Quality of life, symptoms, and experiences of patients with an elevated body mass index, undergoing catheter ablation for atrial fibrillation.

By

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A thesis submitted in partial fulfilment of the requirements for the degree of Doctor of Nursing, Oxford Institute of Nursing, Midwifery and Allied Health Research, Faculty of Health and Life Sciences, Oxford Brookes University

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Declaration of Ethics

The research presented and reported in this thesis was conducted within the guidelines for research outlined in the University guidelines from the Oxford Brookes University Faculty Research Ethics Committee (FREC), number F.02.2019.12

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Abstract

Quality of life, symptoms, and experiences of patients with an elevated body mass index undergoing catheter ablation for atrial fibrillation

Background

Atrial fibrillation (AF) is the most common arrhythmia seen in clinical practice. Previous studies have demonstrated that AF may result in high symptom burden and a reduced quality of life (QoL). Rhythm control in the form of catheter ablation has become an established treatment option for AF. Certain risk factors are associated with the development and progression of AF, notably, an elevated body mass index (BMI). Emerging evidence suggests that risk factor modification in the management of AF is an important component of the patient pathway. The relationship between AF ablation, QoL, symptoms and BMI is poorly understood. We need to understand this further to provide more effective and targeted care. Previous studies concerning the influence of a raised BMI on QoL and symptoms after ablation have been contradictory. Qualitative research in this area has been limited.

Aim

This thesis aims to explore quality of life, symptoms, and experiences in patients with an elevated BMI undergoing catheter ablation for AF.

Methods

This was a single centre, mixed methods, observational cohort study of patients with a BMI >=25 who were eligible for first-time AF ablation. All eligible patients over a nine-month period were invited to take part. Quality of life and symptoms were assessed before ablation and at three and six months afterwards, using the SF-36 and Patient Perception Questionnaire, which are both validated tools previously used in this patient population. Multiple regression models were used to identify predictors for improvements in two of the QoL domains (Vitality and General Health) after ablation. Independent variables which included age, gender, BMI at baseline, classification of AF, left atrial volume index and rhythm control at 6 months were added to the regression model. At six months post ablation semi-structured interviews were undertaken to explore patient experiences of AF ablation and their immediate recovery period.

Results

Eighty-eight patients agreed to participate and 82 of those completed the study. The six that were excluded from analysis either had left atrial appendage thrombus on the day of the ablation and therefore did not undergo ablation or did not complete follow-up. A significant improvement was seen in all domains of quality of life after ablation ($p<0.0005$), at three and six months. Symptom burden also significantly improved at three and six months after ablation ($p<0.0005$). Multiple regression analysis demonstrated the predictors of improved Vitality (V) and General Health (GH) in QoL measures at six months were rhythm control at six months and baseline V and GH scores. Thematic analysis of participants experiences revealed four themes: personal well-being related to AF, care and treatments of AF, interplay of lifestyle and AF and living with AF in a pandemic.

Conclusion

This study has demonstrated that, despite a raised BMI, patients report significant QoL and symptomatic improvements after AF ablation. A multiple regression analysis demonstrated rhythm control at six-month predicts improvements in Vitality components of the SF-36. Framework analysis revealed four themes related to AF, treatments, lifestyle, and the pandemic. Overall, this study suggests that patients with a raised BMI have positive outcomes after catheter ablation for AF and that rhythm control is the most important factor that influences of improved quality of life. Furthermore, patient experiences of the AF diagnosis are challenging, ablation treatment is positive and lifestyle factors play an important role in looking to the future.

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List of abbreviations

AF- atrial fibrillation

ESC-European Society of Cardiology

FHS- Framingham Heart Study

LAVI-Left Atrial Volume Indexed

LVEF- Left Ventricular Ejection Fraction

NHS-National Health Service

NHSE- National Health Service England

NICE- National Institute of health and Care Excellence

PPAQ -Patient Perception Arrhythmia Questionnaire

PROMS-Patient Reported Outcome MeasureS

SF-36- Short Form 36

QoL-Quality of Life

WHO-World Health Organisation

UK-United Kingdom

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Griffiths (2023) Patients QoL, Symptoms & experiences after AF ablation with a raised BMI. *Asian Pacific Cardiology Society, Singapore*

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CHAPTER ONE: INTRODUCTION

1.0 Introduction

Atrial fibrillation and obesity are global epidemics that affect millions of individuals (Churgh *et al.*,2014, Vyas and Lambiase 2019). The link between AF and obesity (or being overweight) has been established within the past ten years. AF is the most common arrhythmia and in 2010 it was estimated that 33.5 million globally suffer from AF (Churgh *et al.*,2014). The consequences of AF on an individual may be substantial, both physically and psychologically (Dorian *et al.*,2000; Schotten *et al.*,2011). Obesity is a major global health concern, and the prevalence is rising (World Health Organisation 2023). The World Obesity Federation (2023). estimates that 2.6 billion, which is 38% of the global population, have a Body Mass Index (BMI) of greater than 25kg/m^2. This means that over a third of the world's population is either overweight or obese.

The Office for National Statistics (2023) report that the cost of treating and managing AF is a major issue for the National Health Service (NHS) in the UK. It is crucial for healthcare professionals, budget holders and planners to be aware of the financial cost of this growing health problem, as finite funds need to be directed appropriately. The direct cost of AF in terms of the NHS total budget is high and is predicted to be between 0.9 and 1.6% of the total NHS budget in the UK over the next 20 years (Burdett and Lip 2022). The main cost to the NHS is due to hospitalisations, as a result of stroke, heart failure or severe symptoms (Burdett and Lip 2022). AF, as a cardiac condition is on the increase and the main reasons for this are not only more favourable survival rates from AF related conditions, such as stroke and heart failure, but also because the population is ageing (Schanbel *et al.,* 2015).

Not only is AF a major health concern, but obesity is also a linked condition that is on the increase in the UK (British Broadcasting Corporation 2023). Being overweight or obese is associated with several physical illnesses, such as coronary heart disease, hypertension, stroke, osteoarthritis, type II diabetes, amongst many others. Obesity also has a financial burden on the NHS. Furthermore, the psychological impact of being overweight or obese has raised major concerns, although the impact of this on health and/or mental health wellbeing is not clearly understood (Djalalinia *et al.,* 2015). The mental health effects of obesity are reported to be depression, anxiety, and reduced quality of life (Rajan & Menon 2017). The association is more complex than cause and effect and the links between both mental health and obesity may be symbiotic (Blasco *et al*.,2020).

It is clear that both AF and obesity or being overweight are matters of grave public health concern, from the perspective of policy makers and health care professionals alike. It is important to explore this topic further because high quality nursing care relies on knowledge and understanding.

1.1 The nursing expertise that informs this research

I have been a nurse in the NHS for 40 years. During this time, I have developed a deep interest and passion for the care of patients with cardiac arrhythmias. I have worked as an arrhythmia nurse for over 30 years and latterly as a Consultant Nurse. Only three Consultant Arrhythmia Nurses exist in the UK. Much of my clinical work is in the care of patients with AF and over the years I have developed an extensive understanding of their condition, treatments, effects, concerns, and outcomes. Not only do I undertake clinical care within the outpatient clinic and the cardiac catheter laboratory, but I also work in several other areas that fulfil the four pillars of advanced nursing practice. Nationally I am a member of the All-Party Parliamentary Group on AF (APPGAF), which aims to “raise awareness of AF and ensure the diagnosis, management and treatment of AF is a priority of the NHS. To improve detection and management of AF in accordance with proven best practice” (Parallel Parliament 2023). I have presented to the APPGAF at the House of Commons (June 2023) and worked with the AF Association, as a member of their Medical Advisory Committee for more than a decade. I am a member of the Arrhythmia Alliance Executive Committee, which is a charitable organisation, aiming to improve the diagnosis, treatment, and quality of life of all those affected by arrhythmias. I have been a faculty member of Heart Rhythm Congress, an international annual meeting held in the UK each year, for patients, healthcare professionals and industry partners. In 2020 I was awarded the

Excellence in Practice Award for my services to Arrhythmia Alliance. As part of the organising committee, I regularly chair and present the arrhythmia nurses annual meeting, which aims to provide education and networking opportunities for specialist arrhythmia nurses. The British Heart Rhythm Society (BHRS) is the professional organisation that represents nurses, cardiac physiologists, and doctors, with whom I have worked for several decades. I have been the nurse representative on council twice and currently am a member of the BHRS Accreditation Committee. This group develops and manages the BHRS annual examination and accreditation process. I have been a founding member of the society to develop the nursing exam and assessment process. I have been especially interested in patient reported outcomes for several decades and have presented internationally at a number of cardiac conferences. As an advanced nurse practitioner, I was one of the first in the UK to be awarded the Royal College of Nursing (RCN) credentials in advanced level nursing practice.

My experience as an arrhythmia nurse and the desire to fulfil the research pillar of advanced and consultant nursing practice has led me to undertake the Doctorate in Nursing (DNurs). After some years of considering a suitable research topic, I realised the practice-based issues of the impact of AF on an individual plus the growing concerns within the multidisciplinary team on the problem of being overweight or obese, needed addressing. My clinical expertise and consultant role has led to the development of the research subject within this thesis and places me in an ideal position to lead and implement evidence-based change, both locally and nationally, in the care of this patient group. The justification for the study is presented later in this chapter (section 1.8).

1.2 The problem of AF

AF has been reported and studied as a clinical finding since the early 19th century (Lip *et al* 1995). AF is defined as a supra-ventricular tachyarrhythmia, with uncoordinated electrical activity arising in the upper chambers of the heart, resulting in unproductive atrial contractions (Hindricks *et al.,* 2021). Although some individuals are asymptomatic, most patients seen in cardiology clinical practice have symptoms, because that is how they initially present. The true case of asymptomatic patients is unknown because they go undetected. However, Saveileva & Camm (2000) suggest that approximately 30% of patients with AF have no symptoms. AF may be detected incidentally at other healthcare interactions, or because stroke is the first sign of AF. Commonly reported symptoms of AF are palpitations, reduced exercise tolerance, breathlessness, and fatigue (Kirchoff *et al.,* 2016). AF symptoms, quality of life, and experiences related to AF, are central to the study presented in this thesis.

AF is usually associated with physical symptoms that result in an individual seeking medical help, either in primary or emergency care. The acute presentation may include chest pain, severe breathlessness, palpitations, heart failure, and/or syncope (National Institute of Health and Care Excellence (NICE 2021). Alternatively, AF may be asymptomatic and only suspected during a routine pulse, blood pressure check, or clinical examination, by the characterisation of an irregular pulse. The gold-standard for AF diagnosis is a 12-lead electrocardiogram (ECG), or at least a 30 second single ECG channel recording, either digitally or on paper (Hindricks *et al.,* 2021). The ECG in AF will reveal absence of normal P wave activity, irregularity of the R-R interval and may be associated with a fast ventricular rate of >100 beats per minute at rest (see sample trace below). In addition to the physical symptoms and reduced QoL associated with AF, is the psychological impact of AF symptoms. (Ladwig *et al.,* 2020). Although the psychological impact of AF is a complex matter, evidence suggests that AF impacts negatively on an individual's QoL and mental health (Ladwig *et al*., 2020; Dorian *et al*., 2020).

Figure 1 Sample ECG trace to demonstrate AF

The ECG demonstrates absence of P waves, with an irregularly irregular pattern in the RR interval.

1.2.0 Incidence and prevalence of AF

Atrial fibrillation has been studied for decades in relation to incidence and prevalence. The Framingham Heart Study (FHS), which began in 1948, is a longitudinal study addressing incidence and prevalence of heart disease, including AF, in a North American cohort (Schanbel *et al.,* 2015). The FHS noted a three-fold increase in AF over the age of 50 years and the European Society of Cardiology Guidelines suggest a lifetime risk of AF as one in three at the age of 55 years (Hindricks *et al.,* 2021). This figure has increased from previous estimates in Europe from a risk of one in four (Staerk *et al.,* 2018). The Global Disease Project estimated that, in 2016, 46.3 million people world-wide were diagnosed with AF (Koronej *et al*., 2020). The increasing incidence of AF is related to a number of factors, including an elevated BMI, which are discussed in the forthcoming section.

1.2.1 Risk factors for atrial fibrillation

A number of risk factors are associated with the development of AF in an individual. Age is the main risk factor for the development of AF (Staerk *et al.,* 2017), whereby advancing age increases the prevalence of AF in an ever-increasing manner (Schanbel *et al*., 2015). Furthermore, it has been suggested that 65 years old is the age at which AF becomes more prevalent (Staerk *et al*., 2017) and continues to increase with age. It is estimated that the number of individuals over the age of 65 years will double from 12% in 2010 to 22% in 2040 (Koronej *et al.,* 2020). This means that AF is also on the increase. The ageing process results in activation of the systemic immune response, which in turn leads to "chronic subclinical inflammation" (Koronej *et al.,* 2020). Such inflammation can lead to the increase of transforming growth factor, endothelial dysfunction, alterations in the extracellular matrix and the breakdown of collagen (Shen *et al.,* 2019). The presence of AF and the ageing process are linked to increased oxidative stress, which affects all systems within the body. In AF the ageing processes that occur within the myocardium and the vasculature system are at multiple levels. These include structure, function, cellular and molecular changes that mean the development of AF is a complex process that continues to be understood (Koronej *et al.,* 2020).

In addition to age, gender differences are seen in the presentation of AF and are reported in the literature suggesting men are more likely to develop AF than women (Staerk *et al.j*2017). This may be related to the higher incidence of coronary artery disease in men and structural cardiac differences. The associated causal link between coronary artery disease and AF is reported to be 5% in men and 1% in women (Benjamin *et al.,* 1994). The presence of coronary artery disease subsequently leads to structural changes within the myocardium. These include the development of atheroma, reduced blood flow, thromboembolism and subsequent impairment of left ventricular function, leading to heart failure (Benjamin *et al.,* 1994). However, the incidence of AF in women is noted to be higher over the age of 75, potentially because women tend to live longer than men (Westerman & Wenger 2019).

Regarding ethnicity, AF is reported to be more common in white people, compared to individuals of other ethnic backgrounds (Estes *et al*., 2011). The reason for this is not entirely clear but could be related to lack of ethnic diversity within early studies, under detection in and lack of access to healthcare in certain ethnic groups or genetic influences and consequences (Staerk *et al*., 2017; Koronej *et al.,* 2020).

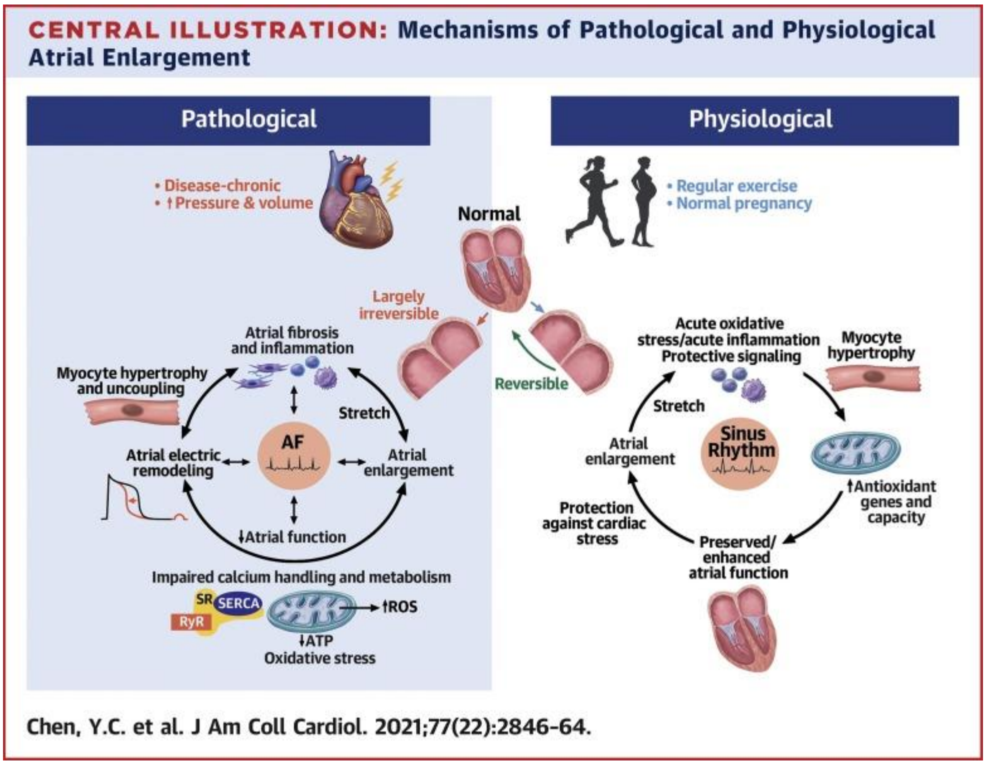
Thus, the prevalence and incidence of AF is seen as age progresses, more common in men until the age of 75 years, when it is higher in women and is related to ethnicity although the mechanism of this is unknown.

