The role of patient support groups in adapting to life with an Implantable Cardioverter Defibrillator

K Sanders

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Abstract

Background: Patients with implantable cardioverter defibrillators (ICD) experience anxiety, depression and reduced quality of life (QoL). Patient groups offer a low-resource option for supporting these patients; however, it is not known how support groups can meet patients’ needs nor what format they should take.

Aim: This thesis aimed to explore the role of support groups in helping patients to adapt to life with an ICD by evaluating the evidence base and exploring ICD recipients attitudes and perceptions of attending a support group.

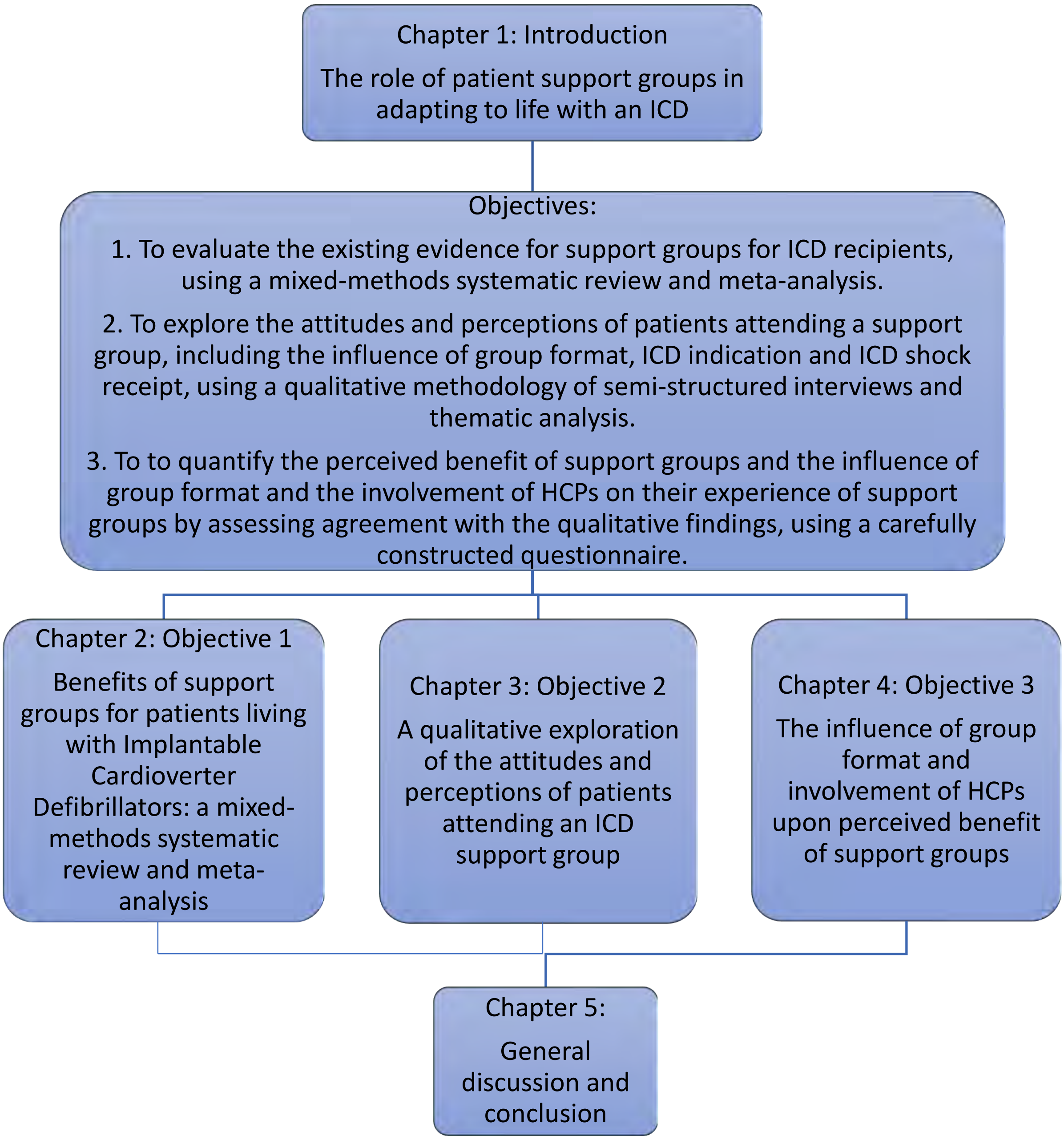
Methods: Three studies were conducted. These comprised of a mixed-methods systematic (MMS) review, a qualitative study using semi-structured interviews and thematic analysis, and finally development and use of a Likert-style questionnaire. For the MMS review, eligible studies investigated patient-led support groups for ICD patients using any quantitative or qualitative design. Meta-analysis of quantitative measures of mental well-being was conducted whilst thematic synthesis was used to generate analytic themes from the qualitative data. The data were integrated and presented using the Pillar Integration Process. For the qualitative study, 14 ICD recipients were interviewed using a semi-structured interview guide. Reflexive thematic analysis methods were employed to code and analyse the transcripts before generating themes. Finally, 28 statements were generated from the qualitative findings for use in a purpose-designed Likert-style questionnaire. 17 questionnaires were returned and agreement with the qualitative findings was assessed using the mean score for each statement.

A Patient and Public Involvement group was consulted with throughout the project.

Results: No clear evidence was found that patient support groups for ICD recipients have a significant effect on quantitative measures of anxiety and QoL. The qualitative findings of this thesis, however, showed that attendees perceived the group as beneficial. Analysis generated themes which suggest support groups may provide ICD recipients with the opportunity to learn and utilise coping skills and complete tasks towards adapting to their life with an ICD. The questionnaire results demonstrated overall agreement that in order to provide this perceived benefit support groups should include opportunities for healthcare professional (HCP)-led education as well peer support and sharing of experiences.

Conclusion: The lack of ethnic diversity in the study samples and the contextual impact of research being undertaken during the Covid-19 pandemic limit the generalisability of the findings, however, this thesis provides new insight into how patient support groups may confer benefit through improving adaptation to life with an ICD by addressing patients' concerns and increasing acceptance. The findings of this thesis suggest that the current lack of significant quantitative evidence in favour of support groups may be attributable to the choice of outcome measures, which focus on anxiety and QoL rather than adaptation or acceptance. Further research is needed to address the limitations and confirm the findings of this thesis before undertaking larger-scale experimental research using appropriate outcome measures.

Thesis organisation



Chapter 1: Introduction

The role of patient support groups in adapting to life with an ICD

Objectives:

1. To evaluate the existing evidence for support groups for ICD recipients, using a mixed-methods systematic review and meta-analysis.

2. To explore the attitudes and perceptions of patients attending a support group, including the influence of group format, ICD indication and ICD shock receipt, using a qualitative methodology of semi-structured interviews and thematic analysis.

3. To to quantify the perceived benefit of support groups and the influence of group format and the involvement of HCPs on their experience of support groups by assessing agreement with the qualitative findings, using a carefully constructed questionnaire.

Chapter 2: Objective 1

Benefits of support groups for patients living with Implantable Cardioverter Defibrillators: a mixed-methods systematic review and meta-analysis

Chapter 3: Objective 2

A qualitative exploration of the attitudes and perceptions of patients attending an ICD support group

Chapter 4: Objective 3

The influence of group format and involvement of HCPs upon perceived benefit of support groups

Chapter 5:

General discussion and conclusion

Publications arising:

Sanders KH, Chousou PA, Carver K, Pugh PJ, Degens H & Azzawi M. Benefits of support groups for patients living with implantable cardioverter defibrillators: a mixed-methods systematic review and meta-analysis. Open Heart 2022;9:e002021. doi:10.1136/ openhrt-2022-002021

Sanders KH, Carver K, Eggleton E, Pugh PJ, Walker L & Azzawi M. A qualitative exploration of the role of patient support groups in adapting to life with an Implantable Cardioverter Defibrillator. Submitted to *Pacing and Clinical Electrophysiology*

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Declaration

No portion of this thesis has been submitted in support of an application for another qualification in any other university or institution of learning.

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Abbreviations

AA	Arrhythmia Alliance
ARVC	Arrhythmogenic Right Ventricular Cardiomyopathy
ATP	Anti-Tachycardia Pacing
BHF	British Heart Foundation
BHRS	British Heart Rhythm Society
CAD	Coronary Artery Disease
CBT	Cognitive Behavioural Therapy
CRT	Cardiac Resynchronisation Therapy
DVLA	Driver and Vehicle Licensing Agency
EMI	Electro-magnetic Interference
EP	Electrophysiology
FPAS	Florida Patient Acceptance Scale
FSAS	Florida Shock Anxiety Scale
GAD	Generalised Anxiety Disorder
HCP	Health Care Professional
HRA	Health Research Authority
HSST	Higher Specialist Scientist Training
ICD	Implantable Cardioverter Defibrillator
ICDC	Implantable Cardioverter Defibrillator-related Concerns
LVEF	Left Ventricular Ejection Fraction
MI	Myocardial Infarction
MMAT	Mixed-Methods Assessment Tool
MMS review	Mixed-Methods Systematic review
MOS	Medical Outcomes Study
MRI	Magnetic Resonance Imaging
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
OSOP	One-sheet-of-paper
QLI	Quality of Life Index
QoL	Quality of Life
PIP	Pillar Integration Process
PPI	Patient and Public Involvement

PTSD	Post Traumatic Stress Disorder
REC	Research Ethics Committee
RCT	Randomised Controlled Trial
SCA	Sudden Cardiac Arrest
SCD	Sudden Cardiac Death
STAI	State-Trait Anxiety Index
TA	Thematic Analysis
VA	Ventricular arrhythmias
VAS	Visual Analogue Scale
VF	Ventricular Fibrillation
VT	Ventricular Tachycardia
WHO	World Health Organisation

Preface

This manuscript outlines a journey which began in 2012 when I qualified as a cardiac physiologist and passed what was then the Heart Rhythm UK (now British Heart Rhythm Society, BHRS) accreditation exam in cardiac devices. As a cardiac physiologist, I had learned to look after implanted cardiac devices very well, but I felt we could improve how well we were looking after the patients who received them. I saw patients in clinic whose devices were working perfectly, but they seemed to be struggling with their implantable cardioverter defibrillator (ICD) mentally and we were ill-equipped to help them in terms of both resources and experience, our implant service having only begun in 2009.

At the time I started independently following-up ICDs, the BHRS standards stated that 'A psychological support and counselling service for ICD and [cardiac resynchronisation therapy defibrillator] CRT-D patients is a necessary part of device follow up and should be provided either by the specialist arrhythmia nurse team or the physiologist team'. We had no specialist arrhythmia nurse team and therefore this role fell to the physiologist team, however, we had little opportunity to develop skills in counselling and no research had explored cardiac physiologist knowledge or confidence regarding counselling ICD recipients. I undertook a Masters module in Clinical Assessment for Healthcare Science (Swansea University) in 2015, where I learned the effective history taking skills which are required to identify signs and symptoms of poor mental and as well as physical health (National Institute for Health and Care Excellence, 2009). There was some guidance available to those performing device follow-up regarding how to promote positive coping mechanisms as well as when to refer for additional support (Sears *et al.*, 2006), but our local options for support remained limited.

By 2017 I had registered as a cardiac clinical scientist and enrolled on the Higher Specialist Scientist Training (HSST) programme, of which this thesis is in partial fulfilment. I had developed a specialist clinic in which I assessed patients with implantable cardiac devices for changes in indication and discussed the indications for ICD with patients who were eligible for upgrade. This further highlighted the need for improving ICD information provision and support for our patients. There was evidence that interventions such as cognitive behavioural therapy (CBT) provide benefit to patients (Dunbar *et al.*, 2012), but drawing conclusions about the most effective intervention was challenging due to methodological issues (Salmoirago-Blotcher and Ockene, 2009). The BHRS (2015) encouraged the use of patient support groups and they seemed to offer a solution to the problem of supporting patients during a time of austerity in the health service (Proietti *et al.*, 2017). I therefore sought to implement a support group, the process of which is described in detail in appendix 1. However, despite being recommended by our national society, it was clear when researching the idea that there was a limited evidence base regarding the benefit of and optimal format for support groups specifically for ICD recipients. Thus, a gap was identified in evidence-based cardiac physiology services for the provision of support groups for patients with ICDs, which was suitable for the research component of a professional doctorate.

This descriptive introduction has provided context to the researcher and the overall clinical and scientific setting in which this research was conceptualised. The following thesis will provide a critical narrative of the research journey, beginning with an overview of ICD technology and indications and a review of the literature base to provide further context to the work.

1 Chapter 1: Introduction

1.1 Overview of Implantable Cardioverter Defibrillators

1.1.1 Introduction

An ICD is a battery-operated implanted device which is used to treat ventricular arrhythmias (VA) and thus terminate sudden cardiac arrest (SCA), which quickly leads to death if left untreated. Approximately 75-80% of sudden cardiac death (SCD) may be attributable to VA (National Institute for Health and Care Excellence, 2014), and therefore effectively treating VA will save many lives. ICDS were introduced to prevent sudden SCD, most frequently caused by coronary artery disease (80% of cases) (Santini et al., 2007). ICDs were originally implanted as a secondary prevention strategy in survivors of SCA, with guidelines being expanded in the early 2000s to include patients at risk of SCD (primary prevention). Implant rates in England quadrupled between 2002 and 2020 (Cunningham, 2005; Murgatroyd and Dayer, 2021), with 160 per million population being implanted in 2019/2020.

1.1.2 Electrophysiology

VA consist of two main subtypes: ventricular tachycardia (VT) and ventricular fibrillation (VF). Zeppenfeld et al. (2022) have outlined definitions of these rhythms:

- VT is ≥3 beats with a rate >100 beats per minute (bpm) which originates from the ventricles and is not dependent on atrial activity or AV node conduction.
- VF is a chaotic rhythm without discrete QRS complexes, which is irregular and erratic in its timing and morphology.

While the chaotic rhythm of VF rapidly leads to haemodynamic collapse and SCA, VT can be tolerated by some patients without leading to SCA (Kanagasundram, Richardson and Stevenson, 2021). However, if left untreated, well-tolerated VT may deteriorate and lead to haemodynamic compromise (Foth *et al.*, 2023). ICDs have the capacity to deliver shocks to immediately terminate VF and faster, less likely to be tolerated, VT and to use anti-tachycardia pacing (ATP) to painlessly terminate slower sustained VT, thus reducing the incidence of shocks for VA (Wathen *et al.*, 2001).

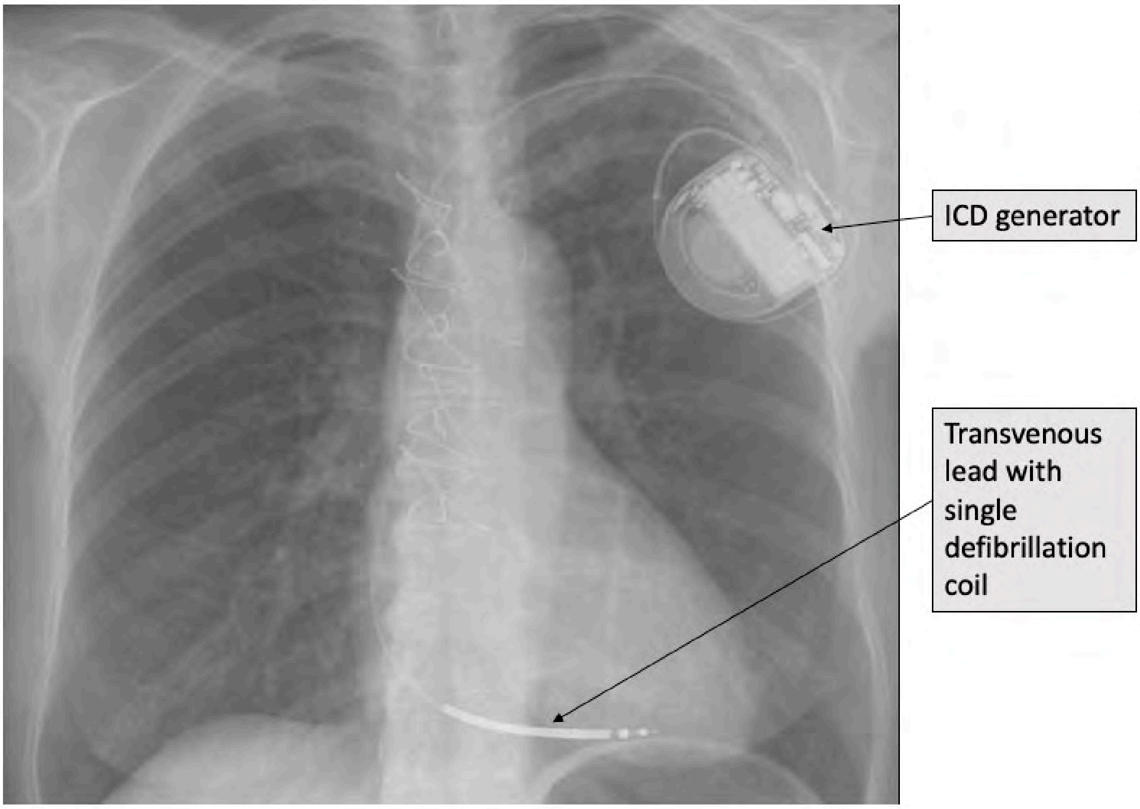
Cardiac conditions which increase the risk of VA include ischaemic and non-ischaemic cardiomyopathies, structural heart disease (adult and congenital), channelopathies, infiltrative disease and inflammatory disease; rarely, idiopathic VA may also occur (Foth *et al.*, 2023). The electrophysiological mechanism for VA differs in these conditions and include re-entry, triggered activity, and enhanced automaticity (Foth *et al.*, 2023). Re-entry is the most common cause of VT due to scar or fibrosis as found in cardiomyopathies, structural, infiltrative and inflammatory conditions (Foth *et al.*, 2023). The re-entry circuit arises because of the different conduction properties of scar tissue which is not able to propagate the electrical signals as quickly as healthy myocardium (Meja Lopez and Malhotra, 2019). Triggered activity is the substrate for VA in conditions such as long QT syndrome, whereas enhanced automaticity is seen most commonly in catecholaminergic VT (Foth *et al.*, 2023)

Regardless of the underlying aetiology of VA, ICDs are designed to detect their occurrence and subsequently terminate them. Defibrillation via the delivery of electrical shock terminates VA by instantaneously depolarising a critical mass of myocardium, thus allowing the normal co-ordinated rhythm to restart (Ellenbogen and Wood, 2008). ATP consists of delivering a burst of high rate overdrive pacing, and is most likely to be effective for re-entry VTs (Ellenbogen and Wood, 2008). The evidence base for ATP is reviewed further in section 1.1.6.1, following a review of the technology and implant indications.

1.1.3 Technology

The first ICD was implanted in a human in 1980 and was a large device implanted in the abdomen, requiring thoracotomy for epicardial lead placement (Mirowski *et al.*, 1980). Early devices were able to detect VA based on heart rate only and were limited to delivering back-up ventricular pacing. Modern devices are smaller, considerably more sophisticated in detection of arrhythmias and pacing function, and are implanted using a transvenous (as shown in Figure 1) or subcutaneous approach (Ellenbogen and Wood, 2008). The ICD system consists of a generator and one or more leads which deliver the energy required for defibrillation from the generator to the myocardium.

Figure 1: Chest x-ray showing transvenous ICD generator and lead system



Despite remarkable transformation in technology in the 40 years since the first ICD implant, the ultimate treatment goal of prevention of SCD is unchanged. The indications for ICD implant, however, have also evolved throughout this period.

1.1.4 Evolution of the evidence base

Initially ICDs were implanted in patients who had survived a SCA and experienced ongoing VA refractory to medical therapy. Early studies compared mortality in patients treated with antiarrhythmic medication or ICDs, until the superiority of ICDs for survivors of SCA was proven in the landmark AVID study in 1997 (The Antiarrhythmics Versus Implantable Defibrillator (AVID) Investigators, 1997). The use of ICDs in this group of patients is known as secondary prevention of SCD.

Whilst use of ICD for secondary prevention indications was confirmed, researchers investigated the potential use of ICDs for prophylactic indications, known as primary prevention of SCD. Initially research focussed on improving survival in patients who had coronary artery disease (CAD), as myocardial scar is a substrate for VA and subsequently patients are at higher risk of SCD. The MADIT and MUSTT (Moss, Higgins and Waldo, 1996; Buxton *et al.*, 1999) trials investigated use of ICDs in patients with ischaemic heart disease, reduced left ventricular ejection fraction (LVEF), and inducible VA; despite differences in methodology and result reporting, both trials concluded that ICD implant improved survival in this patient group. MADIT investigators reported that the hazard ratio comparing the risk of death per unit of time in the ICD group with that in a conventional medical therapy group was 0.46 (Moss, Higgins and Waldo, 1996). This was a relatively small study with methodological limitations, however, these were addressed in the larger MUSTT study (Gold and Nisam, 2000). MUSTT compared electrophysiologically (EP) guided therapy (testing of anti-arrhythmic drugs on inducible VA, followed by ICD implant) to no therapy (Buxton *et al.*, 1999) and reported a 7% reduction in absolute risk of cardiac arrest or death attributable to the use of ICDs. Following these studies, ICD indications were expanded to include patients with CAD, severely reduced LVEF, non-sustained VA and inducible sustained VA on EP testing. However, by the early 2000s studies such as MADIT II enrolled similar patients but without the eligibility criterion of inducible VA and these also showed a reduction in mortality with ICD implant compared to medical therapy (hazard ratio 0.69) (Moss *et al.*, 2002), leading to the removal of inducible VA as an indication for ICD implant in the majority of cases which remains the case today (Zeppenfeld *et al.*, 2022).

SCD-HeFT evaluated the effectiveness of ICDs in reducing mortality in patients with heart failure, and demonstrated that in patients with symptomatic heart failure and LVEF $\leq$35%, mortality was reduced compared to patients in the placebo and antiarrhythmic medication groups (Bardy *et al.*, 2005). There was no difference in effect in patients with heart failure due to ischaemic or non-ischaemic causes, thus expanding the indications for primary prevention ICD use to include patients with non-ischaemic cardiomyopathy. However, not all studies have shown that ICD implant is of benefit in groups thought to be at high risk of VA. The DINAMIT and CABG Patch trials evaluated the use of ICDs at the time of acute MI and coronary artery bypass grafting respectively, and neither found evidence that ICDs improved survival when implanted prophylactically (Bigger, Jr, 1997; Hohnloser *et al.*, 2004).

Expanding indications for ICD implant has been widely researched and the studies described above are a selection of the work which informs current evidence-based practice and guidelines for ICD implant in patients with reduced LVEF (see section 1.1.4). The early research focus on identifying indications in patients with ischaemic heart disease is understandable given that 80% of SCD involves disease of the coronary arteries (Kumar *et al.*, 2021). However, SCA is an important cause of death in patients with non-ischaemic cardiac conditions, as shown by SCD-HeFT. However, the DANISH study (Køber *et al.*, 2016) reported that primary prevention ICDs implanted for non-ischaemic systolic heart failure did not provide a significant survival benefit. The difference between the results of SCD-HeFT and DANISH may be explained by the improvement in treatment of heart failure through use of cardiac resynchronisation therapy (CRT) and medications (Køber *et al.*, 2016).

It has proved more difficult to risk stratify patients at high risk of SCD with normal LVEF, including patients with structural heart disease, hypertrophic cardiomyopathy (HCM), or primary electrical disorders such as Brugada syndrome or long QT syndrome (Ellenbogen and Wood, 2008). Improving the risk stratification process for ICD implant in patients with these conditions is an ongoing area of study. Promising areas of future research which may improve selection of patients for primary prevention ICD are cardiac magnetic resonance imaging (MRI) and genetic testing (Kumar *et al.*, 2021).

1.1.5 Current indications for ICD implant

1.1.5.1 *Primary prevention indications for ICD implant*

In the UK, the National Institute for Health and Care Excellence (NICE) recommends cardiac device therapy as an option for all patients with an LVEF of 35% or less (National Institute for Health and Care Excellence, 2014). Depending on QRS duration and morphology, this may be a form of cardiac pacing known as cardiac resynchronisation therapy (CRT-P), ICD, or a combination of both (CRT-D). ICDs are not indicated for patients with severe symptoms of heart failure (Figure 2) because ICDs are not likely to improve survival in this group due to their already poor life expectancy. This guidance was reviewed in 2017 (National Institute for Health and Care Excellence, 2017a) and moved to the ‘static guidance list’ as new evidence was deemed to be in support of the existing guidance. However, the more recent European Society of Cardiology (ESC) guidelines (Zeppenfeld *et al.*, 2022) take a more nuanced approach to ICD indications in light of more recently published evidence, as described below.

Figure 2: 2014 NICE guidelines for device therapy when LVEF<35%

	NYHA class I	NYHA class II	NYHA class III	NYHA class IV
QRS <120ms	ICD	ICD	ICD	No ICD
QRS 120-149ms without LBBB	ICD	ICD	ICD	No ICD
QRS 120-149ms with LBBB	ICD	CRT-D	CRT-D or CRT-P	No ICD
QRS≥150ms	CRT-D	CRT-D	CRT-D or CRT-P	No ICD
NYHA, New York Heart Association; ms, milliseconds; LBBB, left bundle branch block				

NICE also recommends ICD implant for those with familial conditions with high risk of SCD (Brugada syndrome, HCM, arrhythmogenic right ventricular cardiomyopathy (ARVC), long QT syndrome, surgical repair of congenital heart disease), although does not provide guidance on how to risk stratify (National Institute for Health and Care Excellence, 2014). The ESC provide more up-to-date guidance for risk stratification including identifying high risk features such as family history of SCD, unexplained syncope, or presence of symptomatic VA (Zeppenfeld *et al.*, 2022). These guidelines also reflect the results of the DANISH trial (Køber *et al.*, 2016), as non-ischaemic cardiomyopathy is a class IIa indication for ICD implant, where symptomatic ischaemic cardiomyopathy remains a class I indication.

1.1.5.2 *Secondary prevention indications for ICD implant*

NICE guidance recommends ICD implant as an option for treating people with VA without a treatable cause, including those who have survived a VA cardiac arrest, have sustained ventricular tachycardia (VT) causing syncope/ haemodynamic compromise, or have sustained VT with LVEF ≤35% and NHYA class ≤III, regardless of symptoms (National Institute for Health and Care Excellence, 2014). Similarly, ESC recommend ICD implant for VA with haemodynamic compromise in the absence of a reversible cause (Zeppenfeld *et al.*, 2022).

1.1.5.3 *Psychological considerations prior to ICD implant*

Regardless of the clinical indication for ICD implant, the ESC recommends discussion of quality of life (QoL) issues with patients before ICD implant and as their disease progresses (Zeppenfeld *et al.*, 2022). NICE guidance also acknowledges that ICD recipients may develop psychological distress but provides no specific guidance on management (National Institute for Health and Care Excellence, 2017b). However, the American Heart Association (AHA) have previously published a statement including recommendations to improve psychological outcomes in ICD patients (Dunbar *et al.*, 2012), including improving preimplant and postimplant education and support to patients and their family members. In this AHA paper, a comprehensive review of intervention options was presented along with recommendations for future research areas. A more detailed review of this subject is presented in section 1.2.

1.1.6 Living with an ICD

1.1.6.1 *Anti-arrhythmia therapy*

Most ICDs have the capability to deliver two types of therapy to treat VA: anti-tachycardia pacing (ATP) and shocks. ATP been shown to be particularly effective at terminating VT (Ellenbogen and Wood, 2008). This type of pacing therapy is painless and the patient is often completely unaware of it occurring, and therefore, if effective, is preferable to shock therapy due to the reduction in morbidity caused by shocks (Wathen *et al.*, 2001). ATP is now systematically used prior to shocks in transvenous ICDs, and has been shown to reduce shock therapy without increasing the incidence of arrhythmic syncope or other adverse events (Saeed *et al.*, 2014; Khan *et al.*, 2021).

Shock therapy, on the other hand, involves delivering a large current of energy (usually around 40 joules) between the ICD lead and generator, which are positioned to capture as much of the myocardium as possible. A critical mass of the myocardium must be depolarised in order to achieve defibrillation, which is why careful implant positioning and high energy shocks are required (Ellenbogen and Wood, 2008). Unfortunately, the high energy requires means shock recipients usually find this a very painful experience and as defibrillation is a probabilistic phenomenon, multiple shocks may be necessary to restore a normal heart rhythm. The impact this has on patients recognised in ESC guidelines, which recommend assessment and treatment of psychological distress following recurrent shocks (Priori *et al.*, 2015). The incidence of appropriate ICD shocks reported in published studies ranges from 16.5% in ICD recipients with primary prevention indications (Masini *et al.*, 2021) to 29.5% in those with secondary prevention indications (Blom *et al.*, 2019). Inappropriate shocks occurred in 17.5% of patients in the same study (Blom *et al.*, 2019).

1.1.6.2 *Electro-magnetic interference*

Electro-magnetic interference (EMI) is an important source of restriction upon activity for ICD recipients, due to the risk of electro-magnetic items temporarily affecting the ICD function, which may lead to it delivering an inappropriate shock or withholding a shock which was needed (Medtronic, 2021). ICD manufacturers provide guidance on safe distances between their ICDs and items known to cause interference including frequently used household and workplace items. Workplace items include items such as motors and welding equipment (Medtronic, 2021) and therefore these restrictions may impact some patients' careers.

EMI can also occur in items which are classed as safe in normal conditions, but are not in good working order or not properly wired (Medtronic, 2021). There are multiple examples of this in the literature including from a washing machine (Chongtham *et al.*, 2007), swimming pool (Wight and Lloyd, 2019), and lawn mower (Von Olshausen *et al.*, 2014). Despite sophisticated algorithms to avoid inappropriate therapy (Mukherjee, Bera and Kar, 2022), it remains impossible to guarantee a patient will never receive an inappropriate shock due to EMI.

1.1.6.3 *Driving restrictions*

In the UK, the Driver and Vehicle Licensing Agency (DVLA) provides guidelines on driving for ICD recipients. These are updated regularly but at the time of writing, all patients must not drive a car or motorcycle after implant and after any therapy associated with symptoms (Driver and Vehicle Licensing Agency, 2022); the length of ban depends on individual circumstances. Bus and lorry drivers are permanently barred from driving these vehicles, which clearly has significant implications for patients who drive for a living. Patient perceive a loss of independence and change in self-image as a result of driving restrictions (Johansson and Strömberg, 2010). A Danish study found that patients did not always understand the rationale for driving restrictions and 25% of patients responding to their survey admitted to driving while restricted (Bjerre *et al.*, 2018).

1.2 Implantable Cardioverter Defibrillators, mental health, and support interventions

1.2.1 Background

Patients with ICDs are known to suffer from increased prevalence of mental health disorders compared to the general population. There is an association between ICD shocks and distress (Sears *et al.*, 2018), although this relationship is complex with several mediating factors being proposed in the literature. A wide range of psychological and education interventions have been explored to improve psychological distress and QoL in ICD patients, and patient support groups are currently recommended in professional guidelines, despite a lack of clarity regarding the most effective format for such groups. The evidence surrounding psychological support for ICD recipients and the use of support groups is reviewed below.

1.2.2 Mental health and well-being in ICD recipients

Mental health is defined by the World Health Organisation (WHO) not as the absence of mental illness but “a state of mental well-being that enables people to cope with the stresses of life, realise their abilities, learn and work well, and contribute to their community” (World Health Organisation, 2022). However, the prevalence of mental disorders such as anxiety and depression are commonly measured in healthcare research and reduction in symptoms used to measure the effectiveness of interventions designed to improve mental health. Published literature regarding ICD implant and mental health and/or illness is reviewed below.

1.2.3 Anxiety, depression, and quality of life in recipients of ICDs

Studies have demonstrated high levels of anxiety in ICD recipients, with prevalence ranging from 13 to 76% (Magyar-Russell *et al.*, 2011; Berg *et al.*, 2016; Berg, Rasmussen, *et al.*, 2019). Anxiety can manifest itself as panic disorder, generalised anxiety disorder (GAD) or post-traumatic stress disorder (PTSD) (Ford *et al.*, 2016; Habibović *et al.*, 2017; Berg, Herning, *et al.*, 2019) and can be severe in some patients, requiring psychiatric treatment (Bourke *et al.*, 1997). Depression is also commonly reported with a prevalence of approximately 20% (Magyar-Russell *et al.*, 2011), however anxiety appears to be a more specific issue for ICD recipients (Sears *et al.*, 2007). Anxiety symptoms are more frequently reported by female patients (Magyar-Russell *et al.*, 2011;

Dunbar *et al.*, 2012; Conelius, 2015; Perini *et al.*, 2017; Israelsson *et al.*, 2018), younger patients (Perini *et al.*, 2017), and are associated with a type D personality (Habibović, Broers, *et al.*, 2018; Habibović, Mudde, *et al.*, 2018). It has been shown that anxiety is more common in the first year post ICD implant and that patients may experience symptoms of anxiety regardless of whether their implant indication was primary or secondary prevention and whether they have received shocks from their device (Proietti *et al.*, 2017); however, receiving multiple shocks increases the likelihood of anxiety (Qintar *et al.*, 2015; Perini *et al.*, 2017). QoL in ICD recipients has also been measured and similarly found that shock delivery is associated with a transient drop in QoL (Dunbar *et al.*, 2012; Sears *et al.*, 2018); however, ICD implantation itself has not been found to lower QoL (Perini *et al.*, 2017; da Silva *et al.*, 2018).

Anxiety and reduced QoL are associated with worse outcomes for ICD patients (Berg, Rasmussen, *et al.*, 2019, Ooi *et al.*, 2016). In Denmark, mental as well as physical health was found to predict mortality and readmission to hospital (Berg, Rasmussen, *et al.*, 2019). This study measured patient-reported outcomes including anxiety, depression and QoL at discharge following an ICD-related admission. The admissions included initial implant, shock delivery and generator changes, suggesting that anxiety and reduced QoL can persist long-term post implant, although another large study has shown that there is overall improvement over time (Perini *et al.*, 2017). The potential for anxiety as a predictor of readmission and mortality clearly demonstrates the need to take recognising and managing signs and symptoms of anxiety seriously as the benefit to patients could be significant. The relationship between anxiety and reduced QoL and whether one compounds the other has not been explained in this patient group, however it has been shown that anxiety leads to avoidance of or restriction of activities, including exercise (McDonough, 2009; Flemme *et al.*, 2011) and engagement in social activities (Flemme *et al.*, 2011), which may lead to reduced QoL.

1.2.4 ICDs, anxiety and shock therapy

Some researchers have raised the possibility of whether higher levels of anxiety may actually increase occurrence of arrhythmia and ICD shock; the mechanism for anxiety as a cause of arrhythmia is poorly understood but thought to relate to deregulation of the autonomic cardiovascular nervous system (Proietti *et al.*, 2017). Interestingly, one study found that yoga reduced number of shocks as well as anxiety about shocks (Toise *et al.*, 2014), and raises the question whether the reduction in shocks was directly related to reduction in anxiety or to greater confidence in activity and subsequent improvement in physical health. Exercise intervention studies have tended to explore the effect of exercise upon psychological outcomes (Dunbar *et al.*, 2012), however, one early study demonstrated that patients who took part in a cardiac rehabilitation program had fewer shocks compared to those who did not (Davids *et al.*, 2005).

The possibility of anxiety being a potential cause and even a reversible factor for VA is not proven nor considered in guidelines for ICD therapy (Zeppenfeld, 2022). However, electrophysiologically there must be a substrate for VA (Foth *et al.*, 2023) and therefore while anxiety may increase the occurrence of VA in the presence of a substrate, it seems unlikely to become an independent risk factor which leads directly to ICD implant.

Several researchers have attempted to identify the underlying cause of anxiety and decreased QoL in patients with ICDs which would allow for more targeted intervention. It is probable that some patients may have pre-existing psychological symptoms as many of the underlying conditions which lead to ICD implantation are also associated with anxiety and depression, such as coronary heart disease (Richards *et al.*, 2018). However the risk of shocks and their recurrence is unique to ICD patients and shock anxiety is recognised as a distinct entity which has been assessed in several studies using a specific validated measure, the Florida Shock Anxiety Scale (FSAS) (Morken, Bru, *et al.*, 2014; Morken, Norekvål, *et al.*, 2014; Toise *et al.*, 2014; Qintar *et al.*, 2015; Perini *et al.*, 2017; Sears *et al.*, 2018). A 2016 systematic review (Ooi *et al.*, 2016) demonstrated that both quantitative and qualitative studies consistently find that patients with shocks report more symptoms of psychological distress than those without shocks. However, it has been suggested that the relationship between shocks and anxiety is rather more complex than a simple cause and effect (Lee *et al.*, 2020), and a greater understanding of what influences this relationship could help prevent distress after shock receipt.

1.2.5 Perceived control and ICD-related concerns

The unpredictability of shock therapy is an important contributor to patients' distress (Morken, Severinsson and Karlsen, 2010); many patients experience a sense of loss of control after a shock (Proietti *et al.*, 2017) and it has been suggested that it is the loss of perceived control which leads to anxiety and reduced QoL rather than the shock per se (Hammash *et al.*, 2019; Lee *et al.*, 2020). These studies measured perceived control and ICD-related concerns using the Control Attitudes Scale-Revised and the Patient ICD-related Concerns questionnaire respectively and found that shocks did not directly predict anxiety whereas lower perceived control and higher ICD-related concerns did. The mediating effect of ICD-related concerns upon shock anxiety is supported by findings from a larger Swedish cross-sectional correlation study (Thylén *et al.*, 2016), whose findings also suggested that shock receipt is not directly associated with distress. Lee *et al.* (2020) propose that shocks do not directly cause distress because the patient has to appraise what happened in order to generate emotions, and therefore that lower perceived control and higher ICD-related concerns mediate this appraisal process and lead to greater distress. This theme of ICD-related concerns and unpredictability has been demonstrated in several qualitative studies exploring patient experience (Morken, Severinsson and Karlsen, 2010; Humphreys *et al.*, 2016), including a study with young adults (McDonough, 2009), and with focus on both female (Conelius, 2015) and male (Jakub, 2018) specific issues, with similar findings across all studies. Not surprisingly, it has been suggested that interventions should therefore be targeted to improve perceived control and address concerns (Thylén *et al.*, 2016; Hammash *et al.*, 2019), which may be related to poor information provision and education prior to and after implant (Pedersen *et al.*, 2017).

1.2.6 Acceptance of ICDs

Patient acceptance of their ICD is another area which may influence overall well-being. Acceptance has been defined as "the psychological accommodation and understanding of the advantages and disadvantages of the device, the recommendations of the device to others, and the derivation of benefit in terms of biomedical, psychological, and social functioning" (Burns *et al.*, 2005). In more simple terms, it means realising that despite having an ICD, they will be okay (Kübler-Ross, 1969). The Florida Patient Acceptance Survey (FPAS) is a validated measure of acceptance in ICD recipients and offers an alternative outcome for measuring well-being (Burns *et al.*, 2005). However, it has not been widely used in published research.

Qualitative research provides more insight into the concept of acceptance, and it links to patients' goals of getting back to normal, or 'almost normal' (Zeigler and Nelms, 2009). Studies show that patients do live in fear of receiving a shock (Kamphuis *et al.*, 2004; Conelius, 2015; Garrino *et al.*, 2018), but restrictions to life, such as to sports activities or particular career pathways, are also perceived to have a negative impact on well-being due to the loss of control (Zeigler and Nelms, 2009; Garrino *et al.*, 2018). Creating a positive attitude towards living with these restrictions is an important aspect of normalising life with an ICD, and patients found social support, peer support and spirituality helped them with this challenge (Zeigler and Nelms, 2009). Several studies have advocated for support groups which would allow ICD recipients to access the peer and social support needed for this process of normalisation and acceptance (McDonough, 2009; Zeigler and Nelms, 2009; Conelius, 2015).

1.2.7 Provision of psychological support to ICD recipients in the United Kingdom (UK)

None of the studies discussed above were conducted in the UK; although there are many similarities in ICD service provision between the UK and elsewhere, there is one unique aspect which may affect patient experience. In the UK cardiac device follow-up is almost exclusively undertaken by the scientific workforce (cardiac physiologists / clinical scientists) (British Heart Rhythm Society, 2022) as opposed to medical or nursing staff as in many other countries. While the UK is leading the way in developing senior scientific roles (Campbell, Robinson and Rana, 2019), prior to 2012 there was no route to statutory regulation for cardiac physiologists and standards for training varied from trust to trust; counselling skills were not routinely part of this training (Proietti *et al.*, 2017). It is therefore particularly pertinent to the UK workforce to consider the role they play in supporting ICD patients. Another issue (which applies to but is not unique to the UK) is the move towards remote monitoring of ICDs and the decrease in face-to-face time which patients share with health care professionals (HCPs) (Pedersen *et al.*, 2017), which may also be a contributory factor to higher levels of ICD-related concerns and decreased QoL as satisfaction with information provision is known to relate to QoL (Pedersen *et al.*, 2017).

Current UK guidelines for psychological support for ICD recipients are shown in Figure 3. Aside from support groups, there is no recommendation for ICD-specific psychological interventions, possibly because of the limited evidence base for these as well as resource implications. National charities also recommend support groups and they provide some guidance for this with examples of existing groups, which are varied in their format and aims (Arrhythmia Alliance, 2017; British Heart Foundation, 2021). However, implementation of support groups remains low with no access to such groups for many patients, despite evidence of their interest in attending (Murray *et al.*, 2021).

Figure 3: BHRS guidelines for psychological support, (British Heart Rhythm Society, 2022), p.13

> *CIED follow up services should have access to psychological support and counselling services. Staff involved in the care of patients with ICDs should be able to provide pre-ICD implant, typical day to day advice and education in clinic and through 'helplines' to patients with ICDs. It is recognised however that 'counselling' a patient if they are severely struggling psychologically following cardiac arrest, ICD implant, from shock therapy or other reasons falls outside the skill set of most cardiac scientists/physiologists and specialist nurses. Consequently, it is recommended that there are local procedures and policies in place to help recognise and support this group of patients which should include guidance on referral to appropriate services.*
>
> *Patient support groups are encouraged where possible as many patients find this helpful.*

1.2.8 Psychosocial support interventions

A range of psychological and educational interventions aimed at improving psychological outcomes and QoL for ICD patients have been investigated. Several studies have explored the use of CBT for patients with PTSD (Irvine *et al.*, 2011; Ford *et al.*, 2016) and for patients with anxiety and depression (Sears *et al.*, 2007; Dunbar *et al.*, 2009; Qintar *et al.*, 2015) with promising results, although the extent to which they can be generalised to the whole ICD population is not clear. Ford *et al.* (2016) excluded patients with primary prevention ICD due to ischaemic heart disease, presumably because they were thought to suffer less from PTSD although no research has demonstrated a significant difference in levels of psychological distress between primary and secondary prevention patients (Magyar-Russell *et al.*, 2011; Dunbar *et al.*, 2012). In fact, only a relatively small proportion of included patients had high levels of PTSD symptoms (Ford *et al.*, 2016). Conversely, Qintar *et al.* (2015) included patients with both primary and secondary prevention ICD implants, but only those with at least moderate symptoms of anxiety and depression. These differences in inclusion criteria make comparison of results challenging, and this issue is compounded by the wide variation in interventions themselves; for example, the number of CBT sessions varied from 1 to 8 in these studies.

Two early studies utilised group therapy as part of structured psycho-educational interventions (Sears *et al.*, 2007; Dunbar *et al.*, 2009). Both studies demonstrated reduction in psychological distress, although the group sessions did include some CBT content and it could be argued that these interventions shouldn't strictly be classed as a support group (Delisle *et al.*, 2017). However, these studies raise some interesting points for discussion. Sears *et al.* (2007) included only patients who had previously experienced ICD shock whereas Dunbar *et al.* (2009) included all ICD patients (of whom 15.8% received ICD shock) yet the baseline levels of anxiety measured by the State-Trait Anxiety Inventory were similar in both studies. This is surprising given the volume of literature demonstrating the association with shocks and anxiety (Qintar *et al.*, 2015; Perini *et al.*, 2017), from which it might be expected that the group of patients who had all experienced shocks would have a higher baseline level of anxiety. Both groups also had similar characteristics of age and sex (being female and younger are associated with greater anxiety) making this lack of difference difficult to account for. This suggests the presence of anxiety in ICD recipients is likely to be more complex than simply being caused by receipt of ICD shocks, a novel concept which will be explored throughout the present study.

Dunbar *et al.* (2009) compared group therapy with the same content delivered by telephone and usual care and found greater reduction in anxiety in the participants randomised to the group therapy arm, although those in the telephone arm also reported more improvement than the usual care group. This suggests there may be different benefits from structured CBT therapy and from being in a group; within a group there is an opportunity to meet and talk to others who share your experience, and the benefit of this social and peer support also needs consideration.

Other studies have investigated the impact of exercise-based cardiac rehabilitation on QoL in ICD patients, however, a systematic review paper was unable to assess the effect due to lack of evidence (Nielsen *et al.*, 2019). Another systematic review similarly concluded that although published small scale studies are promising, larger scale randomised controlled trials (RCTs) are required to reliably measure the effect of interventions upon psychological symptoms (Salmoirago-Blotcher and Ockene, 2009). In addition the early published studies are based on secondary prevention populations whereas more recent changes in guidelines have seen a large increase in patients with primary prevention ICDs (Dunbar *et al.*, 2012); this also applies to the early studies exploring the effect of ICD support groups (Badger and Morris, 1989; Dickerson, Posluszny and Kennedy, 2000).

1.2.9 Support groups

The concept of support groups is not new: they date back to 1930s with the establishment of Alcoholics Anonymous (Keil, 2019). What exactly constitutes a support group varies between studies (the majority of which are for other clinical conditions), however there are some consistent features: firstly the group aims are determined by the participants rather than the providers (Carlsen, 2003) and secondly that the group does not have a structured curriculum with a defined beginning and end (Delisle *et al.*, 2017). Support groups are not resource-heavy and thus are a feasible option for support during times of austerity in the health service (Proietti *et al.*, 2017). Several studies into patient experience of living with an ICD advocate the use of support groups, either directly (Garrett Hazelton *et al.*, 2009; Conelius, 2015; Thylén *et al.*, 2016) or by implication (Morken, Bru, *et al.*, 2014; Humphreys *et al.*, 2016; Jakub, 2018).

The perceived benefits of support groups are predominantly seen as the opportunity to talk to others with the same experiences (Conelius, 2015) and being able to talk openly about their fears and anxieties (Humphreys *et al.*, 2016; Jakub, 2018). Sharing these thoughts with others is thought to increase a sense of control which in turn may prevent deterioration into symptoms of anxiety, depression or PTSD (Morken, Bru, *et al.*, 2014). The question of whether the potential role of support groups is as a preventative intervention rather than therapeutic has been raised in the literature (Bourke *et al.*, 1997; Morken, Bru, *et al.*, 2014), theoretically because they could help to address the mediating role of ICD-related concerns and perceived control and their relationship with shock anxiety (Thylén *et al.*, 2016).

As discussed, important perceived benefits of support groups are the concepts of social and peer support. The effect of formal peer support was investigated by Shen *et al.* (2019) in a Chinese population of pacemaker patients. The generalisability of their findings to UK ICD patients is limited due to potential cultural differences, small scale RCT design, and technical differences between pacemakers and ICDs. However, they found symptoms of anxiety and depression were significantly reduced in the peer support group, which suggests further study in the ICD population is warranted and supports use of this in clinical practice. Social support is commonly provided by partners and carers, however there is evidence that partners in particular may also suffer from psychological distress (Dickerson, Posluszny and Kennedy, 2000; Dunbar *et al.*, 2012) and it has been suggested that support interventions should include partners or carers to provide them with the support needed to help the patient learn to live with an ICD (Garrett Hazelton *et al.*, 2009; Hammash *et al.*, 2019).

1.2.9.1 *Support groups in healthcare*

There is considerably more evidence regarding the use of patient support groups for other clinical conditions, most notably cancer. A scoping review into the use of support groups for rare diseases (Delisle *et al.*, 2017) found that perceived benefits of support groups were similar for patients with rare and more common diseases. ICD recipients do have some experience in common with patients with other long-term conditions, however the unique risk of recurrent shock is a significant difference which may limit the generalisability of other studies to this patient group.

Qualitative studies into support groups have included patients with cancer (Devitt *et al.*, 2010; Mallya *et al.*, 2020), heart failure (Lockhart *et al.*, 2014), and allergies (Jones, Sommereux and Smith, 2018). Themes identified in these studies encompassed the perceived benefits of support groups, including the opportunity to meet and talk with people with the same condition or experiences, and for information provision and exchange. A key difference in the cancer and heart failure studies was the focus upon depressive rather than anxiety symptoms, suggesting that different diseases may cause psychological distress in different ways. In comparison, the support group for allergy sufferers focussed on survival from potentially life-threatening anaphylaxis and anxiety surrounding when this may recur, an experience which has more in common with ICD recipients. Each of these studies highlighted the importance of support groups aimed at a very specific subset of patients to allow sharing of similar experiences; for example, the requirement for site-specific cancer support groups (Devitt *et al.*, 2010; Mallya *et al.*, 2020), which ratifies the need for ICD support groups rather than generic cardiology groups. Another applicable finding from the wider literature is from Devitt *et al.* (2010) who explored the attitudes of facilitators as well as patients in their lung cancer support group. They highlighted the different preferences towards meeting content and format between patients and facilitators, describing how facilitators placed greater importance upon social and emotional support whereas patients felt information provision was more important. This demonstrates the importance of ensuring the aims of the patients drive the group format; a key part of the support group definition (Carlsen, 2003).

1.2.9.2 *Support group attendance*

A common theme in the wider supportive care literature is the challenge in finding one intervention to suit all patients. This applies to the differences between diseases and conditions as described above, but also to the differing needs of individual patients, even those with very similar illness experiences. A significant proportion of support group literature focusses on not what the benefits of support groups are, but rather who benefits from them and why patients choose to attend (Williams *et al.*, 2004; Grande, Myers and Sutton, 2006; McDonough, 2009; Grande *et al.*, 2014). Grande, Myers and Sutton (2006) surveyed 107 cancer patients and reported that clinical and demographic characteristics did not predict support group attendance with the exceptions of sex and age (female and younger were more likely to attend). It should be noted however that Grande, Myers and Sutton (2006) did not record ethnicity of their participants, which has been shown to influence patient's preference for support and acceptance of ICDs (Serber *et al.*, 2009; Wilson *et al.*, 2013). Grande, Myers and Sutton (2006) found that psychosocial variables such as social support, perceived beliefs about support groups, and preferred coping strategy did predict attendance of a support group. The authors warn that strategies to increase support group attendance should be planned carefully as they will not suit all patients' coping styles and may in fact be harmful for some patients who already have sufficient existing support. A larger later study gave recommendations for health care professionals (HCPs) to increase support group participation by targeting those patients with less social support and higher disease impact (Grande *et al.*, 2014). Furthermore, age and sex being found to be predictive of support group use in cancer patients (Grande, Myers and Sutton, 2006) is not supported by two studies exploring use of support groups in ICD patients (Williams *et al.*, 2004; McDonough, 2009); these qualitative studies reported females and younger patients were choosing not to attend because they noticed other participants were older and predominantly male. McDonough (2009) described the specific concerns held by younger (18-40 years) ICD patients and recommended separate interventions are offered for this group and older patients due to their different needs; again demonstrating the difficulty in designing a one-size-fits-all approach. Neither of these studies explored the influence of ethnicity on ICD experience or support group attendance; McDonough (2009) simply noted that their sample was predominantly white, whilst Williams *et al.* (2004) did not report ethnicity in their sample at all. This data gap is repeated across the landmark ICD studies and is reflected in ICD utilisation; white patients in the USA are significantly more likely to receive an ICD despite the risk of sudden death being higher in black patients (Kiernan *et al.*, 2022). This has led to bias in our current knowledge about the experience of ICD recipients towards those of white background.

The difficulty in meeting the needs of all patients is reflected by support group participation levels being consistently between 7.6 and 13% of patients (Van Uden-Kraan *et al.*, 2011; Sautier *et al.*, 2014; Hyde and Wada, 2019), with another study reporting that 48% of participants attend once and do not return (Mallya *et al.*, 2020). Despite this low participation rate, use of support groups is felt to be justified but further study is recommended to inform how to ensure groups meet the needs of a wider range of patients, and how to boost participation by those who are likely to benefit. Given the above discussion, it may be that more specific groups are required depending on age, sex, ethnicity, and clinical condition; participation of these could then be boosted by addressing the psychosocial factors described by Grande *et al.* (2014). It is not clear from the literature whether those patients thought to be at higher risk of distress (i.e. with lower perceived control and greater ICD-related concerns) are the same group of patients who are more likely to attend support groups. It has been reported that the psychosocial attributes leading to support group attendance includes having higher perceived control of their illness (Grande *et al.*, 2014), whereas it has also been shown that patients with lower perceived control suffer more from anxiety (Thylén *et al.*, 2016; Lee *et al.*, 2020). This raises the question of whether support groups appeal to those with the greatest need in the ICD population.

1.2.9.3 *The role of healthcare professionals*

The role of HCPs in support groups is also frequently reported on in support group studies (Devitt *et al.*, 2010; Thylén *et al.*, 2016). There is varied opinion on the value of HCP involvement in this type of intervention; on one hand, HCPs cannot provide the sharing of experiences and true empathy which is offered from fellow patients, but on the other hand HCPs can provide information and address concerns and misconceptions should they arise (Proietti *et al.*, 2017). Arrhythmia Alliance (AA) has published guidelines for setting up a support group and state that the most successful groups are run in partnership between patients and HCPs (Arrhythmia Alliance, 2017), although it is not clear what defines successful or upon what evidence these guidelines are based on. The studies discussed in this review have all had some degree of HCP involvement, although only three specifically explored the question of how HCPs influenced the experience of support groups (Dickerson, Posluszny and Kennedy, 2000; Williams *et al.*, 2004; Devitt *et al.*, 2010) and their findings are not consistent. Devitt *et al.* (2010) found that 83% of lung cancer patients preferred the group to be led by an HCP with focus on information on treatment and self-care rather than psychological support. Dickerson *et al.* (2000) reported that patients recognised the importance of the nurse facilitator in their group, who provided expert information and counselling, guided discussions, and made referrals where required. This is in contrast to Williams *et al.* (2004), in which patients described a key benefit being the provision of information and support which was different to what HCPs could provide. More recent publications have considered the role of social media in supporting patients (Naslund *et al.*, 2016; Kramer Freeman *et al.*, 2017). The role of HCPs in support groups, and indeed the role of support groups themselves, may be evolving due to the increasing availability of information and support online and through social media. Social media provides opportunities for peer-to-peer support for those with serious illness or other barriers to in-person attendance (Naslund *et al.*, 2016), however, the authors warn against the risks of potential exposure to misleading information.

It appears that an important perceived role of HCPs within support groups is that of a moderator to ensure information being shared is accurate and good quality (Medina, Loques Filho and Mesquita, 2013; Delisle *et al.*, 2017; Jones, Sommereux and Smith, 2018; Keil, 2019). This is seen as particularly relevant to online support groups, but the principal also applies to in-person groups. However, as mentioned above, this role for HCPs may be missing in support accessed over social media (Naslund *et al.*, 2016). Kramer Freeman *et al.* (2017) in their study of social media use in ICD recipients subsequently suggested that clinicians increase their online offerings to meet patient preferences for gathering information. Overall, the involvement of HCPs in support groups seems to be generally accepted, but the literature does not yet describe how best to do this to maximise benefit to patients. There are concerns that non-constructive involvement may negatively affect a group, as non-constructive support from HCPs towards ICD patients has been reported to hinder device acceptance and become a source of stress (Morken, Bru, *et al.*, 2014; Morken, Norekvål, *et al.*, 2014; Ooi *et al.*, 2016; Thylén *et al.*, 2016). Conversely, it has been suggested that HCPs who are involved with support groups benefit themselves from listening to patients and carers views on their experiences and care they have received, which may lead to improvements in empathy and service provision (Carlsen, 2003; Proietti *et al.*, 2017).

1.2.9.4 *Support groups for ICD recipients*

There are few studies published specifically investigating patient support groups for ICD recipients. After a thorough literature search, ten studies were found which met the definition of a support group: one randomised controlled trial (RCT) (Yardimci and Mert, 2019), two observational studies (Dickerson, Wu and Kennedy, 2006; Myers and James, 2008), two mixed-methods studies (Molchany and Peterson, 1994; Serber *et al.*, 2010), four qualitative studies (Dickerson, Posluszny and Kennedy, 2000; Dickerson SS, Flaig DM, and Kennedy MC, 2000; Williams *et al.*, 2004; Dickerson, 2005) and one service evaluation (Teplitz, Egenes and Brask, 1990). Of these ten studies, one was based in Australia, one in Turkey, and the remainder in the USA, which may reflect the fact that ICD implant rates have historically been 4 to 5 times higher in the USA compared to Europe (Camm and Nisam, 2010).

In these studies, patient support groups were organised in person (Teplitz, Egenes and Brask, 1990; Molchany and Peterson, 1994; Dickerson, Posluszny and Kennedy, 2000; Williams *et al.*, 2004; Dickerson, Wu and Kennedy, 2006; Myers and James, 2008), online (Dickerson SS, Flaig DM, and Kennedy MC, 2000; Dickerson, 2005; Yardimci and Mert, 2019), and using a hybrid approach (Serber *et al.*, 2010). Terminology used within this thesis for types of support groups are shown in Figure 4. None of these studies specifically addressed patient preferences regarding the format and no studies have explored experiences of remote support groups. While in-person attendees of the hybrid meeting found the format acceptable (Serber *et al.*, 2010), the experience of the remote attendees of the meeting was not investigated. This leaves unanswered questions about the acceptability of remote support groups for ICD recipients, however, it has been shown that remote support is acceptable to other patient groups (Banbury *et al.*, 2018).

Figure 4: Support group terminology used in the present thesis

In-person	*The group meeting is held in a physical space at a specified time, occurring at set intervals. Physical attendance is required to participate in the group.*
Online	*Support is offered over the internet using written formats such as forums. Live chat sessions may be utilised at set intervals for real time communication, although members may participate in the forum at any time.*
Remote	*The group meeting is held using video-conferencing technology at a specified time, occurring at set intervals. Remote attendance in real time is required to participate in the group.*
Hybrid	*A meeting is held which allows both in-person and remote attendance.*

The quantitative studies measured a range of outcomes which are aspects of well-being, including anxiety (Molchany and Peterson, 1994; Myers and James, 2008; Yardimci and Mert, 2019), QoL (Dickerson, Wu and Kennedy, 2006; Yardimci and Mert, 2019), and social support (Molchany and Peterson, 1994; Dickerson, Wu and Kennedy, 2006; Myers and James, 2008). No study reported a significant difference in anxiety and QoL between support group attendees and non-attendees, although there were significant improvements in sub-dimensions of the SF-36 QoL measure in one study (Yardimci and Mert, 2019), suggesting that the effect of a support group may be more subtle than reducing generalised anxiety. This is not surprising considering the above discussion of ICD-related concerns, perceived control, and acceptance.

The qualitative studies provide insight into patients' experiences of support groups. Participants perceived a wide range of benefits from attending a support group including gaining meaningful information (Dickerson, Posluszny and Kennedy, 2000; Dickerson SS, Flaig DM, and Kennedy MC, 2000; Williams *et al.*, 2004; Dickerson, 2005; Serber *et al.*, 2010), connecting with others (Dickerson, Posluszny and Kennedy, 2000; Dickerson SS, Flaig DM, and Kennedy MC, 2000; Williams *et al.*, 2004), and coping with fear of death or shocks (Dickerson, Posluszny and Kennedy, 2000; Dickerson, 2005). These themes appeared to be consistent whether the groups were in-person or online. Molchany and Peterson (1994) highlighted the need for gender specific education and support; as previously discussed, there has been gender-specific experiences of ICD recipients described in the literature (Conelius, 2015; Jakub, 2018).

