month trajectories: SF-36 (PCS and MCS), BDI-SF-13 and STAI (state subscale):</b> IPQ: identity and SF-36: PCS (<math>r=-0.29</math>, <math>p&lt;0.05</math>); IPQ: consequence and SF-36: MCS (<math>r=0.26</math>, <math>p&lt;0.05</math>)</p> <p><b>Linear hierarchical multiple regression: SF-36 (PCS) slope (with covariates):</b> IPQ: identity (and medication concerns): <math>R^2</math> change = 0.14, <math>p&lt;0.001</math>. Final model (including IPQ: identity): Adj <math>R^2=0.15</math>; IPQ: identity (<math>\beta=-.30</math>, <math>p=0.01</math>)</p>	<p>Baseline IPQ: identity (number of symptoms attributed to AF) inversely correlated with change in physical HRQOL over 12 months.</p> <p>Baseline perceptions of severity of AF consequences positively correlated with HRQOL mental health change over 12 months.</p> <p>Greater IPQ: identity (and medication concerns) at baseline predicted, with covariates, HRQOL: physical health 12 month trajectory (sharper deterioration/slower improvement).</p>

**Table 2: Summary of study findings continued**

Authors	Analysis	Statistical controls	Associations between illness perceptions and psychosocial functioning	Main conclusions
McCabe and Barnason <sup>37, b</sup>	Hierarchical multiple regression	Gender, age, type of AF (paroxysmal or persistent) and time since AF diagnosis	<p><b>POMS: TMD explained by:</b> IPQ-R subscales (<math>R^2</math> change= 0.47, <math>p&lt;0.001</math>); Perceived symptom frequency (<math>R^2</math> change= 0.06, <math>p&lt;0.001</math>). Final model (including IPQ-R and symptom frequency): Adj <math>R^2</math>= 0.63, <math>p&lt;0.001</math>. IPQ-R: Consequence (<math>\beta</math>= 0.20, <math>p&lt;0.001</math>), Illness coherence (<math>\beta</math>= -0.17, <math>p&lt;0.001</math>), and Psychological cause (<math>\beta</math>= 0.17, <math>p&lt;0.001</math>); Perceived symptom frequency (<math>\beta</math>= 0.34, <math>p&lt;0.001</math>)</p> <p><b>POMS subscale: tension-anxiety explained by:</b> IPQ-R subscales (<math>R^2</math> change= 0.44, <math>p&lt;0.001</math>); Perceived symptom frequency (<math>R^2</math> change= 0.03, <math>p&lt;0.001</math>). Final model (including IPQ-R and symptom frequency): Adj <math>R^2</math>= 0.56, <math>p&lt;0.001</math>. IPQ-R: Illness Coherence (<math>\beta</math>= -0.20, <math>p&lt;0.001</math>), Psychological cause (<math>\beta</math>= 0.25, <math>p&lt;0.001</math>) and Timeline: cyclic (<math>\beta</math>= 0.10, <math>p&lt;0.05</math>); Perceived symptom frequency (<math>\beta</math>= 0.25, <math>p&lt;0.001</math>)</p> <p><b>POMS subscale: depression-dejection explained by:</b> IPQ-R subscales (<math>R^2</math> change= 0.38, <math>p&lt;0.001</math>); Perceived symptom frequency (<math>R^2</math> change= 0.03, <math>p&lt;0.001</math>). Final model (including IPQ-R and symptom frequency): Adj <math>R^2</math>= 0.50, <math>p&lt;0.001</math>. IPQ-R: Consequence (<math>\beta</math>= 0.13, <math>p&lt;0.01</math>), Psychological cause (<math>\beta</math>= 0.18, <math>p&lt;0.01</math>), and Illness coherence (<math>\beta</math>= -0.15, <math>p&lt;0.01</math>); Perceived symptom frequency (<math>\beta</math>= 0.25, <math>p&lt;0.001</math>)</p> <p><b>POMS subscale: fatigue-inertia explained by:</b> IPQ-R subscales and symptom frequency: adj <math>R^2</math>= 0.53, <math>p&lt;0.001</math>. IPQ-R: consequence (<math>\beta</math>= 0.14, <math>p&lt;0.05</math>), Identity (<math>\beta</math>= 0.18, <math>p&lt;0.01</math>) and Psychological Cause (<math>\beta</math>= 0.19, <math>p&lt;0.01</math>); Perceived symptom frequency (<math>\beta</math>= 0.36, <math>p&lt;0.001</math>).</p> <p><b>POMS subscale: confusion-bewilderment explained by:</b> IPQ-R subscales (<math>R^2</math> change= 0.41, <math>p&lt;0.001</math>); Perceived symptom frequency (<math>R^2</math> change= 0.04, <math>p&lt;0.001</math>). Final model (including IPQ-R and symptom frequency): Adj <math>R^2</math>= 0.49, <math>p&lt;0.001</math>. IPQ-R: Illness coherence (<math>\beta</math>= -0.19, <math>p&lt;0.001</math>) and Consequence (<math>\beta</math>= 0.19, <math>p&lt;0.01</math>); Perceived symptom frequency (<math>\beta</math>= 0.29, <math>p&lt;0.05</math>)</p> <p><b>POMS subscale: vigour-activity explained by:</b> IPQ-R subscale (<math>R^2</math> change= 0.24, <math>p&lt;0.001</math>); Perceived symptom frequency (<math>R^2</math> change= 0.04, <math>p&lt;0.001</math>). Final model (including IPQ-R and symptom frequency): Adj <math>R^2</math>= 0.35, <math>p&lt;0.001</math>. IPQ-R: Consequence (<math>\beta</math>= -0.17, <math>p&lt;0.01</math>); Perceived symptom frequency (<math>\beta</math>= -0.29, <math>p&lt;0.001</math>)</p>	<p>Illness perceptions and perceptions of symptom frequency predicted higher morbidity on each model of psychological distress, apart from anger-hostility (not significant).</p> <p>Illness perceptions accounted for 24%-47% of variance across models. Five illness perceptions were unique contributors to the variances of the models. Illness perceptions differed for each model but included: increased illness identity (number of symptoms attributable to AF), lower illness coherence, more psychological causes of illness, increased timeline: cyclic (cyclic and unpredictable in nature), and greater severity of consequences.</p> <p>Across models, the most frequently identified illness perceptions were: coherence, consequence and psychological cause. Perceived symptom frequency accounted for 3%-6% of the variance.</p>

**Table 2: Summary of study findings continued**

Authors	Analysis	Statistical controls	Associations between illness perceptions and psychosocial functioning	Main conclusions
McCabe et al. <sup>38,b</sup>	Pearson correlation	None reported	<p><b>IPQ-R: emotional representation subscale correlated with IPQ-R subscales:</b></p> <p>Timeline cyclic (<math>r = 0.30</math>); Consequence (<math>r = 0.58</math>); Identity (<math>r = 0.27</math>); Psychological cause (<math>r = 0.36</math>); External cause (<math>r = 0.26</math>); Lifestyle cause (<math>r = 0.25</math>); Illness coherence (<math>r = -0.38</math>). All= <math>p &lt; 0.001</math></p>	Perceptions of AF: more symptoms attributable, cyclic and unpredictable, serious consequences, results from psychological, external and lifestyle causes, and perceiving poorer understanding of illness associated with increased negative emotion.
McCabe et al. <sup>39</sup>	Chi-squared  Fisher's exact tests	Educational attainment, age, sex and history of co-morbidities were not associated with treatment-seeking delay	<p><b>Treatment-seeking delay (&gt;1 week) group higher scores:</b></p> <p>Perceiving symptoms to be: Intermittent (<math>X^2=19.01</math>, <math>p &lt; 0.001</math>), Self-manageable (<math>X^2=47.75</math>, <math>p &lt; 0.001</math>) or of Less concern (delay <math>n=23</math>, no delay <math>n=2</math>, <math>p=0.008</math>); Attributing symptoms to: Stress (<math>X^2=5.89</math>, <math>p=0.02</math>), Overwork (<math>X^2=4.50</math>, <math>p=0.03</math>), Lack of sleep (<math>X^2=6.86</math>, <math>p=0.009</math>), Physical deconditioning (<math>X^2=13.03</math>, <math>p &lt; 0.001</math>) or Respiratory illness (delay <math>n=25</math>, no delay <math>n=4</math>, <math>p=0.04</math>); Perceiving a good understanding of symptom causes (<math>X^2=9.72</math>, <math>p=0.002</math>)</p> <p><b>No delay (&lt;1 week) group higher scores:</b></p> <p>Perceiving symptoms to be Life threatening (delay <math>n=3</math>, no delay <math>n=6</math>, <math>p=0.02</math>) or Very serious (delay <math>n=1</math>, no delay <math>n=9</math>, <math>p &lt; 0.001</math>); Attributing symptoms to heart attack (<math>X^2=4.80</math>, <math>p=0.03</math>)</p>	Treatment-seeking delay group more likely to: perceive symptoms as intermittent, self-manageable and not serious, attribute symptoms to lifestyle and believe they knew causes of symptoms. Those not delaying seeking treatment were more likely to perceive symptoms to be very serious or life threatening, and more likely to attribute symptoms to heart attack.
Ong et al. <sup>40</sup>	Regression analysis	Cardiovascular or non-cardiovascular medical conditions, AF frequency and gender	<p><b>SF-36 (PCS):</b> Adjusted <math>R^2 = 0.35</math>: IMQ (<math>\beta = -0.40</math>, <math>p &lt; 0.001</math>)</p> <p><b>SF-36 (MCS):</b> Adjusted <math>R^2 = 0.21</math>: IMQ (<math>\beta = -0.47</math>, <math>p &lt; 0.001</math>)</p> <p><b>HADS:</b> Adjusted <math>R^2 = 0.41</math>: IMQ (<math>\beta = 0.62</math>, <math>p &lt; 0.001</math>)</p>	Increased symptom preoccupation significantly predicted greater psychological distress (anxiety and depression) and poorer physical and mental QOL.

**Table 2: Summary of study findings continued**

Authors	Analysis	Statistical controls	Associations between illness perceptions and psychosocial functioning	Main conclusions
Steed et al. <sup>41</sup>	Pearson-product moment correlation  Multiple linear regression	Chronic vs paroxysmal AF, symptom status (symptomatic/ non-symptomatic), gender and a measure of disease severity	<p><b>Correlations</b></p> <p>IPQ: identity correlated with: PAIS-SR: domestic environment (<math>r=0.72</math>), PAIS-SR: extended family relations (<math>r=0.67</math>), PAIS-SR: social environment (<math>r=0.57</math>), and PAIS-SR: psychological distress (<math>r=0.62</math>). IPQ: consequence correlated with: PAIS-SR: domestic environment (<math>r=0.63</math>), PAIS-SR: extended family relations (<math>r=0.47</math>), PAIS-SR: social environment (<math>r=0.52</math>); and PAIS-SR: psychological distress (<math>r=0.49</math>). IPQ: timeline correlated with PAIS-SR: social environment (<math>r=0.34</math>, <math>p&lt;0.01</math>)</p> <p><b>Multiple linear regression:</b></p> <p>IPQ explaining PAIS-SR: domestic environment (adj <math>R^2</math> change= 0.30, <math>p&lt;0.01</math>). Final model (including IPQ): Adj <math>R^2=0.30</math>, <math>p&lt;0.01</math>: IPQ identity (<math>\beta=0.32</math>, <math>p&lt;0.05</math>) and IPQ: consequence (<math>\beta=0.41</math>, <math>p&lt;0.001</math>)</p> <p>IPQ explaining PAIS-SR: extended family relations (adj <math>R^2</math> change= 0.38, <math>p&lt;0.01</math>). Final model (including IPQ): Adj <math>R^2=0.38</math>, <math>p&lt;0.01</math>: IPQ identity (<math>\beta=0.51</math>, <math>p&lt;0.001</math>)</p> <p>IPQ explaining PAIS-SR: social environment (adj <math>R^2</math> change= 0.21, <math>p&lt;0.01</math>). Final model (including IPQ): Adj <math>R^2=0.31</math>, <math>p&lt;0.01</math>: IPQ: consequence (<math>\beta=0.29</math>, <math>p&lt;0.05</math>)</p>	<p>Perceptions of symptoms attributed to AF (IPQ: identity) and severity of AF consequences positively correlated with adjustment difficulties in: domestic and social environment, extended family relations and psychological distress. Perceiving AF will last longer was associated with increased adjustment difficulties in the social environment.</p> <p>Illness perceptions predicted poorer adjustment in domestic and social environments, and in extended family relations. Perceptions regarding number of symptoms attributable to AF (identity) contributed to the variance in the domestic environment and extended family relations models, and perceptions of more severe consequences contributed to the variance in the domestic and social environment models.</p>
Suzuki and Kasanuki <sup>42</sup>	ANOVA  Regression analysis	Gender and type of underlying disease	<p><b>DSM-IV agoraphobia vs no agoraphobia:</b></p> <p>Agoraphobia had higher perceived: Symptoms (frequency: <math>t=4.13</math>, duration: <math>t=3.74</math>, distress: <math>t=8.78</math>) (all <math>p&lt;0.01</math>); Psychosocial inducers of attack (psychological stress: <math>t=7.63</math>, tension reduction: <math>t=2.67</math>, exercise: <math>t=5.17</math>) (all <math>p&lt;0.01</math>)</p> <p><b>Separate regression analyses – determinants of QOL (SDQL):</b></p> <p>Perceived symptoms of attack (<math>R^2=0.34</math>, <math>p&lt;0.01</math>): Frequency (<math>\beta=-0.17</math>, <math>p&lt;0.01</math>) and Distress (<math>\beta=-0.52</math>, <math>p&lt;0.01</math>); Perceived psychosocial inducers of attack (<math>R^2=0.28</math>, <math>p&lt;0.01</math>): Psychological stress (<math>\beta=-0.44</math>, <math>p&lt;0.01</math>) and Exercise (<math>\beta=-0.15</math>, <math>p&lt;0.05</math>).</p>	<p>Perceiving more severe symptoms (frequency, duration and distress) and psychosocial inducers of attack (psychological stress, tension reduction and exercise) associated with agoraphobic symptoms.</p> <p>Poorer QOL was predicted by perceiving more severe symptoms of attack (contributors to variance were symptom frequency and distress) and perceiving psychosocial inducers of attack (contributors to variance were psychological stress and exercise).</p>

**Table 2: Summary of study findings continued**

Authors	Analysis	Statistical controls	Associations between illness perceptions and psychosocial functioning	Main conclusions
Thompson et al. <sup>43</sup>	Pearson correlation coefficient  ANCOVA	Age, gender, education level and beta-blocker use	<p><b>Correlations:</b> AFSS: severity subscale and PHQ-9 (<math>r^2=0.55</math>, <math>p&lt;0.001</math>); AFSS: severity subscale and HADS-A (<math>r^2=0.37</math>, <math>p&lt;0.001</math>)</p> <p><b>ANCOVA (adjusted):</b> PHQ-9 descriptor and AFSS: symptom severity subscale (<math>p&lt;0.001</math>): No/minimal (AFSS mean=9.2); Mild/moderate (AFSS mean=14.0); Severe (AFSS mean=20.2) HADS-A descriptor and AFSS: symptom severity subscale (<math>p&lt;0.001</math>): Normal (AFSS mean=11.9); Possible (AFSS mean=16.1); Probable (AFSS mean=20.2)</p>	Increased perceived symptom severity was associated with increased severity of depression and anxiety.
Trovato et al. <sup>44</sup>	Multiple linear regression	Gender and age	PSM Final model (including IPQ-R): $R^2=0.92$ , $p<0.0001$ IPQ-R: emotional representation ( $\beta=0.59$ , $p<0.0001$ ); IPQ-R: timeline ( $\beta=0.413$ , $p=0.003$ )	The final model (including illness perceptions and other variables) predicted increased psychological stress. Illness perceptions contributing to variance were: timeline and emotional representation.

<sup>a</sup> Utilised the same participant sample.

<sup>b</sup> Utilised the same participant sample.

**List of abbreviations**

**AF:** Atrial fibrillation.

**ANCOVA:** Analysis of covariance.

**ANOVA:** Analysis of variance.

**BMI:** Body Mass Index.

**CAD:** Coronary artery disease.

**ECV:** Electrical cardioversion.

**HF:** Heart failure.

**HRQOL:** Health-related quality of life.

**QOL:** Quality of life.

**AFEQT:** Atrial Fibrillation Effect on Quality of Life.

**AFSS:** Atrial Fibrillation Severity Scale.

**ATSSS:** Atrial Tachyarrhythmia Symptom Severity Scale.

**BDI-I:** Beck Depression Inventory-I.

**BDI-SF-13:** Beck Depression Inventory-Short form-13.

**CCS-SAF:** Canadian Cardiovascular Society Severity of Atrial Fibrillation Scale.

**CES-D:** Centre for Epidemiologic Studies Depression Scale.

**DSM-IV:** Diagnostic and Statistical Manual of Mental Disorders 4<sup>th</sup> ed.

**HADS:** Hospital Anxiety and Depression Scale.

**HADS-A:** Hospital Anxiety and Depression Scale: Anxiety subscale.

**IPQ:** Illness Perception Questionnaire.

**IPQ-R:** Illness Perception Questionnaire-Revised.

**IMQ:** Illness Management Questionnaire.

**MUIS-C:** Mishel Uncertainty in Illness Scale-Community Form.

**PAIS-SR:** Psychosocial Adjustment to Illness Scale.

**PHQ-9:** Patient Health Questionnaire-9.

**POMS:** Profile of Mood States.

**POMS TMD:** Profile of Mood States Total Mood Disturbance.

**PSM:** Psychological Stress Measure.

**PSS:** Perceived Stress Scale.

**SDQL:** Scale of Disease and Quality of Life.

**SCL:** Symptom Checklist.

**SCLs:** Symptom Checklist-Severity.

**SF-36:** Short Form Health Survey-36.

**SF-36 MCS:** Short Form Health Survey-36 – Mental Component Summary.

**SF-36 PCS:** Short Form Health Survey-36 – Physical Component Summary.

**STAI:** State-Trait Anxiety Inventory.

**UT-AFSS:** University of Toronto Atrial Fibrillation Severity Scale

### 3.6.1. *Associations between illness perceptions and emotional wellbeing*

Five studies included investigations of the association between illness perceptions and depression and/or anxiety. Two studies concluded that perceiving AF symptoms as more severe was significantly associated with elevated depression and anxiety.<sup>32,43</sup> By contrast, Thompson et al.<sup>43</sup> explored perceptions of symptom frequency, finding no significant association with depression or anxiety.

A further study investigated perceptions of symptom severity as the independent constructs of symptom number and frequency.<sup>35</sup> The study identified that both measures of symptom severity were positively associated with depression and anxiety. Furthermore, when entered into regression models as predictors, increased depression and anxiety predicted greater perceptions of symptom number and frequency independent of covariates. However, only depression remained significant when covariates were included in the analysis.

Two studies explored multiple illness perceptions. Using correlations and regression analyses, with the latter operationalising illness perceptions as predictor variables, Kang<sup>33</sup> concluded that: i) greater perceived symptom severity *predicted* greater perceived uncertainty regarding AF, ii) greater perceived uncertainty was *associated* with and *predicted* greater danger appraisal, iii) increased appraisal of uncertainty as danger was *associated* with and *predicted* increased depression, whereas appraisal as opportunity was *associated* with decreased depression, and iv) perceptions of increased symptom severity and uncertainty also directly *predicted* severity of depression. Suzuki and Kasanuki<sup>42</sup> reported AF patients who met the Diagnostic and Statistical Manual 4<sup>th</sup> edition (DSM-IV)<sup>45</sup> criteria for agoraphobia perceived significantly more severe symptoms of attack (frequency, duration and distress) and more psychosocial inducers of AF (psychological stress, tension reduction and exercise) compared to patients who did not meet the diagnostic criteria.

Three studies reported on broader definitions of emotional wellbeing. Ong et al.<sup>40</sup> identified that increased symptom preoccupation, when entered as a predictor variable within regression models, significantly predicted greater psychological distress. McCabe et al.<sup>38</sup> found that perceptions of: a poorer understanding of AF, greater number of symptoms attributable to AF, AF to be cyclic and unpredictable



with more serious consequences, and to have resulted from external and psychological origins were associated with increased negative emotions (a definition incorporating anxiety, depression, fear, worry and anger).

Utilising the same sample, McCabe and Barnason<sup>37</sup> entered illness perceptions as predictor variables within their regression analyses and found that perceiving AF to have psychological causes, to have more severe consequences, and to be poorly understood predicted multiple indices of poorer psychosocial functioning. More specifically, perceiving AF to have resulted from psychological causes significantly contributed to the variance explaining overall psychological morbidity, tension-anxiety, depression-dejection and fatigue-inertia. Perceiving AF to have more severe consequences significantly contributed to the variance explaining overall psychological morbidity, depression-dejection, fatigue-inertia, confusion-bewilderment and vigour-activity. Perceiving a more limited understanding of AF significantly contributed to the variance explaining overall psychological morbidity, tension-anxiety, depression-dejection and confusion-bewilderment.

Furthermore, perceiving AF to be cyclical and unpredictable significantly contributed to the variance explaining tension-anxiety, and perceiving AF to have more symptoms attributable to it significantly contributed to the variance explaining fatigue-inertia. Finally, perceiving increased symptom frequency also contributed to increased psychological morbidity in all aforementioned domains of psychosocial functioning.

Two studies included investigations of the association between illness perceptions and stress. Trovato et al.<sup>44</sup> entered illness perceptions as predictors within regression analyses and concluded that perceptions regarding extended duration and greater emotional impact of AF were significant contributors to the variance of the model explaining perceived stress. Similarly, Kupper and colleagues<sup>35</sup> identified significant positive associations between perceptions of symptom number and frequency, and severity of stress. They also initially found that increased severity of stress, when entered into regression analyses as a predictor variable, predicted greater perceptions of symptom number and frequency. However, such findings were lost in the presence of covariates.

Only two studies included analyses of relationships between illness perceptions and emotional wellbeing over time. Kupper et al.<sup>35</sup> identified that between baseline and four-week follow-up, larger changes in perceptions of symptom number and frequency were associated with larger changes in depression severity. By contrast, Lane et al.<sup>36</sup> found no significant associations between the range of illness perceptions measured by the IPQ at AF diagnosis and trajectories of anxiety or depression over a 12-month period.

### ***3.6.2. Associations between illness perceptions and QOL/HRQOL***

Two studies, both of which considered illness perceptions as predictor variables within their regression analyses, reported that illness perceptions significantly predicted poorer QOL. Suzuki and Kasanuki<sup>42</sup> found perceptions of symptom severity (frequency and distress) and perceiving psychosocial causes of symptoms (psychological stress and exercise) predicted poorer QOL, and Ong et al.<sup>40</sup> found that symptom preoccupation predicted poorer physical and mental QOL.

Two studies investigated the association between illness perceptions and HRQOL. Kang and Bahler<sup>34</sup> found perceived severity and frequency of symptoms were negatively correlated with overall physical and mental HRQOL, as well as most sub-dimensions of these indices (see Table 2). Lane et al.<sup>36</sup> entered symptom number attributable to AF at time of diagnosis as a predictor variable within their regression analyses and found that perceptions of increased symptom number predicted a sharper deterioration/slower improvement in physical HRQOL over a 12-month period. More surprisingly, they also identified that increased concerns regarding the consequences of AF at the time of diagnosis was associated with more rapidly improving mental HRQOL over the 12-month period.