1.2.2 Co-morbidities associated with AF

Co-morbidities are factors that are associated with the likelihood of AF development in the person. They are often linked, and more than one condition may be seen in any individual. Obesity or an elevated BMI is the condition that is central to this piece of research. In recent years it has become increasingly apparent that obesity and AF are linked conditions (Ellis and Reynolds 2012). There appears to be an epidemiological association between obesity and AF, and the greater the BMI, the higher the risk of AF developing (Wang *et al*., 2004). In 2016 there were 1.9 billion individuals who were overweight and 650 million that were obese (Vyas & Lambiase 2019). The Framingham Heart Study revealed parallels between increasing BMI and the incidence of AF. In the US in 67,238 patients, it was reported that obesity was associated with new onset AF, which was independent of age, diabetes, hypertension and gender (Vyas & Lambiase 2019). Being overweight is commonly associated with other cardiovascular risk factors and the relationship between all is a complex one.

Hypertension is well recognised as an associative causal factor in AF and has been noted in the Framingham Heart Study (Schanbel *et al.,* 2015) as a related risk. The long-term effects of abnormally high blood pressure result in the changes to atrial structure that allow AF to develop. Such changes are related to increased left atrial pressure in addition to increased left ventricular end-diastolic pressure (Andrade *et al*., 2014). The atrial remodelling and increased fibrosis that occurs in hearts that have been affected by these changes makes the development of AF more likely. Atrial remodelling relates to the changes that may occur within atrial mycoytes, which, in turn leads to electrical and structural changes within the heart. Such remodelling may perpetuate AF, meaning the greater the amount of AF, the greater the degree of remodelling and the greater the degree of remodelling, the greater the degree of AF and so on. (Verdeccia et al 2018). The remodelling occurs because of external or internal stimuli. The stimuli may be electrical, such as increased and abnormal heart rate, as in the case of AF. This may be reversible, depending on the amount of time this stimulus is present. The stimuli may be haemodynamic, in the case of pressure or volume overload, for example in heart failure or hypertension. (Al Ghandi & Hassan 2004).

Atrial remodelling is shown in figure from Chen et al in 2021.



CENTRAL ILLUSTRATION: Mechanisms of Pathological and Physiological Atrial Enlargement

Chen, Y.C. et al. J Am Coll Cardiol. 2021;77(22):2846-64.

Figure 2 atrial remodelling

In addition to hypertension, coronary disease is common in the general population and the factors involved are often similar to those that contribute to atrial fibrillation (Michniewicz *et al*., 2018).

Another common condition, diabetes mellitus, also increases the risk of developing AF, as reported in the Framingham Heart Study (Benjamin *et al*., 1994). Moreover, a longer duration of diabetes mellitus and poorer glycaemic control are both associated with an increased risk of AF. As with other comorbidities, the pathophysiological relationship is complex, but reported as factors related to inflammatory, fibrotic changes in addition to oxidative stressors (Staerk *et al*., 2017). In addition, obstructive sleep apnoea (OSA) is not only associated with AF, but also diabetes, hypertension, and coronary artery disease and heart failure which means both or more conditions are often seen together (Andrade *et al*., 2014). The mechanism involved in the development of AF in individuals with OSA is complex and multifactorial, but involves thoracic anatomical influences, atrial remodelling as a result of inflammatory changes and oxidative stressors and cellular changes to atrial electrophysiology (Staerk *et al*., 2017).

The consumption of alcohol, even in moderate levels provides an increased risk for AF (Larsson *et al.,* 2014). Alcohol influences not only myocardial function, but cardiac electrophysiology and may contribute to hypertension, which all add to the risk of the development of AF (Koronej *et al.,* 2020).

The issues of an elevated BMI in the context of AF are discussed in the next section.

1.3 An elevated BMI as a matter of public health concern

The definition of obesity, as reported by the World Health Organisation (WHO) (2023, p 1) is "abnormal or excessive fat accumulation that poses a risk to health". Quantifying obesity or being overweight may be undertaken by either direct measurement of fat mass or percentage of body fat, using scanning methods (Purnell 2018). However, such methods may not be practical, affordable, or necessary. Therefore, the most used measurement for calculating the presence of obesity or being overweight is BMI. It is calculated by the weight in kilograms divided by the height squared in metres (kg/m^2). It is a useful tool because it correlates well with the mass of fat in an individual and has been used widely in many studies worldwide (Nimptsch *et al.*, 2019). However, the BMI measurement is not without its limitations. The American Heart Association (2011) suggests that BMI may not accurately predict clinical risk, due to a number of factors. Such factors include ethnicity, gender, bone density and age. The limitations of BMI include the weak sensitivity in assessing excess fat, variation in body composition (such as the increased muscle mass in certain athletes) and the use of self-reported data. Nimptsch, *et al*., (2019) suggest that for more advanced analyses of health outcomes, other measures, such as biomarkers and imaging technologies may be the preferred modalities in future research. Moreover, waist circumference has been used widely and has been shown to correlate with imaging techniques in the assessment of central obesity (Pouliot *et al.,* 1994).The subject of how fat mass and percentage should or could be measured is a matter of some debate but , for most healthcare settings, currently BMI is the most pragmatic and appropriate method of assessment.

Being overweight is defined as a BMI of 25kg/m^2 or above (WHO 2023). Obesity is quantified by a BMI of 30-39.9kg/m^2, with severe (or morbid) obesity being over 40kg/m^2. This clinical definition provides a baseline understanding of the concept, but it is important to explore the current understanding of obesity, in a wider context. Although the term obesity is a medically defined term, it is increasingly used in lay terminology pejoratively, as seen in a number of media articles. Media headlines of “obesity crisis”, Hutton (2023), “obesity time bomb”, (Whitcroft (2005), and the obesity “league of shame”, Borland (2018) are commonplace. These headlines demonstrate the need for a holistic approach to the care of patients with AF, which includes the individual’s views, psychological stress and beliefs. Headlines of this nature are likely to have a negative impact on the psychological well-being of overweight and obese individuals. Paradoxically, some patients may be motivated by this kind of negative publicity to make dietary changes and become more active.

It is well-documented that obesity increases the risk of conditions such as cardiovascular disease, diabetes mellitus, osteoarthritis, and cancer World Health Organisation (2023). Clinical guidance now exists in order to manage obesity from the National Institute of Health and Care Excellence (2019) in the general population, something that would have not been conceivable even 20 years ago. The Royal College of Nursing (RCN) suggests that obesity is a major health issue, and the management of weight is integral to all areas of nursing (Royal College of Nursing 2020).

1.3.0 Obesity and being overweight in the context of AF

The context of an elevated BMI is important for arrhythmia nurses dealing with patients with AF, because nurses are often the healthcare professionals that consistently interact directly with the patient over time, throughout the clinical pathway. Part of the role of the arrhythmia nurse is health promotion and education. The number of patients with AF, who are obese, or overweight is rising (Prystowsky *et al.*,2014; Nalliah *et al.*, 2016; Hindricks *et al.,* 2021). In 2023 it was estimated that 38% of the global population will be obese (World Obesity Federation). AF numbers were estimated to be 8.8 million in 2010 but are predicted to rise to 17.9 million in 2060 (Vyas & Lambiase 2019). The link between AF and obesity has been described in several epidemiological studies.

The mechanism of AF in obesity is somewhat complex and research in this area is new and evolving. Sha *et al.,* (2024) provide a comprehensive review of the latest evidence on the pathophysiology of obesity on the context of AF. They draw on earlier work that more simply focused on the increased pericardial fat and inflammation that may lead to AF development (Nalliah *et al*., 2016). These authors discuss other pathophysiological factors, such as atrial stretch, atrial scar, fibrosis, and diastolic impairment all of which contribute to the association with AF and obesity. Ultimately, fat is arrhythmogenic and can lead to the circumstances that perpetuate AF.

However, Sha *et al.,* (2024) discuss the multiple factors that influence the pathogenesis of AF and how obesity impacts on it. Haemodynamically obesity leads to increased left atrial and left ventricular pressures, which results in dyastolic (filling) dysfunction. The resulting higher blood volumes lead to increased dilation of the left atrium and subsequent myocyte hypertrophy. Sha *et al.,* (2024) suggest that this process is more complex than similar consequences in hypertension, which is already an independent risk factor for AF as discussed in section 1.2.2. Adipose tissue is increased in obese individuals, which means that lipids deposit in the myocardium and pericardium. This results in increased cardiac fibroblasts and subsequent fibrosis. As a result, an arrhythmia substrate develops, leading to reentry or triggered activity, both of which are implicated in the mechanism of AF. In persistent AF there are even more fibrofatty infiltrates. Inflammatory changes occur when cytokines are released, such as C-reactive protein and interlukin-6 & β (Nalliah *et al.,* 2015). An increase in the inflammatory cytokines leads to a process of oxidative stress, collagen deposits and abnormal calcium behaviour (Sha *et al.,* 2024). This process causes localised tissue damage, fibrosis and altered electrophysiology, whereby the sodium and potassium channels affect the myocardial action potential. Additional changes in autonomic function are part of this complex process, which relates to the additional epicardial fat that leads to ganglionic plexus formation and leads to autonomic imbalance.

The following diagram from the Sha *et al*., (2024) paper shows the mechanisms of how obesity may lead to AF.

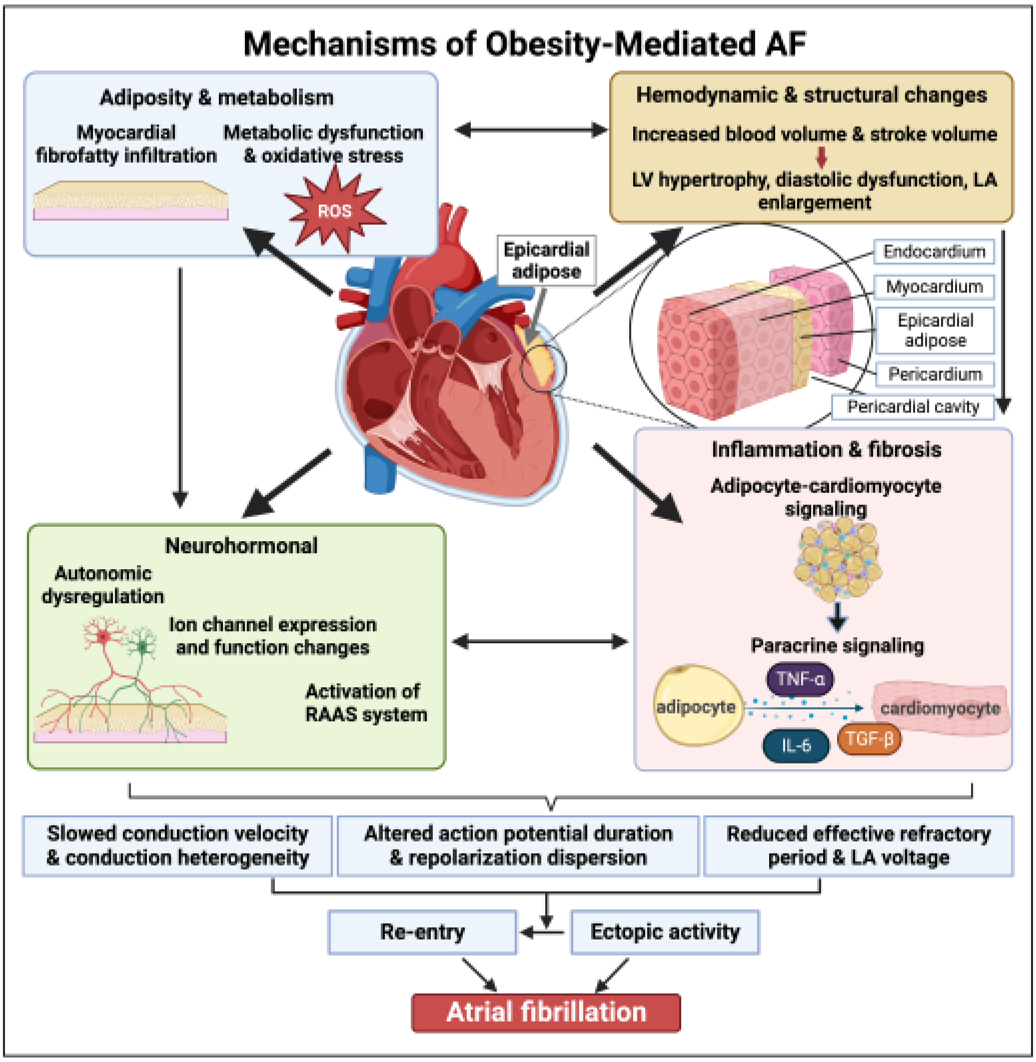


Figure 3 mechanism of obesity-mediated AF

Obesity is central to the research question, which enquires about the quality of life, symptoms, and patient experiences in those who have AF undergoing ablation and have an elevated BMI. As AF and obesity are linked conditions and both are rising in numbers (as discussed in the previous paragraph) from a global perspective, it is important to address these issues, particularly from good quality nursing care. The role of the arrhythmia nurse is, in part, to engage with patients in their clinical pathway in order to enable them to make decisions about treatment options and to promote risk factor management, as suggested by current clinical guidelines NICE (2020; Hindricks *et al*., 2021) Therefore, arrhythmia nurses, in particular, are best placed to engage with patients in regard to education and health promotion, with an emphasis on weight reduction. Weight reduction is an important part of the management of AF, not only to reduce AF burden, but to improve clinical outcomes from treatments, such as catheter ablation (Patak *et al* 2014). Weight reduction, in addition to other risk factor modifciations is in the current AF treatment guidance (Hindricks *et al.,* 2021, Joglar *et al,.* 2023). Risk factor management including weight reduction significantly reduced AF frequency, duration and symptoms following AF ablation compared to that seen in the control group (Patak *et al*,. 2014). Win *et al,.* (2024) from University of Birmingham have published a protocol entitled “Feasibility study of Glucagon-like peptide-1 analogues for the optimization of Outcomes in obese patients undergoing AbLation for Atrial Fibrillation (GOAL-AF) protocol”, which may provide further evidence in this patient group. Before exploring treatments for AF, it is important to consider the patient’s perspectives on their condition. The reason for this is that understanding the relationship between an elevated BMI, AF, and outcomes of ablation in patients who do have raised BMI helps provide info to the patient that enables them to make an informed decision with regards to their treatment.

For clarity, the terms “obesity” and “overweight” will be used under the terms “elevated or raised BMI”, within this thesis.

1.4 Treatments for AF

The treatment of AF is driven by international evidence-based guidelines (Hindricks *et al*., 2021; January *et al.,* 2014; Heidenreich *et al.,* 2020), and National Institute of Health and Care Excellence (2021). All these major guidelines concur in their recommendations and indications. Firstly, stroke prevention is addressed by a process of risk stratification in order to determine the need for anticoagulation treatment. Secondly, symptoms are assessed and treated according to the individual. Such treatments include rate control, with medications, such as beta-blockers, calcium channel blockers or AV node ablation, or rhythm control with medications, cardioversion and/or catheter ablation. Thirdly, the management of comorbidities, including hypertension, coronary artery disease and diabetes are part of the ongoing treatment in the AF pathway. This part of treatment also includes addressing risk factor modification (RFM), such as smoking cessation, alcohol reduction, exercise, and weight loss, where appropriate (Hindricks *et al* 2021; January *et al* 2014; Heidenreich *et al* 2020; National Institute of Health and Care Excellence 2021). The main treatments that apply within the context of this study are rhythm control in the form of catheter ablation and risk factor modifications.

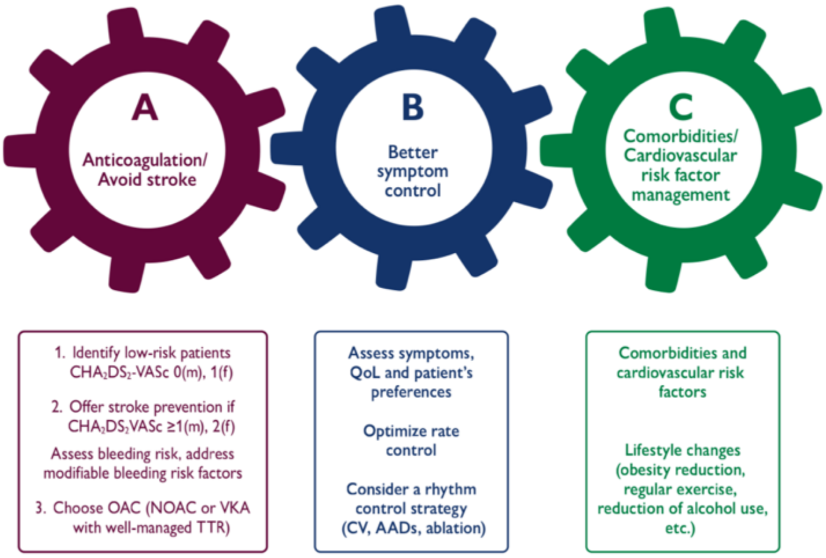


Figure 4 AF treatment pathway (Hindricks et al., 2020)

The next section discusses AF ablation.

1.4.0 Treatment of AF-Catheter ablation

Catheter ablation is an effective treatment for rhythm control in AF, where drug therapies have failed (Calkins *et al*., 2012). The technique of catheter ablation has evolved over the past 30 years. Catheter ablation for the treatment of AF was developed after initial surgical approaches. The Cox Maze procedure involved creating surgical linear lesions in the left atrium, in an attempt to alter the electrophysiological properties within that chamber, thus rendering AF incapable of sustaining (Cox 2011). However, such an approach required major cardiac surgery, with all the complications and recovery that accompany such a procedure. Furthermore, the technique was not widely available and restricted to certain specialist centres.