1.2.9.5 *Covid-19 and support groups*

In early 2020 restrictions on group gatherings due to Covid-19 made in-person support group meetings untenable. There was immediate reaction from established support groups such as Alcoholics Anonymous to maintain contact for group members by promoting meetings by phone or online (Knopf, 2020), and concern that social distancing may lead to anxiety and depression (Abel and McQueen, 2020). Several authors have now published reflections on their experiences of transitioning traditional support groups from in-person to remote meetings (Kaka *et al.*, 2021; Magdamo, Moyer and Dabrowski, 2022) or telephone support (Liese and Monley, 2021). Each of these concluded that the transition had demonstrated that alternatives to in-person meetings are viable and acceptable to patients. Remote meetings removed geographical and time barriers to attending (Kaka *et al.*, 2021), however, there were new barriers such as availability of suitable technology and difficulty engaging with a screen (Magdamo, Moyer and Dabrowski, 2022). A recent survey into remote addiction support group meetings found that these meetings have appeal and are likely to continue once in-person meetings are available again (Timko *et al.*, 2022).

In summary, Covid-19 had rapid and far-reaching effects on traditional support groups, however, they were able to transition to new formats rather than be discontinued (McMullan *et al.*, 2021). There is as yet very little published research into the impact these changes had on support group efficacy.

1.2.10 Gaps in the research

All published studies into ICD support groups recommend further research to improve their efficacy. The paucity of recent studies into ICD support groups despite national recommendations for their implementation is surprising given the level of current evidence. A systematic review of the existing studies would be a valuable start to summarise the current knowledge base.

While there is some data into patient experience of support groups, none have explored the potential differences in support needs for patients with primary or secondary prevention ICD indications or shock experience. We do not know the optimal format for support groups, nor how to effectively involve HCPs to maximise their benefit. The Covid-19 pandemic highlighted the gap in research regarding the patient experience of support groups run remotely rather than in person. Addressing these questions may help to improve group efficacy through meeting the needs of the widest patient group possible while boosting their appeal to those most in need of support.

The present review of the literature has shown that patients with ICDs suffer from mental distress which often, but not exclusively, centres around shock anxiety with more severe symptoms being associated with previous shocks. Several interventions have been studied, but current guidelines for ICD follow-up recommend the use of patient support groups. Perceived benefits of support groups include the opportunity to share experiences and gain information, which in turn is thought to improve perceived control, address ICD-related concerns, and lower anxiety. Further evaluation of existing support groups to address the gaps in the research identified is justified.

1.3 Research aims and objectives

The overall aim of this thesis is to explore the role of patient support groups in adapting to life with an ICD.

The present thesis addresses the following objectives:

1. To evaluate the existing evidence for support groups for ICD recipients, using a mixed-methods systematic review and meta-analysis.
2. To explore the attitudes and perceptions of patients attending a support group, including the influence of group format, ICD indication and ICD shock receipt, using a qualitative methodology of semi-structured interviews and thematic analysis.
3. To quantify the perceived benefit of support groups and the influence of group format and the involvement of HCPs on their experience of support groups by assessing agreement with the qualitative findings, using a carefully constructed questionnaire.

2 Chapter 2: Benefits of support groups for patients living with Implantable Cardioverter Defibrillators: a mixed-methods systematic review and meta-analysis

The work presented in this chapter was published in *Open Heart* in October 2022. The published version is shown in appendix 5. The author's contribution to this work includes:

- Protocol design and PROSPERO registration
- Database searching and screening of papers
- Quality assessment
- Data extraction
- Analysis and write up

PRISMA guidelines (Page *et al.*, 2021) were followed in the reporting of the present systematic review.

2.1 Background

Implantable cardioverter defibrillators (ICDs) were introduced to prevent sudden cardiac death (SCD), most frequently caused by coronary artery disease (80% of cases) (Santini, Lavalle and Ricci, 2007). ICDs were originally implanted as a secondary prevention strategy, with guidelines being expanded in the early 2000s to include patients at risk of SCD (primary prevention). Implant rates in England quadrupled between 2002 and 2020 (Cunningham, 2005; Murgatroyd and Dayer, 2021).

Patients with ICDs experience anxiety and depression (Magyar-Russell *et al.*, 2011; Berg, Herning, *et al.*, 2019). This may be present in patients with or without ICD-delivered shocks, but is increased by higher incidence of shocks (Perini *et al.*, 2017). The delivery of a shock to restore sinus rhythm has been shown to cause a transient reduction in quality of life (QoL) (da Silva *et al.*, 2018). Anxiety and reduced QoL are associated with increased readmissions and one-year mortality for ICD patients (Berg, Rasmussen, *et al.*, 2019). It has also been suggested that there is a correlation between anxiety and the occurrence of arrhythmia (Hoogwegt *et al.*, 2014).

A range of psychological and educational interventions to improve psychological outcomes for patients with ICDs have been investigated (Badger and Morris, 1989; Sears *et al.*, 2007; Dunbar *et al.*, 2009; Irvine *et al.*, 2011; Qintar *et al.*, 2015; Ford *et al.*, 2016; Nielsen *et al.*, 2019). The results of these studies are promising but methodological limitations restrict the extent to which they can be generalised and applied to clinical practice. At present, UK guidance for ICD follow-up (British Heart Rhythm Society, 2022) and high-profile cardiac charities (Arrhythmia Alliance, 2017; British Heart Foundation, 2021) encourage participation in patient support groups. Patient support groups are defined as groups with aims determined by the participants (rather than the providers) and without structured curriculum or end date (Delisle *et al.*, 2017). Support groups also provide an option for supportive care using limited healthcare resources (Sears *et al.*, 2007; Proietti *et al.*, 2017).

There are many support groups for patients with chronic conditions such as cancer and heart failure (Devitt *et al.*, 2010; Lockhart *et al.*, 2014; Mallya *et al.*, 2020). These groups provide benefits for the patients, such as the opportunity to meet and talk with people with the same condition or experiences, and for information provision and exchange (Devitt *et al.*, 2010; Lockhart *et al.*, 2014; Mallya *et al.*, 2020). Although ICD recipients share experiences of patients with other long-term conditions, their risk of recurrent shocks is something unique to these patients and it remains to be seen whether support groups also have a beneficial impact on well-being in ICD patients.

2.1.1 Objectives

The objectives of this mixed-methods systematic (MMS) review are to:

1. evaluate the effectiveness of patient support groups on mental well-being in patients living with ICDs using a meta-analysis, and

2. define the perceived benefits and challenges of attending a support group, using a qualitative synthesis.

2.2 Methods

2.2.1 Design and registration

This MMS review was prospectively registered (PROSPERO: CRD42021262058) by the author, with design input from workplace and academic supervisors. The protocol is included in appendix 2. It was reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement (Page *et al.*, 2021).

An MMS review was chosen as it allows for review of the totality of evidence, bringing together data on effectiveness (quantitative evidence) and experience (qualitative evidence), which may be more useful to guideline development than single method reviews (Aromataris and Munn, 2020). MMS reviews allow for evaluation of the extent of agreement and/or discrepancy between quantitative and qualitative evidence, and examination of whether the two types of data address different aspects of the topic (Aromataris and Munn, 2020). Preliminary searches had yielded a small number of papers with a wide range of research methods, and therefore an MMS review was chosen for this project because it would support integration of the results of these studies, creating a breadth and depth of understanding that could answer the review questions. Advantages of a mixed-methods approach are that it provides a more complete summary of evidence to enable clinical and policy decision-making, and, where quantitative and qualitative data appear contradictory, can be useful to explain the findings and identify gaps for future research (Stern *et al.*, 2020). However, it has limitations as a relatively new method of research synthesis with guidance that remains largely theoretical (Aromataris and Munn, 2020).

2.2.2 Inclusion criteria

2.2.2.1 *Participants*

The patients in the studies had to be 18 years or older and have had an ICD implanted, including single or dual, or biventricular devices.

2.2.2.2 *Intervention*

To be defined as a patient support group, it must have:

- aims determined by the participants rather than the providers
- no structured curriculum with a defined beginning or end.

This definition of a patient support group is that used in a published scoping review (Delisle *et al.*, 2017). Involvement of HCPs to provide education was permitted provided the objectives of the group were patient-led. Forms of HCP-led psycho-social support, including cognitive behavioural therapy, exercise programs, and psycho-educational interventions with a clear curriculum and set duration were excluded.

Following submission for publication, one reviewer commented that justification for excluding self-management groups was needed (see appendix 2). However, on reviewing the search terms (Table 1), the authors felt that self-management groups would have been identified and included in the review, although the specific term was not used.

2.2.2.3 *Comparators*

The comparison was standard care of the ICD without attendance of a support group.

2.2.2.4 *Outcomes*

For quantitative studies the main outcomes were selected *a priori* and are ‘changes in measures of mental well-being’. The definition of 'mental well-being’ is complex but it is widely understood to mean more than simply absence of mental illness and includes the ability to cope with stressors and work productively (Galderisi *et al.*, 2015). Therefore, measures of QoL as well anxiety and depression were chosen as outcomes which are aspects of mental well-being. Instruments to assess these outcomes included general (i.e. State-Trait Anxiety Index) and ICD specific (i.e. Florida Shock Anxiety Scale) measures. QoL measures included but were not limited to the SF-36 and the Quality of Life Index (QLI). ‘Social support’ was added later in the analysis as it was frequently measured. For qualitative studies, the outcomes were anxiety, depression, quality of life, benefits and challenges of attending support groups.

2.2.2.5 *Types of evidence*

A range of study designs, including quantitative, qualitative and mixed-methods designs, were included to allow for review of the totality of existing evidence.

2.2.3 Search strategy and screening

Five databases were searched in July 2021. The initial search strategy was developed for MEDLINE (see Table 1) and adapted for Embase, CINAHL, PsychINFO and Web of Science. CINAHL and PsycINFO were specifically chosen as appropriate to the topic area.

Table 1: Medline search strategy

1	(single or dual or biventricular) adj defibrillator* OR implantable cardioverter defibrillator OR implantable defibrillator* OR implantable cardioverter-defibrillator*	14581
2	Defibrillators, Implantable/	17403
3	1 OR 2	22459
4	support group* OR peer support OR peer counselling OR self-help group* OR self help group* OR education* support OR psychosocial support OR patient mentor*	25883
5	Self-Help Groups/	9314
6	4 OR 5	25883
7	3 AND 6	43

A search filter was used to include all papers published from January 1980 until July 2021. A search of grey literature included hand searches of conference abstracts between 2019 and 2021 (British Cardiovascular Society and Heart Rhythm Congress). Reference lists of included articles were searched for potential eligible papers. Non-English language articles were excluded. The author screened all records by title before the author and a second reviewer screened potentially eligible abstracts and full-texts. Where there was disagreement, a third reviewer's opinion was sought.

The database search was repeated in July 2022 to check for new publications. No eligible papers were identified.

Quality assessment

The Mixed-Methods Assessment Tool (MMAT) (Hong *et al.*, 2018) was utilised by the author and a second reviewer independently to assess quality and risk of bias. The MMAT was designed to appraise the methodological quality of five categories of studies (qualitative research, randomized controlled trials, non-randomized studies, quantitative descriptive studies, and mixed-methods studies), and was therefore chosen as the most suitable tool for the present study due to the methodological variety of studies included.

2.2.4 Data extraction and analysis

The author extracted the design, population, sex, age, comparator, outcome measures, instruments used and key findings from the included articles. Quantitative results were grouped by outcomes indicative of ‘better mental well-being’ including measures of anxiety and QoL. A meta-analysis using pooled outcome measurements was conducted using Review Manager Version 5.4 (Review Manager, 2020). This approach has been used in other published studies (Sin and Lyubomirsky, 2009; Carolan, Harris and Cavanagh, 2017). To allow comparison of data from different instruments, mental well-being data of each parameter was normalised to the average control value for that parameter. Where multiple measures were used in a study, a single parameter was chosen for the analysis with preference to measures of anxiety over generalised QoL. Adjusted data was pooled to calculate weighted standardised mean difference and 95% confidence intervals. Overall effect was calculated using a Z test.

Qualitative results were uploaded verbatim to NVivo 11 (QSR International Inc, 2015) and thematic synthesis methods (Thomas and Harden, 2008) used to generate themes. The author deductively coded for anxiety and depression, and quality of life, and developed inductive codes around perceived benefits and challenges of attending support groups. The quantitative and qualitative data were then integrated and are presented in a joint display using the Pillar Integration Process (PIP) (Johnson, Grove and Clarke, 2019). An MMS review using the PIP was chosen as the PIP permits grouping of outcomes based on conceptual ideas, rather than the quantity of each item or the research methods used (Johnson, Grove and Clarke, 2019).

2.2.5 Patient and Public Involvement

The results of this study were disseminated to members of a Patient and Public Involvement group.

2.3 Results

2.3.1 Study characteristics

From 456 records identified, 10 papers were eligible for inclusion (Figure 5). Most records were excluded because they did not include a support group. Two studies were excluded because the support group intervention was restricted to a set period and therefore had a set curriculum (Badger and Morris, 1989; Forman *et al.*, 2021). Table 2 and Table 3 include the summary characteristics and results for the 10 studies: one randomised controlled trial (RCT) (Yardimci and Mert, 2019), two observational studies (Dickerson, Wu and Kennedy, 2006; Myers and James, 2008), two mixed-methods studies (Molchany and Peterson, 1994; Serber *et al.*, 2010), four qualitative studies (Dickerson, Posluszny and Kennedy, 2000; Dickerson SS, Flaig DM, and Kennedy MC, 2000; Williams *et al.*, 2004; Dickerson, 2005) and one service evaluation (Teplitz, Egenes and Brask, 1990).

One study was based in Australia (Williams *et al.*, 2004) and one in Turkey (Yardimci and Mert, 2019). The remainder were from the USA. In all studies the support group attendees were predominantly male (range 53-91%). The support groups varied considerably in terms of attendee age, format, and frequency (Table 4).

Four papers (Molchany and Peterson, 1994; Dickerson, Wu and Kennedy, 2006; Myers and James, 2008; Yardimci and Mert, 2019) contributed to the quantitative synthesis and were utilised in the meta-analysis for mental well-being (Figure 6). Three of the four reported the mean value of age of attendees but one (Molchany and Peterson, 1994) reported only a range. The authors were contacted for this information, but the raw data was no longer available.

Figure 5: PRISMA 2020 flow diagram

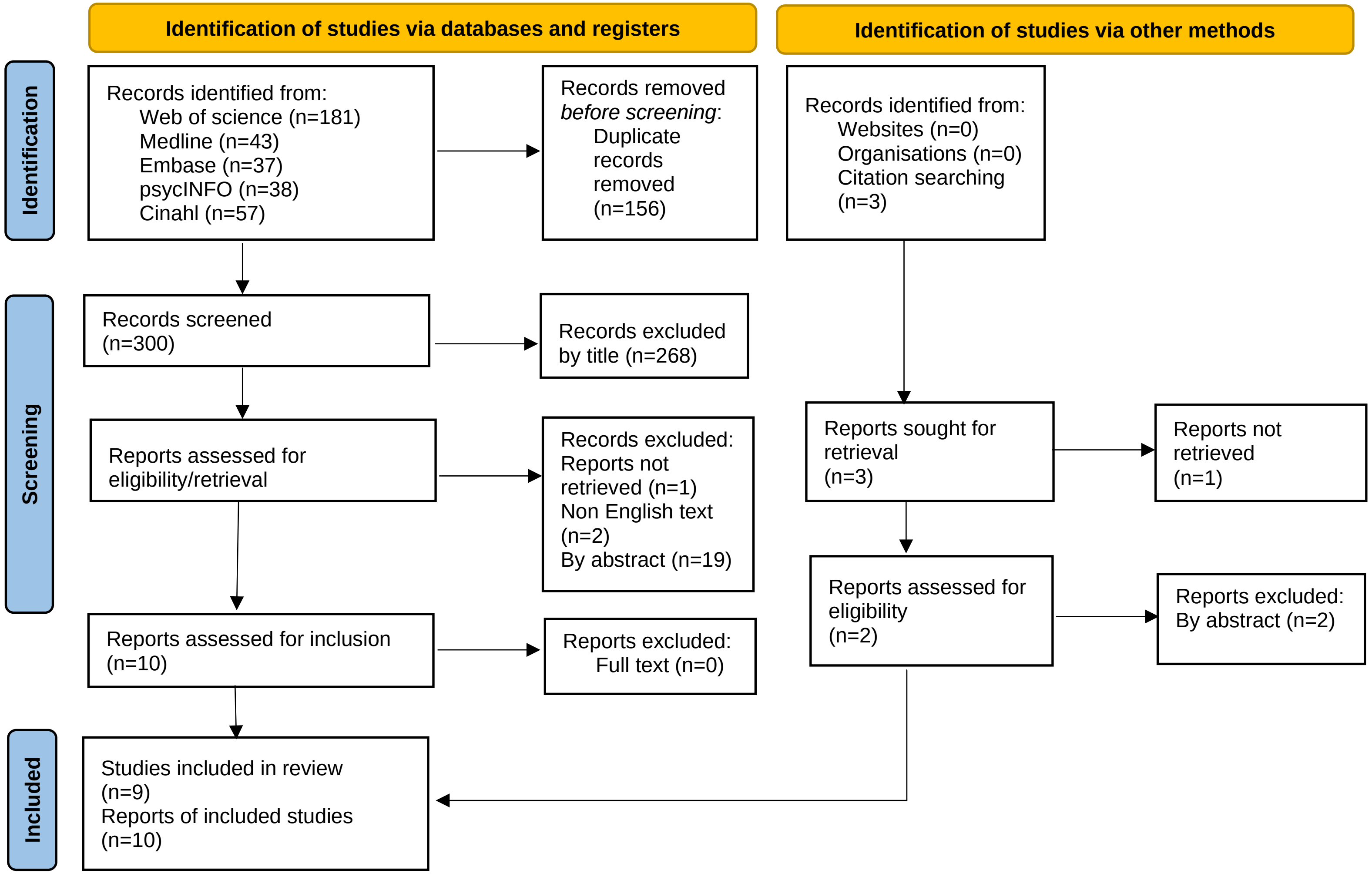


Table 2: Summary of characteristics and results from included quantitative studies. ICD implantable cardioverter defibrillator, QOL quality of life, FSAS Florida Shock Anxiety Scale, QLI:CV quality of life index: cardiovascular, VAS Visual Analogue Scale, MOS Medical Outcomes Study,

Author (Year) Country	**Research Aims**	**Research design**	**Sample characteristics**	**Outcome measures**	**Instruments**	**Key results**	**Key findings**
Yardimci and Mert (2019) Turkey	To compare shock-related anxiety and quality of life in those who access a web-based intervention program and those receiving usual care	Quantitative Randomised, single blind controlled trial	Randomised sample (76 participants) with ICDs >18 years, being able to use computer and internet, able to understand and speak Turkish. Neurologic and psychiatric disorders excluded. Intervention: 82.1% male, mean age 46.2 years Control: 75.7% male, mean age 50.9 years	Collected at 3 time points (baseline, 3 months, 6 months): ICD shock-related anxiety, QOL	Florida Shock Anxiety Scale (Turkish version) and Short Form Health Survey (SF-36, Turkish version)	Mean FSAS at baseline: intervention 14.56, control 17.37 (p=0.207). Mean FSAS after 6 months: intervention 13.30, control 16.78 (p=0.083).	Shock-related anxiety↓over time; no significant difference between intervention and control groups. No significant difference was found in the mean mental or physical summary component score of the SF-36, but significant differences were seen in subdimensions of social functioning, role-physical, mental health, vitality, and bodily pain.
Myers and James (2008) USA	To compare demographics, ICD-related characteristics, anxiety and social support in those who attend a patient support group and those who do not To investigate the relationships between reason for ICD implant, anxiety, and social support	Quantitative non-randomised: observational	Convenience sample (150 participants) 50-80years, first ICD implant, no battery changes, intact cognitive status, able to read, write and understand English. Attendees: (73 participants) 75.3% male, mean age 67.7 years. Non-attendees: (77 participants) 84.4% male, mean age 68.4 years.	Social support, anxiety. Collected at single time point.	Sarason's 6-item Social Support Questionnaire, State-Trait Anxiety Inventory	Mean State anxiety: attendees 35.21, non-attendees 33.1 (p=0.23). Mean Trait anxiety: attendees 37.01, non-attendees 33.36 (p<0.05). Mean satisfaction with social support: attendees 32.03, non-attendees 33.77 (p=0.03)	Groups differed on level of education and household income, and reason for implant. Those attending support group had ↓satisfaction the social support and ↑ trait anxiety than non-attendees**.** Irregular tachycardia associated with higher trait anxiety. Satisfaction with social support has a negative relationship with anxiety. Satisfaction with support has a positive relationship with social network.

Table 3 continued: Summary of characteristics and results from included quantitative studies. ICD implantable cardioverter defibrillator, QOL quality of life, FSAS Florida Shock Anxiety Scale, QLI:CV quality of life index: cardiovascular, VAS Visual Analogue Scale, MOS Medical Outcomes Study,

Dickerson et al. (2006) USA	To compare demographics, ICD-related characteristics, social support and quality of life in those who attend a patient support group and those who do not To investigate the relationship between demographic and clinical factors and QOL	Quantitative non-randomised: observational	Convenience sample (328 surveys mailed, 112 returned: 34% response) of all patients who received ICD at a single centre over 10-year period. Attendees (27 participants) 79% male, mean age 61.8 years. Non-attendees (85 participants) 79% male, mean age 63.2 years	QOL, social support, demographics. Collected at single time point.	Ferrans and Powers' Quality of life index (QLI:CV). No instrument used for social support.	QLI: attendees mean 23.7, non-attendees 23.0 (p= 0.77)	No significant different in QLI scores between attendees and non-attendees of support group. Support group attendance was associated with higher level of education, higher ejection fraction, higher number of supports and value of supports. Age and frequency of shocks were not related to QOL. Comorbidity is related to QOL.
Molchany and Peterson (1994) USA	To compare anxiety and social functioning in those who attend a patient support group and those who do not	Mixed methods (qualitative + quantitative non-randomised)	Convenience sample (26 participants) of those able to attend support group and willing to attend monthly group meeting for 9 months. ICD recipients (11 participants) 91% male, age range 56-75 years. Significant others (10 participants) 10% male, age range 51-90 years. Non-attendees (5 participants) 80% male, age range 51-75 years.	Collected at 2 time points (baseline, 9 months attendees only): Anxiety, social functioning and adaptation, demographics.	Anxiety Visual analogue scale (VAS), State Anxiety Index, Medical outcomes study (MOS) short-form general health survey	Mean state anxiety at baseline: attendees 36.4, non-attendees 33.8. Mean state anxiety after 9 months: attendees 34.8 (p=0.399). Mean VAS at baseline: attendees 20.55, non-attendees 22.5. Mean VAS after 9 months: attendees 34.22. MOS data incomplete.	Anxiety scores did not vary significantly between attendees and non-attendees (both groups were in the normal range), nor did they decrease between time points. No significant difference in social functioning between attendees and non-attendees at baseline. Time point 2 data incomplete and not reported.
Serber et al. (2010) USA	To examine the acceptability of online and interactive nurse-facilitated support groups for the in-person participants	Mixed methods (qualitative descriptive + quantitative descriptive)	Convenience sample (46 participants) of support group attendees. No exclusions. ICD recipients (29 participants) 62.1% male. Caregivers (17 participants) 11.8% male. Exact age not collected. 81% of participants were >60 years	Acceptability of format to in-person attendees. One time survey.	Self-report questionnaire to measure satisfaction developed for this study. 8 5-point Likert-style questions.	Overall satisfaction with the group format: 63% very satisfied, 28.3% somewhat satisfied, 2.2% neither satisfied or dissatisfied, 0% somewhat dissatisfied, 6.5% very dissatisfied	High acceptability of the webcast and group format.

Table 4: Summary of characteristics and results from included qualitative studies. ICD implantable cardioverter defibrillator

Author (Year) Country	**Research Aims**	**Research design**	**Population**	**Outcome measures**	**Instruments**	**Key findings**
Molchany and Peterson (1994) USA	To describe the incidence of group members sharing feelings and experiences and offering social support to other group members	Mixed methods (qualitative + quantitative non-randomised)	Convenience sample (26 participants). ICD patients and their significant others, able to attend support group and willing to attend monthly group meeting for 9 months. ICD recipients (11 participants) 91% male, age range 56-75 years. Significant others (10 participants) 10% male, age range 51-90 years. Non-attendees (5 participants) due to illness/travel restrictions as comparison group: 80% male, age range 51-75 years.	Incidents of sharing and emotional support.	Notes or tape recordings of leader's accounts of the meeting.	Qualitative data highlighted need for gender specific education and support.
Serber et al. (2010) USA	To examine the acceptability of online and interactive nurse-facilitated support groups for the in-person participants	Mixed methods (qualitative descriptive + quantitative descriptive)	Convenience sample (46 participants) of support group attendees. No exclusions. ICD recipients (29 participants) 62.1% male. Caregivers (17 participants) 11.8% male. Exact age not collected. 81% of participants were >60 years	Acceptability of format to in-person attendees. One time survey.	Self-report questionnaire to measure satisfaction developed for this study with 2 open ended questions.	Themes: 1. Gaining information and interaction, 2. Benefiting others and accessibility, 3. Gaining support and education
Williams et al. (2004) Australia	To describe the experiences, concerns and needs of ICD recipients and family caregivers.	Qualitative exploratory descriptive	Purposive sampling (22 participants) of ICD recipients from a single centre, >18 years, able to speak, read and understand English or be able to respond through an interpreter. ICD recipient (11 participants) 73% male. Caregivers (11 participants) 18% male. Exact age not collected. 18% of participants were >60 years. In each group there were 6 attendees and 5 non-attendees.	Experiences of living with an ICD. Experiences of attending a support group.	Semi-structured interviews face-to-face or telephone	Four themes focussing on reasons why participants attend or do not attend support groups. Themes: 1. Providing information, 2. Connecting with others, 3. Helping others, 4. Attendance

Table 5 continued: Summary of characteristics and results from included qualitative studies. ICD implantable cardioverter

Dickerson et al. (2000a) USA	To explore the lived experience of help seeking in a support group for recipients of ICDs and their support persons	Qualitative Heideggarian hermeneutic phenomenology	Convenience sample (24 participants) of support group attendees. No exclusions. ICD recipients (15 participants) 60% male, mean age 65 years. Support persons (9 participants) 44% male, mean age 67 years.	Lived experience of attending an ICD support group	Focus groups and semi-structured interviews	Themes and constitutive pattern: 1. Hearing and telling stories, 2. Triggers that encourage seeking help from group, 3. Meaningful information, 4. Group camaraderie as therapeutic friendship, 5. Importance of a facilitator 6. Support persons' similar view. Constitutive pattern: Coping with the possibility of death
Dickerson et al. (2000b) USA	To explore the common themes and shared meanings of Internet discussions on an informal public electronic bulletin board for persons with ICDs.	Qualitative Heideggarian hermeneutic phenomenology	75 users of an online bulletin board for persons with ICDs (55 ICD recipients, 5 family caregivers, 15 others including doctors, nurses, and friends). 30 users gender identified, 53% male. 25 users age identified, mean age 42.8 years.	Frequency of postings, content of postings	Observation and collection of fifteen months of postings on the public bulletin board	Themes and constitutive pattern: 1. Seeking and giving meaningful information, 2, Sharing personal perspectives, 3. Storytelling as common grounding, 4. Supportive teaching. Constitutive pattern: Therapeutic connection.
Dickerson (2005) USA	To explore the practical knowledge gained from Internet use by implantable cardioverter defibrillator (ICD) recipients.	Qualitative Heideggarian hermeneutic phenomenology	Convenience sample (13 participants) of ICD recipients who were members of the online community. 70% male, mean age 41.2 years.	Experience of seeking online support	Online virtual focus group and follow-up email interviews	Themes and constitutive pattern: 1. Getting past fear with knowledge and support, 2. Gaining context through a window into the future, 3. Internet as a mountain of information: A goldmine of ICD knowledge, 4. Internet as social interaction, 5. Becoming informed consumers. Constitutive pattern: Gaining a context for a healthy life with an ICD.
Teplitz et al. (1990) USA	To describe the development of a support group for ICD recipients and their families.	Service evaluation	34 ICD recipients returned questionnaire prior to group set-up. Informal feedback collected from patients and families at support group meetings. Gender data not recorded. Age range of attendees 21 to 77 years	Experiences of developing and facilitating a support group	Brief questionnaire - no detail of content. Observation of group and recording of informal feedback by facilitators.	Questionnaire indicated high interest in support group attendance (88% indicated they would attend). Describes common themes for patient concerns (fear of shock, travel, driving, adapting to new family role), facilitator strategies to maintain group cohesion, perceived benefits by patients (sharing experiences, feeling connected)

Table 6: Assessment of heterogeneity of support group attendees, format, and frequency. ICD implantable cardioverter defibrillator, Q&A question and answer

Author (Year) Country	**Support group attendee age (years)**	**Support group attendee gender (% male)**	**Support group location**	**Support group format**	**Support group meeting frequency**
Yardimci and Mert (2019) Turkey	Mean 46.2	82.1	Online	Living with an ICD website. Education modules available. Patients able to initiate and respond to web-based discussions.	Continuously available
Myers and James (2008) USA	Mean 67.7	75.3	In person	10 different in-person support groups utilised, all led by facilitator with ICD expertise, lasted at least 2 hours, with educational and support component.	Range 4-10 per year
Dickerson et al. (2006) USA	Mean 61.8	79	In person	In-person group meeting facilitated by a cardiac nurse specialist, consisting of open discussion and sharing, followed by a question-and-answer session.	12 per year
Molchany and Peterson (1994) USA	Range 56-76	91	In person	In-person group meeting led by a psychiatric clinical nurse and a cardiac clinical nurse specialist.	12 per year
Serber et al. (2010) USA	81% >60	62.1	In person and online	Group meeting held in-person and simultaneously cast on the internet with remote attendees. Guided by nurse facilitator and structured to provide education and support.	12 per year
Williams et al. (2004) Australia	18% >60	73	In person	In-person group meeting consisting of education, question time and opportunities for participants to share.	2 per year
Dickerson et al. (2000a) USA	Mean age 65	60	In person	Group meeting facilitated by cardiac nurse specialist, consisting of open discussion and sharing, followed by question-and-answer session.	12 per year
Dickerson et al. (2000b) USA	Mean 42.8 (incomplete data)	53 (incomplete data)	Online	On-line, informal, public electronic bulletin board	Continuously available; live chat meeting 2 per week
Dickerson (2005) USA	Mean 41.2	70	Online	Online community website providing newsletters, bulletin board, live chat, FAQs, ICD news and research data.	Continuously available
Teplitz et al. (1990) USA	Range 21-77	N/R	In person	Support group meeting held facilitated by ICD nurse, cardiac nurse, and expert group facilitator. Includes presentations and Q&A session.	6 per year

Seven papers (Teplitz, Egenes and Brask, 1990; Molchany and Peterson, 1994; Dickerson, Posluszny and Kennedy, 2000; Dickerson SS, Flaig DM, and Kennedy MC, 2000; Williams *et al.*, 2004; Dickerson, 2005; Serber *et al.*, 2010) contributed to the qualitative synthesis. The data from the two mixed-methods studies were extracted and analysed as separate quantitative and qualitative data because quality assessment indicated the rationale for, and integration of, mixed methodology was poor as indicated by the MMAT (Table 5).

Table 5 shows how each study was appraised using the relevant questions to the category of study. Higher quality is indicated by higher proportion of positive responses to the questions. Overall, the more recent qualitative studies were of better quality than those published prior to 2000. Quantitative studies included in the meta-analysis had satisfactory quality, answering ‘yes’ to 6 out of 7 questions.

Integrated synthesis of quantitative and qualitative data are shown in Table 6, where priority was given to studies with better quality ratings as determined by the MMAT (Table 5).

Table 7: Quality assessment using the Mixed-Methods Appraisal Tool

Author (Year)	Q1	Q2	1.1	1.2	1.3	1.4	1.5
Molchany and Peterson (1994)	Y	Y	N	N	N	N	N
Serber et al. (2010)	Y	Y	Y	Y	U	N	U
Williams et al. (2004)	Y	Y	Y	Y	Y	Y	Y
Dickerson et al. (2000a)	Y	Y	Y	Y	Y	Y	Y
Dickerson et al. (2000b)	Y	Y	Y	Y	Y	Y	Y
Dickerson (2005)	Y	Y	Y	Y	Y	Y	Y
Teplitz et al. (1990)	N	U	U	U	U	Y	U

Author (Year)	Q1	Q2	2.1	2.2	2.3	2.4	2.5
Yardimci and Mert (2019)	Y	Y	Y	Y	Y	Y	U

Author (Year)	Q1	Q2	3.1	3.2	3.3	3.4	3.5
Molchany and Peterson (1994)	Y	Y	Y	Y	Y	N	Y
Myers and James (2008)	Y	Y	Y	Y	Y	Y	Y
Dickerson et al. (2006)	Y	Y	Y	Y	Y	Y	Y

Author (Year)	Q1	Q2	4.1	4.2	4.3	4.4	4.5
Serber et al. (2010)	Y	Y	Y	Y	U	Y	Y

Author (Year)	Q1	Q2	5.1	5.2	5.3	5.4	5.5
Serber et al. (2010)	Y	Y	U	N	N	Y	U
Molchany and Peterson (1994)	Y	Y	N	U	U	N	N

For all:

Q1: Are there clear research questions?

Q2: Do the collected data allow to address the research questions?

Qualitative

1.1. Is the qualitative approach appropriate to answer the research question?
1.2. Are the qualitative data collection methods adequate to address the research question?
1.3. Are the findings adequately derived from the data?
1.4. Is the interpretation of results sufficiently substantiated by data?
1.5. Is there coherence between qualitative data sources, collection, analysis and interpretation?

Quantitative randomised controlled trial

2.1. Is randomization appropriately performed?

2.2. Are the groups comparable at baseline?
2.3. Are there complete outcome data?
2.4. Are outcome assessors blinded to the intervention provided?
2.5 Did the participants adhere to the assigned intervention?

Quantitative non-randomised

3.1. Are the participants representative of the target population?
3.2. Are measurements appropriate regarding both the outcome and intervention (or exposure)?
3.3. Are there complete outcome data?

3.4. Are the confounders accounted for in the design and analysis?
3.5. During the study period, is the intervention administered (or exposure occurred) as intended?

Quantitative descriptive

4.1. Is the sampling strategy relevant to address the research question?
4.2. Is the sample representative of the target population?
4.3. Are the measurements appropriate?
4.4. Is the risk of nonresponse bias low?
4.5. Is the statistical analysis appropriate to answer the research question?

Mixed methods

5.1. Is there an adequate rationale for using a mixed methods design to address the research question?
5.2. Are the different components of the study effectively integrated to answer the research question?
5.3. Are the outputs of the integration of qualitative and quantitative components adequately interpreted?
5.4. Are divergences and inconsistencies between quantitative and qualitative results adequately addressed?
5.5. Do the different components of the study adhere to the quality criteria of each tradition of the methods involved?

Colour used for visual representation of quality: Green, met quality criteria; Amber, unclear if met quality criteria; Red, did not meet quality criteria N, No; U, Unclear ; Y, Yes.

Table 8: Integrated synthesis of outcomes from ICD support groups. STAI State-Trait Anxiety Index, VAS Visual Analogue Scale, FSAS Florida Shock Anxiety Scale, ICD Implantable cardioverter defibrillator, SF-36 short-form 36, QLI Quality of life Index, MOS Medical Outcomes Study, QOL quality of life, HCP Health care professional

Quantitative data	**Interpretation**	**MAIN PILLAR**	**Interpretation**	**Qualitative data**
Anxiety and depression				
Measures: STAI, VAS, FSAS	Anxiety measured by STAI decreases over time in all groups, however VAS-A increased. Support group attendees tend to be more anxious than non-attendees in observational studies. STAI, VAS baseline measurements were in normal range. FSAS scores were average for the population.	**Variety of measures used, inconsistent results across studies.** **Optimal measure for anxiety in ICD patients is unclear.** **Support group attendance may need targeting to patients with pre-existing anxiety about their ICD.** **Knowledge acquisition and sharing experiences helps patients control their fear and anxiety.**	Fear of death and ICD shocks are the two sources of anxiety. Support groups may help manage/control fear and anxiety through sharing of experience, knowledge, and coping mechanisms. Positive role modelling provides reassurance that there is life after shocks. Patients have more confidence in support and information from fellow recipients compared to health care professionals and other support persons. Single perspective that support groups act as unwanted reminder of ICD implant.	Measures: Virtual and in-person focus groups, semi-structured interviews, email interviews, observation of meetings and group leader's notes, observation of online postings
Silence		**Effect of support groups on depression in ICD patients is unclear.**	Support groups may help manage depression through promoting hope from positive role models. Support groups can encourage patients to resume normal activity, improving acceptance of ICD.	Measures: In-person focus groups, semi-structured interviews, observation of meetings, observation of online postings
Quality of life				
Measures: SF-36, QLI, MOS	No significant difference in overall QOL scores. Significant difference in subscales of social functioning, role-physical, mental health, vitality, and bodily pain.	**Variety of general measures of QOL used, no evidence for overall improvement.** **Support group attendance may help improve specific sub-dimensions of QOL.** **Data suggests informational support is key to improving QOL.**	Support group attendance helps find ways to live with ICD and deal with limitations through improving technical knowledge and understanding of the ICD, encouraging return to normal activities. Single perspective that gender-specific meetings may be helpful to cope with lifestyle changes.	Measures: Virtual and in-person focus groups, semi-structured interviews, email interviews, observation of meetings and group leader's notes, observation of online postings
Social support and functioning				
Measures: subscales of SF-36 and MOS, Saracon's Social Support Questionnaire	Conflicting data regarding association between support group attendance and social support. No difference in social functioning between attendees and non-attendees but improves over time in both groups.	**Variety of measures used, inconsistent results across studies.** **Existing social support may not predict benefit from support group due to lack of shared experience.** **Online and in-person groups provide social support.**	Support groups provide access to social support with shared experience which is different to existing support. Online support groups may provide similar benefits in terms of social support, and are more easily and frequently accessible.	Measures: Virtual and in-person focus groups, semi-structured interviews, email interviews, observation of meetings, observation of online postings

Table 9 continued: Integrated synthesis of outcomes from ICD support groups. STAI State-Trait Anxiety Index, VAS Visual Analogue Scale, FSAS Florida Shock Anxiety Scale, ICD Implantable cardioverter defibrillator, SF-36 short-form 36, QLI Quality of life Index, MOS Medical Outcomes Study, QOL quality of life, HCP Health care professional

Patient perceived benefits and barriers to attending support groups			
Silence	**Optimal support group format is unclear.** **Support group attendees report significant benefits from attending; sharing experiences is key to facilitating device acceptance.** **Optimal measures for patient perceived benefit are unclear.**	Shared patient experience and humour is seen as providing more credible information than that from HCPs, and facilitates acceptance of ICD. Single perspective that HCP facilitation of a support group is essential. Single perspective that barriers to attendance include travel distance, gender, and age differences. Online support can provide more accessible support than in-person support groups.	Measures: Measures: Virtual and in-person focus groups, semi-structured interviews, email interviews, observation of meetings and group leader's notes, observation of online postings

2.3.2 Quantitative analysis

2.3.2.1 *Anxiety and depression*

Three studies (Molchany and Peterson, 1994; Myers and James, 2008; Yardimci and Mert, 2019) measured anxiety using validated instruments: State Trait Anxiety Inventory (STAI), Visual Analogue Scale – Anxiety (VAS-A) and Florida Shock Anxiety Scale (FSAS). No quantitative data on depression was found.

Only two studies (Molchany and Peterson, 1994; Yardimci and Mert, 2019) measured the effect of support groups on anxiety over time; neither demonstrated a significant difference between support group attendees and non-attendees. Anxiety measured by the FSAS decreases over time in all groups (Yardimci and Mert, 2019). There was an increase in anxiety over time measured by the VAS-A, but no change in state anxiety (Molchany and Peterson, 1994).

Support group attendees tended to be more anxious than non-attendees in observational studies (Molchany and Peterson, 1994; Myers and James, 2008). Attendees had significantly higher trait anxiety than non-attendees (Myers and James, 2008), although this was not significant for state anxiety (Molchany and Peterson, 1994).

2.3.2.2 *Quality of life (QoL)*

QoL was measured in two quantitative studies using the SF-36 (Yardimci and Mert, 2019) and QLI (Dickerson, Wu and Kennedy, 2006). Generic and cardiology-specific quality of life measures were included; to the best of the author's knowledge there is no ICD-specific QoL measure. QoL is relevant to the current study because of the chosen outcome of mental well-being, which is more than the absence of anxiety and depression and includes the ability to cope and live productively (Galderisi *et al.*, 2015), The inclusion of QoL measures therefore increases the relevance of the current study to ICD recipients' lives.

Neither of the included studies recorded a significant difference in overall summary scores between support group attendees and non-attendees. There was significant improvement in specific subscales of the SF-36 (social functioning, role-physical, mental health, vitality, and bodily pain) in support group attendees (Yardimci and Mert, 2019). Age and frequency of shocks were not related to QLI, however greater comorbidity was found to correlate with reduced QoL (Dickerson, Wu and Kennedy, 2006).

2.3.2.3 *Social support*

Social support was not identified as an outcome *a priori* for this review but was measured in three quantitative studies (Molchany and Peterson, 1994; Myers and James, 2008; Yardimci and Mert, 2019) and was seen in the qualitative data; it was therefore included in the analysis to assess whether this contributes to the benefit of support groups.

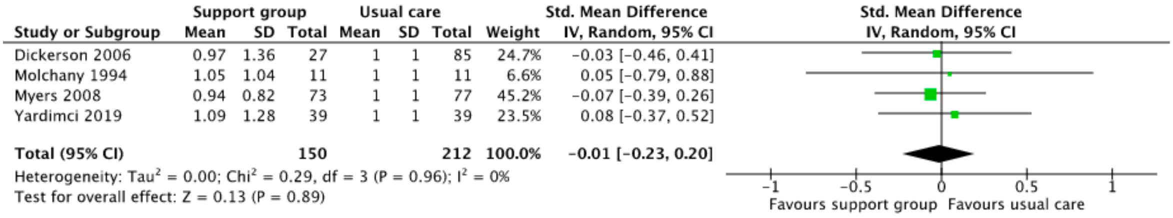
Social support was measured using Saracon's 6-item Social Support questionnaire (Myers and James, 2008), in sub-dimensions of the Medical Outcomes Study (MOS) survey (Molchany and Peterson, 1994) and SF-36 (Yardimci and Mert, 2019). Support group attendance was associated with lower satisfaction with social support (Myers and James, 2008). However, a descriptive study found support group attendees experienced a higher level and value of support than non-attendees (Dickerson, Wu and Kennedy, 2006). There was no difference between groups in social functioning (Molchany and Peterson, 1994; Yardimci and Mert, 2019), where social functioning increased over time in both groups in a RCT (Yardimci and Mert, 2019).

2.3.2.4 *Effect of support groups on mental well-being*

The effect of support groups on mental well-being was examined by normalising anxiety and QoL outcomes to the average control value (Figure 6). The absolute data utilised in this meta-analysis is shown in Table 7. The standardised mean difference between intervention and control groups was 0.02 (95% CI -0.2 to 0.23). The support group attendees scores were not significantly higher than the control group average, $z = 0.16$,

$p = 0.87$, indicating that attending support groups had no significant effect on mental well-being for patients with ICDs.

Figure 6: Effect of ICD support groups on mental well-being. Forest plot for change in normalised values of measure of mental well-being in patients with ICD attending a support group compared to usual care. CI, confidence interval.



	Support group			Usual care				Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Dickerson 2006	0.97	1.36	27	1	1	85	24.7%	−0.03 [−0.46, 0.41]
Molchany 1994	1.05	1.04	11	1	1	11	6.6%	0.05 [−0.79, 0.88]
Myers 2008	0.94	0.82	73	1	1	77	45.2%	−0.07 [−0.39, 0.26]
Yardimci 2019	1.09	1.28	39	1	1	39	23.5%	0.08 [−0.37, 0.52]
Total (95% CI)			**150**			**212**	**100.0%**	**−0.01 [−0.23, 0.20]**

Heterogeneity: $\text{Tau}^2 = 0.00$; $\text{Chi}^2 = 0.29$, df = 3 (P = 0.96); $I^2 = 0\%$
Test for overall effect: Z = 0.13 (P = 0.89)

Table 10: Raw data of aspects of mental well-being included in the quantitative analysis

		Support group attendees		Support group nonattendees		
Study	QOL measure	Mean+/-SD	Total participants	Mean +/- SD	Total participants	
Molchany and Peterson (1994)	SAI (lower score better)	34.8+/-11.26	11	36.4+/-11.67	11	p=0.399
Dickerson et al. (2006)	QLI (higher score better)	23.7+/-3.6	27	23+/-4.9	85	p=0.770
Myers and James (2008)	SAI (lower score better)	35.21+/-12.94	73	33.1+/-10.57	77	p=0.230
Yardimci and Mert (2019)	FSAS (lower score better)	13.3+/-6.13	39	16.78+/-10.62	39	p=0.083
Yardimci and Mert (2019)	SF-36 physical component	52.02+/-9.45	39	47.46+/-13.82	39	p=0.139
Yardimci and Mert (2019	SF-36 mental component	43.29+/-9.02	39	44.69+/-8.08	39	P=0.361

QoL *quality of life*, SAI *state anxiety index,* QLI *quality of life index,* FSAS *Florida Shock Anxiety Scale,* SF-36 *short form 36*

2.3.3 Qualitative analysis

2.3.3.1 *Anxiety and depression*

Patients reported that fear of death and of ICD shocks were the source of their anxiety (Teplitz, Egenes and Brask, 1990; Molchany and Peterson, 1994; Dickerson, Posluszny and Kennedy, 2000; Dickerson SS, Flaig DM, and Kennedy MC, 2000; Dickerson, 2005).

"Knowing a stick of dynamite may go off at anytime and you have little warning, is a head game you are invited to participate in each morning when you wake up." (Dickerson, 2005) p161

Attending a support group helped them to control their fear and anxiety through knowledge acquisition and decision-making skills, including making contingency plans (Dickerson, 2005). Patients also felt that positive role modelling and sharing of experiences within the group helped to manage depression (Dickerson, Posluszny and Kennedy, 2000; Dickerson SS, Flaig DM, and Kennedy MC, 2000).

"I need to turn to a source where I find comments, questions, fears, joys, whatever, also shared by me, that indicate I'm normal to this select group." (Dickerson SS, Flaig DM, and Kennedy MC, 2000) p253

Patients experienced dependency and low self-esteem post implant (Molchany and Peterson, 1994), affecting relationships (Teplitz, Egenes and Brask, 1990) and preventing acceptance of their ICD (Dickerson SS, Flaig DM, and Kennedy MC, 2000). Encouragement from other group members to resume normal life activities helped patients manage their depression (Teplitz, Egenes and Brask, 1990; Molchany and Peterson, 1994).

2.3.3.2 *Quality of life (QOL)*

Patients found that the support group helped them find ways to live with their ICD and deal with their limitations (Dickerson, Posluszny and Kennedy, 2000; Dickerson, 2005). Attending the group improved their knowledge and understanding of the device (Dickerson, Posluszny and Kennedy, 2000; Dickerson SS, Flaig DM, and Kennedy MC, 2000; Williams *et al.*, 2004; Dickerson, 2005), which in turn led to a return to "normal" life and activities (Teplitz, Egenes and Brask, 1990; Molchany and Peterson, 1994).

2.3.3.3 *Social support*

Patient support groups provide a social setting which allow new friendships to form (Dickerson, Posluszny and Kennedy, 2000; Williams *et al.*, 2004). Patients reported difficulties with existing support as family and friends do not understand their experiences (Teplitz, Egenes and Brask, 1990; Dickerson SS, Flaig DM, and Kennedy MC, 2000). Social bonding in the support group provides a setting for humour regarding ICDs (Dickerson, 2005), that was found to facilitate healing and coping (Dickerson, Posluszny and Kennedy, 2000).

"There were comical things that happened, one guy was holding his dog when it [ICD] went off and for a year the dog wouldn't go near him...we had a lot of laughs in there." (Dickerson, Posluszny and Kennedy, 2000, p.92)

Online support groups also provided an opportunity to benefit from this friendship (Dickerson, 2005).

2.3.3.4 *Benefits and challenges of attending support groups*

Two sub-themes were identified: *sharing experiences* and *support group format*.

Sharing experiences

The opportunity to share and compare experiences of life with an ICD is a key perceived benefit of attending a patient support group (Dickerson, Posluszny and Kennedy, 2000; Williams *et al.*, 2004; Dickerson, 2005). Hearing that others felt the same about their life with an ICD provided validation of their own feelings (Dickerson, Posluszny and Kennedy, 2000), which in turn facilitated healing and acceptance (Williams *et al.*, 2004). Attending support groups also provided reassurance and promoted acceptance of their ICD by seeing others lead a 'normal' life and coping with the uncertainty created by their heart condition and device (Teplitz, Egenes and Brask, 1990; Dickerson, Posluszny and Kennedy, 2000; Dickerson SS, Flaig DM, and Kennedy MC, 2000; Dickerson, 2005). Information gained from fellow ICD recipients was more credible than that from health care providers, who can talk theory but not from experience.

"After hours of bombarding my HCP with questions, you feel something missing; they know what you have, but they are just not going through it themselves; you need people that you can relate to." (Dickerson, 2005, p.162)

Support group format

There was considerable variation in meeting frequency between the included studies (Table 4), and patients reported a preference for at least quarterly meetings (Williams *et al.*, 2004). All the in-person support groups were facilitated by HCPs - most often a specialist nurse - and expert speakers to provide education (Teplitz, Egenes and Brask, 1990; Williams *et al.*, 2004; Myers and James, 2008; Serber *et al.*, 2010). Not all studies commented on the role of HCPs; only Dickerson, Poluszny and Kennedy (2000) reported the presence of an HCP at in-person meetings as being essential.

Williams et al. (2004) reported that travel time from rural locations was a major barrier to group attendance, while others did not attend as they did not feel in need of support, did not want to be reminded about their ICD, or perceived that they did not fit in the group due to age or sex. Serber et al. (2010) initiated live streaming of in-person group meetings over the internet to address the barrier of attending due to accessibility; in-person attendees found this acceptable, however the experience of remote attendance was not investigated. Patients reported that the benefits of online support were ease of access (Dickerson, 2005), and timing, as online support was available day and night (Dickerson SS, Flaig DM, and Kennedy MC, 2000).

2.4 Discussion

The findings from this meta-analysis suggest that support groups have no significant effect on objectively-measured mental well-being. However, the qualitative analysis suggests that patients do perceive a benefit from support group attendance in terms of managing fears through positive role modelling and accepting life with their ICD. This may be because mental well-being is more than the absence of mental illness, and this meta-analysis predominantly included measures of anxiety.

The present study found that self-selected attendees have higher trait anxiety and lower social support than non-attendees (Myers and James, 2008) with increased anxiety over time (Molchany and Peterson, 1994) possibly due to facing an issue previously avoided. Some patients preferred not to attend support groups as they did not want to be reminded about their ICD (Williams *et al.*, 2004). In contrast to existing literature this study found no relationship between shock frequency and QoL, but patients did report that fear of shocks is the source of their anxiety. Support groups help to relieve this anxiety by fostering a sense of belonging (Dickerson SS, Flaig DM, and Kennedy MC, 2000) and providing reassurance that there is life after ICD shocks (Dickerson, Posluszny and Kennedy, 2000). Positive role modelling from other attendees and sharing stories with other patients also relieves fear and anxiety in a way HCPs cannot (Dickerson, Posluszny and Kennedy, 2000; Dickerson SS, Flaig DM, and Kennedy MC, 2000).

The lack of a significant effect on mental well-being demonstrated by the quantitative data may be attributable to the fact that the majority of included quantitative studies were observational with self-selected support group attendees, while a usual care comparison group may include patients with lower existing anxiety (Myers and James, 2008). However, the single RCT (Yardimci and Mert, 2019) also did not show reduction in anxiety over time in support group attendees. An alternative explanation is the use of general anxiety and QoL measures that may not be sensitive to the specific fears experienced by ICD patients. The use of different outcome measures to estimate mental well-being is a shortcoming of the meta-analysis, however, it highlights the lack of good quality quantitative data in this important topic.

It is also notable that no study used the Patient Health Questionnaire 9-item depression scale (PHQ-9) or the 7-item Generalized Anxiety Disorder scale (GAD-7), which are well validated and widely used measures of depression and anxiety which have been shown to be sensitive to change when monitoring response to treatment (Kroenke *et al.*, 2016). Conversely, the STAI measures feelings of anxiety at the moment of completing the measure (state), and of general tendency to anxiety (trait) (Julian, 2011). As it includes this assessment of longstanding tendency to anxiety, Julian (2011) advises mindful use of this scale if seeking to detect a change over time. Yardimci and Mert (2019) reported only the state subscale, however, the state scale has lower test-retest coefficients than the trait scale, which is not surprising given it is designed to measure current, possibly transient, levels of anxiety (Julian, 2011). This suggests its use for detecting change should be used with caution. Similarly, while the FSAS has been shown to be a reliable and valid measure to quantify levels of anxiety in ICD recipients, it was not designed to monitor changes over time, although it is increasingly being used to do so (Tripp *et al.*, 2019). Future research could benefit from consistent use of scales which have been shown to be valid at detecting change, such as the PHQ-9 and GAD-7.

The present study shows that sharing experiences is key to facilitating device acceptance, a consistent finding for in-person and online support groups. Gaining information is also an important benefit of support groups, although patients reported that they found information and understanding from fellow attendees more credible than that from HCPs (Dickerson SS, Flaig DM, and Kennedy MC, 2000; Williams *et al.*, 2004; Dickerson, 2005). This suggests that support groups should prioritise patient-to-patient communication. Despite this finding, all in-person support groups utilised an HCP to provide information and education. The online support offered in these studies was in the form of web-based written forums, with the exception of one web-cast group meeting (Serber *et al.*, 2010). The increased availability and use of video-conferencing technology since the Covid-19 pandemic has made remote meetings a viable option and provides the convenience of online meetings alongside the opportunity for patient-to-patient communication and HCP involvement. None of the reported studies conducted a comparison of in-person and online support. Future research could help guide the most efficient format for support groups, including use of HCP time and personnel and the delivery of online and in-person groups.

Most included studies were based in the USA, and it is striking that no Western European studies were found. A recent UK study (Murray *et al.*, 2021) commented that while there is interest in patient support groups, there are not many. Perhaps even more important is the fact that ICD implant rates in the USA have historically been 4 to 5 times higher than in Europe (Camm and Nisam, 2010). This highlights the need for further research in, and implementation of, patient support groups in Europe.

Another area for future research is comparing the support needs of patients with ICDs for primary or secondary prevention of SCD. No data were available regarding participant ICD implant indications, however the dates of most included studies signifies participants will have had ICDs for secondary prevention of SCD, whereas most implants are now primary prevention (Haugaa *et al.*, 2017). In the present study, data showed that patients have a fear of death and of shocks; as survivors of cardiac arrest, secondary prevention patients will have had different experiences leading to these fears compared to patients with ICDs implanted for primary prevention. As sharing experiences appears to be an important benefit of support groups, future research could explore whether primary and secondary prevention patients have sufficiently similar experiences to support each other.

Overall, the current study has highlighted that we do not yet know the optimum format for support groups. The further research questions identified above cluster around questions of experience: of HCP involvement, of attending in-person or online, of what the support needs of primary and secondary prevention ICD recipients are. Given the non-significant quantitative results in the current meta-analysis, answering these questions must be a priority over further quantitative study of support group effectiveness. An improved understanding of what ICD recipients' needs are and how support groups are most likely to provide benefit will be best developed through further exploratory qualitative research. This can then be used to inform the design of quantitative studies to measure the effectiveness of ICD support group using appropriate and sensitive tools, which are as yet unknown.

This MMS review has strengths and limitations. It was inclusive in terms of design, outcomes and publication status and dates. The screening and quality assessment was robust, with clear *a priori* definitions of the intervention of interest and outcomes provided. There was limited opportunity for meta-analysis from the quantitative data as there was no quantitative data regarding depression, device acceptance, or group format, despite these being important themes identified in the qualitative analysis. It is acknowledged that the quality of the evidence produced in the current study is relatively low, particularly the quantitative results due to the range of measures used. This reflects the quality of evidence available in the field and supports the need for further high quality research to improve the existing limited evidence base, and adds strength to the argument that qualitative research is first required to improve understanding of the subject and inform better study design prior to undertaking further quantitative research.

2.5 Conclusion

This MMS review and meta-analysis shows that while there is currently no quantitative evidence that ICD support groups have a significant beneficial effect on mental well-being, qualitative data shows that patient support groups are perceived as beneficial by attendees. This suggests that other quantitative measures are needed to assess the benefits of support groups for mental well-being. Attendees value the opportunity to share their experiences which helps them to accept their new life with an ICD. Further research is recommended into the optimal format of support groups, level of involvement of HCPs, and whether primary and secondary prevention ICD patients have different supportive needs.

3 Chapter 3: A qualitative exploration of the attitudes and perceptions of patients attending an ICD support group

The work presented in this chapter has been submitted for publication to the peer-reviewed journal *Pacing and Clinical Electrophysiology.* The manuscript submitted is shown in appendix 5. The author's contribution to this work includes:

- Liaison with study sponsor and study administration
- Liaison with PPI members and managing meetings
- Patient recruitment and informed consent
- Data collection via patient interviews
- Data management
- Analysis and write up

Pre-registering a study is considered good practice to prevent duplication and allow more people to find out about a study (Health Research Authority (HRA), 2023), and is a requirement for a favourable ethics opinion for clinical trials. A clinical trial is defined as a trial of an investigational medicinal product or medical device, or a trial to study a novel intervention or RCT to compare interventions (HRA, 2023). The current study was designed to explore experiences, attitudes and perceptions of patients in existing clinical practice and therefore the author and supervisors agreed that that it did not meet the definition of a clinical trial as outlined by HRA (2023), and therefore could not be registered as such. Alternative sources of registration were sought through the Trust as sponsor and the British Heart Foundation, but none were found. The lack of a suitable registry was accepted during ethics review and a favourable opinion was provided despite of the lack of pre-registration.

3.1 Background

Patients with Implantable Cardioverter Defibrillators (ICDs) are known to experience psychosocial difficulties including anxiety (Magyar-Russell *et al.*, 2011; Berg *et al.*, 2016; Berg, Rasmussen, *et al.*, 2019), depression (Magyar-Russell *et al.*, 2011) and post-traumatic stress disorder (PTSD) (Habibović *et al.*, 2017). It has been shown that ICD implant itself does not negatively impact quality of life (QoL), however shock delivery does cause deterioration (El Moheb *et al.*, 2018) suggesting that this group may have higher supportive care needs. Addressing deteriorating mental health is important as it has been shown to predict mortality and admission to hospital in ICD recipients (Berg, Rasmussen, *et al.*, 2019). The efficacy of specific interventions to improve mental health following ICD implant or shock delivery has not yet been established, however, the majority of interventions have been studied within one year of implant, with little focus on post-shock (Salmoirago-Blotcher and Ockene, 2009).

There is a substantial body of research demonstrating the effectiveness of support groups for patients with cancer and many other long term conditions (Keil, 2019), however, the extent to which the findings are generalisable to ICD recipients is unclear due to different disease experiences; a common cause for distress in patients with ICDs is shock delivery (El Moheb *et al.*, 2018), an experience unique to this group. The MMS review in chapter 2 showed that while there is no significant quantitative evidence that support groups for ICD recipients improve mental well-being, patients perceived them as beneficial and valued the opportunity to share their experiences.

The British Heart Rhythm Society (BHRS) encourages the use of support groups to the benefit of patients, although provides no guidance on what format a group should take (British Heart Rhythm Society, 2022). Patient support groups are defined as groups with aims determined by the participants (rather than the providers) and no structured curriculum or end date (Delisle *et al.*, 2017), and provide an option for supportive care using limited healthcare resources (Proietti *et al.*, 2017).