### ***3.6.3. Associations between illness perceptions and broader domains of psychosocial functioning***

Two studies explored the relationship between illness perceptions and broader psychosocial domains. Steed et al.<sup>41</sup> concluded that perceptions of increased symptom number attributable to AF and more severe consequences of AF were *associated* with increased distress and poorer adjustment within social and domestic

environments, and extended family relationships. Perceptions of increased AF duration were *associated* with poorer adjustment in social environments. Furthermore, illness perceptions were also entered into regression models as predictor variables and were found to *predict* poorer adjustment to AF. Perceiving a greater number of symptoms as attributable to AF significantly contributed to the variance of the domestic environment and extended family relations models, and perceptions of more severe consequences significantly contributed to the domestic and social environment models.

In the only study examining treatment-seeking as an outcome, McCabe et al.<sup>39</sup> compared individuals who did (>1 week) and did not (<1 week) delay treatment-seeking, revealing the former to be more likely to perceive symptoms as of known cause, attributable to lifestyle, intermittent, of little concern and self-manageable. In contrast, those who did not delay seeking treatment were more likely to perceive their symptoms to be very serious or life threatening, and attributed their symptoms to a heart attack.

### **3.7. Quality appraisal and methodological critique**

Quality appraisal using the QualSyst (version for quantitative studies) (Kmet et al.<sup>29</sup>), indicated that all studies were of either ‘good’ ( $n=2$ ) or ‘strong’ ( $n=11$ ) quality (see Table 3; item ratings for all studies can be found in Appendix D).

Authors	QualSyst converted % score	Descriptor of methodological quality <sup>a</sup>
Gehi et al. <sup>32</sup>	82	Strong
Kang <sup>33</sup>	82	Strong
Kang & Bahler <sup>34</sup>	77	Good
Kupper et al. <sup>35</sup>	86	Strong
Lane et al. <sup>36</sup>	91	Strong
McCabe & Barnason <sup>37</sup>	91	Strong
McCabe et al. <sup>38</sup>	91	Strong
McCabe et al. <sup>39</sup>	77	Good
Ong et al. <sup>40</sup>	86	Strong
Steed et al. <sup>41</sup>	86	Strong
Suzuki & Kasanuki <sup>42</sup>	86	Strong
Thompson et al. <sup>43</sup>	86	Strong
Trovato et al. <sup>44</sup>	82	Strong

<sup>a</sup> Methodological quality was categorised as either: strong (>80%), good (60-79%), adequate (50-59%) or poor (<50%).

Table 3: Quality appraisal percentage scores and associated descriptors

It was somewhat surprising that most studies achieved quality ratings of ‘strong’ and the remaining studies were rated as being of ‘good’ quality. As there was a high degree of inter-rater reliability when scoring study quality, the high ratings do not appear to have resulted from rater error or rater leniency. Rather, it appears that the ratings of high quality may have resulted from the QualSyst, whilst appropriate for the reviewed studies and demonstrating utility in highlighting some study limitations, not fully accounting for the extent of these limitations and not identifying further limitations (see below subsections) within the scoring guidelines.

### 3.7.1. Limitations regarding recruitment

Across the reviewed studies one of the most common limitations was suboptimal reporting of sampling characteristics: some studies failed to provide information regarding ethnicity<sup>35,37,38,40-44</sup> and AF diagnosis (length of diagnosis at time of

participation<sup>32,43,44</sup> and type of AF diagnosis<sup>33,34,39</sup>). Furthermore, three studies did not clearly describe sampling methods,<sup>32,43,44</sup> one did not report participant eligibility criteria,<sup>42</sup> and only two studies reported the number of participants who did not consent to participate in the study.<sup>35,36</sup> Consequently, transparency of these studies is reduced, it is difficult to assess the extent to which samples were representative of the target populations, and the reported findings may have been influenced by these unaccounted factors.

Furthermore, although the methods of participant selection adopted by the studies appeared appropriate, and were rated accordingly using the QualSyst rating guidelines,<sup>29</sup> it should be noted that all studies were conducted within developed countries. Participant recruitment was also fairly constrained; 10 studies<sup>32-36,40-44</sup> sampled from outpatient services' only, seven studies<sup>32,35,36,39,42-44</sup> reported data from single research sites, and the remaining six studies<sup>33,34,37,38,40,41</sup> each sampled from two research sites. Moreover, where reported, studies sampled high proportions of Caucasian participants<sup>32-34,36,39</sup> or estimated a high proportion of Caucasian participants but did not provide data.<sup>37,43</sup> Taken together, this limits generalisability to less developed countries, wider geographical locations, inpatient settings and non-Caucasian groups. Samples also comprised predominantly male participants (median=64% across studies) and older adults, limiting generalisability to younger adults and women.

### ***3.7.2. Limitations regarding data collection***

The included studies utilised diverse psychometric measures of illness perceptions. Some focused only on perceived symptom severity, whereas others (e.g. the IPQ and IPQ-R) explored illness perceptions more broadly, and therefore provided richer information regarding the relationships between illness perceptions and psychosocial functioning. Moreover, as noted in sections 3.4 and 3.5, reporting of psychometric properties for the utilised measures (both illness perception and psychosocial functioning measures) was lacking in some cases. Consequently, the validity and reliability of these measures is less clear and may have resulted in potentially biased findings. In addition, many of the illness perception measures administered,

including the IPQ and IPQ-R, were not AF-specific and any nuances in illness perceptions related to AF may have been overlooked.

### ***3.7.3. Limitations regarding data analysis***

Another common limitation across studies was the variability in the explicit identification and management of potential confounding variables (see Table 2). Some studies utilised exclusion criteria to remove confounding variables such as presence of newly diagnosed co-morbid diseases and terminal illnesses,<sup>33,34</sup> cardiovascular problems other than AF,<sup>36</sup> and pre-specified cardiac conditions and chronic diseases other than AF.<sup>37,38,44</sup>

Some potentially confounding variables, most commonly gender and age, were accounted for relatively well within statistical analyses. Studies tended to enter potential confounds within regression analyses,<sup>35,36,37,40,44</sup> and some studies used additional analyses to assess whether outcome variables differed according to potential confounds<sup>39,41,42,44</sup> or attempted to control potential confounds by entering them as covariates within ANCOVAs.<sup>32,43</sup> However, using ANCOVAs to control for potential confounds may be problematic as sample randomisation was not conducted and the entered covariates, such as gender and age, may have been related to the measured variables (anxiety, depression and symptom severity). Therefore, removing gender and age variance, by entering them as covariates, may have corrupted the analyses of relationships between symptom severity and these measures of psychosocial functioning. Moreover, gender and age variance may have been removed by their inclusion as covariates, but such variables would not have been fully ‘controlled’ if they were meaningfully related to/shared variance with the measured variables (see Miller and Chapman<sup>46</sup>).

Furthermore, other notable potentially confounding factors, such as time between diagnosis and participation, objective measures of illness severity (e.g. heart monitoring or medical AF diagnoses) and co-morbidities, were rarely controlled for in analyses (see Table 2), and two studies did not report on the statistical management of any confounding variables.<sup>34,38</sup> Therefore, the significant associations between

illness perceptions and psychosocial functioning may have been influenced by confounding variables.

There were also limitations concerning the investigation of possible directional/causal relationships between illness perceptions and psychosocial functioning. Perhaps in response to theoretical models of illness perceptions (e.g. the CSM<sup>16</sup>) and previous research, the reviewed studies incorporating directionality within their analyses tended to explore whether illness perceptions predicted psychosocial functioning.<sup>33,36,37,40-42,44</sup> Although these studies, utilising regression analyses, concluded that illness perceptions predicted psychosocial functioning, such findings may have resulted from author approaches to data modelling/analysis. More specifically, choosing to enter illness perceptions as predictor variables and psychosocial functioning as outcome variables, whilst not exploring causality in the reverse direction, may falsely imply directionality. Therefore, these findings should *not* be interpreted to indicate that illness perceptions definitively predict psychosocial functioning or that the relationship between illness perceptions and psychosocial functioning is unidirectional.

A related limitation of the reviewed studies is that they provided a poor account of the possible impacts of psychosocial functioning (e.g. emotional wellbeing) on illness perceptions. Although such directionality appears plausible (e.g. someone with low mood might hold more pessimistic perceptions regarding their illness), only one study investigated the relationship between illness perceptions and psychosocial functioning from this direction, concluding that greater depression predicted increased perceptions of symptom number and frequency.<sup>35</sup>

Lastly, although all studies appeared to have sufficient sample sizes, and were rated accordingly using the QualSyst rating guidelines,<sup>29</sup> only four studies reported priori power analyses.<sup>33,37-39</sup> Therefore, statistical power is not confirmed and it is possible that studies may not have attained sufficient statistical power to identify further significant effects.

## 4. Discussion

The aims of the current review were to elicit, synthesise and evaluate published empirical literature investigating relationships between illness perceptions and broad psychosocial outcomes (emotional wellbeing, QOL/HRQOL, adjustment, and treatment-seeking) in AF patients. Systematic searching and application of rigorous eligibility criteria identified a dearth of studies (13) addressing the review question. The studies demonstrated ‘good’ or ‘strong’ methodological quality, as rated by the QualSyst, but had some notable limitations. Although all 13 studies identified that illness perceptions were associated with, and in some cases appeared to predict poorer psychosocial functioning, limited numbers of papers and diverse domains of interest offered equivocal findings.

### 4.1. Summary of findings and literature links

#### 4.1.1. *Emotional wellbeing*

Emotional wellbeing was the most prominent outcome assessed in relation to illness perceptions, with a total of 10 studies investigating variants of this domain. Concerning studies utilising the IPQ<sup>36</sup> or IPQ-R<sup>37,38,44</sup> perceiving a poorer understanding of AF, and perceiving AF to have a psychological cause and to confer more severe consequences were most frequently associated with, or appeared to predict, indices of reduced emotional wellbeing. Two studies identified relationships between these illness perceptions and multiple domains of emotional wellbeing: a range of negative emotions and variants of psychological distress, including depression and anxiety<sup>37,38</sup>. Although such findings are consistent with the CSM, their generalisability is unclear as they were obtained from studies accessing the same sample of participants.

The identified association between perceptions of more severe AF consequences and poorer emotional wellbeing is consistent with the wider cardiology literature. Such perceptions have been associated with elevated depression and anxiety in chronic heart disease (CHD) patients,<sup>18</sup> and increased depression in male patients with cardiovascular disease (CVD).<sup>47</sup> In addition, Dempster and colleagues<sup>17</sup> meta-analysis, identified that perceptions of more severe illness consequences had the strongest relationship (of all perceptions measured) with depression and anxiety across various physical health conditions (including cardiac conditions).



Furthermore, of the reviewed studies exploring illness perceptions via more circumscribed measures, perceptions of greater symptom severity and frequency were repeatedly associated with, or appeared to predict, increased depression and/or anxiety.<sup>32,33,35,37,42,43</sup> Such findings are supported in the literature<sup>48-50</sup> and, as perceptions of symptom severity and frequency are arguably a proxy for severity of illness consequences, they support the aforementioned findings of studies utilising the IPQ/IPQ-R. Moreover, preoccupation with symptoms appears to result in poorer emotional wellbeing as one reviewed study<sup>40</sup> identified that AF patients overly attending to their symptoms experienced greater psychological distress (anxiety and depression); a finding noted in other chronic health conditions.<sup>51,52</sup>

Taken together, it is possible that those who perceive their condition to have more frequent or severe symptoms, and/or more severe consequences may hold a more pessimistic view of their condition and their life with the condition, which may have negative consequences for their emotional wellbeing in the form of low mood. Furthermore, a preoccupation with symptoms may directly, or indirectly via feelings of pessimism, result in low mood.<sup>52</sup> Individuals perceiving more severe symptoms and consequences may also be more fearful of symptom onset, and/or ruminate regarding the condition's actual or potential impact, with associated increased anxiety.

The relationship between perceptions of poor illness understanding and reduced emotional wellbeing identified in the current review<sup>37,38</sup> concurs with research evidencing that poorer illness understanding is related to elevated depression and anxiety in CHD patients.<sup>18</sup> The conclusion reached also has some likeness to Kang's<sup>33</sup> conclusions that perceptions of illness uncertainty and appraisals of illness uncertainty as threatening predicted increased depression. Therefore, it appears that AF patients who struggled to comprehend their illness experienced poorer emotional wellbeing.

The findings of Kang<sup>33</sup> are consistent with research in other health conditions<sup>53,54</sup> and the Uncertainty in Illness model.<sup>14</sup> The model explains that perceiving illness uncertainty, a neutral cognitive state, occurs when individuals are unable to

determine the meaning of illness-related events.<sup>55</sup> Such uncertainty is cognitively processed as danger/threat or opportunity (based on previous experience), with the former being associated with increased pessimism regarding the illness and the future, greater psychological morbidity and poorer coping.<sup>14</sup>

Therefore, individuals with AF who struggle to comprehend their condition (perceptions of poorer illness understanding and/or increased uncertainty) may hold negatively oriented and threat based perspectives, which may result in poorer emotional wellbeing. Poorer comprehension may also exacerbate the aforementioned perceptions regarding increased symptom severity and negative illness consequences, again, resulting in poorer emotional wellbeing (including greater depression and anxiety). Importantly, Kang<sup>33</sup> also found that appraisals of uncertainty as opportunity were associated with reduced depression. Therefore, suggesting that the way in which uncertainty is appraised is particularly important for emotional wellbeing.

The relationships between perceived psychological causes of AF and poorer emotional wellbeing,<sup>37,38</sup> and perceived psychosocial causes and anxiety symptoms<sup>42</sup> appear more direct, as the IPQ-R psychological causes subscale is constructed of beliefs such as stress, mental attitude and emotional state,<sup>56</sup> and the assessment of psychosocial inducers<sup>42</sup> predominantly comprised a measure of psychological stress.

Lastly, it is difficult to draw conclusions regarding relationships between illness perceptions and emotional wellbeing over time as studies were scarce ( $n=2$ ) and contradictory. No illness perception measured by the IPQ was found to be associated with trajectories of depression or anxiety over 12 months,<sup>36</sup> but greater changes in perceptions of symptom number and frequency were associated with changes in depression severity over a four-week period.<sup>35</sup> The contradictory findings may have resulted from the different illness perceptions measured, different time periods assessed, and/or factors relating to sampling, and should be interpreted with caution.

#### ***4.1.2. Quality of life and health related quality of life***

Although studies were few in number ( $n=4$ ), they identified relationships between illness perceptions and HRQOL/QOL. Perceiving AF as caused by psychological

stress and exercise appeared to predict poorer QOL,<sup>42</sup> and two studies reached congruent conclusions, with one identifying that perceiving greater symptom severity and frequency were associated with poorer HRQOL (mental and physical),<sup>34</sup> and the other suggesting that perceptions of increased symptom severity (frequency and distress) predicted poorer QOL.<sup>42</sup> Furthermore, consistent with the CSM, perceiving a greater number of symptoms as attributable to AF at diagnosis was associated with quicker deterioration/slower improvement of physical HRQOL over time.<sup>36</sup>

The above findings resonate with Foxwell et al.'s<sup>18</sup> systematic review, which identified relationships between perceiving stress as a cause of CHD and poorer QOL (emotional and physical), and found that perceptions of increased symptom number at baseline were related to poorer QOL (physical and emotional) at follow-up. Furthermore, the relationships between symptom severity and reduced QOL/HRQOL identified in the current review have been identified in HF patients,<sup>48</sup> and the conclusion that greater symptom preoccupation predicted poorer QOL (mental and physical)<sup>40</sup> has been documented in other physical health conditions.<sup>57</sup>

It is possible that individuals who perceived their AF to be caused by psychological stress and exercise may inhibit their engagement in activities that are perceived to be physically or mentally strenuous for fear of aggravating symptoms, consequently reducing QOL. Additionally, perceiving symptoms to be more severe and greater in number, and/or a preoccupation with symptoms may have resulted in individuals perceiving that they were unable to partake in activities or, again, may have motivated individuals to avoid activity in the hope of avoiding symptom aggravation, which resulted in poorer QOL/HRQOL (mental and physical) and deteriorating physical HRQOL over time.

Surprisingly, the current review found that perceiving more severe consequences at diagnosis was associated with improving mental HRQOL over time.<sup>36</sup> This is inconsistent with previous studies by French et al.,<sup>58</sup> who identified that perceptions of increased severity of illness consequences within 24 hours of acute MI had poorer HRQOL (physical, emotional and social) six months later, and Sigurdadottir et al.,<sup>59</sup> who identified that perceptions of less severe CHD consequences were associated with improving physical and mental HRQOL over time.

The contrary finding identified within the current review may be explained by several hypotheses. For example, patients' concerns regarding AF consequences could have promoted support/treatment-seeking behaviour, which enhanced mental HRQOL over time,<sup>36</sup> or patients' initial anticipation of severe consequences may have contributed to poorer mental HRQOL at baseline but their concerns were not borne out and mental HRQOL improved over time. Another possible explanation is that the finding resulted from the statistical phenomenon of regression to the mean; more extreme (poorer) scores of mental HRQOL at baseline may have moved closer to the average upon further measurement, thereby giving the impression of improving mental HRQOL overtime. As this finding emerged from a single study, it may be unique and study repetition is warranted.

#### ***4.1.3. Broader domains of psychosocial functioning***

A lack of research exploring broader psychosocial adjustment to AF also suggests a need for caution in interpretation. In the sole study focusing on adjustment, perceptions of greater symptom number attributable to AF and more severe consequences of the condition were most commonly associated with, and in some cases appeared to predict, poorer adjustment as indexed by increased psychological distress and poorer functioning in domestic and social environments, and in extended family relationships.<sup>41</sup> Whilst there appears no parallel literature exploring such determinants of adjustment in cardiac conditions, this finding is consistent with the CSM and research exploring other chronic conditions such as Multiple Sclerosis (MS), where the attribution of greater number of symptoms to the illness<sup>60</sup> and perceiving more severe illness consequences<sup>61</sup> were deemed to predict social and role dysfunction (work, home management, recreation and relationships). It appears that those perceiving more symptoms of AF or more severe consequences feel that their condition has a significant impact on them and their life, which may have resulted in greater difficulties in adjusting to the condition and hindering their functioning across multiple environments.

Assessment of the role of illness perceptions in treatment-seeking delay is similarly limited. However, perceptions centred on symptom interpretation (perceiving symptoms to be intermittent, of little concern, self-manageable, to result from

lifestyle causes, and perceived confidence in knowing the causes of symptoms) were associated with relative delay in seeking treatment.<sup>39</sup> Such illness perceptions, which may in fact be erroneous, may reduce motivation to seek support and therefore inhibit treatment-seeking behaviours. The findings resonate with Nouredine et al.<sup>62</sup> and Dracup et al.'s<sup>63</sup> findings for individuals with acute coronary syndrome (ACS) and MI, who similarly took longer to seek treatment if they perceived symptoms to be intermittent and inconsequential, and, in the former, did not recognise symptoms as of cardiac origin.

## **4.2. Clinical implications**

The findings of the current review highlight important relationships between AF patients' illness perceptions and psychosocial functioning in domains extending beyond anxiety and depression, as summarised in a previous review.<sup>27</sup> Furthermore, as all four studies exploring relationships between objective measures of illness severity (medical diagnoses of paroxysmal, persistent or permanent AF) and psychosocial outcomes (anxiety and physical HRQOL,<sup>36</sup> psychological distress and subdomains of psychological distress,<sup>37</sup> QOL (physical and mental) and psychological distress,<sup>40</sup> and adjustment<sup>41</sup>) failed to identify statistically significant associations, it appears that perceptions of illness severity are more reliably associated with psychosocial functioning than actual illness severity. However, this assumption is tentative as it is based on a limited number of studies.

Considering the above, there is a clear role for health professionals to acknowledge relationships between illness perceptions and psychosocial functioning to best support AF patients in their condition management. This can be initiated during patient consultations through the exploration of patients' illness beliefs/perceptions and perhaps through standardised assessment using psychometric measures such as the IPQ-R<sup>56</sup> and measures of perceptions regarding symptom severity.

Once a clear understanding of the patient's perceptions regarding their AF have been achieved, those endorsing illness perceptions thought to be unhelpful may be offered interventions that aim to modify them. Based on the findings of the current review, it appears particularly important to consider perceptions regarding: poor illness understanding and uncertainty, which may be appraised as threatening; psychological or psychosocial (psychological stress, tension reduction and exercise) factors as causes to

the illness; heightened symptom severity, number attributable to AF and frequency; greater severity of consequences; and preoccupation with symptoms.

As poor illness understanding, increased uncertainty and appraisals of uncertainty as threatening were related to poorer emotional wellbeing it is recommended that AF patients are educated about their condition. Although educational material can be disseminated in a variety of ways, a promising option appears to be the use of structured educational interventions. For example, such interventions have been shown to be efficacious in modifying illness perceptions and increasing illness understanding in cardiac pacemaker patients, resulting in reduced concern and improved emotional wellbeing.<sup>64</sup>

Furthermore, AF patients perceiving psychological or psychosocial (psychological stress, tension reduction and exercise) factors to have precipitated their AF reported lower emotional wellbeing and QOL. It is hypothesised that this relationship was mediated by patients disengaging from meaningful and enjoyable activities for fear of aggravating symptoms. Therefore, it is recommended that patients are educated about the wider causes of AF, and common overestimations regarding stress as a cause of AF are addressed. Again, one way that this could be achieved is through structured interventions with Broadbent et al.<sup>65</sup> and Petrie et al.<sup>26</sup> reporting that illness perception interventions incorporating such educational material, among other content, improved MI patient functioning (including faster return to work and increased exercise).

It is also suggested that perceptions regarding increased symptom burden (severity, number attributable and frequency), severity of consequences, and symptom preoccupation shown to negatively impact emotional wellbeing, QOL/HRQOL and adjustment are addressed through interventions. For AF patients identified to hold maladaptive, and perhaps erroneous, perceptions, Cognitive Behavioural Therapy (CBT) may offer best fit given its privileging of interactive roles between cognitions and behaviour in formulation and intervention, and the modification of unhelpful cognitions.<sup>25</sup> Such interventions explicitly targeting perceptions in other conditions, notably breast cancer, have been shown to facilitate adaptive illness perceptions, reduce distress and improve QOL.<sup>66,67</sup>

Acceptance and Commitment Therapy (ACT)<sup>68</sup> could also play a role in supporting AF patients, especially those who do experience greater symptom burden, to manage detrimental illness perceptions through developing greater acceptance of their condition, whilst also supporting patients to focus on their life values. This suggestion is supported by the finding that group-based ACT for individuals with severe health anxiety was successful in modifying illness perceptions, and reducing emotional distress, health anxiety and somatic symptoms.<sup>69</sup> Moreover, this finding also suggests that ACT based interventions may be effective in reducing symptom preoccupation noted in the current review.

In addition, as the sole study incorporating an exploration of the impact of psychosocial functioning on illness perceptions concluded that depression predicted perceptions of illness severity,<sup>35</sup> interventions, such as those noted previously, should also target the emotional wellbeing of AF patients. As well as potentially improving emotional wellbeing, the findings suggest that this may also support the development of more adaptive/positive illness perceptions, which could further enhance psychosocial functioning.

Lastly, although founded on one study only, the current review suggests that the modification of illness perceptions may foster treatment-seeking. The fact that AF patients showed little concern about their symptoms (including perceiving that their symptoms were self-manageable), and the wider literature highlights a poor awareness of AF in the general population,<sup>70</sup> which has been linked to poor health literacy,<sup>71</sup> suggests a need to educate AF patients and the general population about the condition to mitigate risks related to untreated AF. For example, information regarding the presentation of AF, the potential seriousness of the condition and the importance of seeking treatment should be disseminated widely.