Catheter ablation developed as a technique for simple arrhythmia treatments in the late 1980’s and subsequently, the technology and skill were applied to atrial fibrillation. In the late 1990’s two centres in Europe approached this issue in a similar manner Hassiguerre *et al* (1998), in France and Pappone *et al*.; (2000), in Italy, both developed ablation within the left atrium, which involved electrical isolation of the pulmonary veins. Over the next decade the use of 3-dimensional mapping and improvement in catheter technology resulted in increased success rates and wider application globally (McCarthy *et al*., 2022).

Currently, AF ablation is performed in predominantly two ways. Catheters are introduced into the heart via the femoral vein, then a trans-septal puncture enables the catheters to be placed within the left atrium. Either cryotherapy is delivered via a balloon catheter, or radiofrequency energy delivered in a circumferential fashion around the pulmonary veins, in pairs, after a 3-dimensional map of the chamber is created (Kouloris 2021). A number of novel approaches are in limited use and the development from a technological perspective continues at pace (McCarthy *et al*., 2022). The procedure may be performed with sedation or general anaesthesia and tends to be several hours in duration.

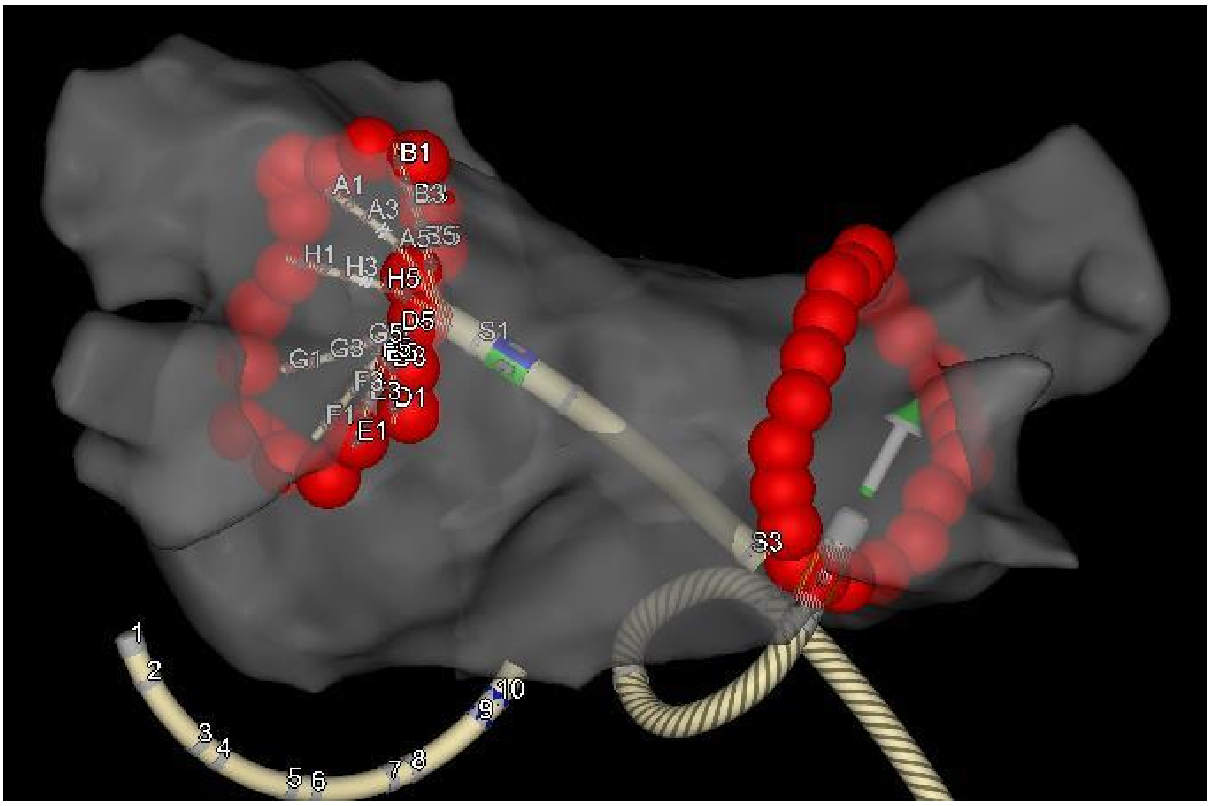


Figure 5 AF ablation technique, showing the left atrium, in grey, pulmonary vein isolation lesions in red and catheters in white

The map was created with Biosense Webster CARTO3™ Mapping system collected with an OCTARAY™ catheter and ablation delivered by a QDOT™ catheter, with permission (see Appendix).

1.4.1 Risks and benefits of AF ablation

As is the case with any invasive procedure, the balance of risks versus benefits of catheter ablation needs to be considered. This forms the foundation of the shared decision-making process (National Health Service England 2022). The following section discusses these issues, which are crucial for patient decision making and procedure selection.

It is widely accepted that patients are considered for catheter ablation of AF if they demonstrate highly bothersome symptoms, which interfere with an individual’s quality of life. This situation is highly subjective, because one person may have infrequent, but extreme symptoms, and another be in persistent AF, with minimal impact on their daily life. It is common practice in the UK for patients to be offered AF ablation when anti-arrhythmic drugs have failed, are not tolerated or contraindicated (National institute for Health and Care Excellence 2020). However, the recent European Society of Cardiology Guidelines (2021) now suggest that in certain cases, AF ablation may be offered as first line therapy (Hindricks *et al.*, 2021).

One group of patients that is considered for AF ablation, even in the absence of symptoms, are those with heart failure. The reason being that the CASTLE-AF trial demonstrated significantly lower mortality rates and hospitalisations in patients who were randomised to ablation, compared to anti-arrhythmic drugs (Marrouche *et al.,* 2018). In the ablation arm of the trial, cardiovascular mortality was 11.2%, compared to 22.3% in the drug arm. Hospitalisations were 20.7% in the ablation arm, compared to 22.3% in the drug arm. This is the only clinical trial that has demonstrated a mortality benefit from AF ablation. In patients without heart failure, there has, to date, been no trial demonstrating stroke reduction or mortality benefit (Packer *et al.,* 2019). This fact supports the reasoning for AF ablation in QoL and symptom improvement rather than any demonstrable prognostic benefit, such as mortality reduction or stroke reduction.

As ablation is an invasive procedure, it is not without risks. In a recent systematic review, which included 15,701 patients worldwide the authors reported severe complication rates at 4.51% (Benali *et al.,* 2023). The most common complication is bruising or haematoma around the site of vascular access (1.31%), with pericardial effusion (0.78%) and stroke (0.17%) being the next most frequently reported. The mortality rate worldwide is 0.06%, which has reduced in the last ten years. Due to the nature of these potentially serious complications, patient selection, education and decision making are crucial and arrhythmia nurses are often at the forefront of these discussions. In clinical practice, those patients with an elevated BMI will often be informed that risks are higher, especially vascular complications. Clinical experience suggests that In those who are obese, it is technically more difficult to deal with the serious complication pericardial effusion, as placement of a pericardial drain may be challenging. However, evidence varies in the reported complications in the elevated BMI group undergoing AF ablation. A very recent observational study reports low complications in all BMI groups, including those with a BMI of greater than 40kg/m^2 (Tabaja *et al.,* 2023).

1.5 Local practice

In the local Trust, patients are referred from a variety of sources, such as their General Practitioner, or more commonly, from their cardiologist, or arrhythmia nurse based in a District General Hospital. Patients are reviewed in the arrhythmia clinic, by either a Dr or arrhythmia nurse. Treatment options are discussed, to determine their suitability for ablation. It is common practice that the procedure is discussed in detail, according to a shared decision-making process. They are placed on a waiting list and attend, as a day case, for the procedure. Patients have contact with the arrhythmia nurses for ongoing support and clinical queries and are reviewed in the clinic three months post procedure. Lifestyle modifications are often discussed, but not always, and this process is not completely standardised within the clinic. A recent internal audit demonstrated that discussions around weight, exercise, smoking, and alcohol varied according to which healthcare practitioner is seen by the patient (Isaac 2021). Currently, no objective evaluation of the patient's quality of life and symptoms is undertaken in this patient group as part of their clinical care. As an experienced arrhythmia nurse, with a clear understanding of the needs of this patient group, access to individual patients within the arrhythmia clinic and a presence within the ablation procedure, it is highly appropriate for me to carry out patient focused research.

1.6 Current national policy in England

Within the last year NHS England have published a policy report to provide guidance and mandate for certain aspects of AF ablation within England. The policy working group consisted of patients, cardiologists, senior NHS managers and a public health specialist. The rationale for the use of ablation was investigated by a number of systematic reviews that focused on mortality benefits, reduction in AF burden, improvement in LV function, reduced hospitalisation, safety, cost effectiveness. They concluded that AF ablation does not improve mortality, but is effective compared with medications in reduces AF burden and reducing hospitalisations. Despite this fact there is little evidence for its cost effectiveness and longterm efficacy.

Within the NHS England Clinical Commissioning Policy on AF ablation (2022), obesity is explicitly mentioned as a concern and risk factor for the progression of AF from paroxysmal to persistent (NHS England 2022, p6). For these reasons, the policy gives guidance and control on patient selection. Patients with a BMI of 35-40kg/m^2 *"must''* lose at least 10% of body weight, after a period of intensive weight management. In terms of the NHS funding for the procedure, AF ablation is no longer funded for those patients with a BMI >40kg/m^2, those with hypertrophic cardiomyopathy and persistent AF, multiple ablations and if antiarrhythmic drugs have not been tried first (National Health Service England 2022). The reasons for these restrictions are based on evidence on success rates and patient safety. The policy assessed the evidence on medical therapy versus ablation and reported that there was no mortality difference from either treatment (Skelly *et al*., 2015). There was a significant difference in favour of ablation over medical therapy in the freedom from AF recurrence. Hospitalisations were significantly reduced in the ablation group compared to medical therapy (Skelly *et al.,* 2015). In terms of patient safety, there was no difference in stroke between ablation and medical therapy. Other complications related to the ablation were reported, such as cardiac tamponade and major bleeding, which were clearly not present in the medical therapy group (Skelley *et al.,* 2015). It is noteworthy that the policy focusses just on ablation and not provision of risk factor modification support, education, or advice.

Other stipulations are in place with this policy, which include the mandatory use of a shared decision-making tools and patient reported outcome measures pre-procedure, three, six- and twelve-months post procedure. The shared decision-making tool, which NHS England have developed is an information sheet, explaining AF, treatment options, with a focus on ablation. It contains potential questions to the clinician (arrhythmia nurse or doctor) and the risks and benefits of ablation versus drug treatment. The recommended PROMS within the policy are the AFEQT and the SF-12, which is discussed later in this chapter. This policy represents a change of approach to the current system of individual hospitals deciding on whom to select for AF ablation. This policy, which is less than a year old and not fully implemented across England, represents a change across the nation. Currently, it is not routine practice to undertake PROMS in patients undergoing AF ablation. The restriction on the BMI cut off 40kg/m^2 is mainly based on the European Society Guidelines (Hindricks *et al*., 2021), which suggests that before an invasive procedure, risk factor modification should be addressed. The main reason being that without removing the substrate for AF, such as inflammatory markers and adipose tissue, there is little point in striving for sinus rhythm with an ablation.

1.7 Patient reported outcome measures

An important development in healthcare has been the assessment of patient reported outcome measures (PROMS), (Devlin *et al*.,2010). A medical outcome means the extent to which a change in a patient's behavioural functioning or well-being meets the patients' needs or expectations (Ware 1993). Medical outcomes from the patients' view have developed over the last few decades and have traditionally been used within research studies to assess treatment effectiveness (Churrucca *et al*., 2021). PROMS may be used in various healthcare settings, conditions, and treatments (Fitzpatrick *et al.,*1992). Aside from research, PROMs may be used to assess treatments, monitor a condition, or prioritise therapies (Thrall *et al.,* 2006).

With the increasing interest in value-based healthcare, which links the outcomes of care, related to cost, Porter *et al*., (2016), suggest that PROMs are key within these principles. The process of encouraging PROMs allows standardisation of care, with the ability to benchmark and assess care delivery (Seligman *et al* 2020). Black (2013) goes further and asserts that PROMs may assist in the transformation of healthcare services. PROMS also support the principle of shared decision making between patient and healthcare professional, which is becoming a key part of modern healthcare (NHS England 2023) . However, PROMS have not been routinely used in clinical care . Foster *et al*., (2018) suggest a number of barriers to the routine use of PROMS. Some clinicians may feel that their clinical performance is judged by receiving patient feedback, although this is an outdated view of patient care.

The lack of resources to implement PROMS is an understandable barrier to their implementation. If services are not planned to incorporate PROMS, the infrastructure required, such as administrative support, computer systems and links with relevant external agencies, mean that a stretched healthcare system may not cope with such requirements. Furthermore, an already embedded system of care may not be in a position to support multiple patient responses within its organisation. In the systematic review carried out by Foster *et al*., (2018) on the implementation PROMS in healthcare, they found that clinicians may not have sufficient training in the type of PROM needed or the delivery to patients, who also require support and training in the completion of the PROM.

Although PROMs have been used in several healthcare settings, they have not been widely used in the clinical management of AF. Reasons for this are speculative, but likely to be similar to the barriers reported by Foster. In addition, despite PROMS being used in research trials, there is a lack of research that supports the use of PROMS to guide clinical practice.

The use of PROMS is vital, because heart disease, including AF, is a major cause of death worldwide (Seligman *et al.,* 2020) and therefore treatments need to be evaluated from the patient's perspective. Furthermore, AF care varies tremendously worldwide, in both treatments and outcomes. Seligman *et al.,* (2020) undertook a Delphi process in order to develop standardised patient outcome measures for those with AF. PROMS were part of the working group's recommendations for the standardisation of care for AF. A number of tools were evaluated, including questionnaires such as the Short Form 12 (SF-12), the AF Symptoms Score (AFSS) and the AF Effect on Quality-of-Life Questionnaire (AFEQT). The working group in this research acknowledged the challenges in the use of PROMS, in AF, with no consensus on whether AF specific or generic PROMS were ideal. They did, however, recommend that further work in this area needs to be undertaken, as the use of PROMS is highly valuable. They recognise the importance of the role of the arrhythmia nurse within the patient pathway (Seligman *et al*.,2020). Although not part of routine clinical practice, PROMS have been used in several clinical trials in AF to assess treatment effects. This approach has been seen in the Catheter Ablation versus Antiarrhythmic Drug Therapy for

Atrial Fibrillation (CABANA) trial, which was a randomised controlled trial (RCT), investigating anti-arrhythmic drugs versus AF ablation (Packer *et al*.,2019).

In addition to the lack of routine use of PROMS in AF care, there appears to be a lack of understanding or consensus on how to apply these ideologies and tools to a clinical service (Kotecha *et al.,* 2016). A number of reasons could explain why this is the case, which are likely to be the same as the barriers to the use of PROMS in general. AF services may focus on the delivery of treatments, rather than their effectiveness, from the patient's perspective. Personal clinical experience suggests that there is a lack of understanding, training, and resources in order to implement PROMS in patients with AF, within an already stretched service. Despite this, PROMS are highly relevant in AF treatments, and these are discussed in the next section.

1.7.0 Quality of life

Quality of life (QoL) is a term that is often applied in healthcare. Although the WHO defines health as "absence of disease" (Testa & Simonson 1996), there appears to be no widely accepted definition for the term quality of life. The terms quality of life, or in this context, health-related quality of life (HRQoL) tends to refer to the physical, psychological, and social domains of health, perceived as distinct areas that are influenced by patients' beliefs, perceptions, and expectations (Testa 1996). The primary reference to quality of life may be found in Pigou's "The Economics of Welfare" in 1920, whereby he examined government support for the poor regarding personal well-being and the national dividend (Pigou 1920, cited in Jenkinson 1994). Jenkinson (1994) explains that quality of life in its purest form refers to the capability of an individual and, by extension, to a general population.

HRQoL was mentioned in the literature more than half a century ago and relates to the physical, emotional, and social well-being of an individual (World Health Organisation 1948). The subject of QoL continues to have unanswered questions, despite the work of researchers, including nurses (Bubien *et al*., 1996; Wood *et al*., 1992), in the field of QoL in patients with arrhythmias. It has been suggested that the application of QoL tools in AF care has limited application or understanding (Kotecha *et al.,* 2016). This is for several reasons, but mainly because AF is in itself a complex condition, with a variety of presentations and effects. The measurement of QoL in AF is complex because AF may be permanent, persistent, or paroxysmal and the treatments, such as medications, may impair QoL independently. Other influences, such as comorbidities, for example, a raised BMI may also impact QoL, regardless of the presence of sinus rhythm. Although the evidence base for the assessment of QoL in AF patients is relatively small compared to the clinical problem, it is generally accepted that AF impairs quality of life overall.

According to Seligman *et al*., (2020), one of the goals of healthcare is to improve QoL and symptoms as well as reducing complications and mortality. All of these targets need to be in the context of providing care in a culture of cost effectiveness. The measurement of healthcare impact is important, especially in the current economic climate and has implications, not only for clinicians and researchers, but budget holders and commissioners of healthcare services. An example of this would be in patients with AF undergoing cardioversion, to restore normal sinus rhythm. In the absence of heart failure, the only, evidenced-based reason to do this, is for improved patient reported outcomes, such as QoL (Hindricks *et al*., 2021). This means that it is vital to assess how the patient feels after such a treatment, ideally in an objective manner.