Support group format was highlighted as a useful area of future study in chapter 2. It is not clear to what extent health care professionals (HCPs) should be involved in a successful ICD support group (Proietti *et al.*, 2017) as patient-only groups permit the sharing of experiences and true empathy from fellow patients which HCPs cannot provide. However, HCPs can provide information and address concerns and misconceptions should they arise (Proietti *et al.*, 2017).

3.1.1 The present study

Given the existing recommendations and evidence, a support group for ICD recipients was established in 2019 by a committee of five patients with support from the clinical team. In the absence of guidelines and literature to direct the format of the group, the patients were encouraged to develop the group meetings in a format which they felt would be most beneficial according to their own experience as patients. The group initially organised face-to-face meetings in the community but in March 2020 changed to remote meetings using Zoom due to restrictions imposed by the Covid-19 pandemic. Meetings were organised quarterly and facilitated by HCPs, with specialist education including topics such as exercising with an ICD and ICD technology.

The Covid-19 pandemic led to self-isolation for many patients and the ongoing need for social distancing led to reduced access to many forms of social and formal support and increased the likelihood of mental illness (Kumar and Nayar, 2020). This highlighted the importance of ongoing psychosocial support for ICD recipients yet limited the opportunities for delivering this in practice. Therefore, the present study aims to explore the attitudes and perceptions of patients attending an ICD support group before and during the pandemic. Second, it aims to evaluate patient's perceptions of the influence of group format on their experience of the support group.

The following two chapters present the results of the research study undertaken by the author. The study protocol and documentation (appendix 3) were designed by the author, however, due to local research and development (R&D) requirements and the NHS Trust being the Sponsor the chief investigator role had to be filled by a consultant and Dr Peter Pugh, the author's workplace supervisor, accepted this role. The study was approved by the Health Research Authority (HRA) and Cambridge Central Research Ethics Committee (REC) in November 2020 (appendix 3).

A mixed-method sequential exploratory study design was utilised in the present study. There was a paucity of existing evidence which justified the choice of beginning the project with an in-depth qualitative exploration of perceptions of support groups. This informed the design of a quantitative survey, which aimed to assess the level of agreement with selected results.

This chapter presents the first qualitative phase of the study. The author personally undertook all the work of data collection and led the interpretation and analysis of the data, with advice and contributions from a Specialist Cardiac Nurse with a PhD and experience of qualitative research (KC), a Masters student in Cardiac Science (EE), and academic supervisors (MA and LW). Their contributions are described in more detail below. The quantitative aspect of the study is presented in chapter 4.

3.2 Methods

3.2.1 Study design

The epistemological and ontological position for the present study is contextual critical realism, recognising that the results of the study are shaped by context, situation, and the experiences of the patients and the investigators (Braun and Clarke, 2013). An experiential thematic analytic approach was used, following the methods for reflexive thematic analysis (TA) outlined by Braun and Clarke (2006, 2022). TA was suitable because its flexibility offered the opportunity for inductive analysis as well as the possibility of introducing theory to inform more deductively-orientated analysis later in the process. Furthermore, TA is suitable for a lone researcher and is flexible enough to answer a range of research questions; it can be used to explore experiences, understandings and perceptions, and influencing factors (Braun and Clarke, 2013). TA therefore provided an analytic method which was suited to the research question, and to the practicality of a student undertaking a medium-sized research project in part fulfilment of a professional doctorate. Braun and Clarke's extensive guidance (2006, 2021, 2022) and twenty questions to guide assessment of TA research quality (2020) were constantly referred to ensure consistent engagement with the method.

Semi-structured interviews were used to explore participant's perceptions of their support group attendance in their own words. Interviews were chosen as the data collection method because they are ideally suited to exploring ideas in which the participant has a personal stake in (Braun and Clarke, 2013). A reflective journal, an essential tool in reflexive TA (Braun and Clarke, 2022), was used by the researcher to identify and interrogate the choices made throughout the research process and how these influenced the knowledge produced.

Ethical approval for the study was granted by the East of England – Cambridge Central Research Ethics Committee in November 2020. Participation in the interview was voluntary and unpaid.

3.2.2 Study participants

To ensure the study covered a range of perspectives a maximum variation, purposive sampling technique was used to achieve diversity in gender, age, social background, and ICD experience including length of time since implant, shock experience, and support group attendance. Sixteen eligible patients were invited to join the study in person when possible or by telephone during Covid-19 restrictions. They were given time to review the patient information sheet before consenting to take part. Most patients were recruited during or after support group meetings which they had attended. Two patients who had not attended the group were recruited during routine ICD clinic checks; these participants were purposively chosen to gain an alternative perspective on support groups. Fourteen patients agreed to participate, whereas two patients declined to participate – one due to feeling their experience was not useful to the study, and one for reasons of poor mental health. 9 males and 5 females were recruited, aged 39-86 years. Length of time with an ICD varied from 3 months to 104 months.

3.2.3 Patient and Public Involvement (PPI)

A PPI advisory group was involved throughout the study. Three members were recruited through the British Heart Foundation and one via the local support group, to bring a range of experience to support the study. Three of the PPI group had lived experience of an ICD (TF, CP and AC) and one (MO) had prior experience of qualitative research methods.

The PPI group contributed to the design of the interview guide (appendix 3) prior to ethical approval for the project. Once the project commenced, a total of 15 PPI meetings were held over Zoom at regular intervals between January 2021 and August 2022 to discuss the interview transcripts and check the interpretations of the author were consistent with their experiences from a patient perspective. MO also coded the first five transcripts and contributed to the development of the codes in a separate meeting. TF, CP and AC provided invaluable insight during the generation and refining of themes later in the data analysis period. Concept maps of potential themes were shared during the meetings and used to move around codes to explore the ideas under discussion.

3.2.4 Data collection

Interviews were conducted between December 2020 and July 2022 either face-to-face or via Zoom, depending on existing Covid-19 restrictions and patient preference, using a semi-structured interview guide. Interviews were chosen as the primary data collection method because they are the ideal format to explore patient experience and perceptions, particularly when they have a personal stake in the subject (Braun and Clarke, 2013). Participants names have been changed to pseudonyms to maintain anonymity. Written consent was obtained from participants prior to face-to-face interviews, whereas audio consent was recorded for participants prior to interviews using Zoom. Zoom has been shown to be a viable tool for qualitative data collection (Archibald *et al.*, 2019). The interviews lasted around an hour (range 47 to 118 minutes). The first section of the interview was narrative, with the respondents asked to tell why they have an ICD to give context to their story. Open questioning was then used to explore patient perceptions of the support group including their reasons for attending, positive and negative experiences of the group, and how the format of the group may have influenced their experience, including the involvement of HCPs. All interviews were undertaken by a doctoral student with a cardiac science background. The interviewer was known to some of the patients from their role as a cardiac clinical scientist, and the interview questions were carefully worded and reviewed by the PPI group to allow participants to express their experiences as freely as possible. Reflective practise was used to consider the influence this relationship may have had on the participant's responses and how this may have shaped the results.

3.2.5 Data analysis

Data analysis began after the first interview and continued in parallel with data collection, which allowed for active decision making throughout the data collection and interpretation processes. Although widely conceptualised as the gold standard for determining sample size in qualitative inquiry, the use of saturation is troublesome in reflexive TA because it implies that codes or themes are pre-existent in the data (Braun and Clarke, 2021). The sample of 14 in the present study was a situated, interpretative judgement by the research team that sufficient rich data had been collected to generate themes which fulfilled the aims of the study.

The six phases of reflexive TA as outlined by Braun and Clarke (2022) were engaged with throughout the analysis (Table 8). The interviews were all audio-recorded, fully transcribed, and checked for accuracy by the author. The transcripts were uploaded to NVivo 11 software (QSR International Inc, 2015) to facilitate the analysis. Although widely recommended as a form of 'credibility check' (Elliott, Fischer and Rennie, 1999), member checking of the transcript and analysis by the participants was not carried out because the analysis process involved latent coding and the interpretation of the data may not be recognisable to or in the awareness of the participants. This is consistent with a critical realist approach to analysis, which assumes that the 'truth' is knowable but is obscured by researcher subjectivity and the context in which the knowledge is produced.

The author read and re-read the transcripts before making familiarisation notes. Each transcript was shared and reviewed with the PPI group to ensure the interpretation of the data was not limited to a health care professional's perspective, which may have led to misunderstanding of the participants meaning. A junior member of the clinical team was also present at these meetings to take notes to allow the author to concentrate on the discussion, and to bring another perspective to the analysis.

Transcripts were first inductively and semantically coded by the author. The first five transcripts were also coded by a PPI group member to encourage discussion of ideas and challenge the assumptions of the author, bringing a patient perspective to the development of the codes. Critical memoing (Vanover, Mihas and Saldaña, 2022) and the one-sheet-of-paper (OSOP) technique (Ziebland and McPherson, 2006) were used by the author to explore the data, alongside PPI group meetings during which reflective discussions were encouraged.

The initial themes lacked a single unifying concept and were difficult to delineate clearly, and therefore substantial revisions were made during the developing and reviewing themes stage. Example memos are included in appendix 4 to illustrate the thought process behind the theme development.

As the analysis developed, more latent and deductive coding was utilised to permit application of theory to the data. The work of Elizabeth Kübler-Ross (1969) was referred to by a PPI member during one of the meetings, and this provided a valuable starting point that was grounded in patient experience. The mobilising theory section in appendix 4 provides some context and explanation for the choice of and application of theory in this study. Samson and Siam's (2008) task-model approach offered a good fit with the interview data and inductive analysis, providing a useful framework for the role of support groups in adapting to life with an ICD. Other models were considered (Corr, 1992; Doka, 1996; Stroebe and Schut, 1999) but ultimately rejected because they were not as comprehensive and did not fit as well with the analysis.

The advantages of task-based approaches are explained by Corr (1992), who espouses that tasks promote empowerment of individuals who are dying, allowing them to retain some influence and control over the process which is in contrast to the stage-based approach which implies the individual passively moves through the stages. As discussed in chapter 1, perceived control can have important influence upon health-related quality of life (Hammash *et al.,* 2019). Corr's (1992) task-based approach to coping with dying therefore seemed relevant to the present study; however, it has been argued that the four task dimensions described (physical, psychological, social and spiritual) do not cover all aspects of life which are affected by illness, and therefore it may not be sufficiently comprehensive (Samson and Siam, 2008).

Doka (1996) presented a further critique of Kübler-Ross' work, including that her observations were completed in a hospital setting and were framed around a relatively short time between diagnosis and death. An interesting aspect of Doka's paper is the description of how coping with acute and chronic stages of disease may require different strategies, providing suggestions of how a counsellor can identify the phase and thereby advocate the task most likely to assist with their coping. This appears attractive is it provide practical guidance for HCPs working with ill or dying patients. However, similarly to Kübler-Ross' work, Doka presents vignettes and observations and the empirical underpinnings for the theory also appear unproven. Samson and Siam (2008) also critique this model as an attempt to merge stage and task-based models, which they argue are mutually exclusive as task-based models were developed to address the limitations of stage-based models.

The dual process model (Stroebe and Schut, 1999) initially appeared potentially relevant to the present study as it describes how people may move back and forth between focusing on their loss and focusing on their future, and emphasises how coping may differ between individuals and cultural groups. However, while this may be more applicable to modern multicultural society, it focussed on coping with bereavement rather than personal illness, and therefore was not appropriate to apply to the analysis in the current study.

Samson and Siam (2008) present more recent task-based approach which was developed based on a critique of previously existing models, and therefore this approach is most likely to be reflective of modern western society in which the present study is based. Samson and Siam's model is heavily influenced by Corr's (1992) task-based approach, but they have addressed their own criticism by including a fifth dimension, vocational tasks. This therefore provided the most comprehensive model which was ultimately chosen as the best fit for the present study.

Quote selection for this report was undertaken with input from the PPI group. During the meetings, the author presented several pages of data extracts for each theme; extracts from these are included in appendix 4. The group reviewed the theme summaries before discussing and selecting quotes which evidenced the analytic claims. Care was also taken to select extracts across the range of participants to demonstrate that patterns were identified across the dataset and not only from one or two articulate participants (Braun and Clarke, 2022).

Table 11: Six phase process of thematic analysis

Phase	Process
1. Familiarising yourself with the dataset	Interviews transcripts were read and re-read, checked for accuracy, and familiarisation notes made (KHS). The research team (KHS, EE) and PPI group discussed the transcripts for initial topics and interpretations of responses.
2. Coding	Single concepts within the data were identified inductively and semantically coded (KHS). A PPI group member with qualitative research experience (MO) also coded the first five interviews. Later discussions between the research team (KHS, KC, EE) and PPI group led to more latent coding.
3. Generating initial themes	Candidate themes were developed (KHS) and discussed with the research team (EE) and PPI group.
4. Developing and reviewing themes	Substantial revisions to initial themes after checking for consistency with the original dataset (KHS). Descriptions and boundaries of each theme were discussed with the research team (KHS, EE) and PPI group.
5. Refining, defining and naming themes	Specifics of the themes were discussed and refined (KHS, EE, PPI group).
6. Writing up	A first draft was written (KHS) and reviewed (MA, EE, KC, LW, PJP). Quotes were selected to provide empirical evidence for the analysis (KHS, EE, PPI group).

3.3 Results and Discussion

Fourteen participants were interviewed and were included in the analysis. Participant characteristics are presented in Table 9.

Table 12: Participant characteristics

Participant pseudonym	Sex	Age (years)	Length of time with ICD (months)	ICD indication	Shock experience	Attended support group
Ann	Female	74	104	Primary	No	Yes
Bryan	Male	86	22	Secondary	No	No
Caroline	Female	69	18	Primary	No	Yes
Daniel	Male	39	29	Primary	No	Yes
Ethan	Male	73	77	Secondary	Multiple episodes with single shock	Yes
Felix	Male	69	42	Secondary	Multiple shocks in single episode	No
Graham	Male	73	27	Primary	No	Yes
Henry	Male	70	14	Primary	No	Yes
Irene	Female	78	66	Secondary	Single shock	Yes
James	Male	48	8	Secondary	No	Yes
Kathy	Female	59	14	Secondary	No	Yes
Lee	Male	46	39	Primary	No	Yes
Mel	Female	60	45	Primary	No	Yes
Neil	Male	49	3	Primary	No	Yes

After coding the interviews, 45 codes were generated (appendix 4). These were clustered into topics including experience of support groups, living with an ICD, concerns about ICD, support group practicalities, involvement of care team, and facing death. Patterns and unifying concepts across these topics were identified during the process of theme generation to answer the research questions. Four themes were generated: confronting mortality, coping through sharing, coping through learning, and providing space. A thematic overview is shown in Figure 7. Illustrative quotes are provided as empirical evidence for each theme, with participant’s pseudonym and length of time since ICD implant following in parentheses. Additional extracts are included in appendix 4 to illustrate the richness and depth of the data which informed this analysis.

3.3.1 Theme 1: Confronting mortality

This theme centred around participants being forced to confront their own mortality, either because they had survived a cardiac arrest or have been told they were at risk of it. Two sub-themes were identified: facing death, and hope.

3.3.1.1 *Sub-theme 1: Facing death*

Participants feared death, and feared arrhythmia and shocks as a precursor to or escape from death:

'I think I just was overall thinking tomorrow I'm going to die' (Henry, ICD for 14 months)

The concept that patients with ICDs are required to confront their mortality has been described previously (Kamphuis *et al.*, 2004; Sert, Turan Kavradim and Canli Özer, 2021). The influential work of Elizabeth Kübler-Ross (1969) was the first to describe stages of grief in patients who were facing their own death. Deductive coding was carried out for the stages of grief and there was examples of these across the dataset (Table 10).

Table 13: Participant quotes in relation to the five stages of grief according to Kübler-Ross, (1969)

Denial: putting aside the possibility of death to allow them to pursue life	*I didn't think about it. And I think, had I thought about it, I would have changed my behaviour, wouldn't have done all sorts of things. (Ethan, ICD for 77 months)*
Anger: angry about illness and envious of the healthy	*I have the other feeling is if I go through my whole life and it never goes off I'll be really cross, really resentful… (Lee, ICD for 39 months)*
Bargaining: looking for ways to resume normality	*I was frightened to go out and things, but after reading up on it and going to the support group I realised that, you know, I can live a normal life. (Kathy, ICD for 14 months)*
Depression: responding to a sense of loss	*I just felt alone and I was always worried that it was going to fire and didn't know what to do if it did. (Kathy, ICD for 14 months)*
Acceptance: recognising that despite the situation, you will be OK	*I narrowed my shock down to the fact that the only time it's going to happen is when I'm needing it. (Henry, ICD for 14 months)*

To the best of the author's knowledge the present study is the first to identify that patients with ICDs express emotions consistent with the five stages of grief described by Kübler-Ross (1969), which was neatly described by one of the participants who had learned to accept her ICD and was now actively involved in running the support group to help others:

'And you go through all kinds of things before like, you know, bursting into tears and anger or whatever, I think it's the same thing about this because you're grieving for your past life and this is your real life now and once you've accepted it, it's alright.' (Mel, ICD for 44 months)

Although stage-based models such as Kübler-Ross' are popularly utilised, they have been subject to significant criticism in recent years (Corr, 2019, 2021). The five stages are frequently presented as a linear, prescriptive journey through coping with dying; while attractive due to its simplicity, this interpretation is not grounded in evidence and indeed Kübler-Ross herself argued that the process is fluid and people may not experience all of stages, nor in the order described (Kübler-Ross, 1969). Furthermore, her 1969 seminal work was based on observations and was not subject to robust analysis or empirical testing (Corr, 2019) and the soundness of the theory is unproven. It is also subject to the bias and assumptions associated with the culture of the time; the role of gender, ethnicity and other aspects of a modern multi-cultural society have changed dramatically in the over 50 years since Kübler-Ross first presented her theory. For example, she interviewed patients with strong Christian beliefs but coping strategies may be very different in today's secular society, and her observations regarding gender roles were out-dated to a modern reader. This theory should therefore be applied with care and with reference to its limitations in contemporary work (Corr, 2021); indeed, Corr (2019) also argues that it should be set aside as unreliable. However, the stage model is widely understood in popular culture and was recognisable to the patients involved in the present study, and therefore utilising it as a bridge to apply more contemporary theory helped to ensure the analysis remained grounded in patient experience.

Task-based models are now considered more relevant to current practice (Samson and Siam, 2008) and they differ from stage-based models in providing a framework to reconstruct one's existence rather than a linear pathway to acceptance. In the current study, this theoretical model was applied to the analysis to reflect the most up to date contemporary thinking on the subject. The model fit well with the original inductive analysis and therefore provided a plausible explanation for the perceptions of the participants. For example, support groups provide patients with the opportunity to acquire and utilise the coping skills required to complete the adaptation tasks such as re-establishing emotional balance (psychological task) and developing a sense of hope (spiritual task).

The support group also provided a setting where participants could openly consider their mortality, which was perceived as an unwelcome topic away from the support group.

'I do recognise that maybe I'm the only person that's processing their mortality in that way and so I feel like I'm possibly bringing something unwelcome into a conversation. Whereas, yeah, it's I don't, if I go there I don't have to apologise in a room like that, in a support group I suppose, yeah' (Lee, ICD for 39 months)

Providing ICD recipients with the opportunity to process their mortality is important; applying the theoretical lens of adaptation to chronic illness (Samson and Siam, 2008), this cognitive appraisal of the situation shapes their perceptions of coping skills and adaptive tasks. Cardiac patients in particular may be deprived of these opportunities within their usual care; even before the advent of ICDs, Kübler-Ross (1969) found that discussing death with a cardiac patient was particularly difficult as it was perceived that death was less predictable compared to cancer patients. In more contemporary literature, the barriers to discussing ICD deactivation at end of life (Goldstein *et al.*, 2008) illustrates the difficulties clinicians have in discussing mortality with these patients.

Participants expressed a range of reasons for their fear of receiving a shock from their ICD. Some feared the physical sensation, some that this meant they had a life-threatening heart rhythm, and others feared the practical consequences such as a driving ban. Shock delivery has been shown to be an important predictor of anxiety for patients with ICDs (Perini *et al.*, 2017), particularly multiple shocks, and this is reflected in the dataset:

'…sometimes if I'm lying in bed and you know when you get your feeling of boom, boom, boom, your heart's going like that, I'm lying there worried "please don't go off, please don't go off".' (Felix, ICD for 42 months, experience of multiple shocks)

When the data was searched for patterns relating to shock experience and how they used the support group, no pattern was identified which felt relevant to the overall analysis. However, the subject of shocks and the opportunity to hear other patients' experience of them was perceived as valuable by those who had not yet received a shock. This suggests that although shocks may predict support group attendance in terms of timing, the support needs of sharing and learning from other group members are unchanged regardless of shock experience. However, the present study's participants had limited personal experience of shocks and of sharing that experience at a support group, and this may be a valuable area for further qualitative exploration of support groups.

3.3.1.2 *Sub-theme 2: Hope*

The concept of hope was evident throughout the dataset; participants found hope in seeing other people living with their ICDs for many years, and realised that although they will die one day, it may not be imminent.

'You know, for example you meet somebody and you think, you don't think it out loud, but you think it in your head, actually they've had their device five years and they're still

standing up, and that may seem trivial to you, but the realisation of that is huge' (Ann, ICD for 104 months)

Hope is an important emotion which is frequently referred to in grief stage theory. Kübler-Ross (1969) did not define it as a stage in her model but stated that it is pervasive through all stages. It was striking in the dataset that the simple act of meeting a fellow ICD recipient who has lived with their device for years, or survived a shock, helped participants believe that they could and would be able to do the same. This shows how support groups can provide new ICD recipients with a valuable opportunity to meet 'experienced' recipients. This allows a re-kindling of their sense of hope, one of the spiritual tasks in Samson and Siam's model (2008).

3.3.2 Theme 2: Coping through sharing

This theme focused on shared experiences, with an emphasis on patient-to-patient communication. Two sub-themes outline specific aspects of shared experience: accepting the ICD as necessary, and comparison with others.

Most participants found connecting with other ICD recipients beneficial and cited this as a reason for attending for the group. Friends and family may offer support but this was not perceived as having the same benefit because they did not have personal experience and could not understand what the participant was going through. For the same reason, some participants preferred to hear from other ICD recipients rather than HCPs because patients can talk about living with an ICD compared to HCPs who only know the stories which arise during a hospital or clinic visit, as described by a participant with a recent ICD implant:

'So it is nice, you know even when you've talked to a healthcare professional to be able to ask somebody else that you know really knows and understands what it feels like more than sort of the practicalities of it.' (Neil, ICD for 3 months)

They found reassurance in seeing other patients also struggling with their ICD, to know they aren't alone in their struggles. It was also reassuring to see patients who had got used to their ICD and to see that it is possible to 'get back to normal' and live a fulfilling life. These experiences are consistent with the coping skills described in the task-based model for adaptation (Samson and Siam, 2008) in which the five tasks described (physical, social, psychological, spiritual and vocational) form part of a broader conceptualisation of adaptation which can be applied beyond the limits of grief theory.

3.3.2.1 *Sub-theme 1: Accepting the ICD as necessary*

One participant was struggling to accept that having their primary prevention ICD had been the right decision and found it helpful to compare their situation to patients who had survived a cardiac arrest.

'So in a sense of like, in a way that like that might be a similar experience to me and I could hear how wow they really did need it, you know, in a way that was helpful because I thought "yeah, I mean it could have, that could have been the way it played out for me' (Lee, ICD for 39 months)

In contrast patients with secondary prevention ICDs, having survived a life-threatening arrhythmia, appeared to find it easier to accept their ICD and had less doubt in their decision-making to have the ICD implanted. For some patients with ICDs for secondary prevention indications, it may not even be seen as a decision, but rather an offer they cannot refuse (Ågård *et al.*, 2007).

'…it's very, very difficult, and the thing is we're now talking to other people, we've got no idea about how you should be feeling, what questions you should be asking, you know, and things like that, so that that's… but equally on the flipside you've got, I've got a second chance, so it's that kind of helps a lot' (James, ICD for 8 months)

While recipients of secondary prevention ICDs still found sharing experiences of adapting to an ICD and its accompanying restrictions useful, this difference in acknowledging the necessity of having an ICD appears to be an important factor which helped patients learn to accept or cope with their situation. A recent study comparing the effect of a social cognitive intervention on primary and secondary prevention ICD recipients also found that secondary prevention patients had greater improvement (Auld, Thompson and Dougherty, 2020). Applying the task-based model of adaptation, the analysis suggests that secondary prevention patients are able to more readily perceive adapting to their ICD as a challenge rather than a threat, allowing them to move on and complete their adaptive tasks (Samson and Siam, 2008).

3.3.2.2 *Sub-theme 2: Comparison with others*

Younger participants felt they had less in common with older group members, and that to benefit from sharing experiences they needed to have similar goals, for example getting back to work or exercise.

'I suppose it's about having a big enough group whereby there's somebody there for me and I'm there for somebody rather than me being with somebody who's maybe in their 60s or 70s and actually isn't really that interested in whether or not they can get their jogging pace down, you know' (Daniel, ICD for 29 months)

This suggests it may be challenging for support groups to meet the needs of younger patients due to lack of shared experience, because there are relatively few younger patients compared to older. The youngest participant was 39 years old and therefore the perceptions of young adults (generally defined as 18-40 years (McDonough, 2009)) were not well represented in the present study. Younger patients have been shown to report poorer device acceptance and higher shock anxiety compared to older patients (Ng *et al.*, 2020), and to have unique concerns such as child bearing and child rearing (McDonough, 2009). Future research could consider how support groups can meet the needs of younger ICD recipients.

3.3.3 Theme 3: Coping through learning

Learning about their ICD was also important to participants and this was another reason given for attending the support group. They wanted to understand how their ICD worked and what to expect from it in the future, which reduced their fear of the unknown. Formal education and question and answer sessions supported the patients to learn about their ICD beyond the specific questions they might think to ask in clinic.

'…what I always find very interesting, to listen to the questions that other people have, because they might ask a question that you've forgotten or haven't thought about yet or something that might come up for you in the future and it might be helpful to know' (Caroline, ICD for 18 months)

This finding reflects the coping skills described in the task-based model for adaptation (Samson and Siam, 2008), demonstrating information seeking and efforts to reintegrate into vocational environments. The benefit of learning about ICDs from both HCPs and fellow patients has been described in previous support group literature (Williams *et al.*, 2004). The data from this study suggests that a blend of learning from HCPs and patients is preferred within the support group. This is consistent with Dickerson et al. (Dickerson, Posluszny and Kennedy, 2000; Dickerson SS, Flaig DM, and Kennedy MC, 2000) in their qualitative explorations of support groups, who use the term 'meaningful information' to define the information participants sought to cope with their ICD; while the HCP provides technical information about the device, the other group members experiences help to translate this into a meaningful understanding of how to live with an ICD.

Having an HCP present at the meeting was important to the participants as it was felt that their advice was more reliable and they enjoyed the education sessions and the opportunity to ask questions about a wide range of subjects.

'I think it is important to have support groups with health care professionals in there to answer such questions, because I'm sure we don't really know what everything is that's going on. I mean, I've had a couple of ablations but I'm not exactly sure what's happened there, what paths have been taken out. You know, it's very difficult for me to understand' (Ethan, ICD for 77 months)

In the present study, analysis highlighted the importance of HCP involvement to deliver education and provide advice, however, this contrasts with another study which found that information gained from fellow ICD recipients was perceived as more credible than that from HCPs (Dickerson, 2005). Dickerson's (2005) study was based on internet-based support and it may be that participants who choose to use online-only support have different needs from those who attend in-person meetings. In the present study, participants who attended the support group valued both aspects (patient advice vs HCP) of the group but to a greater or lesser extent. The task-based model for adaptation (Samson and Siam, 2008) may provide some explanation for this as patients may have different pre-existing coping skills and therefore need to focus on different tasks while attending the support group.

3.3.4 Theme 4: Providing space

The support group provided the participants with both the physical and the psychological space to meet, share and learn. While participants found Zoom convenient and recognised that it was necessary during the Covid-19 restrictions, they preferred meeting in person. While it was possible to deliver education over Zoom, they found it more difficult to make beneficial interpersonal connections.

[On Zoom] '…there was no opportunity to go, you're roughly the same age as me, what's your deal, why are you here, you know, I'm the same. So those kind of learning a bit about people's stories and being able to relate to those obviously been almost kind of lost almost entirely, hasn't it?' (Daniel, ICD for 29 months)

Covid-19 itself did not appear to make a difference to participants enthusiasm for the support group, and one participant who had her ICD implanted during a lockdown period described how the support group was even more of a lifeline as she was not able to access her usual forms of social support. However, attendee numbers were in general lower over Zoom than at in-person meetings and this is probably due to the preference for in-person meetings which was unanimously expressed. A survey of substance abuse self-help groups undertaken during the Covid-19 restrictions found that online meetings had appeal to younger members and were more useful for those earlier in their recovery (Timko *et al.*, 2022). This may in part explain the lack of enthusiasm for Zoom from the participants in the present study, who were generally older and had their ICD implants for months to years.

A community venue with parking and easy access helped them to attend and promoted a relaxed environment. A relaxed environment was perceived to make it easier to make connections, to ask questions of HCPs, and gave them more ownership of their lives with ICDs away from the hospital.

'I think we all have more than enough hospital appointments anyway, so or travelling to the hospital and I know you know, travelling to a hospital causes a lot of people mental stress, so yeah no I think community halls and village halls and things' (James, ICD for 8 months)

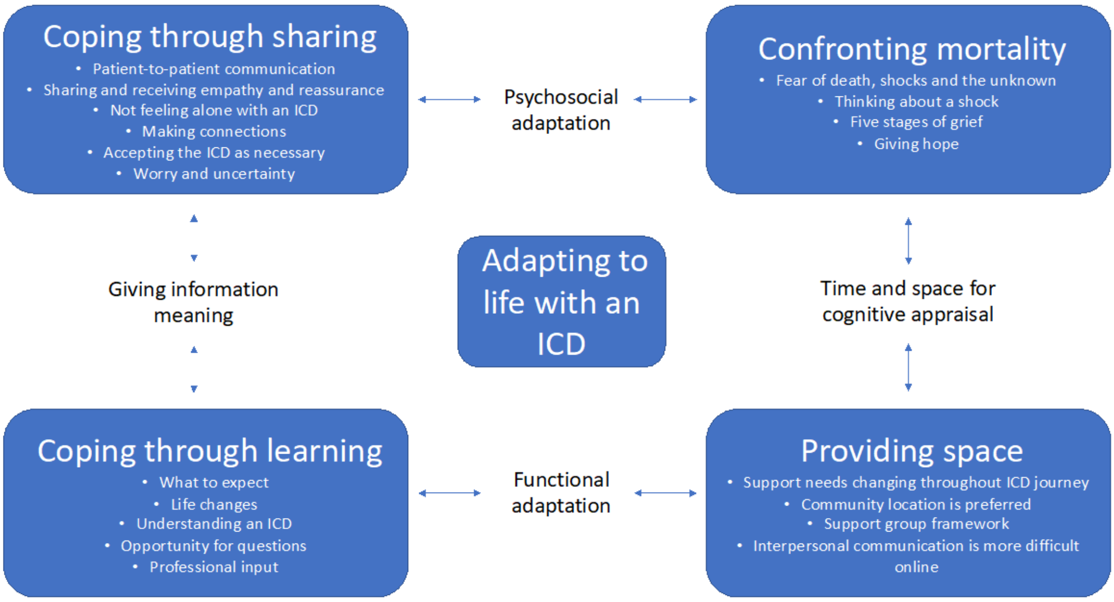
Most participants felt that the support group was most useful around the time of implant, as this is when they had the most unanswered questions and life changes to adapt to. Some ICD recipients advocated accessing the support group before the implant procedure. These were usually participants with a primary prevention ICD, who felt meeting other ICD recipients and learning about life with an ICD had helped them to decide to consent to the implant, or to prepare for it. In contrast, the participants with secondary prevention ICDs didn't feel they had this time ('*there wasn't a before' – Kathy)* or didn't feel ready to engage with the support group for some time after implant. Participants also felt that education through the support group should be offered to patients as they may not seek it, especially early in their ICD journey when they may be in shock or denial at their diagnosis.

'I just sat with this kind of like dread, you know, and then called my dad and had that conversation, but it is interesting that the option of doing a little education myself was just gone from my head' (Lee, ICD for 39 months)

This difference in timing of accessing a support group to the best of the author's knowledge has not previously been described. The earlier use of the support group by recipients of primary prevention ICDs may be explained by time since diagnosis rather than time since implant, as one study of patients with brain tumours found patients who were less likely to attend the support group were more recently diagnosed (Mallya *et al.*, 2020). In the present study, secondary prevention ICD recipients tended to have their ICD implant during their admission, while primary prevention ICD recipients had their procedures electively, suggesting they had more time to reflect on their diagnosis before the procedure. Several previous studies into psychosocial interventions for anxiety in ICD patients have provided an intervention with a curriculum and set duration (Sears *et al.*, 2007; Dunbar *et al.*, 2009; Irvine *et al.*, 2011), however, the present study suggests that support should not be time restricted. Support groups, being open-ended, can provide support whenever the patient wishes to access it.

Figure 7: An overview of the generated themes.

Note: Each theme is presented in a box with the most important codes which contributed to the analysis. The themes are linked by what the support group was perceived to provide.



3.4 Discussion

The aim of the present study was to explore the attitudes and perceptions of patients attending an ICD support group. Four themes were generated in the thematic analysis: confronting mortality, coping through sharing, coping through learning, and providing space.

The theme of confronting mortality shows that participants were often struggling to cope with the possibility of death, and that the support group is perceived as a safe setting which provides opportunities for them to openly discuss their mortality and ICD-related concerns without fear of judgement. The task-based model for adapting to chronic illness (Samson and Siam, 2008) provided a theoretical framework which links together the themes generated in the analysis. The adaptive tasks described by Samson and Siam (2008) are physical, spiritual, psychological, social and vocational; in the present study, analysis found that participants saw opportunities within the support group to undertake tasks in all of these areas. A blend of patient-to-patient communication as described in the theme coping through sharing, and HCP education as described in the theme coping through learning, was perceived as important by the participants. The final theme, providing space, described how participants found it easier to undertake these tasks in person and in an informal, non-hospital-based setting.

Although the participants in the present study preferred in-person meetings, during the pandemic the group organised remote meetings using Zoom rather than online forums such as those in other published studies (Dickerson SS, Flaig DM, and Kennedy MC, 2000; Dickerson, 2005). It is not known whether in-person and online support groups appeal to the same patients and meet the same support needs. This would be a useful area for future study.

The experience of participants in the present study of living with an ICD appears to be consistent with the findings of other qualitative studies. The present study highlighted the need for participants to acquire meaningful information at the support group, and lack of knowledge is commonly described in the literature with some participants being unable to explain how their ICD works (Rosi *et al.*, 2020) and others being frustrated by the lack of meaningful information about how the ICD may affect their lives (Garrino *et al.*, 2018). Living with fear of shocks is reported across the literature (Kamphuis *et al.*, 2004; Garrino *et al.*, 2018; Rosi *et al.*, 2020; Sert, Turan Kavradim and Canli Özer, 2021) and trying to learn how to avoid shocks through avoiding specific activities was a common goal for participants in these studies. The role of the support group in reducing the fear of shocks and encouraging return to normal activities through sharing experiences with other ICD recipients is an important finding in the present study.

The exploration of the data in the present study also demonstrated the importance of support groups being openly available rather than for a set time as is the case with other psycho-social or educational interventions. This may be due to the difference in support needs for patients with primary and secondary prevention indications for ICD, and the unpredictable nature of shock delivery. The findings of the present study suggest that ICD recipients with primary and secondary prevention devices may follow a different journey towards acceptance, and highlights that it is not only the ICD but the underlying heart condition which they have to adapt to. This explains why the adaptation to chronic illness theory (Samson and Siam, 2008) fits well in the present study, as patients are not preparing to die but to adapt to their diagnosis.

The application of theory in the present study was a novel approach which contributed to the development of new knowledge in the field of support groups. This is the first time theory has been applied to provide an explanation for how support groups may benefit ICD recipients. To the best of the author's knowledge, task-based theories have not been applied in research regarding support groups for any health conditions, and therefore the findings of the present study may have a wider impact upon the understanding of the role support groups. Importantly, applying relevant theory has demonstrated how support groups may offer more than reducing anxiety as a narrow aspect of mental illness, but may help patients undertake tasks which help them to cope with the impact of their illness or condition over broader dimensions of life and therefore contribute to overall improved mental well-being.

3.4.1 Limitations

The present study provides some strong insight into the perceptions of patients attending an ICD support group, however, there are some limitations present. The interviewer being known to some of the participants through clinical contact may have introduced some restrictions to their responses. Using focus groups in place of interviews may have reduced the power dynamic between the researcher and participants due to the numerical advantage of participants (Braun and Clarke, 2013). Focus groups may therefore have allowed participants to express their views more freely regarding topics such as HCP involvement. However, effort was made to design the interview guide accordingly and reflexivity was practised to take this into account during the analysis.

All participants were white and of British background. This reflects the demographics of the area in which the research was undertaken which is predominantly white British. No patients from minority backgrounds attended the support group during the study period and therefore their views and reasons for not attending the group are not represented in this study which limits the transferability of these results. 9 (64%) participants were male, which is consistent with implant rates across Europe being considerably higher in males (Sticherling *et al.*, 2018). As discussed above, the perceptions of younger patients (<40 years) are also not well reflected in this study.

3.4.2 Reflexivity

The lead researcher (KHS) was a doctoral student and practising cardiac clinical scientist and was therefore known to several participants through ICD follow-up or attending the support group. Critical memoing was used to reflect on how the researcher's involvement may have influenced participant’s responses and the interpretation of these. Excerpts from the author’s reflective journal are presented in appendix 4. PPI group meetings were also used to minimise bias from an HCP perspective, by reflecting on their own experiences as ICD recipients and finding nuances in the data which the researcher from their HCP positionality had missed. None of the other members of the research team were known to the participants, however, KC’s experience of qualitative research in cardiology may have influenced the analysis by recognising patterns and findings from their previous research in this study’s dataset. EE, as a trainee cardiac scientist, provided valuable outsider insight and challenged the assumptions made by clinical experts during the analysis.

3.4.3 Future research

Future research could consider actively seeking the views of under-represented populations regarding support groups, including younger patients and those from minority backgrounds. Further research is needed to explore the differences in adapting by patients who received an ICD for primary or secondary prevention indications. The needs of patients using online vs in-person support groups would be also a useful area of future study.

3.5 Conclusion

The present study identified that patients with ICDs perceive changing emotions which may be caused by having to consider their own mortality and adapt to major life changes. Support groups provide the space for patients to undertake adaptive tasks necessary to cope with these emotions, including sharing of experiences as well as HCP-facilitated education and advice. The results of this study can have an impact on clinical practice by helping clinicians and patients understand how to develop support groups to address patient’s key concerns.

4 Chapter 4: The influence of group format and involvement of healthcare professionals upon perceived benefit of support groups

4.1 Background

ICD recipients have been shown to experience a range of emotions and challenges in adapting to life with their ICD. Quantitative studies have demonstrated that ICD recipients experience significant levels of anxiety and depression (Magyar-Russell *et al.*, 2011), while qualitative research has provided greater understanding of the experiences of ICD recipients and how ICD implant affects their lives psychologically, socially and physically (Kamphuis *et al.*, 2004). A mixed-method systematic review (Ooi *et al.*, 2016) highlighted the impact that shock experience, fear and anxiety regarding shocks, loss of independence, and resentment regarding limitations, have upon ICD recipients' lives. Ooi *et al.*, (2016) also reported that there was often a lack of professional support from the patient's care team due to lack of continuity in care or time constraints, which left their concerns about their ICD unanswered.

A range of coping strategies used by ICD recipients have been identified (Ooi *et al.*, 2016). Many of the adaptive coping strategies (e.g., talking about it and educating others, understanding own diagnosis to reduce uncertainty, and searching for meanings and rationalising situations) could be undertaken within a support group and are consistent with reasons for attending identified in a qualitative study (Williams *et al.*, 2004). However, some ICD recipients may use coping strategies which tend to be maladaptive, such as distraction, evasiveness and avoidance (Ooi *et al.*, 2016) and it is unlikely these patients would choose to attend a support group. Rate of support group attendance among ICD recipients in unknown, but has been shown to be fairly low (10%) in patients with other conditions (Van Uden-Kraan *et al.*, 2011). Identifying the range of reasons for attending and adaptive coping strategies for ICD recipients may help to improve support groups appeal and perceived benefit.

In chapter 3, a task-based theory of adaptation to chronic illness (Samson and Siam, 2008) was applied to explore how ICD recipients perceive the benefits of attending a support group. It concluded that the support group provides ICD recipients with a safe setting where they can reflect on their mortality, connect with other ICD recipients, and gain meaningful information. This allows them to reframe their lives, undertaking the tasks required in adapting to and accepting the changes needed to live with their ICD. This chapter presents the second phase of the research study which was designed to enhance the validity of qualitative findings presented in chapter 3 by triangulating these with a quantitative survey to assess agreement from a wider cohort of support group attendees using a fixed-response self-completion questionnaire. This combining of research strategies produced a more complete picture of the subject as data were also collected around practical topics which did not feature strongly in in the interview data but were relevant to the overall study objectives of evaluating the influence of group format upon the experience of support groups.

The objective of this chapter is to quantify the perceived benefit of support groups and the influence of group format and the involvement of HCPs on their experience of support groups by assessing agreement with the qualitative findings, using a carefully constructed questionnaire which is based on the themes generated from the patient interviews (chapter 3).

4.2 Methods

4.2.1 Questionnaire design

Batterton and Hale (2017) recommend using existing scales to ensure appropriate questions are asked, however, acknowledge that these do not yet exist for all research problems. No existing Likert scale was found which was suitable for the present study and therefore a purpose-designed questionnaire was developed. The use of specific tools such as Exploratory Factor Analysis (EFA) is recommended when building a new Likert Scale (Batterton and Hale, 2017), however, formal validation and psychometric testing of the questionnaire was not possible in the present study due to time constraints and the small population being studied, as a sample size of at least 200 is recommended for EFA (Batterton and Hale, 2017). Careful consideration was given to the development of the questions with input from the research team and PPI to ensure they were in line with best practice. This includes ensuring the question’s meaning is appropriately conveyed, it is not too complex, vague, or double-barrelled, and that it does not include assumptions or perceived intent.

A four-page document was produced consisting of a two-page patient information sheet and introduction to the study followed by a two-page questionnaire which took 10-15 minutes to complete (appendix 3).

The questionnaire was purposely designed for the present study. A total of 44 statements were drafted by the author during the process of theme generation described in chapter 3. All statements were written in the first person to reflect the participant's perceptions of support groups. The 44 statements were presented to three members of the study's PPI advisory group (TF, AC and CP) to ensure they were unambiguous and reflected the findings of the qualitative data analysis. PPI is known to be helpful in developing written documents for patients (National Institute for Health and Care Research, 2021), and this approach ensured the questionnaire was suitable for patient use and appropriately targeted at ICD recipients.

16 of the statements were deemed repetitive, not suitable for patient use, or not key to the study findings by the PPI group. After discussion with the study team and comparison with the interview data, they were omitted from the final version of questionnaire and the wording of remaining statements were altered for clarity.

The final 28 statements were grouped into subject topics of a lifeline, involvement of healthcare professionals, sharing experiences, timing of support, and meeting practicalities to improve ease of interpretation for respondents (Robson and McCartan, 2016). Respondents were asked to mark their agreement with each statement using a symmetrical 5-point Likert-style scale (Strongly disagree – Strongly agree). A Likert-style scale was chosen because it is suitable to capture the feelings and attitudes of the participants around the phenomenon being studied (Joshi *et al.*, 2015) and therefore was consistent with the research aims.

To encourage open and honest completion the questionnaire was designed to be entirely anonymous, and no demographic data was collected. This approach was chosen because of the relatively small support group membership, many of whom were known to the researcher clinically and who may have been identifiable from this data. As the questionnaire was anonymously returned and no personal data stored, written consent was not collected but consent was implied by the return of the questionnaire to the study team.

4.2.2 Study participants

The sample was one of convenience, consisting of all current members of the support group. This approach was necessary due to smaller than expected membership by the time the questionnaire was produced. It is possible that the support group development and recruitment was adversely affected by the Covid-19 pandemic, as patients were not attending hospital and seeing clinicians and therefore opportunities to raise awareness of the group were limited in clinical practice.

The support group maintains its own membership list to which the clinical and research team did not have access. The self-completion questionnaire was disseminated to 54 existing support group members by the patient-led committee in-person at two meetings where hard copies were provided, and electronically via email to capture those members who had not been able to attend. An email reminder was sent out two weeks later. 17 responses were received, indicating a 31.5% response rate.

4.2.3 Data collection

The questionnaires were either returned in-person at support group meetings, via post using stamped addressed envelopes provided by the research team, or via email. To allow for anonymity, patients receiving the questionnaire via email were given the option to request a hard copy and return envelope. Where a participant chose to return the questionnaire via email, their response was not immediately viewed but was printed and stored separately to maintain anonymity.

4.2.4 Data analysis

Descriptive statistics were used to analyse the data. Whilst a true Likert scale is aggregated and requires analysis of the items as a group, the purpose-designed questionnaire in this study has not been psychometrically tested and therefore individual line-by-line analysis is acceptable (Harpe, 2015). Number of responses and percentage of the total responses were calculated for the individual items on the questionnaire. 8 questionnaires were returned with at least one question left unanswered. Due to the overall low response rate, it was decided to include these questionnaires in the analysis.

Scores were allocated to each response (Strongly disagree =1 to Strongly agree =5) and the mean calculated. The natural boundaries of the integers were used as boundaries for categories when interpreting the mean (Pornel and Saldaña, 2012). In the absence of a control group for comparison, inferential statistics were not performed.

4.2.5 Patient and Public Involvement

A PPI advisory group was involved throughout the study. Three members were recruited through the British Heart Foundation and one via the local support group, to bring a range of experience to support the study. Three of the PPI group had lived experience of an ICD and co-produced the questionnaire with the researcher.

4.3 Results

17 respondents returned their questionnaire to the study team. The questions were grouped in the topics of a lifeline, involvement of healthcare professionals, timing of support, and meeting practicalities. The topic of sharing experiences on the questionnaire had only three statements which each overlapped another topic, and they were therefore grouped into the most suitable other topic for presentation in the present thesis. The full results are presented in Table 11. The interpretation scheme of the mean scores and number of questions with a mean in each category is shown in Table 12.

Table 14: Number of responses for each question on the fixed-response questionnaire, expressed as n (%)

	1 Strongly disagree	2 Disagree	3 Neither disagree nor agree	4 Agree	5 Strongly agree	Total	Mean score
A lifeline							
1. Seeing other people living with their ICD gave me reassurance and/or hope that I could live a normal life.	0	0	1 (6%)	10 (63%)	5 (31%)	16	4.25
2. Meeting other people living with their ICD helped me decide whether to have an ICD.	1 (6%)	1 (6%)	10 (63%)	4 (25%)	0	16	3.06
3. I would have welcomed the opportunity to speak to other patients in the support group before the implant.	0	1 (7%)	3 (21%)	3 (21%)	7 (50%)	14	4.14
4. Talking to other people living with an ICD helps me keep my problems in perspective.	0	0	3 (19%)	9 (56%)	4 (25%)	16	4.06
5. The support group helps me feel like I'm not on my own with my ICD.	0	0	2 (13%)	4 (27%)	9 (60%)	15	4.47
6. I find it reassuring that other people find living with an ICD challenging, and that I am not alone in this.	0	2 (13%)	1 (6%)	11 (69%)	2 (13%)	16	3.81
7. I would expect any patients offering formal support to other patients to have undergone some training.	0	4 (24%)	4 (24%)	3 (18%)	6 (35%)	17	3.65
8. Talking to other patients has helped me find ways to manage the limitations on my life caused by my ICD.	1 (6%)	3 (19%)	4 (25%)	8 (50%)	0	16	3.19
9. Hearing other people's experiences of ICD shocks reduced my anxiety about it happening to me.	0	1 (8%)	4 (31%)	8 (62%)	0	13	3.54
10. It is easier to share my experiences during one-to-one conversation than during a group meeting	0	7 (44%)	3 (19%)	5 (31%)	1 (6%)	16	3.00
Involvement of healthcare professionals							
11. Having a healthcare professional present at the meeting is important because they can ensure advice and information being shared or discussed is accurate and safe.	0	0	1 (6%)	11 (65%)	5 (29%)	17	4.24
12. The support group should be led by patients because lived experience is important.	0	1 (6%)	6 (35%)	8 (47%)	2 (12%)	17	3.65
13. Healthcare professionals can't provide all the support I need because only patients know what it's like to live with an ICD.	0	2 (12%)	3 (18%)	11 (65%)	1 (6%)	17	3.65
Timing of support							
14. The support group was most useful to me around the time I had my ICD implanted.	0	1 (8%)	7 (54%)	4 (31%)	1 (8%)	13	3.38

Table 15 continued: Number of responses for each question on the fixed-response questionnaire, expressed as n (%)

15. I will probably only attend the support group if I have a problem or have a bad experience with my ICD.	2 (13%)	10 (63%)	3 (19%)	0	1 (6%)	16	2.25
16. It would be helpful if one-to-one support was available in between the regular group meetings.	0	2 (13%)	6 (38%)	8 (50%)	0	16	3.38
17. The support group offers a welcome point of contact in between my hospital appointments.	0	1 (6%)	0	15 (88%)	1 (6%)	17	3.94
Meeting practicalities							
18. Meetings once a quarter are not frequent enough to offer the support I need.	0	9 (53%)	4 (24%)	4 (24%)	0	17	2.71
19. I prefer to attend support group meetings in a community setting rather than in a hospital.	0	2 (12%)	5 (29%)	10 (59%)	0	17	3.47
20. An online forum as part of the support group would be convenient to me because I can connect with other people in the group and read their questions and answers.	0	2 (12%)	2 (12%)	12 (71%)	1 (6%)	17	3.71
21. Now Covid-19 restrictions have lifted, I would prefer that the meetings were available in person.	0	1 (6%)	2 (12%)	14 (82%)	0	17	3.76
22. Even though Covid-19 restrictions have been lifted, I would prefer the meetings to be available over Zoom	1 (6%)	10 (59%)	3 (18%)	3 (18%)	0	17	2.47
23. I prefer to share experiences with other patients at a face-to-face meeting compared to over Zoom.	0	1 (6%)	5 (29%)	10 (59%)	1 (6%)	17	3.65
24. The educational talks help me understand how my ICD works and why I need it.	0	0	1 (6%)	11 (69%)	4 (25%)	16	4.19
25. The social aspect of the support group meetings is an important part of its appeal to me.	0	1 (6%)	1 (6%)	12 (75%)	2 (13%)	16	3.94
26. The educational talks at the support group meetings are an important part of its appeal to me.	0	0	1 (6%)	13 (81%)	2 (13%)	16	4.06
27. I find it reassuring to have something in common (e.g. age or specific heart condition) with other people at the support group.	0	1 (6%)	2 (12%)	12 (71%)	2 (12%)	17	3.88
28. I was more reliant on the group for support during the Covid-19 pandemic because I couldn't access my usual forms of support.	0	4 (29%)	6 (43%)	4 (29%)	0	14	3.00

Table 16: Interpretation scheme of the mean scores and total number of questions with a mean response in each category

Level of agreement	Mean score	Number of questions with mean score in this category
High agreement	4.5-5	0
Agreement	3.5-4.49	18
Neutral	2.5-3.49	8
Disagreement	1.5-2.49	2
High disagreement	1 - 1.49	0

4.3.1 A lifeline

Figure 8 and Figure 9 indicate overall agreement with 7/10 of the questions around the support group as a lifeline. Respondents agreed that that the ICD support group provided reassurance that they could lead a normal life, helped to keep their problems in perspective, and helped them feel less alone in living with their ICD.

Respondents were neutral regarding whether meeting another ICD recipient helped them to decide to have an ICD. However, there was agreement that they would have welcomed the opportunity to access the support group prior to implant.

There was a neutral response to finding it easier to share experiences during one-to-one conversation rather than at a group meeting. One-to-one support was available to group members on request in the form of a 'buddy', and there was agreement that they would expect a 'buddy' to have received some training.

4.3.2 Involvement of healthcare professionals

Figure 10 shows that respondents agreed that it is important to have HCPs present at, but not leading, the group meetings and that having an HCP present at the meeting is important to ensure advice and information is accurate and safe. However, they also agreed that HCPs cannot provide all the support they need as they do not have personal experience of living with an ICD.

4.3.3 Timing of support

The level of agreement to questions around timing of support are shown in Figure 11. Respondents were neutral regarding whether they found the support group most useful around the time of implant and whether one-to-one support meetings would be helpful.

They disagreed that they would only attend the support group if they had a problem or bad experience.

Respondents agreed that they found the support group a welcome point of contact in between their hospital visits.

4.3.4 Meeting practicalities

The final group of questions were based around meeting practicalities and the responses are shown in Figure 12 and Figure 13. There was agreement that both the social and educational aspects of the support group were important parts of the support groups appeal.

Respondents were neutral that meetings once a quarter are not frequent enough. In contrast, there was agreement that an online forum would be convenient to provide access to support at any time. There was more interest in an online forum for support between meetings than for one-to-one support.

Covid-19 appeared to make little difference to the enthusiasm for the support group, with a neutral response that they felt they were more reliant on the group due to Covid-19 restrictions. However, there was agreement that they preferred meeting in person compared to over Zoom.

Figure 8: Number of responses to questions 1-5 around 'a lifeline'. The full questions are shown in Table 11.

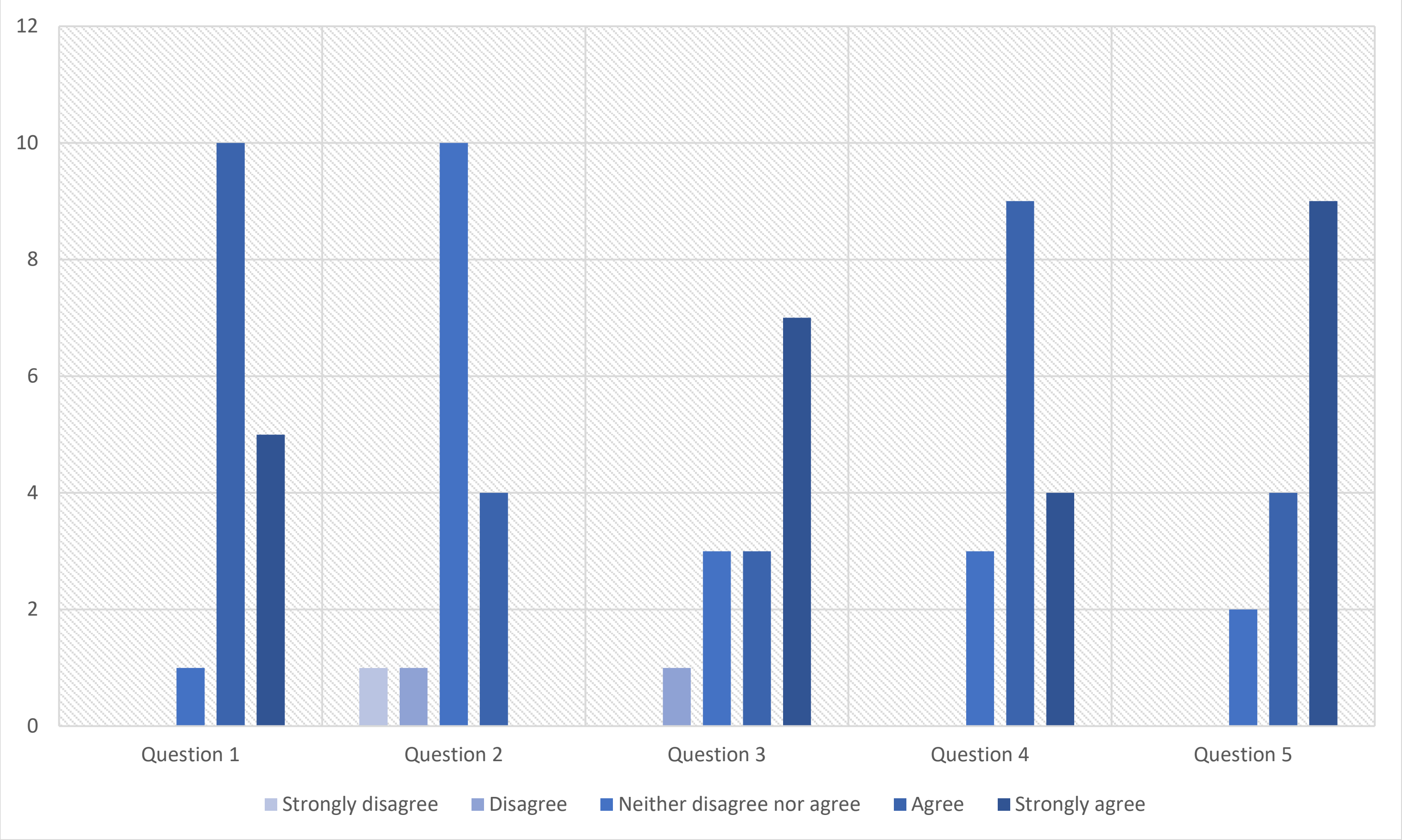


Figure 9: Number of responses to questions 6-10 around 'a lifeline'. The full questions are shown in Table 11.

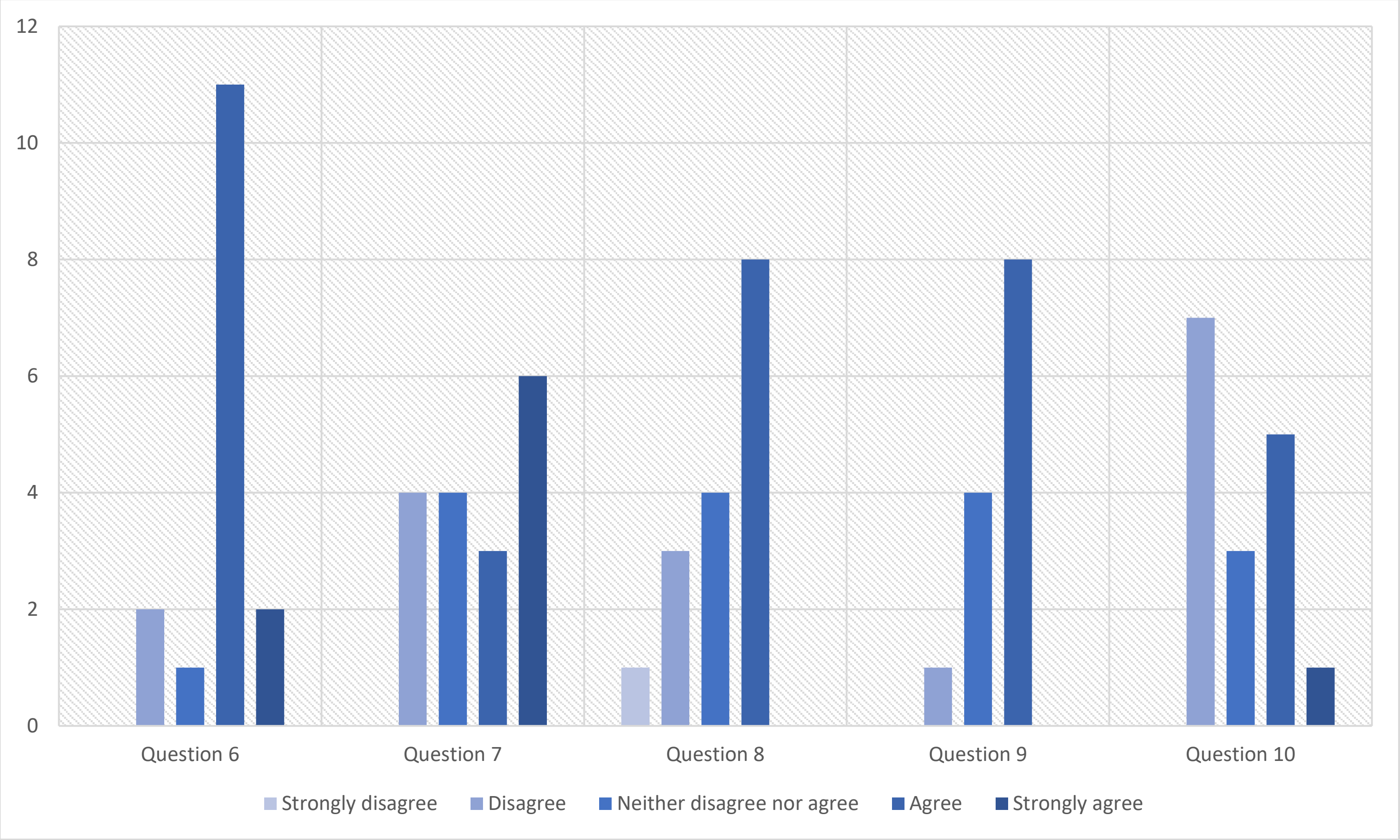


Figure 10: Number of responses to questions around involvement of healthcare professionals. The full questions are shown in Table 11.