#### **4.3. Recommendations for further research**

Given that AF is a common condition<sup>5,6</sup> and the review identified important associations between illness perceptions and psychosocial functioning in AF patients but the literature base is relatively sparse, further investigation into these relationships is warranted. In addition to replicating the studies reviewed here, research should look to further explore possible directionality/causality in the relationship between illness perceptions and

psychosocial functioning. In addition, longitudinal designs may address the dearth of research exploring relationships between illness perceptions and psychosocial functioning over time, and the use of cluster analysis, rather than correlational and regression analyses commonly used in the reviewed studies, would provide the opportunity to identify any clusters of illness perceptions and their relationship to psychosocial functioning. This latter methodology has been informative in CAD<sup>72</sup> and wider health conditions.<sup>73,74</sup>

Moreover, given deficiencies in reporting observed in many of the reviewed studies, clearer reporting of sample recruitment and characteristics, alongside adequate powering, recruitment of under-sampled populations (non-Caucasian, female and younger age) and improved controls for confounding variables, since co-morbidity for this condition is notable<sup>75</sup> and studies rarely incorporated objective measures of symptom severity within their analyses, appears much needed. Furthermore, as this review identified an important role for interventions that explicitly address illness perceptions held by AF patients but the application of such interventions to this population appear to be lacking, it is recommended that interventions are trialled and evaluated with AF populations, and the findings are published.

#### **4.4. Strengths and limitations of the current review**

This is the first review to explore the associations between illness perceptions and diverse indices of psychosocial functioning for those with AF. It utilised a comprehensive and systematic search strategy, including the review of grey literature, and contact with authors to assess for unpublished papers (which did not emerge). It is further strengthened by utilising a quality appraisal tool,<sup>29</sup> where an ‘almost perfect’<sup>31</sup> interrater reliability score was achieved, revealing studies of ‘good’ ( $n=2$ ) or ‘strong’ ( $n=11$ ) quality. However, there are some limitations. Synthesis is based on relatively few studies, which were restricted to being published in English and varied in aims, design, sample and psychosocial variables examined. Furthermore, despite scoring well on the chosen quality appraisal tool, studies had notable methodological limitations. Conclusions may thus be an artefact of the limited literature and caution should be exercised in interpretation, especially when interpreting directionality of the relationships between illness perceptions and psychosocial functioning.



#### **4.5. Conclusions**

Despite a lack of research, the current literature review identified significant relationships between illness perceptions, including those incorporated within and beyond the CSM, and indices of psychosocial functioning in AF patients. The relative lack of published papers is surprising given the high and increasing prevalence of AF,<sup>6</sup> its costs to the individual and to health care systems,<sup>76</sup> and the growing evidence regarding associations between illness perceptions and psychosocial functioning. The findings of the current review support a need to explore perceptions of AF at diagnosis and over time (e.g. through triage), to offer education regarding AF and, where indicated, provide interventions targeting erroneous or maladaptive perceptions and emotional wellbeing. However, review recommendations should be considered provisionally given the circumscribed evidence base and limitations of the reviewed articles. More research appears warranted to address such limitations and the dearth of studies exploring relationships, especially directional relationships, between illness perceptions and psychosocial functioning in AF populations.

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## **PART 2: Research Report**

**After the storm: How do partners of those receiving an implantable cardioverter defibrillator (ICD) experience episodes of electrical storm, which have resulted from ICD activation (shocks)?**

**An exploration using Interpretative Phenomenological Analysis**

(Author guidelines for the intended journal can be found in Appendix A)



## **Abstract**

**Background:** Implantable cardioverter defibrillators (ICDs) may be surgically implanted when an individual has had, or is at risk of having a life-threatening arrhythmia. Although potentially life-saving devices, both ICD recipients and their partners may experience negative psychosocial consequences following implantation and any isolated device activations/shocks. Furthermore, ICDs may activate multiple times, with three or more activations within 24 hours being classed as an electrical storm (ES). There is a dearth of research into the psychosocial impact of ESs on ICD recipients but psychological morbidity has been noted. Furthermore, there does not appear to be any research exploring the impact of ESs on partners. Therefore, the current study aimed to explore the experiences of partners who have witnessed an ES, both during and following the event.

**Method:** Semi-structured interviews were conducted with six participants who had witnessed their partner suffering an ES. Interview data were analysed using Interpretative Phenomenological Analysis (IPA).

**Results:** The analysis identified four superordinate themes, which were interpreted as being experienced as a process, whereby partners progressed from the ES event to a position of improved adjustment. Superordinate themes included: 'Feeling overwhelmed during the ES (all at sea)', 'Challenges in post-ES adjustment', 'Trying to cope (not being becalmed)', and 'Living and growing'. Each superordinate theme had three or four associated subthemes.

**Conclusions:** Partners witnessing ES described considerable difficulties at the time of the event and following the event, but appear to progress towards a position of greater adjustment over time. Findings were considered alongside relevant literature and psychological theory. It is recommended that: following ICD fitting partners are adequately prepared for the possibility of ESs, partners are involved in post-ES patient care where possible, and professionals explore/assess the emotional wellbeing of partners post-ES, and offer support and intervention as indicated. Recommendations for future research are also suggested.

## **1. Introduction**

### **1.1. Background**

Arrhythmias (abnormal heart rhythms) can cause a person's heart to beat too rapidly (tachycardia), too slowly (bradycardia) or irregularly. Such disorders of cardiac rhythm can occur without warning and can be life threatening. For individuals who have already experienced a life-threatening arrhythmia, or for those at risk, one treatment option is an implantable cardioverter defibrillator (ICD).<sup>1</sup> The number of ICDs fitted in England has risen gradually over the past few years; the new ICD implantation rate per million population was 69 during 2013/14, 83 during 2014/2015 and 94 during 2015/16.<sup>2,3</sup>

ICDs are electronic devices implanted under the collarbone, which monitor heart rhythm and respond to dangerous rhythms through: pacing (a series of low-voltage electrical impulses delivered at a rapid rate to correct the heart rhythm), cardioversion and defibrillation (shock therapy). Appropriate defibrillation involves the administration of an electric shock that attempts to restore a normal heart rhythm. However, inappropriate defibrillation/shocks can sometimes occur (the device delivers a shock in the absence of an abnormal heart rhythm) because of factors such as lead fracture and displacement, electromagnetic noise, or device malfunction.<sup>4</sup>

Although potentially life-saving devices, ICDs are associated with negative psychosocial outcomes for some recipients, including anxiety symptoms resulting from fears of receiving shocks, device malfunction, embarrassment and death.<sup>5</sup> Furthermore, isolated device activations/shocks have a considerable physical impact on the recipient, with individuals reporting that the sensation is like being punched in the chest or stomach and that their entire bodies jolted due to the force of the shock.<sup>6</sup> Recipients may perceive isolated shocks as traumatic<sup>7</sup> and experience a range of psychosocial difficulties when they occur. For example, reduced quality of life (QOL) (mental and physical),<sup>8</sup> constrained leisure activities,<sup>9</sup> lowered affect and vitality,<sup>10</sup> greater anxiety and depression symptomatology,<sup>11</sup> and increased fatigue and psychological distress.<sup>10</sup> Moreover, Von Kanel et al. (2011) identified that those who received >5 shocks over a 3.5yr follow-up period demonstrated post-traumatic stress disorder (PTSD) symptomatology.<sup>12</sup>

Although investigations regarding the impact of ICD implantation and solitary ICD activations have largely focused on ICD recipients themselves, there is a limited body of research examining the possible effects of ICDs on the partners of ICD recipients.<sup>13,14</sup> Such studies have examined partner reactions to the ICD to better understand broader repercussions of device implantation, but investigation also appears driven by the awareness that recovery from serious heart conditions occurs within a family context, and that partner responses may influence patient recovery.<sup>14-18</sup>

To date, research assessing partners suggests that ICD implantation is associated with costs to partner wellbeing, with anxiety (36%), depression (24%) and nervousness (66%) noted in a sample of 134 partners.<sup>19</sup> Available population data indicates that such rates were much greater than those identified in the UK around the same time (2014); anxiety was identified in 5.9% of the population and depression in 3.3%.<sup>20</sup> Although a systematic review has identified that depression reported by partners is of equivalent magnitude to that of recipients, and partner anxiety is greater, studies tended to recruit relatively low participant numbers.<sup>18</sup> However, wider psychosocial difficulties have also received some exploration, suggesting decrements in physical and family functioning,<sup>21</sup> increased stress, and concerns about resuming sexual activities.<sup>22,23</sup>

Quantitative research exploring whether, and how, isolated ICD shocks affect partners appears sparse, is generally based on small sample sizes, and is inconclusive. However, some studies have identified that shocks were associated with increased partner anxiety and distress,<sup>18</sup> which is greater if the partner previously witnessed the recipient having a cardiac arrest,<sup>24</sup> and poorer family adjustment.<sup>25</sup>

The few qualitative studies exploring the impact of ICDs on partners have tended to utilise samples who have not experienced isolated ICD shocks or samples that include a mixture of partners who have and have not experienced isolated shocks, where analyses do not consistently differentiate the experiences of both groups. Themes emerging in such studies included concerns regarding: the ICD, ICD influences on the couple relationship, caring for the ICD recipient, uncertainties regarding the future,<sup>26</sup> feeling helpless and uncertain in the event of a shock,<sup>18</sup> and anticipating the occurrence of further shocks.<sup>27</sup>

In some cases, ICDs may activate/shock repeatedly within a short space of time, with three or more appropriate ICD activations within 24 hours being defined as an electrical storm (ES).<sup>28</sup> Such ESs are reported to occur in 4%-28% of ICD recipients.<sup>29</sup> Although there is scant research exploring the impact of ESs on the patient, a circumscribed cadre reveals that the occurrence of ESs is associated with increased anxiety and distress,<sup>4,30</sup> and PTSD.<sup>31</sup> However, thus far no published research has explored the impact of ESs on partners.

## **1.2. Rationale and aims of the current study**

Previous research indicates that ICD recipients experience psychological difficulties following ICD implantation and in response to ICD activations and ESs. Although the literature base suggests that partners of ICD recipients also experience difficulties following ICD implantation and activation, research is lacking and findings are inconsistent. Furthermore, investigation into the impacts of ESs on partners does not appear to have been undertaken.

Given such limitations in research, the reported negative impacts of discrete ICD activations on partners, the potential for poor partner coping to affect relationships and patient recovery, and the challenging nature of ESs for ICD recipients, it seems appropriate to examine the impact of ESs on partners. Research exploring partner and significant other (commonly partners) responses to isolated ICD activations/shocks,<sup>18,25,27</sup> acute cardiac events<sup>32,33</sup> and wider critical life events<sup>34-36</sup> note similarities. That is, partners experience shock, distress, anxiety, depression, helplessness and uncertainty during such events, and may experience ongoing psychological morbidity, hypervigilance, marital challenges, difficulties in family adjustment and challenges when adopting new caregiver roles following the events. Therefore, it is anticipated that partners (participants) in the current study may report similar experiences in response to witnessing ESs; repeated ICD activations (acute cardiac events), which may be perceived as critical/life threatening. However, such experiences may be more intense/severe and challenging due to the nature of ESs; repeated ICD activations within a relatively short space of time (less than 24 hours).

Moreover, although there does not appear to be any investigation into the occurrence of PTSD in partners witnessing ESs, isolated ICD shocks, or even wider acute cardiac

events, DSM-V criteria for PTSD acknowledges that witnessing threatened death, serious injury or threatened serious injury, or learning that a significant other (relative or close friend) has been exposed to trauma may contribute to the development of PTSD.<sup>37</sup> Therefore, it is speculated that the partners of ES sufferers may be at risk of experiencing trauma and developing PTSD symptomology.

Further research in this area may enhance the understanding of partners' experiences of ESs and inform professional support. Moreover, reducing partner difficulties may also improve the recovery of ICD recipients, given broader relationship impacts. Therefore, the aim of the current study was to explore the ways in which partners of ICD recipients experience and make sense of ESs, during and after the episode. The following research questions were considered:

- How do partners of ICD recipients experience ESs?
- How to partners of ICD recipients experience any aftereffects of ESs?

## **2. Method**

### **2.1. Design**

A qualitative design was adopted given that the aim of the study was to explore the ways in which partners of ICD recipients experience and make sense of ESs.

Interpretive Phenomenological Analysis (IPA) was utilised in the design and analysis of the current study. IPA was selected over other qualitative methodologies as its philosophies and construction appeared to be the most suitable method to address the research aim (to offer a detailed exploration, including any idiosyncrasies/nuances, of the experiences of participants/partners who have encountered ESs). More specifically, its inductive and ideographic nature permits rich and personal information to be gleaned from individual cases,<sup>38</sup> its phenomenological stance prioritises lived and subjective experiences,<sup>39</sup> and the principle of hermeneutics privileged participants' interpretations of their experiences, whilst also acknowledging the researcher's influence (e.g. through preconceptions) as he interpreted participants' interpretations (double hermeneutic).<sup>40</sup> Furthermore, IPA is considered useful for exploring complex, emotive and ambiguous topics,<sup>41</sup> the approach is reputable, and it aligned with the researcher's<sup>1</sup> epistemological position.

### **2.2. Epistemological position of the researcher**

The study was conducted from a critical realist epistemological position (see Appendix E).

### **2.3. Recruitment**

Recruitment took place between September 2016 and February 2017. Participants comprised partners of ICD recipients who were in receipt of treatment from a regional NHS cardiology service following an ES. Consistent with Smith et al.'s<sup>40</sup> recommendation that IPA studies should recruit three to six participants, six participants were recruited.

#### ***2.3.1. Inclusion/exclusion criteria***

Since IPA is concerned with the detailed analysis of individual cases, a homogenous sample is recommended.<sup>40</sup> To maximise homogeneity, purposive sampling was undertaken and inclusion/exclusion criteria were applied. The inclusion/exclusion

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<sup>1</sup> The researcher is the author of this report

criteria were also applied to ensure the sampling of participants who were immersed within the experience under investigation, and to protect participants.

The inclusion/exclusion criteria included:

- The ICD recipient has experienced at least one confirmed appropriate episode of ES (three or more ICD activations attempting to restore normal heart rhythm within 24 hours).
- The participant and ICD recipient were in a relationship at the time of the ES.
- The participant and ICD recipient have lived together since the ES.
- The participant is willing and able to provide informed consent.
- The participant is sufficiently able to understand the interview questions.
- The participant is aged 18 years or above.

### ***2.3.2. Recruitment procedure***

Potential participants were purposively sampled by the local collaborator, who screened ICD recipient files to identify those who had experienced ESs, and then checked participant eligibility using the inclusion/exclusion criteria. The local collaborator invited eligible participants to engage in the study by providing a participant invitation letter (Appendix F) and information sheet (Appendix G), either in person or via post. Nine eligible participants were invited to engage in the study, six of whom expressed their interest in participating (these six participants comprised the final sample). The researcher contacted potential participants, having waited at least 48 hours since their expression of interest, to clarify any questions, confirm eligibility, and arrange a meeting between the potential participant and the researcher.

### ***2.3.3. Final sample***

The final sample comprised five females and one male. Five respondents defined themselves as “White-British” and one as “White-and-Black-Caribbean”, and all were married to the ICD recipients. Regarding age, four partners fell within the ‘55-64 years old’ bracket, one fell within the ‘65-74 years old’ bracket and one fell within the ‘44 years old and under’ bracket. Although the medical definition of ES is three

or more appropriate ICD activations within 24 hours,<sup>28</sup> all partners witnessed three or more shocks within a much shorter period of time (the ICD repeatedly activated over a course of minutes to hours). Five participants witnessed one ES, and one participant witnessed three ESs. Further sample characteristics are provided in Table 4 (to promote confidentiality generalised data is provided).

	<b>Average length of relationship (years)</b>	<b>Average length of time living together (months)</b>	<b>Average length of time ICD has been implanted (months)</b>	<b>Average length of time since last ES (months)</b>
<b>Mean</b>	25.5	25.5	90.7	27.3
<b>Range</b>	10 - 40	9 - 40	10 - 204	2 - 45

Table 4: Sample characteristics

## 2.4. Materials

The materials used in the current study included: the Impact of Event Scale-Revised (IES-R)<sup>42</sup> (brief trauma questionnaire) (Appendix H), a participant demographic information sheet (Appendix I), a semi-structured interview schedule (Appendix J) and an audio recording device.

Although there appears to be no empirical study, it is speculated that partners of ICD recipients may experience PTSD symptoms in response to ESs. Therefore, the IES-R was administered to all participants to provide further context to the recruited sample and qualitative data generated (the degree to which participants were experiencing ES related trauma symptoms at the time of interview). The scale required individuals to consider the traumatic event and rate how distressing each item (e.g. ‘I had trouble staying asleep’) had been over the previous week via a scale of 0 (not at all) to 4 (extremely). The reliability and validity of the measure has been established.<sup>43-45</sup>



## **2.5. Procedure**

Appendix K contains a chronology of the overall research process.

### ***2.5.1. Ethical Approval***

Ethical approvals were established prior to recruitment and data collection (see section 2.6).

### ***2.5.2. Data collection***

One-to-one meetings between the researcher and participants took place in a quiet room in the cardiology unit. During the meeting the participant information sheet was reviewed, informed consent (Appendix L) was obtained, the demographic information sheet and the IES-R were completed, and the interview was conducted.

Semi-structured interviews were chosen as the method of data collection as they are considered appropriate for IPA methodologies;<sup>40</sup> they permit the detailed exploration of participants' accounts and provide rich data that can be analysed comprehensively. Development of the interview schedule was informed by the research aims, previous research, liaison with the research supervisor and local collaborator, and IPA methodology.

Smith et al.<sup>40</sup> suggest that an interview schedule consisting of six to ten open-ended questions with prompts will result in an interview lasting between 45-90 minutes. Therefore, interviews were scheduled to last between 60-90 minutes and the interview schedule consisted of nine questions, which were a mixture of open-ended and closed questions with additional prompts.

Interviews lasted between 70 and 80 minutes, and were audio recorded. The interview process was iterative with the researcher reflecting on the process of each interview and modestly refining the interview schedule where felt to be beneficial. The semi-structured nature of the interview schedule afforded responsiveness to the participants, whilst retaining the interview focus.

### **2.5.3. Analysis**

Transcription of the audio-recorded interviews was completed by the researcher. Transcriptions were comprehensive; they were typed verbatim and included silences, gestures, hesitations and laughter. Analysis of transcripts was also conducted by the researcher using the framework outlined by Smith et al.<sup>40</sup> (Appendix M). Furthermore, the researcher took notes during each interview and recorded reflections in a reflexive diary (see Appendix N for an extract) following interviews, both of which were used to inform analysis.

The IES-R was analysed using the relevant guidelines, and the PTSD cut-off point suggested by Creamer et al.<sup>44</sup> (33/88) was adopted.

## **2.6. Ethical considerations**

### **2.6.1. Ethical approval**

Ethical approval was granted by the Research Ethics Committee (REC) and Health Research Authority (HRA), after internal peer review and service user scrutiny. Sponsorship and indemnity insurance were provided by the University of Leicester. Furthermore, the study was approved by the NHS Trust Research and Innovation Department associated with the recruitment site. See Appendix O for documents related to ethical approval.

### **2.6.2. Informed consent**

Potential participants were provided with full details of the research project via a participant invitation letter and participant information sheet. It was ensured that potential participants were in receipt of these documents for at least 48 hours prior to their formal invitation to engage in the study. Furthermore, prior to recruitment potential participants were provided opportunities to ask questions regarding the study.

Those who agreed to participate were asked to confirm that they had read and understood the participant invitation letter and information sheet, and were required to review and sign a consent form prior to their engagement. Principles of confidentiality and right to withdraw were explained verbally and within study documents.

### ***2.6.3. Confidentiality and anonymity***

All participant information and data were stored securely and data were anonymised. All names were changed to pseudonyms and identifiable information was altered or excluded at the point of transcription. From the outset participants were made aware of the requirement to breach confidentiality if they disclosed information indicating risk to self or others.

### ***2.6.4. Participant wellbeing***

As the topic of discussion was sensitive in nature, time was allocated for participants to relax and prepare themselves, and for the interviewer to build rapport prior to the interview. Participants were also reminded that they could take breaks during the interview as required, and that they could withdraw from the interview (and study) at any point should they wish to do so.

Furthermore, the researcher remained alert and responsive to signs of distress and fatigue, and following the interview participants were debriefed and directed to further support as necessary. The debrief involved thanking the participant for taking part in the interview, checking their wellbeing, offering the opportunity to ask any questions, and providing contact details to enable participants to ask questions at a later date. Participants were also asked whether they would like to receive a copy of the research report.

## **2.7. Quality issues**

### ***2.7.1. Quality***

Ensuring rigour, trustworthiness and integrity is essential in qualitative research.<sup>46</sup> To achieve this, the current study adopted Yardley's<sup>47</sup> recommendations of adhering to sensitivity to context, commitment and rigour, transparency and coherence, and impact and importance.

Regarding sensitivity to context, the researcher educated himself in the relevant fields (ICDs and ESs, and the impact of health conditions on partners and family members) by consulting the relevant literature and engaging in discussions with professionals working with ICD recipients and their partners.

Concerning commitment and rigour, Yardley<sup>47</sup> promotes the importance of ensuring methodological competence. The study utilised an established method of research and analysis closely followed the recommended steps of Smith et al.<sup>40</sup> (Appendix M). The researcher developed competences in IPA methodology by attending a training event, accessing literature and theory, and engaging in discussions with peers also interested in IPA methodology. Furthermore, the research proposal underwent peer review.

In-depth engagement with the research topic is also recommended. The researcher was fully immersed within the data having conducted, listened to, transcribed, checked and analysed all interviews. In addition, opportunities were taken to reflect on the analysis with others during a peer supervision group, and supervision with the research supervisor.

Consistent with the recommendation of transparency and coherence, audit trails of the analytic process and all decisions were retained. Quotations, ensuring representation of all participants, were used to evidence interpretations, and examples of transcript coding are provided (Appendix P). Furthermore, the researcher maintained a reflexive approach (see following subsection).

Regarding impact and importance, this is the first known study investigating the impact of ESs on partners of ICD recipients, and there is a dearth of research exploring the impact of ICDs on partners more generally. Developing understandings of partners' experiences of ES may enhance the literature base and provide recommendations for service provision.

### ***2.7.2. Researcher reflexivity***

Reflexivity, whereby a researcher reflects on the ways in which s/he may influence the research project during data collection and analysis, is both beneficial and integral to qualitative study.<sup>48</sup> Through personal reflection, research supervision and peer supervision the researcher reflected on the ways in which he might influence the study. Furthermore, as recommended by Larkin and Thompson,<sup>49</sup> the researcher utilised strategies such as 'free coding' (reading each transcript prior to its analysis

and freely writing down any thoughts or feelings that occurred) and a reflexive diary (see Appendix N).

The researcher had no professional or personal experience of ICDs or ES but has experience of working within a physical health setting as a Trainee Clinical Psychologist. The potential for researcher impact/bias on the study is further discussed within the critical appraisal (page 106).

### 3. Results

Following detailed analysis of individual cases, cross-case analyses of all six participants revealed four superordinate themes, each subsuming three or four subthemes (Figure 2). The diagrammatic representation captures partners' responses over time; from the ES event (**'Feeling overwhelmed during the ES (all at sea)'**), ES aftermath (**'Challenges in post-ES adjustment'**), attempts to cope in the aftermath (**'Trying cope (not being becalmed)'**), to greater adjustment (**'Living and growing'**). Extracts from participant interviews are provided to illustrate subthemes<sup>2</sup>. Subtheme frequency is provided in Appendix Q.