Generic healthcare measurements have been developed since the 1980's (Hunt *et al.,* 1988*,* Berger *et al., 1981*). The Rand Corporation in the United States of America designed several healthcare questions for the Health Insurance Study, designed to allocate appropriate health insurance to individuals (Bowling 1995). A standardised survey called the Medical Outcomes Study was used to measure healthcare status in a scientific and validated way, involving detailed analysis of patient outcomes in variable systems of medical care (Stewart & Ware 1992). From this the Short Form 36 was developed (SF-36), which is a 36-item questionnaire method of assessing health status. This survey has been used in many conditions and as a subjective measure in healthy subjects to examine ten thousand population norms (Jenkinson *et al*.,1996). Furthermore, the SF-36 has been shown to be reliable, valid, and sensitive to age (Brazier 1992, Wagner *et al.,* 1993, Mangione *et al.,* 1993). A shorter version of the SF-36 is available and known as the SF-12, which has also been used as a generic instrument in several conditions (Ware *et al.,* 1996). Quality of life has been used in a wide range of clinical settings and is relevant to AF, as a long-term condition (Thrall *et al*.,2005). Several tools may be used to assess HRQoL, and the previously mentioned Short-Form 36 (SF-36) has been described as the gold standard questionnaire in assessing patient outcomes. The other generic QoL tool that has been used in the AF population is the EuroQoL-5D, which has five dimensions of health, which are measured on three levels, from none to severe. Furthermore, it is reported to have ease of use and has generalisability (Aliot *et al* 2014). Whilst these measurement tools have been used in the AF population, they have disadvantages. The limitations of these generic instruments is that they may not capture the specific aspects of QoL that relate to AF and may not be sensitive to changes in the older AF population (Aliot *et al.,* 2014).

Several AF specific QoL questionnaires have been developed over the years (Kotecha *et al.,* 2016, Alliot *et al.,* 2014). The most widely reported is the AF Effect on QualiTy (AFEQT), which includes treatment satisfaction, symptoms, and activities. A number of other questionnaires have been developed, but are said to lack reliability, responsiveness, and validity (Kotecha *et al*., 2016). Despite this, there seems to be no doubt that AF impacts negatively on QoL when compared to healthy controls (Thrall *et al*., 2006), when using the more commonly used generic tools. The AF Follow-up Investigation of Rhythm Management (AFFIRM) trial (AFFIRM Investigators 2002) aimed to assess clinical outcomes in 4060 patients randomised to either cardioversion or rate control. At this time, AF ablation was in the early stages of development and not widely available. The trial concluded that rhythm control offered no benefits in terms of survival or stroke. QoL was assessed in a subset of both groups (n=845) and no significant differences were found between groups. However, the limitations in this trial included the fact that true comparisons were not possible for several reasons. The rhythm control group had a number of AF recurrences (38.4% at 5 years) and the rate control group had a number of patients in sinus rhythm at 5 years (34.6%). In addition, the study may have been biased to not find QoL differences because of patient selection, which is suggested by (Reynolds *et al.,* 2008). Within the AFFIRM Trial it is worth noting that the QoL scores improved from baseline to the timepoints up to five years in both rate and rhythm control groups. These results are not in line with other studies that demonstrate more favourable QoL outcomes in those patients receiving rhythm control, in the form of catheter ablation, as reported by Thrall *et al.,* (2006), in their systematic review of patients QoL in AF. Of the nine studies in this review, using ablation for rhythm control, all demonstrated significant improvements in SF-36 scores post procedure (Thrall *et al.,* (2006). Similar outcomes have been reported more recently in the context of ablation versus antiarhhythmic drugs (Oral *et al.,* 2006; Packer *et al*., 2019; Mark *et al*., 2019). In addition to the assessment of QoL, exploring the needs of patients with AF also should include an assessment of symptoms, which is separate from the physical, emotional, and functional aspects of QoL (Alliot *et al.,* 2014). This aspect of patient care is discussed in the next section.

1.7.1 Symptoms

The majority of patients with AF report symptoms, such as palpitations, dyspnoea, fatigue, and reduced exercise tolerance (Hindricks *et al*., 2021). However, assessment is challenging because there is no single tool that can evaluate symptoms. To measure symptoms, several instruments have been developed.

The AF Severity Scale (AFSS) is a 19-item subjective and objective scale, designed to capture symptoms, health care usage, AF burden and severity (Dorian *et al.,*2000). This scoring checklist was developed by researchers in the University of Toronto over 20 years ago and has been tested for validity and reliability (Maglio *et al.,* 1998). The 14-item, disease specific scale includes objective scores which include AF burden, frequency and duration, patient perceptions of AF and healthcare use. The authors concluded that the AFSS is both valid, reproducible and reliable in the AF population and continues to be used within research studies, especially those related to treatment interventions (Patak *et al.,* 2014). These researchers went on to develop a tool that encompasses both QoL and symptoms, known as the Canadian Cardiovascular Society Severity of AF Scale (CCSSAF), (Dorian *et al.,* 2006). This scale has the advantage of being both simple and designed for use at the bedside. Although it correlates well with the SF-36, from a QoL perspective, it is said to be poorly correlated with AF burden and may not be helpful for more general use (Rienstra *et al.,* 2016). The European Heart Association (EHRA) uses a scale based purely on symptom impact (Kirchoff *et al*., 2007). It is a simple score from I-IV but is highly subjective and may not be generalisable to all AF patients. Despite this it has been used widely in common clinical practice. It is often used within the initial assessment of a patient within the clinic environment and may be used within the history taking process. Its use is not standardised or used by all and outside the arrhythmia team, has little meaning or explanation. A patient would not know what a score of IV means, for example, unless an explanation is given. This view is supported by Rienstra *et al.,* (2016) who assert that there is a lack of a standardised approach to symptom assessments and the presentation of symptoms is highly variable.

An alternative symptom questionnaire has been developed, called the Patient Perception of Arrhythmia Questionnaire (PPAQ), (Wood *et al.,* 2009). This questionnaire was developed using several processes, to ensure robust validity and reliability. The process of patient codesign (Withers *et al* 2015) was also used, but this was in the context of a wider PROM development for the UK ablation population, not simply for AF. In this PROM, the PPAQ was used in conjunction with the EuroQoL-5D to assess ablation outcomes in a number of arrhythmias and is known as the Cardiff Cardiac Ablation PROM (C-CAP). The PPAQ has been shown to be useful in assessing ablation outcomes, with confirmation that ablation resulted in improved symptoms for the majority of patients (Withers *et al.,* 2014). The PPAQ asks on the frequency and duration of AF, the individual 12 symptoms, the "bothersomeness" of those symptoms, the impact of AF on daily life and finally the number of days missed from work and activities (Wood *et al*., 2009).

It is widely accepted that symptoms in AF are both important in assessing patients' health status and with regard to treatment considerations (Hindricks *et al.,* 2021), (January *et al*.,2014; Heidenreich *et al*., 2020), and National Institute of Health and Care Excellence (2021). Moreover, there appears to be little research on symptoms caused by only obesity. Overall, symptom evaluation may be challenging and requires further research (Gleason *et al*.,2018).

1.7.2 Patient experiences

Understanding AF from the patient's perspective is important for healthcare professionals to not only tailor individual treatments, but improve the delivery of those treatments, and provide education, and support. However, there is a paucity of research into the patient's experiences of AF ablation (Wood 2017). The small number of papers that exist about AF and patient experiences suggest that AF has a negative impact on an individual's life, especially from an emotional perspective.

McCabe and Barnason (2012) undertook surveys in 207 patients with AF to "identify the extent to which illness perceptions, coping strategies, symptom frequency and severity contributed to psychological distress in recurrent persistent AF" (p 432). These authors found that psychological distress was a common theme and concluded that AF has a negative impact and the lack of understanding of the condition resulted in more psychological distress than the physical AF symptoms. These findings were similar to a study by Withers *et al*., (2015), which consisted of 25 patient interviews in those undergoing ablation for arrhythmias. Whilst this study did not purely focus on AF, the underlying themes could be applied to this patient population. These authors suggested themes related to fear, impact of the arrhythmia, education, and the ablation procedure, all of which were challenging experiences. This study highlights the importance of the arrhythmia nurse in the patient pathway in the patient's educational requirements for undergoing an invasive procedure (Withers *et al.,* 2018). The issue of psychological distress in AF was also evident in a study by McCabe *et al*., (2011), whereby patients reported AF in a negative manner, with unpredictable and serious consequences. This factor is supported by the qualitative study by Taylor *et al*., (2017), who found that patients reported the unpredictability of AF and accompanying poor knowledge added to lower ablation expectation outcomes.

Whilst there are few studies regarding experiences of those undergoing AF ablation, Wood *et al.,* (2017) provide evidence that patients have difficulties in managing their symptoms after AF ablation. This was the first study to demonstrate the clinical course of recovery after AF ablation. The same lead author then used the qualitative data to examine the issue of fatigue after AF ablation (Wood *et al.,* 2022). The study identified two "trajectories" of recovery after ablation that did not align with the medical assumption of recovery, which is related to physical healing. The trajectories of recovery related to physical and emotional recovery. The trajectory of physical recovery was slower than expected and the emotional trajectory was related to setbacks and slower than expected progress. In addition, this study concurs with Taylor *et al's.,* study (2017), which reported that education and support on AF, treatments and expectations are lacking and limited. The need for support and education is a common finding in other studies. A recent qualitative systematic review by Wang *et al.*, (2022) found that, in the 25 included studies, five themes were generated that relate to the diagnosis of AF, living with AF and the need for external support. Whilst this review is important in highlighting the lived experiences of those with AF, lifestyle factors, in particular BMI, were not part of the study. The research by Bergtun *et al.*, (2019) described the patient's experiences in a holistic manner after AF ablation. In 19 patients they identified five themes that related to recovery after the procedure, coping strategies, and the need for support, which are all in line with the previously discussed research on patient experiences.

It is worth noting that mixed-methods research in this area is distinctly lacking. A preliminary literature search revealed a paper by Stridman *et al.*, (2019) on the experiences and the QoL of patients with AF. It is limited by the small numbers of those in the quantitative part of the study (n=18). Nevertheless, the results demonstrate the negative impact that AF had on the ability to undertake daily activities, with the additional worries that ensue. This is an important step in the right direction in understanding the issues that patients with AF face but does not include the issue of an elevated BMI.

The studies mentioned in this section are vital in developing a deeper understanding of how patients feel, what they require and the issues they face in the diagnosis of AF. Furthermore, the research related to ablation highlights the challenges faced in recovery and the individual's expectations of the procedure. Whilst all these papers are valuable in understanding patient perceptions and experiences, there seems to be little research on patients with AF and an elevated BMI. This gap in the evidence is evidently an area of significance for arrhythmia nurses, due to the increasing numbers of AF presenting with an elevated BMI.

1.8 Justification for this study

Although AF is a huge clinical problem and a substantial amount of research, from the medical perspective exists and continues to add to the body of evidence, this is not the case for nursing research. It doesn't really matter which healthcare professional carries out research, as long as patients benefit in the long run. However, an arrhythmia nurse is with the patient throughout the clinical pathway and is often the first point of contact, before and after treatment. This makes them ideally placed to interact, from a research perspective. Furthermore, the lifestyle factors that are recommended as part of the clinical guidance is often an issue that is addressed by nurses. This means that nursing research in this clinical area would enhance the patient pathway for high quality care. In this local centre its currently unknown if patients with a raised BMI have improved QoL and symptoms after AF ablation. Furthermore, patient experiences of AF, the ablation, in the context of an elevated BMI are undetermined.

A number of library and database searches have revealed that there is a paucity of nursing research in AF patients, worldwide. Wood (2017) has suggested that there is an explicit requirement for arrhythmia nurses to add to the body of knowledge in such patients. The main reason being that nurses are at the forefront of the care of these patients. Within advanced nursing practice, arrhythmia nurses are making complex decisions on a daily basis in the care and management of patients with AF. Therefore, arrhythmia nurses are wellplaced to investigate AF and ablation, particularly from the patient's perspective. The reasons for this include patient support, education, information, and shared decision making on treatment options.

The role of nurses in the management of AF has been shown to be crucial in the improvement of patient outcomes, including reductions in hospitalisation and mortality (Gallagher *et al.,* 2017). This work is further supported by the work of Hendricks *et al*., (2013), who undertook a randomised controlled trial, where 712 patients were randomised to usual care versus nurse-led care. After almost two years of follow-up those randomised to nurse-led care had significantly fewer deaths and hospitalisations. After a mean of 22 months, the primary endpoint occurred in 14.3% of 356 patients of the nurse-led care group compared with 20.8% of 356 patients receiving usual care [hazard ratio: 0.65; 95% confidence interval (CI) 0.45–0.93; P 1⁄4 0.017]. Cardiovascular death occurred in 1.1% in the nurse-led care vs. 3.9% in the usual care group (hazard ratio: 0.28; 95% CI: 0.09–0.85; P 1⁄4 0.025). Cardiovascular hospitalization amounted (13.5 vs. 19.1%, respectively, hazard ratio: 0.66; 95% CI: 0.46– 0.96, P 1⁄4 0.029). This powerful evidence is compelling in indicating the importance of nurse-led care. However, such treatment pathways are not necessarily standardised, and services vary widely. Such integrated care, which includes nurse-led care in AF patients is key for these improved outcomes. In the systematic review and meta-analysis by Khan *et al.,* (2022), it was concluded that nurses are important for education and support to patients. Despite this important work, gaps in the knowledge base remain, especially on understanding patient outcomes after ablation, in those with an elevated BMI. In order to improve patient care and outcomes, of those patients with an elevated BMI, further research is proposed to identify if current service provision and care is optimal.

Existing evidence suggests that catheter ablation for AF is a suitable treatment option, but the main reason for undertaking this procedure is to improve symptoms and quality of life, not reduce stroke risk or mortality. Studies have demonstrated that QoL improves after ablation (Dorian *et al.,* 2002, Packer *et al.,* 2019). According to Gray (2017), value-based healthcare is an emerging concept, whereby the health service, with its finite resources, is required to allocate appropriately to the relevant population. This is especially true in the case of catheter ablation, which is an expensive treatment, with significant risks and is designed to improve symptoms and quality of life. Furthermore, in individuals with modifiable risk factors, such as obesity, obstructive sleep apnoea or hypertension, there is less value in exposing a patient to a procedure when additional lifestyle adjustments have not been addressed (Chatterjee & Albert 2017). This is because lifestyle modifications may alter the AF burden, thus rendering ablation unnecessary. Furthermore, AF ablation is not curative, but designed to control AF in a more durable way than medications. In undertaking ablation, the preference is to do so in an individual who is most likely to have a successful outcome, with least complications. The risk factors associated with AF may reduce success of ablation and increase the chances of complications. Arrhythmia nurses are at the forefront of the patient interactions that include shared decision making in ablation treatment and the lifestyle modifications that are needed to improve their health overall.

Another gap in the knowledge base is the lack of qualitative research exploring patients' experiences or perceptions of the process of the ablation procedure, including the treatment decisions, recovery, and impact. There is little qualitative work reporting the perspectives of patients with AF, in the context of an elevated BMI. Understanding the patient's lived experiences of AF may inform the development of effective nursing care in what continues to be a complex clinical pathway. In order to develop breadth and depth in understanding quality of life, symptoms and subjective experiences of those with AF undergoing ablation, a mixed methods approach is proposed. By addressing symptoms and quality of life before and after ablation at three time points and by undertaking qualitative interviews, it is anticipated that the mix of both data sets will provide new and rich insights with a deeper level of understanding in this patient group and inform ways to optimise patient care. In doing so, patient care may be enhanced, and it is possible that resources may be directed into other areas, such as lifestyle modification clinics, prior to catheter ablation. Exploring qualitative experiences of a procedure and AF treatments may reveal areas of care with unmet needs, areas of care valued by the patient, understanding any problems, barriers to recovery, how a patient makes sense of their condition and motivations for lifestyle modifications. All these factors may influence the development of the nurse's role in their pathway of care. Furthermore, patient selection for the procedure may be clearer, which would enable a better management of patient expectations for this invasive procedure. The issues discussed within this chapter has led to a period of reflection and inquiry about the needs of this patient group, which requires further research.

This chapter has identified the knowledge gaps within this area of practice. A solution to the various issues discussed is to undertake a mixed methods approach. As arrhythmia nurses are central to the patient pathway, in terms of shared decision making, patient assessment, education and care, it is entirely appropriate that this study is undertaken by an experienced arrhythmia nurse. A study using mixed methods would address both the objective evaluation of both QoL and symptoms, in addition to the subjective assessment of patient experiences. The significance and benefits of the proposed study are presented in the next section.

1.9 The research question and study details

This section introduces the research question, with the aims and objectives of the study. The gaps in the evidence base have led to the development of a research question and study, which will help arrhythmia nurses and other healthcare professionals understand the problems faced by overweight/ obese patients within this patient group. A chance meeting with Professor Patricia Davidson, who was then Professor of Nursing at Johns Hopkins University in Baltimore was a light bulb moment in my academic journey. It was 2016 when I was seriously considering Doctoral level research. I had many ideas related to work-based issues but could not narrow the scope to one question. Meeting Professor Davidson was interesting and significant. We discussed my work as an arrhythmia nurse, and I explained that I was stuck on a possible research question. She simply stated that for Professional Doctorates the key is to identify an everyday problem or issue in practice and search for a way to answer that question. This led to the development of the research question and study within this thesis.