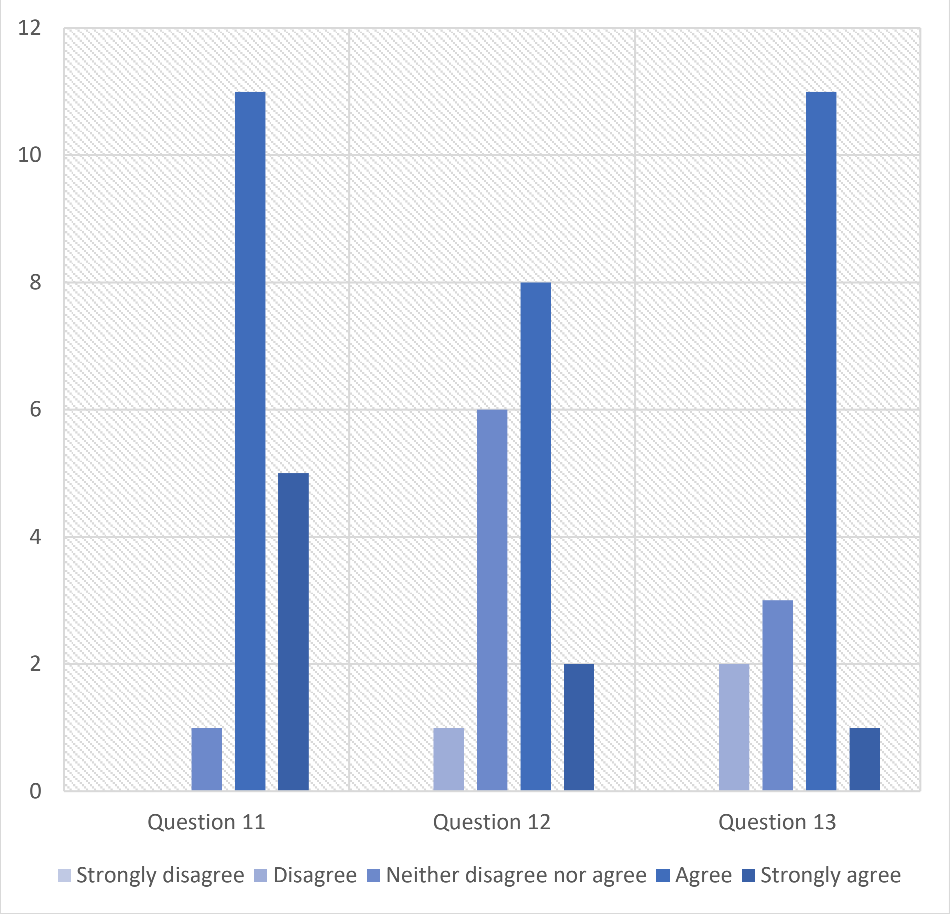


Figure 11: Number of responses to questions around timing of support. The full questions are shown in Table 11.

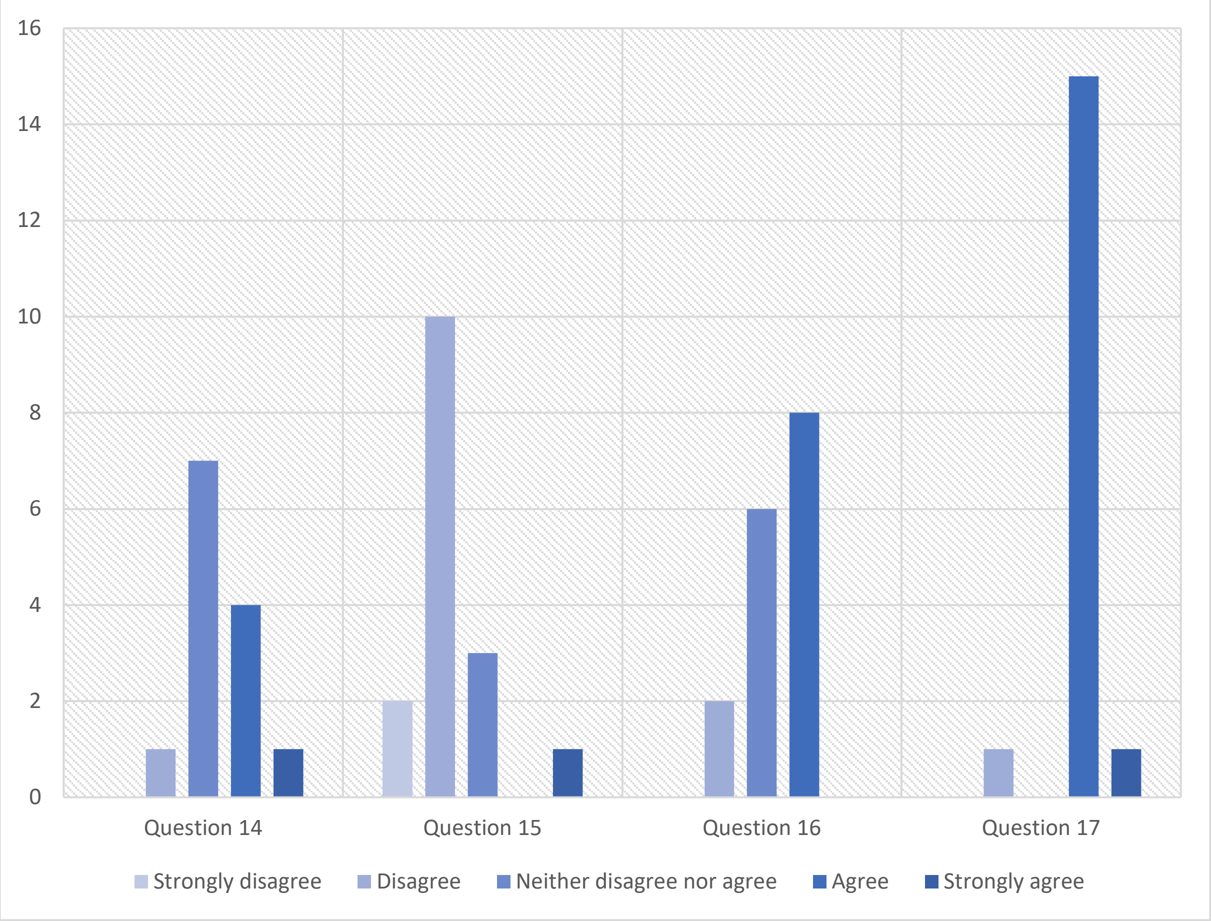


Figure 12: Number of responses to questions 18-22 around meeting practicalities. The full questions are shown in Table 11.

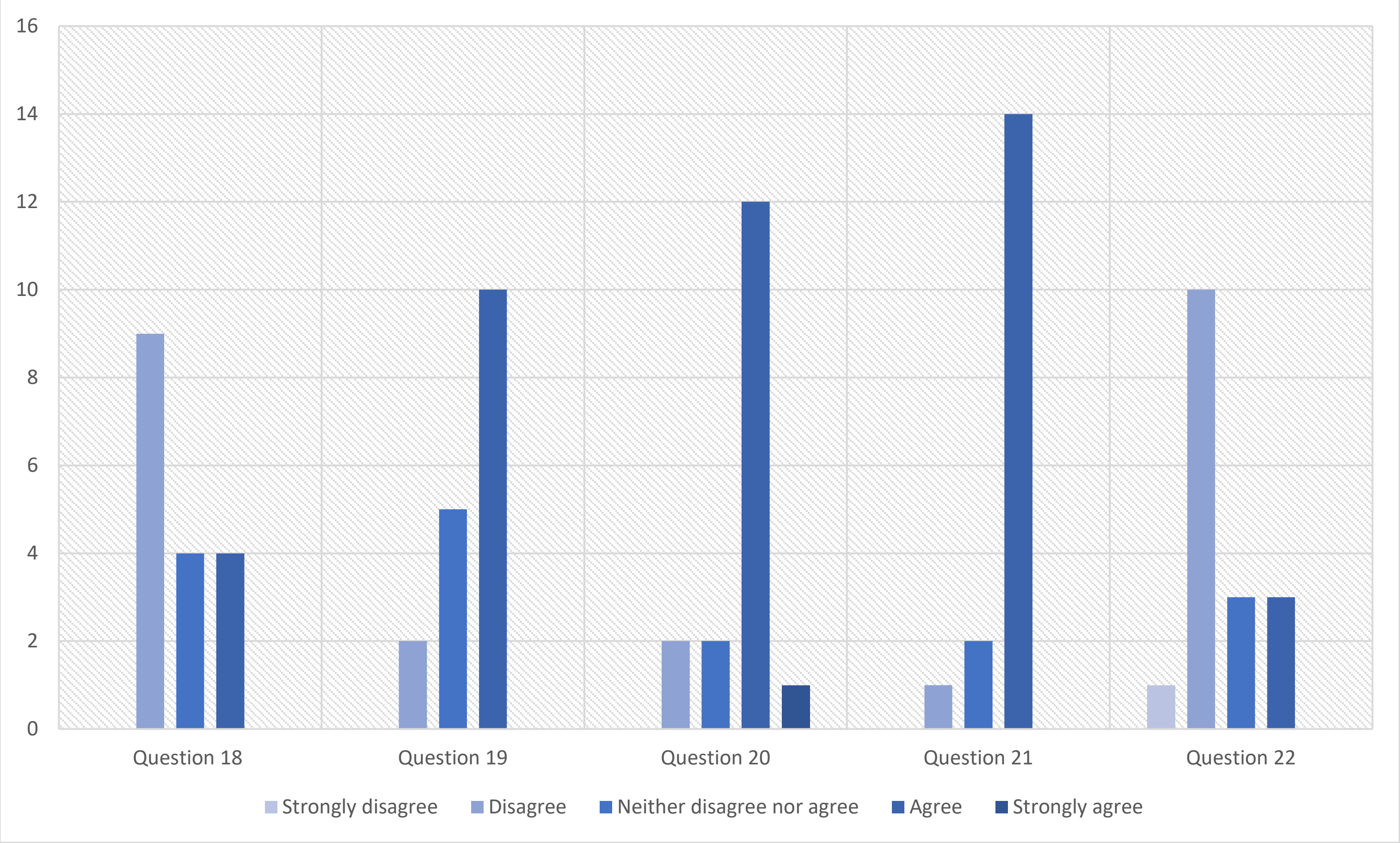
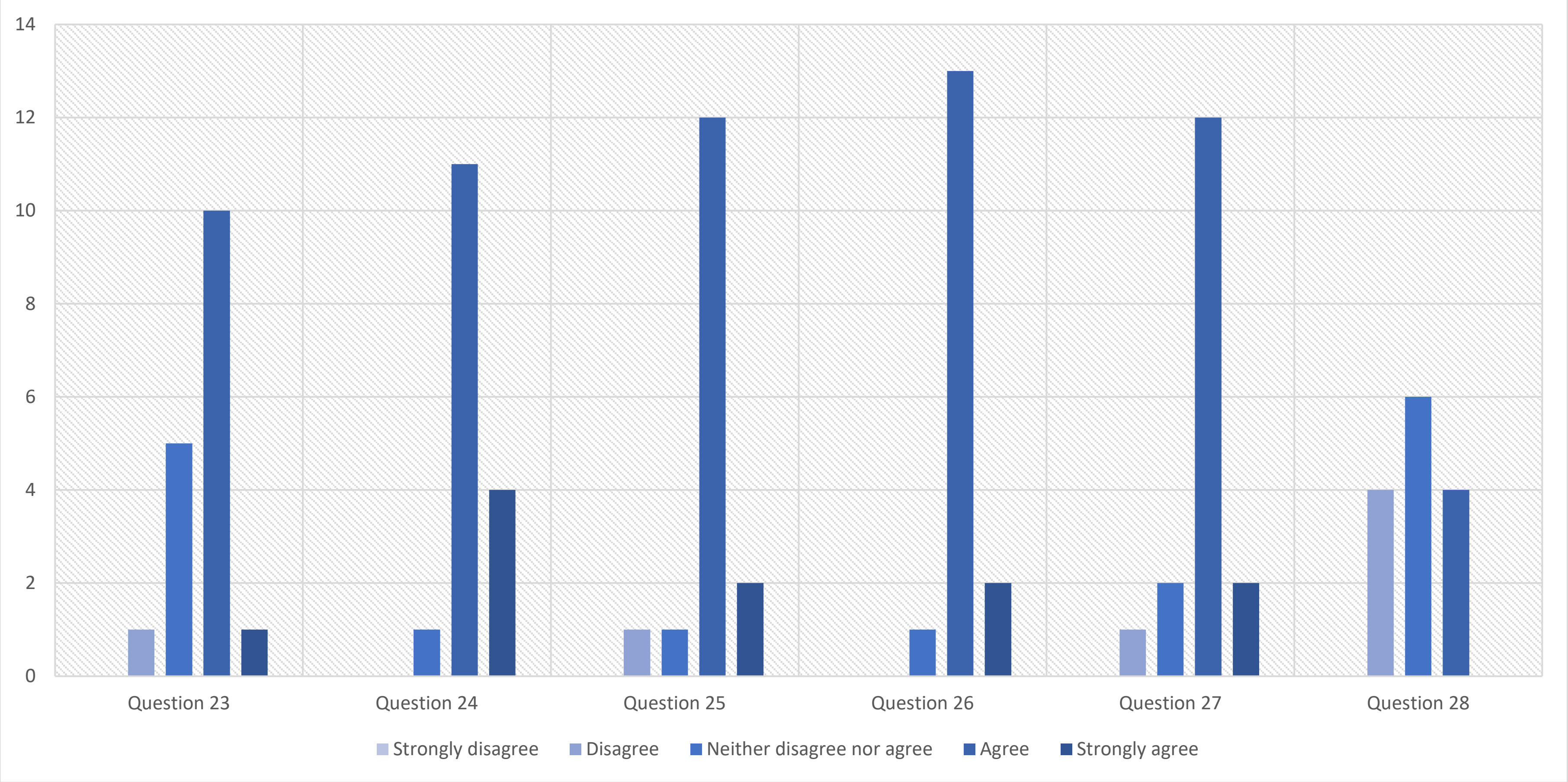


Figure 13: Number of responses and the mean response to questions 23-28 around meeting practicalities. The full questions are shown in Table 11.



4.4 Discussion

The objective of the present study was to assess agreement with the key findings of the qualitative study and further explore practical aspects of the support group which were not considered in the qualitative analysis. These are considered in the subject topics below before bringing them together discussing in the context of the wider literature.

4.4.1 A lifeline

The findings of the present study demonstrate that support group members find reassurance that they can live a normal life with an ICD and that sharing experiences about ICD shocks reduces anxiety about future shocks, which is consistent with the qualitative results in chapter 3.

In the interview data a range of opinions had been expressed around the provision of training for volunteer ‘buddies’, which was in the process of being organised by the support group during the research period. This was not reported in the qualitative analysis as no clear pattern was identified, so a question was included in the questionnaire to gauge the opinions of the wider support group membership. Although there was overall agreement (mean 3.65) there was some split in responses, with a small majority (53%) of respondents agreeing or strongly agreeing that they would expect a ‘buddy’ to have received some training compared to 24% who disagreed and a further 24% who were neutral. This reflects the variation seen in the literature, in which some peer supporters have undergone training (Shen *et al.*, 2019) and others have not (Lockhart *et al.*, 2014). Lockhart *et al.* found that some of the peer relationships in their study were more successful and supportive than others and recommended further research into the factors which lead to effective peer support. The present study’s finding of an overall neutral response that it is easier to share experiences during one-to-one conversation than during a group meeting supports this call for further research into how to effectively deliver peer support. It is also possible that individual personality types influence whether sharing is easier in a one-to-one or group setting (Allen and Brock, 2013), and it may be that support groups need to offer both opportunities to meet all member’s needs.

4.4.2 Involvement of healthcare professionals

Respondents agreed that HCP involvement in the support group is important, although HCPs cannot provide all the support patients need due to lack of lived experience. A previous study into ICD support groups (Dickerson, Posluszny and Kennedy, 2000) reported that HCP presence was an important therapeutic element and recommended future research into this area, however, it has also been reported that ICD recipients found information from fellow recipients more valuable than that from HCPs (Dickerson, 2005). This demonstrates the need to balance patient and HCP involvement to maximise the benefit of support groups. A case study (Carlsen, 2003) into involvement of HCPs in a self-help group for Chronic Fatigue Syndrome provides further insight into the collaborative relationship between group members and HCPs. Carlsen suggests that it is important to clarify what the motives are for professional involvement in a group as this affects the way in which they can best be involved. In the present study, qualitative findings suggested that the role of HCPs (as perceived by the attendees) is to provide professional advice and education about living with an ICD; for this role, Carlsen proposes that it may be appropriate for HCPs to lead the group. However, the results show that respondents prefer a patient-led group due to the importance of lived experience, although 35% expressed no preference.

4.4.3 Timing of support

The preferred time to access support appears not to be solely restricted to the peri-implant period. There was some discrepancy in the responses in the present study; the mean response was neutral that attending the support group helped them to decide to have an ICD and that the support group was most useful around the time of implant, however, there was agreement that attending prior to implant would have been a welcome opportunity. This may be explained by the support group only being available since 2019; although demographic data was not collected from questionnaire respondents it is likely that for at least some the support group was not available when they had their ICD implanted. They could not therefore agree to having found it most useful at implant, but perhaps could recognise the hypothetical value of having done so. This would be consistent with other studies which reported the highest rates of psychological distress are seen post implant and decrease over time, regardless of psychosocial intervention (Molchany and Peterson, 1994; Kapa *et al.*, 2010; Yardimci and Mert, 2019), although a systematic review concluded that there is insufficient evidence to determine changes in prevalence of anxiety and depression over time (Magyar-Russell *et al.*, 2011).

An alternative explanation for the neutral response that support groups are most useful around implant is the difference in support needs in terms of timing for ICD recipients for primary and secondary indications as described in the qualitative analysis in chapter 3, although this has not been described in previously published literature. It may also be that support groups continue to be perceived as beneficial over the lifetime of the ICD, which would explain the disagreement with the statement “I will probably only attend the support group if I have a problem or bad experience with my ICD”. It has been shown that a small cohort of patients continue to experience significant levels of psychopathology after 12 months (Kapa *et al.*, 2010). A ’watchful waiting’ approach has been suggested to avoid treating psychological distress which will resolve spontaneously, allowing support to be targeting to those who need it the most (Habibović, Burg and Pedersen, 2013). Support groups, not being time-limited, allow patients to access support whenever they need it, and it may be that those who continue are attend are those whose distress does not resolve spontaneously, although further study would be needed to confirm this in practice.

4.4.4 Meeting practicalities

There was agreement that in-person meetings are preferable to Zoom, which may explain the general drop in attendance observed over Zoom during the pandemic. This is in contrast to a UK survey which reported that support groups experienced an increase in calls to their helplines and in followers to their websites and social media pages (McMullan *et al.*, 2021). This suggests that the provision of an online forum rather than Zoom meetings may have better met ICD recipients needs during the pandemic, which is supported in the present study as respondents agreed that an online forum would be convenient despite the preference for in-person meetings. Online support may also be better suited to providing support for younger ICD recipients (Timko *et al.*, 2022), allowing them to access support more flexibly. The interest in online forum-style support, which can be accessed 24 hours a day, may also explain the neutral response that quarterly meetings are not often enough; this suggests a blend of online support interspersed with in-person meetings would meet many ICD recipient’s needs.

The opportunity for education about ICDs was an important part of the support group's appeal. This may be due to lack of information provision in clinical practice; a Danish study found that over 40% of patients received no information on topics such as who to contact with social and work-related questions and the impact on obtaining insurance (Pedersen *et al.*, 2017). These vocation-based questions fit with the proposal that support groups provide the opportunity to complete adaptive tasks (chapter 3). The switch to remote monitoring, accelerated by the Covid-19 pandemic, has also reduced the opportunities ICD recipients have to ask HCPs questions during routine clinic care. This suggests that the support group may provide an alternative source of advice and information, particularly in the face of reluctance to access healthcare services due to perception of risk during the Covid-19 pandemic in an over-burdened health care service (Forsyth *et al.*, 2021).

4.4.5 Limitations and future research

The use of a purpose-designed questionnaire and involving patients in its development is a strength of the present study, however, there are limitations. The development of questions that are based on empiric data and carefully constructed with PPI input has provided some valuable insight into the attitudes of support group attendees. The questionnaire could have been improved by pre-testing prior to dissemination (Robson and McCartan, 2016), however, it could be considered a pilot test of the questionnaire in preparation for future use. Pre-testing for the present study was not possible due to time constraints and insufficient respondents due to the smaller than expected membership of the support group following the Covid-19 pandemic. Further work to establish the validity and reliability of the questionnaire is needed before it should be used in future research.

Response rate may have been improved by using fewer questions as the final questionnaire appeared quite lengthy which may have been off-putting to busy potential respondents (Robson and McCartan, 2016), although less than 20 questions is not recommended for Likert type questionnaires due to the coarseness of results (Pornel and Saldaña, 2012). An interview-based approach to data collection using the questionnaire as a structured interview guide would also have offered a viable alternative to this problem. The low response rate was below that usually considered acceptable for publication (Robson and McCartan, 2016) and conclusions from these results must therefore be drawn with caution. The small sample size and use of convenience sampling means the results may not be representative of the ICD recipient population. Although the decision not to collect demographic data was justified to preserve anonymity, the lack of this data makes assessing the representativeness of the sample difficult.

Likert-type questionnaires are well-documented to be subject to a range of potential biases, including acquiescence, central tendency, social desirability, and mis-response to reversed items biases (Weijters, Cabooter and Schillewaert, 2010). Effort was made in the present study to mitigate against these; for example, although there was disagreement with 2 of the statements, this was expected due to wording of certain statements. The statements around Covid-19 (*Now Covid-19 restrictions have lifted, I would prefer that the meetings were available in person* vs *Even though Covid-19 restrictions have been lifted, I would prefer the meetings to be available over Zoom*) were in effect asking mutually exclusive questions and agreement for both was not likely. This balanced approach was taken deliberately to ensure not all questions were worded in the same direction to mitigate against the risk of acquiescence bias, an important concern in survey design (Lelkes and Weiss, 2015). The potential for mis-response to reversed items bias as a result of this approach was mitigated by the use of only 5 items which were fully labelled (Weijters, Cabooter and Schillewaert, 2010).

Several respondents did not answer specific items on the questionnaire and the reason for this is unknown, increasing the risk of non-response bias. The addition of open-ended questions on the questionnaires may have provided some explanation for why some respondents chose not to answer specific questions. Some questions also had a high proportion of neutral responses which may reflect central tendency bias, which has been well-documented in Likert-type questionnaires (Douven, 2018). However, there is also potential for misuse of the neutral option (Chyung *et al.,* 2017). In the present study, the midpoint was labelled as *Neither agree or disagree*; respondents who were undecided, felt the question did not apply or depended on context, or felt more information was required, had no option to express this and may have chosen the neutral option as a 'dumping ground' (Chyung *et al.*, 2017). An off-the-scale option such as *I don't know* or *Not applicable* could have mitigated against misuse of the neutral option and risk of central tendency bias in the present study.

4.5 Conclusion

This quantitative section of the present study evaluated the level of agreement with the findings of the qualitative analysis using a purpose-designed questionnaire. Perceptions of a support group for ICD recipients was explored with a focus on preferred format and involvement of healthcare professionals. Overall, there was agreement with 18 (64%) of the 28 statements included in the questionnaire, supporting the key findings from the qualitative phase of the present study and indicating that these statements reflect the perceptions of the wider support group membership. The highest levels of agreement centred around the topics of a lifeline and involvement of health care professionals. On a basic level, there is agreement with *what* support group members perceive as beneficial, but more variation when it comes to *how* and *when*. This suggests that both core support group activities of providing HCP-led education and the opportunity to share experiences with fellow ICD recipients are necessary to adequately support attendees. However, preferences for format, such as online vs in-person and group vs one-to-one, varies between individuals and a support group should offer a blend of formats if it is to meet the needs of the highest proportion of patients.

Overall, respondents in the present study agreed that attending an ICD support group provided reassurance, reduced their sense of anxiety about shocks, and restored their hope that they could live a normal life with an ICD. There was agreement that involvement of HCPs and provision of education is important at group meetings, however there was considerably more variation in responses regarding other aspects of group format. The findings provide a contribution to an understanding of the role of support groups for ICD recipients which are discussed in conjunction with the findings of the systematic review (chapter 2) and qualitative analysis (chapter 3) in the general discussion in chapter 5.

5 Chapter 5: General discussion

5.1 Introduction

The research presented in this thesis achieved the overall aim of exploring the role of patient support groups in adapting to life with an ICD. This was achieved through addressing three objectives: (1) to evaluate the existing evidence for support groups for ICD recipients using a mixed-methods systematic review (MMS review, chapter 2), (2) to explore the attitudes and perceptions of patients attending a support group using qualitative methods (chapter 3), and (3) to assess agreement with the qualitative findings regarding the influence of group format and HCP involvement upon the experience of the support group using a questionnaire (chapter 4). The findings provide a richer understanding of the perceived benefits of support groups and the influence that group format has upon these benefits. The present study shows that support groups offer something more than reducing anxiety: acceptance, management of ICD-related concerns, peer support. The role of the support group in helping ICD recipients return to normal activities without fear of shocks is an important finding of the present study.

To the author's knowledge the present study is the first to explore the influence of group format and of ICD indication upon the perceived benefit of support groups. The experience of ICD recipients having to consider the possibility of their own death has been described in previous research (Kamphuis *et al.*, 2004; Sert, Turan Kavradim and Canli Özer, 2021), however, this is the first time theory (Kübler-Ross, 1969; Samson and Siam, 2008) has been applied to provide an explanation for the role of support groups in adaptation to life changes. This shift in focus from reducing anxiety as seen in previous studies (Molchany and Peterson, 1994; Myers and James, 2008; Yardimci and Mert, 2019) to improving adaptation is unique to the present study and contributes new knowledge to the field of support groups for ICD recipients which will be important to clinicians and clinical scientists caring for this patient group. The present chapter provides an overall a summary of these findings, followed by a general discussion of the wider implications of the research and how these can be applied to clinical practice.

5.2 Key summary of findings

The key findings of the MMS review presented in chapter 2 are:

- Support groups had no significant effect on mental-being when measured using standard tools for anxiety and QoL.
- Support group attendees were more anxious than non-attendees and anxiety reduced over time in all groups.
- Attendees perceived the group as beneficial; they described being fearful of death and of shocks which was controlled by knowledge acquisition and shared experience.
- Mental well-being is more than the absence of mental illness (Galderisi *et al.*, 2015) and that this needs consideration when evaluating support groups.
- Further research was recommended into the optimal format of support groups, level of involvement of HCPs, and whether primary and secondary prevention ICD patients have different supportive needs.

The qualitative research presented in chapter 3 was designed to explore these questions. Through the generation of the four themes (confronting mortality, coping through sharing, coping through learning, and providing space) using thematic analysis, the perceptions of ICD recipients regarding the benefit of support groups have become clearer:

- The support group provides a setting where ICD recipients can openly consider and process their own mortality, share their experiences with empathic fellow patients, and learn both from the experiences of other patients and from expert speakers.
- The support from the group allowed them to develop coping skills and ultimately lead a normal life.
- Although shock experience and ICD indication did not appear to influence the type of support needed, participants with ICDs for primary prevention indications appeared to need support at different times in their journey compared to secondary prevention.
- ICD recipients who had not experienced a shock found it reassuring to hear from those who had.

The quantitative phase of the study (chapter 4) used a survey to provide validation of the qualitative findings, importantly:

- Through attending the support group participants found reassurance and hope that they could return to a normal life with an ICD.
- There was strong support for both educational and social aspects of the group, highlighting the importance of both HCP involvement and patient-to-patient interaction.

5.3 General discussion

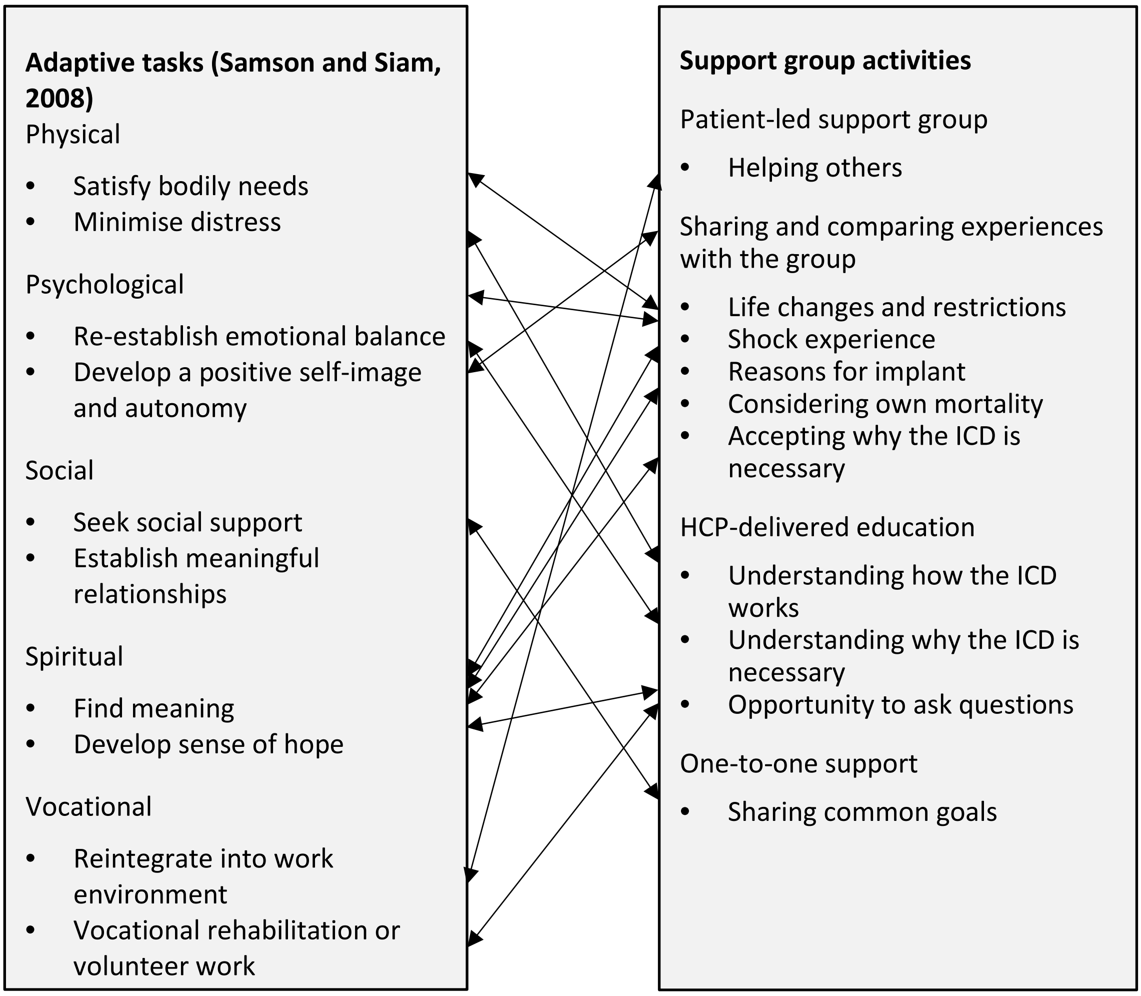
5.3.1 The role of support groups in adapting to life with an ICD

The results presented in the present thesis demonstrate that a key role for support groups is to help ICD recipients adapt to their new life with their device. The perceived benefits of the support group had an emphasis on ‘getting back to normal’ and finding the hope and reassurance that this was possible. The qualitative findings showed how this was achieved through gaining meaningful information and providing the time and space for cognitive appraisal of their new life situation. The need for meaningful information has been highlighted in previous research (Dickerson, Posluszny and Kennedy, 2000), however, in the present study theory was applied to consider how support groups can maximise the opportunity for adaptation. The experience of ICD recipients having to consider the possibility of their own death (Kamphuis *et al.*, 2004; Sert, Turan Kavradim and Canli Özer, 2021) allowed the application of relevant theory (Kübler-Ross, 1969; Samson and Siam, 2008) that provided an explanation for the role of support groups in adaptation to life changes. This differs from the role of support groups in reducing anxiety as explored in previous studies (Molchany and Peterson, 1994; Myers and James, 2008; Yardimci and Mert, 2019). The present study’s reframing of the role of support groups towards adaptation is unique and contributes new knowledge to the field of support groups for ICD recipients.

The task-based model for adaptation to chronic illness (Samson and Siam, 2008) provides a comprehensive approach to the process of adaptation and fits well with the findings of the qualitative analysis (chapter 3). The five tasks described (physical, psychological, social, spiritual, and vocational) reflect the broad impact that a chronic condition may have upon a person’s life, and subsequently the broad range of support that could be offered via a support group to assist the process of adaptation. Ensuring support groups offer a range of activities which provide attendees with the opportunity to achieve each of the adaptive tasks described by Samson and Siam (2008) could improve the overall benefit of groups. Information presented in Figure 14 shows how the support group activities identified in the present study could help attendees achieve the adaptive tasks.

Figure 14: Linking the adaptive tasks described by Samson and Siam (2008) to specific support group activities.

Note: This figure demonstrates that a range of activities are needed to provide the opportunities for ICD recipients to complete all the adaptive tasks.



The range of support group activities required to meet the adaptive tasks demonstrates the importance of a delivering support using a format which provides the opportunity to meet as many of these tasks as possible, which is discussed in more detail in section 5.3.4.

5.3.2 The influence of ICD indication upon perceived benefit of ICD support groups

Exploring the influence that ICD indication has upon the perceived benefit of support groups was an objective of the present study; the qualitative findings provided a new understanding of the similarities and differences between the experiences of ICD recipients with primary and secondary prevention ICDs. The support needs of connecting with other ICD recipients and gaining meaningful information and reassurance regarding their ICD appeared to be the same in both groups. Both groups of patients may have to consider their own mortality and adapt to life changes because of the implant; the adaptive tasks (Samson and Siam, 2008) are therefore equally applicable. The qualitative analysis identified differences between ICD recipients with primary and secondary prevention indications in decision-making and accepting the ICD as necessary, and the timing of accessing the support group. This suggests that support groups do not need to offer different activities but emphasises the importance of being able to access the support group before implant to help with decision-making, and at any time afterwards depending on need. Previous research into ICD support groups has not explored the impact of ICD indication upon support needs, with the majority being undertaken prior to common use of primary prevention ICDs. However, Myers and James (2008) compared rates of anxiety in patients with ICDs following SCA or myocardial infarction (MI) and found no significant difference, which supports the present findings that they appear to have similar needs for support.

5.3.3 The influence of shock experience upon the perceived benefit of ICD support groups

Shock experience appears to make little difference to the practical support needs of sharing and learning; in the present study, both shocked and non-shocked participants perceived benefit from hearing about other’s shock experience and that they have returned to normal lives afterwards, although experience of shocks was limited to three participants. This finding was unexpected due to previous research reporting that shocks are associated with anxiety (Qintar *et al.*, 2015; Perini *et al.*, 2017), suggesting that they may have different support needs. However, fear of shock (as opposed to pathological anxiety) is reported in all patients in earlier studies (Sears *et al.*, 2007). While the present study found that participants with shock experience reported anxiety about further shocks, so did participants who had never received a shock, although the level of anxiety was not objectively measured. As discussed in chapter 1, previous research has suggested perceived control and ICD-related concerns may be mediating factors between shocks and anxiety (Lee *et al.*, 2020) and QoL (Hammash *et al.*, 2019). This may explain the role of support groups in addressing fear of shocks (regardless of prior shock experience); while they do not provide an intervention specifically designed to treat anxiety, they provide an opportunity for participants to address these mediating factors through education and reassurance. Interestingly, Qintar *et al.* (2015) reported that, despite being associated with increased anxiety, ICD shock is associated with increased device acceptance in the long-term. This demonstrates the complexity of individual responses to ICD implant and shocks and therefore the difficulty in providing a single intervention likely to meet all patient's needs.

5.3.4 The influence of group format upon the perceived benefit of ICD support groups

The findings of the present study suggest that group format does influence perceived benefit and there were high levels of agreement about certain aspects of format in the questionnaire results (chapter 4). However, there was no single format which suited every participant and therefore a flexible approach, combining a range of formats, is recommended to meet the needs of as many ICD recipients as possible. The practical ways in which the support group can provide these opportunities to maximise the potential benefits were explored in this study and discussed in more detail below.

The opportunity to share experiences with other ICD recipients has been identified as an important role of support groups in helping patients adapt. Therefore, the present study has provided a new understanding of how to create a setting where ICD recipients feel comfortable and safe to do so. A community setting for in-person meetings was preferred, with participants describing a sense of ownership of their ICD and of their recovery when meeting away from the hospital setting. This may link to the concept of perceived control which has been shown to be a mediating factor between shocks and anxiety (Hammash *et al.*, 2019; Lee *et al.*, 2020). Perceived control in healthcare is important because the perception that one has control results in better adjustment; furthermore, the perception of having lost control having previously had it is thought to be particularly detrimental (Wallston *et al.*, 1987). Hammash *et al.* (2019) explored the relationship between perceived control and QoL and concluded that interventions which address patients' concerns and other psychosocial factors through education are needed to improve perceived control. The present study has shown that this may be achieved through well-designed patient support groups.

The findings of the present study suggest that in-person meetings held quarterly alongside support accessible in-between the meetings in the form of one-to-one peer support or an online forum would meet the needs of most ICD recipients. In-person meetings were preferred over remote meetings, however, there was agreement that an online forum would be useful. There was a mixed response regarding one-to-one peer support, with this being preferred by some participants but not others. The results presented in chapter 4 show that it is expected that those offering peer support have received some training, however, a systematic review of the effect of training for peer facilitators of support groups found there is no significant evidence that training improves support group member outcomes (Delisle *et al.*, 2016) and therefore the importance of delivering this in practice is not yet clear. Younger patients were not well-represented in the interview phase of the study and demographic data was not collected from questionnaire respondents so it is not possible to draw conclusions about age preferences from the findings, however, research into support for other health conditions suggest that online support may appeal to younger ICD recipients (Timko *et al.*, 2022). Recommendations for the design and implementation of online support for cancer survivors exist (Weiss *et al.*, 2013) which may provide a useful framework for integrating online support with in-person support. This is important because, while some support groups may be online only and provide valuable opportunity for sharing experiences and seeking advice from other ICD recipients (Dickerson SS, Flaig DM, and Kennedy MC, 2000; Dickerson, 2005), the findings of the present study suggest that this would omit another important perceived benefit of support groups: that of formal, HCP-led education and the opportunity to ask questions and seek professional (rather than peer) advice to address specific concerns. Online only groups also risk the exchange of poor quality information due to the lack of a facilitator (Delisle *et al.*, 2017). Education being perceived as an important aspect of support groups was supported by both the qualitative and quantitative results of the present study. Satisfactory information provision is correlated with QoL, however there are often unmet needs in clinical practice (Pedersen *et al.*, 2017) and support groups can provide an alternative avenue to meet these needs.

5.3.5 The role of healthcare professionals in an ICD support group

Education was perceived as a key beneficial aspect of the support group in the present study. It was important to participants that this was delivered by or with support from HCPs, as this validated the information being provided and ensured any advice provided was accurate and safe. However, although HCP involvement during the educational portion of the meeting is recommended, some attendees may benefit from speaking to other ICD recipients without an HCP present. Previous research has found that support group attendees feel more comfortable sharing their experiences with fellow ICD recipients than with HCPs who do not have personal understanding of life with an ICD (Dickerson, Posluszny and Kennedy, 2000). Furthermore, non-constructive support from HCPs has been shown to hinder device acceptance (Morken, Norekvål, *et al.*, 2014). This is consistent with the findings of the present study as during the interviews some patients reported that they would prefer not to discuss their experiences with a member of their direct care team present.

The preference for sessions to be facilitated by HCPs is consistent with research findings in other health conditions, for example 83% of patients with lung cancer preferred sessions to be conducted by a HCP (Devitt *et al.*, 2010). This study was interesting because it compared the preferences of patients and HCPs and identified several discrepancies. This supports the need for patient-led support groups to ensure patient needs are met, rather HCP-led groups offering what they think patients need which may not be the same thing.

Interestingly, some studies have found that the group members thought that their experiences would be useful for the HCPs to hear and that it may improve their care (Carlsen, 2003; Delisle *et al.*, 2017). In the present study this was not reflected in the analysis of interview data from a patient perspective, however, personal reflections by the researcher have demonstrated learning and adaptation of clinical practice based on involvement in the support group. This merits further study to improve clinical practice.

5.3.6 Timing and availability of support before and after ICD implant

While most published studies into supportive interventions have been undertaken post implant, the present study has found that the timing and need for support is more complex than related to the implant; instead, diagnosis, ICD indication and individual coping styles all appear to influence when support may be needed. Both Kübler-Ross (1969) and Samson and Siam (2008) recognise denial and avoidance as coping strategies which are used by many patients at some point in their journey. ICD recipients who are using denial and avoidance to cope are not likely to find a support group beneficial at this stage, however, they may need this support later in their journey. This may mean the continuous availability of support groups and flexibility of access to them has an advantage over fixed time interventions, particularly in terms of allowing for individual coping strategies. This also suggests that attending support groups shouldn't be prescribed post-implant, but that it is important to raise awareness of their existence so patients can easily access support when it is needed.

This finding of the present study that respondents disagreed that they would only attend the support group if they had a bad experience was unexpected, as this implies that shock delivery would not predict attendance. However, as discussed in 5.3.3, shock experience did not appear to influence support needs, suggesting that the role of the support group is wider than addressing fear of shocks, although this is a frequently reported source of distress (Sears *et al.*, 2007).

5.3.7 ICD support groups and the impact of Covid-19

Covid-19 had a significant impact on the support group and the present study. The existing patient support group was in its infancy as the pandemic arrived in early 2020, having only held the first meeting in October 2019. It had to adapt to the social restrictions and meetings were held over Zoom between March 2020 and July 2021, with one further Zoom meeting in January 2022. Attendee numbers on Zoom were noticeably lower than in person, and the group has struggled to return to pre-pandemic numbers, possibly because people remain cautious about meeting in public. The effect Covid-19 had upon the support group development unfortunately reduced the number of participants eligible for inclusion in this study.

The initial research protocol was about to be submitted in March 2020 when the Health Research Authority stopped accepting applications for student research and would only approve projects related to Covid-19. Because of the impact Covid-19 had upon support group and participants' lives in general, the research objectives were adapted to take these into account as they were likely to remain relevant throughout the study period. The author also adapted the study protocol and other documentation to reflect Covid-19 restrictions prior to ethical approval. The interview schedule was updated to include questions around the impact of Covid-19 and the option was provided for interviews over Zoom or in-person, depending on social distancing requirements and participant preference. An audio consent procedure was outlined for Zoom interview in addition to standard written consent forms.

Both the qualitative and quantitative findings of the present study suggest that Covid-19 made little difference to support needs, although some who had their ICD implanted during lockdowns did find it “a lifeline”. The enforced change to remote meetings during the study period due to the lockdown restrictions provided an opportunity to explore perceptions of the advantages and disadvantages of in-person, remote and online support. There was a strong preference for in-person meetings compared to remote meetings in this study. Although the interview participants accepted that remote meetings had offered a feasible alternative during the pandemic, attendance was lower compared to in-person meetings, supporting the preference for in-person meetings. This differs to the findings of a pre-Covid-19 systematic review into the use of video-conferencing for support groups (Banbury *et al.*, 2018), which reported that overall there was high acceptance of remote support groups, although one included study found that some participants preferred face-to-face and that participation in remote groups was lower.

Banbury et al’s (2018) systematic review reported that the effectiveness of remote and face-to-face studies were similar, although only included two studies had a comparative design. Remote support groups were also seen to remove some barriers to attending, particularly for patients living in less accessible rural locations. Rural location has been reported as a barrier to attending a support group in other studies (Williams *et al.*, 2004; Doolan-Noble *et al.*, 2021), however, it did not feature in the present study’s analysis, probably because of its location in a relatively central, highly populated area of the UK. This may explain the stronger preference for in-person meetings in the present study compared to other published studies which are mainly based in countries with different geography leading to more remote rural participants (USA, Canada, Australia and Scandinavia) (Banbury *et al.*, 2018).

5.3.8 Support needs and group attendance

As described in chapter 1, it was not clear whether patients who are most likely to experience ICD-related distress (i.e., those with shocks, or lower perceived control and greater ICD-related concerns) are the same group of patients who are likely to attend support groups. The findings of previous studies which found that support group attendees tend to be more anxious than non-attendees (Molchany and Peterson, 1994; Myers and James, 2008) lend some credence to the idea that those with lower perceived control and more ICD-related concerns would be likely attendees. While the present study did not directly address this question, the findings suggest that support group attendance is likely to be predicted by coping strategy, rather than ICD experience; as discussed above, those with maladaptive coping strategies (denial, avoidance) would not be likely to access a support group. However, coping strategies are flexible and patients tend to utilise different strategies as they progress through their journey (Kübler-Ross, 1969). This endorses the use of support groups compared to fixed-term interventions as they can be accessed by ICD recipients when they feel it will be beneficial according to their coping strategies at the time.

5.3.9 Evaluating the effectiveness of ICD support groups

Previous quantitative research has used measures of anxiety and QoL to measure the effects of support groups. However, the MMS review (chapter 2) indicated that alternative measures may be more sensitive to detect to effectiveness of support groups. The findings of the empirical research in the present thesis provide some insight into the potentially measurable effects of support groups which may play a mediating role in reducing anxiety and depression; for example, a relationship has been demonstrated between ICD-related concerns and anxiety and depression (Thylén *et al.*, 2016; Lee *et al.*, 2020). It has also been suggested that positive adaptation to cardiac disease may prevent the onset of mood disorders (Ceccarini, Manzoni and Castelnuovo, 2014) which implies that if support groups successfully promote adaptation they may have a role in play in preventing rather than improving symptoms of mental ill health. Judging the effectiveness of support groups solely on reduction of anxiety and depression would be to ignore these benefits and future research should consider using instruments such as the ICD patient concerns questionnaire (ICDC) (Frizelle *et al.*, 2006) or the Florida Patient Acceptance Survey (FPAS) (Burns *et al.*, 2005) to measure the effect of support groups. These instruments are discussed in more detail below.

The findings of the present study found that, through the support group, ICD recipients were reassured about life with their ICD and that the blend of learning from HCPs and other ICD recipients helped to address their concerns and gave them hope that they could live a normal life. Addressing ICD-related concerns has been recommended as an important focus when designing interventions to reduce distress in ICD recipients (Thylén *et al.*, 2016; Lee *et al.*, 2020). This suggests that support groups may be a useful resource in reducing distress despite the lack of existing quantitative evidence as shown in chapter 2. The perceived benefits of support group attendance described in the present study are aspects of the ICDC, and this may be a more useful tool to evaluate the effect of support groups in future research.

The present study's findings also suggest that participants perceived that the support group helped them to accept their ICD. Measuring patient acceptance may therefore be a more sensitive tool to evaluate the effect of support groups. One such tool is the FPAS, a self-completion survey comprised of four factors: return to function, device-related distress, positive appraisal, and body image concerns (Burns *et al.*, 2005). This has been psychometrically tested and found to have good internal consistency (Cronbach's alpha = 0.83) and discriminant validity compared to other self-report measures such as QoL and anxiety (Burns *et al.*, 2005). It has been used in several published studies which overall show that patient acceptance is high, but that is negatively affected by shocks (Qintar *et al.*, 2015), presence of sleep disorders and PTSD (Gallagher *et al.*, 2015), and younger age and presence of poorer QoL pre-implant (Carroll *et al.*, 2012). To the best of the author's knowledge, no study has used the FPAS for pre/post intervention analysis, and this may be a useful approach for future study into support groups for ICD recipients.

5.4 Contribution to the field

The present thesis adds to the limited body of literature exploring the role of support groups for ICD recipients. The mixed-methods synthesis performed in the systematic review was valuable because it enhanced understanding of the less easily measured perceived benefits of support groups and guided the direction of the empirical research. The qualitative study used thematic analysis which is suitable for a lone researcher (although additional members of the team provided input and advice where required), was appropriate to answer the research question, and has clear guidance to assess quality (Braun and Clarke, 2020, 2022). This allowed for thorough, rich, and justifiable interpretation of the interview data. The addition of the quantitative survey for an overall mixed-methods design allowed for more complete examination of the role of support groups for ICD recipients. It has been shown that support groups provide ICD recipients with the opportunity to learn coping strategies and undertake adaptive tasks which allow them to reframe their life with an ICD. This can be achieved through a blend of education and sharing experiences which enables acquisition of meaningful information. Recommendations for how support groups can provide this in clinical practice are included in 5.4.2.

5.4.1 Contribution to support group theory

The qualitative analysis presented in chapter 3 and discussed in 5.3.1 above linked the findings to theories of grief and adaptation. Whilst the seminal work of Kübler-Ross (1969) helped to explain the experiences and emotions of ICD recipients in being faced with their own mortality, the comprehensive task-model for adapting to chronic illness (Samson and Siam, 2008) provided a contemporary framework to explain the role of support groups in helping patients adapt to and accept their new life with an ICD. Mobilising these theories in the analysis of this study has provided a clearer understanding of the role of a support group. Previous empirical studies, as reviewed in chapter 2, have focused on their role in reducing anxiety and improving quality of life. The present study has shifted this focus towards adaptation and addressing mediating factors for anxiety such as perceived control, lack of meaningful information and ICD-related concerns.

5.4.2 Implications for clinical practice

The findings of the present study can be utilised to generate recommendations to improve the perceived benefit of support groups for ICD recipients (Figure 15). Support groups should be available to patients before and after ICD implant, for as long as they wish to attend, as this study shows that they are perceived as beneficial by new ICD recipients and those who have lived with their ICD for many years.

Figure 15: Recommendations generated from the findings of the present study

- Professional involvement should be seen as collaborative and reciprocal
    - HCP-led education is encouraged
    - Patient leaders of the support group are recommended
    - Include opportunities for patient-to-patient communication without HCP present
- An online forum in conjunction with in-person groups meetings held in community settings may help meet the needs of a wider range of ICD recipients.
- Access to support groups should not be time-limited, and available before and after implant

It should be acknowledged that support groups are not directly comparable to interventions designed to treat significant psychosocial distress such as severe anxiety and depression. While support groups are recommended for patients adapting to life with an ICD and can be provided with limited resources, they are not designed to treat severe mental illness. There is evidence that interventions such as CBT have a promising role in treating these patients (Li *et al.*, 2022), and referral routes should be in place for ICD recipients with signs and symptoms of significant mental illness.

5.4.3 Wider implications for provision of support groups for other cardiac and non-cardiac conditions

A recent study (Rafsanjani *et al.*, 2021) found that patients with pacemakers have comparable levels of anxiety and depression to ICD recipients, suggesting that this group of patients may also benefit from education and support about adapting to life with an implanted cardiac device even though they do not face the risk of shocks. The restrictions to life in terms of avoiding sources of EMI (described in chapter 1) also apply to pacemaker recipients and the device technology has much in common. Given that shock experience appeared to make little difference to support needs, the findings of the present study may therefore also be applied to supporting patients with pacemakers. Shared support groups for patients with any type of cardiac device may be feasible providing information is delivered carefully to avoid confusion where differences between devices do exist. This caveat already applies to ICD support groups as ICDs may have one, two, three or even no leads in the heart.

The findings of the present study may also be transferable to support groups for other health conditions; for example, the recommendations for group format generated in this study have some similarities to those tentatively suggested from a qualitative study of support groups for cancer patients, including a preference for non-clinical meeting locations and for open-ended support groups (Mallya *et al.*, 2020). The need to reframe life or return to ‘normal’ when adapting to a new diagnosis has been described in patients with myocardial infarction (Petriček *et al.*, 2017), allergies (Jones, Sommereux and Smith, 2018) and cancer (Grande, Myers and Sutton, 2006). The role of support groups in helping cancer patients deal with the fear of dying has also been described (Weis, 2003). The application of a theory of adaptation to the analysis in the present study allows the findings to be generalised to support groups for other conditions because the concept of adaptation is not disease specific (Audulv *et al.*, 2016).

5.5 Patient and Public Involvement

The empirical research was undertaken in existing clinical practice and the results therefore have real-world generalisability. This was further enhanced by a patient and public involvement (PPI) advisory group which was in place during the study, enabling co-production of the research and maintenance of the patient perspective throughout. PPI in research is defined as "research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them" (National Institute for Health and Care Research, 2021). The rationale for PPI in the present study was to provide a personal and/or patient perspective to the topic and ensure the research focused on what was important to people living with ICDs.

The opportunity to be involved with the project was advertised via the National Institute for Health and Care Research (NIHR), the British Heart Foundation (BHF), and the existing support group. 24 expressions of interest were received. Age, gender, ICD recipient, support group attendance and prior research experience were all considered to ensure the group would bring a diverse range of perspectives to the study. The author also personally spoke to each applicant to ensure they were able to develop a good rapport which would be needed for a successful partnership over the study period.

Six people were invited to the first meeting but only four attended. The meeting was successful, and all members agreed to continue in the role for the duration of the study. A PPI Induction Pack was provided to each member which outlined the research project and the role of the PPI advisory group. A form was included to allow PPI members to claim a £25 voucher for each meeting they attended in recognition and appreciation of their time commitment, and they were reminded of the opportunity to do this after each meeting.

The roles of the PPI group in the present study have been described in chapters 3 and 4. UK Standards for Public Involvement (National Institute for Health and Care Research, 2019) provide a framework for good quality PPI. While these standards are aimed at organisations rather than individual researchers, the principles can be applied to appraise the quality of PPI in the present study. The Induction Pack, outlining the roles, responsibilities, and expectations of group members and where to seek further information and support, meets several of the standards. Offering a voucher and holding meetings over Zoom removed some barriers to involvement, although monetary recompense rather than a voucher may have been preferred by some potential PPI members. A quarterly newsletter was used to update the PPI members on the progress of the whole study.

5.6 Limitations

The work presented in the present thesis has some limitations, many of which can be addressed in future research. The author being known to some ICD support group attendees through prior clinical encounters presented the risk of influencing the findings as an ‘insider’ researcher. Having familiarity with the subject and/or participants may enhance rapport and trust between interviewer and interviewee, but there is potential for the interviewer to impose their own values, beliefs and experiences upon the participants or steer the conversation towards experiences which the researcher has prior knowledge of rather than allow the participant to tell the stories which are most meaningful to them (Berger, 2015). Participants may also not have expressed certain aspects of their story under the assumption that the researcher knew or understood without the need to say it aloud, but this meant that unsaid aspect was omitted from the later analysis. The author had to remain alert and aware of these concepts throughout data collection, and the use of reflexivity helped to maintain distance between their clinical role and that of a researcher. While every effort was made to use reflection and PPI input to ensure the insider researcher role had a constructive impact on the study, it is possible that an ‘outsider’ researcher would generate different findings. However, the contextual critical realist approach used in this study posits that reality is not directly observable and therefore that the knowledge generated must be situated and shaped by the values and interpretations of the researcher (Braun and Clarke, 2022); therefore, the author’s role as an insider is not necessarily a weakness provided it is reflected on and considered in the presentation of the results, as has been done in the present study. It should also be acknowledged that some of the present study’s findings may be contextual and situational due to the impact of Covid-19 during the research period, which may limit the generalisability of the findings to future support groups not subject to the same restrictions.

The transferability of the results of the present study are hindered by the lack of ethnic diversity in the participants. This is important to acknowledge because in a previous study African Americans had significantly lower device knowledge and acceptance than whites (Wilson *et al.*, 2013). The present study has found these to be important perceived benefits of support groups and this suggests that ICD recipients from a non-white background may be in more need of support, however, whether they benefit from the same format of group due to cultural differences is unknown.

The use of a purpose-designed questionnaire and involving patients in its development is a strength of the present study, however, there are limitations. First, time restrictions meant that the questionnaire was developed before the qualitative analysis and theme generation was finalised. The questions were grouped into topics such as health care professional involvement and meeting practicalities, which reflected the organisation of codes (as shown in appendix 4) rather than the themes. It could be argued that this was preferable as the questions were therefore more recognisable from the interview transcripts and matched participants' wording, however, aligning the questions with the themes may have improved the ease of triangulation between qualitative and quantitative findings. If more time had been available, using a Delphi technique to address 'what could/should be' may have offered a useful alternative method to developing recommendations for the most beneficial support group format (Hsu and Sandford, 2007).

Individual line-by-line analysis of the questionnaire was acceptable as it was purpose-designed to assess agreement with the qualitative results of this study (Harpe, 2015). Future use of the questionnaire to assess patient perceptions of support groups is not recommended without further psychometric evaluation of the scale items. Re-wording of certain statements so that a higher level of agreement was a positive finding for every statement would also make the results clearer and easier to undertake further statistical analysis.

The PPI activities described above are all evidence of good quality PPI (National Institute for Health and Care Research, 2019), however, there is room for improvement. Communication was all conducted online, and therefore public without internet access were not included. The impact of PPI upon the research was not assessed, which limits the opportunity to share any learning which may have occurred about the PPI process itself.

5.7 Implementation and dissemination

The quarterly newsletter generated for the PPI group and research participants was also shared with the support group patient committee. This led to changes being made to the support group format during the study period, including increasing the frequency of meetings from 4 to 6 per year, and introducing a meeting which did not include a formal speaker but which focused on sharing experiences and making connections with other group members. Evaluating the impact of these changes was outside the scope of the present study. An online forum has not yet been developed but this is under discussion.

The author has also presented aspects of the present study to relevant healthcare and academic groups:

- Overview of the whole study to a Nursing, Midwifery and Allied Health Profession research group (October 2022)
- Overview of the whole study to the local cardiac science department (October 2022)
- In-depth review and personal experience of the MMS review to a later cohort of DClinSci students (November 2022)
- In-depth discussion of qualitative study to the University of Cambridge Qualitative Research Forum (invited to present in January 2023)

Abstracts of the MMS review and early qualitative findings from this thesis were disseminated to cardiology colleagues at a national conference in poster form in October 2022 (appendix 5), leading to discussions with doctors, arrhythmia nurses, and cardiac physiologists and scientists who were keen to set up support groups in their own area, or share experiences of running their own groups. A common concern was the sustainability of groups from a workforce perspective, and therefore the patient-led model presented in this study was of particular interest.

The MMS review was published in *Open Heart* in October 2022. It was subject to peer review and a major revision was requested based on the reviewer’s feedback prior to acceptance. The response to reviewers is included in appendix 2 and final paper in appendix 5. This process improved the quality of the paper, in particular through the clarification of the term ‘mental well-being’ and justification of the use of pooled outcome measures for the meta-analysis.

The full qualitative findings of the present study have been reported and submitted for publication in *Pacing and Clinical Electrophysiology* (appendix 5). The outcome was pending at the time of thesis submission.

Finally, an abstract of the overall mixed-methods study presented in the present thesis has been submitted for consideration for presentation at the European Heart Rhythm Association conference in 2023. The outcome is expected in January 2023.

5.8 Further research

Areas for future study have been highlighted throughout this discussion. To fully understand the role of support groups in adapting to life with an ICD, future qualitative research should seek the views of under-represented groups (including younger ICD recipients and ethnic minority groups) regarding their perceptions of support groups and reasons for non-attendance.