For context, the average IES-R score of the recruited sample was 25/88, which is below the suggested cut-off for PTSD (33/88) as suggested by Creamer et al.<sup>44</sup> However, there was considerable variability in scores with one participant scoring extremely low (1/88) and another scoring considerably higher (45/88) than Creamer et al.'s<sup>44</sup> recommended cut-off. This elevated score was the only score above the cut-off.

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<sup>2</sup> Three dots without brackets '...' illustrates the removal of words where they do not add meaning, or where the researcher has interrupted the participant with a validating response. Three dots within brackets '(...)' illustrates a >3 second pause in speech.

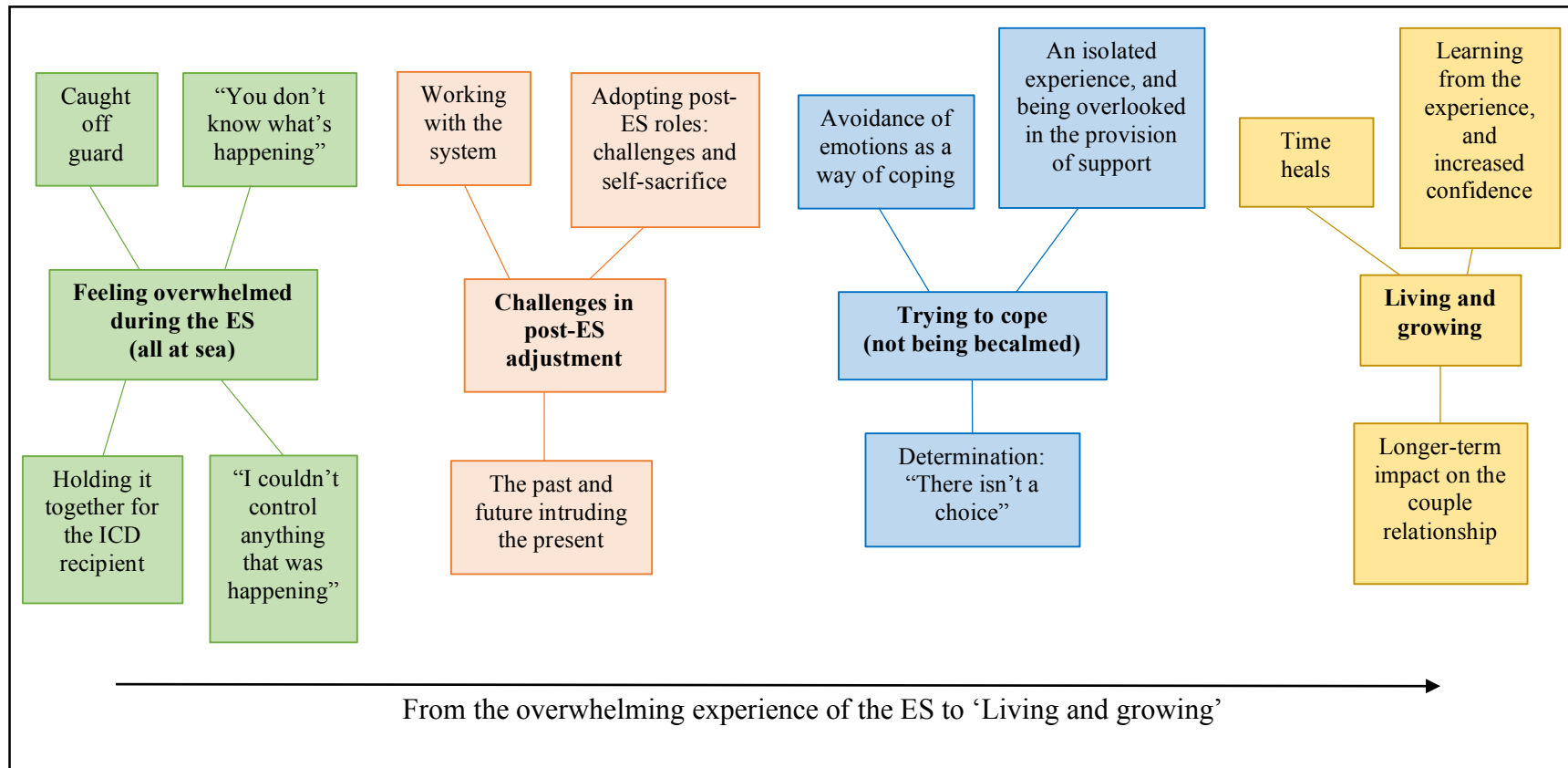


Figure 2: Superordinate themes (bold) and their associated subthemes

### 3.1. Feeling overwhelmed during the ES (all at sea)

This superordinate theme, encompassing all participants' responses, sought to convey the difficulty in processing and making sense of the ES. Partners reported multiple, simultaneously occurring dimensions of the event, which appeared to culminate in a sense of feeling overwhelmed.

#### 3.1.1. *Caught off guard*

All partners reported that they felt unprepared and taken aback when the ES began, and five respondents noted that the possibility of any ICD activation was not an immediate concern:

*We [partner and ICD recipient] never considered it [activations] because we'd sort of been told that it [ICD] was there as an emergency and as a backup, as an insurance. So, we felt, you know, 'oh, it's there' but we never thought about it (Mary).*

Mary perceived the device as inconspicuous, with activations/shocks considered unlikely from a device of last resort. Her repetition of "we" suggested a collective and established construction of life continuing as before with her partner, giving little thought to potential activations. Respondents described being oblivious to potential activations for several reasons: a brief period of time since implantation (Louise), a long period of time since implantation without activations (Sally), and the ICD recipient's heart condition being managed by medication (Ann).

All respondents reported the ES as particularly disturbing because it had occurred in an innocuous context without obvious cause:

*... He sat down in his chair, picked up a magazine and it [ICD] started going off, so there was no warning sign (emphasised), no nothing. He felt well... (Sally).*



Sally's use of language seemed to highlight the extent of the shock she experienced due to the ICD activating whilst her husband felt well and was at rest. She also described the absence of warning signs and sudden onset of the ES, noted by all partners apart from Helen. Ann also commented on both the innocuous context and the lack of warning signs:

*He was even relaxed, he wasn't even exerting himself, you know, he just sat up in bed. So, it wasn't as if he'd been running up and down the stairs and I've said, "oh well, there you are you see"... (Ann).*

Ann appeared perplexed since she seemed to expect any activations to follow a clear precipitant. She contrasted this with previous experiences of her partner's ill-health with a gradual, rather than traumatic onset; the latter being unexpected and impossible to prepare for:

*... An illness that sort of creeps up on you like pneumonia, you get prepared- yourself- for it but something like a car crash, everything is instantaneous and you've got to like, sort of, think quickly (Ann).*

Here, Ann appeared to describe her experience of needing to swiftly respond to a chaotic and fast paced scene.

### **3.1.2. "You don't know what's happening"**

All partners reported struggling to comprehend what was happening during the ES, which they felt as distressing. Three participants reported fluctuating attributions as to whether the multiple shocks represented appropriate or inappropriate device activity. Neither construction appeared reassuring since, as Sally noted, appropriate shocks connoted the heart is faulty and inappropriate shocks may be inducing unneeded distress:

*... It raises your anxiety because you think... if each time he has it [irregular heart rhythm], it's supposed to put the rhythm back to*

*normal, something dramatic is happening because clearly the rhythm isn't going back to normal, so it's having to keep shocking... I was thinking the damn thing's gonna be malfunctioning. You know, why-why is it going off so many times... It's gone wrong... (Sally).*

This evaluation of cause and effect was accompanied by uncertainty about shock duration in five respondents:

*... The fact that they happened relatively close together and there was a lot of them... Yeah, that was a factor there. It was, yeah, that- that-yeah, was a factor because (deep breath), because you start thinking, when is this gonna end (Kevin).*

The structure and tone of Kevin's language conveyed emotional burden from an experience with no certainty of conclusion. This inability to establish an endpoint was reported by Ann, Helen and Louise as a precursor to anticipation of further shocks, and hypervigilance to their partner's physical status. Moreover, Helen commented on the distress caused by this sense of anticipation:

*You're looking at that person [ICD recipient] waiting for it to go off again... You're panicking but you're trying to keep calm but you're waiting for it again... (Helen).*

Although Helen made attempts to remain calm, it appeared that the anticipation and related panic were difficult to manage.

### **3.1.3. "I couldn't control anything that was happening"**

All partners reported that acute upset in witnessing the ES emerged from their lack of control and a sense of helplessness:

*... [The ES] was frightening because you feel, I suppose, out of control... I couldn't control anything that was happening. I couldn't*

*stop it, which was frightening because it was distressing to hear him and he was asking me to help, and- and- if you can't help somebody that's in distress, and you can't stop the distress either... (Sally).*

This quote demonstrated Sally's sense of impotence during the ES. Although she desired control over the situation, apparently amplified by her husband's requests for help, she was powerless to stop the cause of the distress (ICD activations) or reduce the distress itself. Kevin, who witnessed the ES whilst his wife was in hospital, described a similar experience:

*My options are to hit the panic button or go and get a nurse, and that's- that's it... that's the sum total of what you can do for your wife is it? When she's in that sort of condition... (...) (sigh) (...) it just makes you feel worthless (...) because what good are you when your wife really needs you? ... (Kevin).*

Here, Kevin appeared to express feelings of irrelevance and insignificance at being unable to help his wife when he felt she needed him most. Furthermore, his use of language highlighted high levels of associated distress.

Louise reported that her instinct to provide physical comfort and reassurance was rebuffed by a professional. This imposed role as a bystander appeared to increase her fear, and reduce her sense of agency in wanting to support her husband. She seemed to feel that her verbal consolation was insufficient:

*It was scary really, watching it. It was- there was nothing we could do. The paramedic kept telling us we couldn't stand near him and we couldn't touch him... We just had to stand back and watch... and you just couldn't reassure- well, you just had to verbally reassure him... (Louise).*

Seeking support from the emergency services appeared the only way in which partners could gain a sense of control over the ES:

*... Once I'd done that [telephoned for an ambulance] then I felt like I was more in control because now I was waiting for somebody. Now I'd done something, which, you know, would have a result or an impact... (Ann).*

Ann described feeling more in control of the situation once she had sought medical support. She had acted and was waiting for the medical response; someone who could take control of the situation and support her husband, where she (and the other respondents) felt unable to do so.

#### **3.1.4. Holding it together for the ICD recipient**

Acute distress when overwhelmed, and impotence in the face of repeated shocks, appeared compounded by a need, expressed by four respondents, to contain their own emotional response to the ES to mitigate partner distress. Helen described the importance of this and reported finding the enormity of the task difficult to articulate:

*... I don't think I could ever put into words how you feel actually 'cos you just- you've got multi things going on at the same time, but trying to keep calm for him because the worst thing you can do is panic and make him upset. So, you're trying to keep calm to hopefully keep him calm (Helen).*

Similarly, Ann described attempts to suppress her own response to avoid further adverse impact to her husband and to reassure him, akin to adopting a parental role:

*... The only way of keeping your kids calm is to be calm yourself... It's a case of thinking about the other person... and trying to keep them from being totally afraid... It's just something that you do (Ann).*

The containment of emotions appeared fairly natural for Ann (“*It's just something that you do*”), whereas Mary described this responsibility as challenging, and questioned whether her inability to remain unperturbed influenced the continuation of the ES:

*... I found it really hard to compose myself... and I think maybe him seeing me distressed didn't help his, you know, condition either (Mary).*

### **3.2. Challenges in post-ES adjustment**

This superordinate theme encapsulated the numerous challenges reported by all partners in adjusting to their lives following the ES.

#### **3.2.1. Working with the system**

This subtheme aimed to capture the challenges of engaging with the health service post-ES, as experienced by four respondents. Such challenges related to a lack of agency, uncertainties and oscillating emotions.

Louise expressed fluctuating hopes, fears and uncertainty regarding her partner's medical care, as though “*on a rollercoaster*”, conveying uncontrollable momentum:

*It's like going on a rollercoaster all over again really... Not knowing how long it's [medical care] gonna take, being told that they can do something that you think might fix it [ICD recipient's irregular heart rhythm] but it might not, and... [feeling] petrified to know that he's about to undergo something that is so dangerous (Louise).*

The sense of impotence expressed in the acute phase of device shocks was repeated in hospital as partners, again, felt as though the situation was out of their control. Helen noted:

*You've got to hospital and he's [ICD recipient] in another- another room... and you're out of control... (Helen).*

This was associated with variable levels of information about the recipient's care elicited from medical professionals:

*... Sometimes when you go they're really good and they keep you informed, and other times they don't (Helen).*

Similarly, Sally commented on the unpredictable and potentially unreliable access to information:

*... If I saw a doctor that was good but I... didn't see doctors that often so I was getting feedback second hand (Sally).*

Like Helen, Sally wished to reduce her uncertainties but limitations in direct communication represented missed opportunities to achieve this:

*... That would have enabled me to have a better understanding [of the ICD recipients care] (Sally).*

The immediacy of the shocks, and comfort gained from prompt responses to hospitalise partners, was contrasted with subsequent delayed procedures, which heightened respondents' anxiety. For example, Ann explained:

*... [I] just wanted to get there [the operation]... having to come back out [of hospital], having blood thinning was a bit of a blow (Ann).*

*... The scariest time [was] when he came out [of hospital] before he had the ablation because there was this period of time where you know that it's [ICD recipient's heart] got a problem and it's not been resolved yet... (Ann).*

Ann's initial hope that the apparent cause of ICD shocks would be addressed speedily was dashed, leaving her disappointed and fearful when her husband was discharged without the underlying problem being addressed.

### **3.2.2. Adopting post-ES roles: challenges and self-sacrifice**

This subtheme aimed to capture the experiences of all partners as they adopted new roles following the ES. These were described as testing to occupy and maintain, and were suffused with narratives of self-sacrifice.

All partners apart from Mary and Ann described difficulties with the extent and complexity of changes forced upon them whilst their partners were admitted to hospital, which as Louise described:

*It just rocks your world I suppose. When he's back in hospital it just-it's the biggest upheaval ever because normal life has just changed. I have to plan a small child, visiting, just so many things have to be changed and mapped out in your head and sorted out... (Louise).*

Normality had been ruptured, with numerous consequences imposed, requiring intricate planning. Louise appeared to feel that she had little choice in the matter, and she described her position as “stressful” and “tiring”. All respondents also reported a need to shoulder responsibility for their partners' emotional wellbeing, with adverse consequences for themselves, Louise noting that this was particularly taxing:

*... I think that's what made the first year so hard... it knocked Tom's [ICD recipient] confidence for six... So, to try and boost yourself and*

*keep a child, and go back to work, it just- it's- I found it really hard... I just found that I felt so down in the dumps but I think that was because, in hindsight, I'd spent all my energy trying to boost him (Louise).*

Similarly, Helen and Sally described that they felt compelled to undertake practical roles as a means of mitigating partners' emotional burden. Helen reported that she did "... everything around the house" to avoid the ICD recipient becoming "agitated when he doesn't need to". This self-sacrifice was "tiring" and she reported being occasionally "peeved" with the situation.

The sole male respondent offered a different position regarding role changes. Kevin perceived himself as offering care to his wife prior to the ES, and appeared to emphasise his loss of control over the delivery of care and a loss of previous roles (through examples of male agency), rather than taking on additional, often emotionally-valenced roles that had been privileged by female partners:

*... What do I do?... I know the machine's [ICD] there and it'll do everything... If that's doing that, is- what's my role? Have I got a role?... If a machine's doing my job for me (slight laugh)... It's my wife... I should be running this show, I should be making the important decisions, I should be looking after her... That's my role (emphasised), I'm her husband and partner (...) that's what I do, and that's what I've done for many years... (Kevin).*

Furthermore, all participants apart from Helen noted that the mindful holding of their own emotions to protect their partner by mitigating distress continued beyond the acute event, appearing during the hospital stay and post-discharge. Sally commented on the former:

*... Trying to support him through that [hospital admission] but then also dealing with my thoughts and emotions through it as well, some of which I couldn't verbalise to him because that would have been- had a*



*negative effect... and obviously, I didn't want to do that because I'm trying to be positive (Sally).*

Sally described an awareness of her own negative affect but her role of the positive and encouraging carer could not permit its expression. Instead, she described:

*... [Putting on] the brave face, the façade when I was here [visiting the hospital], which then, you know, I could let slip a bit once I'd gone (Sally).*

Here, Sally reported discordance between her brave presentation in the presence of her husband and her internal feelings, which could only be expressed when away from her partner. Similarly, Mary described her roles in sacrificing her own emotional expression post-discharge:

*He was frightened to leave hospital because of this safety net he felt. He was, you know, safe, and going home, it presented fear... and I shared that with him, but I was very conscious to try to reassure him, try and comfort him... (Mary).*

Some respondents described a greater pressure to contain their emotions: the requirement to contain feelings for the benefit of other family members as well as their partner. For example, Helen spoke about the importance of regulating her emotions so they didn't "rub off" onto her child:

*... I had to be normal, and [act as though] everything was fine and hunky-dory... (Helen).*

### **3.2.3. The past and future intruding the present**

All partners appeared to experience difficulties living in the present following the ES due to the past and future intruding on their lives. Louise, Sally and Helen

reported that thoughts/memories concerning the ES could easily permeate their consciousness. Sally commented; *“I still think about it”* and went on to explain:

*... It’s kind of the imprint of the- the picture of it happening... (Sally)*

Here, Sally suggested the powerful visual image of the ES impressed upon her with lasting impact. Thoughts and memories could also be provoked by external stimuli:

*... You see stuff like Casualty [hospital-based television programme] or anything like that and I get- very often if it’s anything remotely related I can’t watch it. I have to walk out... It brings back too many memories that I don’t want to re-live (Helen).*

Helen reported that numerous, medically-focused stimuli could trigger a re-experience of the ES, which she attempted to address through avoidance. Helen also reported that conversations about the ES could have the same effect. She became tearful when commenting:

*... If I ever stop and talk to somebody or think about it too much you can feel it welling (Helen).*

Future intrusions also appeared to adversely impact living in the present. Five partners expressed fears regarding the occurrence of further ESs, which took the form of anxiety and hypervigilance to the physical presentation of their partners. For example, Sally described looking for cues that another ES may occur:

*... keeping an eye on things I suppose, for any physical signs... (Sally).*

Furthermore, Mary described difficulties sleeping and hypervigilance during the night:

*... I couldn't go to sleep, erm, because I was really, really anxious about him... I couldn't settle until he'd gone to sleep... Every twitch he made, I was on edge. I was on alert, thinking it's [ES] gonna happen again (Mary).*

Fears and orientation to a future ES also appeared evident in cognitive and behavioural preparation. For example, Sally described living in a state of psychological preparedness:

*... I'm mindful that it could happen again anytime... I need to be ready to do whatever is required... (Sally)*

Similarly, Ann described modifying her behaviour during a period of heightened concern that another ES may occur (her partner was waiting for an operation):

*... Things that I would normally do that we didn't do because I didn't want it [ES] to happen while we were doing something... out somewhere... It did have a bit of a restrictive effect I think at that time because of the feeling, if it happens I didn't want it to be in the middle of the night and I'd got my grandchildren staying, so we didn't have them to stay (Ann).*

Such changes appeared to be motivated by prevention. Restrictions in behaviour were viewed as a means of obviating further triggers, and there was a desire to control the environment in order to be “free to sort it out” and “take him to the hospital” should another ES occur. However, this appeared to circumvent the pleasure of engaging in activities and spending time with family members in the present.

### **3.3. Trying to cope (not being becalmed)**

This superordinate theme aimed to encapsulate the experiences of all partners as they attempted to cope with the post-ES challenges within the previous superordinate theme.

### **3.3.1. Avoidance of emotions as a way of coping**

Kevin, Ann and Helen appeared to use avoidance to manage the emotional repercussions of the ES and the past and future intrusions noted previously. Kevin explained that he had attempted to watch the television as a way of distracting himself from difficult thoughts (“... *Take my mind of it*”) whilst his wife was admitted to hospital following the ES. Helen discussed more sustained use of avoidance which appeared to be covertly agreed within the family:

*... If I try and talk to John [ICD recipient] about it [the ES] I can feel myself welling up, if Mark [son] and I talk about it I can feel myself welling up, as does Mark, which I why I think we don't talk about it very often either, it's too emotive (**Helen**).*

This use of avoidance, restrictions in conversation and emotional expression, appeared to compound internal holding of upsetting/distressing emotions and thoughts. Furthermore, Ann and Helen described internal forms of avoidance. Ann reported her conscious attempts to quash distressing thoughts, and Helen attempted to suppress her emotions:

*You start to think [about the ES and aftereffects] and then you think, 'oh, don't think about that, don't think about that' (**Ann**).*

*It's there [emotions regarding the ES and aftereffects], locked away. Don't open the box. Don't let the floodgates open (**Helen**).*

For these respondents, energy appeared directed to keep intense discomfort away, framed as an injunction to the self. Ann's repetition suggested panicked efforts, and Helen's use of metaphor: a “box” and “floodgates” implied that emotions felt or expressed may be overwhelming, uncontrollable and unsafe.

Sally and Mary made no reference to avoidance, rather they spoke about their active engagement with faith in coping post-ES, and the strength derived from belief in a greater being, for example:

*... We [Mary and the ICD recipient] pray a lot because we know that we can't cope with this on our own... We need help from a strong source, a divine source and that keeps us strong enough to get through challenges like that (Mary).*

### **3.3.2. An isolated experience, and being overlooked in the provision of support**

This subtheme attempted to capture the sense of isolation, which, to varying degrees, was compounded by experiences of being overlooked in the provision of professional support when trying to cope post-ES. The sense of isolation was relevant for all partners and appeared to be experienced for several reasons, notably the inability to relate to others with the same experience:

*I don't know many people with them [ICDs]... nobody I really know that's witnessed one [ES] and how they feel about it... and whether their reaction is the same as mine (Ann).*

This lack of opportunity to relate to others who had witnessed an ES made it difficult to locate/align experiences externally and compare responses to establish their normalcy or uniqueness. A further contributor to the sense of isolation were difficulties sharing experiences with a partner:

*... I would never speak to my husband about it [the ES] because... it would just depress him or- or- make him feel unsafe... My son and daughter, I wouldn't burden them with it. I'm sure I'll cope... (Ann).*

Ann actively censored her experiences to avoid burdening her partner and wider family, and to maintain their wellbeing. Whilst Ann appeared stoic, Helen appeared more frustrated:

*... But he [ICD recipient] won't talk at all about how I feel about it or how he feels about, you know, these continuing problems [ongoing impact of the ES]. He won't talk about it... He just shuts off (**Helen**).*

Here, Helen also alluded to isolation in having to keep her thoughts and feelings within, and she later noted that she felt “let down” due to her hopes of reciprocity within her marital relationship being unmet.