I believe this study, as outlined below addresses the current questions that are part of everyday practice within arrhythmia care and addresses current knowledge gaps. It is noteworthy that this study aligns with the recently published NHSE recommendations within AF clinical commissioning, although this study was completed before NHSE publication, which highlights its current relevance. I had several discussions before, during and after my study, with the NHSE National Director for Cardiology (Dr Nick Linker) about my study and the progress of the NHSE policy. It is important to me that both quantitative and qualitative outcomes were addressed, using a mixed-methods approach for several reasons. Using quantitative outcomes in this local patient group has provided objective measurements of the ablation effects, which is appealing to doctors performing the procedure, nurses who are involved in the patient journey and, of course the patient who is at the centre of and experiencing the treatment. By using a mixed-methods approach, both ends of the philosophical and methodological spectrum are satisfied within a multi-disciplinary team of healthcare professionals. Within the Consultant Nurse role, I have developed my research pillar as a way of generating new knowledge and by using quantitative and qualitative methods I feel this has been achieved.

1.9.0 The Research Question

The study research question is as follows:

What are the quality of life, symptoms, and experiences of patients with an elevated body mass index, undergoing catheter ablation for atrial fibrillation?

1.9.1 Aims and objectives

Aim: To explore QoL, symptoms and experiences of patients with an elevated BMI undergoing catheter ablation for atrial fibrillation

Objectives:

- To review the literature on the experience and outcomes of patients with an elevated BMI and AF
- To explore changes in QoL and symptoms in patients with AF and an elevated BMI from before ablation to three and six months afterwards
- To explore the factors which influence a change in QOL and/or symptoms between baseline and six months.
- To explore the experiences of patients with AF and an elevated BMI who undergo ablation. The initial scoping exercise determined that recruitment for those with a normal BMI would take twice as long and, for pragmatic reason, was not feasible in the time available in this study.
- To make practice recommendations

1.10 Organisation of this thesis

This thesis is organised into several chapters. The first part of this chapter introduced the hugely concerning health issues of both AF and a raised BMI. The treatments and current clinical guidance related to AF were presented, with particular emphasis on catheter ablation. What is currently known about the impact of AF on individuals is discussed in relation to their reported outcomes, in particular the quality of life, symptoms and experiences of patients. The link between an elevated BMI and AF has been discussed. Furthermore, this chapter has presented why researching this topic is so important and will help inform nursing care. The research study within this thesis has been introduced, with the intention of enhancing the care of patients suffering from this common arrhythmia.

The second chapter presents the literature review, which was undertaken to appraise and evaluate the underpinning research on the research question. A narrative synthesis has been produced to address the evidence base on the subject of QoL and symptoms in those patients with an elevated BMI, undergoing ablation for AF. The literature review methods are described and the gaps within the literature identified.

The third chapter presents the underpinning philosophy selected for this study and the subsequent methodology that has been selected to carry out the research. Pragmatism is discussed as the most appropriate paradigm for the research. Furthermore, a mixed methods methodology is presented as the most suitable approach in order to answer the research question. The second part of the third chapter describes the methods used to undertake the study that answers the research question. This includes the regulatory process required to start the study and the collection of data within the two phases. The methods of data analysis are provided.

The fourth chapter demonstrates the quantitative results from the QoL questionnaires, which are the SF-36 and the symptoms scores from the Patient Perception Questionnaire (PPQ). The statistical results from both questionnaires are presented in addition to the characteristics of the study population, the BMI at three time points and the presence of rhythm control post ablation.

The fifth chapter contains the findings from the patient interviews, using a framework analysis approach. The four main themes that emerged from the analysis are discussed. These themes are as follows:

- personal well-being related to AF
- care and treatments of AF
- interplay of lifestyle and AF
- living with AF in a pandemic

Chapter six provides a discussion on both the quantitative and qualitative findings, in relation to the current evidence base, and the meaning of such results in relation to nursing. The use of Orem's nursing model of self-care is offered as a framework on which to base nursing care within the issues raised in the discussion and from the research findings.

The final chapter seven demonstrates the strengths and limitations of the research presented within this thesis. Conclusions are drawn and dissemination of this research is presented. The implications of the research are afforded in accordance with the four pillars of advanced nurse practice and how the care of such patients may be enhanced. The Appendices at the end of the thesis display the relevant material on how the study was conducted. The references list is the final part of this thesis.

1.11 Summary of Chapter 1

This chapter has introduced the subject of atrial fibrillation, in the context of an elevated BMI and catheter ablation. The background evidence base has been explored over a number of years, within a complex and evolving clinical picture. Moreover, this chapter has provided a justification for expanding the understanding of what is currently known of the issues related to AF, BMI, QoL, symptoms and experiences of those undergoing AF ablation. The role of a consultant arrhythmia nurse is crucial in this context. The research question, aims and objectives of the study are presented, including some of the methods required to undertake the research.

The next chapter presents the literature review findings that are specific to the research question within this thesis.

CHAPTER TWO: Literature Review

2.0 Introduction

This chapter presents a review of the literature to date, regarding the quality of life, and symptoms of patients with an elevated BMI who are undergoing catheter ablation for atrial fibrillation. Although a number of papers were found on patient experiences of AF and ablation, there were none in the context of an elevated BMI.

A narrative synthesis was carried out to evaluate the relevant research literature. In doing so, the scope of existing knowledge was explored, and the gaps identified, therefore providing the rationale for the study. The chapter is divided into sections to demonstrate justification for the research described in this thesis. The following section begins by outlining the aims and objectives of the literature review, before describing the approach and methods used to conduct the review.

2.1 Aims and Objectives

The aim of this literature review was to examine the research literature related to the quality of life and symptoms in patients with a raised body mass index (either being overweight or obese), after ablation for atrial fibrillation.

The objectives of this literature review were as follows:

- To synthesise the data in relation to QoL related to AF following ablation
- To synthesise the data related to AF symptoms following ablation ● To explore the outcome measures used in this context

The literature review question is – *what is known about the quality of life and symptoms of patients with an elevated BMI undergoing AF ablation?*

2.2 Literature review

A literature review is a process of identifying and analysing the body of evidence that exists related to a given research question (Aveyard *et al.,* 2021). Traditional literature reviews, termed systematic reviews, with meta-analyses are often used for randomised control trials and are considered a well-established and highly structured method of appraising published literature (Aveyard *et al.,* 2021). A systematic literature review is defined as "a review of the evidence on a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant primary research" (National Institute for Health and Care Excellence 2016, p2). Discovering what is already known within a certain area allows the identification of potential gaps within the knowledge and development of new ideas for further research (Bonfield 2017). This type of literature review has allowed the development of treatment guidelines and consensus agreement on various aspects of healthcare, such as Cochrane reviews (Higgins *et al.,* 2019). Such reviews have allowed the strengths and limitations of research to be evaluated and summarised in a transparent and concise way. Other types of literature reviews have developed over the past few decades. These include integrative, scoping, and systematic reviews without meta-analysis.

Another type of review, known as a narrative synthesis, has been developed, which is an alternative to a traditional systematic review and may be useful in situations where the evidence base is heterogeneous. The narrative synthesis is explored further in the following section, as a suitable method for the appraisal of the literature within this thesis.

2.3 Narrative synthesis literature review

This literature review was conducted systematically, with narrative synthesis used as the method of analysing the findings. Narrative synthesis is a form of literature review that has been developed in the last 20 years (Pope and Mays, 2006). Although Campbell *et al.,* (2019) report that there is no clear definition of narrative synthesis, there is a useful definition and guidance in the work of Popay *et al.,* (2006). These authors describe narrative synthesis as a form of "storytelling", whereby evidence is used to construct a narrative, which provides convincing evidence for a wide range of research questions. Although these authors suggest that narrative synthesis was hitherto viewed as inferior to meta-analysis, it has become widely accepted within the range of available evidence for both quantitative and qualitative research methodologies (Popay *et al.,* 2006).

Narrative synthesis may be used for several literature review scenarios. It may be that the subject of interest is not well understood or requires a narrative, rather than a metaanalysis of statistical results. Furthermore, a meta-analysis is not always possible, due to the nature of the data gathered and therefore, a narrative synthesis offers a way of comparing and contrasting data to present a consensus of findings (Popay *et al.,* 2006). Narrative synthesis has the advantage of being able to assemble the body of evidence about AF, ablation, a raised BMI, QoL and symptoms, which may have been established using varied methods and methodologies. This approach allows the evidence to be presented in a manner that compares research findings. This clustering or grouping of findings is useful in establishing the underpinning evidence related to the research question. Within this thesis it became apparent that, whilst a number of published papers exist on the subject matter, aims, methodologies and results are heterogeneous and therefore a meta-analysis would not be appropriate or even possible. A narrative synthesis was chosen as the most suitable form of literature review for this thesis to present the whole range of relevant findings related to AF, QoL, symptoms, ablation and a raised BMI. In this literature review, systematic methods were used to search for the literature, but a narrative synthesis was used to analyse and discuss the results.

2.4 Methods

The following section presents the methods that were used to complete the literature review.

2.5 Search Strategy

Prior to the systematic literature search, the use of a tool or framework to develop the question was explored. The use of such a framework has been suggested by Sisson (2017) to be useful in providing structured guidance for the literature review process. While other frameworks exist, I decided to use the Patient/Population, Exposure, Outcome (PEO) framework, as described by Kesternbaum (2019). The reasons for this were that it is a widely used model, it had been used commonly in nursing research and it was useful in providing structure to the literature search. In the case of this study, the *Population* was patients with AF and a raised BMI; the *Exposure* was the ablation procedure, and the *Outcome* was QoL and/or symptoms and/or experiences.

As the research question and literature review question contained a medical treatment, it was decided to search the Cochrane database which indexes literature investigating medical treatments. An initial scoping review of the Cochrane database found only one paper on catheter ablation for AF, which was otherwise not related to the research question and therefore this database was no longer used within the searches.

The literature search was carried out using two electronic databases - the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and PubMed (which includes the database MEDLINE). Both are widely accepted databases and are commonplace worldwide. The CINAHL database allows the use of subject headings and PubMed uses Medical Subject Headings (MeSH) titles to aggregate search concepts, such as BMI, overweight and obese. Preliminary searches were undertaken in 2018, and repeat searches were conducted regularly until June 2023. The last search was conducted on (10/06/23).

The MeSH and subject headings were decided upon, based on the research question, and may be seen in Table 1, below.

Table 1 MeSH and subject used in the literature search.

P	E	O
Atrial fibrillation	**Ablation** OR pulmonary vein isolation	**Quality of life** OR well-being OR health related quality of life
Body mass index OR obesity OR overweight OR BMI		
		Symptoms **Experiences**

Boolean operators were used as conjunctions, to combine terms such as *BMI*, *body mass index*, *overweight* and *obesity*. Due to the large volume of published papers on the subject of AF and ablation, the search was conducted in a stepwise manner, as advised by the librarian, for example searching for AF then searching for BMI and then combining the two before searching for ablation and so on. This enabled the search to narrow its focus on the specific research and literature review question. The following table (2) offers an example of a search that was conducted via CINAHL.

Table 2 Example of an initial search on CINAHL

Search 7	S5 AND S6
Search 6	quality of life OR well-being OR well-being OR health-related quality of life
Search 5	S3 AND S4
Search 4	ablation or pulmonary vein isolation
Search 3	S1 AND S2
Search 2	atrial fibrillation
Search 1	obesity OR BMI OR body mass index OR overweight

2.6 Journal searches

In addition to database searching, the following specialist journals were particularly relevant to the review question. Therefore, using the same search terms as above the following journals' websites were searched for relevant material:

- British Journal of Cardiac Nursing
- European Heart Journal
- Heart and Lung
- European Journal of Cardiovascular Nursing

2.7 Other data sources

Searching for other sources of literature was undertaken at several time points from 2018 to

2023. Such searches included searches within published theses via the university repository (RADAR) and the British Library E-Theses Online Service (EThOS). In addition, other forms of searches intended to capture relevant grey literature were periodically undertaken using social media platforms such as Twitter) and search engines such as Google. Reference lists of papers that were found were also searched for relevant publications.

2.8 Inclusion and exclusion criteria

To keep the search focused on the literature review question, particularly as the volume of published work on certain elements was large, a set of inclusion and exclusion criteria was applied as detailed in Table 3. There were no limits placed on dates of publication. As catheter ablation has only been a recognised treatment since 1998, it was known that there would be no relevant studies prior to this date.

Table 3 Inclusion and exclusion criteria

Inclusion	**Exclusion**
Primary research on AF ablation in patients with raised BMI that reports QoL or symptoms	Publications on ablation of any other arrhythmia
All research designs	Abstracts
Adults over 18 years	Case reports
Published in English language	Publications on surgical ablation
	Publications on COPD or heart failure outcomes, with AF

2.9 Search results

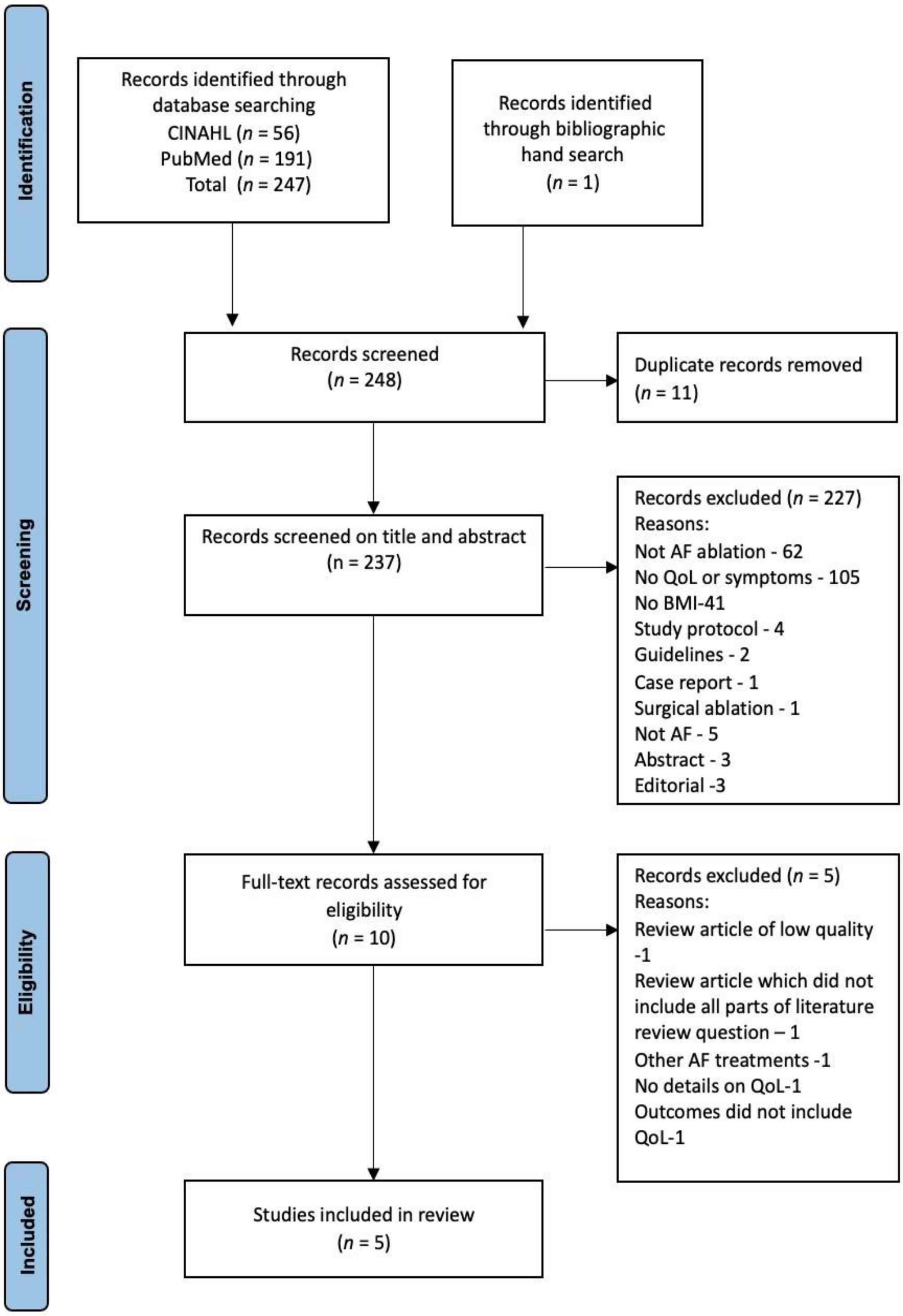
The following section presents the process of how the relevant papers were selected for the literature review. Findings are reported according to The Preferred Reporting Items for Systematic Reviews and Meta Analyses (PRISMA) (Moher *et al.,* 2015).

2.10 Studies excluded in the review

The studies excluded from the review were those that did not meet the inclusion criteria. The papers that were duplicated between PubMed and CINHAL were removed at the start of the data extraction process. A total of 237 were screened on title and abstract and 227 were excluded for the following reasons, studies related to AF, but not ablation; AF and ablation were not related to BMI; they were study protocols; they were not primary research; they were surgical rather than catheter ablation; and primary conditions such as COPD or heart failure, with AF as a secondary problem.