A previous study (Carlsen, 2003) reported that patients perceived a benefit to their clinical care from HCP involvement in support groups. Future research could examine this further from a patient and HCP perspective, utilising exploratory techniques such as focus groups to consider whether improving HCP understanding of patient experience via the support group influences the clinical care provided.

Finally, larger-scale experimental research is needed to evaluate the effect of support groups. The present study’s findings suggest that measures of ICD-related concerns such as the ICDC or acceptance such as the FPAS may be useful to evaluate the effectiveness of support groups, as these appear to be reflective of the perceived benefits of support group attendees as described in this study.

5.9 Conclusion

The present study explored the role of patient support groups in adapting to life with an ICD. An MMS review was used to evaluate the existing evidence for support groups for ICD recipients and identified areas for further study. The attitudes and perceptions of patients attending the support group were explored using a mixed-methods sequential study design. A new understanding of how support groups help patients to adapt to life with an ICD was generated by applying a theory of adaptation during the qualitative data analysis. This provided an explanation for the perceived benefit of support groups and was used to generate recommendations for support group format to maximise the opportunities for attendees to fulfil adaptive tasks and learn the necessary coping skills.

The present study has shifted the focus regarding the effect of support groups from reducing anxiety to improving adaptation. This new knowledge will be important to HCPs and patients involved in running existing support groups. Overall, this study supports the view that patient support groups are beneficial to many ICD recipients, which is reflected by the encouragement to offer them from the BHRS (2022). The author urges the BHRS to consider updating professional body standards to provide further guidance for the delivery of support groups in clinical practice.

6 References

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7 Appendices

7.1 Innovation: Implementing a support group for ICD recipients

Innovation: Implementing and improving a support group for Implantable Cardioverter Defibrillator recipients

Situation

The cardiology department at the author's centre was not supported by an arrhythmia nurse as recommended by the British Heart Rhythm Society (BHRS) (British Heart Rhythm Society, 2015) which limited the provision of pastoral support available to patients. There was no direct referral route for psychological support for outpatients, with the only available option being self-referral by patients to local well-being services. There was no provision for disease-specific support from professionals or peers who understand the challenges of living with an ICD.

Background

Patients with ICDs are known to experience psychosocial difficulties including anxiety and depression (Magyar-Russell *et al.*, 2011), particularly in the first year after implant (Proietti *et al.*, 2017). Receiving shock therapy from their ICD to terminate a life-threatening arrhythmia may increase anxiety (Qintar *et al.*, 2015; Perini *et al.*, 2017) and reduce quality of life (Dunbar *et al.*, 2012; da Silva *et al.*, 2018). Support group have been consistently recommended by the BHRS (British Heart Rhythm Society, 2015, 2022) and high-profile charities (Arrhythmia Alliance, 2017; British Heart Foundation, 2021) to provide psychosocial support to these patients, who are often living in fear of receiving a shock. Patient support groups are defined as groups with aims determined by the participants (rather than the providers) and no structured curriculum or end date . They need relatively few resources and therefore are a feasible support option within the limited resources of the National Health Service (NHS) (Proietti *et al.*, 2017).

Assessment

Patient support groups are widely used for patients with chronic conditions such as cancer (Keil, 2019), but they are not yet in common use in cardiac rhythm management (Murray *et al.*, 2021). Despite being recommended by the BHRS there was no guidance about what format of support is beneficial to ICD patients, whose disease experience is unique. The research evidence base for ICD support groups was limited and the most beneficial format for them is unclear, as demonstrated by the author's recent systematic review (Sanders *et al.*, 2022). Although by definition support groups are patient-led, all of the support groups in the reviewed studies (Sanders *et al.*, 2022) had health care professionals (HCPs) present at meetings in facilitator or educational roles. The optimum approach to involve HCPs in patient support groups was not known.

Recommendation: the innovation

The innovation was to establish a patient-led support group specifically for patients with ICDs. The existing evidence suggested that targeted education and sharing of their unique experiences was beneficial to a patient group, however, to be patient-led the objectives of the group had to be decided by the patients themselves. The challenge was for the author (an HCP) to initiate a support group which met this definition, as patients needed to be motivated and mobilised to organise the group themselves, while also ensuring the existing evidence base was considered.

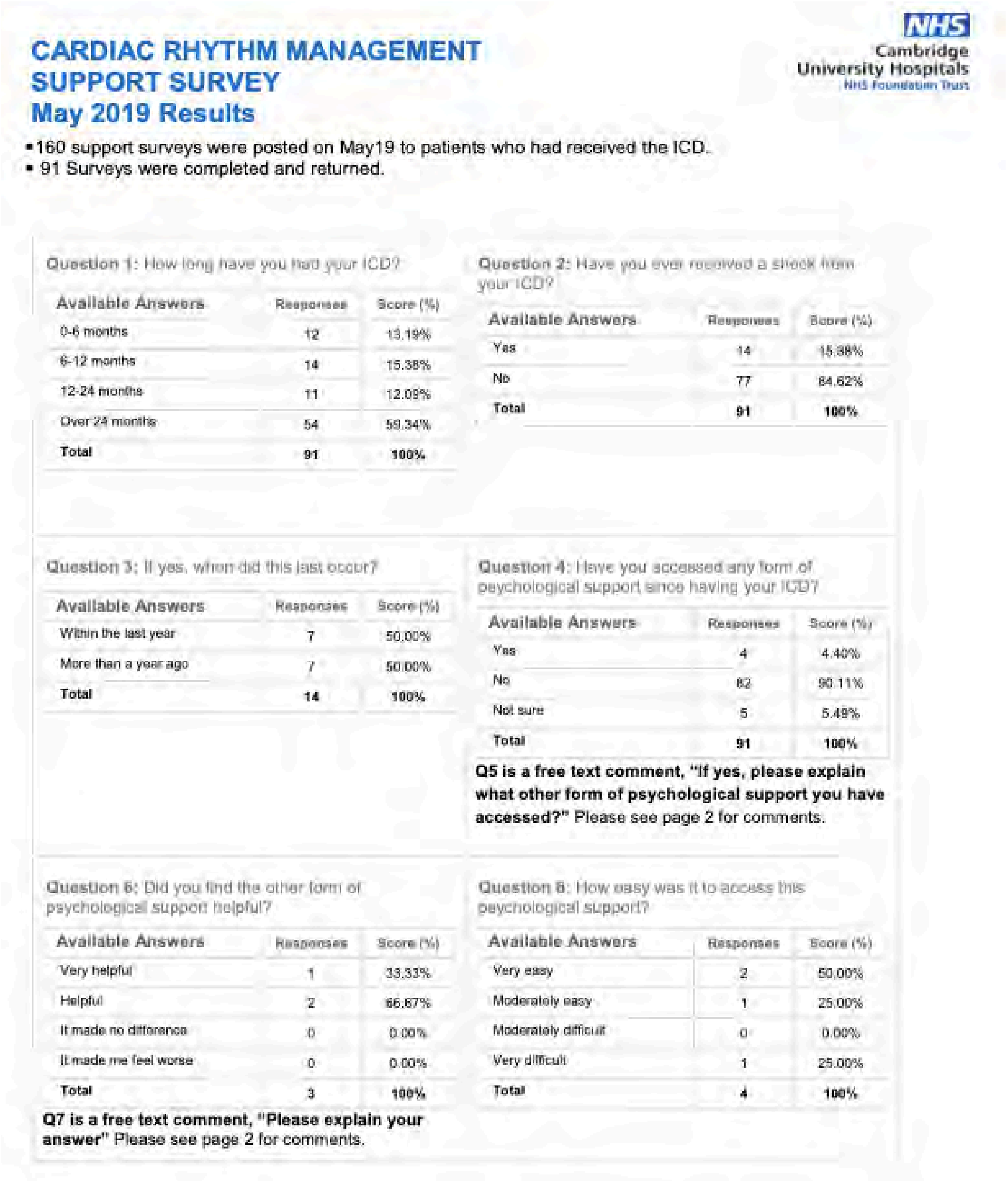
Once the support group was established, the author's research project started with the aim of exploring the role of support groups in adapting to life with an ICD and the influence that format may have on the perceived benefit of attending the group. New knowledge generated from this research needed to be introduced into practice to improve the delivery of the support group and maximise the benefit to patients. This required a careful approach to ensure the patient-led objectives were not compromised, which is discussed further in section 4.

Stakeholder engagement in the project

Preparing for a patient-led ICD support group

A patient experience survey was developed (Figures 1 and 2) to assess interest in support groups from this centre's patient cohort; there was a positive response with 91 out of 160 responding to the survey. Of the 91, 58 (64%) patients expressing interest in attending a support group. 9 patients indicated they may be willing to volunteer to help running the group and provided contact details. The author contacted each of these patients by telephone to confirm their interest and arranged a meeting to discuss in person.

Figure 16: Patient survey results regarding ICD experience and support



NHS
Cambridge
University Hospitals
NHS Foundation Trust

CARDIAC RHYTHM MANAGEMENT SUPPORT SURVEY
May 2019 Results

- 160 support surveys were posted on May19 to patients who had received the ICD.
- 91 Surveys were completed and returned.

Question 1: How long have you had your ICD?

Available Answers	Responses	Score (%)
0-6 months	12	13.19%
6-12 months	14	15.38%
12-24 months	11	12.09%
Over 24 months	54	59.34%
Total	**91**	**100%**

Question 2: Have you ever received a shock from your ICD?

Available Answers	Responses	Score (%)
Yes	14	15.38%
No	77	84.62%
Total	**91**	**100%**

Question 3: If yes, when did this last occur?

Available Answers	Responses	Score (%)
Within the last year	7	50.00%
More than a year ago	7	50.00%
Total	**14**	**100%**

Question 4: Have you accessed any form of psychological support since having your ICD?

Available Answers	Responses	Score (%)
Yes	4	4.40%
No	82	90.11%
Not sure	5	5.49%
Total	**91**	**100%**

Q5 is a free text comment, "If yes, please explain what other form of psychological support you have accessed?" Please see page 2 for comments.

Question 6: Did you find the other form of psychological support helpful?

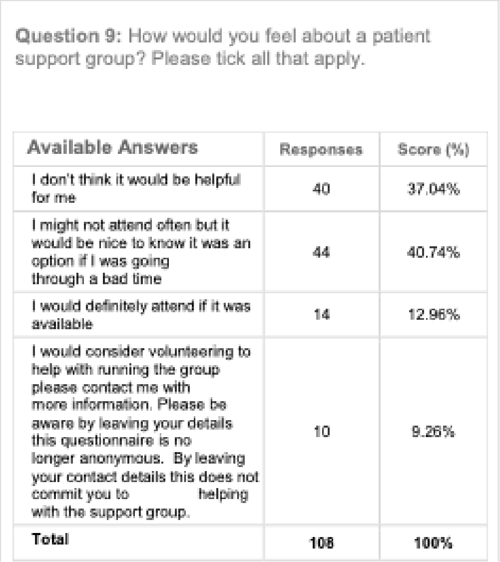
Available Answers	Responses	Score (%)
Very helpful	1	33.33%
Helpful	2	66.67%
It made no difference	0	0.00%
It made me feel worse	0	0.00%
Total	**3**	**100%**

Q7 is a free text comment, "Please explain your answer" Please see page 2 for comments.

Question 8: How easy was it to access this psychological support?

Available Answers	Responses	Score (%)
Very easy	2	50.00%
Moderately easy	1	25.00%
Moderately difficult	0	0.00%
Very difficult	1	25.00%
Total	**4**	**100%**

Figure 17: Patient survey results regarding ICD experience and support (continued)



Question 9: How would you feel about a patient support group? Please tick all that apply.

Available Answers	Responses	Score (%)
I don't think it would be helpful for me	40	37.04%
I might not attend often but it would be nice to know it was an option if I was going through a bad time	44	40.74%
I would definitely attend if it was available	14	12.96%
I would consider volunteering to help with running the group please contact me with more information. Please be aware by leaving your details this questionnaire is no longer anonymous. By leaving your contact details this does not commit you to helping with the support group.	10	9.26%
Total	**108**	**100%**

The author also met with staff who were involved with patient support groups for different conditions (cancer and hearing loss). This, alongside review of available literature, helped to prepare for the first meeting with potential patient volunteers.

Setting up a patient committee

To meet the definition of a support group the objectives and format of the group had to be determined by patients. For the first meeting with potential patient volunteers, questions were carefully planned to ensure the needs and goals of the patients were considered (Figure 3). Six patients attended the first planning meeting, and all agreed to form a committee to run the group. They decided on their individual roles and their preferred format of meeting based on their own experiences. They felt strongly that clinical support from HCPs was required for the group to run as they envisaged.

Patient and Public Involvement (PPI) in research

After the support group was initiated in clinical practice, the author began the research project presented in this thesis. A PPI group was in place throughout the project to ensure the patient perspective was considered in the research questions and in the analysis of data. Quarterly newsletters were shared with PPI members and the support group patient committee to keep them up to date with progress of the project and allow early implementation of any relevant findings.

Figure 18: Questions for initial patient meeting to ensure patient-led objectives were adopted

What are the goals of the group? (e.g. provide info and support for members and/or partners, interact with other groups and/or health care professionals, provide talks and/or activities)

- Who is the group for? (e.g. ICD patients, PPM patients, partners, carers)
- What format could the group take? (e.g. informal support discussions, talks from health care professionals, exercise sessions, walking group, art classes, and what type of environment)
- What are the potential costs? (e.g. meeting rooms, refreshments, office supplies, presenting equipment , website, banners and group merchandise)
- How will it be funded? (e.g. membership fees, fundraising such as raffles, events, local sponsorship, BHF affiliation start-up grant)
- Would it be helpful to form a committee and what roles may be required? (e.g. chair, secretary, treasurer)
- What else could the group offer? (e.g. buddy system for new patients, newsletters, fundraising to providing external defibrillators in the community, paying for CPR training for relatives)
- What level of input from health care professionals would be useful? (e.g. attend every meeting as additional support, or as invited speakers only)
- How, when and where could the group be launched and how will we reach our audience? (e.g. patient day, leaflets and posters at Addenbrooke’s, GPs, newsletters to interested patients from the survey, press release)
- What boundaries on confidentiality are required? (e.g. what information will be required from members and for what reason, what will be kept and where, are there circumstances when confidentiality rules can be broken?)

Business case for a patient support group

Benefits of a patient-led support group to improve well-being

It has been shown that patients attending support groups perceive a beneficial effect on well-being (Sanders *et al.*, 2022) and mental health. Improving mental health is important because mental health problems are the largest cause of disability in the UK, and the cost to the economy is estimated at over £100 billion a year (Mental Health Taskforce, 2016). It is known that people with long-term physical conditions experience worse outcomes if they develop mental health problems. Pilot schemes providing psychological support to these patients improve health and reduce costs by up to 25 per cent (Mental Health Taskforce, 2016).

There is evidence that this general data applies to ICD recipients: for example, anxiety and depression have been shown to predict mortality and readmission to hospital following shock therapy (Berg, Rasmussen, *et al.*, 2019). The reference cost of a non-elective NHS hospital admission in 2015-16 was £1609 (Department of Health, no date), and therefore reducing ICD-related readmissions would contribute to significant savings to the health service.

Funding considerations

NHS support is needed to permit at least one member of the care team to provide clinical supervision at the support group meetings (allowing approximately 3 hours per meeting). Meetings are currently held six times per year and therefore this equates to 18 hours per annum; allowing for an Agenda for Change band 7 member of staff, the cost to the service is estimated at £380 per annum. Whilst there is no direct evidence that support groups reduce readmissions which makes calculating the potential healthcare cost savings difficult, it is known that improving mental health and well-being in patients with long-term illnesses, such as ICD recipients, could reduce health care costs by 25 per cent (Mental Health Taskforce, 2016) and therefore lead to significant savings.

When implementing the support group in partnership with the patient committee, it was decided that for the remainder of expenditures (e.g., room hire, refreshments), the group needed to be self-funding. Routes for funding were discussed and the patient committee opted for applying for a BHF start-up grant followed by fundraising activities, as they felt strongly that group membership and meeting attendance should be free to all patients.

Improving the support group through implementing research findings

The research presented in this thesis led to the development of recommendations to improve the delivery of support groups in practice. In addition to disseminating the results through presentations and publications, it was important that the research findings were introduced to the existing patient support group. As mentioned above, this needed to be done carefully to ensure the patient-led objectives were not compromised. Three recommendations were developed from the research findings and how these were, or will be, introduced to the support group are discussed individually below.

Professional involvement should be seen as collaborative and reciprocal, as both patients and HCPs benefit from improved understanding of living with an ICD.

The support group had already been set up with a patient committee who maintained a good relationship with the HCP involved in the project and who usually attended the in-person meetings. HCPs from a range of disciplines (doctors, nurses, physiologists, industry) had also attended to deliver educational talks on specific subjects. All HCPs involved had to be mindful of the need not to lead the group, but to act on invitation of patient leaders. A set of ground rules for HCPs attending the group meetings may be a useful way to ensure these boundaries are understood by invited HCP. The potential benefit to clinical care for HCPs to be involved in support groups is likely to mean that a larger number of HCPs attend; for example, in this group the author has been the physiologist who always joins the meetings, but it may be beneficial to rotate this duty around all physiologists in the department. A document detailing guidance and ground rules for facilitating the support group would a useful tool to ensure HCP involvement is constructive and beneficial to patients.

An online forum in conjunction with in-person groups meetings held in community settings may help meet the needs of a wider range of ICD recipients.

The support group initially offered quarterly group meetings which were held in the community prior to the covid-19 pandemic, before switching to remote meetings over Zoom. The research findings supported the committee’s decision to return to in-person meetings once covid-19 restrictions eased. To offer support in between the quarterly group meetings, the committee developed a ‘buddy system’, to allow patients the opportunity to access peer support by being put in contact with an experienced group member. Uptake of ‘buddies’ by new members was low and the research findings suggested this form of support was not favoured by all patients.

The findings suggested that an online forum would be an acceptable option for support between group meetings, as it is convenient and allows access at a time that suits the individual. The existing patient committee do not have the interest nor the technical skills to manage an online forum as part of the support group at present, preferring to focus on the in-person meetings and buddy system. However, there are existing forums on social media platforms which the support group provides signposting to. This allows support group members the opportunity to access support online without overburdening the volunteer patient committee.

Access to support groups should be open-ended, and available before and after implant

Support groups by definition do not have a set curriculum or end date (Delisle *et al.*, 2017), and in practice the support group was developed to be open-ended. Patients were informed about the support group in practice by cardiac physiology staff, whose first contact with the patient was on the day of their procedure. However, the research findings indicated that patients may find it beneficial to attend the support group prior to their ICD implant. Improvements were needed to ensure patients were aware of the support group and had the opportunity to access this prior to implant. An important role for the HCPs involved in the group is to raise awareness, both with other HCPs and appropriate patients. Posters and leaflets have been placed in cardiology clinic areas and referring doctors have been reminded repeatedly about the group as a potentially helpful supportive avenue for patients who are unsure whether to consent to ICD implant. Regular reminders are needed to ensure the profile of the group is maintained due to high staff turnover and staff meetings may be a useful forum for this.

Lay summary

People who have an Implantable Cardioverter Defibrillator (ICD implanted may experience feelings of worry, stress or depression after their implant. This can affect their quality of life and even increase their risk of being readmitted to hospital. Improving patients' well-being, confidence and ability to live a normal life with their ICD is important because mental ill-health is the largest cause of disability in the UK with a significant cost to the health service and wider economy. Patient support groups offer a low-resource option to improve the lives of patients living with an ICD. Medical studies have shown that patients find support groups beneficial through the sharing of their experiences and gaining meaningful information about their ICD. However, few support groups exist in practice and we do not yet know what the best format for these groups is. The research findings from this project allowed the development of recommendations to ensure support groups meet the needs of as many patients as possible. Improving the delivery of a support group for patients with ICDs is important because it helps them to adapt to their new life without living in fear.

The innovative improvements recommended as a result of this research project need to be adopted by patient leaders in partnership with healthcare professionals. Education and knowledge provided by healthcare professionals is an important aspect of support groups, however, defining the boundaries of professional involvement with the support group is equally essential to ensure the patient-led aims and objectives are respected. Combining in-person and online support will allow the group to support more patients in line with their individual preferences. Finally, it is important that healthcare professionals raise awareness of support groups and their value so that all patients are allowed the opportunity to access a group before and after their ICD implant.

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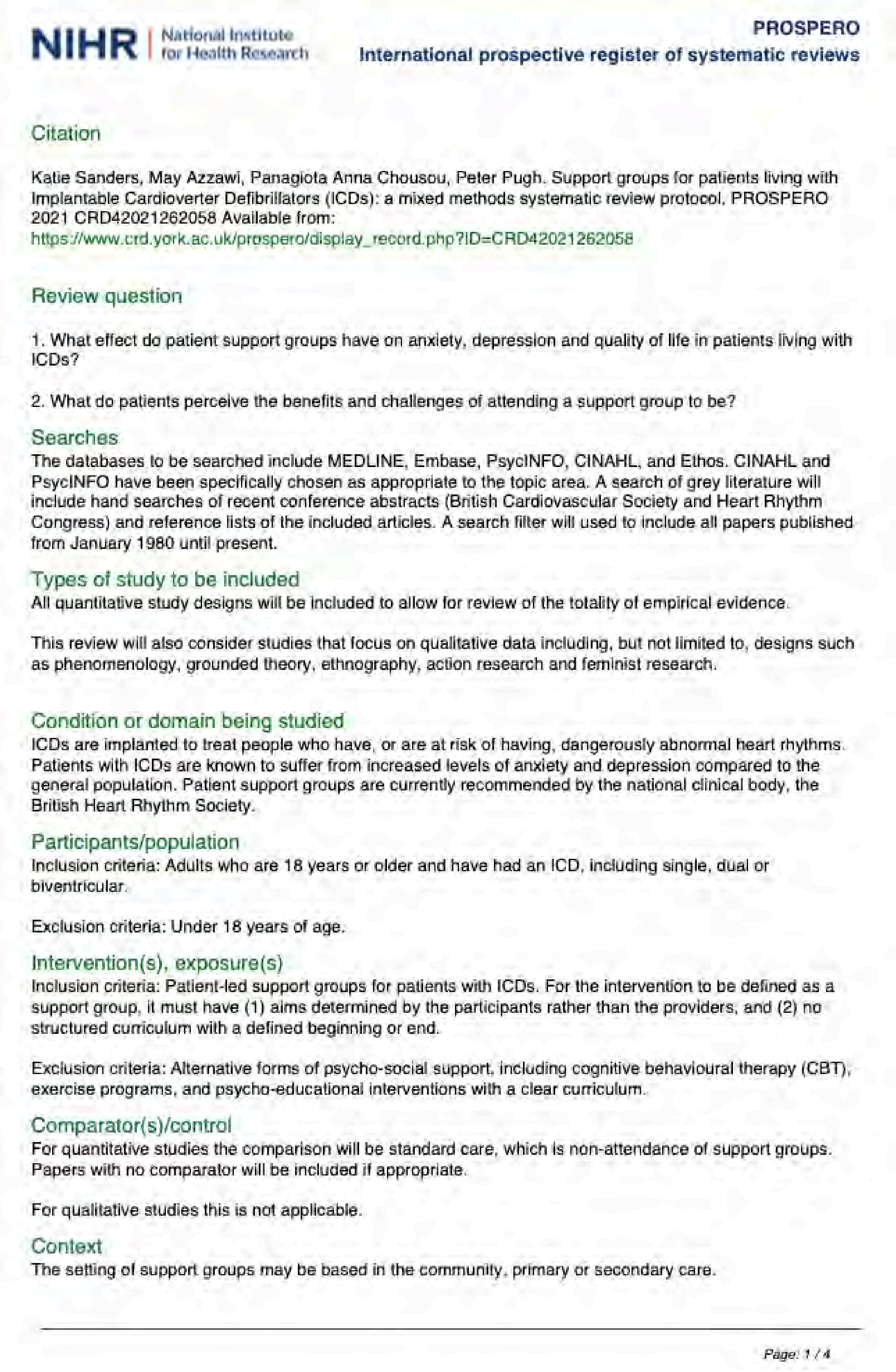
7.2 Mixed-methods systematic review: supporting documentation

7.2.1 Review protocol



NIHR | National Institute for Health Research

PROSPERO
International prospective register of systematic reviews

Citation

Katie Sanders, May Azzawi, Panagiota Anna Chousou, Peter Pugh. Support groups for patients living with Implantable Cardioverter Defibrillators (ICDs): a mixed methods systematic review protocol. PROSPERO 2021 CRD42021262058 Available from:
https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021262058

Review question

1. What effect do patient support groups have on anxiety, depression and quality of life in patients living with ICDs?

2. What do patients perceive the benefits and challenges of attending a support group to be?

Searches

The databases to be searched include MEDLINE, Embase, PsycINFO, CINAHL, and Ethos. CINAHL and PsycINFO have been specifically chosen as appropriate to the topic area. A search of grey literature will include hand searches of recent conference abstracts (British Cardiovascular Society and Heart Rhythm Congress) and reference lists of the included articles. A search filter will used to include all papers published from January 1980 until present.

Types of study to be included

All quantitative study designs will be included to allow for review of the totality of empirical evidence.

This review will also consider studies that focus on qualitative data including, but not limited to, designs such as phenomenology, grounded theory, ethnography, action research and feminist research.

Condition or domain being studied

ICDs are implanted to treat people who have, or are at risk of having, dangerously abnormal heart rhythms. Patients with ICDs are known to suffer from increased levels of anxiety and depression compared to the general population. Patient support groups are currently recommended by the national clinical body, the British Heart Rhythm Society.

Participants/population

Inclusion criteria: Adults who are 18 years or older and have had an ICD, including single, dual or biventricular.

Exclusion criteria: Under 18 years of age.

Intervention(s), exposure(s)

Inclusion criteria: Patient-led support groups for patients with ICDs. For the intervention to be defined as a support group, it must have (1) aims determined by the participants rather than the providers, and (2) no structured curriculum with a defined beginning or end.

Exclusion criteria: Alternative forms of psycho-social support, including cognitive behavioural therapy (CBT), exercise programs, and psycho-educational interventions with a clear curriculum.

Comparator(s)/control

For quantitative studies the comparison will be standard care, which is non-attendance of support groups. Papers with no comparator will be included if appropriate.

For qualitative studies this is not applicable.

Context

The setting of support groups may be based in the community, primary or secondary care.

Main outcome(s)

For quantitative studies the main outcomes are changes in measures of anxiety, depression and QOL including but not limited to State-Trait Anxiety Index, Beck Depression Inventory, Florida Shock Anxiety Scale, Health-related QOL.

For qualitative studies, the aim of the review is to summarise patient experience of support groups, including perceived benefits of and challenges to attending.

Measures of effect

The review aims to create a narrative synthesis of the overall impact of support groups on quality of life, anxiety and depression. Meta-analysis of specific statistical measures will not be performed.

Additional outcome(s)

None

Data extraction (selection and coding)

Study selection:

Titles and abstracts will be screened by the first reviewer against the inclusion criteria. Potentially relevant studies will be retrieved and the full text studies will be independently reviewed by two reviewers. Where there is disagreement, the opinion of a third reviewer will be sought. Reasons for exclusion of any full text studies will be recorded and reported. The results of the search will be reported in full and presented in a flow diagram consistent with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement (Page et al., 2020).

Data extraction:

For quantitative studies, the data extracted will include specific details about the population, study methods, intervention and outcomes relevant to the review question.

For qualitative studies, the data will be extracted will include details about population, context, study methods, the phenomena of interest and authors conclusions relating to the review question.

An Excel spreadsheet will be used to record the extracted data.

Authors will be contacted for missing information or additional data where appropriate.

Risk of bias (quality) assessment

The Mixed Method Appraisal Tool (Hong et al 2018) will be used for qualitative and quantitative literature, by two independent reviewers. Where there is disagreement, a third reviewer's opinion will be sought.

Strategy for data synthesis

For quantitative studies, studies will be grouped by outcome measures (anxiety, depression and QOL) and methodological options (for example, State-Trait Anxiety Index, Beck Depression Inventory, Florida Shock Anxiety Scale, Health-related QOL). Where there is evidence of effect in more than one study, P values will be combined to estimate this effect. Heterogeneity will be assessed by ordering a table with modifiers including age, gender, frequency and format of support group meetings. Data regarding the study design, quality and risk of bias and key results will presented in a tabular form.

For qualitative studies, the results and findings as reported in each record will be uploaded verbatim to NVivo. Thematic synthesis (Thomas and Harden 2008) will be applied in three stages: line-by-line coding of text, development of descriptive themes, and the generation of analytical themes. Where there is discordance in primary study results, priority will be given according to study quality when developing descriptive themes. Data regarding the study design, quality and risk of bias and key results will presented in a tabular form.

The synthesised quantitative and qualitative data will then be integrated and presented using the Pillar Integration Process (Johnson, Grove and Clarke, 2019), a technique for integrating and presenting qualitative and quantitative findings in a joint display.

Analysis of subgroups or subsets

None planned

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Dr Peter Pugh. Cambridge University Hospitals

Type and method of review

Narrative synthesis, Systematic review

Anticipated or actual start date

01 June 2021

Anticipated completion date

28 February 2022

Funding sources/sponsors

Higher Specialist Scientist Training programme, funded by Health Education England

Conflicts of interest

Language

English

Country

England

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Defibrillators, Implantable; Humans; Self-Help Groups

Date of registration in PROSPERO

10 August 2021

Date of first submission

13 July 2021

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions

10 August 2021

7.2.2 Response to reviewers at *Open Heart*

Editor at Statistic

1. The authors very briefly describe the statistical analyses and associated methods, but they are fine so far.
2. In the section "Data extraction and analysis" the quantitative and qualitative variables are explained. In the corresponding tables, there are only mean values without associated variance (standard error/standard deviation) and confidence intervals. Here it would be better to present these in another table in a clearer way. Please make up for it.
   We have added table 7 which displays more detail for the quantitative data, including standard deviation. Confidence intervals were not reported in the articles.
3. In the same section the authors choose the I^2 test statistic. Please explain and describe the chosen test statistic in more detail.
   Thank you for alerting us to this error. We should have presented the overall effect *z* and *p* values. We have updated the methods and results section to report this (page 6, line 15 and page 8, line 4).
4. In the result section of quantitative analysis in the "effect of support groups on mental well-being" the last sentences must be rewritten. This expression is not statistically correct.
   We have updated this section to read '*The effect of support groups on mental well-being was examined by normalising anxiety and QoL outcomes to the average control value (Fig. 2). The absolute data utilised in this meta-analysis is shown in Table 7. The standardised mean difference between intervention and control groups was 0.02 (95% CI -0.20 to 0.23). The support group attendees scores were not significantly higher than the control group average, z = 0.16, p = 0.87, indicating that attending support groups had no significant effect on the mental well-being for patients with ICDs.*'
5. In table 5 the study by Molchany 1994 was the only study of the four considered in the meta-analysis that did not report the mean value at the age of the support group, but the range. Improve or explain why.
   The mean value was not reported in the paper. We contacted the authors for this information but the raw data was no longer available.

Reviewer: 1

Comments to the Author

Thank you for letting me review this interesting paper that is very relevant for clinical practice. Thank you for your comprehensive answers to the prior reviewers' comments. I only have few comments to the paper at this stage:

1. You have conducted a mixed-methods systematic review please use this name for it all the way through the paper. It is confusing that you call it a systematic review in your objectives.

   This has been updated throughout as requested.

   Methods

2. Please add a definition of mental well-being to the method section since you use that term in your objectives.

   We have updated the outcomes section of the Methods to include a definition of mental well-being (page 5, lines 17-19)

3. Describe more in detail the MMAT that you use.

   We have added this to the quality assessment section (page 5, lines 50-55).

4. Do not refer to results in the method section (table 2).

   We have removed this as requested.

   Results

5. Describe in more details the quality ratings (table 2).

   We have added more detail about the quality assessment to the study characteristics section (page 6, lines 54-59). Please note the quality ratings are now in table 6.

6. I'm confused by the results of the qualitative studies. You describe in the method section that you use thematic synthesis to generate themes. But in the result section you have the following headlines: Anxiety and depression, Quality of life (QOL), Social support and then you describe that the two next headlines are key themes. So what are the first three ones? (I see that it is the same themes as in the quantitative data – but then describe in the method section that you were looking for those (outcomes), if that was the case. Now you write: For qualitative studies, the outcome was patient experience of support groups). Please clarify.

   Thank you for this very useful comment. We have updated the methods sections to clarify that anxiety and depression, QoL, social support and benefits and challenges of attending support groups are the over-arching themes, and within them we identified two sub-themes (page 6, lines 18-19).

7. Page 6, line 25: You write that reference 34 is contributing to the quantitative synthesis. This is not clear, you do not reference it under Quantitative analysis page 6-7, line 45-39.

   Thank you for noticing this error, we have removed the reference.

8. Page 6, line 34-37: Please move this down to the discussion section: "It is striking that……… than in Europe (41)".

We have moved this as requested.

Discussion

9. You write: "The discrepancy in outcomes between quantitative and qualitative data…" Qualitative studies do not measure outcomes like quantitative studies do and you go on and discuss the methods of the quantitative studies in the sentence. Please rephase or erase the sentence.

   We have rephrased this sentence to focus on the quantitative data and results in this paragraph.

10. You write: "Most included studies were based in the USA where the situation differs from that in the UK with a greater input from the cardiac science workforce (17), who have different skills to nurses…" I'm not sure I understand this sentence. Who have different skills? And please compare wider maybe to Europe if possible, it seems a little narrow to compare only to the U.K. in this international journal.

    We have removed this sentence and replaced it with the sentence moved from results section "*Most included studies were based in the USA, and it is striking that no Western European studies were found. A recent UK study* (Murray *et al.*, 2021) *commented that while there is interest in patient support groups, there are not many. Perhaps even more important is the fact that ICD implant rates in the USA have historically been 4 to 5 times higher than in Europe (Camm and Nisam, 2010). This highlights the need for further research in, and implementation of, patient support groups in Europe.*", as this included a comparison to Europe. (page 10, lines 19-23)

In general

11. Be aware if you have a line between your headline and text or not.

    The formatting has been corrected.

12. Make sure to write out all abbreviations under your tables.

    We have now added these.

Reviewer: 2

Comments to the Author

openhrt-2022-002021: Benefits of support groups for patients living with Implantable Cardioverter Defibrillators: a mixed-methods systematic review and meta-analysis

Comments to the Author

Thanks to the authors for bringing up the topic! I read your work with great interest.

Here are my comments and suggestions:

1. The background and the objectives are linked. However, the authors didn't clearly describe how outcomes were defined and measured in the methods section. Some descriptions have been made in the results section and should be brought up in the

methods section. One of the explanations why the pooled estimate of the mental well-being didn't show significant differences could be explained by the variations used in measuring each outcome. This should be addressed in the paper.

We have expanded on the outcomes descriptions within the methods section, including a definition of mental well-being (page 5, lines 17-19). Mental well-being data was normalised to the average control value for a parameter and adjusted to allow comparison of data from different instruments. We have acknowledged this is a shortcoming of our study (page 9, lines 55-57).

Methods:

2. Outcome measures:

   Could the authors clearly describe how QoL was measured? Was QoL assessed consistently across all the included studies? Adding more descriptions on how outcomes (anxiety, depression, and social support) were assessed and defined would be great.

   We have expanded on the outcomes descriptions within the methods section, including a definition of mental well-being. QoL was measured in two studies, using the SF-36 and the Quality of Life Index respectively. (page 5, lines 17-23)

3. How could outcomes measured using different measures (anxiety, QoL) be pooled together to examine mental well-being?

   We have described in the methods section how mental well-being data was normalised to the average control value for a parameter to allow comparison of data from different instruments. We have added references for published studies which have taken a similar approach. (page 6, lines 5-11)

4. To mention one of the QoL measurements: there are several different SF-36 scores i.e. domain scores (physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH)) or summary component scores (Physical Component Summary (PCS), and Mental Component Summary (MCS)). Overall SF-36 score is not a well-accepted method (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5052926/). Please specify which SF-36 score(s) has been summarized across studies?

   Only one study used the SF-36, and we have included in the key findings column of table 2 which of the domain scores had significant improvement. We have also added the data for PCS and MCS to table 7.

   Search strategy:

5. The Authors mentioned that the grey literature search was limited between 2019 and 2021. Could there be any justification for this?

We assume that any abstract before 2019 has in the meantime been published as a full paper and would have been detected in our search.

Data extraction

6. Line 46-47 on page 5: Quantitative results were grouped by outcomes indicative of 'better mental health' … What does better mental health mean? How was it measured? Using mean, median scores ….?

   We have changed this to better mental well-being for consistency as this term has been used in the methods section. We have provided the following definition for the term: *"The definition of 'mental well-being' is complex but it is widely understood to mean more than simply absence of mental illness and includes the ability to cope with stressors and work productively. We chose to include measures of QoL, anxiety and depression as outcomes which are aspects of mental well-being."* (page 5, lines 17-21)
7. If different measurements were used, how was the pooling done?

   As for point 3 above, we have described in the methods section how mental well-being data was normalised to the average control value for a parameter to allow comparison of data from different instruments. We have added references for published studies which have taken a similar approach.

Results:

8. Details of outcome measures need to be reported in the methods section NOT in the result section. Still, the description needs more work.

   The methods and outcomes sections have been updated.

Discussion:

9. Page 9, line 19-20: "The findings from our meta-analysis suggest that support groups have no significant effect on objectively-measured mental well-being." This is one of the study limitations as different outcomes were combined to get a single estimate. Authors need to revisit their definition and measure of outcomes or discussed why they have chosen this.

   We believe we have addressed this by providing a definition of mental well-being and more detail on the process of pooling outcomes as described above.
10. The use of different outcome measures and pooling them together should be discussed in the study limitation as well. Limitation of pooling results from different study designs?

    We have expanded on this in the discussion.

Reviewer: 3

Comments to the Author

Thank you for the opportunity to read this interesting review.

1. It would be useful to have the definition of support groups in the introductory part of this article.

   We have added the definition of support groups to the introduction. (page 4, lines 24-26)

2. Justification for why self-management groups were excluded could be strengthened - particularly as healthcare professional involvement was included but once this was patient-led. Many self-management intervention programmes could argue they are patient-led.

   We have reviewed the definition of self-management groups and believe studies into such groups would have been identified in our literature search, as we used the search terms shown in table 1: (support group* OR peer support OR peer counselling OR self-help group* OR self help group* OR education* support OR psychosocial support OR patient mentor*) and the MeSH term Self-Help Groups. Any groups labelled as self-management groups would have been included in our analysis provided they met our definition of patient-led and, importantly, without a set curriculum or end date. We believe these criteria are important due to the uniquely unpredictable nature of living with an ICD.

3. Why only support groups, could be strengthened by placing greater emphasis on support groups in the introduction section

   Support groups are recommended by the British Heart Rhythm Society and are a feasible option for healthcare services with limited resources. We have added this to the introduction (page 4, lines 26-27).

4. A narrative description on the quality of included studies would be helpful.

   We have added this to results section (page 6, lines 54-59).

5. Conducting a meta-analysis is not sufficiently justified and it is not clear what this adds to the results

   The meta-analysis provides an important overview of the literature, even if it is a negative outcome. Therefore, we believe it is important to report this.

6. Greater depth of discussion regarding online versus face to face would be useful as this appears almost as an adhoc sentence in the results section.

   We have expanded on this in the discussion as this could be an area for useful future research given the changes in technology and face-to-face availability since the Covid-19 pandemic (page 10, lines 11-17).

7. The benefits and challenges of attendance at a support group provided important insights in this review and presents important findings which could be applied to other long term conditions

Thank you for this comment. We agree that the qualitative data synthesis generated important findings regarding support groups and believe this provides evidence for their continued use despite the lack of effect seen from the quantitative data analysis.

Reviewer: 4

Comments to the Author

1. The authors have made some changes and the main problem lies in the quality of the cited studies and not in the quality of the authors' analysis. I have no further comments.

   We have acknowledged the limited opportunity for meta-analysis in our study due to the variation in outcomes being measured. However, we believe our meta-analysis provides an important overview of the literature even if it is a negative outcome and therefore that it is important to report this. Good quality studies were included in the qualitative synthesis and we believe we have presented some important findings which will be useful to current practice.

7.3 Study documentation

7.3.1 Study protocol (V6) as submitted to IRAS

FULL/LONG TITLE OF THE STUDY	Understanding patient experience of an Implantable Cardioverter Defibrillator (ICD) support group, preferences towards education and support modalities, and the impact of Covid-19 upon support provision
SHORT STUDY TITLE / ACRONYM	Understanding Patient Experience of
an ICD Support	Group
PROTOCOL VERSION NUMBER AND DATE	Version **6** 07/06/22
IRAS Number:	274856
SPONSORS Number:	A095408

This protocol has regard for the HRA guidance and order of content

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: ……………………………………………………………………………………… Date: ……/……/…

Name (please print):
………………………………………………………………………………………

Position: ………………………………………………………………………………

Chief Investigator:

Signature: ……………………………………………………………………………… Date: ……/……/…

Name: (please print):
………………………………………………………………………………………

LIST of CONTENTS

KEY STUDY CONTACTS

Chief Investigator	Dr Peter Pugh, Consultant Cardiologist Email: peter.pugh@addenbrookes.nhs.uk Tel: 01223 349147
Investigator/researcher	Katie Sanders, Chief Cardiac Physiologist Email: katie.sanders@addenbrookes.nhs.uk Tel: 01223 349313
Sponsor	Cambridge University Hospitals NHS Foundation Trust

STUDY SUMMARY

Study Title	Understanding patient experience of an ICD support group, preferences towards education and support modalities, and the impact of Covid-19 upon support provision
Internal ref. no. (or short title)	Understanding Patient Experience of an ICD Support Group
Study Design	Flexible multi-strategy design using semi-structured interview and questionnaires
Study Participants	Patients with ICDs and their relatives/carers
Planned Size of Sample (if applicable)	Approximately 15 interviews Approximately 50 questionnaires

Planned Study Period	2020 - 2022
Research Question/Aim(s)	To understand patient experience of an ICD support group, how this is influenced by involvement of healthcare professionals, and the impact of Covid-19 social restrictions upon preferred group format.

FUNDING AND SUPPORT IN KIND

FUNDER(S)	**FINANCIAL AND NON FINANCIAL SUPPORT GIVEN**
Cardiology Department, Addenbrooke's Hospital Head of Department: Viki Carpenter Tel: 01223 349313	Time allowed for the researcher to conduct research activities
National School of Health Care Sciences Tel: 0121 695 2529	Training allowance (£13,000 p.a. until November 2022) paid to Cardiology department to be used by the researcher for research activities and/or clinical cover as appropriate.
Manchester Metropolitan University Supervisors: Dr May Azzawi Tel: 0161 247 3332	Academic supervision of the project

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

Patient and Public Involvement (PPI)

The original study proposal was reviewed by the independent Cambridge University Hospitals (CUH) PPI panel and their comments used to develop the protocol.

A PPI advisory group will be in place to support the project. The role of this group will include input into the development of the interview schedule, analysis and interpretation of the emerging themes from the data, and checking of the questionnaire questions to confirm they have suitable clarity and accessibility.

KEY WORDS:

Implantable Cardioverter Defibrillator (ICD)

Patient support group

STUDY TIME LINE

August 2020	PPI focus groups for interview schedule development
December 2020	First round of 3-4 interviews
February 2020	Identify themes from initial data analysis to develop questions further
April 2020	Second round of interviews begin, with simultaneous data analysis and coding in iterative process of developing interview questions and themes for exploration
July 2021	Interim summary to be completed
Early 2022	Second round of interviews complete PPI focus groups for development of questionnaire
May 2022	Questionnaire data collection and analysis
October 2022	Write up complete

STUDY PROTOCOL

Understanding patient experience of ICD support groups, preferences towards education and support modalities, and the impact of Covid-19 upon support provision.

1 BACKGROUND

Patients with ICD are known to experience psychosocial difficulties including anxiety, depression and post-traumatic stress disorder (PTSD) (1).The British Heart Rhythm Society (BHRS) states that patient support groups are of enormous benefit to patients and should be encouraged, although provides no guidance on what format a group should take (2). It is not clear to what extent health care professionals should be involved in a successful ICD support group (1). On one hand, such groups permit the sharing of experiences and true empathy from fellow patients which a health care professional cannot provide; on the other hand a health care professional can provide information and address concerns and misconceptions should they arise.

A systematic review (3) found that psychosocial interventions including patient support groups reduce anxiety and depression in patients living with ICDs but highlighted the wide variation in interventions used and difficulty in applying rigorous quantitative research methods to behavioural interventions.

In UK the Covid-19 pandemic has led to self-isolation for many patients and the ongoing need for social distancing has led to reduced access to many forms of social and formal support and may increase the likelihood of mental illness (4). This highlights the importance of ongoing psychosocial support for ICD patients yet limits the opportunities for delivering this in practice.

2 RATIONALE

Few studies have evaluated the unmet need for supportive care for patients living with ICDs, and the experience of patients with an ICD of support groups and the mechanism by which patients benefit from these groups has not been explained. There is a significant body of research demonstrating the effectiveness of support groups for patients with cancer and many other long term conditions (5), however the extent to which the findings are generalisable to ICD patients is unclear due to different disease experiences; a common cause for distress in patients with ICDs is shock delivery (6), an experience unique to this group. It has been shown that ICD implant itself does not negatively impact quality of life, however shock delivery does cause deterioration (6) suggesting that this group may have higher supportive care needs. The efficacy of specific interventions to decrease distress following ICD shock delivery has not yet been established (7).

ICDs have been implanted at CUH for a decade but a patient support group has not been available until recently. 2018 BHRS standards (2) encouraged the implementation of such a group which was launched in October 2019 by a group of five patients with support from the clinical team. In the absence of guidelines and literature to direct the format of the group, the clinical team supported the patients to develop the group meetings in a format which they felt would be most beneficial according to their own experience as patients; see appendix 2 for further description of the group's aims and format. The group initially organised face-to-face meetings in the community but in March 2020 had to change to online meetings due to restrictions imposed by the Covid-19 pandemic.

This study therefore proposes to explore how the support group is experienced by patients who have not previously had access to such an intervention, and whether having received a shock from their ICD influences this experience. The project will also develop a theory of what format of meeting is perceived to provide benefit, and how involvement of health care professionals influences the experience. Finally, the project will explore the impact of self-isolation and social distancing on the needs of patients and the provision of a support group in practice.

3 THEORETICAL FRAMEWORK

A qualitative approach using thematic and iterative data analysis techniques will be used to develop a deeper understanding of the experiences of patients with ICDs attending the support group.

4 RESEARCH QUESTION/AIM(S)

To understand patient experience of an ICD support group, and how this is influenced by group format and involvement of healthcare professionals.

4.1 Objectives

1. To critically assess patient perception of an ICD support group and whether supportive needs differ depending on experience of ICD shock delivery

2. Contribute to an increased understanding of what format of ICD support group may provide greatest benefit to patients, taking into account the restrictions imposed due to the Covid-19 pandemic

3. Develop a tentative theory of how involvement of health care professionals influences the patient experience of ICD support groups

4.2 Outcome

The study will describe the experience of patients who attend an ICD support group and develop a theory and recommendations regarding effective group format and involvement of health care professionals.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

A flexible multi-strategy design will be utilised to fulfil the research aim. The study will be primarily qualitative in nature using narrative data collected from semi-structured interviews. A self-completion questionnaire using fixed alternative responses will be developed from the interview data results to confirm the findings with a wider patient group.

The interview schedule has been developed in a PPI focus group to identify questions likely to elicit a valuable response. The PPI focus group consisted of four members: one patient member recruited from the existing support group, and three public members recruited through the British Heart Foundation (BHF) PPI panel. The focus group followed a two-stage process in which stage one asked the group to contribute their preferences and ideas, before insights gained from a literature review were put forward for discussion in stage two. The focus group was conducted using an online video platform due to Covid-19 restrictions, and was be led by the researcher and attended by member of the clinical team who documented the discussion and outcomes.

Data will be collected iteratively through semi-structured interviews expected to last up to 60 minutes to permit in-depth collection of rich data. Interviews will be conducted either by video online or in person by the researcher and will be recorded using a digital recording device. The audio recordings will be checked for identifiable data before being transcribed by a third party service. Data derived from the interview transcriptions will be organised using NVivo, a qualitative data analysis package. The participants will be only identified by a study specific participant's number and/or code in any database. The name and any other identifying detail will not be included in any study data electronic file. All electronic data will be kept only on the Trust's secure password-protected computers and paper copies of transcripts in locked on-site storage.

A first round of interviews (3-4 patients) will be undertaken to identify key emerging themes and thematic and iterative analysis techniques will be used to develop the questioning further for the second round of interviews, which will be undertaken on a staggered basis.

A narrative approach will initially be applied to data analysis in which individual case summaries will be analysed independently. A PPI advisory group will be used to guard against researcher bias through checking of transcripts and interpretation, and provide a PPI perspective through co-analysis of the data. The PPI group and researcher will analyse the transcripts independently before pulling the two analyses together for discussion of the findings which will then be coded thematically and iteratively using the constant comparison method. This will include analysis of deviant cases to challenge the emerging theories (8).

A self-completion questionnaire using fixed alternative responses has been developed based on the analysis of qualitative interview data. The questions were reviewed for clarity and accessibility by the PPI advisory group. The questionnaire will be issued as a stand-alone questionnaire to the wider patient group attending the ICD support group to challenge the validity of the interpretations made by the researcher and check whether the findings reflect the experiences of the wider patient group. The questionnaire along with a covering letter will be given to the support group leaders for dissemination to patients at support group meetings. Pre-paid envelopes will be provided to allow anonymous return of the questionnaires, which will be assigned a number. Exploratory data analysis techniques (frequency distribution) will be applied to data collected from the questionnaires.

6 STUDY SETTING

The ICD support group is based at CUH but meetings were held in the community until March 2020, after which they have been held online using a video conferencing platform. Potential participants will be accessed at the group meeting or at the ICD clinic within CUH. CUH has approximately 450 patients with ICDs and implants a further 50 per year, all of whom may access the support group. The last community support group meeting was just the second meeting and had 22 attendees; numbers were expected to grow as the group became more established, however the impact of Covid-19 and the change to online meetings is as yet unclear. Interviews may be conducted at CUH or by using online meeting technology according to the patient's preference and health risk to ensure they are in a comfortable and safe environment.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

Patients will be recruited through purposive sampling of those who have accessed the support group. Patients will be invited by a member of the clinical team to become involved in the study whilst attending ICD support group sessions or the CUH ICD follow-up clinic.

7.1.1 Inclusion criteria

≥18 years of age with an ICD, or relatives/carers of a patient with an ICD.

Sufficient English literacy to provide consent and respond to interview questions as the nature of the study does not cover the use of foreign language translators.

7.1.2 Exclusion criteria

<18 years of age

Insufficient English literacy which is justified due to the nature of the study requiring in depth interviews

7.2 Sampling

7.2.1 Size of sample

The sample size for interviews will be determined when theoretical data saturation is reached. Power calculation is not required for qualitative research however the literature suggests that approximately 15 participant interviews would provide sufficient data to address the research question (8).

Questionnaires will be issued towards the end of the study. The size of sample is predicted to be approximately 50 (based on 100 patients and 10% margin of error) but this may necessarily alter depending on numbers of patients who access the support group.

7.2.2 Sampling technique

For the interviews, purposive sampling of patients attending the ICD support group will be used. Theoretical sampling may also lead to recruitment of others with relevant experiences such as relatives or carers of those who attended, or of patients who have chosen not to attend to delineate the boundaries of the emerging theory.

For the questionnaire phase of the study, a convenience sample of all patients, relatives and carers attending support group meetings held in early 2022 will be utilised.

7.3 Recruitment

Eligible patients will be approached in person by a member of the clinical team and provided with a written patient information sheet (PIS) and consent form regarding the study.

7.3.1 Sample identification

Patients attending the ICD support group will be considered eligible for the initial round of interviews. For the second round of interviews and in accordance with the principles of theoretical sampling, potential participants will be invited on the basis of ongoing analysis in order to further develop the theory as it emerges, and may include relatives, carers and patients who have chosen not to attend the support group. The researcher will ensure that the experiences of patients who have and have not received a shock from their ICD are given equal consideration in the interview selection process.

Once the self-completion questionnaire has been developed towards the end of the study, all patients accessing support group meetings will be invited to participate in this phase.

7.3.2 Consent

Informed consent will be sought prior to any study data being collected. Prior to undertaking an interview or completing a questionnaire, the researcher will confirm with the participant that they have read and understood the PIS. The researcher will verbally explain the study again and answer any questions the participant may have. The voluntary nature of the study and option to withdraw at any time will be clarified. If there is any doubt about the participant's ability to provide informed consent, they will not be enrolled in the study. If in agreement, the participant will be asked to sign and date the Informed Consent Form (ICF). For participants who are being interviewed and consented using online video technology, audio consent may be recorded in place of written consent. A master record of consent documentation will be maintained by the researcher.

The questionnaires will be returned anonymously; return of the questionnaire to the study team implies consent to use the data in the analysis.

ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

This study has potential risk to reveal information about which the researcher has safeguarding concerns. Due to the nature of the study, participants are likely to have experienced or be experiencing mental health difficulties, and in depth exploration of their experiences may cause distress. Good interview technique which allows the patient's own agenda to be explored should reduce the likelihood of a negative experience (8), however the risk remains and the researcher must provide opportunities to refuse to participate at any time.

Where distress does occur and there are safeguarding concerns for the participant or others based on the information obtained, the study team have a responsibility to raise their concerns with the safeguarding team at CUH in the first instance. The patient's GP and consultant in charge of their care will also be informed as appropriate, to make onward referrals as required.

Risk of Covid-19 infection will also be present throughout the study period. To minimise this risk, participants may be interviewed using video conferencing technology to support the need for self-isolation and social distancing.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

This research is sponsored by Cambridge University Hospitals NHS Foundation. All research in the NHS is reviewed by an ethics committee and given approval by the Health Research Authority (HRA). Ethics approval for this study will be sought.

For any amendment to the study, the researcher, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The researcher will work with R&D department so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

8.3 Peer review

The CUH Research Advisory Committee will provide independent, expert peer review of the protocol.

8.4 Patient & Public Involvement

A patient and public advisory group will be in place to support the project, consisting of two patients who attend the ICD support group and two lay members. The role of this group will include input into the development of interview questions, analysis of the emerging themes from the data, and development and validation of the self-completion questionnaire.

8.5 Protocol compliance

Accidental protocol deviations can happen at any time. They will be adequately documented and reported to the Chief Investigator and Sponsor immediately.

8.6 Data protection and patient confidentiality

The study staff will ensure that the participants' anonymity is maintained. The participants will be identified only by initials and a participants ID number on the CRF and any electronic database. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so. Data will be kept on the Trust's secure password-protected computers and paper copies of transcripts in locked on-site storage.

8.7 Indemnity

This research is sponsored by Cambridge University Hospitals NHS Foundation Trust and will be covered by NHS Negligent Indemnity Insurance.

8.8 Access to the final study dataset

The researcher will be the only person with complete access to the study dataset.

9 DISSEMINATION POLICY

9.1 Dissemination policy

The researcher will analyse the data and prepare a final study report at the end of the project. The project report will form the basis of a thesis to be submitted to Manchester Metropolitan University as part of an academic qualification (Doctorate of Clinical Science) sought by the researcher. The researcher will have rights to publish any findings arising from the study.

No funding or supporting bodies need to be acknowledged in any publications.

Participants will be provided with contact details to request the results of the study after the final report has been prepared. Results may also be shared at an ICD support group meeting.

Study results will be submitted by the researcher for presentation at the national conference hosted by BHRS, with the aim of sharing recommendations for ICD support groups. The findings will also be shared with the BHF and Arrhythmia Alliance charities who provide affiliation and guidance for patient-led support groups.

9.2 Authorship eligibility guidelines and any intended use of professional writers

The researcher will be solely responsible for writing the final report.

10 REFERENCES

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2. British Heart Rhythm Society. STANDARDS FOR IMPLANTATION AND FOLLOW-UP OF CARDIAC RHYTHM MANAGEMENT DEVICES IN ADULTS [Internet]. 2018 [cited 2019 Jun 3]. Available from: http://bhrs.com/files/files/Guidelines/180122-sp-BHRS Standards - Implantation and Follow-Up of CRM Devices in Adults.pdf
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11. APPENDICES

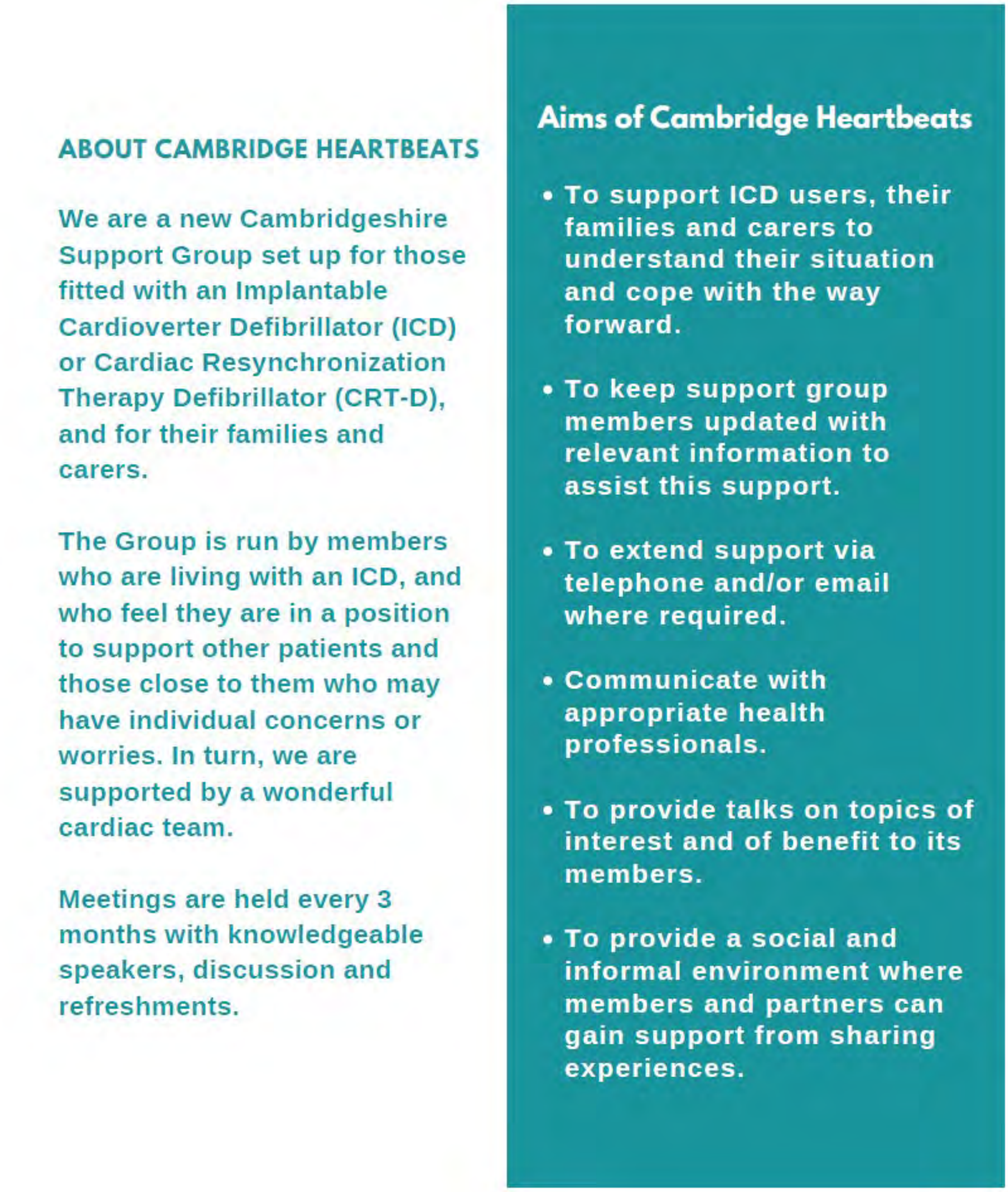
11.1 Appendix 1 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	2	24/02/20	Katie Sanders	Amendments as recommended by CUH Research Advisory Committee Independent Review
2	3	27/06/20	Katie Sanders	Amendments to clarify structure of patient and public involvement and take into account social distancing requirements due to Covid-19 pandemic.
3	4	14/08/20	Katie Sanders	Details of academic supervisor updated. Timeline updated.
4	5	28/10/20	Katie Sanders	Details of data analysis and storage and option for audio consent added.
5	6	07/06/22	Katie Sanders	Details of questionnaire development and data collection updated.