Mary's experience was somewhat different to the other partners:

*... Occasionally we [Mary and the ICD recipient] talk about it, like I said, [as] a bit of a landmark in our relationship... We don't walk away when things get bad, that- it brings us closer together (**Mary**).*

Rather than experiencing isolation from her partner, Mary described discussing the experience with her husband as a shared experience between them, with positive impact; it increased the closeness of their relationship. However, whilst a sense of coupledom increased, Mary struggled with feeling isolated from her family, and lacking the support she might have expected:

*... We didn't get any, erm, support from our family. We were kinda left to get on with it and we struggled with that... because that was the one thing that we felt would have helped us get through this [ES and aftereffects] (**Mary**).*

Isolation could be magnified further by respondents' needs being overlooked by professionals. For example, Ann and Helen explicitly reported that additional support had not been offered to them:

*There wasn't anything. Nobody ever asked me (**Ann**).*

*... Help was never offered... It would have been nice to be asked and then have the choice (Helen).*

In addition, Kevin and Louise highlighted their experiences of support being offered to the ICD recipient whilst they were overlooked:

*... Everything, quite rightly, centres around them [the ICD recipient]... but there's gonna come a point where I'm gonna have to look after her... but no one tells you how to do that... (Kevin).*

*Sometimes it would be nice if you could have somebody, like, there is always the support for the person going through it [ES], and whether it be support from a- a counsellor point of view or just knowing how other people deal with it... (Louise).*

Kevin's quote suggested that he felt professionals had failed to provide him with the advice/direction he desired to support him in caring for his wife. Louise contrasted the availability of support for the ICD recipient and herself as the partner; she felt that support for herself was lacking and that she would have benefited if it had been offered. Furthermore, Louise's wish to know how other partners cope with experiences of ES appeared to express a desire to overcome the isolation of the experience resulting from the inability to relate to others, as noted previously. Although Louise did seek private counselling sometime after the ES, she felt overlooked again:

*...I stopped [counselling] in the end because I just, kind of, felt like she [counsellor] was putting all the emphasis on me fixing him [ICD recipient] and I couldn't do that. I needed to find a way of fixing me (Louise).*

In this quote, Louise described a further experience of professional support being directed towards the ICD recipient, rather than herself. This appeared to

emphasise her ES experience being overlooked, and she may have felt doubly burdened and impotent by the counsellor's expectation that she would offer support to, and 'fix' her partner.

### **3.3.3. Determination: "There isn't a choice"**

Despite the expressed difficulty in coping and perceptions of isolation and insufficient support, as noted in the previous two subthemes, all partners except Mary and Helen explicitly expressed determination; through their use of imperatives they appeared to perceive that coping with the ES and its aftereffects was their only option.

*... People would just say "oh my gosh, how did you deal with that", like "how do you cope with that?", and it's like, well, you just- you just have to. There isn't- there isn't a choice (Louise).*

Louise's response suggested a position of forced coping with the ES and its aftereffects but she remained determined to cope ("you just have to [cope]"). Kevin described his experience comparably:

*... This is where I am, this is where we are, this is what we've been dealt with. We just deal with it and move on. I mean, what option have you got?... You just deal with it, get on with it... (Kevin).*

Here, Kevin took stock of his circumstances having experienced the ES. Like Louise, he also expressed being in a position of forced coping, as well as his determination to "deal" with and "move on" from the ES and its aftereffects. Again, Sally touched upon the position of forced coping:

*He's had done what they can do [heart surgery]. So, until something else happens, which I'll deal with at the time, we will- we will continue with our life as best we can... There's no other option. We can't just live in waiting for something or- so, we just carry on (Sally).*



Although Sally appeared to take some reassurance from her husband's surgery, her use of language suggested that she was expecting his health to deteriorate at some point in the future. Despite this, Sally expressed determination in stating that she will continue to live her life, trying to remain in the present by managing difficulties as they arise, rather than living in anticipation.

### **3.4. Living and growing**

The final superordinate aimed to capture the experiences of partners as they appeared to progress to a position of living with (adjusting) and, in some cases, growing from the experience of ES.

#### **3.4.1. Time heals**

For Kevin, Mary and Louise, time appeared to be an important factor in their adjustment to the ES. Kevin noted:

*I've come to a point now, after this time, that I've accepted that what's happened, happened (Kevin).*

Adjustment seemed to be closely related to the diminishing potency of the past (difficult memories regarding the ES) and future intrusions (worries about another ES) on the present. Mary and Louise commented on the enduring, but reduced impact of their experiences over time:

*... Once you've had that experience [ES], I don't think it ever leaves you, but it subsides a bit (Mary).*

*... The vision of what had happened [ES] doesn't ever go away. I guess [with] time you- you don't forget it, it just doesn't seem quite so raw... I don't think the storms are that forefront of your mind now to stop you from doing things" (Louise).*

Time appeared to modulate the immediacy of the ES and, as Louise noted, a more normal level of activity seemed to resume. Kevin more explicitly suggested that he felt a period with no further ICD activity reduced likelihood of further activation, diminishing prominence of fears regarding future shocks and affording an opportunity to settle in the present.

*... You start getting a bit more relaxed about it [possibility of another ES]. The more time goes on, you get it in your mind set that you're starting to think 'well, it's [further ES] probably not going to happen now'... (Kevin).*

The passage of time also appeared to afford partners the opportunity to reflect on the ES (and ICD) at a time when their concerns and emotions were less intense. Temporal distance was acknowledged by all partners to contribute to a more nuanced appreciation of the ES and ICD. For example:

*... It sounds weird but it just makes me feel probably, although at the time I'm worried and panicking, it makes me grateful. That sounds ridiculous but because I'm grateful (slight laugh) that the machine [ICD] is doing it's- it's job and it's keeping him alive... (Helen).*

Helen appeared to grapple with her previous constructions of the ES as threatening having evolved to a position where the device had explicit life-saving benefit. Her humour may reflect surprise that she could reach such a position of grateful acceptance.

However, gratitude for the life-saving capacity of the ICD/ES did not imply that respondents were always reconciled to the device. Ann and Sally both discussed the potential for the ICD to disrupt the peaceful deaths of their partners. Sally reported professional experiences of ICDs and end-of-life care, and appeared quite pragmatic in her stance:

*... If he has a massive stroke, don't resuscitate, you know, make sure the defibrillator's turned off, otherwise... you're not gonna have a dignified death (Sally).*

Alternatively, the prospect of potential excessive shocks at the end of life seemed to be a significant worry for Ann:

*... If it happens again and- and he's beyond bringing back, am I gonna witness this- this shaking and- and jumping? ... 'Cos I think that would be quite- quite- not a very nice thing to see when you're losing somebody. Rather than a peaceful going, you know, it would be a bit- I don't know- it would probably stay in your mind a long while... (Ann).*

In invoking imagery from her previous experience and fearing that this would undermine her capacity to cope with her partner's death, Ann appeared to remain troubled by her experience of ES.

#### **3.4.2. Learning from the experience, and increased confidence**

Four respondents described their experience of ES as conferring confidence in managing a further ES should it occur. Sally and Ann explained:

*... If it does happen again I'm not going to be frightened in the same way because I will know what's happening... and I know the first time it goes off [ICD activates], I will be straight on the phone (Sally).*

*... I've seen it- done it once, so I can do it again. I perhaps know a bit more this time, perhaps I'll be a bit quicker to ring [999], or perhaps I'll be- be more- not quite so shocked by it because I'll know what it is (Ann).*

Both Sally and Ann reflected on greater understandings of ES and appeared to take comfort from this. They anticipated better coping than their previous

emotional responses and practical management, with actively planned and focused strategies.

Mary did not share specific strategies, rather an understanding that the experience of ES afforded greater self-awareness of her capabilities that should permit her to cope if ES recurs.

*I could probably tolerate more because of what I've been through and what I understand about myself 'cos it's made me stronger. I can cope with that again [another ES] because I understand it (Mary).*

### **3.4.3. Longer-term impact on the couple relationship**

Four respondents explicitly reported that the ES had longer-term consequences for their marital relationships. These could be experienced as positive because experiences had been shared:

*We just felt (...) a stronger bond if you like because- because of going through that experience together. I suppose we valued each other a lot more as well (Mary).*

*We're definitely closer... I think we appreciate each other more than we perhaps did... I appreciate our time together... We go away at weekends and things. We never did that before. I think it's just the realisation of, your time isn't infinite (Kevin).*

As noted by Mary and Kevin, experiencing the intensity of the ES and its attendant challenges alongside one another appeared to enhance togetherness and mutual appreciation within some couples. Furthermore, as noted by Kevin, a greater appreciation of mortality prompted a re-prioritisation of activities so that more could be shared. However, longer-term impacts on the relationship could be more equivocal as, whilst it prompted realisation about the feelings for the other in the

relationship, different modes of addressing the experience could be felt as divisive:

*It's brought us closer because maybe I'm not as demonstrative as some partners are so it's probably made him realise how much I do care and love him, but then in- in some ways it- it's also, kind of emotionally maybe, driven us apart because he can't talk about it... (Helen).*

This divergence was further emphasised by Helen:

*... [The experience] made us [partner and ICD recipient] take two, almost parallel paths, but maybe not quite meeting on occasion (Helen).*

## **4. Discussion**

### **4.1. Summary of research findings**

The current study aimed to explore the ways in which partners of ICD recipients experience ESs during and after the episode. Six partners described their experiences, which were analysed utilising IPA. Four superordinate themes were identified, interpreted as being experienced as a process whereby partners progressed from the ES episode to a position of greater adjustment. The superordinate themes were: 'Feeling overwhelmed during the ES (all at sea)', 'Challenges in post-ES adjustment', 'Trying to cope (not being becalmed)', and 'Living and growing'.

### **4.2. Theory and literature links**

Due to the absence of literature exploring the experiences of partners who have witnessed an ES, findings are considered alongside research exploring partner experiences of ICDs more generally, and the wider health literature.

#### ***4.2.1. Feeling overwhelmed during the ES (all at sea)***

Quantitative research exploring whether isolated ICD shocks negatively impact the emotional wellbeing of partners is inconclusive.<sup>18</sup> Although the current study did not measure emotional wellbeing, respondent accounts suggest that their experiences of ES (witnessing multiple shocks over the course of minutes and hours) were distressing and overwhelming.

Consistent with research exploring the experiences of partners and significant others (commonly partners) witnessing acute cardiac<sup>32,33</sup> and critical life events,<sup>34-36</sup> respondents reported the experience of numerous emotional and cognitive stressors during the ES, which appeared to act synergistically and contribute to distress and feeling overwhelmed. Notably, respondents disclosed their difficulty in witnessing a traumatic event, making sense of the sudden ES and its trajectory, their lack of psychological preparedness, and feeling impotent to support their partner. Moreover, respondents' apparent sense of feeling overwhelmed seemed to be compounded by their sense of responsibility to suppress their emotions to

mitigate partner distress. Such experiences echo the Cognitive Transactional Perspective's<sup>50</sup> account of situational factors that provoke stress: encountering a novel, unpredictable, and ambiguous event with no temporal constraint. Furthermore, from this model it is suggested that ESs may be experienced as more distressing than isolated ICD activations given the ambiguous, particularly regarding duration and frequency, and enduring nature evident in multiple shocks. However, further research is required to substantiate this hypothesis.

#### ***4.2.2. Challenges in post-ES adjustment***

In addition to the ES being significantly difficult for partners at the time, all partners shared their experiences of multiple post-ES challenges. Several partners described challenges when engaging with the health service: oscillating emotions, experiences of uncertainty, and reduced agency. Such experiences seemed related to limited information regarding the ICD recipient's medical care and, in some cases, delays in medical procedures. Although respondents appeared to suggest that their uncertainties could be addressed, and their agency improved through the provision of information and involvement in medical discussions, this rarely occurred. Limited communication and information provision, and associated anxieties have been noted following other cardiac conditions<sup>26,51</sup> and ICD implantation,<sup>27</sup> and may be indicative of service pressures resulting in resources not stretching to partners.

As is the case following ICD implantation,<sup>52-54</sup> new and challenging roles were reported by respondents following the ES; additional practical and emotional responsibilities, including holding emotions to mitigate partner distress, were adopted. These roles may be pragmatic and meaningful but have significant costs as, similar to studies exploring ICDs more generally<sup>26,55</sup> and wider physical health conditions,<sup>56</sup> some partners appeared to experience increased emotional and physical burden. The adoption of additional roles may result in poorer physical health,<sup>21</sup> as well as perceived inequity, which has been associated with increased caregiver burnout, low mood, feelings of resentment and poorer relationship quality.<sup>57,58</sup> Moreover, the adoption of roles by partners may inadvertently reduce

the independence and confidence of the ICD recipient.<sup>59</sup> Therefore, it appears important for the couple to find a balance in the roles undertaken post-ES.

Kevin, the sole male respondent, expressed concern that his longer-term caring role might be usurped by the ICD and the problem-solving meaning of his caring role, as well as his control/leadership over the delivery of care, would diminish. In contrast, the female respondents reported struggles adopting additional roles, which were often emotionally-oriented. This may echo gender differences in responses to caring, with masculinity and its attendant strategies (problem solving and taking control)<sup>60</sup> challenged rather differently. However, as this finding has not been identified previously in ICD literature, it is unclear as to whether it is unique to this sample.

Another apparent post-ES challenge concerned difficulties living in the present. Consistent with wider cardiology and ICD literature, reports of past intrusions (upsetting/distressing memories)<sup>26,53</sup> and future intrusions (worries regarding further ESs, leading to hypervigilance and lifestyle modifications to limit risk)<sup>27,53,61</sup> on the present were noted. As such intrusions are considered within DSM-5 PTSD symptomology<sup>37</sup> this may suggest that partners experienced the ES as a traumatic event and may have experienced PTSD in the aftermath. Although the findings of the IES-R contradict this hypothesis (only one participant scored above the suggested PTSD cut-off score), scores may have resulted from the measure being completed some time after the ES (average of approximately 2 years) where symptoms associated with PTSD may have reduced.

Lastly, partners appeared to be holding a dilemma in that they experienced the onset of ESs occurring without obvious precursor or warning, yet they were hypervigilant to warning signs and made lifestyle changes, hoping to reduce the risk of further ESs and increase preparation should one occur. Hypervigilance may negatively impact the partner, and restrictions to activity may reduce the emotional wellbeing and QOL of both the partner and the ICD recipient. In more extreme cases partner protectiveness, including restriction of activities, may cause



ICD recipients to feel trapped, resulting in negative repercussions for the relationship in the form of altered communication, and feelings of frustration and anger.<sup>62</sup>

#### ***4.2.3. Trying to cope (not being becalmed)***

Resources, both personal and external, to cope with the ES and its aftereffects were largely noted by their scarcity. Similar to spouses of myocardial infarction (MI) patients,<sup>63</sup> respondents' personal resources appeared to be avoidance-oriented,<sup>64</sup> which may suggest that experiences of the ES and aftereffects remained too painful and risky to engage with. Avoidance can be an appropriate stress reaction but longer-term reliance can lead to poorer adjustment,<sup>63</sup> and cognitive avoidance has been shown to predict anxiety and depression following negative life events.<sup>65</sup> Therefore, it seems important for partners to develop a repertoire of coping strategies. Furthermore, the use of avoidance is also a feature of PTSD symptomology,<sup>37</sup> which supports the previous suggestion that respondents may have experienced the ES as traumatic and may have experienced PTSD following the event. Although, this suggestion has not been verified through adequate testing.

Also congruent with partners of MI patients,<sup>51</sup> respondents appeared to experience a sense of isolation in their experiences following the ES. For some, this partly resulted from an inability to meet or relate to others who had also experienced ESs. This relating and evaluation, which can be affirming and enriching, is a key facet of social comparison theory. Without a relatable subject for comparison (someone who has witnessed an ES) respondents may struggle to fully incorporate understandings of their ES experiences.<sup>66</sup> Indeed, some respondents did directly express desires to compare their experiences of, and responses to, the ES with relatable others.

Lack of external resource and isolation for many partners appeared magnified by limited communication of experiences between the couple. For most respondents, this appeared to emerge from wanting to avoid upsetting the ICD recipient by

sharing their thoughts or feelings, as well as there being the potential for more latent concerns not to provoke further ICD activation by distressing their partner. Such findings,<sup>52,54</sup> as well as the finding that partners may inhibit strong emotions more generally for fear of causing ICD activations, are evidenced in earlier research.<sup>67</sup> Moreover, consistent with previous research exploring ICD implantation,<sup>27</sup> Helen appeared to experience communication barriers stemming from the ICD recipient's unwillingness to discuss the ES and its aftereffects, which contributed to an apparent sense of isolation, as well as some marital difficulty (see following subsection).

The sense of isolation disclosed by respondents was also framed in relation to feeling overlooked when engaging with professionals. As this has previously been noted by partners following ICD implantation,<sup>26,27</sup> there appears to be a wider lack of provision for partners. As suggested previously, this may result from services not having the resources to extend support beyond the patient.

Despite the noted limitations in personal and external resource, some partners explicitly expressed their determination to cope with their unchangeable circumstances, and all partners appeared to move towards a position of greater adjustment, as described in the following subsection.

#### ***4.2.4. Living and growing***

Time without further ICD activation was a dominant narrative in aiding relative equanimity with the device. Over time partners appeared better able to live in the present, which may suggest the assimilation of the ES (a potentially traumatic event),<sup>68</sup> and appeared to be more accepting of the ICD and ES. Respondents' scores on the IES-R at the time of interview may support the suggestion of assimilation as only one recipient met the cut-off for PTSD. However, this is speculative as PTSD symptoms were not assessed at a previous time-point for comparison (it may be that partners did not experience PTSD symptoms at all). Although this is unclear, the findings are consistent with research indicating that partners become more adjusted to the fitting of the ICD and appraise the device

more positively following time without activation.<sup>26,27,52,54</sup> Despite this, concerns regarding the ICD at end of life remained for some respondents in the current study.

Longer-term impacts of the ES on the couple were noted by several respondents. Consistent with research into partner experiences following ICD fitting,<sup>26,27</sup> some partners described increased coupledness, whereas Helen reported divergence between her and her partner's experience and relationship. Research has identified that marital adjustment is reduced when couples are incongruent in their coping strategies to manage chronic illness.<sup>69</sup> This may explain Helen's experience of divergence as it appears she and her partner may have adopted different coping strategies; she wished to discuss the ES on occasion whereas her partner was less willing to do so. Thus, it appears the alignment of coping strategies and the communication of experiences have important influences on couple functioning, and potentially recovery from ESs.

Lastly, four participants seemed to describe learning from their experiences of ES and feeling more confident in their ability to manage further ESs should they occur. This is similar to the findings of Flurr et al.,<sup>27</sup> where partners reported that their experiences of isolated ICD activations resulted in the ICD becoming more integrated into their lives and improved their confidence in managing any further activations. It appears that first-hand experiences, although challenging, afforded partners the opportunity to develop a fuller understanding of what it is like to experience ESs as a partner and provided a greater awareness of their capacities to cope. Therefore, resulting in feelings of greater preparedness should another ES occur.

#### **4.3. Clinical implications**

The current study offered a detailed insight into the experiences of partners who had witnessed ESs. Partners found the ES distressing and overwhelming, and experienced challenges when trying to manage the ES aftereffects. Although partners appeared to adjust over time, healthcare services have a role to support partners in this venture.

Furthermore, as research has identified that partner coping can influence patient coping,<sup>15,17</sup> supporting partners may have the secondary benefit of improving the adjustment of ICD recipients experiencing ESs. Therefore, the following recommendations are suggested:

#### ***4.3.1. Adequately preparing the partners of ICD recipients***

To go some way in countering the apparent contributors to the overwhelming and distressing nature of the ES, partners may be provided with information regarding ESs at the point of ICD implantation. It may be beneficial for such information to acknowledge the possibility of ESs, and explain what an ES is, what the partner might witness and how they should respond. As some participants in the current study, as well as participants in wider studies,<sup>26,27,52</sup> reported that they received limited and/or inconsistent information and advice regarding ICD shocks and how to respond (e.g. whether they could touch the ICD recipient during an activation/shock), information provided should be comprehensive, consistent and based on the most up-to-date research. Moreover, it would be helpful for such information to be provided through direct discussions with healthcare professionals as this would allow sensitive delivery of information and provide an opportunity for questions. Further information could be provided via written material.

#### ***4.3.2. Involving and empowering partners post-ES***

To reduce the sense of uncertainty and impotence experienced following the ES, information regarding the ICD recipient's care and prognosis may be regularly shared with the partner, and partners could be involved in recipient care more directly where possible (e.g. during discussions, attending follow-up appointments and engaging in cardiac rehabilitation programmes<sup>70</sup>). It would also be beneficial for partners to be provided with information regarding ESs and opportunities to discuss end of life care.<sup>27</sup>

#### ***4.3.3. Provision of post-ES support***

The current study, and associated literature, suggests that partners receive limited

support following ICD related matters (fitting, isolated shocks and ESs), which could be addressed. Focusing on ESs, it may be beneficial for professionals to assess the wellbeing and coping of partners following ESs, and again at later time-points where partners may be encountering difficulties in adapting to new roles. Furthermore, as they featured in partner experiences, it may be beneficial to assess for the presence of PTSD symptoms and avoidant coping strategies.

Support should be offered to partners as required. Psychoeducation, which has demonstrated positive outcomes in supporting couples following cardiac surgery,<sup>71</sup> could be offered by frontline staff and, where indicated, partners should be signposted to further support. Individual therapy, perhaps including Mindfulness,<sup>72</sup> Trauma Focused-Cognitive Behavioural Therapy (TF-CBT) and/or Acceptance and Commitment Therapy (ACT),<sup>73</sup> may be useful. As communication of experiences appears important but may be difficult, consideration could also be given to the provision of a facilitated space where couples can hopefully feel safer in sharing and processing their experiences of ES.

Support could also be offered through the delivery of ES support groups, attended ICD recipients and partners. Such a modality has several potential advantages: they are more cost-effective than individual therapies, they provide an opportunity for peers to share experiences, understandings and learnings, which may reduce the sense of isolation noted by many participants, and support networks between couples may form outside of the group setting, again reducing isolation.<sup>74</sup>

Areas of focus may include: the delivery of therapeutic concepts and practices such as those noted previously, developing coping strategies and problem solving skills, encouraging a balance between the support offered to the ICD recipient and self-care, dispelling any myths about the ICD and causes of activations to encourage engagement with activities, and developing communication within the couple. Furthermore, it may also be beneficial to offer partners private space to share any concerns that they do not wish to discuss with/in front of the ICD recipient or other family members.

#### **4.4. Strengths and limitations**

The current study appears to be the first investigation into the experiences of partners who have witnessed an ES, and there is a general dearth of research exploring partners' responses to ICDs and isolated ICD shocks. The adopted methodology, IPA, is an established method of analysis and permitted the detailed exploration of partners' experiences. The findings of the study can be applied to clinical practice, enhance the literature base, and can be used to inform further, much needed, research.

To promote study credibility the principles of transparency were adhered to;<sup>47</sup> the researcher's epistemological position, matters relating to study quality and rigour, a statement of reflexivity, participant quotes, and examples of transcript coding and an extract from the researcher's reflexive diary have been provided.

Homogeneity of samples is deemed to be important when adopting an IPA methodology.<sup>40</sup> There were some demographic differences amongst the sample: one of the six participants were male, one participant witnessed multiple distinct episodes of ES, and there were participant variations in terms of length of time since ICD implantation, length of time since ES occurrence, length of relationship and length of time living together at study participation. However, the ages of the participants were similar and the reported experiences of ESs were largely homogeneous across participants: all participants were immersed within the experience (they were in a relationship at the time of the ES, witnessed the ES, and lived with the ICD recipient following the ES), all ESs were medically appropriate (ICDs delivered corrective shocks/discharges), and all ESs involved the delivery of multiple shocks within a short space of time (minutes and hours).