Following initial screening, a total of ten full text papers were assessed for eligibility. A further four papers were removed as neither QoL nor symptoms were reported. Another paper mentioned QoL in the abstract, but there were no details within the paper and was also excluded. A total of five papers were therefore extracted for the literature review. These results are presented in Figure 1.

Figure 6 PRISMA diagram for the literature search



2.11 Studies included in the literature review

A total of five papers met the eligibility criteria and were included in the review. Publication dates ranged from 2008 to 2017. Four of the studies were conducted in the United States of America and one in Australia. All were quantitative, prospective, and observational cohort studies. Patient reported outcomes were measured using a variety of quality of life and/or symptom assessment tools. The participant numbers ranged from 90 to 660. Mean ages ranged from 54±10 to 64±10 years. The percentage of males ranged from 56% to 84%. AF classification varied from 27-65% paroxysmal, to 35-100% persistent. BMI measurements ranged from 29 ± 5 to 38 ± 4 kg/m^2. Two of the papers included a risk factor modification intervention (RFM), comparing usual care versus risk factor modification groups. These groups were not randomised, but participants chose whether to opt for the RFM intervention or not. All the studies included questionnaires to assess either symptoms, quality of life or other psychological aspects, to assess pre and post ablation patient reported outcome measures. Follow-up time points ranged from 12 to 36 months.

2.12 Critical appraisal

The Critical Appraisal Skills Programme (CASP 2018) tool for critical appraisal of cohort studies was utilised in this literature review. CASP allowed a systematic assessment of the study aims, design, recruitment, relevance, validity, bias, results, and implications for practice of the research papers. CASP covers areas relevant for appraisal in a straightforward and succinct manner. It enabled the appraisal of the studies included in the review and assisted in “making sense” of the data (CASP 2023). Furthermore, the appraisal process requires a simple “yes, no or can’t tell” response, which is helpful in appraising research papers. The prompts that the CASP tool provides allows the reviewer to consider wider questions that are important when conducting a literature review. Whilst CASP does not recommend a scoring system, the tool provides space for additional comments and thoughts that may arise in the reviewing process. Finally, the CASP tool concludes with the implications for the study in question in terms of practice application, which fits well with this Doctoral thesis.

The table presenting the quality appraisal using the CASP checklist for the included papers can be found in Appendix 1. Overall, the studies included were reasonably well conducted and there was no reason to exclude any based on methodological rigour.

2.13 Synthesis

This section explains the approach used to synthesise the findings from the five papers within this literature review. Campbell *et al.,* (2019) provide guidance for synthesis without meta-analysis (SWiM) in systematic reviews, which contains nine steps to synthesising the results from published research. The focus of this approach is to allow transparency of results, which may not be suitable for meta-analysis. They suggest that not all steps are necessary or applicable and their guidance is not intended to be used to assess quality of published work, but more to frame the process. Popay *et al.,* (2006) recommend four steps to guide narrative synthesis. Although a stepwise approach is useful, these authors suggest that the process of a literature review is an iterative one and does not follow a linear structure or format. This is certainly true of the literature review presented within this thesis, which evolved over a five-year period, often re-visiting the literature, and searching for new evidence. The narrative synthesis presented here is influenced by the guidance of Campbell *et al.,* (2019) and Popay *et al.,* (2006). However, as with any review, not all the steps within the guidance are applicable and a pragmatic approach has been taken to appraise the literature.

The decisions relating to which data to extract from each of the papers was guided by the review question. As recommended by Popay *et al*., (2006) the data included details of all relevant aspects of the study - the participant sample, the study aims and designs and the findings. The process of data extraction consisted of reading and re-reading the papers, highlighting features relevant to the review question, and compiling these on one electronic document. The evidence included in the review was of a quantitative nature. All studies were of an observational, prospective design and none were randomised controlled trials.

Following the preliminary synthesis, the studies were summarised (see Table 4).

Table 4 Summary of studies included in the literature review.

Author & year	**Study design**	**Number of participants**	**Aims & objectives**	**Methods:** **BMI Grouping**	**Methods:** **QoL & Symptom tool**	**Results**	**Follow-up period (months)**	**Limitations**
Cha *et al.,* (2008)	prospective observational	523	To determine if AF ablation is effective in patients with obesity	3 BMI groups Lean-<25, overweight -2529.9 & obese->29.9	SF-36	At 12 months post ablation, 72% of subjects had freedom from AF without anti-arrhythmic drugs and a total of 84% of patients were free from AF when anti-arrhythmic drugs were included. Within the BMI groups at 12 months 75% of lean, 72% of overweight & 70% of obese subjects were free from AF, the differences were not statistically significant. QoL scores were significantly lower in the higher BMI at baseline and post ablation. The composite physical & mental QoL scores improved in all groups significantly after ablation at 12 months.	24	Not randomised Single centre Follow-up ECGs were not prolonged, meaning AF detection may have been missed. Not every participant had an ECG at follow-up. Asymptomatic AF was not accounted for.

Author & year	Study design	Number of participants	Aims & objectives	Methods: BMI Grouping	Methods: QoL & Symptom tool	Results	Follow-up period (months)	Limitations
Wokhulu *et al.,* (2010)	prospective observational	502	To determine the relationship between AF ablation efficacy, QoL & AF symptoms at 2 years	None Except in multivariate analysis BMI ≤29.9 vs BMI ≥ 30	SF-36 MAFSI	At 2 years follow-up 72% of subjects were free from AF, without anti-arrhythmic drugs. 15% of subjects had rhythm control on anti-arrhythmic drugs and 13% had ongoing AF. The composite physical & mental health scores on QoL significantly improved after ablation in all subjects. Post ablation improvements were seen in all ablation outcomes, with no significant differences seen in those with successful ablation and those with recurrent AF. In a sub-group of subjects who completed the MAFSI, a symptom specific survey, there were significant improvements in the group with successful ablation and off anti-arrhythmic drugs. Multivariate analysis showed that decreases in SF-36 scores were associated with warfarin use, obesity, and higher baseline scores. All three of these covariates were significant predictors of lower QoL improvement.	36	Not randomised. Single centre. BMI only mentioned in in multivariate analysis.

Mohanty *et al.,* (2011)	prospective observational	660	To study the association between baseline BMI & QoL improvement in patients with AF after ablation	BMI<25 vs ≥25	SF-36 BDI HAD STAI	At baseline, obese subjects were more likely to have coronary artery disease, hypertension, diabetes, abnormal lipids and larger left atrium. The QoL & anxiety scores were significantly lower at baseline in the higher BMI group. AT 12 months follow up there were no significant improvements in what? QoL? the normal BMI group. In the higher BMI group QoL scores improved significantly in all domains except physical functioning & bodily pain. At 12 months there was no difference in ablation success (69% normal BMI vs 63% high BMI). Multivariate analysis demonstrated that baseline QoL scores and BMI>25 were independent predictors of QoL improvement. Significant improvement after ablation in QoL in high BMI group	12	Not randomised Single centre SF-36 is a generic QoL tool. AF specific tool was not used to assess QoL or symptoms. Biomarker evaluation, which may predict risk of AF recurrence, was not used in this study. Biomarkers may show relationship between BMI and QoL.
Author & year	**Study design**	**Number of participants**	**Aims & objectives**	**Methods:** **BMI Grouping**	**Methods:** **QoL & Symptom tool**	**Results**	**Follow-up period (months)**	**Limitations**
						In all domains except physical function and pain		

Patak *et al.,* (2014)	prospective observational, with an intervention and control group	149	To evaluate the impact of physician-led risk factor and weight management on AF ablation outcomes	Risk factor management vs control BMI>27 for both groups	AF Symptom Score	No differences in baseline characteristics, numbers of procedures or follow up duration between the 2 groups. RFM resulted in greater reduction in weight, blood pressure, better glycaemic control and lipid levels. In the RFM group at follow up AF symptoms (frequency, duration & severity) significantly decreased more than in the control group. Ablation outcomes, related to AF freedom was significantly better in RFM patients compared with control subjects. Multivariate analysis demonstrated that type of AF & RFM independently predicted AF freedom.	14.2	Not randomised Single centre The risk factors were all targeted, meaning it is not possible to conclude on individual risk factor modification.
Mohanty *et al.,* (2017)	Multi-centre prospective observational with an intervention and control group	90	To investigate the impact of dietician -led targeted weight loss in long standing persistent AF patients undergoing ablation	All had BMI>30. Two groups: 1) weight loss 2) control	SF-36 AFSS	Significant reduction in body weight in group 1) & no change in group 2). The physical and mental QoL scores improved significantly in group 1), with no change in group 2). Symptoms did not change from baseline in both groups. At 1 year follow up 63.8% in group 1) & 59.3% in group 2) remained free from AF and off anti-arrhythmic drugs. –	12	Not randomised Single centre

2.14 Literature review findings

In accordance with the narrative synthesis guidance (Popay *et al.,* 2006, Campbell *et al* 2019), the papers were grouped according to the study design. Each aspect of the studies – their aims, methods, and results – were synthesised separately. This was a useful way of developing an in-depth understanding not only of the evidence base, but also of the ways in which different methodologies and methods were applied. In understanding the results, the gaps within the literature became evident, providing a justification for the study.

2.15 Aims and Objectives

The aims of the included studies varied. Cha *et al.,* (2008) sought to determine if AF ablation is effective in patients with obesity. Their aim was concerned with the technical and procedural success of ablation in a group of patients who had not been evaluated for efficacy on the basis of their BMI and part of this aim included evaluation of QoL. Wokhulu *et al.,* (2010) had similar aims, but went further in regard to patient evaluation, as these authors' aims were to determine the relationship between ablation efficacy, QoL and symptoms at two years post ablation. This correlation between successful ablation outcome and patient reported outcomes is an important one, in providing evidence for patient suitability for the procedure. In other words, if there is no direct correlation between the heart rhythm and QoL or symptoms, then rhythm control measures may not be beneficial. This point is echoed in the aims of the Mohanty *et al.,* (2011) study, which aimed to evaluate the association between baseline BMI & QoL improvement in patients with AF after ablation. Two of the studies included in the review had an intervention as part of the study protocol. The Patak *et al.,* (2014) study aimed to evaluate the impact of risk factor and weight management on AF ablation outcomes and the Mohanty *et al.,* (2017) study aimed to investigate the impact of a weight loss intervention in long standing persistent AF patients undergoing ablation. Although both studies had interventions related to lifestyle, the Patak *et al.,* (2014) protocol included a greater level and more focused risk factor management process. This study included factors, such as blood pressure control, weight and lipid management, glycaemic control, obstructive sleep apnoea management, and smoking and alcohol cessation. Whereas the Mohanty *et al.,* (2017) study included weight loss management and exercise.

2.16 Study Design

All the studies were prospective and observational in design, although the Patak *et al.,* (2014) and the Mohanty *et al.,* (2017) studies also included an intervention. None of the studies were randomised. Patak *et al.,* (2014) offered risk factor management to all patients undergoing ablation and those that declined formed the control group. Similarly in the Mohanty *et al.,* (2017) study, those participants that declined weight loss intervention became the control group. The participant numbers varied within the papers included in the literature review. In the Cha *et al.,* (2008), Wokhulu *et al.,* (2010) and Mohanty *et al.,* (2011), numbers of participants were 523, 502 and 660 respectively. In the two intervention studies, Patak *et al.,* (2014) recruited 165 participants, with 69 accepting risk factor management and 96 as the control. In this study a total of 16 participants were either excluded or lost to follow-up, giving a total of 149 participants included in the study. In the Mohanty *et al.,* (2017) study a total of 90 participants were recruited, with 58 in the intervention group and 32 in the control group and none were lost to follow up. Both of these studies have the potential for bias, in the way that the control groups may or may not have behaved. The intervention group may have been a more motivated group and the control group less so, for example. Although in an observational, non-randomised trial, such biases are possible.

2.17 Methods

There was variation in the methods used in the five included studies within this literature review. In the Cha *et al.,* (2008) study the participants were divided into three groups, which were lean-BMI ≤=25, overweight-BMI ≥25.1-29.9 and obese-BMI ≥=30 kg/m^2. Participants underwent a series of clinical investigations, such as ECG, ambulatory ECG monitoring, chest x-ray, cardiac CT scan, and echocardiography (both transthoracic and trans-oesophageal). All patients underwent ablation under general anaesthesia, using 3-D mapping with CARTO system (Biosense Webster). Intracardiac echocardiography was used to guide the transseptal puncture into the left atrium. Two different ablation techniques were used in this study. The first technique was pulmonary vein isolation at the ostia of the pulmonary veins. The other technique was wide area circumferential ablation. All patients also underwent cavo-tricuspid isthmus ablation for typical atrial flutter in the right atrium. In regard to aftercare, participants were kept in hospital for 24 hours and all were prescribed either beta-blockers or calcium channel blockers. Those with early AF recurrence or persistent AF were given anti-arrhythmic medications in addition. All participants underwent follow-up at three months, with ECG, ambulatory ECG and a chest CT scan. In addition to ablation outcomes, the Cha *et al.,* (2008) study used the SF-36 to assess QoL pre ablation and at three and 12 months after ablation. These measures were used in conjunction with the objective assessments of heart rhythm, such as ambulatory ECG monitoring, to allow for correlation of QoL with the presence of AF. Participants also underwent survey follow-up at 12 months, with the use of the SF-36.

By contrast the Wokhulu *et al.,* (2010) study did not describe the clinical data collected at the start of the study. Participants were not grouped according to BMI as part of the study methods. The ablation protocol included patients either undergoing pulmonary vein isolation, or wide area circumferential ablation, using 3-D mapping, although the specific type was not defined. Participants were hospitalised for up to 48 hours and then followed up at three and 12 months. Follow-up included QoL assessment using the SF-36 and these scores were compared to population norms. In addition to the eight domain scores, composite scores of physical and mental health outcomes were calculated. The Mayo AFSpecific Symptoms Inventory (MAFSI) was launched and was used two years into the study, to assess AF specific symptoms. AF recurrence was noted, via questionnaire but also via ECG monitoring. AF ablation success or failure was defined as freedom from AF, without the use of anti-arrhythmic drugs, control of AF on antiarrhythmic drugs or recurrent AF. In addition to changes in SF-36 and MAFSI scores, the statistical analysis included univariate and multivariate linear regression in which BMI was included as a predictor of QoL improvement.

The Mohanty *et al.,* (2011) study grouped participants into two groups, those with BMI<25 and those with BMI≥25. Participants completed surveys before and 12 months after ablation. In this study a total of four surveys were used. Like the two previously mentioned studies, the SF-36 questionnaire was used to assess QoL, in addition to three other questionnaires. The three used for this study were the Beck Depression Inventory (BDI), Hospital Anxiety and depression (HAD) scale and the State-Trait Anxiety Inventory (STAI). In regard to ablation technique, the procedure was a little different to the other two studies. In paroxysmal AF pulmonary vein isolation was performed. In persistent AF additional linear ablation was performed on the posterior left atrium as well as complex fractionated atrial electrogram (CFAE) ablation. As with the previously discussed studies participants stayed in hospital overnight and were followed up with an ECG and ambulatory ECG monitoring. Statistical analysis included comparisons of outcomes with the two groups. In addition, and similar to the Wokhulu *et al.,* (2010) study, multivariate linear regression was performed in order to predict QoL improvement.

In contrast to the other three papers, the Patak *et al.,* (2014) and the Mohanty (2017) studies both included an intervention related to risk factor modification. The Patak *et al.,* (2014) study recruited patients and offered a risk factor modification programme. Those that agreed became the intervention group and those that declined became the control group. The intervention group were reviewed in a medically managed risk factor modification clinic. The clinic managed blood pressure, weight, lipids, blood glucose, sleep apnoea, smoking, and alcohol. The control group were given risk factor modification information and continued treatment from their referring medical practitioner. The ablation procedure was a little different from the other aforementioned studies and included wide area ablation, with some patients undergoing further substrate modification, such as linear ablation of the left atrial roof and mitral isthmus line. Repeat ablation was offered if participants developed AF after the three-month blanking period. Unlike the other studies, no further technical ablation details were given, but this was because the study's aims were focused on the risk factor modification programme, rather than technical outcomes. Of note, the ablation physicians were blinded to the participant's study group, as were the physicians at follow-up. Follow-up was every three months for the first year and then six months afterwards, for a maximum of 14.2 months. Similar to the previously mentioned studies, follow-up included ECGs, ambulatory ECGs, and echocardiography. In addition, the various risk factors that were modified were reported. However, the patient reported outcomes measure was different from the previously mentioned studies. This study assessed the AF symptoms reported by participants before and after ablation using the AF symptoms score (AFSS). In addition, these researchers assessed the impact of risk factor modification on a number of cardiovascular risk factors, such as BMI, blood pressure, blood glucose, and cardiac dimensions on echocardiography.

The other intervention study by Mohanty *et al.,* (2017) differed from Patak *et al.,* (2014) study in that all participants had a BMI of over 30, rather than 27. Furthermore, the intervention was purely weight loss and exercise and did not include the other modifiable cardiovascular risk factors. In this study all patients were advised to lose weight, as is common clinical practice. However, 58 participants agreed to undergo a programme of weight loss, with dietician-led support and exercise, based on a structured programme of 150 minutes per week of brisk walking. In the 32 participants that declined the intervention and formed the control group, they were given dietary and exercise advice, but were not asked to keep a record of these activities. The goal of the intervention group was to lose at least 10% of body weight in three months and maintain the loss over the year study period. Participants were asked to complete the SF-36 QoL scores, with composite physical and mental health scores calculated from the eight domains of the survey. In addition, symptoms were assessed using the AFSS at baseline and at 12 months follow-up, which was the same as the Patak *et al.,* (2014) study.