11.2 Appendix 2 – ICD support group

Cambridge Heartbeats: a new support group for people living with heart rhythm problems and their associated devices.

Formal meetings are held quarterly. Additional social meetings and a patient buddy system are also planned.



ABOUT CAMBRIDGE HEARTBEATS

We are a new Cambridgeshire Support Group set up for those fitted with an Implantable Cardioverter Defibrillator (ICD) or Cardiac Resynchronization Therapy Defibrillator (CRT-D), and for their families and carers.

The Group is run by members who are living with an ICD, and who feel they are in a position to support other patients and those close to them who may have individual concerns or worries. In turn, we are supported by a wonderful cardiac team.

Meetings are held every 3 months with knowledgeable speakers, discussion and refreshments.

Aims of Cambridge Heartbeats

- To support ICD users, their families and carers to understand their situation and cope with the way forward.
- To keep support group members updated with relevant information to assist this support.
- To extend support via telephone and/or email where required.
- Communicate with appropriate health professionals.
- To provide talks on topics of interest and of benefit to its members.
- To provide a social and informal environment where members and partners can gain support from sharing experiences.

7.3.2 Patient information sheet (PIS)

Cambridge University Hospitals NHS
NHS Foundation Trust

Research Study: **Understanding patient experience of an Implantable Cardioverter Defibrillator support group, preferences towards education and support modalities, and the impact of Covid-19 upon support provision**

PATIENT INFORMATION SHEET

You are invited to take part in a research study. You have been chosen because you have either have an Implantable Cardioverter Defibrillator (ICD), or have accessed a support group for patients with an ICD. You may have an ICD implanted yourself, or have attended as a relative or carer or a patient an ICD. Joining the study is entirely up to you; before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully and feel free to discuss it with anyone else if you wish. Please do ask a member of the research team if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

We wish to undertake a study to investigate the experiences of patients attending the ICD support group to help us to optimise the design of such groups. We aim to use interviews to:

- Explore whether there is a difference between the needs for support from those whose device has worked to give them a shock, and those who have not had this experience.
- Understand whether different formats of group meetings are experienced as being more or less beneficial to patients, and whether this has changed due to Covid-19 social distancing restrictions.
- Discover if patients and their relatives or carers prefer a patient-led support group with health care professionals contributing, and if so how this can be done effectively.

What is an ICD?

ICDs are implanted to treat people who have, or are at risk of having, dangerously abnormal heart rhythms. An ICD sends electrical pulses (referred to as a shock) to the heart to regulate abnormal heart rhythms and prevent cardiac arrest. This treatment can be life-saving, but patients may feel very unwell and find the shock painful.

Why is this study necessary?

Some patients with an ICD experience feelings of worry, stress and depression after their implant. This can affect their quality of life, for example by avoiding certain activities they used to enjoy due to fear of a shock, or finding it difficult to talk about their ICD with their family. Many patients feel they are alone in this experience as they have not met anyone else with the same problem.

Patient support groups provide an opportunity for patients to meet others who have similar health concerns to their own. They are widely used to provide support for patients with many different conditions. Medical studies have shown that support groups provide significant benefit to patients with cancer and other long term health conditions. However we do not know if patients with an ICD benefit from the same format of group in the same way.

A support group for patients living with ICDs was organised by a small group of patients with clinical support from cardiology staff at Addenbrooke's Hospital in 2019; prior to this there was no provision for local ICD support groups. As the most effective format for ICD support groups is currently unknown, the format was decided by consensus based on the format of similar groups in other areas and using general guidance from the British Heart Foundation. Since March 2020 the group has been running online meetings due to the impact of Covid-19.

The results of this study could benefit patients by improving our understanding of how to effectively support those who are living with ICDs through the implementation of patient-led support groups.

Why have I been invited?

You have been invited to participate because you either have an ICD, or have accessed a support group for patients with an ICD. You may have an ICD implanted yourself, or have attended as a relative or carer or a patient an ICD.

Do I have to take part?

It is entirely up to you to decide whether or not to take part. If you or your relative or carer decide to take part, you will be given this information sheet and be asked to sign a consent form. You are free to withdraw at any time without giving a reason. If you decide to withdraw from the study, we will keep the information that we have already obtained. If you choose not to take part in the study, or decide to withdraw at any time, this will not affect the care you receive in any way.

What will happen to me if I take part?

Once you have signed the consent form you will then be asked to participate in an interview undertaken by a member of the research team. The interview is expected to last approximately 60 minutes but this may vary depending on your experiences. The interview will need to take place in a quiet and comfortable environment which can be arranged at Addenbrooke's Hospital or via an online video link depending on your preference. Please be aware that reimbursement for travel or other expenses incurred in attending the interview is not available. The interview will be audio recorded.

The recording will be anonymised before being sent for transcription. This means that your name will not be attached to either the audio recording or written record and these records will only be identifiable by a unique reference number. The recording will be transcribed by *The Typing Works*, an organisation specialising in transcription for academic and research purposes. This written record will be used by the research team to analyse the data. After the interview no further interaction with the research team will be needed. If you have an ICD, you will be seen in the ICD follow-up clinic as per your usual schedule. If you have any health concerns during your participation in the study, you should discuss these with your GP or usual healthcare provider.

We will keep the audio and written recordings of the interview for 6 years for potential use in future research if you are in agreement. At the end of this period, the recordings will be deleted.

Who can take part in the study?

You can take part in the study if:

1. You are aged 18 years or above
2. You are able to give written consent
3. You have accessed the ICD support group
4. You are comfortably able to participate in an interview using English

Who cannot take part in the study?

You can NOT take part in the study if:

1. You are under 18 years of age
2. You do not have sufficient English literacy to participate comfortably in an interview

What are the possible disadvantages and risks of taking part?

We do not expect that participation in this study will be associated with any risks, however the interview may bring up topics which you find upsetting or difficult to talk about. You will be able to stop the interview at any point and further support as described below will be recommended if necessary.

The Psychological Wellbeing Service offers therapy for anxiety, depression, stress, obsessive compulsive disorder and low self-esteem. Options include personal therapy (face-to-face, telephone or through instant messaging), computerised CBT, guided self-help and telephone support. This is a free NHS service for persons aged 17 years and older. There is no upper age limit with sites across the county. If you feel this may be of benefit to you, please discuss a referral with your GP, or self-refer directly at: www.cpft.nhs.uk or telephone: 0300 300 0055 for people who live in Cambridgeshire and Peterborough. If you live outside Cambridgeshire and

Peterborough, the study team can provide contact details for your local service. Please note this is not an emergency service and if you are in crisis and need urgent support or are worried about immediate risk of harm to self or others, please call 999. Alternatively you can contact your GP and ask for an emergency appointment or visit your local A&E department. You can also contact the following services 24 hours a day, 7 days a week: NHS Helpline (111) and the Samaritans (116 123).

What are the possible benefits of taking part?

There may be no direct clinical benefit to you by exploring your experiences of an ICD support group. However, the results from the study might help improve the effectiveness of this and other support groups in helping patients living with an ICD.

What if something goes wrong?

This is extremely unlikely, as this study is not going to affect your clinical care in any way. If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for legal action but you may have to pay for it. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you. You may contact the Chief Investigator in the first instance on 01223 256233. You can also contact the NHS Patient Advice and Liaison Service (PALS) on 01223 216756.

Will my taking part in this study be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential. Your name will not be linked with any personal or clinical information.

What will happen to the data?

Patients eligible for the study will be identified by the direct care team and the study investigators during contact with the ICD support group. Only members of the direct clinical care team and the study investigators will access patient’s records in order to identify potential participants, check whether they meet the inclusion criteria and make the initial approach to patients. Identifiable data will be reviewed only in the screening process. All personal identifiers will be removed before analysis.

You will be identified only by a study-specific participant’s number and/or code in the database. Your name and any other personal identifying detail will not be included in any study data electronic file but will be held separately and securely in the department. All study data will be kept in the Trust’s secure computers/ NHS servers.

Consent forms that contain your name and other personal information will be kept separately and securely within the department and only members of the direct clinical care team and the study investigators will have access to the folders.

The data generated will be analysed at Addenbrooke's Hospital by the Chief Investigator and the investigators after removal of your identifying details.

Your data will be kept for 6 years after the end of the study. At the end of this period, electronic records will be deleted and paper records destroyed.

All study related documentation and data will be archived in accordance with the Sponsor's Policies and Procedures and General Data Protection Regulation (GDPR) requirements - for full GDPR statement see p.5.

What will happen to the results of the research study?

The results will be presented in local, national and international meetings and published in medical journals. We will send you an information letter to inform you about the results of the study.

Who has reviewed the study?

This research is Sponsored by Cambridge University Hospitals NHS Foundation Trust and funding has been provided by the Cardiology department. All research in the NHS is reviewed by an ethics committee and given approval by the Health Research Authority (HRA). Cambridge Central Research Ethics Committee has reviewed the study and approval has been given. The Patient and Public Involvement panel has also reviewed the study and the participant information sheet.

Who is funding the study?

The study is funded by the Cardiology department at Addenbrooke's Hospital. The study has not been funded by the manufacturers of ICDs.

Contacts for Further Information

If you have any concerns about the study and wish to contact someone independent, you may telephone the hospital patient advice liaison service (PALS). They are available on 01223 216756.

Alternatively, you can contact the Cardiology department and discuss any issues with the Chief Investigator or any other study Investigators.

Dr Peter Pugh, Consultant Cardiologist

Box 263, Ward K2, Addenbrooke's Hospital

Hills Road, Cambridge CB2 0QQ

Tel 01223 256233

Kate Sanders, Chief Cardiac Physiologist

Box 263, Ward K2, Addenbrooke's Hospital

Hills Road, Cambridge CB2 0QQ

Tel 01223 256233

General Data Protection Regulation (GDPR) statement

The Data Protection Act 2018 is the UK's implementation of the General Data Protection Regulation (GDPR) and your personal data will be managed in accordance with its principles. Cambridge University Hospitals NHS Foundation Trust (CUH) is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Cambridge University Hospitals NHS Foundation Trust will keep identifiable information about you for 6 years after the study has finished.

Your rights to access, change or move your information are limited as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personal identifiable information.

You can find out about how we use your information by contacting gdprenq@addenbrookes.nhs.uk.

CUH will collect information from you and your medical records for this research in accordance with our instructions.

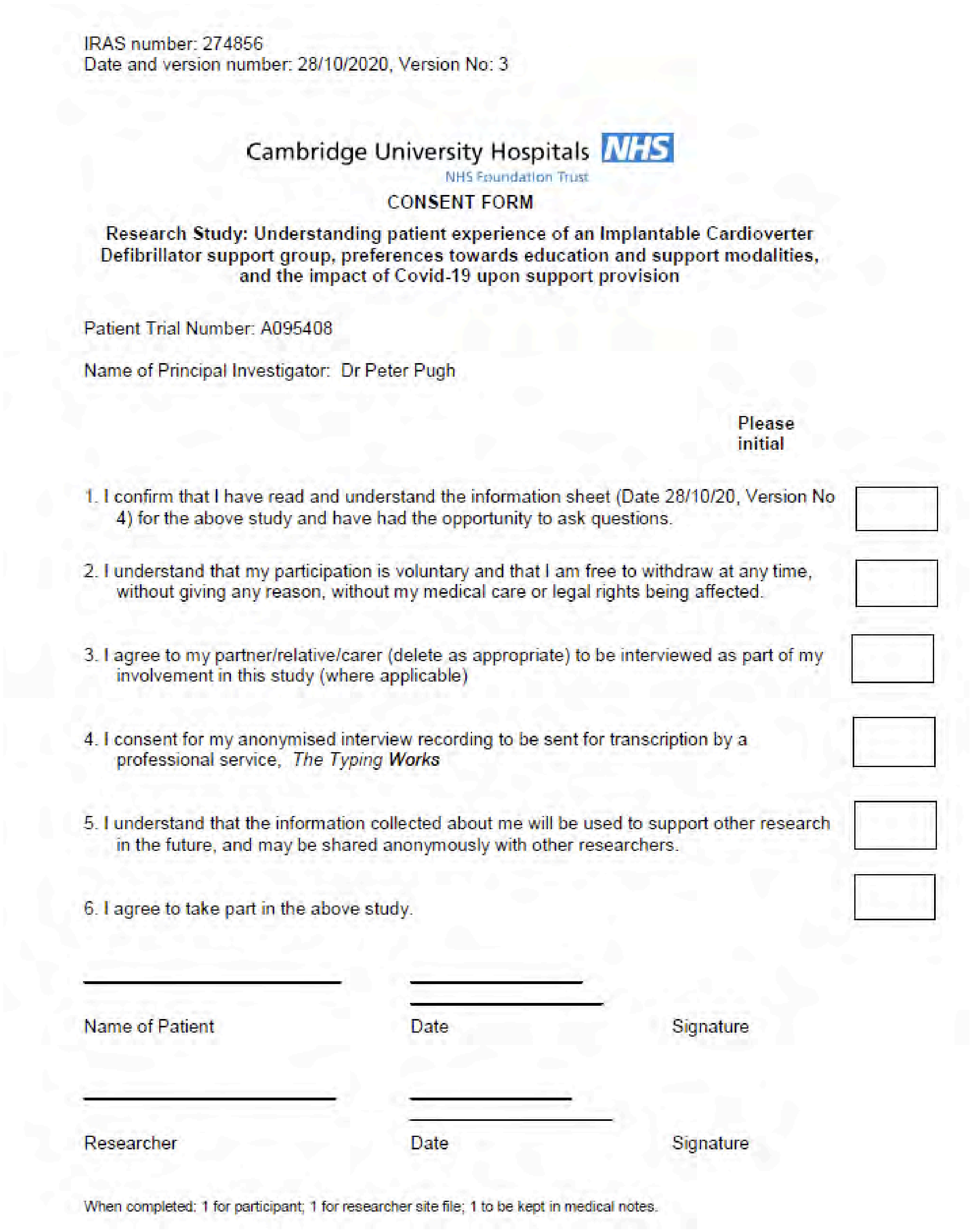
CUH will use your name, hospital number, NHS number, date of birth and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Cambridge University Hospitals NHS Foundation Trust and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in Cambridge University Hospitals NHS Foundation Trust who will have access to information that identifies you will be people who need to contact you to for any clinical reasons, the purposes of the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

CUH will keep identifiable information about you from this study for 6 years after the study has finished.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. More information regarding how your data is used in research can be found online at: www.hra.nhs.uk/patientdataandresearch. You can ask the research team for a printed copy of this information if you do not have access to the internet.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you such as insurance.

7.3.3 Informed Consent Form



IRAS number: 274856
Date and version number: 28/10/2020, Version No: 3

Cambridge University Hospitals NHS
NHS Foundation Trust

CONSENT FORM

Research Study: Understanding patient experience of an Implantable Cardioverter Defibrillator support group, preferences towards education and support modalities, and the impact of Covid-19 upon support provision

Patient Trial Number: A095408

Name of Principal Investigator: Dr Peter Pugh

Please initial

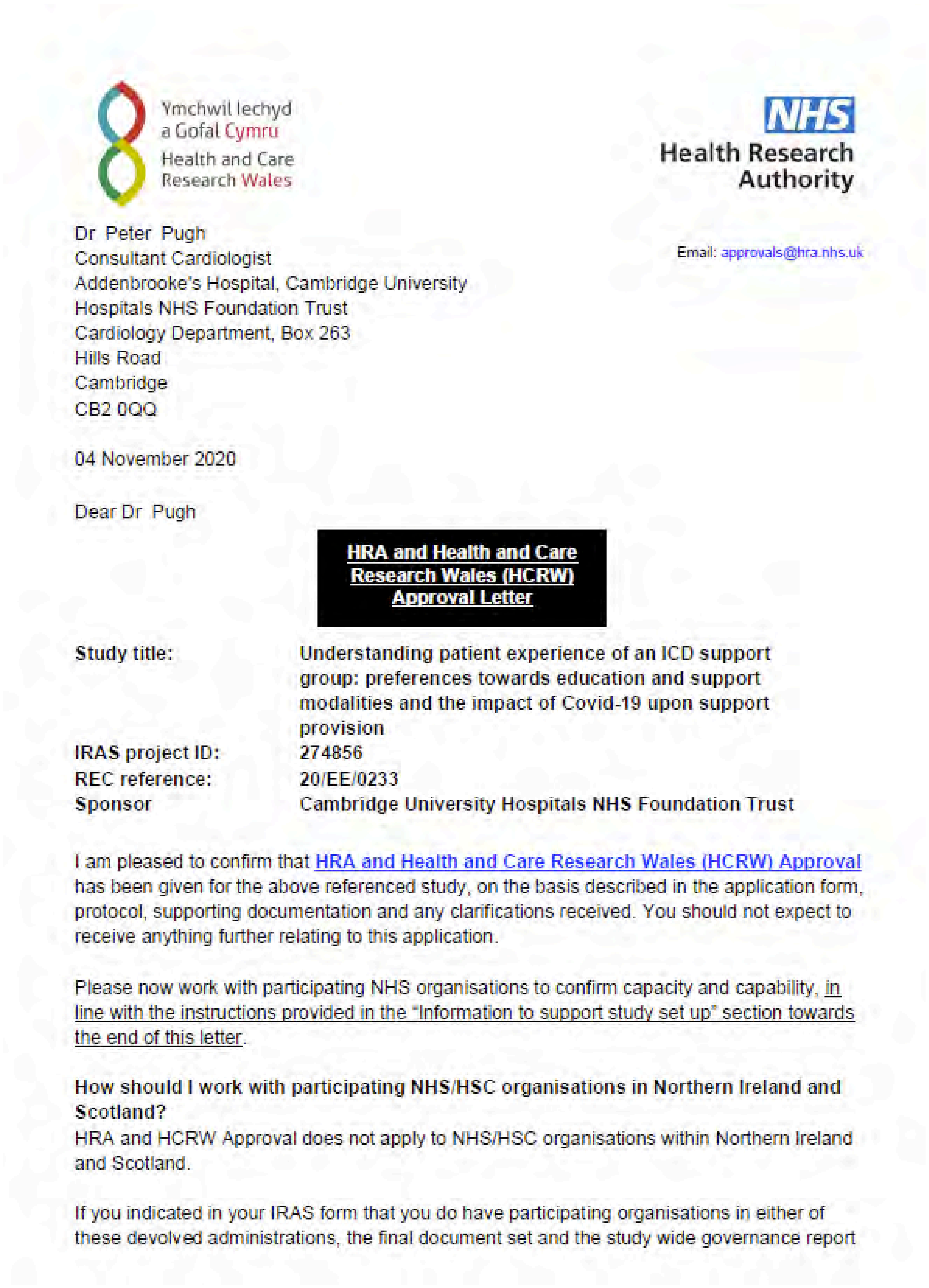
1. I confirm that I have read and understand the information sheet (Date 28/10/20, Version No 4) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I agree to my partner/relative/carer (delete as appropriate) to be interviewed as part of my involvement in this study (where applicable) ☐
4. I consent for my anonymised interview recording to be sent for transcription by a professional service, *The Typing **Works*** ☐
5. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐
6. I agree to take part in the above study. ☐

Name of Patient Date Signature

Researcher Date Signature

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.

7.3.4 Approval letters from HRA and REC



Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales

NHS
Health Research
Authority

Email: approvals@hra.nhs.uk

Dr Peter Pugh
Consultant Cardiologist
Addenbrooke's Hospital, Cambridge University
Hospitals NHS Foundation Trust
Cardiology Department, Box 263
Hills Road
Cambridge
CB2 0QQ

04 November 2020

Dear Dr Pugh

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Understanding patient experience of an ICD support group: preferences towards education and support modalities and the impact of Covid-19 upon support provision**
IRAS project ID:	**274856**
REC reference:	**20/EE/0233**
Sponsor	**Cambridge University Hospitals NHS Foundation Trust**

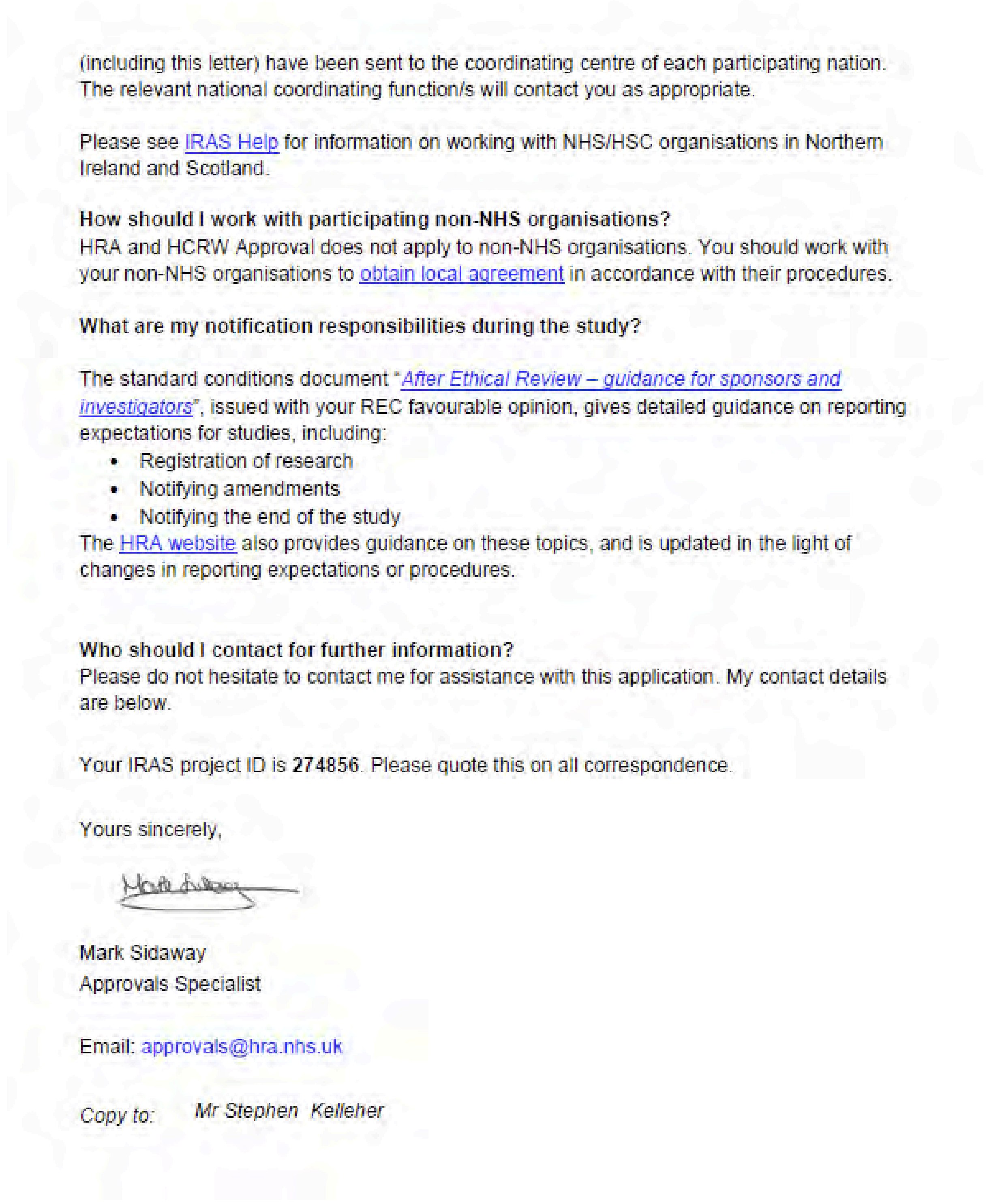
I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report



(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions 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.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

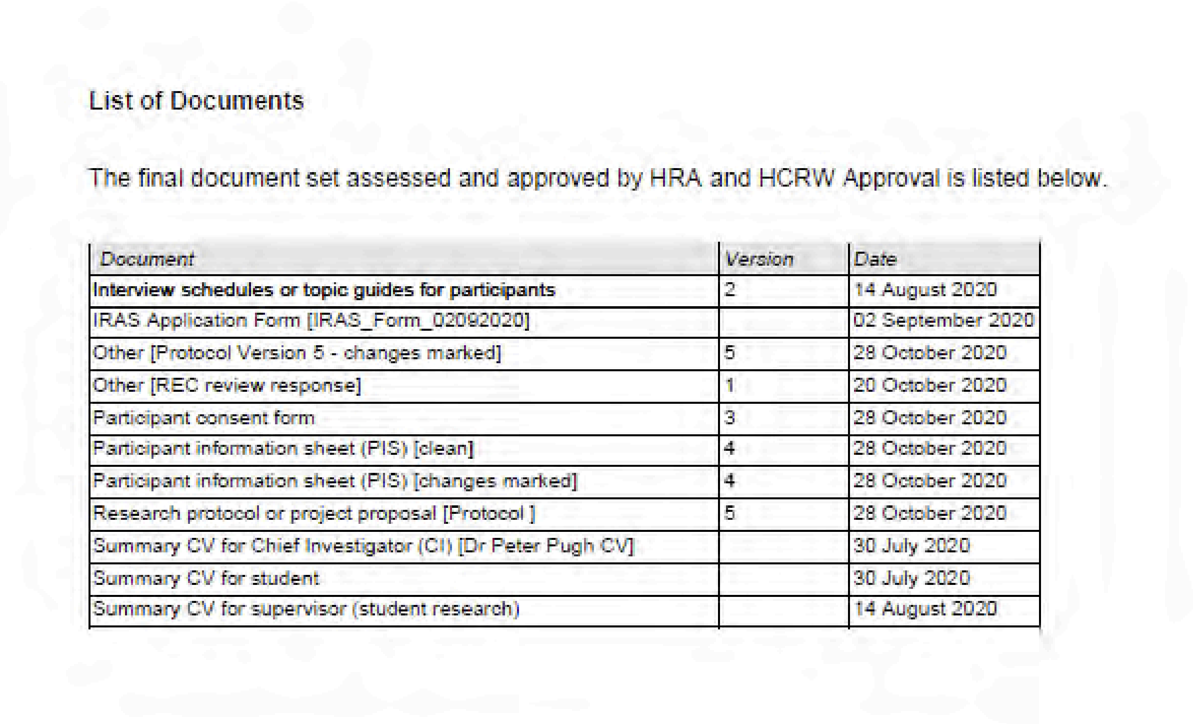
Your IRAS project ID is **274856**. Please quote this on all correspondence.

Yours sincerely,

Mark Sidaway
Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Mr Stephen Kelleher*



List of Documents

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

Document	*Version*	*Date*
Interview schedules or topic guides for participants	2	14 August 2020
IRAS Application Form [IRAS_Form_02092020]		02 September 2020
Other [Protocol Version 5 - changes marked]	5	28 October 2020
Other [REC review response]	1	20 October 2020
Participant consent form	3	28 October 2020
Participant information sheet (PIS) [clean]	4	28 October 2020
Participant information sheet (PIS) [changes marked]	4	28 October 2020
Research protocol or project proposal [Protocol]	5	28 October 2020
Summary CV for Chief Investigator (CI) [Dr Peter Pugh CV]		30 July 2020
Summary CV for student		30 July 2020
Summary CV for supervisor (student research)		14 August 2020

NHS
Health Research
Authority

East of England - Cambridge Central Research Ethics Committee
Royal Standard Place
Nottingham
NG1 6FS

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

02 November 2020

Dr Peter Pugh
Consultant Cardiologist
Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust
Cardiology Department, Box 263
Hills Road
Cambridge
CB2 0QQ

Dear Dr Pugh

Study title:	**Understanding patient experience of an ICD support group: preferences towards education and support modalities and the impact of Covid-19 upon support provision**
REC reference:	20/EE/0233
IRAS project ID:	274856

Thank you for your letter of 28 October 2020, 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..

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

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

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

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

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

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

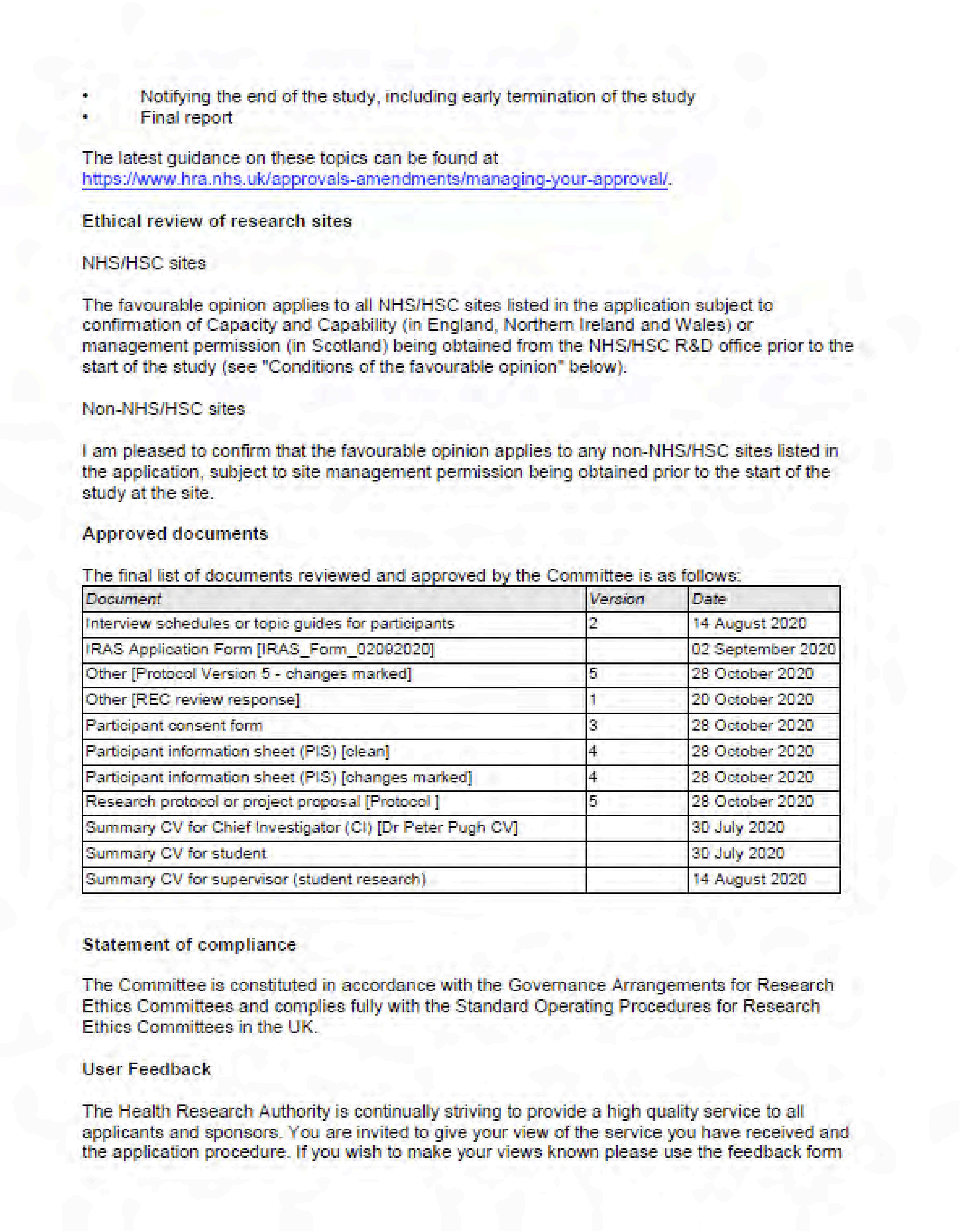
You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

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).

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, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

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

Document	*Version*	*Date*
Interview schedules or topic guides for participants	2	14 August 2020
IRAS Application Form [IRAS_Form_02092020]		02 September 2020
Other [Protocol Version 5 - changes marked]	5	28 October 2020
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Research protocol or project proposal [Protocol]	5	28 October 2020
Summary CV for Chief Investigator (CI) [Dr Peter Pugh CV]		30 July 2020
Summary CV for student		30 July 2020
Summary CV for supervisor (student research)		14 August 2020

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.

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 Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 274856 Please quote this number on all correspondence

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

Yours sincerely

pp

Miss Stephanie Ellis
Chair

Email:cambridgecentral.rec@hra.nhs.uk

Copy to: Mr Stephen Kelleher

7.3.5 Interview schedule

Understanding patient experience of an ICD support group: Interview Guide

ICD support groups: Semi-structured interview

M/F

ICD implanted / relative / carer

Has attended support group / not attended support group

Age

1. Qualitative interview introduction

Length: 60 minutes

Primary goal: Understand the experience from your point of view – a conversation about your experience, including your opinions and what you think or feel about the topics covered

2. Verbal consent

Would you like to participate in this interview?

Verbal consent was obtained from the study participant

Verbal consent was NOT obtained from the study participant

3. Background information

I know you have a background of living with an ICD; could you tell me briefly why you (or your relative) had an ICD implanted?

4. ICD support group experience

Could you tell me a little bit about why you attended the support group? (*or chose not to, if applicable)*

- How did you find out about it?

Did you find attending the group beneficial, or not helpful for you?

- If beneficial, what was the benefit?
- If not helpful, was there something in particular which was not helpful?

5. Format of support group

In an ideal world, where would you like to see one of these groups? (i.e. hospital, people’s homes, community public venues)

How often would you like the meetings to be available?

What would you like to get out of the support group? (*Were they looking for informational or emotional support?)*

Is there anything which would make you more likely to attend?

6. Impact of Covid-19

Explain that Covid-19 pandemic changed the group format from community meetings to online video-conferencing. There is evidence that social distancing and self-isolation can negatively affect mental health and the provision of support.

Has Covid-19 made a difference to your enthusiasm for the support group?

Do you feel you would be adequately supported by a support group which is run remotely?

If no:

- Did you have any issues with the online format?
- What alternatives/changes could make it more user-friendly?

7. Involvement of health care professionals (HCPs)

Be clear that I am not talking about myself and it's really important we have your views. It is not about me!

Consider both the role of facilitator supporting the group and formal speakers.

Would you prefer a group with a health care professional involved, or would you prefer it to be entirely patient-led?

If prefer involvement:

- To what extent would you like the HCP to be involved?
- It would be really helpful for me to understand why this is your preference (*Is it easier to share your feelings or experiences with other patients or with an HCP?)*

8. Shock experience

Can you tell me whether you think about having shock? *(whether you fear it, or anticipate it?)*

If had a shock:

- How did you feel after having a shock?
- How did it affect your life?
- How could you see yourself moving forward?

- Do you think this changed what you wanted to get from the support group?

If not had a shock but think about it:

- How could/does attending the group support you? (*with regards to your fears)*

If don't think about it:

- What else do they get from the group (if they attend)?

9. Feedback and recommendations

Explore whether the conversation has highlighted any ideas from the interviewee about how the support group could be improved.

Is there anything we discussed today you would like to come back to?

7.3.6 Questionnaire

Cambridge University Hospitals NHS
NHS Foundation Trust

Research Study: **Understanding patient experience of an Implantable Cardioverter Defibrillator support group, preferences towards education and support modalities, and the impact of Covid-19 upon support provision**

PATIENT INFORMATION SHEET

You are invited to take part in a research study. You have been invited because you have attended a support group for people who have an ICD. Taking part in the study is entirely up to you; before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully and feel free to discuss it with anyone else if you wish. Please do ask a member of the research team if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

We wish to undertake a study to investigate the experiences of patients attending the ICD support group to help us to optimise the design of such groups. We have designed the enclosed questionnaire based on our analysis of patients' experiences, which we have collected using interviews.

Why is this study necessary?

As the most effective format for ICD support groups is currently unknown, the format of our existing group was decided by consensus based on the format of similar groups in other areas and using general guidance from the British Heart Foundation. The results of this study could benefit patients by improving our understanding of how to effectively support those who are living with ICDs through the implementation of patient-led support groups.

What will taking part involve?

You are asked to read the questionnaire statements carefully and circle the answer which most accurately matches your experience. It will take approximately 10-15 minutes to complete. A pre-paid envelope has been provided for you to return your questionnaire. By completing and returning this questionnaire, you consent to your responses being included in the analysis of the above research study.

What are the possible benefits of taking part?

The main benefit of taking part in this research study is being actively involved in developing programmes to optimise support groups for ICD patients and their families. This will ensure support groups will be effective and sustainable in the longer term, whilst ensuring patients get the most benefit from them.

What will happen to the data?

Your responses will be anonymous and we will not store any personal data.

Who has reviewed the study?

This research is Sponsored by Cambridge University Hospitals NHS Foundation Trust and funding has been provided by the Cardiology department. All research in the NHS is reviewed by an ethics committee and given approval by the Health Research Authority (HRA). Cambridge Central Research Ethics Committee has reviewed the study and approval has been given. The Patient and Public Involvement panel has also reviewed the study and the questionnaire.

Who is funding the study?

The study is funded by the Cardiology department at Addenbrooke’s Hospital. The study has not been funded by the manufacturers of ICDs.

Contacts for Further Information

If you have any concerns about the study and wish to contact someone independent, you may telephone the hospital patient advice liaison service (PALS). They are available on 01223 216756.

Alternatively, you can contact the Cardiology department and discuss any issues with the Chief Investigator or any other study Investigators.

Dr Peter Pugh, Consultant Cardiologist

Box 263, Ward K2, Addenbrooke's Hospital

Hills Road, Cambridge CB2 0QQ

Tel 01223 256233

Kate Sanders, Chief Cardiac Physiologist

Box 263, Ward K2, Addenbrooke's Hospital

Hills Road, Cambridge CB2 0QQ

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Cambridge University Hospitals NHS
NHS Foundation Trust

Research Study: **Understanding patient experience of an Implantable Cardioverter Defibrillator support group, preferences towards education and support modalities, and the impact of Covid-19 upon support provision**

Please read the below statements carefully and circle the answer which most accurately matches your experience. It will take approximately 10-15 minutes to complete this questionnaire.

A lifeline
Seeing other people living with their ICD gave me reassurance and/or hope that I could live a normal life. Strongly disagree Disagree Neither disagree or agree Agree Strongly agree
Meeting other people living with their ICD helped me decide whether to have an ICD. Strongly disagree Disagree Neither disagree or agree Agree Strongly agree
I would have welcomed the opportunity to speak to other patients in the support group before the implant. Strongly disagree Disagree Neither disagree or agree Agree Strongly agree
Talking to other people living with an ICD helps me keep my problems in perspective. Strongly disagree Disagree Neither disagree or agree Agree Strongly agree
The support group helps me feel like I'm not on my own with my ICD. Strongly disagree Disagree Neither disagree or agree Agree Strongly agree
I would expect any patients offering formal support to other patients to have undergone some training. Strongly disagree Disagree Neither disagree or agree Agree Strongly agree
Talking to other patients has helped me find ways to manage the limitations on my life caused by my ICD. Strongly disagree Disagree Neither disagree or agree Agree Strongly agree
It is easier to share my experiences during one-to-one conversation than during a group meeting.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

Involvement of healthcare professionals

Having a healthcare professional present at the meeting is important because they can ensure advice and information being shared or discussed is accurate and safe.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

The support group should be led by patients because lived experience is important.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

Healthcare professionals can't provide all the support I need because only patients know what it's like to live with an ICD.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

Sharing experiences

I prefer to share experiences with other patients at a face-to-face meeting compared to over Zoom.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

Hearing other people's experiences of ICD shocks reduced my anxiety about it happening to me.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

I find it reassuring that other people find living with an ICD challenging, and that I am not alone in this.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

Timing of support

The support group was most useful to me around the time I had my ICD implanted.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

I will probably only attend the support group if I have a problem or have a bad experience with my ICD.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

It would be helpful if one-on-one support was available in between the regular group meetings.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

The support group offers a welcome point of contact in between my hospital appointments.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

Meeting practicalities

Meetings once a quarter are not frequent enough to offer the support I need.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

I prefer to attend support group meetings in a community setting rather than in a hospital.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

An online forum as part of the support group would be convenient to me because I can connect with other people in the group and read their questions and answers.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

Now Covid-19 restrictions have lifted, I would prefer that the meetings were available in person.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

Even though Covid-19 restrictions have been lifted, I would prefer the meetings to be available over Zoom

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

The educational talks help me understand how my ICD works and why I need it.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

The social aspect of the support group meetings is an important part of its appeal to me.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

The educational talks at the support group meetings are an important part of its appeal to me.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

I find it reassuring to have something in common (e.g. age or specific heart condition) with other people at the support group.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

I was more reliant on the group for support during the Covid-19 pandemic because I couldn't access my usual forms of support.

Strongly disagree Disagree Neither disagree or agree Agree Strongly agree

By completing and returning this questionnaire, you consent to your responses being included in the analysis of the above research study.

Please return your questionnaire in the pre-paid envelope provided.

7.4 Qualitative data analysis: supporting documentation

7.4.1 Codes

Code	Definition
Experience of support group	
Making connections	General references to meeting/seeing/talking to people at the support group who also have an ICD
A lifeline	One-on-one peer support, whether formally or informally arranged. Includes references to training of buddies.
Helping others	Refers to the participant being able to / wishing to help other people – sense of altruism
Sharing experiences	Split into: 1. sharing and receiving empathy and reassurance. 2. looking for ideas and learning from others. 3. not feeling alone (with an ICD). 4. Voice from the future
Feeling better off compared to others	More specifically about thinking whether others are better/worse off than themselves.
Learning from talks	Educational talks provided at support group meetings
Alternative sources of support	The participant discusses alternative sources of support, such as cardiac rehab, IAPT
Reason for attending	Motivation for accessing the support group
Support needs changing throughout ICD journey	When in their journey of having an ICD do they need the support group?

Social support	The role of support group extending existing social circle
Living with an ICD	
Thinking about a shock	Any thoughts about shocks
Coping with an ICD	Split into 2 codes: 1. Accepting the ICD is necessary 2. Getting used to life with an ICD
Family relationships	Impact of ICD/life changes etc on relationships.
Understanding an ICD	Participants looking for practical understanding of how ICDs work, what it will do, how it will be managed
Reasons for implant	Background to implant, experience of decision-making process to have an ICD
Life changes	Making practical changes because of the ICD, either optional or enforced, including driving restrictions
Worry and uncertainty	About the ICD, activities, future
Other health problems	Any mention of non-cardiac health problems which may or may not influence experience of ICD
Fear of death, shocks and the unknown	Feeling frightened or scared of shocks or device malfunction, or of their heart condition
Shock experience	Describing their own experience of shocks

Concerns about ICD	
A control thing	Feeling in/out of control of health or of ICD, including deactivation of ICD
What to expect	Regarding living with an ICD
Support group practicalities	
Online access	Experience of Zoom meetings, pros/cons of online meetings Split into: 1. Convenience of online meetings 2. Difficulty in interpersonal connection 3. Online forum offers immediate patient to patient connection
Covid-19 and support groups	How Covid-19 has affected their experience of or opinions about face-to-face support groups
Parking and access	Locations for face-to-face meetings Split into: Community location is preferred (Free) parking is important
Frequency of meetings	Formal support group meetings
Opportunities for questions	At support group meetings, to support group outside of meetings, to HCPs during routine care
Face to face group meetings	Experience of face-to-face meetings, pros/cons of in-person meetings

	Split into: Informal chat is useful Need space to move/mix
Support group framework	Leadership and management of the group; goals and objectives of the group; structure and membership
Involvement of the care team	
Trust in care team	Trust in the care team’s experience (compared to patient experience)
Recommended by doctor	Referring to any aspect of care (to have ICD, to join the support group, other treatments etc)
Professional input	Input into the support group specifically
Facing Death	
Denial	Avoidance, confusion, shock, fear
Anger	Frustration, irritation, anxiety
Bargaining	Struggling to find meaning, reaching out to others
Depression	Overwhelmed, helplessness, hostility, flight
Acceptance	Exploring options, new plan in place, moving on
Giving hope	Either giving hope to others, or experiencing something which gives the participant hope

7.4.2 Quotes

Five stages of grief in ICD recipients

The quotes below are a selection of those discussed at a meeting with the PPI group on 19/04/22, where we explored the concept the five stages and identified examples of these in the dataset.

Denial

I try not to think about it because it sounds like there's nothing good about it. *Caroline*

But, no, I didn't think about it. And I think, had I thought about it, I would have changed my behaviour, wouldn't have done all sorts of things. *Ethan*

I did have, you know, 24 hours because I delayed the decision, I wasn't then kind of looking up…and I'm kind of curious about like why that, I wasn't even curious, didn't even want to look at that, you know. I just sat with this kind of like dread… *Lee*

Anger

And they were completely smothering me and making it more difficult, and I think they did it with all the best intentions in the world, but if I'd, I'd have been able to talk to somebody I would, they would have said, oh come on, they're just being kind, you know, and shout at them… *Ann*

I just feel frustrated when I feel these things happening inside, and I don't want them to happen… I wish I'd never picked up that virus… *Caroline*

I also have a kind of feeling of like just go off, I just want it to go off to prove its point, you know, to make it, to show that I did need a pacemaker after all. I have the other feeling is if I go through my whole life and it never goes off I'll be really cross, really resentful… *Lee*

Bargaining

Just generally it's been, you know, and like the rehab classes as well, I've found them really, really helpful… Those kind of things, just to help people to build up their lives again and try to get, you know, to as much to normal as is possible for them, that is just brilliant, really helpful, yeah. *Caroline*

I wanted to get back to those kind of things that people of my kind of age do and 70 and 80 year olds tend not to. *Daniel*

I haven’t really got a long-term plan at the moment, and that’s, it’s not worrying but it’s kind of I’d prefer to have some plan in place for when things are going to go back to some semblance of normality. *James*

…obviously I was frightened to go out and things, but after reading up on it and going to the support group I realised that, you know, I can live a normal life. *Kathy*

Depression

…then he felt guilty when he could go out and play golf, and I said, “Well, you might as well, at least one of us enjoy themselves. And at least I know you’re keeping yourself healthy then”. *Caroline*

I’ve just now got this unattractive, well the rest of me is unattractive as well, [laughter] but this particularly lumpy thing here. *Graham*

I just felt alone and I was always worried that it was going to fire and didn’t know what to do if it did. *Kathy*

…you’ve got so many questions you don’t really know what questions to ask… *Caroline*

Well I really had to watch out not to be down in the dumps. *Caroline*

Acceptance

I think to myself, well if I’m going to have a shock there’s probably nothing I could have done about it anyway… *Ann*

…I narrowed my shock down to the fact that the only time it’s going to happen is when I’m needing it. *Henry*

…also sometimes you just have to be in the right place to accept that some things aren’t going to change…there is no point worrying about it, either it’s going to happen or it isn’t going to happen… *James*

…now I know that it’s there to protect me and that, you know, I can live a normal life with it. *Kathy*

Themes

On 30/06/22 the PPI group reviewed the themes and chose the quotes to be used in Chapter 3. Below is a selection of the quotes which were meaningful but were not selected for the final report.

Confronting mortality

…and just being alive, so that people can, that they can make that connection. (Ann)

I come back to the thing of like what's the real anxiety and it's dying and I think seeing somebody walk into the ward and go "I've got one on, I'm still alive, like I've had the operation, I didn't die" and also maybe somebody who's had one that's gone off and saved their life and not killed them, you know, like for me like that's the underlying thing of being faced with that decision is if I get it wrong I might die. (Lee)

I was a bit apprehensive about not worried about having a shock, but I'd be, let's be honest I was just worried about dying really (Henry)

But, essentially, it can come down to, can't it really? If you don't have this implant then the chances are you'll die fairly soon. (Ethan)

…the guy I spoke to he'd had two shocks and he said they were bloody uncomfortable, yeah, and it made me think again, but being bloody uncomfortable from keeping you alive comes back to what I said very early on, you know, I'm going to live with that (Henry)

I think it's interesting to be in a room of people who have in one way or another to a greater or lesser extent been forced to think about their mortality in a way that maybe a lot of other people haven't. That's quite moving actually. (Lee)

It's not explicit but it's a sense of we must have all had a little bit more thought about our death than, you know, another group of people in another room. (Lee)

Coping through sharing

I mean that was the most important thing to me was to meet somebody who had one, because there's lots of unconscious signals, that meeting somebody gives you, that you don't realise. (Ann)

And he didn’t say anything, it was just seeing him and making the realisation that actually he was still able to do things, it didn’t stop him doing anything and he was still standing up after ten years (Ann)

I just think it’s, just generally the feeling that you aren’t on your own and that there are people that could help you.(Caroline)

So there’s just so much uncertainty in that respect, so it’s just good to have erm… some anchors that you can, you know, feel you can turn to. (Caroline)

You remember the stories about whenever it went off in the house or, you know, what people describing it as like being kicked in the chest by a horse, you know, so they're not exactly, you know, no-one really apart from people who live with it realise that it's just, you know, unthought, you know, like you don't think about it and it's only whenever you roll over onto your side and you go oh, it's annoying, you know. (Daniel)

I mean the meetings, I’ve been to one in person, I’ve joined one via Zoom and I found them really, really helpful, and talking to other people that have experienced it as well it’s made me feel a lot happier about having the ICD. (Kathy)

I don’t like flying at the best of times and I was like really worried, but my buddy sort of reassured me that it’s fine, she’d been on quite a long flight so, you know, it was fine and it put my mind at rest. (Kathy)

Like, little things because doctors tend to show you the big things and it's not all the little things that you find out when you get home, you know? (Irene)

I would always have in the back of my mind well, you're different from, your goals are different from my goals (Daniel)

I think that’s why it’s helpful, that if you’re together with other people, they think of other things or they ask questions as well (Caroline)

I’m thinking about going back actually, going to a meeting because it feels like I do need that support or the identification, you know, the recognition of “is it still annoying to you fifteen years down the line?” kind of thing or whatever. (Lee)

So I think there’s two aspects really, is specific things which could help my lifestyle shall we say, and the other thing is to have personal experiences of any, which is a similar sort of thing really, yeah, that if something’s happened to somebody else I perhaps would like to try to learn from it (Henry)

(talking about shocks) I didn’t feel proud of that particular fact but it would have been… perhaps it might have been nice to have shared the experience with someone else who had. (Ethan)

it’s just a matter of sharing and realising that you are part of a select group of people who are carrying something rather precious probably in the left-side of their chest. (Ethan)

Coping through learning

…that was good but the structure, with speakers and things like that adds a different dimension to it doesn’t it, it formalises that part of the meeting to lead onto other discussions can’t it. (Graham)

And the length of the wires, I was amazed, I thought well how the hell are they in? And it's things like that that are really good, you know, which I've enjoyed. (Irene)

I mean I’ve had cancer as well and when I had cancer I was given this book and I knew exactly what to do when, but there was nothing like that with the ICD. (Kathy)

…so I think that’s one of the purposes of the talks is open up the challenges so that people start to process things themselves. (Ann)

I like it that we’ve had presentations on subjects that, you know, will be of interest to us erm…, because normally healthcare professionals are busy by nature and they’re not really accessible unless there is a real problem. (Caroline)

I think for sort of actual medical information, it's got to come from a medical person and I think probably anything more personal or worries and fears, it's, like, a patient. (Irene)

…the reason it’s interesting is because it might affect my care, and it might affect my chance of survival, you know, there’s all sorts of things, because we are in quite an exclusive group when we have devices fitted, you know, if you have a device fitted, so it’s nice to know why when how it, you know, yeah, these are all good things to find out basically. (James)

I found [the talks] really useful because again that kind of helped me kind of regulate my anxiety about having what’s the device going to do in the event of x, y, z? (Lee)

I remember asking some pretty outrageous questions of somebody about like what if I’m in a car crash and I’m bleeding to death, you know, will the device keep going off or not? (Lee)

I’ve gone online to check about defibrillators and when I do go online they come up with these external defibrillators, you know, that’s what mainly, the one that I’ve got inside of me I haven’t really gone into but I’ve got a sketchy outline of how they work and so I’ll leave it at that. It’s like when you’re writing with a pencil, you know, do you want to know where the lead comes from? (Felix)

Because even if you have one question answered, or you have one little thing explained that you weren’t sure of before, even though you might not have known that you wanted to know it, then it’s a good thing. (James)

I mean that’s where my experience you see of nurses in healthcare, specialist nurses in healthcare and support groups, that’s where I think that’s been tremendously helpful to me, because that sort of environment empowers you, empowers you to actually make the changes that you need to make, to give yourself a better lifestyle… and I feel I’m in control of my destiny (Ann)

It’s helpful to hear of other people’s experiences, but they’re not healthcare professionals. So, if somebody were to make a suggestion, “Oh, you should be doing this or that”, I wouldn’t be sure if that’s correct advice or not (Caroline)

Providing space

…when you first got it or even before you have it fitted because that's where I find a lot of the, from reading, like, in the group, it's where a lot of the fear is, like, the unknown so I think it'd be more beneficial before rather than, you know, and immediately after because then you sort of get used to it. (Irene)

I was going along lovely, didn't even think about it, fine, and then when it fired it was [sharp intake of breath] and you find you're back to the uncertainty. (Irene)

And I think in my mind it kind of like speaks into the story of like we’re out in the world with our pacemakers doing our thing and living our lives and we’re not tied to the hospital all the time. (Lee)

It’s nice to have that together because it makes people feel relaxed, comfortable and sort of familiar with people so that they feel they can ask their question in front of other people, etc, so I think it aids to that. (Caroline)

I’ve only been to one, as I said one meeting, and I think I didn’t absorb, the answer is I think at the time I wasn’t, I wasn’t quite, you know, I’m not saying I was unwell, I just was not quite with it in life and I didn’t take proper usage of it (Henry)

I know that, you know, a meeting once every three months is not easy access, but at least there are people there that might be able to say, well, you know, if you have any issues, I’m just always thinking, well suppose something is going wrong with my heart and I’m not quite sure, and I want to ask a question, who do I ask? …so the direct availability of a place where you can ask questions is, it’s just peace of mind for people. (Caroline)

And it is just good to have that support on standby even though, you know, you might not end up calling anybody regularly. But it’s just to know that that’s there, so that’s one thing. (Caroline)

And so creating space in terms of a literal meeting space but also time and in a way like everybody knows how to kind of, like what you would do at a coffee morning kind of thing of like you have a little, a focus and then a reflective bit and then there’s just the social bit, it’s like that to me was the most useful, beneficial part of the meetings and I think also what that means is it’s within the abilities of a lot of people to do that. (Lee)

7.4.3 Reflective Practice Excerpts

A sample of the author’s reflective practice is presented in this appendix. Necessarily this section is written in the first person as these notes are presented as written in the author’s reflective journal.

7.4.3.1 *Familiarisation with dataset*

Ann - interviewed 09/12/20

There was a lot of reference to and understanding on her part of ‘different perspectives’ – what she needed and what worked for her, while acknowledging that might not suit everyone. However she seemed surprised that some people wouldn’t consider a support group for reasons other than practical / access issues.

Her background of working in healthcare as a nurse will certainly have influenced how she makes sense of her life with an ICD. I picked up a bit of a sense of her feeling intellectually superior to many others; her comments about engaging her brain and how she got things from the heart failure talk but maybe others wouldn’t have. In this respect she does come from a position of privilege in being white, educated, heterosexual, relatively young – being female appears to be her only key position of marginality.

When I read the interview back I find some of her comments quite grating, in particular as I know there are errors and exaggerations, which I think make me tempted to discount her comments. I suppose I should think about why she has recalled these things with a more negative slant. Is she disappointed by the support group, or disappointed she didn’t end up being involved? One thought that crossed my mind is that she would always be critical of it simply because she wasn’t involved because of her sense of superiority and self-importance – but am I being unfair because I feel defensive/protective of what I and the committee have managed to achieve? Is it also possible she wanted more support from the group and felt let down?

Research question 1. Shock delivery

She seemed to equate a ‘near miss’ as the same experience as having a shock. However being ‘caught’ and being contacted to prevent shocks gave her real ‘faith in the system' – would she have the same faith and 'laissez-faire' if she had been shocked? I'm not convinced the experience is the same - if she'd had shocks, she could still feel out of control, lose faith in the system. In terms of needs however, she still felt she needed somebody to talk to – this needed to be fairly immediately available, not several weeks past the event. This suggests support needs are time dependent.

2. Format of group and covid-19

She had a lot of practical considerations – community centre and need for parking etc.

She didn't comment on the loss of the opportunity to chat 1:1 on Zoom compared to in-person meetings. The buddy system would provide an opportunity for that 1:1 interaction, so does she see the 1:1 need as being a more formal relationship with more privacy and time than a friendly chat at a meeting? She did enjoy the talks and education, says these were her main source of benefit (despite claiming a bigger knowledge base than others), but does feel a buddy is important, so there were two clear and different aspects to a support group for her. Does therefore a support group need to offer both these aspects to meet more people's needs?

3. Involvement of HCPs

Ann enjoys the talks so the formal education role was appreciated. She did say it was important to have HCP input as clinical supervision, although I'm aware I introduced this term. She used the term 'moderate'. I discussed with the PPI group whether feeling HCP involvement was important was down to having an old-fashioned 'Dr knows best' sort of understanding of health, but they felt not; they interpreted this that Ann supports the group being patient-led, but needing some professional oversight.

Felix - interviewed 02/06/21

I found this a difficult interview because I knew the participant's history fairly well and we'd met clinically on a number of occasions, including at very difficult periods of his journey living with an ICD. I had actually expected and prepared for more negativity about his ICD and care team, and in the end was surprised at the amount of faith he appeared to have in me personally. I'd remembered having very challenging conversations with him in the past and wasn't sure how positively he would remember them. Overall I find his positivity towards me and care team in general quite intriguing as he did say he felt let down about having shocks and felt his ICD had been set up wrong. Perhaps he has been able to balance that negative experience against many other more positive ones?

I think interpreting Felix's feelings about his ICD is challenging for me because I do see the situation differently as a HCP – I know and understand why his ICD was programmed as it was and don't believe any mistakes were made or that it went wrong. However I think I was able to listen to Felix's feelings about it without becoming defensive or trying to explain it from an HCP perspective so I think he was able to express his feelings honestly, so it might be useful to discuss his story with non-expert colleagues.

I think his apparent lack of symptoms with VT must make having an ICD and shocks more difficult to accept. In a way, despite technically having a secondary prevention implant and appropriate shocks, does the lack of symptoms make him respond more like he had a primary prevention ICD? I do think it will be helpful for my analysis if I differentiate between primary and secondary prevention patients.

Felix's previous experience of a group (sounds like cardiac rehab) hadn't been enjoyable which will have influenced his feelings about an ICD support group. However I'm not sure that he would be keen on the group regardless of the prior experience; he just doesn't seem interested in other people's experiences and doesn't see that he would find them helpful. It also never seemed to cross his mind that sharing his experience might be helpful to other people. It also didn't cross his mind that maybe his partner would enjoy going, or benefit from it; she expresses more interest in going but more in that she thought it might be helpful for him than seeing benefit for herself.

7.4.3.2 *Coding and analysis*

Excerpts from memos I wrote during the analysis of the qualitative data. I kept different memos for individual codes and for more overarching reflection on the process of coding. I used the One-sheet-of-paper (OSOP) technique to look for patterns in the data.