Overall, the sample differences did not appear to significantly influence study findings as there were consistencies in the accounts, subthemes and superordinate themes noted across participants with, as would be expected, some nuances in participant experiences (see Appendix Q). However, the inability to achieve an entirely homogenous sample in terms of gender appeared to have some bearing on the findings as the experiences of the sole male respondent when experiencing 'challenges in post-ES adjustment' differed to

that of his female counterparts. That is, the male participant appeared to struggle with a loss of roles, compared to females who encountered difficulties in adopting additional roles (see sections 3.2.2 and 4.2.2).

Although IPA does not strive to obtain generalisable results, it is worth highlighting that due to the homogeneity of the sample, the results may not be generalisable to partners differing to the current sample. For example, the participants in the current study were predominantly White-British, female and fell within the '55-64' years old age bracket. Moreover, the findings of the current study may have resulted from the fact that all ESs were a result of appropriate shocks and, on average, a considerable amount of time had passed since the ESs (approximately two years).

Although the method of analysis was consistent with an IPA approach, study credibility could have been improved if the analysis was co-conducted and triangulation could occur.<sup>75</sup> Although this was not possible due to constraints, the researcher consistently reflected on the analysis and sought guidance through supervision and peer group discussions to promote credibility and rigour.

#### **4.5. Recommendations further research**

The current findings highlight the importance of understanding the experiences of partners who witness an ES. As there is a dearth of research investigating the impact of ESs (and isolated shocks) on partners, further research is recommended in order to improve the literature base and inform clinical practice.

Based on the findings of the current study suggestions for further research include additional exploration of: the impact of ESs on the wellbeing of partners (quantitative studies may wish to measure psychological morbidity, including PTSD symptoms), the difficulties in coping experienced by partners post-ES (quantitative and qualitative studies may explore QOL and caregiver burden), factors surrounding coping and adjustment in partners, associations between couple communication and outcomes such as coping, adjustment and emotional wellbeing, and potential influences of gender and gender roles on experience and coping.

As previously noted, the homogeneity of the sample reduces the generalisability of the results. Conducting quantitative studies with partners experiencing ES and further qualitative studies with partners representing different characteristics (e.g. a younger and/or male sample, different time periods between the ES event and study recruitment) would go some way in addressing this limitation. Moreover, the current study sampled participants who had witnessed ESs resulting from appropriate ICD activations. It would be interesting to investigate whether partners have similar or different experiences when ESs arise due to inappropriate activations, such as device malfunction.



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### **PART 3: Critical Appraisal**

## **1. Introduction**

Within this section I will offer personal and professional reflections from my experiences of completing the research project, as well as offering critiques of the research. This section has been informed by the use of a reflexive diary, which was completed throughout the research process.

### **1.1. Study design**

#### ***1.1.1. Choosing a research topic***

Although I have no direct personal or professional experience within the field of cardiology, I developed an interest into the impacts of wider physical health conditions on psychological wellbeing during my experiences of working as a Trainee Clinical Psychologist within a medical psychology setting. Furthermore, during my clinical psychology training I have also developed an interest in systemic theories and family processes. With these interests in mind I met with my research supervisor to discuss potential research options.

Amongst discussions of research ideas, my supervisor shared her knowledge and experience of working with couples in distress due to one partner having experienced an electrical storm (ES; three or more device activations/shocks within 24 hours) from their implantable cardioverter defibrillator (ICD).<sup>1</sup> I found this contradiction fascinating; the device could have great physical benefits (potentially lifesaving) but have significant psychological costs to both members of the couple. I then carried out a literature review of the topic area and identified that there was a dearth of research exploring the impact of ICD implantation and isolated activation on partners,<sup>2</sup> and that there was no research into the impact of ESs on partners.

Addressing this gap in the research, by investigating the impact of ESs on the partners of ICD recipients, seemed important as anecdotal information and the available, albeit limited, research into the impact of ICDs more generally suggested that partners experiencing ESs may suffer considerably. My interest in

this area and my feelings regarding the importance of the study increased further when I liaised with members of staff from a regional Cardiac Rhythm Management Team.

### ***1.1.2. Choice of methodology***

The main reason for adopting a qualitative approach was its suitability to the research aims. The research project was interested in exploring the experiences participants, which aligns with qualitative research approaches. Furthermore, an inductive (bottom-up) approach appeared to be a more suitable considering the lack of research in the literature base. Another reason for the adoption of a qualitative methodology was my interest in the approach. I feel that one of the most important skills that clinical psychology can offer is the expertise in clinical formulation: developing a detailed understanding of people's lives and their difficulties. I felt that a qualitative approach, privileging ideography, would be most akin to this.

When deciding on the type of qualitative design and analysis to use, several options were considered before Interpretative Phenomenological Analysis (IPA) was adopted. IPA was selected as it was felt to better align with the research aims/questions than other methodologies. For example, IPA was preferred over Grounded Theory (GT) as the research project intended to adopt a strong idiosyncratic focus and aimed to explore the nuances of participant experience (objectives of IPA), rather than aiming to generate a broader 'theory' of the studied phenomenon (an objective of GT<sup>3</sup>).

Although I had some basic knowledge of IPA, I learnt a great deal more about the underpinnings of the approach through the reading I undertook when selecting a methodology. Developing my understanding of the principles of phenomenology, ideography and hermeneutics confirmed that this was the approach I wanted to utilise. Such principles were consistent with my epistemological position of a critical realist (Appendix E), I saw value in the concept of the 'double hermeneutic'<sup>4</sup> and the importance of reflexivity and transparency, and I felt that

the ideographic and phenomenological nature of IPA could provide a rich account of the research topic and therefore inform the limited literature base.

### ***1.1.3. Developing the interview schedule***

This research project was my first experience of designing and conducting a piece of qualitative research. I developed an interview schedule based on the recommendations of Smith et al.,<sup>4</sup> by considering previous IPA research, through research supervision, and through liaison with professionals working with ICD recipients and their partners. I feel that not having any personal or professional experience of ICDs or wider cardiac difficulties minimised my assumptions and biases somewhat, and that I was able to put assumptions attained through the reading of relevant literature (e.g. what I may expect to find if my study was to elicit participant experiences consistent with previous research) to one side.

I designed the interview schedule so that the first question provided a context to the interview, an opportunity to build rapport and space for the participant to settle into the interview (“please can you briefly describe the circumstances leading up to the fitting of your partner’s ICD?”). I felt that beginning the interview by asking the participant ES related questions would have been unhelpful as the experience may have been more distressing. My following questions aimed to explore the participant’s experiences at the time of the ES (e.g. “your partner has experienced X episode/s of electrical storm. Please could you describe your experiences?”) and following the ES. Then my questions towards the end of the interview aimed to summarise the previous, open-ended questions (e.g. “have there been more difficult/challenging aspects...?” and “have there been more positive aspects...?”).

I reflected on this design several times prior to my first interview. I realised that my schedule was quite structured and reflected that this was a result of my anxieties about undertaking research interviews (a new experience) and feeling anxious that I might not achieve good quality data. I decided that I would feel most comfortable continuing with the schedule as it was but considered that I

would not focus too much on the summary questions. This proved to be the case in the first interview where I realised that I was obtaining a lot of data from my initial questions and I quickly ran out of time to ask the summary questions. Following the first interview I further reflected on my interview schedule and the summary questions took more of a prompt-like status in subsequent interviews.

Although I don't feel as though the interview schedule unduly impacted the interviews, it would have been helpful to have been able to conduct a pilot interview to enable the trial and reflection of the interview schedule prior to data collection. Should I undertake further qualitative research I would aim to develop a schedule that is less structured, and having conducted this piece of research I believe that I would feel more confident in doing so.

## **1.2. Ethical considerations**

This research project provided my first experience of being the lead applicant for ethical research approval. Overall, I found the process quite confusing and overwhelming, which was worsened by the fact that new application processes were being implemented (submission of protocols and documents to the Health Research Authority (HRA) and NHS Research and Ethics Committee (REC)). As such processes were new it was, understandably, difficult for others to provide comprehensive guidance. Furthermore, the change in application procedures, a high volume of applicants, and the requirement for me to amend my protocols and participant documents resulted in considerable delays in obtaining ethical approval, and subsequently delayed participant recruitment.

Although the ethical approval process was challenging, I also found it informative and a good developmental experience. I now feel like I am more familiar with the process of completing and submitting ethical applications, and more aware of the ways in which research can, and should, be conducted ethically. My key learning points from the application process include: identifying and making contact with relevant parties earlier, initiating the ethical approval process earlier and allocating more time for ethical approval, and, as I sometimes got confused, keeping more detailed records of key contacts and processes as I progress through them.

Regarding ethical considerations during the study, I remained vigilant to ensuring that the ethical principles outlined in the proposals were adhered to. I was particularly conscious of the emotional wellbeing of participants as some participants became quite upset as they shared their experiences during the interviews. I attempted to appease such upset by pacing the interview appropriately, allowing time for participants to collect their thoughts and emotions, offering the opportunity for participants to take as many breaks as they required, and ensuring that participants were aware that they could terminate the interview at any point if they wished to do so.

Moreover, prior to the study my understanding of ethics very much focused on the practical aspects (e.g. ensuring that participants fully understood the study, informed consent was obtained and that participants were protected throughout), whilst neglecting the importance of record keeping, including the evidencing of ethical adherence. Through my experiences of this research project, I have become more familiar with the importance of good record keeping, especially as my study was randomly selected for a site monitoring visit. Although anxiety provoking, this experience afforded me the opportunity to reflect on my maintenance of the site file and the ethical considerations of the research project with individuals who are experts in this area.

### **1.3. Data collection**

#### ***1.3.1. Recruitment***

Recruitment was quite anxiety provoking as I was acutely aware of the need to recruit my sample within good time as I would need to allocate a considerable amount of time for transcription and data analysis. As previously noted, delays in ethical approval resulted in delays in starting recruitment, which initiated my anxieties. My anxiety was heightened as a result of a poor participant response rate over the Christmas period; I felt increasingly concerned that I would not reach my target number of participants in good time or that the target sample would be exhausted. I was relieved when I did meet my target quota but felt quite pressured during the data analysis stage as the setbacks meant that I was still transcribing and analysing some data later than I would have liked. Furthermore, ideally, I

would have recruited an additional participant so that I could use the initial interview as a pilot interview to experience the interview process and test the application of my interview schedule. However, time constraints meant that I needed to conclude recruitment.

The requirement to recruit a homogenous sample<sup>4</sup> raised some complications as I had a very small target sample, which meant there was little room for flexibility in recruitment. However, through liaison with the local collaborator, who identified and recruited participants, we considered that we could achieve homogeneity in terms of recruiting participants who had witnessed appropriate ESs, were in a relationship with the ICD recipient prior to the ES, and had lived with the ICD recipient since the ES.

As noted previously, in hindsight it would have been advantageous to initiate ethical applications sooner and allocate more time for ethical approvals. This would have avoided the delays in recruitment and related anxieties, afforded me more time to recruit participants in order to conduct a pilot interview, and reduce pressures felt during the analysis phase. Through recruitment I further developed my understanding of the service from which I was recruiting, and I was required to work collaboratively with members of staff from the recruitment site. This provided opportunities to liaise with the service manager and local collaborator, meet team members, present my study protocol, answer questions and receive feedback.

### ***1.3.2. Conducting interviews***

I attempted to remain open and curious during interviews; a stance which I am familiar with in my professional role. I also attempted to remain reflective throughout the interviews, trying to remain focused on my interview schedule and topics that appeared important to the participant, rather than leading the discussion in directions that I was biased towards (e.g. content that I perceived to be personally interesting, had read in the literature or had experienced in previous interviews). I feel that my learning and experiences of working within



psychodynamic psychotherapy, engaging with concepts such as undertaking therapeutic sessions ‘without memory or desire’,<sup>5</sup> supported me in achieving this.

One of the most challenging aspects of conducting the interviews was remaining within the role of a researcher. On several occasions, I noticed an urge to slip into the role of a therapist; wanting to paraphrase and offer reflections, especially when wanting to convey empathy due to participants becoming upset. Maintaining a researcher role was particularly challenging during the first interview and I recognised the possibility that adopting a therapist role might influence the direction of the interview. However, as I gained more experience of interviews I felt that I developed a better awareness of my urges to switch roles and was more able to control it. Again, this emphasised the importance of conducting pilot interviews and gaining experience prior to data collection.

#### **1.4. Data analysis**

##### ***1.4.1. Post-interview reflections***

Following each interview, I made an entry in my reflexive journal, noting any free-flowing thoughts, feelings and experiences I had during or immediately after the interview. Being busy with other commitments around the time of data collection meant that this was sometimes arduous and rushed. However, when it came to analysing the data I was glad that I had made efforts to record my reflections as they were helpful in structuring my thoughts. Furthermore, I used my reflections as a ‘quality check’ once I’d analysed all of the cases; comparing the emerging themes to my post-interview reflections allowed me to check whether the analysis had retained the material that I felt was most important at the time of the interviews. As this approach was helpful I would ensure I used it again in conducting further research. I would also allocate a period of time post-interview to ensure sufficient time is set aside to reflect fully and to avoid rushing the process.

### ***1.4.2. Free-coding of transcripts***

As recommended by Larkin and Thompson,<sup>6</sup> I printed two copies of each transcript. The first was used to free-associate, recording any thoughts or feelings, knowing that this work would not directly form the analysis itself. Although time consuming, I found this helpful. I felt less pressure to get it 'right', which enabled me to feel freer to write down anything that came to mind, it provided a method to actively engage with the data and increase my familiarity, and it enabled me to identify my personal assumptions and feelings, which I could then 'bracket' (put aside) more effectively when undertaking the actual analysis of the second printed copy.

### ***1.4.3. Developing emerging themes***

With this being my first experience of undertaking a qualitative study and my first experience of applying IPA, I spent some time attempting to prepare myself for the data analysis stage. Two written resources were particularly helpful,<sup>7,8</sup> as was the previous teaching I had received, my attendance to an IPA training session, and being involved in a peer-group with others who were undertaking IPA methodologies in their theses.

However, inevitably, data analysis remained a challenge and was sometimes overwhelming as an inexperienced IPA researcher. During the coding phase I found it helpful to remain close to Smith et al.'s<sup>4</sup> suggestion of breaking the coding down into descriptive, linguistic and interpretive codes. I found the latter quite difficult initially and felt as though many of my interpretive codes were quite descriptive in nature. With experience, I found that the most effective process was to go through the transcript coding descriptively and linguistically first, and then passing back through the transcript to code interpretively. Repeating this process multiple times, whilst considering the hermeneutic circle,<sup>4</sup> enabled me to code the data more fully and differentiate codes that were more descriptive and those that were more interpretive; thereby ensuring my commitment to interpreting the data and the double hermeneutic.<sup>4</sup>

I felt fairly confident in developing emergent themes within each transcript. Again, informed by the recommendations of Smith et al.<sup>4</sup> I ensured that I remained close to the data by re-reading the transcripts, reflecting on the hermeneutic circle<sup>4</sup> and my own assumptions, and collating examples (quotes) that represented the emerging themes. Creating tables of collated codes helped me to identify patterns within the data set and name emerging themes that appeared to best represent the groups of codes. As suggested by Smith et al.,<sup>4</sup> this involved processes such as sublimation, abstraction and polarization.

However, moving to cross-case analysis was particularly challenging due the culmination of data from each participant (some convergent and some divergent). Making sense of the participants' sense making at this level was quite overwhelming whilst also trying to remain mindful of not influencing the analysis based on my own assumptions. For example, I noticed that particular patterns within the data reminded me of findings of previous literature and it was important to reflect and ensure that my data were providing these patterns, rather than me seeking them out them based on my previous readings.

I attempted to gain some sense of control over the data by printing and cutting out all of the emerging themes for each participant (different colours) and spreading them out on the floor. Using distance as a visual representation I tried to establish the convergence and divergence of themes. This process was iterative whereby I would regularly return to my lists of codes, reflecting on how well they represented the themes, considering the appropriateness of theme labels, and reconfiguring accordingly.

I felt quite unconfident and uncertain throughout this process and I was reminded of a family therapy article, and model, regarding 'safe-uncertainty'.<sup>9</sup> This appeared relevant as I felt in a position of 'unsafe uncertainty' during my analysis and was aware that it would be more beneficial for me to embrace the uncertainty and adopt a position of 'safe-uncertainty'. Several of the principles within this position, although rooted in therapy, felt applicable to IPA and my analysis. For

example, trying to not understand too quickly, remaining respectfully curious and entertaining different possibilities.<sup>9</sup> It was also helpful to reflect on my analysis during research and peer group supervision. I felt that I developed greater familiarity with my data and analysis by talking through it, and I was able to consider the reflections of others. In hindsight, I feel that having the opportunity for triangulation,<sup>10</sup> and having more detailed reflections and interpretations of another, would have enhanced this.

### **1.5. Write-up**

I also found the write-up quite challenging as I encountered numerous conflicting pressures. I wanted to dedicate ample time to the write-up but earlier delays meant that my deadline was fast approaching. Part of me felt like I needed a much longer period of time to do the data justice and communicate it effectively, but another part of me acknowledged that I probably wouldn't ever feel completely happy with my write-up, and that I needed to reach a point where I felt content. Another significant pressure was finding a balance between giving all of the participants' a voice and maintaining the idiosyncrasies of the data, whilst also having to adhere to what felt like a very constraining word limit. However, to maintain idiosyncrasies I developed a frequency table (Appendix Q) to ensure participant representation. I also followed the recommendation of Smith,<sup>11</sup> which suggests that for a sample of 4-8 participants, each theme should include quotations from at least three participants.

### **1.6. Further learning points and conclusions**

Although I have undertaken research projects before as part of previous academic studies, this was my first experience of leading ethical applications and conducting a larger scale project with more autonomy than previously. Overall, the research project was challenging, and at times quite overwhelming. However, I feel like I have developed both personally and professionally as a result. Regarding personal developments, I feel like I am more resilient to manage stressors and multiple demands, my organisational skills have been tested and improved, and I have developed my skills in communication, liaison and presentation. The key learning points I have taken from this project include: the need to plan early, anticipate delays and remain organised.

Professionally, I feel like this research project has enhanced my understanding of research in multiple ways. I have a greater understanding and appreciation of processes associated with ethical applications and conducting research in an ethical manner. I have also developed my understanding and skills in conducting qualitative research more generally, and IPA more specifically. For example, conducting interviews and data analysis whilst considering principles related to phenomenology, interpretation, idiosyncrasies, and hermeneutics (and double hermeneutics).<sup>4</sup> Moreover, learning about and experiencing the double hermeneutic aspect of IPA afforded me the opportunity to hold a more reflective stance and consider the ways in which I may impact on the research process and findings, something that I had not fully considered previously. The research project also afforded me the opportunity to attend training events (Good Clinical Practice, Informed Consent and IPA), thereby developing my knowledge and skills.

Finally, undertaking this piece of research reminded me of the importance of research-practice links. As the area of study was under researched and the sample population (partners of ICD recipients) were often overlooked in the provision of support, it made me acutely aware of the importance of giving such individuals a voice through the identification of clinical implications, recommendations for further research and the dissemination of findings. Regarding dissemination, I intend to publish the findings in a peer review journal, develop a conference poster, feedback my findings to the service from which participants were recruited, and provide participants with a lay-summary of the research.

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## **PART 4: Appendices**

**\* = Mandatory appendices**

### **\*Appendix A: Intended journal guidelines**

#### **Aims:**

*The European Journal of Cardiovascular Nursing* is a peer-reviewed international journal dedicated to the advancement of knowledge in the field of cardiovascular nursing and the promotion evidence-based clinical practice.

The journal publishes original articles, short report reviews and editorials in order to improve the quality of nursing care for patients with cardiovascular disease. Original contributions on the broad field of cardiovascular nursing are welcome, including chronic and acute care, paediatric cardiology, grown up congenital heart disease, cardiac rehabilitation, primary and secondary prevention, heart failure, acute coronary syndromes, interventional cardiology, cardiac care, preventive cardiology, and vascular nursing.

Scientific contributions can be related to all aspects of care: education, research, patient care or organisational aspects. Additional contributions on epidemiology, physiology, pharmacology or psychology related to cardiovascular nursing are welcome.

#### **Guidelines:**

This Journal is a member of the [Committee on Publication Ethics](#)

This Journal recommends that authors follow the [Uniform Requirements for Manuscripts Submitted to Biomedical Journals](#) formulated by the International Committee of Medical Journal Editors (ICMJE)

**Article types:** The journal accepts original research, short reports and review articles.

**Original research:** The text should be arranged as follows: (1) Title Page, (2) Abstract, (3) Keywords, (4) Introduction, (5) Methods, (6) Results, (7) Discussion, (8) Implications for Practice, (9) Acknowledgments, (10) References, (11) Figures and Tables.

The maximum length for original research and review articles is **3,500 words**. The maximum length for a short report is 2,000 words.

**(1) Title page:** Please include the following:

*Title:* Concise and informative. Avoid abbreviations and formulae where possible.

*Author names and affiliations:* Where the family name may be ambiguous (e.g., a double name), please indicate this clearly. 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 telephone and fax numbers (with country and area code) are provided in addition to the e-mail address and the complete postal address.

*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 submit the title page separately to the main text of the article to facilitate anonymous peer review (see section 2.1 below).

**(2) Abstract:** An abstract (maximum 250 words) should be typed double spaced on a separate page. It should be structured and include background, aims, methods and results and conclusion.

**(3) Keywords:** No more than six keywords are required.

*Important note:*

*The title, keywords and abstract are key to ensuring readers find your article online through online search engines such as Google. Please refer to the information and guidance on how best to title your article, write your abstract and select your keywords by visiting the SAGE Journal Author Gateway for guidelines on [How to Help Readers Find Your Article Online](#)*

**(4) Introduction:** This section should position the study with regard to objective, rationale and preceding work of other authors.

**(5) Methods:** This section should contain a statement that "The investigation conforms with the principles outlined in the Declaration of Helsinki" (Br Med J 1964;ii:177). The methods section should be sufficiently detailed for repetition of the study by other scientists. If pertinent, the section may be divided into headed subsections.

**(6) Results:** If pertinent, the section may be divided into headed subsections. For presentation of data, figures are preferred to tables. Data should not be presented in both figures and tables. Also, extensive numerical data should appear in legends to the figures rather than in the main body of text. SI units should be used.

**(7) Discussion:** This section should deal with topics that are beyond the scope of the study, compare and interpret the data with regard to previous work by (other) authors.

**(8) Implications for Practice:** Please provide three to five key bullet points that summarise the implications of their paper for practice. The aim of these is to encourage others to use the findings in their daily practice of patient care, education or research based on the stated points. Please ensure each bullet is no longer than 50 characters. These bullet points will be published as part of the article.

**(9) Acknowledgments:** please refer to guidance in section 2 below.

**(10) References:** please refer to guidance in section 4 below.

**(11) Figures and Tables:** Figures should be designed in a way compatible with reproduction of one column width. Figures over two columns should be kept to a minimum. Tables should not contain data not mentioned in the text. Laser prints of good quality are sufficient for graphs and tables. Glossy prints are needed for micrographs, etc. Figure legends should start on a new page of the manuscript, but one page may contain legends to more than one figure.

**Short Reports:** These reports **should not exceed 2,000 words** and should consist of:

- Background section
- Abstract
- Methods
- Results
- Conclusion

The (maximum number of) 2,000 words may be allocated as you consider appropriate. The editorial team reserves the right to decide which tables/figures submitted are necessary.

### **Preparing your manuscript**

#### **Word processing formats**

Preferred formats for the text and tables of your manuscript are Word DOC, RTF, XLS. LaTeX files are also accepted. The text should be double-spaced throughout and with a minimum of 3cm for left and right hand margins and 5cm at head and foot. Text should be standard 10 or 12 point. Word and (La)Tex templates are available on the [Manuscript Submission Guidelines](#) page of our Author Gateway.