2.18 Results

The results from the five studies varied. The Cha *et al.,* (2008) study firstly presented ablation outcomes and reported that 72% of participants had rhythm control at 12 months. When BMI groups were compared, rhythm control was present in 75% of the lean group, 72% of the overweight and 70% of the obese group. This was a non-significant difference (p=0.41). At 24 months 72% of the total participants had rhythm control without and 83% with anti-arrhythmic drugs. The authors report that although there were no statistically significant differences between the groups, the ablation success rate was lower in the higher BMI groups. The rate of drop-out of participants within the BMI groups was not significantly different at 12 months but was significant (p=0.04) at 24 months, with 35% in the lean group, 43% in the overweight group and 48% in the obese group). Additional analysis suggests that those participants that were lost to follow-up did not significantly affect the overall results.

In addition to ablation outcomes, Cha *et al.,* (2008) performed univariate analysis to establish predictors of AF recurrence. BMI was not associated with an increased risk of AF recurrence. The factors that increased the probability of AF recurrence included younger age, longer history of AF and a greater number of failed anti-arrhythmic drugs. A diagnosis of hypertension decreased the risk of AF recurrence. Further analysis included assessing if ablation technique and obesity were linked. However, the logistic regression model showed a non-significant interaction (p=0.36). Additional analysis of a multivariate model demonstrated that AF duration was the only predictor of AF recurrence (OR 1.04;95% CI, 1.01 to 1.08; p=0.02). The factors that were associated with a lower risk of AF recurrence were higher left ventricular ejection fraction and older age.

The QoL outcomes demonstrated that there were significant differences between the three groups in certain domains of the SF-36 at baseline. The differences were seen in Physical Function, Social Function, Emotional role, Vitality, Pain, General Health, and Mental Health when ANOVA was applied ($p<0.05$). There were lower functional QoL scores as the BMI increased. The highest BMI group has the lowest physical and mental health score ($p<0.0001$). Multivariate analysis showed that age, diabetes, non-paroxysmal AF, structural heart disease and BMI were all significantly associated with those QoL scores. In all groups at follow-up, all QoL scores improved significantly. Adjustment for these variables demonstrated that BMI was independently significant ($p=0.001$). The lean group participants had the highest QoL scores compared to the other two groups. In order to determine whether rhythm control was the factor in overall QoL improvement, further analysis was undertaken. These results showed that rhythm control was associated with improved QoL. The complications reported in this study included four strokes: 1 in the <25 BMI group, 2 in the 25-29.9 BMI group and 1 in the ≥ 30 group.

The Wokhulu *et al.,* (2010) study did not compare BMI groups and the only mention of BMI within the analysis was as part of the multivariate analysis. Initially they presented QoL outcomes, which demonstrated significant improvements in QoL after ablation, compared to baseline. A difference in the analysis in this study, compared to Cha *et al.,* (2008) was the data comparison to population norms in the United States. All of the pre-ablation scores were lower, and all of the post ablation scores were higher than population norms. All scores, except pain, improved significantly after ablation. These authors reported that 59 of the participants had more than one ablation and in these cases QoL improved at follow-up.

In terms of rhythm control 69% of participants in the Wokhulu *et al* (2010) study were free from AF at two years, which is similar to the Cha *et al* (2008) study. However, the study designs were different, making comparisons difficult. The QoL correlated with rhythm control, meaning that increased QoL was associated with rhythm control compared to those with ongoing AF, but these differences were not significant.

At two years follow-up 20% of participants remained on anti-arrhythmic drugs, which was lower than the Cha *et al.,* (2008) study. Unlike the other studies in this review, this study analysed the impact of anticoagulation. All participants were discharged on warfarin and the authors discuss warfarin usage that is in keeping with clinical practice. Warfarin was continued in 31% of participants during the follow-up period. At two years, those participants that remained on warfarin had lower QoL scores. In addition to QoL, Wokhulu *et al.,* (2010) assessed AF symptoms. The MAFSI was launched part of the way through the study which meant that 45% of the cohort completed a baseline questionnaire. In terms of follow-up, 21% of participants completed both baseline and 2-year follow-up MAFSI. Symptoms decreased significantly after ablation (p=0.0001). Significant improvements were seen in the typical individual symptoms after ablation. Moreover, symptom scores correlated highly with QoL scores. There were significant improvements in those participants who had rhythm control from ablation only compared to those who continued on anti-arrhythmic drugs post ablation. Like the Cha *et al.,* (2008) study, Wokhulu *et al.,* (2010) undertook univariate analysis to predict QoL benefit. Of all the covariates within the model, three were identified as predictors of improved QoL: obesity, warfarin use at followup and baseline SF-36 scores. In the smaller group of patients who completed the MAFSI, higher baseline scores predicted QoL outcomes. In multivariate analysis warfarin predicted a 10-point decrease in QoL and obesity predicted a 6.8 decrease in QoL score improvement. Baseline SF-36 scores that were higher at baseline predicted lower QoL improvement at follow-up. This study assessed the effect of complications on long-term QoL outcomes, and the results showed that despite complications such as stroke, QoL was not impacted. This study did not report complications from the ablation procedure.

Unlike the other two studies, the Mohanty *et al.,* (2011) study presented results by comparing the two BMI groups. The participants in the higher BMI group were more likely to have coronary artery disease, hypertension, diabetes, larger left atrium and hypercholesterolaemia. QoL outcomes were similar at baseline, to the Cha *et al.,* (2008) study, by BMI group, but in contrast post ablation. In this research the normal BMI group participants had higher baseline QoL scores compared to the higher BMI group, who had an increased prevalence of related co-morbidities. There was no significant improvement in QoL at 12 months post ablation follow-up. The least level of improvement was seen in the physical domains of the SF-36 in the normal BMI group and physical functioning worsened. Although General Health improved, the result was not significant. Furthermore, the HAD scale, BDI and STAI scores all reduced post-ablation, but were not statistically significant. Conversely, in the high BMI group, there were significant improvements in QoL, except for physical functioning (close to significance) and pain. The HAD scale and BDI scores all significantly reduced post ablation. The STAI scores did not alter in the T-anxiety component, but the S-anxiety ones were significantly lower post ablation. As with the Wokhulu *et al.,* (2010) study Mohanty *et al.,* (2011) analysed QoL scores in relation to ablation outcomes. At 12-month, post ablation 64% of participants had rhythm control, with 69% of those with a normal BMI and 63% in the high BMI group. This finding was not statistically significant. Those with rhythm control had higher physical composite SF-36 scores, whilst the mental composite scores improved in both groups. The improved mental health as measured by HAD anxiety scale (p=0.003) and depression scale (0.001), correlated with ablation success. The BDI scores (p=0.24) improved post ablation. However, the STAI scores were not associated with rhythm control. Additional analysis assessed the degree of QoL change with rhythm control in the BMI groups. The high BMI group had a significant improvement in QoL scores, HAD score and BDI scores when rhythm control was achieved. In the normal BMI group, there were no significant improvements in QoL, HAD scores or BDI scores related to rhythm control. Multivariate regression analysis was undertaken to establish predictors of QoL improvement. The results showed that baseline QoL scores and high BMI were independent predictors of QoL improvement. Complications in this study included one participant with pericardial effusion, who had a normal BMI. There were four participants with high BMI who suffered pericardial effusion. All five of these required a pericardial drain, but none required surgery.

The results of the Patak *et al.,* (2014) differed from the three previous papers. The reason for this being that this study included a physician-led risk factor modification programme in those undergoing AF ablation. Patak *et al.,* (2014) report the effect of the risk factor modification on a number of cardiovascular risk factors. There was a significant decrease in blood pressure (p=0.006) in the risk factor modification group compared to the control group. In both groups both weight and BMI decreased, but the difference was significant in the risk factor modification group (weight-p=0.002, BMI-p<0.00011). In regard to lipid management, in the risk factor management group lipid levels were well controlled in 46.2% of the risk factor modification group and 17% of the control group, with a significant difference of p=0.01. Diabetes control was significantly improved in the risk factor management group compared to the control group, with 100% of the risk factor group compared to 29% of the control group having better glycaemic control (p<0.001). In terms of obstructive sleep apnoea (OSA), those participants with a diagnosis of severe OSA, 50% of the risk factor modification group had a reduction in severity of the condition, to a level of mild or no OSA at follow-up, which compared to 15% of the control group. Smoking cessation and alcohol reduction was successful in both groups, with most participants achieving a positive outcome and with that was no significant difference between groups. All participants underwent echocardiography before ablation and at follow-up, to assess cardiac structure and function. Significant improvements were seen in the left atrial volume index (LAVI) and the left ventricular septum measurements in the risk factor modification group compared to the control group (p=0.001, p<0.001). Other measurements of left ventricular function did not improve significantly in either group. Rhythm control was observed in 32.9% of the risk factor modification group compared to 9.7% of the control group after a single ablation procedure. This was significant with a p value of<0.001.

Multivariate analysis demonstrated that predictors of AF recurrence were classification of AF and being in the control group. Regarding the need for additional ablation procedures, univariate predictors of AF recurrence were control group, classification of AF and presence of hypertension. The single largest predictor of AF recurrence was the grouping of participants. Unlike the other studies, Patak *et al.,* (2014) did not use a QoL survey, but used the AF Symptom Score (AFSS) instead. The AFSS at baseline were similarly high in both groups and decreased in both groups at follow-up. However, the reduction was significantly higher in the risk factor modification group (p<0.001).

Mohanty *et al.,* (2017) reported the ablation procedure results, with a brief description of the technical aspects of the procedure. All the 90 participants underwent PVI plus posterior left atrial wall ablation and what is described as “non-PV trigger ablation”. Ablation of nonPV triggers were seen in several areas in the left and right atrium. Rhythm control, without the need for anti-arrhythmic drugs was achieved at follow-up in 63.8% of the intervention group and 59.3% of the control group. This finding was non-significant (p=0.68). complications were minimal with 3.3% of patients suffering groin haematoma and only one having a small pericardial effusion, which did not require drainage. The weight loss intervention revealed a median reduction in BMI of 24.9kg, which compared to the control group, was highly significant (p<0.001). At one year follow-up 51.7% of the intervention group had maintained their weight loss and 53.3% of these had AF recurrence. This weight loss resulted in significant improvements in blood pressure (<0.001) and BMI classification (p<0.001), in the intervention group compared to the control group. Similar to the other studies, with the exception of Patak *et al.,* (2014), this study used the SF-36 to assess QoL and, like Patak *et al.,* (2014), the AFSS for symptom evaluation. The results demonstrate that AF frequency, severity and duration was not significantly different in the intervention group compared to the control group. Although the AFSS improved at one year post ablation in both groups, these improvements were not significant. In regard to QoL, the composite physical and mental QoL scores were significantly improved (p=0.013, p<0.02) in the intervention group, but not in the control group (p=0.43, 0.53).

2.19 Discussion

The studies included in this review broadly addressed the same topic, but there were marked differences in the aims, methods, and results. This discussion addresses key outcomes that were reported in the studies. These include the QoL and symptoms assessments, rhythm control and ablation success and the complexity of the link between AF and BMI.

A key question in the management of AF is; does sinus rhythm improve QoL and/or symptoms in the context of an elevated BMI? The decision to undertake ablation of AF is a crucial one, for patient and clinician for a number of reasons, related to the invasive nature of the procedure and associated risk, as well as cost effectiveness and satisfaction with the procedure. The studies within this review have variable findings related to QoL improvement in the context of BMI. Cha *et al.,* (2008) found that QoL improved regardless of BMI after ablation, whereas Mohanty *et al.,* (2011) showed that there were no significant improvements in the normal BMI group post ablation. The obese group had improved QoL post ablation and this finding is often referred to as the "obesity paradox" in other research and conditions. The obesity paradox refers to those with an elevated BMI having better outcomes than those with a normal BMI (Amundson *et al,.* 2010). Although the authors provide a number of explanations for this paradox, such as regression to the mean and that they had a different cohort compared to Cha *et al.,* (2008), it is feasible that the Mohanty *et al.,* (2011) normal BMI group were minimally symptomatic from the outset and started from a higher QoL baseline score. In contrast, the Wokhulu *et al.,* (2010) study demonstrated that QoL improvements were lower in those with obesity, warfarin usage and a high BMI score at baseline, although one potential limitation with this study is the lack of comparison with obese and non-obese participants, other than in multivariate analysis. In a different cohort of long-standing persistent AF, Mohanty *et al.,* (2017) showed that weight loss improved

QoL but not symptoms. Whereas Patak *et al.,* (2014) only measured symptoms, not QoL and demonstrated significant improvements in the risk factor modification group.

Ablation success was not influenced by weight loss in the Mohanty *et al.,* (2017) study, although it was in the Patak *et al.,* (2014) study. Cha *et al.,* (2008) reported similar ablation success in all three BMI groups, although there was a weak trend towards reduced efficacy in the obese group. In the Wokhulu *et al.,* (2010) study, improved QoL was not linked to ablation success, as improvements were also seen in those on anti-arrhythmic drugs. Furthermore, those participants with significant QoL improvements, despite rhythm control demonstrated reduced improvements in symptoms reporting. This finding raises questions around the use of disease-specific surveys versus generic QoL assessments in these participants and whether different tools may be preferable.

The role of the interplay between AF and BMI is central to the papers included in this review. As discussed in the previous chapter, AF and raised BMI often coexist and addressing both conditions is important for patient care. Patients with raised BMI are more likely to have other relevant comorbidities that increase cardiovascular risk, such as diabetes and hypertension. The management of these conditions with medications, commonly referred to as "upstream therapy", such as angiotensin-converting enzyme (ACE) inhibitors and statins may explain some of the results in terms of benefit in the raised BMI groups. Furthermore, these treatments may be relevant in those with improved QoL, despite AF recurrence, as seen in the work of Wokhulu *et al.,* (2010). This concept is supported by the Patak *et al.,* (2014) study, which not only addressed the BMI, but also adjusted other modifiable risk factors.

The studies within this review are of a heterogenous nature, with varying results. Interventions, such as risk factor modifications have an important contribution in the management of AF. Moreover, the available research on the literature review question is low in numbers and is from several years ago, when ablation technology was less advanced.

2.20 Limitations of the studies

There are always limitations in any research and this section discusses those issues. Firstly, as recognised by the authors of each study, neither of the interventional studies were randomised and all were observational in design. All except Mohanty *et al.,* (2017) were from a single arrhythmia centre. Cha *et al.,* (2008) and Wokhulu *et al.,* (2010) discuss the issue of asymptomatic AF as a limitation, within their studies, presumably because they monitored for evidence of AF in the follow-up period. Cha *et al.,* (2008) reported that not every patient had an ECG at follow-up, which is used to determine the heart rhythm at the time of follow-up. The assessment of AF recurrence was usually performed by ambulatory ECG monitoring and both authors suggest that more prolonged monitoring, in the form of an implantable loop recorder may offer greater insights to the overall AF burden and the impact of sub-clinical or potentially asymptomatic AF. Mohanty *et al.,* (2011) suggest that the use of generic QoL tools may be a limitation and an AF specific questionnaire may be more appropriate. In addition, Mohanty *et al.,* (2011) report that the absence of biomarkers performed as part of follow-up is a limitation. The absence of these metabolic measures suggests that it was not possible to find associations with these measures related to QoL and BMI. The implication here is that in the weight loss study, the authors suggest that the assessment of any changes to metabolic or biomarker measurements were not performed. Therefore, any potential changes to other comorbidities, such as diabetes mellitus, were not demonstrated. Patak *et al.,* (2014) report that in their study on risk factor modification, each risk factor was targeted, meaning there are no conclusions to be drawn on the significance of each individual risk factor, such as weight loss or blood pressure control, for example. Another limitation seen in the Wokhulu *et al.,* (2010) study was the absence of information related to the two BMI groups that were only mentioned within the multivariate analysis.

2.21 Limitations of this literature review

There are a number of limitations within this literature review. Firstly, although supervisors peer reviewed all aspects of the design, screening process, overall, this review was undertaken by one reviewer. Such an approach has the possible increased risk of bias.

2.22 Justification of research

The purpose of this literature review was to understand what is known about the QoL and symptoms of patients with a raised BMI who are undergoing AF ablation, and their reported outcomes before and after the procedure. The results of the literature review suggest that there is heterogeneity in the evidence base, with differences in patient reported outcomes after ablation and differences in QoL and symptoms at various time points. Furthermore, there is conflicting evidence on the subject of rhythm control and AF recurrence. It is crucial to be certain that patients benefit from rhythm control in the form of catheter ablation because the procedure is associated with morbidities and mortality. In addition, healthcare resources are not infinite and are required to be targeted at those that would benefit the most.

The subject of AF, ablation and raised body mass index is an important one for healthcare professionals, but there is a paucity of evidence, bearing in mind the prevalence of AF and the numbers of AF ablations undertaken yearly. There appears to be no research directly related to the research question posed in this thesis in the UK population, where clinical practice varies from North America or Australia. Currently, arrhythmia nurses are enabling shared decision making with patients on the subject of AF ablation and raised body mass index, but with no patient reported outcome data related to their local population. Although QoL and/or symptoms evaluation is evident in the studies within the literature review, there are no mixed methods studies directly related to the research question. It is important for healthcare providers to understand the experiences of patients within their care in order to enhance and improve the services and potentially the education related to conditions and treatments.