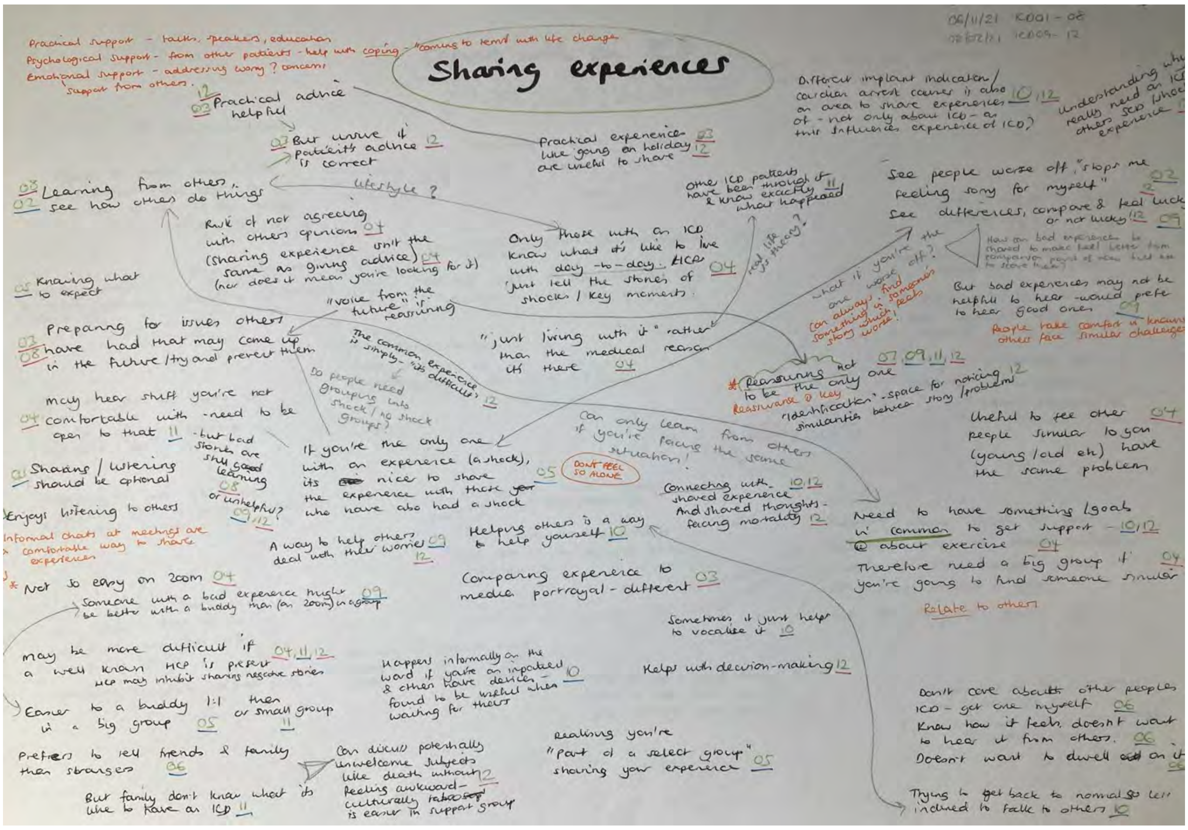
07/11/21 – *sharing experiences*

Started an OSOP (Figure 1) using interviews A-H. There is definitely some variation regarding what is considered useful - Bryan likes to see that others are worse off than him, and Graham finds it reassuring that that's he's not the only one. Caroline and Henry both felt that hearing about problems others people have had may help them prepare for similar scenarios in their future.

However, Ethan found it less helpful when he was the person sharing his shock experience, that he was the only one who had had one in that meeting; he said it would have been nicer if it was truly a shared experience. This raises the question - what if you are the one who is the worst off?

Also I wondered if Ethan's experience suggests it would be helpful to group together people who have had shocks, so they can share and compare experience? It does however sound like the people who haven't had shocks find it really helpful to speak to people who have - for a mix of reasons (feeling better about their own experience [comparing] or preparing/knowing what to expect if it happens to them [learning])

Figure 19: OSOP for the code sharing experiences



22/02/22 – Reviewing codes

I was reading Braun and Clarke's 2021 textbook today about coding, to help me decide whether I was ready to move on from coding to generating initial themes. I was worrying that I'd decided on a rigid coding framework too early which isn't good practice for reflexive TA, but on reviewing the codebooks I've saved and the memos I can see my coding has developed over time.

I grouped my codes together into rough categories (experience of support group, living with an ICD, concerns about ICD, support group practicalities, involvement of care team) to help me easily look for codes when I was coding. I can see if take these categories as themes, I'll be creating topic summaries which aren't the goal of TA, so I think I will remove these now so I more easily search for search meaning in the codes between these groups.

I want to reflect now on what sort of codes I have created - have I coded inductively or deductively, and are my codes semantic or latent? (i.e. how have I coded, and at what level of meaning?)

I think I have mostly coded inductively, so the codes are data-driven and largely descriptive and reflective of what is being said by the participants. But as Braun and Clarke say, my engagement with this data can never be purely inductive as I have experience of working with patients with ICDs and in the support group, so this will always shape what I have noticed in the data. Also, the subjects that are being discussed come about in response to my questions, so for example, considering the code 'frequency of meetings', this is always in response to me asking how often meetings should take place. Therefore I think this code is possibly more deductive as it is researcher-driven and designed to directly answer my research question. But - my research question is about patient experiences, which means an inductive approach using participant's articulated responses as starting point for my coding and themes is appropriate, and I think overall I have mostly coded with an inductive orientation.

Today I considered coding deductively by coding for the stages of Kübler-Ross's five stages of grief. Or I could leave the codes as predominantly inductive, and apply this theory later in the analysis; given the reflection above, I think this is probably the way to go.

So are my codes semantic or latent? I expect they are mostly semantic due to my inexperience. Also when I did the Oxford QRM course I remember them telling us to keep codes quite descriptive and try not to over-analyse at this stage, so I feel this encouraged me to code on a semantic level. However I think a couple of my codes are more implicit and latent; diversity and inclusivity for example. I think Trust in care team is also more latent. Generally I think semantic codes are suitable to help me answer my research questions, so I don't think I need to go back and look for latent codes in my dataset.

Finally I wonder if some of my codes are a little broad and encompass too many different and contradictory meanings; for example, as I found in coping with an ICD yesterday, there seemed to be two meanings within there. And we identified 3 causes for fear when we discussed this within the PPI group - should I split these into different codes? Or should there be a separate code for no fear?

This brings me to consider Braun and Clarke's 'take away the data' exercise; if I lost my dataset, would my codes reflect the richness, diversity and contradictions of meanings contained within the dataset? I'm not sure it does for all codes, and I don't think they give an indication of my analytic take on things, so I will need to look at splitting some codes up and giving them pithier labels. I can see this clearly for the codes I've done OSOPs on (coping with an ICD, sharing experiences, fear) so I think I will carry on with this process for some other of the key codes and refine the codes further before moving on to generate initial themes.

22/03/22 – sharing experiences

Looking at my sharing experiences OSOP and how this reflect the ideas below, and looking for names for these needs in participants words.

Emotional: (stop) feeling sorry for myself

Psychological: Reassuring not to be the only one - take comfort in knowing others face similar challenges - "voice from the future" - "part of a select group"

Informational: Just living with it/learning to live with it

I'm not sure that trying to split it along these lines is useful - am I trying to make my data "fit" an idea, rather than looking at what the data really says? Perhaps I'll sit on that idea for a while...

I suppose a lot of my codes could be split into these areas:

Emotional: fear, worry and uncertainty, trust in care team, thinking about a shock

Psychological: coping with an ICD, sharing experiences, buddying, timing of support

Informational: Learning from talks, professional input, life changes, understanding an ICD

01/04/22 – *sharing experiences*

Looking below, could I code this dataset in more detail into feeling sorry for myself, voice from the future, and learning to live with it? I think if I use these terms which are from the data, rather than calling them emotional, psychological and informational, it will be more meaningful and reflective of the data. I'm starting to wonder if this could become a small theme, so these codes then fit into the central organising concept of sharing experiences , which seems to be an important aspect of how support groups are beneficial. Perhaps meeting the needs of members will become an overarching theme?

Later I added another code voice from the future as I found there was parts of sharing experiences which didn't fit the three codes I chose above. See new 'Candidate themes' memo for more on how this could develop into a theme.

12/05/22 – *sharing experiences*

Not sure what happened but on reviewing my last coding report in February I see I planned to split this into:

1. share and receive empathy and reassurance. *feeling sorry for myself*
2. looking for ideas, how they can learn from others. *learning to live with it*
3. prevent feeling alone. *Not the only one*

These are probably better code names than the ones I chose in italics next to them so I will update these.

Also on reviewing the code, I realised I'd added voice from the future here but I already have a code for seeing your future - but when I looked at the report, there is no crossover! On looking at the seeing your future code, I don't actually see anything useful or different in there, so I think I will remove it.

7.4.3.3 *Generating themes*

02/04/22

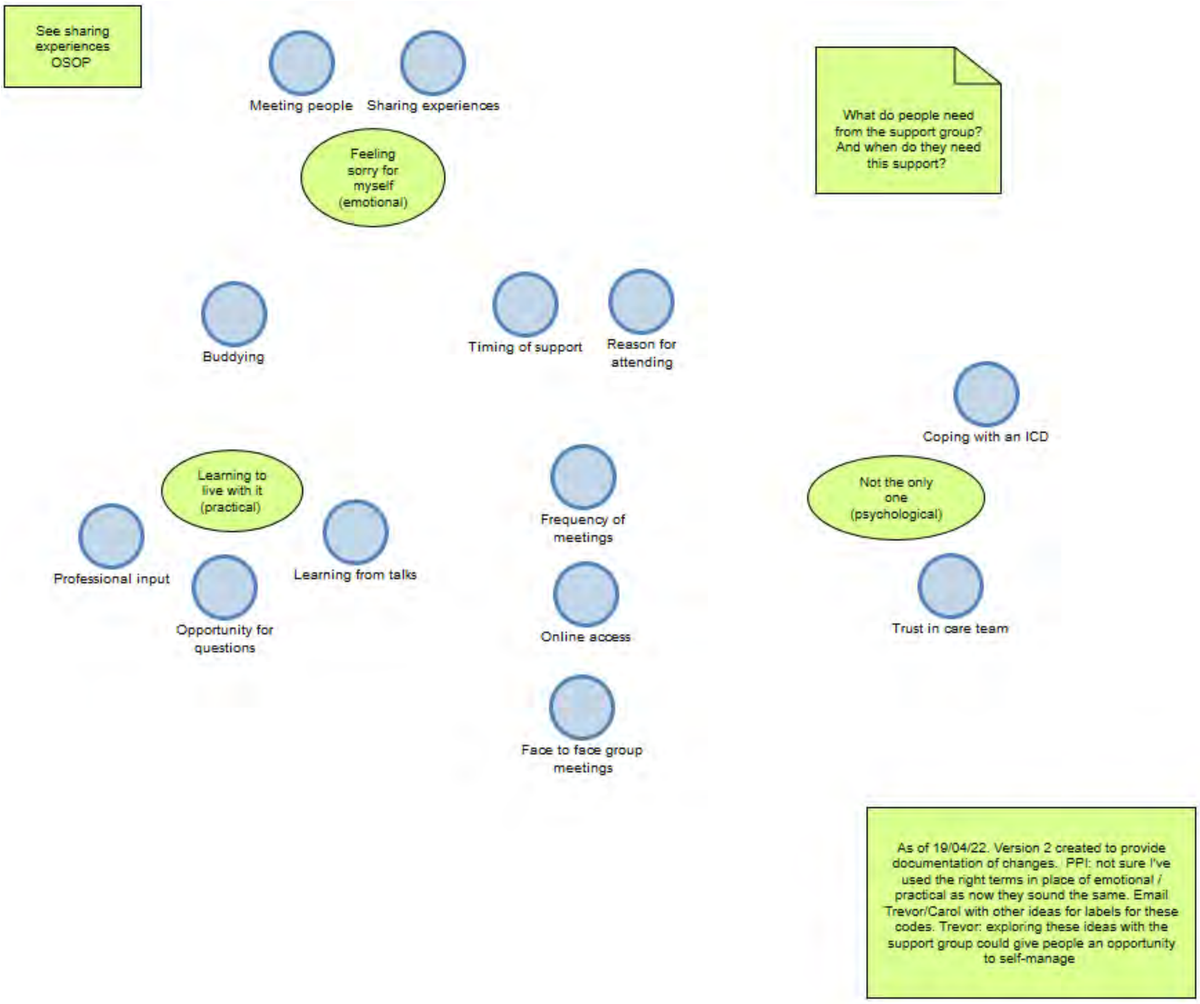
I've been trying to generate candidate themes; I had the idea of *meeting the needs of members* (Figure 2) but I don't think it has a single organising concept. It may be a useful overarching theme? I'm considering *coping through sharing* as a theme as I'm seeing a pattern of people learning to accept their ICD through the sharing of experiences, which I've broken down into a number of codes. Initially I wondered if just *sharing experiences* was the theme in itself, but there was real cross-over between this and *coping with ICD* in terms of learning to live with an ICD. I think it will have more meaning to my research question if I can go a step further in my analysis to explain how the support group is beneficial - i.e. how it can help people cope with their ICD.

I'm not sure yet that this fits with the *accepting an ICD as necessary* code. I think this code is important, something about it is really resonating with me, but I'm not yet convinced that's part of the same story as sharing experiences.

What is going on from the practical side - about the formal talks v sharing, professional input, location etc? Is that all under *meeting the needs of members* too?

....What isn't under *meeting the needs of members*?

Figure 20: meeting the needs of members concept map



What do people need from the support group? And when do they need this support?

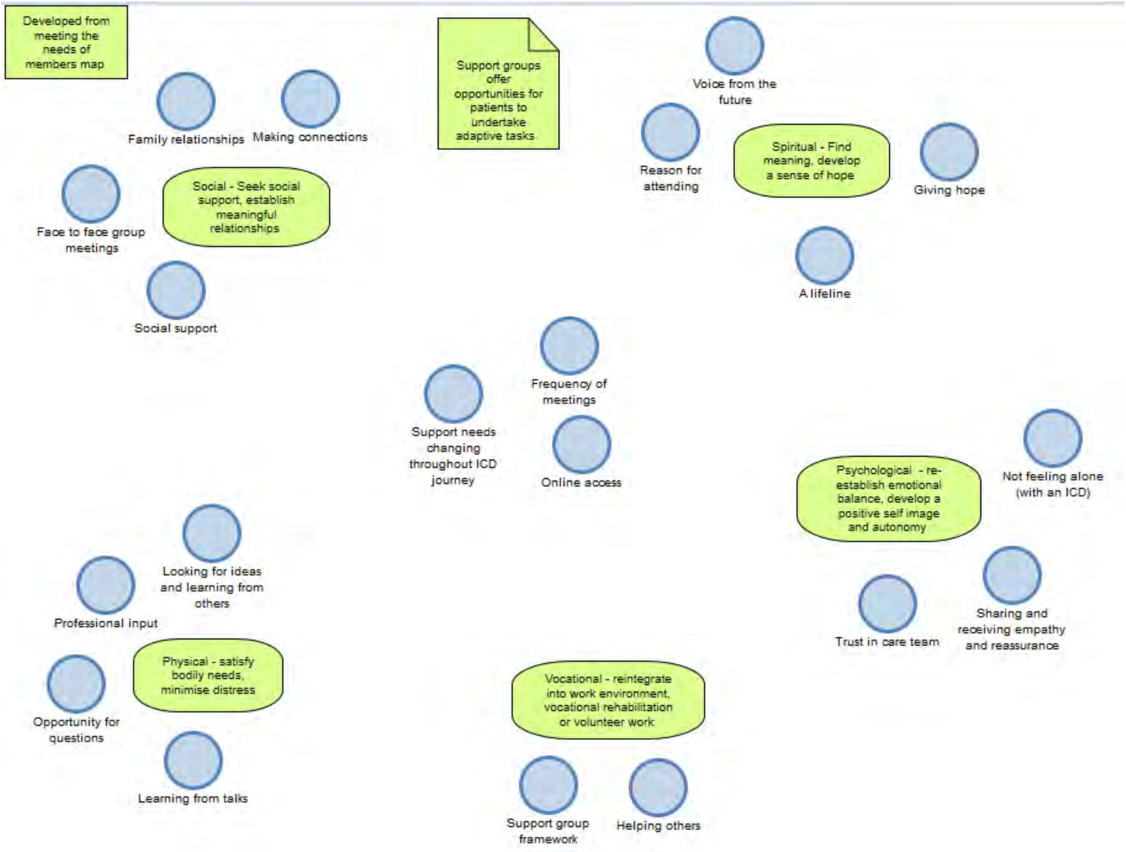
As of 19/04/22. Version 2 created to provide documentation of changes. PPI: not sure I've used the right terms in place of emotional / practical as now they sound the same. Email Trevor/Carol with other ideas for labels for these codes. Trevor: exploring these ideas with the support group could give people an opportunity to self-manage

10/05/22

I was making notes about my research questions and then wondered how I fit these into my candidate themes. Perhaps I need to consider a theme which pulls together the ideas in my reflections about the specific research questions?

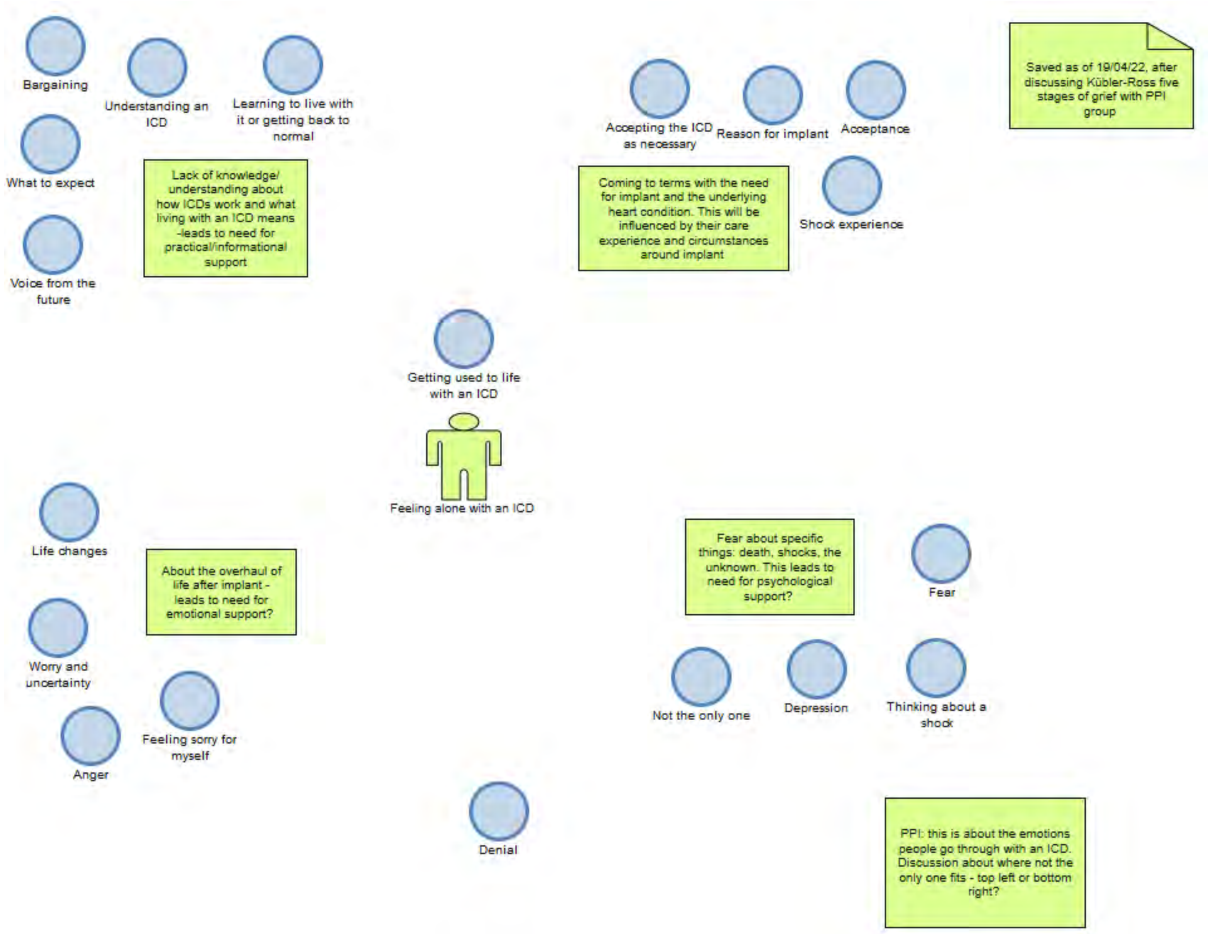
Looking at my concept maps; I've changed *meeting the needs of members* to *support group and adaptive tasks* (Figure 3) which reflects the deductive analysis I've done based on Samson and Siam's paper. As below, I'm still not sure it's a theme - it feels too big and unwieldy.

Figure 21: support group and adaptive tasks concept map



Similarly, *getting used to life with an ICD* (Figure 4) may need splitting up.

Figure 22 Getting used to life with an ICD concept map



Lack of knowledge/ understanding about how ICDs work and what living with an ICD means -leads to need for practical/informational support

Saved as of 19/04/22, after discussing Kübler-Ross five stages of grief with PPI group

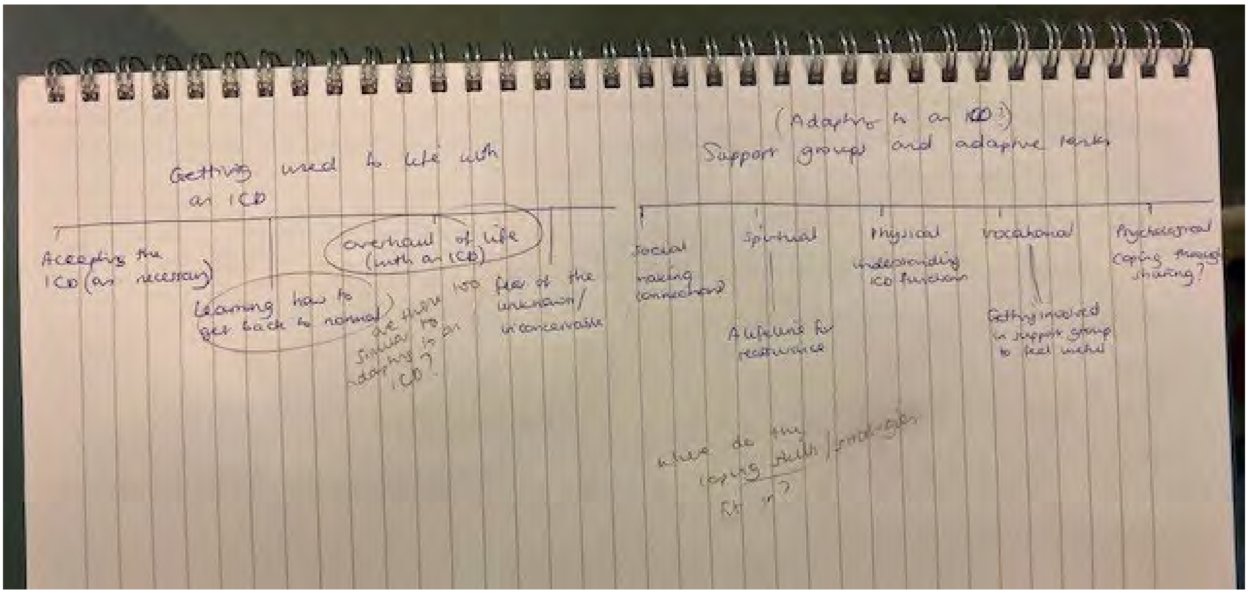
Coming to terms with the need for implant and the underlying heart condition. This will be influenced by their care experience and circumstances around implant

About the overhaul of life after implant - leads to need for emotional support?

Fear about specific things: death, shocks, the unknown. This leads to need for psychological support?

PPI: this is about the emotions people go through with an ICD. Discussion about where not the only one fits - top left or bottom right?

Perhaps these are two overarching themes and they can both be split into sub-themes? I started a brainstorm below as shown below.



02/06/22

Returning to my data after a break. On looking at this again, I ask myself - What's the difference between *Getting used to life with an ICD* and *Adapting to an ICD*? I'm still not convinced I'm really pulling out themes which each tell us something different about the data.

Would *coping through sharing* work as a theme? I think that pulls together some of the specifics about coping in terms of acceptance, but the organising concept here would be the sharing of experiences. Time for a new concept map!

04/06/22

I like *coping through sharing* as a theme. I'm also thinking about *confronting mortality* as a theme; and then I think the theory can be applied to link this back to support groups?

12/06/22

Having completed the OSOP for *life changes* and finding it oddly thin, I wonder if actually is the over-arching theme - does it work better than *getting used to life with an ICD*?

Tried a concept map using *Life changes* and *Adapting to an ICD* as over-arching themes, and then realised really, aren't they the same thing? Aren't they adapting TO the changes? So I'm going to abandon the idea of overarching themes. I don't want to use the adaptive tasks framework as the themes, but I think *confronting mortality* as a theme will work well and bring out that theory.

Then I thought of *coping through learning* as another theme, and this seems to fit and fill the gap, including codes which hadn't applied to the other two themes.

21/06/22

For some weeks I'd been feeling like my analysis was at the tip of my fingers, I knew there was something there but just couldn't quite grasp it. I knew the initial themes I'd developed weren't right, they were too diverse and wide-ranging (or too thin). I felt I knew the story but not the patterns of a central organising concept. Looking at Braun and Clarke's textbook, I'd been in phase 4 (developing and reviewing themes) for a while and was struggling to move on.

Last weekend I had the deadline for the HRC abstract draft and I decided to see what I could put together, and in trying to do that I looked my data and project a bit differently and suddenly the themes fell into place and I could see them and grasped them!

So I've settled on:

Confronting mortality

Patients with ICDs are forced to confront their own mortality, either because they have survived a cardiac arrest or have been told they are at risk of it. They fear death and also fear arrhythmia and shocks as a precursor or escape from to death. There was evidence of patients experiencing each of Kübler-Ross's five phases of grief, however given more recent criticism of her theory, I also explored alternative theories as discussed.

Coping through sharing

Most patients found connecting with other ICD patients beneficial and cited this as reason for attending for the group. They found seeing other patients also struggling with their ICD reassuring to know they aren't alone, and also reassuring to see patients who had got used to their ICD and to see that it is possible to 'get back to normal'. They found hearing other people's experiences of ICD shocks or problems helped them feel more prepared for their future.

Coping through learning

Learning about their ICD was also important to participants and this was another reason for attending the support group. They wanted to understand how their ICD worked and what to expect from it in the future. Having an HCP present at the meeting was important to them as it was felt that their advice was more reliable and they enjoyed formal education sessions and the opportunity to ask questions.

Providing space

The support group environment was key to allow the above processes to occur. While participants found Zoom convenient and recognised that it was necessary during the Covid-19 restrictions, they preferred meeting in person. While it was possible to deliver education over Zoom they found it more difficult to make beneficial interpersonal connections. A community venue with parking and easy access helped them to attend and promoted a relaxed environment. A relaxed environment was seen to make it easier to make connections, to ask questions of HCPs, and gave them more ownership of their lives with ICDs away from the hospital.

I've got a PPI meeting planned for 30 June where I will present these themes and we can choose the best quotes to illustrate them. I will also ask if they feel there is anything important in the data which has not been captured here.

For writing up, the concept maps for each of these are really helpful.

7.4.3.4 *Mobilising theory*

19/04/22 – mobilising theory draft

I employed Kübler-Ross' theory of five stages of grief from her seminal 1969 work "On Death and Dying" (Kübler-Ross, 1969). The theory states that there are five phases to the grieving process: denial, anger, bargaining, depression, and acceptance (popularly known as DABDA). These stages are not passed through in a linear journey, but patients may move between phases multiple times.

Kübler-Ross was a pioneering psychiatrist who dedicated her career to improving care for dying patients. Her 1969 book presented the five stages of grief model which she had developed after interviewing over 200 terminally ill patients. The model focussed on the grieving experience of the patient who was facing their own death, rather than that of the family. Kübler-Ross explains how humans cannot conceive of their own death, and how the five stages are the process by which a dying patient can conceive of and accept their coming death.

It was the concept of humans being unable to conceive of their own death which drew me to this theory. My participants had told me how they had survived cardiac arrests, feared their own deaths, and feared having a shock from an ICD because of what that meant (they had a life-threatening arrhythmia). It seemed to me that, although they were not dying in the immediate sense, they were having to consider their own death and grieving in the same way in order to accept their diagnosis and need for a life with an ICD. This could explain why patients access a support group and an awareness of these grieving stages could improve what support is offered, as support is accessed during specific stages (most often during the bargaining and depression stages). As far as I'm aware, this theory has not been applied to ICD patients and this offers a unique insight into their experiences.

I employed this theory during the analysis stage of my research. The interviews were undertaken without knowledge of this theory and without questions designed to highlight any specific stages. I initially inductively coded the transcripts and began analysis, before deciding to apply this model. I then deductively coded for the five stages of grief, and presented this to a PPI group. They felt the model worked well and matched their own experiences of living with an ICD.

Applying the five stages of grief model has changed the way I approached the analysis as it provided what had felt like a missing link between having an ICD implanted and attending a support group. It provided a framework which explained why patients found living with an ICD difficult and improved my understanding of their reactions to their situation.

26/04/22

Further reading around Kübler-Ross' stage theory highlighted significant criticism of the stage theory (see Corr, 2019), in that it implies a linear, prescriptive journey through grieving; although Corr acknowledges that this is not how Kübler-Ross described it, it is frequently how the theory is implied. If I do use Kübler-Ross in my analysis, I must ensure I understand and acknowledge the limitations of the theory. Corr also argued that the stage theory was based on Kübler-Ross' observations and not empirically tested or proven. Coming from a qualitative background I'm not sure how important empirical testing of a theory like this is, but it was attempted by Maciejewski et al. (2007), who did support the stage theory of grief (although this applied different stages to Kübler-Ross and participants were the bereaved rather than the dying).

Therefore contemporary theoretical models for coping with dying and adapting to chronic illness were reviewed; Corr suggested some alternatives to the five stages of grief so I will explore these to see if they may be more appropriate to my research: Corr's four areas of task work in coping with dying, Doka's five phases and typical tasks in living with life-threatening illness, and Stroebe and Schut's dual process model. I will read about these three theories, compare and contrast how they fit with my data, so I can justify the chosen theory which I do apply.

Corr (1992) A task-based approach to coping with dying

Four dimensions to coping with dying are outlined: physical, psychological, social, and spiritual. Corr describes what a model should do, including four things: understanding of the dimensions, fostering empowerment, emphasise participation or the shared aspects of coping with dying, and provide guidance for care givers. This links to a criticism of Kübler-Ross which resonated with me: that she describes people's reactions to dying, but offers no guidance on how to deal with it. I wonder then if I can use Kübler-Ross' theory to demonstrate how ICD patients do react with grief or in ways consistent with her theory, and then look to apply another model which explains how a support group provides opportunity to fulfil some of the tasks which help to cope with the ICD.

This may be unnecessarily complicated but although I like some of Corr's task ideas, he doesn't explain the reactions of the patients and why I can apply grief theory to my research. Now I'm reflecting on it, it seems they are almost two different things - Corr suggests they are alternatives which I'd choose between, but do I have to?

Physical: minimising physical distress - I think this links to my practical support needs, and reflects how we in the hospital worry about making the ICD work correctly, but not always good at remembering the whole patient

Psychological: I really like the description of this, in maximising security, autonomy, and richness in living, and I think it reflects well on the experience of ICD patients

Social: "task work in coping with dying is to sustain and enhance interpersonal attachments significant to the person in question." I'm finding this more difficult to fit with my research

Spiritual: encompasses acceptance, self-worth, meaning and purpose in living, and also concerns hope.

It may be worth revisiting my interviews looking for evidence of task work being undertaken in these dimensions?

Doka (1996) Coping with life-threatening illness: a task model

Doka describes phases of illness which match well with my research: my participants have tended to be in the acute or chronic phases. The recovery phase is also relevant as death from cardiac disease is not certain.

Vignettes of patients in each stage are presented to demonstrate different issues individuals may struggle with, with suggestions on how counsellors can assist them in understanding the ways in which they are coping with illness. I'm not sure how this is any better than Kübler-Ross' in terms of 'proving' a model...

The table presenting tasks in each phase may be useful, but my instinct is that I don't like this model!

Adapting to major chronic illness: a proposal for a comprehensive task-model approach (Samson and Siam, 2008)

Reviewed four task-based models, including Corr's. Interestingly Doka's was left out as the author's felt that he attempted to merge task-based and stage-based models, which they feel are mutually exclusive. If I did as discussed above then I would need to work hard to justify this approach.

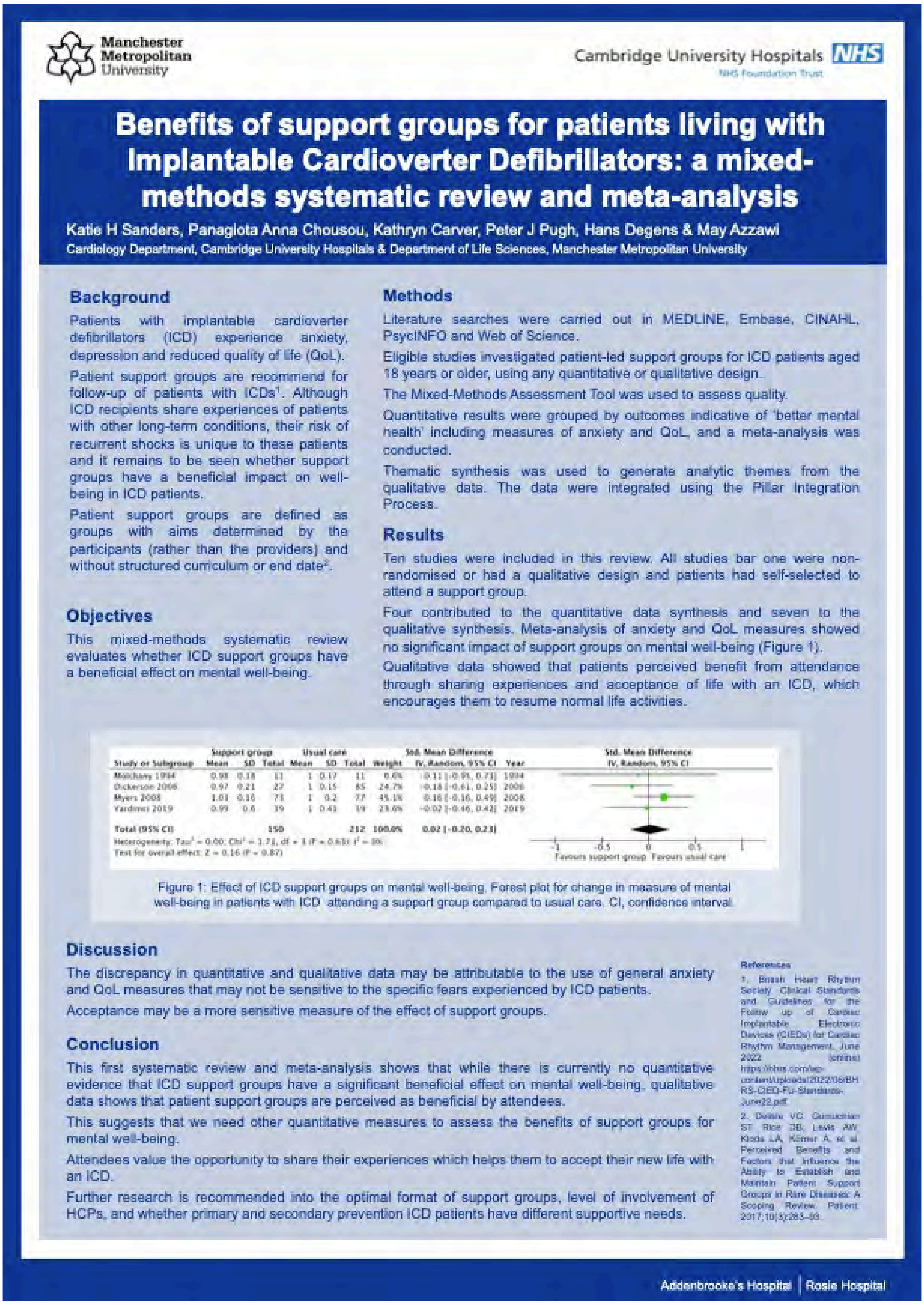
The same four dimensions for tasks (physical, psychological, social, spiritual) are included, as well as vocational, which I think is useful for my patient group. This model is much more comprehensive than Corr or Doka's. My first impression is that I like it and it fits well with my research - I appreciate the more comprehensive model, and the differentiation between adaptive tasks and coping skills.

Stroebe and Schut's dual process model (1999) in end I have decided not to review/include - it is a theory of bereavement, rather than one of dying or coping with illness.

End result: explore how I could apply Samson and Siam's model to my research.

7.5 Output and dissemination

7.5.1 Poster accepted at Heart Rhythm Congress 2022 ‘Benefits of support groups for patients living with Implantable Cardioverter Defibrillators: a mixed-methods systematic review and meta-analysis’



Manchester Metropolitan University

Cambridge University Hospitals NHS
NHS Foundation Trust

Benefits of support groups for patients living with Implantable Cardioverter Defibrillators: a mixed-methods systematic review and meta-analysis

Katie H Sanders, Panagiota Anna Chousou, Kathryn Carver, Peter J Pugh, Hans Degens & May Azzawi
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Background

Patients with implantable cardioverter defibrillators (ICD) experience anxiety, depression and reduced quality of life (QoL).

Patient support groups are recommend for follow-up of patients with ICDs[1]. Although ICD recipients share experiences of patients with other long-term conditions, their risk of recurrent shocks is unique to these patients and it remains to be seen whether support groups have a beneficial impact on well-being in ICD patients.

Patient support groups are defined as groups with aims determined by the participants (rather than the providers) and without structured curriculum or end date[2].

Objectives

This mixed-methods systematic review evaluates whether ICD support groups have a beneficial effect on mental well-being.

Methods

Literature searches were carried out in MEDLINE, Embase, CINAHL, PsycINFO and Web of Science.

Eligible studies investigated patient-led support groups for ICD patients aged 18 years or older, using any quantitative or qualitative design.

The Mixed-Methods Assessment Tool was used to assess quality.

Quantitative results were grouped by outcomes indicative of ‘better mental health’ including measures of anxiety and QoL, and a meta-analysis was conducted.

Thematic synthesis was used to generate analytic themes from the qualitative data. The data were integrated using the Pillar Integration Process.

Results

Ten studies were included in this review. All studies bar one were non-randomised or had a qualitative design and patients had self-selected to attend a support group.

Four contributed to the quantitative data synthesis and seven to the qualitative synthesis. Meta-analysis of anxiety and QoL measures showed no significant impact of support groups on mental well-being (Figure 1).

Qualitative data showed that patients perceived benefit from attendance through sharing experiences and acceptance of life with an ICD, which encourages them to resume normal life activities.

	Support group			Usual care				Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	Year
Molchany 1994	0.98	0.18	11	1	0.17	11	6.6%	-0.11 [-0.95, 0.73]	1994
Dickerson 2006	0.97	0.21	27	1	0.15	85	24.7%	-0.18 [-0.61, 0.25]	2006
Myers 2008	1.03	0.16	73	1	0.2	77	45.1%	0.16 [-0.16, 0.49]	2008
Yardimci 2019	0.99	0.6	39	1	0.43	39	23.6%	-0.02 [-0.46, 0.42]	2019
Total (95% CI)			**150**			**212**	**100.0%**	**0.02 [-0.20, 0.23]**	

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 1.71$, $df = 3$ ($P = 0.63$); $I^2 = 0\%$
Test for overall effect: $Z = 0.16$ ($P = 0.87$)

Figure 1: Effect of ICD support groups on mental well-being. Forest plot for change in measure of mental well-being in patients with ICD attending a support group compared to usual care. CI, confidence interval.

Discussion

The discrepancy in quantitative and qualitative data may be attributable to the use of general anxiety and QoL measures that may not be sensitive to the specific fears experienced by ICD patients.

Acceptance may be a more sensitive measure of the effect of support groups.

Conclusion

This first systematic review and meta-analysis shows that while there is currently no quantitative evidence that ICD support groups have a significant beneficial effect on mental well-being, qualitative data shows that patient support groups are perceived as beneficial by attendees.

This suggests that we need other quantitative measures to assess the benefits of support groups for mental well-being.

Attendees value the opportunity to share their experiences which helps them to accept their new life with an ICD.

Further research is recommended into the optimal format of support groups, level of involvement of HCPs, and whether primary and secondary prevention ICD patients have different supportive needs.

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2. Delisle VC, Gumuchian ST, Rice DB, Levis AW, Kloda LA, Körner A, et al. Perceived Benefits and Factors that Influence the Ability to Establish and Maintain Patient Support Groups in Rare Diseases: A Scoping Review. Patient. 2017;10(3):283–93.

Addenbrooke's Hospital | Rosie Hospital

7.5.2 Poster accepted at Heart Rhythm Congress 2022 "Tomorrow I'm going to die": The role of patient support groups in adapting to life with an Implantable Cardioverter Defibrillator'

Manchester Metropolitan University

Cambridge University Hospitals NHS
NHS Foundation Trust

"Tomorrow I'm going to die": The role of patient support groups in adapting to life with an Implantable Cardioverter Defibrillator

Katie H Sanders, Peter J Pugh & May Azzawi

Cardiology Department, Cambridge University Hospitals & Department of Life Sciences, Manchester Metropolitan University

Background

Patients with ICDs are known to experience psychosocial difficulties such as anxiety and depression.

The British Heart Rhythm Society encourages the use of patient support groups for patients with Implantable Cardioverter Defibrillators (ICDs)[1], however, it is not clear what patients need from a support group or what format they should take to meet these needs.

Objectives

The goal of this study was to understand patient perceptions of attending a support group for patients with ICDs.

Methods

A local support group was delivered in the community and then over Zoom during the Covid-19 lockdowns.

12 ICD recipients were interviewed between December 2020 and November 2021 using a semi-structured interview guide which was based on insights from a literature review.

Reflexive thematic analysis methods were utilised to code the transcripts before generating themes. The interview guide and analyses were co-produced with a patient and public involvement (PPI) advisory group.

Results

Six participants had primary prevention indications for ICD implant, whilst the remaining six were secondary prevention. Three participants had experienced shocks from their ICD. Ten participants had attended the local support group.

Analysis of the data elicited four themes: confronting mortality, coping through sharing, coping through learning, and providing space. A thematic overview is shown in figure 1.

Participants expressed experiences consistent with the five stages of grief described by Kübler-Ross in her work with terminally ill patients[2].

Making connections with other ICD patients, access to information and reassurance, and advice from health care professionals were important perceived benefits of the support group.

Although Zoom was perceived as convenient, participants found it easier to share their personal stories when meeting in person.

When interpreted through the theoretical lens of a task-based model for adapting to chronic illness[3], support groups provide patients with the opportunity to learn and utilise the coping skills required to complete these tasks.

Coping through sharing
- Patient-to-patient communication
- Sharing and receiving empathy and reassurance
- Not feeling alone with an ICD
- Making connections
- Accepting the ICD as necessary
- Worry and uncertainty

Confronting mortality
- Fear of death, shocks and the unknown
- Thinking about a shock
- Five stages of grief
- Giving hope

Coping through learning
- What to expect
- Life changes
- Understanding an ICD
- Opportunity for questions
- Professional input

Providing space
- Support needs changing throughout ICD journey
- Community location is preferred
- Support group framework
- Interpersonal communication is more difficult online

Adapting to life with an ICD

Psychosocial adaptation

Giving information meaning

Time and space for cognitive appraisal

Functional adaptation

Figure 1: Thematic overview

Conclusion / implications for practice

Patients with ICDs may have to confront their own mortality and adapt to considerable life changes after implant.

Support groups should provide a space for interpersonal communication and sharing of experiences as well as health care professional-provided education and advice to maximise their benefit to patients and encourage their continued adaptation to life with an ICD.

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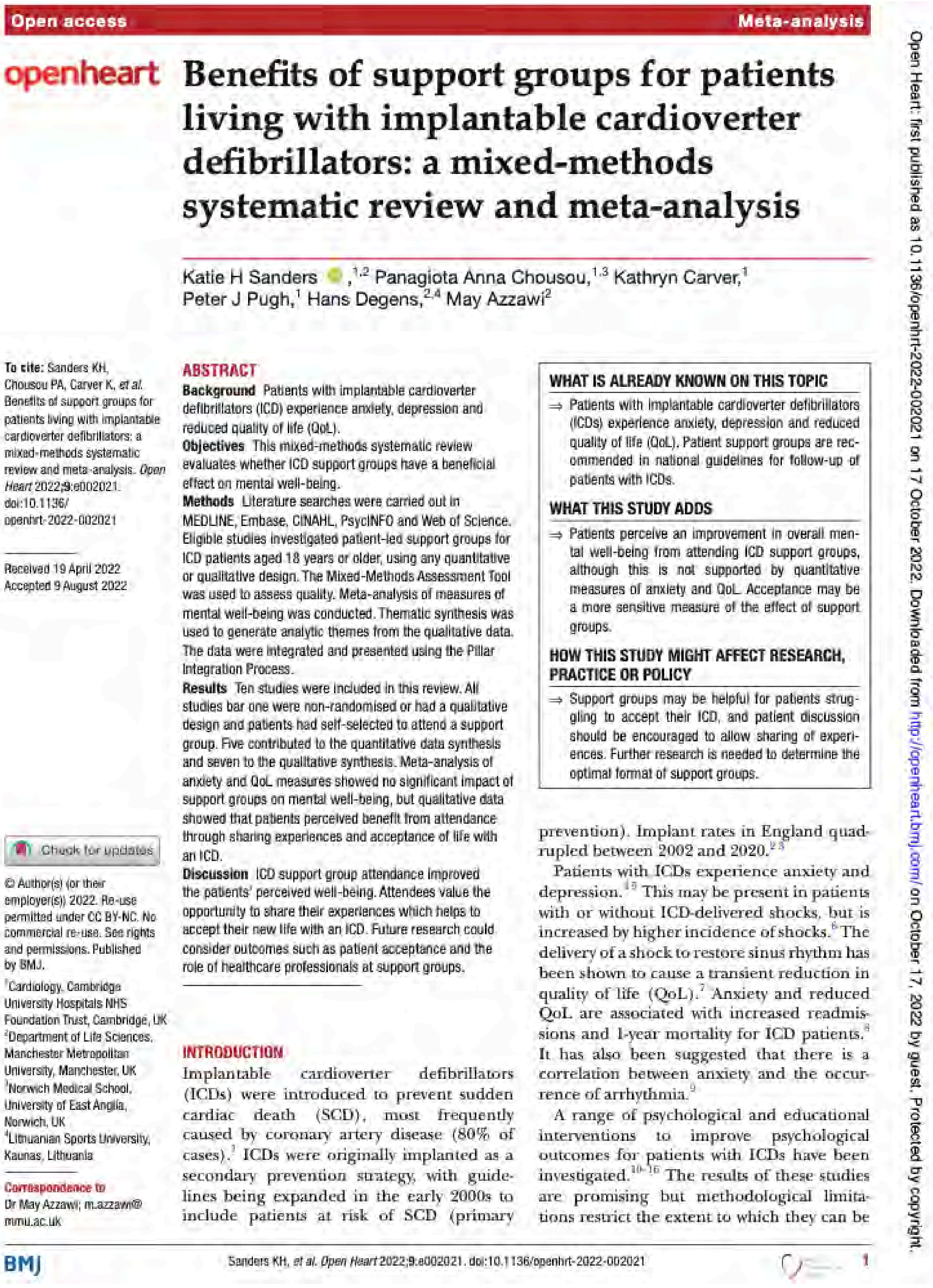

Open access **Meta-analysis**

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Benefits of support groups for patients living with implantable cardioverter defibrillators: a mixed-methods systematic review and meta-analysis

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ABSTRACT

Background Patients with implantable cardioverter defibrillators (ICD) experience anxiety, depression and reduced quality of life (QoL).

Objectives This mixed-methods systematic review evaluates whether ICD support groups have a beneficial effect on mental well-being.

Methods Literature searches were carried out in MEDLINE, Embase, CINAHL, PsycINFO and Web of Science. Eligible studies investigated patient-led support groups for ICD patients aged 18 years or older, using any quantitative or qualitative design. The Mixed-Methods Assessment Tool was used to assess quality. Meta-analysis of measures of mental well-being was conducted. Thematic synthesis was used to generate analytic themes from the qualitative data. The data were integrated and presented using the Pillar Integration Process.

Results Ten studies were included in this review. All studies bar one were non-randomised or had a qualitative design and patients had self-selected to attend a support group. Five contributed to the quantitative data synthesis and seven to the qualitative synthesis. Meta-analysis of anxiety and QoL measures showed no significant impact of support groups on mental well-being, but qualitative data showed that patients perceived benefit from attendance through sharing experiences and acceptance of life with an ICD.

Discussion ICD support group attendance improved the patients' perceived well-being. Attendees value the opportunity to share their experiences which helps to accept their new life with an ICD. Future research could consider outcomes such as patient acceptance and the role of healthcare professionals at support groups.

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Patients with implantable cardioverter defibrillators (ICDs) experience anxiety, depression and reduced quality of life (QoL). Patient support groups are recommended in national guidelines for follow-up of patients with ICDs.

WHAT THIS STUDY ADDS

- ⇒ Patients perceive an improvement in overall mental well-being from attending ICD support groups, although this is not supported by quantitative measures of anxiety and QoL. Acceptance may be a more sensitive measure of the effect of support groups.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ Support groups may be helpful for patients struggling to accept their ICD, and patient discussion should be encouraged to allow sharing of experiences. Further research is needed to determine the optimal format of support groups.

INTRODUCTION

Implantable cardioverter defibrillators (ICDs) were introduced to prevent sudden cardiac death (SCD), most frequently caused by coronary artery disease (80% of cases).[1] ICDs were originally implanted as a secondary prevention strategy, with guidelines being expanded in the early 2000s to include patients at risk of SCD (primary prevention). Implant rates in England quadrupled between 2002 and 2020.[2,3]

Patients with ICDs experience anxiety and depression.[4,5] This may be present in patients with or without ICD-delivered shocks, but is increased by higher incidence of shocks.[6] The delivery of a shock to restore sinus rhythm has been shown to cause a transient reduction in quality of life (QoL).[7] Anxiety and reduced QoL are associated with increased readmissions and 1-year mortality for ICD patients.[8] It has also been suggested that there is a correlation between anxiety and the occurrence of arrhythmia.[9]

A range of psychological and educational interventions to improve psychological outcomes for patients with ICDs have been investigated.[10-16] The results of these studies are promising but methodological limitations restrict the extent to which they can be generalised and applied to clinical practice. At present, UK guidance for ICD follow-up[17] and high-profile cardiac charities[18 19] encourage participation in patient support groups. Patient support groups are defined as groups with aims determined by the participants (rather than the providers) and without structured curriculum or end date.[20] Support groups also provide an option for supportive care using limited healthcare resources.[21]

There are many support groups for patients with chronic conditions such as cancer and heart failure.[22–24] These groups provide benefits for the patients, such as the opportunity to meet and talk with people with the same condition or experiences, and for information provision and exchange.[22–24] Although ICD recipients share experiences of patients with other long-term conditions, their risk of recurrent shocks is something unique to these patients and it remains to be seen whether support groups also have a beneficial impact on well-being in ICD patients.

The objectives of this mixed-methods systematic review are to: (1) evaluate the effectiveness of patient support groups on mental well-being in patients living with ICDs using a meta-analysis and (2) define the perceived benefits and challenges of attending a support group, using a qualitative synthesis.

METHODS

Design and registration

This mixed-methods systematic review was prospectively registered (PROSPERO: CRD42021262058) and reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.[25]

Inclusion criteria

Participants

The patients in the studies had to be 18 years or older and have had an ICD implanted, including single or dual, or biventricular devices.

Comparators

To be defined as a patient support group, it must have (1) aims determined by the participants rather than the providers and (2) no structured curriculum with a defined beginning or end. This definition of a patient support group is that used in a published scoping review.[20] Involvement of healthcare professionals (HCPs) to provide education was permitted provided the objectives of the group were patient-led. Forms of HCP-led psycho-social support, including cognitive behavioural therapy, exercise programmes and psycho-educational interventions with a clear curriculum and set duration were excluded. The comparison was standard care of the ICD without attendance of a support group.

Outcomes

For quantitative studies the main outcomes were selected a priori and are 'changes in measures of mental well-being'. The definition of 'mental well-being' is complex but it is widely understood to mean more than simply absence of mental illness and includes the ability to cope with stressors and work productively.[26] We chose to include measures of QoL, anxiety and depression as outcomes which are aspects of mental well-being. Instruments to assess these outcomes included general (ie, State-Trait Anxiety Index) and ICD specific (ie, Florida Shock Anxiety Scale (FSAS)) measures. QoL measures included but were not limited to the Short-Form 36 (SF-36) and the Quality of Life Index (QLI). 'Social support' was added later in the analysis as it was frequently measured. For qualitative studies, the outcomes were anxiety, depression, QoL, benefits and challenges of attending support groups.

Table 1 Medline search strategy

1	(((single or dual or biventricular) adj defibrillator*) OR implantable cardioverter defibrillator OR implantable defibrillator* OR implantable cardioverter-defibrillator*)	14 581
2	Defibrillators, Implantable/	17 403
3	1 OR 2	22 459
4	(support group* OR peer support OR peer counselling OR self-help group* OR self help group* OR education* support OR psychosocial support OR patient mentor*)	25 883
5	Self-Help Groups/	9314
6	4 OR 5	25 883
7	3 AND 6	43

Types of evidence

A range of study designs, including quantitative, qualitative and mixed-methods designs, were included to allow for review of the totality of existing evidence.

Search strategy and screening

Five databases were searched in July 2021. The initial search strategy was developed for MEDLINE (see table 1) and adapted for Embase, CINAHL, PsychINFO and Web of Science.

A search filter was used to include all papers published from January 1980 until July 2021. A search of grey literature included hand searches of conference abstracts between 2019 and 2021 (British Cardiovascular Society and Heart Rhythm Congress). Reference lists of included articles were searched for potential eligible papers. Non-English language articles were excluded. KHS screened all records by title before two authors (KHS/PAC) screened potentially eligible abstracts and full-texts. Where there was disagreement, a third reviewer's (MA) opinion was sought.

The database search was repeated in July 2022 to check for new publications. No eligible papers were identified.

Quality assessment

The Mixed-Methods Assessment Tool (MMAT)[27] was used by two independent reviewers (KHS and PAC/KC) to assess quality and risk of bias. The MMAT was designed to appraise the methodological quality of five categories of studies (qualitative research, randomised controlled trials, non-randomised studies, quantitative descriptive studies and mixed-methods studies), and was therefore chosen as the most suitable tool for the current study due to the methodological variety of studies included.

Data extraction and analysis

KHS extracted the design, population, sex, age, comparator, outcome measures, instruments used and key findings from the included articles. Quantitative results were grouped by outcomes indicative of 'better mental well-being' including measures of anxiety and QoL. A meta-analysis using pooled outcome measurements was conducted using Review Manager V.5.4.[28] This approach has been used in other published studies.[29 30] To allow comparison of data from different instruments, mental well-being data of each parameter was normalised to the average control value for that parameter. Where multiple measures were used in a study, a single parameter was chosen for the analysis with preference to measures of anxiety over generalised QoL. Adjusted data were pooled to calculate weighted standardised mean difference and 95% CIs. Overall effect was calculated using a Z-test.

Qualitative results were uploaded verbatim to NVivo V.11 and thematic synthesis methods[31] used to generate themes. KHS deductively coded for anxiety and depression, and quality of life, and developed inductive codes around perceived benefits and challenges of attending support groups. The quantitative and qualitative data were then integrated and are presented in a joint display using the Pillar Integration Process (PIP).[32] A mixed-methods systematic review using the PIP was chosen as the PIP permits grouping of outcomes based on conceptual ideas, rather than the quantity of each item or the research methods used.[32]

Patient and public involvement

The results of this study were disseminated to members of a Patient and Public Involvement group.

RESULTS

Study characteristics

From 456 records identified, 10 papers were eligible for inclusion (figure 1). Most records were excluded because they did not include a support group. Two studies were excluded because the support group intervention was restricted to a set period and therefore had a set curriculum.[10 33] Tables 2 and 3 include the summary characteristics and results for the 10 studies: one randomised controlled trial (RCT),[34] two observational studies,[35 36] two mixed-methods studies,[37 38] four qualitative studies[39–42] and one service evaluation.[43]

One study was based in Australia[42] and one in Turkey.[34] The remainder were from the USA. In all studies the support group attendees were predominantly male (range 53%–91%). The support groups varied considerably in terms of attendee age, format and frequency (table 4).

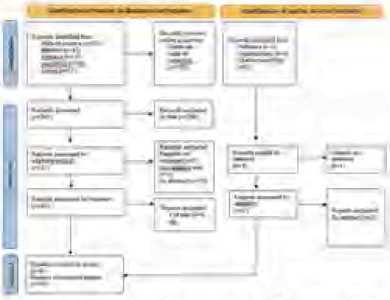

Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 flow diagram.

Four papers[34–37] contributed to the quantitative synthesis and were used in the meta-analysis for mental well-being (figure 2). Three of the four reported the mean value of age of attendees but one[37] reported only a range. We contacted the authors for this information, but the raw data was no longer available.

Seven papers[37–43] contributed to the qualitative synthesis. The data from the two mixed-methods studies were extracted and analysed as separate quantitative and qualitative data because quality assessment indicated the rationale for, and integration of, mixed methodology was poor as indicated by the MMAT (table 5). Table 5 shows how each study was appraised using the relevant questions to the category of study. Higher quality is indicated by higher proportion of positive responses to the questions. Overall, the more recent qualitative studies were of better quality than those published prior to 2000. Quantitative studies included in our meta-analysis had satisfactory quality, answering 'yes' to six out of seven questions.

Integrated synthesis of quantitative and qualitative data are shown in table 6, where priority was given to studies with better quality ratings as determined by the MMAT (table 5).