#### **Artwork, figures and other graphics**

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- Save text in illustrations as 'graphics' or enclose the font
- Only use the following fonts in your illustrations: Arial, Courier, Times, Symbol
- Number the illustrations according to their sequence in the text
- Use a logical naming convention for your artwork files
- Provide captions to illustrations separately
- Produce images near to the desired size of the printed version
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*Please do not:*

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A covering letter should include a declaration that "the manuscript, or part of it, has neither been published (except in the form of abstract or thesis) nor is currently under consideration for publication by any other journal". Secondly, the submitting author should declare that the co-author(s) has (have) read the manuscript and approved its submission to the European Journal of Cardiovascular Nursing.

## **Appendix B: Systematic literature review glossary of terms**

**Arrhythmia:** irregular heartbeat or abnormal heart rhythm.

**Atrial walls (atria):** The top two chambers of the heart.

**Fibrillate/fibrillation:** A shallow and fast rhythm, as the muscular walls contract in an irregular and uncoordinated fashion.

**Sinus node:** A cluster of cells responsible for maintaining the normal heart beat (**sinus rhythm**).

**Ventricle function (ventricles):** The main pumping chambers of the heart.

## Appendix C: Systematic literature review database search terms

Rationale	Database	Search terms
Systematic literature search for articles relating to the illness perceptions of atrial fibrillation patients.	The Cochrane Library. PsycINFO. PubMed. Scopus. CINAHL. Google Scholar.	<ul style="list-style-type: none"> <li>atrial fibrillation AND illness perception*</li> <li>atrial fibrillation AND perception*</li> <li>atrial fibrillation AND perceive*</li> <li>atrial fibrillation AND perspective*</li> <li>atrial fibrillation AND apprais*</li> <li>atrial fibrillation AND represent*</li> <li>atrial fibrillation AND belief*</li> <li>atrial fibrillation AND judge*</li> <li>atrial fibrillation AND depict*</li> <li>atrial fibrillation AND account*</li> <li>atrial fibrillation AND opinion*</li> <li>atrial fibrillation AND view*</li> <li>atrial fibrillation AND underst*</li> <li>atrial fibrillation AND attitud*</li> <li>atrial fibrillation AND cogn*</li> <li>atrial fibrillation AND distort*</li> <li>atrial fibrillation AND think*</li> <li>atrial fibrillation AND thought*</li> <li>atrial fibrillation AND meaning*</li> <li>atrial fibrillation AND somati*</li> </ul>
Search of 'grey' literature	Google.	<ul style="list-style-type: none"> <li>atrial fibrillation and illness perception*</li> <li>atrial fibrillation and perception*</li> <li>atrial fibrillation and perceive*</li> <li>atrial fibrillation and apprais*</li> <li>atrial fibrillation and represent*</li> <li>atrial fibrillation and belief*</li> <li>atrial fibrillation and view*</li> <li>atrial fibrillation and cogn*</li> <li>atrial fibrillation and distort*</li> <li>atrial fibrillation and think*</li> <li>atrial fibrillation and thought*</li> </ul>
Focused searching	Other	The reference lists of the reviewed articles were searched for additional publications.

## Appendix D: Systematic literature review quality appraisal ratings

Item	Gehi et al. <sup>32</sup>	Kang <sup>33</sup>	Kang & Bahler <sup>34</sup>	Kupper et al. <sup>35</sup>	Lane et al. <sup>36</sup>	McCabe & Barnason <sup>37</sup>	McCabe et al. <sup>48</sup>	McCabe et al. <sup>39</sup>	Ong et al. <sup>40</sup>	Steed et al. <sup>41</sup>	Suzuki & Kasanuki <sup>42</sup>	Thompson et al. <sup>43</sup>	Trovato et al. <sup>44</sup>
1. Question/ objective sufficiently described?	2	2	2	2	1	2	2	1	1	2	2	2	2
2. Study design evident & appropriate?	2	2	2	2	2	2	2	2	2	2	2	2	2
3. Method of subject/ comparison group selection or source of information/input variables described & appropriate?	1	2	2	2	2	2	2	2	2	2	1	1	1
4. Subject characteristics sufficiently described?	1	1	1	1	2	1	1	1	1	1	1	1	1
5. If interventional & random allocation was possible, was it described?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
6. If interventional & blinding of investigators was possible, was it reported?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
7. If interventional & blinding of subjects was possible, was it reported?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
8. Outcome & (if applicable) exposure measure(s) well defined & robust to measurement/ misclassification bias? Means of assessment reported?	1	1	1	2	2	2	2	2	2	1	2	2	2
9. Sample size appropriate?	2	2	2	2	2	2	2	2	2	2	2	2	2
10. Analytic methods described/ justified & appropriate?	2	2	2	2	2	2	2	2	2	2	2	2	2
11. Some estimate of variance is reported for the main results?	2	2	1	2	2	2	2	0	2	2	2	2	2
12. Controlled for confounding?	2	1	1	1	1	1	1	1	1	1	1	1	1
13. Results reported in sufficient detail?	2	2	2	2	2	2	2	2	2	2	2	2	1
14. Conclusions supported by the results?	1	1	1	1	2	2	2	2	2	2	2	2	2
<b>Total quality score (converted %)</b>	<b>82</b>	<b>82</b>	<b>77</b>	<b>86</b>	<b>91</b>	<b>91</b>	<b>91</b>	<b>77</b>	<b>86</b>	<b>86</b>	<b>86</b>	<b>86</b>	<b>82</b>

A rating of 2 was awarded if criteria were fully met, 1 if the criteria were partially met, and a rating of 0 if the criteria were not met. Items not relevant to the studies were not scored and marked as 'N/A'. See QualSyst (version for quantitative studies)<sup>29</sup> for additional scoring criteria.

## **\*Appendix E: Epistemological position**

The researcher adopted a critical realist position. Critical realism can be viewed as sitting between naïve realism and extreme relativism.<sup>1</sup> For context, the former assumes that there is a ‘reality’ (a ‘knowable world’), which is independent of human understanding.<sup>2</sup> Furthermore, there is believed to be a ‘truth’, which researchers can access directly, and their data will directly represent this ‘truth’ (the phenomenon being measured).<sup>2,3</sup> Extreme relativism, on the other hand, rejects concepts such as ‘knowledge’ and ‘truth’ entirely.<sup>3</sup>

In the middle, critical realism assumes that there is a ‘reality’ independent of human understanding but there is subjectivity as individuals experience different parts of this ‘reality’.<sup>4</sup> It is proposed that the ‘reality’ is located behind subjective and socially constructed knowledge.<sup>1</sup> Therefore, the researcher’s data can provide information about the ‘real’ world but the relationship is indirect, and interpretation is necessary in order to achieve an understanding of the underlying structures that produce the phenomenon under investigation.<sup>3</sup>

The critical realist position aligns with an Interpretative Phenomenological Analysis (IPA) framework as IPA emphasises ideography, phenomenology and hermeneutics; an interest in gleaning rich accounts of subjective lived experiences and the ways in which such experiences are interpreted/understood by the participant.<sup>5</sup> Furthermore, the interpretative nature of IPA requires the researcher to look deeper into the underlying structures of the participant’s language and understandings in an attempt to access their ‘reality’.

Critical realism also proposes that beliefs and expectations influence perceptions of facts, especially within the social domain.<sup>1</sup> It was important for the researcher to consider this alongside the double hermeneutic,<sup>5</sup> remaining mindful not to accept his own views/interpretations as the only ‘reality’ and remaining conscious of the influences that he may have on the research project.

Furthermore, the IES-R psychometric measure was applied and analysed from a critical realist position: that there is an independent concept (‘reality’) of trauma/PTSD but this

can only be accessed through the subjective knowledge and experiences of each participant. Therefore, the IES-R, a subjective self-report measure, was utilised as a tool to further access participants' subjective experiences/'realities' of ESs, exploring whether they subjectively experienced PTSD symptomology, with the aim of contextualising the qualitative data obtained.

### **References**

1. Madill A, Jordan A and Shirley C. Objectivity and reliability in qualitative analysis: Realist, contextualist and radical constructionist epistemologies. *Br J Psychol* 2000; 91: 1-20.
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3. Willig C. *Introducing qualitative research in psychology*. 3<sup>rd</sup> ed. Berkshire: Open University Press, 2013.
4. Fade S. Using Interpretative Phenomenological analysis for public health nutrition and dietetic research: A practical guide. *Proc Nutr Soc* 2004; 63: 647-653.
5. Smith JA, Flowers P and Larkin M. *Interpretative Phenomenological Analysis: Theory, Method and Research*. London: Sage, 2009.



## Appendix F: Participant invitation letter



Dear potential participant,

### **Letter of invitation to a research project**

**After the storm: How do partners of those receiving an Implantable Cardioverter Defibrillator (ICD) experience episodes of Electrical Storm, which have resulted from ICD activation (shocks)?**

I would like you to consider taking part in this research project, which is investigating the experiences of people whose partners have had at least one episode of Electrical Storm (three or more shocks from their Implantable Cardioverter Defibrillator within 24 hours). The aim of the study is to get a better understanding of how the partners of ICD recipients are affected by Electrical Storms.

Please read the accompanying Participant Information Sheet (version 1.3, dated 11/08/2016) which provides full details of the project. In summary, if you would like to take part, your involvement in the project would involve meeting with myself in order to sign a consent form, complete a short questionnaire and demographic information sheet, and take part in a one-to-one interview with myself. The interview will last between 60-90 minutes and you will be asked to share your experiences of your partner's episode/s of Electrical Storm. In some, but not all, cases I may ask to undertake a follow-up interview with you, lasting no more than 30 minutes, in order to clarify and/or further explore the information you provided in the initial interview (you are not obliged to agree). The interview(s) will take place at the [redacted]. You will be able to claim travel and parking expenses up to the value of £11.60.

Your participation in the study would be very valuable and it is hoped that the findings from the study will improve the way in which professionals work with ICD recipients and their partners, as well as improving psychological interventions and other supportive strategies (e.g. support groups).

If you decide you would like to take part, or would like any additional information, please contact myself or [redacted] using the contact details below. Alternatively, please return the attached response slip. Thank you for taking the time to read this letter.

Yours faithfully,

Carl Rideout  
Trainee Clinical Psychologist

### **Carl Rideout (chief investigator)**

Email: [redacted]

### **[redacted] (Cardiac Rhythm Nurse Specialist and Field Supervisor)**

Email: [redacted]

Phone: [redacted]

Title: Participant Invitation Letter  
Version: 1.2  
Date: 11/08/2016  
IRAS Reference: [redacted]

## \*Appendix G: Participant information sheet



After the storm: How do partners of those receiving an Implantable Cardioverter Defibrillator (ICD) experience episodes of Electrical Storm, which have resulted from ICD activation (shocks)? An exploration using Interpretative Phenomenological Analysis

### - Participant Information Sheet -

**This information sheet is available in large font. Please ask a member of staff for a copy if you would like one.**

You are being invited to participate in a research study. Before you decide if you would like to take part it is important that you understand why the study is being carried out and what it will involve if you do wish to participate. Please take the time to read this information sheet carefully and discuss it with others and/or ask any questions if you wish to do so.

#### **Why is the study being carried out?**

The study aims to explore the experiences of people whose partners have had at least one episode of Electrical Storm (three or more shocks from their Implantable Cardioverter Defibrillator within 24 hours). The aim of the study is to get a better understanding of how the partners of ICD recipients are affected by Electrical Storms. It is hoped that the findings from this study will improve the way in which professionals work with ICD recipients and their partners, as well as improving psychological interventions and other supportive strategies (e.g. support groups).

#### **Why have I been chosen to take part?**

Participants for this study were identified through the [redacted] NHS Trust. As you are a partner of a person who has had accessed this service following an episode of Electrical Storm, and you met the requirements of the research aims, you have an opportunity to take part in the study.

#### **Do I have to take part?**

No. You can decide whether you would like to be involved in this study or not.

It is also ok if you say that you wish to take part in the study now but change your mind at a later date. If this happens you can withdraw from the study at any point. Any data/information you have provided before withdrawing will continue to be used for the purposes of this research project but no further information/data relating to you will be collected.

You do not have to give reasons if you do not wish to take part in the [redacted] draw at a later date. The care that you and your partner receive from the [redacted] will not be affected by any decisions to not take part or to withdraw.

#### **What will happen if I agree to take part?**

If you think you would like to take part in the study, please contact **Carl Rideout** (chief investigator) or [redacted] (Cardiac Rhythm Nurse Specialist) using the contact details at the end of this document, or by returning the reply slip that can be found with the accompanying invitation letter (Version 1.2, dated 11/08/2016). You will have an opportunity to discuss the study with the chief investigator and ask any questions you may have. If you decide you would like to participate, arrangements will be made for you to meet the chief investigator at the research site ([redacted]) where you will be asked to provide written consent (confirming that you are willing to take part in the study), complete a brief questionnaire and a short demographic information form, and take part in an interview.

The questionnaire will explore your current level of distress relating to your partner's episode/s of Electrical Storm. The interview will last between 60-90 minutes, during which you will be asked to share your experiences of your partner's episode/s of Electrical Storm. You will be able to take as many breaks during the interview as you wish. The interview will be audio recorded so that the chief investigator can listen back to the interview at a later date. The information you provide will be combined anonymously with information given by other participants in order to explore the experiences of partners of ICD recipients.

After the interview you will have an opportunity to ask any questions you may have and share your thoughts and feelings about the interview.

In some, but not all, cases the chief investigator may wish to undertake a follow-up interview with you in order to clarify and/or further explore the information you provided in the initial interview. (follow-up interviews will also take place at the research site: [REDACTED])

[REDACTED] If this is the case, the chief investigator will contact you (with your permission) within one month after your initial interview in order to arrange a follow-up interview (lasting no more than 30 minutes). You are under no obligation to agree to be contacted or to engage in a follow-up interview (for example, you can engage in the initial interview but refuse to be involved in a further interview).

#### **What are the possible risks or disadvantages of taking part in the study?**

There are no significant risks involved in taking part but you might find talking about your partner's ICD and episodes of Electrical Storm upsetting. Therefore, the researcher will offer support as required and there will be an opportunity following the interview to discuss any concerns. You can decline to answer questions, request a break at any point during the interview, and you can withdraw from the interview should you wish to do so. You can also withdraw from the research project at any point (before, during or after the interview) should you wish to do so.

If you agree to take part in the study you will be required to travel to the research site [REDACTED] in order to engage in the interview, and you may also be asked to attend a follow-up interview at the same site (you do not have to agree to this). To minimise the inconvenience caused your travel and parking costs will be reimbursed up to the value of £11.60 (combined) if you complete a claim form. Petrol costs will be paid at 45p per mile (the mileage is calculated from your home address to the research site: [REDACTED]), parking and bus tickets will be paid in full (for parking and bus reimbursement a receipt/parking ticket must be provided along with the claim form). As already noted, the maximum you can claim is £11.60.

#### **What are the possible benefits of taking part?**

Although it cannot be guaranteed, you may find it helpful to share your experiences of being a partner of someone who has had episodes of Electrical Storm. It is also hoped that the findings from this study will develop an understanding of how partner's of ICD recipients experience episodes of Electrical Storm, which will improve the quality of care offered to couples where one partner has an ICD fitted.

#### **What happens if you are unhappy with the study?**

If you are unhappy with any aspect of the study you can speak to the chief investigator, lead supervisor or field supervisor (contact details are provided at the end of this information sheet), and/or follow the usual NHS complaints procedure.

#### **Will my involvement in the study and personal information be kept confidential?**

Yes. Your name will not appear on any of the information that is collected, or in the final study write-up. All of your information will be stored securely at the research site and ordinarily will only be accessible by individuals who are directly involved in the research project. Following the completion of the research project your information will be stored securely at the Clinical

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Title: Participant Information Sheet  
Final Version: 1.3  
Date: 11/08/2016  
IRAS Reference Number: [REDACTED]



Psychology Base at the University of Leicester. Personal information (names and contact details) will be stored for three months and research data (interview, questionnaire and unidentifiable demographic data) will be stored for five years – at these points the respective data will be destroyed.

There are some exceptional circumstances where confidentiality may need to be breached. If you state something during the interview or questionnaire that suggests there is a significant risk of harm to yourself or others, in line with [redacted] NHS Trust policies, the chief investigator is required to share this information with appropriate others. Should there be a requirement for confidentiality to be breached, you will be notified wherever possible.

Furthermore, relevant sections of your medical notes (if applicable) and/or data collected during the study, may be looked at by individuals from the University of Leicester as sponsor or from the NHS Trust, where it is relevant to your taking part in this research.

#### **What will happen to the results of the study?**

The final write-up of the study will be available in 2017. The write-up will form the chief investigator's doctoral thesis and will be submitted to the University of Leicester. It is also anticipated that the write-up will be submitted to a peer-reviewed journal. A summary of the study will be provided to the [redacted] NHS Trust, [redacted] any participants who express a wish to receive a copy. Your involvement in the study and contributions will not be identifiable – no one will know that you have taken part or what you have said.

#### **What happens if I lose capacity to consent during the study?**

Should you lose capacity during the study you will be withdrawn from the study and no further information relating to you will be collected. Any information you have provided prior to the loss of your capacity will be retained and will continue to be used for the purposes of the study.

#### **Who is overseeing the study?**

This piece of research is being supervised and sponsored by the University of Leicester. In addition, the research has been granted NHS ethical permission by the Health Research Authority: [redacted] Research Ethics Committee, and approval from Research and Innovation department, [redacted]. It is possible that these groups, as well as regulatory authorities may view the information/data collected for this research study in order to monitor the conduct of the study.

#### **Contact details**

If you have any questions about this piece of research, would like any further information or would like to take part in the research please contact one of the researchers on the following numbers:

Carl Rideout (Chief investigator)

Email [redacted]

[redacted] (Cardiac Rhythm Nurse Specialist and Field Supervisor)

Email [redacted]

Phone: ([redacted])

If you have any concerns regarding the study please contact [redacted] (Lead Supervisor):

Email [redacted]

Phone: [redacted]

Thank you for considering taking part in this study.

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Title: Participant Information Sheet

Final Version: 1.3

Date: 11/08/2016

IRAS Reference Number: [redacted]

## Appendix H: Impact of Event-revised Scale (IES-R)



After the storm: How do partners of those receiving an Implantable Cardioverter Defibrillator (ICD) experience episodes of Electrical Storm, which have resulted from ICD activation (shocks)? An exploration using Interpretative Phenomenological Analysis

### - Impact of Events Scale – Revised -

**Researcher use:**

Participant number: \_\_\_\_\_

Below is a list of difficulties people sometimes have after stressful life events. Please read each item, and then indicate how distressing each difficulty has been for you DURING THE PAST SEVEN DAYS with respect to your partner's episode/s of Electrical Storm occurring on \_\_\_\_\_ (date). How much have you been distressed or bothered by these difficulties?

	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Any reminder brought back feelings about it.	0	1	2	3	4
2. I had trouble staying asleep.	0	1	2	3	4
3. Other things kept making me think about it.	0	1	2	3	4
4. I felt irritable and angry.	0	1	2	3	4
5. I avoided letting myself get upset when I thought about it or was reminded of it.	0	1	2	3	4
6. I thought about it when I didn't mean to.	0	1	2	3	4
7. I felt as if it hadn't happened or wasn't real.	0	1	2	3	4
8. I stayed away from reminders of it.	0	1	2	3	4
9. Pictures about it popped into my mind.	0	1	2	3	4
10. I was jumpy and easily startled.	0	1	2	3	4
11. I tried not to think about it.	0	1	2	3	4
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	0	1	2	3	4
13. My feelings about it were kind of numb.	0	1	2	3	4
14. I found myself acting or feeling like I was back at that time.	0	1	2	3	4
15. I had trouble falling asleep.	0	1	2	3	4
16. I had waves of strong feelings about it.	0	1	2	3	4
17. I tried to remove it from my memory.	0	1	2	3	4
18. I had trouble concentrating.	0	1	2	3	4
19. Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.	0	1	2	3	4
20. I had dreams about it.	0	1	2	3	4
21. I felt watchful and on-guard.	0	1	2	3	4
22. I tried not to talk about it.	0	1	2	3	4

## Appendix I: Demographic information sheet



After the storm: How do partners of those receiving an Implantable Cardioverter Defibrillator (ICD) experience episodes of Electrical Storm, which have resulted from ICD activation (shocks)? An exploration using Interpretative Phenomenological Analysis

### **- Demographic Information Form -**

Thank you for agreeing to take part in this research study. Please complete the following form by ticking one option from each question.

#### **Researcher use:**

Participant number: \_\_\_\_\_

1) **Gender:** ☐ Male

☐ Female

☐ *Prefer not to answer*

2) **Age:** ☐ 44 and under

☐ 45-54

☐ 55-64

☐ 65-74

☐ 75+

☐ *Prefer not to answer*

3) **Ethnicity:** \_\_\_\_\_

4) **Current relationship to ICD recipient:** ☐ Husband

☐ Wife

☐ Unmarried partner

☐ *Prefer not to answer*

5) **Length of relationship (if married, total relationship length rather than length of time married):** \_\_\_\_\_ years, \_\_\_\_\_ months ☐ *Prefer not to answer*

6) **Length of time the ICD recipient has had the ICD fitted:** \_\_\_\_\_ years, \_\_\_\_\_ months

☐ *Prefer not to answer*

7) **Length of time living together:** \_\_\_\_\_ years, \_\_\_\_\_ months

☐ *Prefer not to answer*

8) **Number of Electrical Storm episodes the ICD recipient has experienced:** \_\_\_\_\_

☐ *Prefer not to answer*

9) **Approximate date that the ICD recipient had their most recent episode of Electrical**

**Storm:** \_\_\_\_/\_\_\_\_/\_\_\_\_ ☐ *Prefer not to answer*

**This form is available in large font. Please ask the chief investigator for a copy if you would like one.**

## Appendix J: Interview schedule



After the storm: How do partners of those receiving an Implantable Cardioverter Defibrillator (ICD) experience episodes of Electrical Storm, which have resulted from ICD activation (shocks)? An exploration using Interpretative Phenomenological Analysis

### - Interview Schedule -

**Researcher use:**  
Participant number: \_\_\_\_\_

1. Please can you briefly describe the circumstances leading up to the fitting of your partners ICD?
  - What prompted the consideration of the ICD?
  - How did it feel?
  - What were your thoughts (concerns and positive thoughts)?
2. Your partner has experienced XX episode/s of Electrical Storm (three or more episodes of ventricular tachycardia or fibrillation from the ICD within 24 hours). Please could you describe your experience of these episodes?
  - How did you become aware of the event/s (were you present/when were you informed)?
  - What happened?
  - Any similarities/differences between Electrical Storm and isolated shocks?

If more than one episode of Electrical Storm...

  - Any differences between episodes?
  - Any episodes more pertinent/significant?
3. What impact did the episode/s of Electrical Storm have on you at the time?
  - Thoughts, feelings, worries/fears at the time?
  - How did you manage?
  - Any similarities/differences between Electrical Storm and isolated shocks?
  - Relate to presence/not being present during the Electrical Storm.

If more than one episode of Electrical Storm...

  - Any differences between episodes?
  - Any episodes more pertinent/significant?
4. What impact did the episode/s have on you over the following days/weeks?
  - Thoughts, feelings, worries/fears?
  - Changes to functioning (daily living, relationship/roles, work, social and family life) over the following days/weeks?
  - How managed?
  - Any similarities/differences between Electrical Storm and isolated shocks?