Quantitative analysis

Anxiety and depression

Three studies[34 36 37] measured anxiety using validated instruments: State Trait Anxiety Inventory, Visual Analogue Scale-Anxiety (VAS-A) and FSAS. No quantitative data on depression was found. Only two studies[34 37] measured the effect of support groups on anxiety over time; neither demonstrated a significant difference between support group attendees and non-attendees. Anxiety measured by the FSAS decreases over time in all groups.[34] There was an increase in anxiety over time measured by the VAS-A, but no change in state anxiety.[37]

Support group attendees tended to be more anxious than non-attendees in observational studies.[36 37]

Table 2 Summary of characteristics and results from included quantitative studies

Author country	Research aims	Research design	Sample characteristics	Outcome measures	Instruments	Key results	Key findings
Yardimci and Mert[24] Turkey	To compare shock-related anxiety and quality of life in those who access a web-based intervention programme and those receiving usual care	Quantitative randomised, single blind controlled trial	Randomised sample (76 participants) with ICDs>18 years, being able to use computer and internet, able to understand and speak Turkish. Neurological and psychiatric disorders excluded. Intervention: 82.1% male, mean age 46.2 years. Control: 75.7% male, mean age 50.9 years	Collected at 3 time points (baseline, 3 months, 6 months): ICD shock-related anxiety, QoL	Florida Shock Anxiety Scale (Turkish version) and Short Form Health Survey (SF-36, Turkish version)	Mean FSAS at baseline: intervention 14.56, control 17.37 (p=0.207). Mean FSAS after 6 months: intervention 13.30, control 16.78 (p=0.083)	Shock-related anxiety↓over time; no significant difference between intervention and control groups. No significant difference was found in the mean mental or physical summary component score of the SF-36, but significant differences were seen in subdimensions of social functioning, role-physical, mental health, vitality and bodily pain
Myers and James[illegible] USA	To compare demographics, ICD-related characteristics, anxiety and social support in those who attend a patient support group and those who do not. To investigate the relationships between reason for ICD implant, anxiety and social support	Quantitative non-randomised: observational	Convenience sample (150 participants) 50–80 years, first ICD implant, no battery changes, intact cognitive status, able to read, write and understand English. Attendees: (73 participants) 75.3% male, mean age 67.7 years. Non-attendees: (77 participants) 84.4% male, mean age 68.4 years	Social support, anxiety. Collected at single time point	Sarason's 6-item Social Support Questionnaire, State-Trait Anxiety Inventory	Mean state anxiety: attendees 35.21, non-attendees 33.1 (p=0.23). Mean trait anxiety: attendees 37.01, non-attendees 33.36 (p<0.05). Mean satisfaction with social support: attendees 32.03, non-attendees 33.77 (p=0.03)	Groups differed on level of education and household income, and reason for implant. Those attending support group had ↓satisfaction the social support and ↑trait anxiety than non-attendees. Irregular tachycardia associated with higher trait anxiety. Satisfaction with social support has a negative relationship with anxiety. Satisfaction with support has a positive relationship with social network
Dickerson *et al*[illegible] USA	To compare demographics, ICD-related characteristics, social support and quality of life in those who attend a patient support group and those who do not To investigate the relationship between demographic and clinical factors and QoL	Quantitative non-randomised: observational	Convenience sample (328 surveys mailed, 112 returned: 34% response) of all patients who received ICD at a single centre over 10-year period. Attendees (27 participants) 79% male, mean age 61.8 years. Non-attendees (85 participants) 79% male, mean age 63.2 years	QoL, social support, demographics. Collected at single time point	Ferrans and Powers' Quality of life index (QLI:CV). No instrument used for social support	QLI: attendees mean 23.7, non-attendees 23.0 (p=0.77)	No significant different in QLI scores between attendees and non-attendees of support group. Support group attendance was associated with higher level of education, higher ejection fraction, higher number of supports and value of supports. Age and frequency of shocks were not related to QoL. Comorbidity is related to QoL
Molchany and Peterson[27] USA	To compare anxiety and social functioning in those who attend a patient support group and those who do not	Mixed-methods (qualitative+quantitative non-randomised)	Convenience sample (26 participants) of those able to attend support group and willing to attend monthly group meeting for 9 months. ICD recipients (11 participants) 91% male, age range 56–75 years. Significant others (10 participants) 10% male, age range 51–80 years. Non-attendees (5 participants) 80% male, age range 51–75 years	Collected at 2 time points (baseline, 9 months attendees only): Anxiety, social functioning and adaptation, demographics	Anxiety Visual Analogue Scale (VAS), State Anxiety Index, Medical Outcomes Study (MOS) short-form general health survey	Mean state anxiety at baseline: attendees 36.4, non-attendees 33.8. Mean state anxiety after 9 months: attendees 34.8 (p=0.399). Mean VAS at baseline: attendees 20.55, non-attendees 22.5. Mean VAS after 9 months: attendees 34.22. MOS data incomplete	Anxiety scores did not vary significantly between attendees and non-attendees (both groups were in the normal range), nor did they decrease between time points. No significant difference in social functioning between attendees and non-attendees at baseline. Time point 2 data incomplete and not reported

Continued

Table 2 Continued

Author country	Research aims	Research design	Sample characteristics	Outcome measures	Instruments	Key results	Key findings
Serber *et al*[47] USA	To examine the acceptability of online and interactive nurse-facilitated support groups for the in-person participants	Mixed-methods (qualitative descriptive+quantitative descriptive)	Convenience sample (46 participants) of support group attendees. No exclusions. ICD recipients (29 participants) 62.1% male. Caregivers (17 participants) 11.8% male. Exact age not collected. 81% of participants were >60 years	Acceptability of format to in-person attendees. One time survey	Self-report questionnaire to measure satisfaction developed for this study. 8 5-point Likert-style questions	Overall satisfaction with the group format: 63% very satisfied, 28.3% somewhat satisfied, 2.2% neither satisfied or dissatisfied, 0% somewhat dissatisfied, 6.5% very dissatisfied	High acceptability of the webcast and group format

FSAS, Florida Shock Anxiety Scale; ICD, implantable cardioverter defibrillator; MOS, Medical Outcomes Study; QLI:CV, quality of life index: cardiovascular; QoL, quality of life; VAS, Visual Analogue Scale.

Attendees had significantly higher trait anxiety than non-attendees,[36] although this was not significant for state anxiety.[37]

Quality of life

QoL was measured in two quantitative studies using the SF-36[34] and QLI.[35] Neither study recorded a significant difference in overall summary scores between support group attendees and non-attendees. There was significant improvement in specific subscales of the SF-36 (social functioning, role-physical, mental health, vitality and bodily pain) in support group attendees.[34] Age and frequency of shocks were not related to QLI, however, greater comorbidity was found to correlate with reduced QoL.[35]

Social support

Social support was not identified as an outcome a priori for this review but was measured in three quantitative studies[34 36 37] and was seen in the qualitative data; it was therefore included in the analysis to assess whether this contributes to the benefit of support groups.

Social support was measured using Saracon's 6-item Social Support questionnaire,[36] in sub-dimensions of the Medical Outcomes Study survey[37] and SF-36.[34] Support group attendance was associated with lower satisfaction with social support.[36] However, a descriptive study found support group attendees experienced a higher level and value of support than non-attendees.[35] There was no difference between groups in social functioning,[34 37] where social functioning increased over time in both groups in an RCT.[34]

Effect of support groups on mental well-being

The effect of support groups on mental well-being was examined by normalising anxiety and QoL outcomes to the average control value (Fig. 2). The absolute data used in this meta-analysis are shown in Table 7. The standardised mean difference between intervention and control groups was 0.02 (95% CI −0.2 to 0.23). The support group attendees scores were not significantly higher than the control group average, z=0.16, p=0.87, indicating that attending support groups had no significant effect on mental well-being for patients with ICDs.

Qualitative analysis

Anxiety and depression

Patients reported that fear of death and of ICD shocks were the source of their anxiety.[37 39–41 45]

> Knowing a stick of dynamite may go off at anytime and you have little warning, is a head game you are invited to participate in each morning when you wake up. (39, p161)

Attending a support group helped them to control their fear and anxiety through knowledge acquisition and decision-making skills, including making contingency plans.[39] Patients also felt that positive role modelling

Table 3 Summary of characteristics and results from included qualitative studies

Author country	Research aims	Research design	Population	Outcome measures	Instruments	Key findings
Molchany and Peterson[37] USA	To describe the incidence of group members sharing feelings and experiences and offering social support to other group members	Mixed-methods (qualitative+quantitative non-randomised)	Convenience sample (26 participants). ICD patients and their significant others, able to attend support group and willing to attend monthly group meeting for 9 months. ICD recipients (11 participants) 91% male, age range 56–75 years. Significant others (10 participants) 10% male, age range 51–90 years. Non-attendees (5 participants) due to illness/travel restrictions as comparison group: 80% male, age range 51–75 years	Incidents of sharing and emotional support	Notes or tape recordings of leader's accounts of the meeting	Qualitative data highlighted need for gender specific education and support
Serber *et al*[38] USA	To examine the acceptability of online and interactive nurse-facilitated support groups for the in-person participants	Mixed-methods (qualitative descriptive+quantitative descriptive)	Convenience sample (46 participants) of support group attendees. No exclusions. ICD recipients (29 participants) 62.1% male. Caregivers (17 participants) 11.8% male. Exact age not collected. 81% of participants were >60 years	Acceptability of format to in-person attendees. One time survey	Self-report questionnaire to measure satisfaction developed for this study with 2 open ended questions	Themes: (1) Gaining information and interaction, (2) benefiting others and accessibility, (3) gaining support and education
Williams *et al*[42] Australia	To describe the experiences, concerns and needs of ICD recipients and family caregivers.	Qualitative exploratory descriptive	Purposive sampling (22 participants) of ICD recipients from a single centre, >18 years, able to speak, read and understand English or be able to respond through an interpreter. ICD recipient (11 participants) 73% male. Caregivers (11 participants) 18% male. Exact age not collected. 18% of participants were >60 years. In each group there were 6 attendees and 5 non-attendees	Experiences of living with an ICD. Experiences of attending a support group	Semi-structured interviews face-to-face or telephone	Four themes focussing on reasons why participants attend or do not attend support groups. Themes: (1) providing information, (2) connecting with others, (3) helping others, (4) attendance
Dickerson *et al*[40] USA	To explore the lived experience of help seeking in a support group for recipients of ICDs and their support persons	Qualitative Heideggarian hermeneutic phenomenology	Convenience sample (24 participants) of support group attendees. No exclusions. ICD recipients (15 participants) 60% male, mean age 65 years. Support persons (9 participants) 44% male, mean age 67 years	Lived experience of attending an ICD support group	Focus groups and semi-structured interviews	Themes and constitutive pattern: (1) hearing and telling stories, (2) triggers that encourage seeking help from group, (3) meaningful information, (4) group camaraderie as therapeutic friendship, (5) importance of a facilitator (6) support persons' similar view. Constitutive pattern: coping with the possibility of death

Continued

Table 3 Continued

Author country	Research aims	Research design	Population	Outcome measures	Instruments	Key findings
Dickerson *et al*[41] USA	To explore the common themes and shared meanings of internet discussions on an informal public electronic bulletin board for persons with ICDs	Qualitative Heideggarian hermeneutic phenomenology	75 users of an online bulletin board for persons with ICDs (55 ICD recipients, 5 family caregivers, 15 others including doctors, nurses and friends). 30 users gender identified, 53% male. 25 users age identified, mean age 42.6 years	Frequency of postings, content of postings	Observation and collection of fifteen months of postings on the public bulletin board	Themes and constitutive pattern: (1) seeking and giving meaningful information, (2) sharing personal perspectives, (3) storytelling as common grounding, (4) supportive teaching. Constitutive pattern: therapeutic connection
Dickerson[70] USA	To explore the practical knowledge gained from internet use by implantable cardioverter defibrillator (ICD) recipients	Qualitative Heideggarian hermeneutic phenomenology	Convenience sample (13 participants) of ICD recipients who were members of the online community. 70% male, mean age 41.2 years	Experience of seeking online support	Online virtual focus group and follow-up email interviews	Themes and constitutive pattern: (1) getting past fear with knowledge and support, (2) gaining context through a window into the future, (3) internet as a mountain of information: a goldmine of ICD knowledge, (4) internet as social interaction, (5) becoming informed consumers. Constitutive pattern: gaining a context for a healthy life with an ICD
Teplitz *et al*[42] USA	To describe the development of a support group for ICD recipients and their families	Service evaluation	34 ICD recipients returned questionnaire prior to group set-up. Informal feedback collected from patients and families at support group meetings. Gender data not recorded. Age range of attendees 21–77 years	Experiences of developing and facilitating a support group	Brief questionnaire—no detail of content. Observation of group and recording of informal feedback by facilitators	Questionnaire indicated high interest in support group attendance (88% indicated they would attend). Describes common themes for patient concerns (fear of shock, travel, driving, adapting to new family role), facilitator strategies to maintain group cohesion, perceived benefits by patients (sharing experiences, feeling connected)

ICD, implantable cardioverter defibrillator.

Table 4 Assessment of heterogeneity of support group attendees, format and frequency

Author country	Support group attendee age (years)	Support group attendee gender (% male)	Support group location	Support group format	Support group meeting frequency
Yardimci and Mert[34] Turkey	Mean 46.2	82.1	Online	Living with an ICD website. Education modules available. Patients able to initiate and respond to web-based discussions	Continuously available
Myers and James[36] USA	Mean 67.7	75.3	In person	10 different in-person support groups utilised, all led by facilitator with ICD expertise, lasted at least 2 hours, with educational and support component	Range 4–10 per year
Dickerson *et al*[35] USA	Mean 61.8	79	In person	In-person group meeting facilitated by a cardiac nurse specialist, consisting of open discussion and sharing, followed by a question-and-answer session	12 per year
Molchany and Peterson[37] USA	Range 56–76	91	In person	In-person group meeting led by a psychiatric clinical nurse and a cardiac clinical nurse specialist	12 per year
Serber *et al*[38] USA	81%>60	62.1	In person and online	Group meeting held in-person and simultaneously cast on the internet with remote attendees. Guided by nurse facilitator and structured to provide education and support	12 per year
Williams *et al*[42] Australia	18%>60	73	In person	In-person group meeting consisting of education, question time and opportunities for participants to share	2 per year
Dickerson *et al*[40] USA	Mean age 65	60	In person	Group meeting facilitated by cardiac nurse specialist, consisting of open discussion and sharing, followed by question-and-answer session	12 per year
Dickerson *et al*[41] USA	Mean 42.8 (incomplete data)	53 (incomplete data)	Online	On-line, informal, public electronic bulletin board	Continuously available; live chat meeting 2 per week
Dickerson[39] USA	Mean 41.2	70	Online	Online community website providing newsletters, bulletin board, live chat, FAQs, ICD news and research data	Continuously available
Teplitz *et al*[43] USA	Range 21–77	N/R	In person	Support group meeting facilitated by ICD nurse, cardiac nurse and expert group facilitator. Includes presentations and Q&A session	6 per year

ICD, implantable cardioverter defibrillator; Q&A, question and answer.

and sharing of experiences within the group helped to manage depression.[40 41]

> I need to turn to a source where I find comments, questions, fears, joys, whatever, also shared by me, that indicate I'm normal to this select group. (41, p253)

Patients experienced dependency and low self-esteem post implant,[37] affecting relationships[43] and preventing acceptance of their ICD.[41] Encouragement from other group members to resume normal life activities helped patients manage their depression.[37 43]

Figure 2 Effect of ICD support groups on mental well-being. Forest plot for change in measure of mental well-being in patients with ICD attending a support group compared to usual care. CI, confidence interval.

Quality of life

Patients found that the support group helped them find ways to live with their ICD and deal with their limitations.[39 40] Attending the group improved their knowledge and understanding of the device,[39–42] which in turn led to a return to 'normal' life and activities.[37 43]

Social support

Patient support groups provide a social setting which allow new friendships to form.[40 42] Patients reported difficulties with existing support as family and friends do not understand their experiences.[41–43] Social bonding in the support group provides a setting for humour regarding ICDs,[39] that was found to facilitate healing and coping.[40]

> There were comical things that happened, one guy was holding his dog when it [ICD] went off and for a

Table 5 Quality assessment using the Mixed-Methods Appraisal Tool

Author	Q1	Q2	1.1	1.2	1.3	1.4	1.5	**For all:**	Q1: Are there clear research questions?
Molchany and Peterson[37]	Y	Y	N	N	N	N	N		Q2: Do the collected data allow to address the research questions?
Serber *et al*[38]	Y	Y	Y	Y	U	N	U		**Qualitative**
Williams *et al*[42]	Y	Y	Y	Y	Y	Y	Y		1.1. Is the qualitative approach appropriate to answer the research question?
Dickerson *et al*[40]	Y	Y	Y	Y	Y	Y	Y		1.2. Are the qualitative data collection methods adequate to address the research question?
Dickerson *et al*[41]	Y	Y	Y	Y	Y	Y	Y		1.3. Are the findings adequately derived from the data?
Dickerson[39]	Y	Y	Y	Y	Y	Y	Y		1.4. Is the interpretation of results sufficiently substantiated by data?
Teplitz *et al*[43]	N	U	U	U	U	Y	U		1.5. Is there coherence between qualitative data sources, collection, analysis and interpretation?
Author	Q1	Q2	2.1	2.2	2.3	2.4	2.5		**Quantitative randomised controlled trial**
Yardimci and Mert[34]	Y	Y	Y	Y	Y	Y	U		2.1. Is randomisation appropriately performed?
									2.2. Are the groups comparable at baseline?
									2.3. Are there complete outcome data?
									2.4. Are outcome assessors blinded to the intervention provided?
									2.5. Did the participants adhere to the assigned intervention?
Author	Q1	Q2	3.1	3.2	3.3	3.4	3.5		**Quantitative non-randomised**
Molchany and Peterson[37]	Y	Y	Y	Y	Y	N	Y		3.1. Are the participants representative of the target population?
Myers and James[36]	Y	Y	Y	Y	Y	Y	Y		3.2. Are measurements appropriate regarding both the outcome and intervention (or exposure)?
Dickerson *et al*[35]	Y	Y	Y	Y	Y	Y	Y		3.3. Are there complete outcome data?
									3.4. Are the confounders accounted for in the design and analysis?
									3.5. During the study period, is the intervention administered (or exposure occurred) as intended?
Author	Q1	Q2	4.1	4.2	4.3	4.4	4.5		**Quantitative descriptive**
Serber *et al*[38]	Y	Y	Y	Y	U	Y	Y		4.1. Is the sampling strategy relevant to address the research question?
									4.2. Is the sample representative of the target population?
									4.3. Are the measurements appropriate?
									4.4. Is the risk of non-response bias low?

Continued

Table 5 Continued

Author	Q1	Q2	5.1	5.2	5.3	5.4	5.5	4.5. Is the statistical analysis appropriate to answer the research question?
								Mixed-methods
Serber *et al*[38]	Y	Y	U	N	N	Y	U	5.1. Is there an adequate rationale for using a mixed-methods design to address the research question?
Molchany and Peterson[37]	Y	Y	N	U	U	N	N	5.2. Are the different components of the study effectively integrated to answer the research question?
								5.3. Are the outputs of the integration of qualitative and quantitative components adequately interpreted?
								5.4. Are divergences and inconsistencies between quantitative and qualitative results adequately addressed?
								5.5. Do the different components of the study adhere to the quality criteria of each tradition of the methods involved?

Colour used for visual representation of quality: Green, met quality criteria; Amber, unclear if met quality criteria; Red, did not meet quality criteria.
N, No; U, Unclear ; Y, Yes.

> year the dog wouldn't go near him … we had a lot of laughs in there. (40, p92)

Online support groups also provided an opportunity to benefit from this friendship.[39]

Benefits and challenges of attending support groups

Two sub-themes were identified: *sharing experiences* and *support group format*.

Sharing experiences

The opportunity to share and compare experiences of life with an ICD is a key perceived benefit of attending a patient support group.[39 40-42] Hearing that others felt the same about their life with an ICD provided validation of their own feelings,[40] which in turn facilitated healing and acceptance.[42] Attending support groups also provided reassurance and promoted acceptance of their ICD by seeing others lead a 'normal' life and coping with the uncertainty created by their heart condition and device.[39-41 43] Information gained from fellow ICD recipients was more credible than that from healthcare providers, who can talk theory but not from experience.

> After hours of bombarding my HCP with questions, you feel something missing; they know what you have, but they are just not going through it themselves; you need people that you can relate to. (39, p162)

Support group format

There was considerable variation in meeting frequency between the included studies (table 4), and patients reported a preference for at least quarterly meetings.[42] All the in-person support groups were facilitated by HCPs—most often a specialist nurse—and expert speakers to provide education.[36 38 42 43] Not all studies commented on the role of HCPs; only Dickerson *et al* reported the presence of an HCP at in-person meetings as being essential.[40]

Williams *et al* reported that travel time from rural locations was a major barrier to group attendance, while others did not attend as they did not feel in need of support, did not want to be reminded about their ICD, or perceived that they did not fit in the group due to age or sex.[42] Serber *et al* initiated live streaming of in-person group meetings over the internet to address the barrier of attending due to accessibility; in-person attendees found this acceptable, however, the experience of remote attendance was not investigated.[38] Patients reported that the benefits of online support were ease of access,[39] and timing, as online support was available day and night.[41]

DISCUSSION

The findings from our meta-analysis suggest that support groups have no significant effect on objectively measured mental well-being. However, the qualitative analysis suggests that patients do perceive a benefit from support group attendance in terms of managing fears through positive role modelling and accepting life with their ICD.

Table 6 Integrated synthesis of outcomes from ICD support groups

Quantitative data	Interpretation	Main pillar	Interpretation	Qualitative data
Anxiety and depression				
Measures: STAI, VAS, FSAS	Anxiety measured by STAI decreases over time in all groups, however, VAS-A increased. Support group attendees tend to be more anxious than non-attendees in observational studies. STAI, VAS baseline measurements were in normal range. FSAS scores were average for the population	Variety of measures used, inconsistent results across studies. Optimal measure for anxiety in ICD patients is unclear. Support group attendance may need targeting to patients with pre-existing anxiety about their ICD. Knowledge acquisition and sharing experiences helps patients control their fear and anxiety	Fear of death and ICD shocks are the two sources of anxiety. Support groups may help manage/control fear and anxiety through sharing of experience, knowledge and coping mechanisms. Positive role modelling provides reassurance that there is life after shocks. Patients have more confidence in support and information from fellow recipients compared with healthcare professionals and other support persons. Single perspective that support groups act as unwanted reminder of ICD implant	Measures: virtual and in-person focus groups, semi-structured interviews, email interviews, observation of meetings and group leader's notes, observation of online postings
Silence		Effect of support groups on depression in ICD patients is unclear	Support groups may help manage depression through promoting hope from positive role models. Support groups can encourage patients to resume normal activity, improving acceptance of ICD	Measures: in-person focus groups, semi-structured interviews, observation of meetings, observation of online postings
Quality of life				
Measures: SF-36, QLI, MOS	No significant difference in overall QoL scores. Significant difference in subscales of social functioning, role-physical, mental health, vitality and bodily pain	Variety of general measures of QoL used, no evidence for overall improvement. Support group attendance may help improve specific sub-dimensions of QoL. Data suggest informational support is key to improving QoL	Support group attendance helps find ways to live with ICD and deal with limitations through improving technical knowledge and understanding of the ICD, encouraging return to normal activities. Single perspective that gender-specific meetings may be helpful to cope with lifestyle changes	Measures: virtual and in-person focus groups, semi-structured interviews, email interviews, observation of meetings and group leader's notes, observation of online postings
Social support and functioning				
Measures: subscales of SF-36 and MOS, Saracon's Social Support Questionnaire	Conflicting data regarding association between support group attendance and social support. No difference in social functioning between attendees and non-attendees but improves over time in both groups	Variety of measures used, inconsistent results across studies. Existing social support may not predict benefit from support group due to lack of shared experience. Online and in-person groups provide social support	Support groups provide access to social support with shared experience which is different to existing support. Online support groups may provide similar benefits in terms of social support, and are more easily and frequently accessible	Measures: virtual and in-person focus groups, semi-structured interviews, email interviews, observation of meetings, observation of online postings
Patient perceived benefits and barriers to attending support groups				
Silence		Optimal support group format is unclear. Support group attendees report significant benefits from attending; sharing experiences is key to facilitating device acceptance. Optimal measures for patient perceived benefit are unclear	Shared patient experience and humour is seen as providing more credible information than that from HCPs, and facilitates acceptance of ICD. Single perspective that HCP facilitation of a support group is essential. Single perspective that barriers to attendance include travel distance, gender and age differences. Online support can provide more accessible support than in-person support groups	Measures: virtual and in-person focus groups, semi-structured interviews, email interviews, observation of meetings and group leader's notes, observation of online postings

FSAS, Florida Shock Anxiety Scale; HCP, healthcare professional; ICD, implantable cardioverter defibrillator; MOS, Medical Outcomes Study; QLI, Quality of Life Index; QoL, quality of life; SF-36, Short-Form 36; STAI, State-Trait Anxiety Index; VAS, Visual Analogue Scale.

This may be because mental well-being is more than the absence of mental illness, and our meta-analysis predominantly included measures of anxiety.

The present study found that self-selected attendees have higher trait anxiety and lower social support than non-attendees[36] with increased anxiety over time[37] possibly due to facing an issue previously avoided. Some patients preferred not to attend support groups as they did not want to be reminded about their ICD.[12] In contrast to existing literature our study found no relationship between shock frequency and QoL, but patients did report that fear of shocks is the source of

Table 7 Quantitative data included in analysis

Study	QoL measure	Support group attendees		Support group non-attendees		
		Mean±SD	Total participants	Mean±SD	Total participants	
Molchany and Peterson[37]	SAI (lower score better)	34.8±11.26	11	36.4±11.67	11	p=0.399
Dickerson *et al*[40]	QLI (higher score better)	23.7±3.6	27	23±4.9	85	p=0.770
Myers and James[36]	SAI (lower score better)	35.21±12.94	73	33.1±10.57	77	p=0.230
Yardimci and Mert[34]	FSAS (lower score better)	13.3±6.13	39	16.78±10.62	39	p=0.083
Yardimci and Mert[34]	SF-36 physical component	52.02±9.45	39	47.46±13.82	39	p=0.139
Yardimci and Mert[34]	SF-36 mental component	43.29±9.02	39	44.69±8.08	39	p=0.361

FSAS, Florida Shock Anxiety Scale; QLI, Quality of Life Index; QoL, quality of life; SAI, State Anxiety Index; SF-36, Short Form 36.

their anxiety. Support groups help to relieve this anxiety by fostering a sense of belonging[41] and providing reassurance that there is life after ICD shocks.[40] Positive role modelling from other attendees and sharing stories with other patients also relieves fear and anxiety in a way HCPs cannot.[40 41]

The lack of a significant effect on mental well-being demonstrated by the quantitative data may be attributable to the fact that the majority of included quantitative studies were observational with self-selected support group attendees, while a usual care comparison group may include patients with lower existing anxiety.[36] However, the single RCT[34] also did not show reduction in anxiety over time in support group attendees. An alternative explanation is the use of general anxiety and QoL measures that may not be sensitive to the specific fears experienced by ICD patients. The use of different outcome measures to estimate mental well-being is a shortcoming of our meta-analysis, however, it highlights the lack of good quality quantitative data in this important topic.

The present study shows that sharing experiences is key to facilitating device acceptance, a consistent finding for in-person and online support groups. Gaining information is also an important benefit of support groups, although patients reported that they found information and understanding from fellow attendees more credible than that from HCPs.[39 41 42] This suggests that support groups should prioritise patient-to-patient communication. Despite this finding, all in-person support groups used a HCP to provide information and education. The online support offered in these studies was in the form of web-based written forums, with the exception of one web-cast group meeting.[38] The increased availability and use of video-conferencing technology since the COVID-19 pandemic has made remote meetings a viable option and provides the convenience of online meetings alongside the opportunity for patient-to-patient communication and HCP involvement. None of the reported studies conducted a comparison of in-person and online support. Future research could help guide the most efficient format for support groups, including use of HCP time and personnel and the delivery of online and in-person groups.

Most included studies were based in the USA, and it is striking that no Western European studies were found. A recent UK study[44] commented that while there is interest in patient support groups, there are not many. Perhaps even more important is the fact that ICD implant rates in the USA have historically been 4–5 times higher than in Europe.[45] This highlights the need for further research in, and implementation of, patient support groups in Europe.

Another area for future research is comparing the support needs of patients with ICDs for primary or secondary prevention of SCD. No data were available regarding participant ICD implant indications, however, the dates of most included studies signifies participants will have had ICDs for secondary prevention of SCD, whereas most implants are now primary prevention.[46] Our data showed that patients have a fear of death and of shocks; as survivors of cardiac arrest, secondary prevention patients will have had different experiences leading to these fears compared with patients with ICDs implanted for primary prevention. As sharing experiences appears to be an important benefit of support groups, future research could explore whether primary and secondary prevention patients have sufficiently similar experiences to support each other.

Our mixed-methods systematic review has strengths and limitations. It was inclusive in terms of design, outcomes and publication status and dates. The screening and quality assessment was robust, with clear a priori definitions of the intervention of interest and outcomes provided. There was limited opportunity for meta-analysis from the quantitative data as there was no quantitative data regarding depression, device acceptance, or group format, despite these being important themes identified in the qualitative analysis.

In conclusion, this first mixed-methods systematic review and meta-analysis shows that while there is currently no quantitative evidence that ICD support groups have a significant beneficial effect on mental well-being, qualitative data show that patient support groups are perceived as beneficial by attendees. This suggests that we need other quantitative measures to assess the benefits of support groups for mental well-being. Attendees value the opportunity to share their experiences which helps them to accept their new life with an ICD. Further research is recommended into the optimal format of support groups, level of involvement of HCPs, and whether primary and secondary prevention ICD patients have different supportive needs.

Contributors KHS, PJP and MA designed the study and took overall responsibility for its content; KHS, PAC and MA assessed study eligibility; KHS, PAC and KC assessed study quality; KHS, HD and MA analysed the data; KHS, HD, MA and KC contributed to the data interpretation; all authors contributed to the drafting of the manuscript and approved the final version to be published. KHS acts as guarantor for the study.

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7.5.4 Paper as submitted to *Pacing and Clinical Electrophysiology*

A qualitative exploration of the role of patient support groups in adapting to life with an Implantable Cardioverter Defibrillator

Short title: Adapting to an ICD

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All authors declare no competing interests.

Abstract (250/250 words)

Background: The British Heart Rhythm Society encourages the use of patient support groups for patients with Implantable Cardioverter Defibrillators (ICDs), however, it is not clear what patients need from a support group or what format they should take. The aim of the present study was therefore to explore the attitudes and perceptions of patients attending an ICD support group.

Methods: 14 ICD recipients were interviewed using a semi-structured interview guide. Reflexive thematic analysis methods were utilised to code and analyse the transcripts before generating themes.

Results: Four themes were constructed during the analysis: confronting mortality, coping through sharing, coping through learning, and providing space. Making connections with other ICD patients, access to information and reassurance, and advice from health care professionals were important perceived benefits of the support group. When interpreted through the theoretical lens of a task-based model for adapting to chronic illness, support groups provide patients with the opportunity to learn and utilise the coping skills required to complete tasks for adaptation.

Conclusion: Patients with ICDs may have to confront their own mortality and adapt to considerable life changes after implant. The findings from the present study have improved understanding of how support groups are perceived and how ICD indication and group format influence the experience. A blended format of in-person community meetings, online forums, HCP-led education and space for patient-patient interaction is recommended. Importantly, provision of support should not be time-limited to allow patients to access it when it most likely to be of benefit to them.

Introduction

Implantable cardioverter defibrillators (ICDS) were introduced to prevent sudden cardiac death (SCD) by delivering an electrical shock to the myocardium to treat ventricular arrhythmias, which accounts for up to 80% of SCD (1). Implant rates have increased dramatically, quadrupling between 2002 and 2020 in England (2,3). However, patients with ICDs are known to experience psychosocial difficulties including anxiety (4–6), depression (6) and post-traumatic stress disorder (PTSD) (7). It has been shown that ICD implant itself does not negatively impact quality of life (QoL), however shock delivery does cause mental health deterioration (8) suggesting that this group may have higher supportive care needs. Addressing deteriorating mental health is important as it has been shown to predict mortality and admission to hospital in ICD recipients (5). The efficacy of specific interventions to improve mental health following ICD implant or shock delivery has not yet been established, however, the majority of interventions have been studied within one year of implant, with little focus on post-shock (9).

The effectiveness of support groups for patients with cancer and many other long term conditions has been previously investigated (10), however, the extent to which the findings are generalisable to ICD recipients is unclear due to different disease experiences; a common cause for distress in patients with ICDs is shock delivery (8), an experience unique to this group. A recent mixed-methods systematic review (11) showed that while there is no significant quantitative evidence that support groups for ICD recipients improve mental well-being, patients perceived them as beneficial and valued the opportunity to share their experiences. However, the qualitative synthesis was based on only seven studies which explored different questions and a variety of support group formats indicating there remains considerable gaps in the qualitative evidence base.

Patient support groups are defined as groups with aims determined by the participants (rather than the providers) and no structured curriculum or end date (12), and provide an option for supportive care using limited healthcare resources (13). The British Heart Rhythm Society (BHRS) encourages the use of support groups to the benefit of patients, although provides no guidance on what format a group should take (14).

Support group format has been highlighted as a useful area of future study (11) to maximise the benefit to patients and inform the development of guidance for developing such groups. It is not clear to what extent health care professionals (HCPs) should be involved in a successful ICD support group (13) as patient-only groups permit the sharing of experiences and true empathy from fellow patients which HCPs cannot provide. However, HCPs can provide information and address concerns and misconceptions should they arise (13).

In the present study, a support group for ICD recipients was established in 2019 by a committee of five patients with support from the clinical team from a district general hospital. In the absence of guidelines and literature to direct the format of the group, the patients developed the group meetings in a format which they felt would be most beneficial according to their own experience. The present study aimed to explore the attitudes and perceptions of patients attending an ICD support group. The secondary aim was to evaluate patient perceptions of group format and how this influenced their experience, and use these findings to develop practical recommendations for support groups.

Methods

Study design

Given that the results of the present study are shaped by context, situation, and the experiences of the patients and the investigators, a contextual critical realism position was adhered to (15). An experiential thematic analytic (TA) approach was used, following the methods outlined by Braun and Clarke (16,17). TA was suitable because its flexibility offered the opportunity for inductive analysis as well as the possibility of introducing theory to the analysis later in the process (17).

Semi-structured interviews were used to explore participant’s perceptions of their support group attendance in their own words. Interviews were chosen as the data collection method because they are ideally suited to exploring ideas in which the participant has a personal stake in (15). A reflective journal, an essential tool in reflexive TA (17), was used by the researcher to identify and interrogate the choices made throughout the research process and how these influenced the knowledge produced.

Ethical approval for the study was granted by the East of England – Cambridge Central Research Ethics Committee (20/EE/0233) in November 2020.

Study participants

To ensure the study covered a range of perspectives a maximum variation, purposive sampling technique was used to achieve diversity in gender, age, social background, and ICD experience including length of time since implant, shock experience, and support group attendance.

Fourteen patients agreed to take part in the study. They were given time to review the patient information sheet before consenting to take part. Most patients were recruited from the support group, however, two patients who had not attended the group were recruited during routine ICD clinic checks to gain an alternative perspective on support groups. 9 males and 5 females were recruited, aged 39-86 years. Length of time with an ICD varied from 3 months to 104 months. There were 8 participants with an ICD implanted for primary prevention indications, and 6 for secondary prevention indications. 3 participants had experience of receiving one or more shocks from their ICD.

Patient and Public Involvement (PPI)

A four-person PPI advisory group was involved throughout the study. Three of the PPI group had lived experience of an ICD, two of whom had attended support groups, and one had prior experience of qualitative research methods. They co-produced the interview guide and contributed to the analysis of the interview transcripts. A total of 16 PPI meetings were held over Zoom at regular intervals between January 2021 and August 2022 to discuss the interview transcripts and check the interpretations of the author were consistent with their experiences from a patient perspective. The PPI group provided invaluable insight during the generation and refining of themes later in the data analysis period.

Data collection

Interviews were conducted between December 2020 and July 2022 either face-to-face or via Zoom, depending on Covid-19 restrictions and patient preference, using a semi-structured interview guide. Participants names have been changed to pseudonyms to maintain anonymity. The interviews lasted around an hour (range 47 to 118 minutes). The first section of the interview was narrative, with the respondents asked to tell why they have an ICD to give context to their story. Open questioning was then used to explore patient perceptions of the support group. All interviews were undertaken by a doctoral student with a cardiac science background. The interviewer was known to some of the patients from their role as a cardiac clinical scientist, and the interview questions were carefully worded and reviewed by the PPI group to allow participants to express their experiences as freely as possible. Reflective practise was engaged with throughout to carefully consider the influence this relationship may have had on the participant's responses and how this may have shaped the results.

Data analysis

Data analysis began after the first interview and continued in parallel with data collection, which allowed for active decision making throughout the data collection and interpretation processes. Although widely conceptualised as the gold standard for determining sample size in qualitative inquiry, the use of saturation is troublesome in reflexive TA because it implies that codes or themes are pre-existent in the data (18). The sample of 14 for the present study was a situated, interpretative judgement by the research team that sufficient rich data had been collected to generate themes which fulfilled the aims of the study.

The six phases of reflexive TA as outlined by Braun and Clarke (17) were adhered to throughout the analysis. The interviews were all audio-recorded, fully transcribed, and checked for accuracy by the first author. The transcripts were uploaded to NVivo 11 software (19) to facilitate the analysis. Transcripts were inductively and semantically coded by the first author before developing more latent coding as the analysis developed. The first five transcripts were also coded by an experienced PPI group member to encourage discussion of ideas and challenge the assumptions of the first author. Critical memoing (20) and the one-sheet-of-paper (OSOP) technique (21) were used to explore the data, alongside PPI group meetings during which reflective discussions were encouraged. Theoretical models for coping with dying and adapting to chronic illness (22–27) were reviewed and informed a more deductive analysis of the data. Multi-faceted themes with a single unifying concept were generated from these discussions and refined with input from the rest of the research team.

Results and Discussion

Fourteen participants were interviewed and were included in the analysis. After coding the interviews, 45 codes were generated. These were clustered into topics including experience of support groups, living with an ICD, concerns about ICD, support group practicalities, involvement of care team, and facing death. Patterns and unifying concepts across these topics were identified during the process of theme generation to answer the research questions. Four themes were generated: confronting mortality, coping through sharing, coping through learning, and providing space. A thematic overview is shown in Figure 1. Illustrative quotes are provided for each theme, with participant's pseudonym and length of time since ICD implant following in parentheses.

Theme 1: Confronting mortality

This theme centred around participants being forced to confront their own mortality, either because they had survived a cardiac arrest or have been told they were at risk of it. Two sub-themes were identified: facing death, and hope.

Sub-theme 1: Facing death

Participants feared death, and feared arrhythmia and shocks as a precursor to or escape from death:

'I think I just was overall thinking tomorrow I'm going to die' (Henry, ICD for 14 months)

The concept that patients with ICDs are required to confront their mortality has been described previously (28,29). The influential work of Elizabeth Kübler-Ross (22) was the first to describe stages of grief in patients who were facing their own death. Deductive coding was carried out for the stages of grief and there were examples of these across the dataset (Table 1).

To the best of the author's knowledge the present study is the first to identify that patients with ICDs express emotions consistent with the five stages of grief described by Kübler-Ross (22). However, although stage-based models such as Kübler-Ross' are popularly utilised, they have been subject to significant criticism in recent years (23). Task-based models are now considered more relevant to current practice (27) and they differ from stage based models in providing a framework to reconstruct one's existence rather than a linear pathway to acceptance. Samson and Siam's task-based model (27) was developed to describe the psychosocial adaptation process to chronic illness. The model fits well with the inductive analysis of the current study and therefore provided a plausible explanation for the perceptions of the participants; support groups provide patients with the opportunity to acquire and utilise the coping skills required to complete the adaptation tasks such as re-establishing emotional balance (psychological task) and developing a sense of hope (spiritual task).

Participants expressed a range of reasons for their fear of receiving a shock from their ICD. Some feared the physical sensation, some that this meant they had a life-threatening heart rhythm, and others feared the practical consequences such as a driving ban. Shock delivery has been shown to be an important predictor of anxiety for patients with ICDs (30), particularly multiple shocks, and this is reflected in the dataset:

'sometimes if I'm lying in bed and you know when you get your feeling of boom, boom, boom, your heart's going like that, I'm lying there worried "please don't go off, please don't go off".' (Felix, ICD for 42 months, experience of multiple shocks)

When the data was searched for patterns relating to shock experience and how they used the support group, no pattern was identified. However, the subject of shocks and the opportunity to hear other patients' experience of them was perceived as valuable by those who had not yet received a shock. The present study's participants had limited personal experience of shocks and of sharing that experience at a support group, and this may be a valuable area for further qualitative exploration of support groups.

Sub-theme 2: Hope

The concept of hope was evident in the dataset; participants found hope in seeing other people living with their ICDs for many years, and realised that although they will die one day, it may not be imminent.

'You know, for example you meet somebody and you think, you don't think it out loud, but you think it in your head, actually they've had their device five years and they're still standing up, and that may seem trivial to you, but the realisation of that is huge' (Ann, ICD for 104 months)

Hope is an important emotion which is frequently referred to in grief stage theory. Kübler-Ross did not define it as a stage in her model, however, the author did note that hope is pervasive through all stages (22). It was striking in the dataset that the simple act of meeting a fellow ICD recipient who has lived with their device for years, or survived a shock, helped participants believe that they could and would be able to do the same. This shows how support groups can provide new ICD recipients with a valuable opportunity to meet 'experienced' recipients. This allows a re-kindling of their sense of hope, one of the spiritual tasks in Samson and Siam's model (2008).

Theme 2: Coping through sharing

This theme focused on shared experiences, with an emphasis on patient-to-patient communication. Two sub-themes focus on aspects of shared experience: accepting the ICD as necessary, and comparison with others.

Most participants found connecting with other ICD recipients beneficial and cited this as a reason for attending for the group. Friends and family may offer support, but this was not perceived as having the same benefit because they did not have personal experience and could not understand what the participant was going through. For the same reason, some participants preferred to hear from other ICD recipients rather than HCPs because patients can talk about living with an ICD compared to HCPs who only know the stories which arise during a hospital or clinic visit.

'So it is nice, you know even when you've talked to a healthcare professional to be able to ask somebody else that you know really knows and understands what it feels like more than sort of the practicalities of it.' (Neil, ICD for 3 months)

They found reassurance in seeing other patients also struggling with their ICD, to know they aren't alone in their struggles. It was also reassuring to see patients who had got used to their ICD and to see that it is possible to 'get back to normal' and live a fulfilling life. These experiences are consistent with the coping skills described in the task-based model for adaptation (27) in which the five tasks described (physical, social, psychological, spiritual and vocational) form part of a broader conceptualisation of adaptation which can be applied beyond the limits of grief theory.

Sub-theme 1: Accepting the ICD as necessary

One participant was struggling to accept that having their primary prevention ICD had been the right decision and found it helpful to compare their situation to patients who had survived a cardiac arrest.

'So in a sense of like, in a way that like that might be a similar experience to me and I could hear how wow they really did need it, you know, in a way that was helpful because I thought "yeah, I mean it could have, that could have been the way it played out for me' (Lee, ICD for 39 months)

In contrast patients with secondary prevention ICDs, having survived a life-threatening arrhythmia, appeared to find it easier to accept their ICD and had less doubt in their decision-making to have the ICD implanted. For some patients with ICDs for secondary prevention indications, it may not even be seen as a decision, but rather an offer they cannot refuse (31).

'it's very, very difficult, and the thing is we're now talking to other people, we've got no idea about how you should be feeling, what questions you should be asking, you know, and things like that, so that that's… but equally on the flipside you've got, I've got a second chance, so it's that kind of helps a lot' (James, ICD for 8 months)

While recipients of secondary prevention ICDs still found sharing experiences of adapting to an ICD and its accompanying restrictions useful, this difference in acknowledging the necessity of having an ICD appears to be an important factor which helped patients learn to accept or cope with their situation. A recent study comparing the effect of a social cognitive intervention on primary and secondary prevention ICD recipients also found that secondary prevention patients had greater improvement (32). Applying the task-based model of adaptation (27), the analysis suggests that secondary prevention patients are able to more readily perceive adapting to their ICD as a challenge rather than a threat, allowing them to move on and complete their adaptive tasks.

Sub-theme 2: Comparison with others

Younger participants felt they had less in common with older group members, and that to benefit from sharing experiences they needed to have similar goals, for example getting back to work or exercise.

'I suppose it's about having a big enough group whereby there's somebody there for me and I'm there for somebody rather than me being with somebody who's maybe in their 60s or 70s and actually isn't really that interested in whether or not they can get their jogging pace down, you know' (Daniel, ICD for 29 months)

This suggests it may be challenging for support groups to meet the needs of younger patients due to lack of shared experience, because there are relatively few younger patients compared to older. The youngest participant was 39 years old and therefore the perceptions of young adults were not well represented in the present study.

Coping through learning

Learning about their ICD was also important to participants and this was another reason given for attending the support group. They wanted to understand how their ICD worked and what to expect from it in the future, which reduced their fear of the unknown. Formal education and question and answer sessions supported the patients to learn about their ICD beyond the specific questions they might think to ask in clinic.

'what I always find very interesting, to listen to the questions that other people have, because they might ask a question that you've forgotten or haven't thought about yet or something that might come up for you in the future and it might be helpful to know' (Caroline, ICD for 18 months)

This finding reflects the coping skills described in the task-based model for adaptation (27), demonstrating information seeking and efforts to reintegrate into vocational environments. The benefit of learning about ICDs from both HCPs and fellow patients has been described in previous support group literature (33). The findings from the present study suggests that a blend of learning from HCPs and patients is preferred within the support group. This is consistent with Dickerson et al. (34,35) in their qualitative explorations of support groups, who used the term 'meaningful information' to define the information participants sought to cope with their ICD; while the HCP provides technical information about the device, the other group members experiences help to translate this into a meaningful understanding of how to live with an ICD.

Providing space

The support group provided the participants with both the physical and the psychological space to meet, share and learn. While participants found Zoom convenient and recognised that it had been necessary during the Covid-19 restrictions, they preferred meeting in person. While it was possible to deliver education over Zoom, they found it more difficult to make beneficial interpersonal connections.

[On Zoom] *'there was no opportunity to go, you're roughly the same age as me, what's your deal, why are you here, you know, I'm the same. So those kind of learning a bit about people's stories and being able to relate to those obviously been almost kind of lost almost entirely, hasn't it?'* (Daniel, ICD for 29 months)

A survey of substance abuse self-help groups undertaken during the Covid-19 restrictions found that online meetings had appeal to younger members and were more useful for those earlier in their recovery (36). This may in part explain the lack of enthusiasm for Zoom in the present study's participants, who were generally older and had their ICD implants for months to years.

Most participants felt that the support group was most useful around the time of implant, as this is when they had the most unanswered questions and life changes to adapt to. Some ICD recipients advocated accessing the support group before the implant procedure. These were usually participants with a primary prevention ICD, who felt meeting other ICD recipients had helped them to decide to consent to the implant, or to prepare for it. In contrast, the participants with secondary prevention ICDs didn't feel they had this time (*'there wasn't a before'* – Kathy) or didn't feel ready to engage with the support group for some time after implant. Participants also felt that education through the support group should be offered to patients as they may not seek it, especially early in their ICD journey when they may be in shock or denial at their diagnosis.

'I just sat with this kind of like dread, you know, and then called my dad and had that conversation, but it is interesting that the option of doing a little education myself was just gone from my head' (Lee, ICD for 39 months)

This difference in timing of accessing a support group is a relatively under explored topic in relation to ICDs. The earlier use of the support group by recipients of primary prevention ICDs may be explained by time since diagnosis rather than time since implant, as one study of patients with brain tumours found patients who were less likely to attend the support group were more recently diagnosed (37). In the present study, secondary prevention ICD recipients tended to have their ICD implant during their admission, while primary prevention ICD recipients had their procedures electively. Previous studies into psychosocial interventions for anxiety in ICD patients have provided an intervention with a curriculum and set duration (38–40), however, the present study suggests that support should not be time restricted.

Discussion

The aim of the present study was to explore the attitudes and perceptions of patients attending an ICD support group. The findings show that a key role for support groups is to help ICD recipients adapt to their new life with their device. The perceived benefits of the support group had an emphasis on 'getting back to normal' and finding the hope and reassurance that this was possible. The experience of ICD recipients having to consider the possibility of their own death (29,41) allowed the application of relevant theory (22,27) that provided an explanation for the role of support groups in adaptation to life changes. This differs from the role of support groups in reducing anxiety as explored in previous studies (42–44). The present study's reframing of the role of support groups towards adaptation is unique and contributes new knowledge to the field of support groups for ICD recipients, which will be important to clinicians and clinical scientists caring for this patient group.

The task-based model for adaptation to chronic illness (27) provides a comprehensive approach to the process of adaptation and reflects the broad impact that a chronic condition may have upon a person's life, and subsequently the broad range of support that could be offered via a support group to assist the process of adaptation. Ensuring support groups offer a range of activities which provide attendees with the opportunity to achieve each of the adaptive tasks described by Samson and Siam (2008) could improve the overall benefit of groups. Information presented in Figure 2 shows how the support group activities identified in the present study could help attendees achieve the adaptive tasks. The range of support group activities required to meet the adaptive tasks demonstrates the importance of a blended format to provide the opportunity to undertake as many of these tasks as possible.

The data analysis found that ICD indication and shock experience made little difference to support needs in terms of undertaking the activities described above, although experience of shocks was limited to three participants. There were differences between ICD recipients with primary and secondary prevention indications in decision-making, accepting the ICD as necessary, and the timing of accessing the support group. This emphasises the importance of being able to access the support group before implant to help with decision-making, and at any time afterwards depending on need. Both shocked and non-shocked participants perceived benefit from hearing about other's shock experience and that they have returned to normal lives afterwards. Previous research has suggested perceived control and ICD-related concerns may be mediating factors between shocks and anxiety (45) and QoL (46). This may explain the role of support groups in addressing fear of shocks (regardless of prior shock experience) as they provide an opportunity for participants to address these mediating factors through education and reassurance.

Support group format appears to influence perceived benefit, however, there was no single format which suited every participant. A flexible approach, combining a range of formats, is therefore recommended to meet the needs of as many ICD recipients as possible. The findings of the present study suggest that in-person meetings held quarterly, alongside support accessible in-between the meetings in the form of one-to-one peer support or an online forum would meet the needs of most ICD recipients. While some support groups may be online only and provide valuable opportunity for sharing experiences and seeking advice from other ICD recipients (35,47), the findings of the present study suggest that this would omit another important perceived benefit of support groups, that of HCP provided education and the opportunity to ask questions and seek professional (rather than peer) advice to address specific concerns. It was important to participants that this was delivered by or with support from HCPs, as this validated the information being provided and ensured any advice provided was accurate and safe. However, although HCP involvement during the educational portion of the meeting is recommended, some attendees may benefit from speaking to other ICD recipients without an HCP present. Previous research has found that support group attendees feel more comfortable sharing their experiences with fellow ICD recipients than with HCPs who do not have personal understanding of life with an ICD (34). Furthermore, non-constructive support from HCPs has been shown to hinder device acceptance (48). This is consistent with the findings of the present study as during the interviews some patients reported that they would prefer not to discuss their experiences with a member of their direct care team present.

The opportunity to share experiences with other ICD recipients has been identified as an important role of support groups in helping patients adapt. Therefore the present study has provided a new understanding of how to create a setting where ICD recipients feel comfortable and safe to do so. A community setting for in-person meetings was preferred, with participants describing a sense of ownership of their ICD and of their recovery when meeting away from the hospital setting. This may link to the concept of perceived control which has been shown to be a mediating factor between shocks and anxiety (45,46). Perceived control in healthcare is important because the perception that one has control results in better adjustment; furthermore, the perception of having lost control having previously had it is thought to be particularly detrimental (49). Hammash et al. (46) explored the relationship between perceived control and QoL and concluded that interventions which address patients' concerns and other psychosocial factors through education are needed to improve perceived control. The present study has shown that this may be achieved through well-designed patient support groups.

While most published studies into supportive interventions have been undertaken post implant, the present study has found that the timing and need for support is more complex than related to the implant itself; instead, diagnosis, shock experience and individual coping styles all appear to influence when support may be needed. Both Kübler-Ross (1969) and Samson and Siam (2008) recognise denial and avoidance as coping strategies which are used by many patients at some point in their journey. ICD recipients who are using denial and avoidance to cope are not likely to find a support group beneficial at this stage, however, they may need this support later in their journey. This may mean the continuous availability of support groups and flexibility of access to them has an advantage over fixed time interventions, particularly in terms of allowing for individual coping strategies.

Implications for clinical practice

The role of the support group in helping ICD recipients return to normal activities without fear of shocks is an important finding of the present study. This can be achieved through a blend of education and sharing experiences which enables acquisition of meaningful information.

The findings of the present study support the development of recommendations for how support groups can provide this in clinical practice. The recommendations are that:

- Professional involvement should be seen as collaborative and reciprocal
    - HCP-led education is encouraged
    - Patient leaders of the support group are recommended
    - Include opportunities for patient-to-patient communication without HCP present
- An online forum in conjunction with in-person groups meetings held in community settings may help meet the needs of a wider range of ICD recipients.
- Access to support groups should not be time-limited, and available before and after implant

Limitations

The interviewer was known to some of the participants through clinical contact, which may have introduced some restrictions to their responses. Using focus groups in place of interviews may have reduced the power dynamic between the researcher and participants due to the numerical advantage of participants (15). All interview participants were white and of British background. No patients from minority backgrounds attended the support group during the study period and therefore their views and reasons for not attending the group are not represented in the present study. Despite these limitations, the commitment to PPI to maintain the patient perspective throughout the study ensured it adds to the limited body of existing knowledge regarding the role of support groups for ICD recipients.

Reflexivity

The lead researcher was a doctoral student and practising cardiac clinical scientist and was therefore known to several participants through ICD follow-up or attending the support group. Critical memoing was used to reflect on how the researcher's involvement may have influenced participant's responses and the interpretation of these. PPI group meetings were also used to minimise bias from an HCP perspective, by reflecting on their own experiences as ICD recipients and finding nuances in the data which the researcher from their HCP positionality had missed. None of the other members of the research team were known to the participants and therefore also provided a valuable outsider insight and challenge to the assumptions made in the initial analysis.

Future research

Future research could consider actively seeking the views of under-represented populations regarding support groups, including younger patients and those from minority backgrounds. The needs of patients using online vs in-person support groups would be also a useful area of future study. Larger-scale experimental research is also needed to evaluate the effect of support groups. The current study's findings suggest that measures of ICD-related concerns or acceptance may be useful to evaluate the effectiveness of support groups, as these appear to be reflective of the perceived benefits of support group attendees as described in the present study.

Conclusion

The findings from the present study have improved understanding of why support groups are perceived as beneficial and how ICD indication, HCP involvement and group format influence the experience. A flexible format of in-person community meetings, online forums, HCP-led education and opportunities for patient-patient interaction is recommended to meet the support needs of a diverse group of patients. Importantly, provision of support should not be time-limited to allow patients to access it at the time when it is most likely to be of benefit to them.

Figure legends

Figure 1: An overview of the generated themes.

Note: Each theme is presented in a box with the most important codes which contributed to the analysis. The themes are linked by what the support group was perceived to provide.

Figure 2: Linking the adaptive tasks described by Samson and Siam (2008) to specific support group activities.

Note: This figure demonstrates that a range of activities are needed to provide the opportunities for ICD recipients to complete all the adaptive tasks.

Author contributions

KHS, PJP, KC and MA designed the study; KHS, EE and KC analysed the data; KHS, EE, KC, LW and MA contributed to the data interpretation; KHS drafted the manuscript, and all other authors revised it critically and approved the final version to be published; KHS and MA accept overall responsibility for the content of the study.

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Table 17: Participant quotes in relation to the five stages of grief according to Kübler-Ross (1969)

Denial: putting aside the possibility of death to allow them to pursue life	*I didn't think about it. And I think, had I thought about it, I would have changed my behaviour, wouldn't have done all sorts of things. (Ethan, ICD for 77 months)*
Anger: angry about illness and envious of the healthy	*I have the other feeling is if I go through my whole life and it never goes off I'll be really cross, really resentful… (Lee, ICD for 39 months)*
Bargaining: looking for ways to resume normality	*I was frightened to go out and things, but after reading up on it and going to the support group I realised that, you know, I can live a normal life. (Kathy, ICD for 14 months)*
Depression: responding to a sense of loss	*I just felt alone and I was always worried that it was going to fire and didn't know what to do if it did. (Kathy, ICD for 14 months)*
Acceptance: recognising that despite the situation, you will be OK	*I narrowed my shock down to the fact that the only time it's going to happen is when I'm needing it. (Henry, ICD for 14 months)*

Figure 1

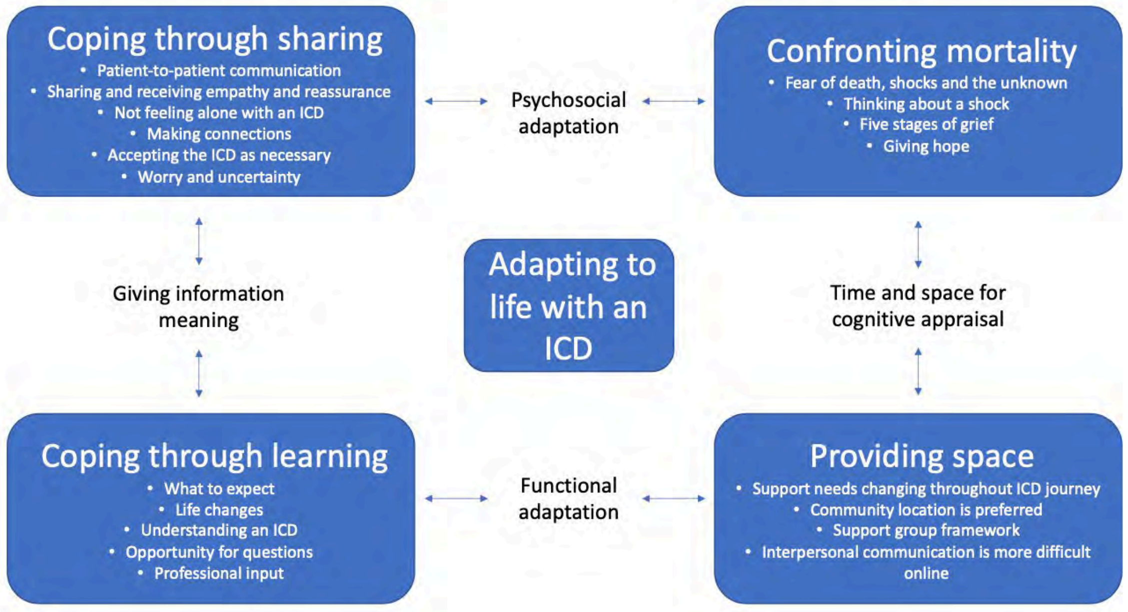
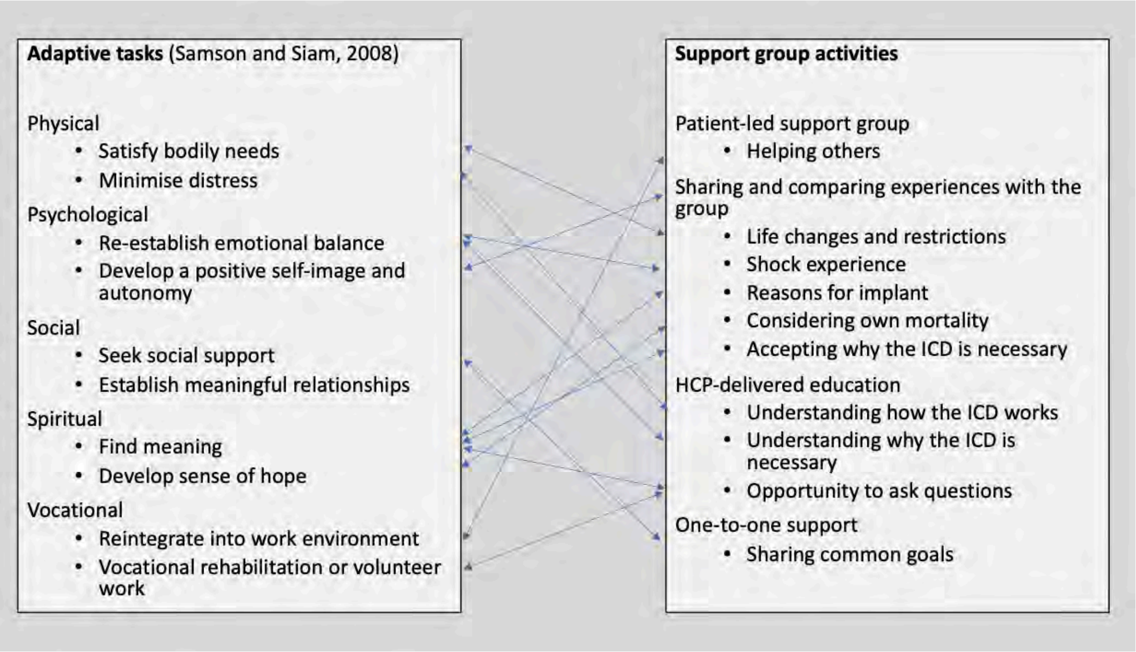


Figure 2



Adaptive tasks (Samson and Siam, 2008)

Physical
  - Satisfy bodily needs
  - Minimise distress

Psychological
  - Re-establish emotional balance
  - Develop a positive self-image and autonomy

Social
  - Seek social support
  - Establish meaningful relationships

Spiritual
  - Find meaning
  - Develop sense of hope

Vocational
  - Reintegrate into work environment
  - Vocational rehabilitation or volunteer work

Support group activities

Patient-led support group
  - Helping others

Sharing and comparing experiences with the group
  - Life changes and restrictions
  - Shock experience
  - Reasons for implant
  - Considering own mortality
  - Accepting why the ICD is necessary

HCP-delivered education
  - Understanding how the ICD works
  - Understanding why the ICD is necessary
  - Opportunity to ask questions

One-to-one support
  - Sharing common goals