If more than one episode of Electrical Storm...

  - Any differences between episodes?
  - Any episodes more pertinent/significant?
5. Please could you describe the longer-term consequences of the Electrical Storm/s?
  - What impact have they had on you over the following months/years?
  - Thoughts, feelings, worries/fears over the following months/years?
  - Longer-term changes to functioning (daily living, relationship/roles, work, social and family life) compared to before the Electrical Storm/s?
  - How managed/adapted to these changes?
  - Perception of the ICD?
  - Any similarities/differences between Electrical Storm and isolated shocks?

Page 1 of 2

Title: Interview Schedule  
Final Version: 1.0  
Date: 02/03/2016  
IRAS Reference Number: \_\_\_\_\_

If more than one episode of Electrical Storm...

- Any differences between episodes?
- Any episodes more pertinent/significant?

6. Have there been more difficult/challenging aspects of your partner's episode/s of Electrical Storm?
7. Have there been any positive aspects of your partner's episode/s of Electrical Storm?
8. Have you sought any professional support as a result of the episode/s of Electrical Storm?
  - Why did you seek help?
  - Have you ever received a psychiatric diagnosis?
  - How was the experience of accessing support?
9. Considering your partner has experienced episode/s of Electrical Storm, tell me about how you view your future.
  - Expectations?
  - Roles/relationship?
  - Functioning (family, work and social life)?
  - Worries/fears?
  - Positive possibilities?
  - Perception of the ICD?
  - Do you think there would be any similarities/differences if your partner had only received shocks, rather than an episode of Electrical Storm?
  - Do you think there would be any similarities/differences if your partner had not received any shocks at all?

**Explain the possibility of the chief investigator wishing to undertake a follow-up interview.**


Is the participant willing to be contacted by the chief investigator if a follow-up interview is felt to be appropriate?

☐ Yes ☐ No

**Would the participant like a summary of the findings?**

☐ Yes ☐ No

Page 2 of 2

Title: Interview Schedule  
Final Version: 1.0  
Date: 02/03/2016  
IRAS Reference Number: 



**\*Appendix K: Chronology of research process**

<b>Chronology of research process</b>	
Thesis proposal peer reviewed	January 2016
Sponsor application	3 <sup>rd</sup> February 2016
Trust Research and Innovation Department application	7 <sup>th</sup> April 2016
Integrated Research Application System (IRAS) application for Research and Ethics Committee (REC) and Health Research Authority (HRA) approvals	6 <sup>th</sup> May 2016
REC approval received	18 <sup>th</sup> July 2016
HRA approval received	18 <sup>th</sup> July 2016
Sponsor approval received	19 <sup>th</sup> July 2016
Trust Research and Development approval received	19 <sup>nd</sup> July 2016
Systematic literature review database searches and write up	July 2016 - May 2017
Recruitment and data collection	September 2016 - February 2017
Empirical research write up, supervision and amendments	January - May 2017
Data analysis for empirical research	February 2017
Thesis Submission	May 2017
Research Viva	11 <sup>th</sup> July 2017
Preparation for trainee research conference and dissemination	July - September 2017

## Appendix L: Participant consent form



After the storm: How do partners of those receiving an Implantable Cardioverter Defibrillator (ICD) experience episodes of Electrical Storm, which have resulted from ICD activation (shocks)? An exploration using Interpretative Phenomenological Analysis

### - Consent Form -

Chief Investigator: Carl Rideout  
IRAS Reference Number: [REDACTED]

Participant Number: \_\_\_\_\_

	Consent statements	Please initial
1.	I confirm that I have read the participant information sheet for the above study (11/08/2016, Final Version 1.3) and I am aware of that my participation will involve completing a questionnaire and a demographic information form, and undertaking an audio recorded interview. I have had the opportunity to consider the study and ask questions. Any questions I have asked have been answered satisfactorily.	
2.	I understand that participation in this study is voluntary and my decision to participate or not will not impact on the care my partner or I receive from the [REDACTED]	
3.	I understand that I can withdraw from the study at any point and do not have to provide a reason. I understand that my decision to withdraw will not affect the care that my partner or I receive from the [REDACTED]. I understand that any information/data I have provided prior to my withdrawal will continue to be used for the purposes of this research project but no further information/data relating to me will be collected.	
4.	I understand that should I lose capacity to consent in the future I will be withdrawn from the study and no further information relating to me will be collected. Any information collected prior to my loss of capacity will be retained and used for the purposes of the study.	
5.	I understand that all of my information will be kept confidential and will be stored securely. Following the completion of the study all personal information (names and contact details) will be stored for a further three months and research data (interview, questionnaire and unidentifiable demographic data) will be stored for a further five years – at these points the respective data will be destroyed. I understand that if the chief investigator is concerned that I may be a risk to myself or others he may be required to breach confidentiality and share these concerns with appropriate others (in the first instance, his supervisor).	
6.	I understand that relevant sections of my medical notes (if applicable) and/or data collected during the study, may be looked at by individuals from [REDACTED] or from the NHS Trust, where it is relevant to my taking part in the research. I give permission for these individuals to have access to my records.	
7.	I understand that a potential risk of this study is that I may become upset through speaking about my experiences. I am aware that I can ask for breaks during the interview and that I can terminate the interview at any point, without providing a reason.	
8.	I understand that I may be contacted (with my prior permission) if the chief investigator wishes to undertake a follow-up interview. I understand that I can decline to be contacted for this purpose. I also understand that if I initially agree to be contacted, I can change my mind and refuse the follow-up study when it is requested.	
9.	I agree to take part in the above study.	

Would you like to receive a copy of the final study summary at the end of the study? **Yes / No**  
(please delete as appropriate)

Participant Name (block capitals)

Date

Signature

Name of person taking consent  
(block capitals)

Date

Signature

Page 1 of 1

Title: Consent Form  
Final Version: 1.3  
Date: [REDACTED]

When completed: 1 copy to participant.  
1 copy to researcher

## **Appendix M: Process of Interpretive Phenomenological Analysis**

As recommended by Smith et al.<sup>1</sup> the following stages of IPA analysis were conducted:

1. Reading and re-reading of individual interview transcripts, and listening to the interview audio recordings: active engagement and immersion within the data.
2. Initial phenomenological coding: writing notes and comments in the right-hand margin of the transcript, which focus on the descriptive, linguistic and conceptual content of the participant's words.
3. Developing emergent themes: identifying themes from coding conducted in stage two (writing themes (concise statements) in the left-hand margin of the transcript that encapsulate their respective codes).
4. Searching for connections across emergent themes: using diagrammatical maps to identify the ways in which themes fit together (visually clustering themes that converge according to conceptual similarities). This involves processes such as abstraction (clustering similar emergent themes and naming the cluster), subsumption (clustering similar emerging themes and one of the emerging themes becomes the title for the cluster) and polarization (looking for difference in the transcripts and incorporating divergence into the clusters). Themes with weak evidence are dropped. This process results in a list of superordinate and associated subordinate themes representing the individual transcript.
5. Moving to the next case: repeating the previous steps with a further transcript, whilst trying to remain idiographic and not being influenced by the previous transcripts
6. Looking for patterns across cases: using visual diagrams to compare cases and identify patterns and connections between cross-case superordinate and subordinate themes. Consequently, themes may be reconfigured and relabelled (e.g. cross-case themes may share higher order concepts, leading to them being clustered, modified and renamed). During this process attempts are also made to retain the unique idiosyncrasies of each case (e.g. case differences within any shared higher order concepts are retained). The reconfigured and relabelled themes comprise the final analysis: the superordinate and associated subordinate themes aiming to represent all cases (whilst retaining idiosyncrasies). Finally, a table is developed to report case frequency of themes, and a diagrammatical representation mapping the final superordinate and subthemes is constructed.

1. Smith JA, Flowers P and Larkin M. *Interpretative Phenomenological Analysis: Theory, Method and Research*. London: Sage, 2009.

## **Appendix N: Extract from reflexive diary**

**Date of entry:** 26/01/2017

**Topic:** Interview reflections – participant 04.

*Participant presented as confident/assertive but difficulties in organising memories/events. Interview jumped around a lot. Reflect some chaos??*

*Felt quite overwhelmed and required a lot of effort to make sense of experiences! Tired! Having to check what was being said a lot – leading? Check audio. Difficult to make sense of experiences – reflect participant's difficulty in making sense?*

*Active family prior to storm. Participants role in – observer or active also? Impact of the ES on this? Check audio (mentioned towards start?).*

*Decision making important generally, and inability to make decisions during the storm. Helplessness, impotence?? Desiring control? Contrast to the norm?*

*Passionate about need for partner and family members to be considered – was interested in study and said (off tape) felt participating important. Strong sense of isolation? Not being heard? Emotive topic? Wanting to express emotions/feelings? Get off chest?*

*Unable to talk to patient about - causing conflict and distance in relationship. More isolation? Coping strategies? Was this there before or a function of the ES? How was their relationship pre-ES? Impact on intimacy. Mixed impact: one sense relationship is closer, separation in another. Communication of experiences appears important. Not able to talk related to wanting to take part in study?*

*Large impact on family. Discussion of ES appears difficult within family. Maintained? Each holding onto experiences and emotions? Why? A change from before?*

*Focused on practical implications of post-storm, quite matter of fact/pragmatic in places but emotions appeared. Upset when discussing relationship and memories of ES. Having to avoid. Avoidance as a coping strategy? Something still painful?*

**\*Appendix O: Ethical correspondence**



**Health Research Authority**

**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

18 July 2016

Mr Carl Rideout  
Trainee Clinical Psychologist

Dear Mr Rideout

<b>Study title:</b>	<b>After the storm: How do partners of those receiving an Implantable Cardioverter Defibrillator (ICD) experience episodes of Electrical Storm, which have resulted from ICD activation (shocks)? An exploration using Interpretative Phenomenological Analysis</b>
<b>REC reference:</b>	
<b>Protocol number:</b>	
<b>IRAS project ID:</b>	

Thank you for your letter, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

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 opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager,

## 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], subject to the conditions specified below.

## Conditions of the favourable opinion

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 NHS permission for research is available in the Integrated Research Application System, [www.hra.nhs.uk](http://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 within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

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 contest the need for registration they should contact [redacted] the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

**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

### NHS 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" below).

### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Interview schedules or topic guides for participants [Interview schedule]	V1.0	02 March 2016
IRAS Application Form [IRAS_Form_01072016]		01 July 2016
IRAS Application Form XML file [REDACTED]		01 July 2016
IRAS Checklist XML [Checklist [REDACTED]]		13 May 2016
IRAS Checklist XML [REDACTED]		01 July 2016
Letters of invitation to [REDACTED] at invitation letter - added following REC review]	1.1	30 June 2016
Other [NHS to NHS letter of access]		09 February 2016
Other [Chief investigator GCP certificate]		13 January 2016
Other [Chief investigator Informed Consent certificate]		13 January 2016
Other [Participant demographic information form]	V1.0	02 March 2016
Other [University research costs form]	V0.2 (final)	23 February 2016
Other [Local collaborator CV]		05 May 2016
Other [Insurance doc - clinical trials]		30 June 2016
Other [Insurance doc - indemnity insurance]		30 June 2016
Other [Response letter]		30 June 2016
Participant consent form [Amended Participant consent form following REC and HRA reviews]	Final 1.2	30 June 2016
Participant information sheet (PIS) [Amended Participant information sheet following REC review]	Final 1.2	30 June 2016
Research protocol or project proposal [Amended research protocol following REC review]	Final 1.2	30 June 2016
Summary CV for Chief Investigator (CI) [Chief investigator CV]	V0.1 (final)	18 January 2016
Summary CV for student [Chief investigator (doctoral student) CV]	V0.1 (final)	18 January 2016
Summary CV for supervisor (student research) [Supervisor CV]	V1.0	23 March 2016
Validated questionnaire [Impact of events scale - revised]	V1.0	02 March 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.

### **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 use the feedback form available on the HRA website:

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

### **HRA Training**

We are pleased to welcome researchers and R&D staff at our training days – see details at

<http://www.hra.nhs.uk/hra-training/>

**Please quote this number on all correspondence**

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

Yours sincerely

 (Chair)

**Chair**

Email:

Enclosures:

researchers”

Copy to:



Mr Carl Rideout  
Trainee Clinical Psychologist

Email: [REDACTED]

18 July 2016

Dear Mr Rideout

**Letter of HRA Approval**

**Study title:** After the storm: How do partners of those receiving an Implantable Cardioverter Defibrillator (ICD) experience episodes of Electrical Storm, which have resulted from ICD activation (shocks)? An exploration using Interpretative Phenomenological Analysis

**IRAS project ID:**  
**Protocol number:**  
**REC reference:**  
**Sponsor**

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 and further information about working with the research management function for each organisation can be accessed from [www.hra.nhs.uk/hra-approval](http://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 [REDACTED]
- [REDACTED] 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 [REDACTED]. 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 [REDACTED]. Please quote this on all correspondence.

Yours sincerely

[REDACTED]

**Assessor**

Email: [REDACTED]

Copy to:

[REDACTED] [Sponsor Contact]

[REDACTED] [Lead NHS R&D Contact]

[REDACTED] [Academic Supervisor]

## 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>
Contract/Study Agreement [Schedule of Events]	2	29 June 2016
Contract/Study Agreement [Statement of Activities]	2	29 June 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Clinical Trials Insurance Certificate]		03 August 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Professional Indemnity Insurance Certificate]		03 August 2015
Interview schedules or topic guides for participants [Interview schedule]	V1.0	02 March 2016
IRAS Application Form		01 July 2016
IRAS Application Form		01 July 2016
IRAS Checklist XML [C		01 July 2016
Letters of invitation to participant [Participant invitation letter - added following REC review]	1.1	30 June 2016
Other [Chief investigator GCP certificate]		13 January 2016
Other [Chief investigator Informed Consent certificate]		13 January 2016
Other [Participant demographic information form]	V1.0	02 March 2016
Other [University research costs form]	V0.2 (final)	23 February 2016
Other [Local collaborator CV]		05 May 2016
Other [Insurance doc - clinical trials]		30 June 2016
Other [Insurance doc - indemnity insurance]		30 June 2016
Participant consent form [Amended Participant consent form following REC and HRA reviews]	Final 1.2	30 June 2016
Participant information sheet (PIS) [Amended Participant information sheet following REC review]	Final 1.2	30 June 2016
Research protocol or project proposal [Amended research protocol following REC review]	Final 1.2	30 June 2016
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Summary CV for student [Chief investigator (doctoral student) CV]	V0.1 (final)	18 January 2016
Summary CV for supervisor (student research) [Supervisor CV]	V1.0	23 March 2016
Validated questionnaire [Impact of events scale - revised]	V1.0	02 March 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 queries about the study:

Miss (Tel:

### 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 with the schedule of events will form the agreement between the sponsor and participating NHS organisations in England.  The sponsor has confirmed that no other agreement will be used.
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 defence organisation covers the

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			activities expected of them for this research study.
4.3	Financial arrangements assessed	Yes	No funding will be provided to participating NHS organisations.
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	Not Applicable	No Comments.
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	REC Favourable Opinion was issued on 18 July 2016.
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	Not Applicable	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.*

The statement of activities with the schedule of events will form the agreement between the sponsor and participating NHS organisations in England.

The sponsor has confirmed that no other agreement will be used.

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

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).*

The sponsor has confirmed that a Local Collaborator would be required at each participating NHS organisation and these have already been identified.

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*

A letter of access will **not** be required for the researcher if the research activity is being carried out in an office within the participating NHS organisations.

A letter of access will be required for the researcher to carry out research activities for this study if the research activity is being carried out within a care setting on the premises of participating NHS organisations. If the researcher holds an NHS contract, an NHS to NHS letter of access will be required. No Disclosure and Barring Service or Occupation Health checks will be needed where a letter of access is required.

**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.



From: [REDACTED]  
 Subject: [REDACTED]  
 Date: [REDACTED]  
 To: [REDACTED]  
 Cc: [REDACTED]

Dear Carl

IRAS Project ID:	[REDACTED]
REC Reference:	[REDACTED]
Short Study Title:	How do partners of ICD recipients respond to ICD Electrical Storms?
Date complete amendment submission received:	15 August 2016
Amendment No./ Sponsor Ref:	15 August 2016
Amendment Date:	13 August 2016
Amendment Type:	Non-substantial

Thank you for notifying the HRA (which manages the Research Ethics Service in England) of the above amendment.

Non-substantial amendments do not require an ethical opinion from the Research Ethics Committee and do not need to be notified to the Committee. Please follow the guidance in the Categorisation section below to ensure that the amendment is notified appropriately to NHS/HSC R&D offices. You should also take note of the Confirmation of Assessment Arrangements section for information on when you may implement this amendment at participating NHS organisations in England.

#### Categorisation of Amendment

In line with the [UK Process for Handling UK Study Amendments](#) I can confirm that this amendment has been categorised as:

**Category C** - An amendment that has no implications that require management or oversight by the participating NHS organisations

As such, the sponsor may implement this amendment **as soon as any relevant regulatory approvals are in place** (for participating organisations in England, please see 'Confirmation of Assessment Arrangements' below).

As Chief Investigator/Sponsor, it remains your responsibility to ensure that the research management offices and local research teams (if applicable) at each of your participating organisations are informed of this amendment.

**Note:** you may only implement changes described in the amendment notice or letter.

#### Participating NHS Organisations in England – Confirmation of Assessment Arrangements

Further to the details above, I can confirm that no HRA assessment of this amendment is needed.

- If this study has HRA Approval, this amendment may be implemented at participating NHS organisations in England once the conditions detailed in the categorisation section above have been met
- If this study is a pre-HRA Approval study, this amendment may be implemented at participating NHS organisations in England that have NHS Permission, once the conditions detailed in the categorisation section above have been met. For participating NHS organisations in England that do not have NHS Permission, these sites should be covered by HRA Approval before the amendment is implemented at them, please see below;

- If this study is awaiting HRA Approval, I have passed your amendment to my colleague in the assessment team and you should receive separate notification that the study has received HRA Approval, incorporating approval for this amendment.

Please do not hesitate to contact me if you require further information.

Kind regards



REC Manger –

Health Research Authority



The HRA is keen to know your views on the service you received – our short feedback form is available [here](#)

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## Appendix P: Example of transcript coding

P06

Interview date: 23/02/2017 Transcription date: 01/03/2017

334 P: Yeh, it was. I think hopelessness for lots of reasons. I couldn't physically touch him

335 which is, I think, whenever anybody's upset or in pain or distressed or whatever, your

336 natural reaction would be to go and comfort them.

337 R: Right.

338 P: And to not be able to physically do that and then also not knowing how to do it in

339 any other way, there was- I didn't know what was going on so there's nothing I can

340 say that I could try and say it's alright, it'll be ok but it might not be and I couldn't-

341 I couldn't really say that- I- I probably did say it but I don't remember. Erm, I suppose

342 you do what you would automatically try and do, and just try verbally reassuring but

343 inside you don't feel very reassured.

*Handwritten notes:*

- Helplessness for lots of reasons* (written vertically on the left margin)
- Helpless!* (written above line 334)
- want to comfort physically but couldn't* (written above line 334)
- Forced divide* (written below line 334)
- forced divide:* (written above line 338)
- not able to physically comfort + not knowing how to* (written above line 338)
- unknown / uncertain* (written above line 340)
- Trying to reassure when not feeling reassured* (written above line 341)
- holding / inhibits* (written above line 342)
- emotions* (written above line 343)
- key feeling* (written vertically on the left margin)
- helplessness for lots of reasons* (written vertically on the left margin)
- couldn't physically touch* (written above line 334)
- reaction to go + comfort* (written above line 334)
- but comfort is* (written above line 334)
- very want to* (written above line 334)
- next able to physically* (written above line 338)
- comfort + word to find* (written above line 338)
- alternative ways - options* (written above line 338)
- after verbal but* (written above line 338)
- not knowing what's happening* (written above line 338)
- unknown* (written above line 338)
- Trying to verbally reassure but don't feel reassured* (written above line 341)
- difficult* (written above line 341)
- try to say what be* (written above line 341)
- ok but don't believe* (written above line 341)
- not believed self* (written above line 342)
- empty* (written above line 342)
- but might be* (written above line 342)
- trying to reassure* (written above line 342)
- deceive* (written above line 342)
- mode to reassure* (written above line 342)
- holding out* (written above line 342)
- major feeling* (written above line 342)
- and what* (written above line 342)
- say* (written above line 342)

35

>3 sec pause, ... 3-6 second pause, ... >6 seconds

P05

Interview date: 26/01/2017 Transcription date: 13/02/2017

Conflict between urgency /  
disparation to get  
home + needing to  
keep everyone safe

Stem induces worry about  
pr. mortality / life threatening

Utilising coping strategies to  
Can function / manage through  
Stem - Compartmentalise  
(box / separate units need to  
address)

175 home as quickly as I could without killing us in the car. And that's all I could think  
176 about is just- I just needed to get him home...

177 R: Was there anything in particular you- you were worried about?

178 P: Obviously, him dying. I suppose. I don't think... I suppose deep down you think that  
179 but you don't want to think that so you- you don't let it surface. I'm very much a

180 person, and I've always been the same, I compartmentalise my life so my work is my  
181 work, my social is my social, my home is my home. So, I suppose I- I compartmentalise

182 it. It's in that box and this is what has gotta be done because that's that box that I'm  
183 concerned about at the moment. So, I think that's how I've always coped with it, I-

184 it's in that box. It mustn't affect anything else.

(Compartmentalisation)  
Context to prev. comments  
Urgency  
Rush  
Want to get home ~~fast~~  
but without accident - limited to  
what can do /  
power / urgency  
Conflict / have to manage pressures  
Mortality / death worry - is a fear  
related to  
society  
Deeper worry - death access -  
don't allow self to think to future  
part of coping - box off / avoid /  
Suppress / compartmentalise in  
box. Control over - control well  
worry?  
Concerned about box / issue  
when need to be  
- why lack of urgency?  
Stem - Compartmentalise / thinking of  
not access it -  
- don't want to affect  
other things -  
pattern for life other than  
work / social / home

19

>3 sec pause, ... 3-6 second pause, ... >6 seconds

## Appendix Q: Frequency of themes

Superordinate themes and associated subthemes	Participants					
	Mary	Kevin	Sally	Ann	Helen	Louise
<b>Feeling overwhelmed during the ES (all at sea)</b>	✓	✓	✓	✓	✓	✓
Caught off guard	✓	✓	✓	✓	✓	✓
“You don’t know what’s happening”	✓	✓	✓	✓	✓	✓
“I couldn’t control anything that was happening”	✓	✓	✓	✓	✓	✓
Holding it together for the ICD recipient	✓			✓	✓	✓
<b>Challenges in post-ES adjustment</b>	✓	✓	✓	✓	✓	✓
Working with the system			✓	✓	✓	✓
Adopting post-ES roles: challenges and self-sacrifice	✓	✓	✓	✓	✓	✓
The past and future intruding the present	✓	✓	✓	✓	✓	✓
<b>Trying to cope (not being becalmed)</b>	✓	✓	✓	✓	✓	✓
Avoidance of emotions as a way of coping	✓	✓	✓	✓	✓	
An isolated experience, and being overlooked in the provision of support	✓	✓	✓	✓	✓	✓
Determination: “There isn’t a choice”		✓	✓	✓		✓
<b>Living and growing</b>	✓	✓	✓	✓	✓	✓
Time heals	✓	✓	✓	✓	✓	✓
Learning from the experience, and increased confidence	✓		✓	✓	✓	
Longer-term impact on the couple relationship	✓	✓		✓	✓	