The gaps within the literature and the need for a deeper understanding of this subject provides a strong case for a mixed methods study exploring the QoL, symptoms and experiences in those patients with a raised BMI undergoing AF ablation. By adding to the evidence base, it is anticipated that the services around AF ablation, particularly related to an elevated BMI will be enhanced for the benefit of patients. Arrhythmia nurses are central to the provision of care to patients with AF and are becoming increasingly aware of and involved in the management of additional comorbidities, such as an elevated BMI. Within Consultant level practice there is a higher level of autonomy in making complex clinical decisions and managing patients care. Therefore, a holistic approach is critical in delivering high quality care and also in the provision of advice, education, and support according to the current evidenced based guidelines.

2.23 Chapter summary

This chapter has described the literature review that was performed systematically to understand the body of evidence underpinning the research question. Once the review was completed, a process of narrative synthesis was adopted to describe the results of the research related to AF, ablation, QoL, symptoms in those undergoing ablation. The narrative synthesis presents the studies in a way that grouped the papers into their aims, methods, and results. The discussion section presents the similarities, contrasts, and key findings from the five papers within the review. The limitations of the studies are demonstrated in order to fully appreciate the context of the research and where further research may be necessary. Finally, the justification for further research is presented, with the knowledge of the existing research.

The next chapter describes the methodology that underpins the research question and the methods used to undertake the study within this thesis.

CHAPTER THREE: Methodology and methods

3.0 Methodology introduction

Nursing research is a fundamental part of nursing practice (Tingen *et al*., 2009) and crucial in the improvement of patients' care and experiences of healthcare. The first section presents the chosen methodology for the study, which addresses the question of quality of life, symptoms and experiences in patients undergoing AF ablation, with an elevated BMI. The aims and objectives of the study will be demonstrated, and the broad theoretical basis of the research question will be included. The methodological stance will be presented, from the nursing perspective. The justification for the methodology used to answer the research question will be stated, including personal assumptions, as a researcher. Finally, the rationale for this research question, the unique contribution to the body of knowledge and the potential impact of the research will be reported.

3.1 Philosophical foundations

This section presents the foundations of thoughts and beliefs that drive the process of enquiry for the question of QoL, symptoms and experiences in patients undergoing AF ablation with a raised BMI. The philosophical theories and underpinning belief systems related to the research will be presented. The paradigms and methodologies related to this research question will be expounded.

Understanding the philosophy of research, originates in the appreciation of the ontological and epistemological stances. It is acknowledged that there is very little consensus on the precise definitions of these terms and the literature is often contradictory and sometimes confusing. However, the following discussion will focus on what these terms mean related to this piece of research and to this research question.

The ontological stance is the branch of metaphysics that deals with the nature of being or reality (Tubey *et al*., 2018). The epistemology within the process of enquiry relates to the way in which knowledge is developed and gained. Houghton *et al.*, (2012) describe it as the relationship between the researcher and what may be known. The ontology and epistemology influence the type and the methodology of the research (Tubey *et al.,* 2018).

In order to undertake research, it is necessary to examine the thinking at the foundation of our quest for knowledge. Khun (1970) states that science evolves over a series of revolutions. Within a revolution is a cluster of beliefs, which have become known as paradigms. Paradigms, or worldviews are part of the belief system on which to develop research thinking and provide philosophical assumptions to consider what it is researchers want to know (Brannen 2005). A paradigm is a pattern or a clear example, an exemplar or a distinct set of concepts or an archetype (Merriam Webster 2019). Alternative terminology for the word paradigm exists, for example, Morgan (2007) refers to paradigms as “models for research”, although whichever term is used, the purpose is to provide the basis for enquiry. Moreover, definitions within the literature may be variable and not always distinct, in that the word paradigm is sometimes used in place of methodology and vice versa. It is widely acknowledged that paradigm is the most commonly used term in this context in current nomenclature.

It is widely thought that adopting a particular paradigm for research is the foundation on which to begin to develop the research question. Paradigms tend to lead to a dichotomy of thought amongst researchers, because each paradigm has one particular standpoint and consequently an opposing view to the other. Researchers often adopt either objective or subjective epistemology and which either favours quantitative or qualitative methodology. The methodology relates to the practical application of the philosophical principles in the ability to conduct the research using a framework (Tubey *et al*., 2018). The objectivist viewpoint aligns to positivist and post-positivist paradigms and involves gathering quantitative evidence and observable data, which is deductive in nature. An example of this is using validated surveys to quantify quality of life or symptoms in patients with AF. The associated methodologies are detached and of a scientific, experimental type. Conversely, the subjectivist view, which aligns with naturalistic enquiry and phenomena, states that the world is socially constructed. Such values align with the methodology that is qualitative in nature, is inductive, has unmeasurable phenomenon and are process based and participative (Durham *et al*., 2015). Naturalistic enquiry, in this narrative, is the broader term to include such paradigms as constructivism, interpretivism, phenomenology, critical realism amongst others. This approach may be seen in asking patients to share their experiences of having AF and undergoing ablation, in the context of a raised BMI. The positivist and post-positivist ontology within the objective context suggest that there is one, observable truth. Although the ontology in these two examples is nuanced. Post-positivism suggests that the one reality is relative to our capacity to measure or observe it. Conversely, naturalistic thought centres on an individual's experiences, perceptions, or beliefs (Tuohy *et al*., 2013), whereby there is more than one truth. This dichotomy is discussed widely in the literature, but there remains a lack of clarity in the definitions and the detail (Feizer 2010.) It is more reasonable to suggest that although this dichotomy amongst paradigms has created opposing views in the past, the current reality is that such opinions are shades of grey, rather than black or white. Rather than a dichotomy, views are more a matter of scale and dimension.

Although in the past, positivist research has dominated the literature, and Rapport & Braithwaite (2018) state this remains so, the shift towards other paradigms such as naturalistic enquiry is increasingly evident. Greenhalgh *et al*., (2016) have challenged the dominance of quantitative research and the literature is suggesting a more nuanced approach is not only the way forward but reflects the needs of particular spheres of research (Rapport & Brathwaite 2018). Relying on one methodology would not provide the true answers to the problem and question of patients QoL, symptoms and experiences, with AF and undergoing ablation. Positivist-based research would provide objective evaluations of aspects of QoL and symptomology, but would not give rich, in-depth insights into a participant experiences and pure naturalistic enquiry would not necessarily provide generalisable deductive and reasoning but would provide depth and breadth of the experience of having AF, a raised BMI and undergoing ablation. This piece of research aims to collect the objective data of quality-of-life measures and symptoms of patients and subjective experiences of atrial fibrillation and the ablation procedure, in the context of a raised BMI. Adopting one paradigm alone would not achieve these aims, nor truly answer the research question.

Bearing in mind that this thesis forms part of a Professional Doctorate, thinking and learning on the research question led to what Costley & Fulton (2019, p.12) have termed “practical reasoning”. This view is reflective of the purpose of practice-based research, whereby the work-based experience drives the research question. It mirrors the concept of phronesis, initially described by Aristotle, but what Costley & Fulton (2019 p12) refer to as “thoughts leading to action”. These authors further state that professional doctorate research emanates from a series of work-based experience and critical reflection, which is aimed at enriching practice. Such views are reflected within the thinking that drove the research question in this particular piece of research. They refer to the understanding of practicebased knowledge as mode two knowledge. This type of knowledge is in contrast to mode one knowledge, which is generated in an academic discipline, as opposed to a professional setting (Costley & Fulton 2019 p6). Such views concur with Davison’s (2017) stance that in the identification of professionally based research questions, the flow arises from every day clinical scenarios and lend themselves to insider research. Reflecting on the philosophical stances that underpin the quest for knowledge, it is clear that positivism and naturalism alone will not answer this research question. The clinical question requires mode two/ practice-based knowledge to satisfactorily answer what the QoL, symptoms and experiences are of patients with AF undergoing ablation in the context of a raised BMI.

In contemplating the preferred paradigm for this thesis, a number of philosophical stances were considered. I reflected on the positivist influences that have shaped my assumptions over the years and concluded that, as a nurse, I am also drawn to naturalistic enquiry. A process of enquiry into the underlying philosophies that shape us all took place early on this academic journey. The dialogue with tutors, supervisors, and peers, combined with the reading and searching for an appropriate paradigm on which to base this study led to the discovery and learning on the subject of pragmatism. With minimal prior knowledge of pragmatism, a process of seeking information took place over a period of several months and even years. Although alternative paradigms have been explored over the years and whilst the nomenclature may vary, it is widely accepted that pragmatism offers an alternate option for researchers (Morgan 2007). It was early on in this process that pragmatism appealed to me, as a clinical nurse and nurse researcher. Pragmatism is a particular paradigm that befits the social sciences and will be explored in the next section.

3.2 Pragmatism

As not all research nor researchers have purely dichotomous views, an alternative paradigm has emerged. An alternative paradigm, pragmatism, was evolved as a reaction to the "prevailing philosophy of the metaphysical views" at the time (Bragg 2018). Pragmatism, which has a range of meanings, was developed in North America in the late 18th century, initially by Pierce and later by Dewey, James, and Schiller (Geyer 1914, p 3). Pierce's original views were described by Geyer (1914p.4) as not simply a theoretical basis for discovering the truth, but in addition, a mind-set, and a process of investigation. In this context, truth is multifaceted and how things appear may differ from how they actually are, which is a relativist ontology. Dewey's (1925, cited in Geyer 2014, p. 35), view is researchers can measure multiple realities that may occur in layers, some of which are objective, some subjective or a mix of the two. Therefore, pragmatists reject the dichotomised traditional view and favour a merging of judgements, with the aim of seeking answers (Feitzer 2010). In seeking answers, the truth and answers rely on context and language, which is in line with a pragmatic approach (Rorty 1991).

According to Shannon-Baker (2016), pragmatism is outcome-orientated, transferable and has shared meaning, which makes it suitable for healthcare and applied research. Moreover, pragmatism uses abduction, which allows the movement between induction and deduction and vice versa, which is useful for evaluating the best approach to answer the research question (Shannon-Baker 2016). It is often described as "what works best", but this is perhaps an over-simplification of a paradigm that has gained credibility within the research arena. Morgan (2007) states pragmatism is far more than just a simplified approach, but rather it connects the abstract, the epistemology, to the methods, in other words, it links thoughts to action. In using pragmatism, we reach the end point of our enquiry by pursuing facts and information. Unlike the dichotomy within objectivity and subjectivity, pragmatism's relationship to the research process is intersubjectivity.

The term intersubjectivity was first described by Edmund Husserl in the early 20th century. As a transcendental phenomenologist, Husserl described intersubjectivity as being the process of sharing experiences with others, but with the ability to include objective and subjective thoughts. An example of this is when we experience empathy, we have shared meanings, with both felt and imagined thoughts (Beyer 2020). Therefore, pragmatism is multi-layered, fluid, and complex. Younas (2020) discusses a more profound view of pragmatism and disputes the simplistic tones of using a belief system to get the job done. He discusses the issues of operationalist and inferentialist pragmatism. Both strands of the theory have the same aim of inquiry. Operationalist pragmatism aligns with Peirce's views and is concerned with clarity of thought and method, whereas inferentialist pragmatism supports James' views on the need to assess ideas and theorise on the truth within research (Younas 2020). Both strands of pragmatism allow a pluralistic view of knowledge. The knowledge gained from pragmatist research is contextualised and practice based and may connect theory to practice and action. Younas (2020) also reports that pragmatism is suitable for approaching knowledge with everyday experiences, whilst using critical reflection.

Pratt (2016) suggests that pragmatism is a flexible form of social ontology, which fits well within healthcare research. This flexibility fits with Feilzer's (2010) view of the need for pragmatic researchers to be open-minded and flexible to unexpected findings within the data. Depending on the context researchers may adopt both constructivist and positivist stance with fluidity throughout the research endeavour. The roots of pragmatism lie within relativism, which suggests the nature of reality is multi-dimensional and is shaped by many different experiences (Houghton et al 2012). Such beliefs are true in regard to the question of quality of life after AF ablation, as a variety of factors may influence outcomes, based on individual experiences and perceptions.

Pragmatism is not without its critics. The views of Allmark and Machaczek (2018) are that pragmatism lacks detail, and it is questionable whether it is a paradigm or theory. This view needs to be taken in the context of the authors, who's main argument is that realism is their preferred paradigm in a mixed-methods study. Although not explored in depth, a view exists which suggests that pragmatism is not even a paradigm and assumes a position of no theory or method (Feitzer 2010). For the purpose of this study, the stance is the more conventional approach, whereby pragmatism is an alternative paradigm, with its roots in a modern philosophy related to obtaining the truth and practice knowledge.

In the pursuit of answers to the research question, "What are the quality of life, symptoms, and experiences of patients with an elevated BMI undergoing AF ablation?", it is insufficient to obtain just quantitative data on patient reported outcomes, as this will not generate understanding of individual experiences and the trajectory of their care. Quantitative data is highly useful and has been obtained in the use of validated questionnaires in the past (Dorian *et al.*, 2000). However, in optimising our understanding of the clinical problem, the understanding of the objective data with subjective data would be beneficial to understand where healthcare delivery may improve or be enhanced. The patient with AF has a complex and multi-faceted journey even before they undergo catheter ablation, therefore pragmatism is an ideal paradigm to explore both the objective and subjective experiences of the patient on their journey and their destination. This section has explored pragmatism, as a paradigm, which lends itself well to the mixed-methods methodology. The following section discusses mixed-methods methodology and explains why it is eminently appropriate to answer the research question.

3.3 Mixed methods research

The use of mixed methods is presented in this section and a discussion of the different approaches of mixed methods will clarify the most appropriate version for this study. Finally, limitations of mixed methods will be discussed, which is essential in the overall critique of methodology selection.

As with paradigms, the terminology and definitions related to the theory of research, paradigms and methodologies vary and are occasionally not compatible or consistent.
Creswell and Plano Clarke (2018) explain that earlier views of Greene, Caracelli and Graham (1989) focused mostly on the mixing of quantitative and qualitative methods, whereas later academics, such as Tashakkori and Tedlie (1998) preferred to include multiple aspects of the methodological process. Plue and Hong (2014) give a rich definition and explanation of mixed-methods research. Their view is that the approach of mixed methods is to integrate the research question, methods, designs, data collection, analysis, and results. The understanding of mixed methods has evolved over time with different nuanced applications. This definition is consistent with a pragmatist paradigm and applied research. Moreover, Johnson, Onwuegbuzie and Turner (2007) provide clarity in their definition. Their view is that mixed methods combine the features of both qualitative and quantitative research approaches with the intention of developing depth and breadth of a given subject.

A mixed-methods approach has driven this research from the very beginning, and in particular, the research question, which aims to understand patients’ quality of life, symptoms, and experiences undergoing AF ablation in the context of an elevated BMI. By searching for multiple meanings in this patient group, it is anticipated that deeper understandings of the patient needs will be gained. The arrhythmia nurse and in particular, the consultant nurse is able to holistically care and interact with these patients in this complex clinical journey.

3.4 Mixed methods

Over the years, mixed methods research has been subdivided into different categories, or types, whereby the lexicon has evolved. These three main core types, as described by Creswell & Plano Clark (2018), provide a useful framework on which to design a research study. However, as the methodology has evolved, so has the terminology. An example of this is in the term triangulation, which is a phrase that has led to misunderstandings and confusion amongst the research community. In qualitative research alone, the term is used to mean cross-checking and validating data with the purpose of providing rigour to the study (Denzin 2010). However, the term later became associated with mixed-methods methodology, to describe the usage of qualitative and quantitative methods combined in one study. Other authors, such as Greene, Caracelli and Graham (1998) have described triangulation as a type of mixed methods, within the evaluation and Morse (1991) has used the term, as a methodology within nursing research. In the last ten years or so, the term has become outdated, and Denzin (2010) tends to favour the term crystallisation. In current parlance, the process of combining methods is known as integration and synthesis (Plue & Hong 2014). Mixed methods remain in adolescence and our understanding and consensus use of the terminology is still evolving.

In order to understand the application of mixed methods in the context of this study, it is useful to examine the three broad types of design, commonly used, such as convergent, exploratory sequential and explanatory sequential (Creswell & Plano Clarke 2018). The following section will provide justification for the chosen approach in this research.

3.4.0 Convergent design

Convergent design is the most used mixed-methods design and is most suited to more novice researchers. In this approach the qualitative and quantitative data are collected and analysed in a similar time frame. By combining and comparing results, or validating one set of results with the other, it is anticipated that a deeper level of understanding is gained within the area of inquiry (Creswell & Plano Clark 2018). However, Fetters (2013) suggests in convergent design, the mixing of the methods and merging process should take place at the design phase of the study, not just at the point of analysis. By considering, for example, qualitative based interview questions that are linked to a quantitative questionnaire, the study is truly embedded and merged from the outset. When it comes to the analysis component of convergent design, a number of approaches are possible, including weaving, merging and data transformation (Creswell & Clark 2018). However, Clark (2019) suggests a structured tactic is useful and by this she proposes the use of a joint display chart. This involves a visual representation of the both sets of data, which may be parallel visually, colour-coded and a narrative to explain the results.

3.4.1 Exploratory sequential design

In exploratory sequential design, qualitative research is undertaken first, followed by quantitative data gathering. This approach is particularly useful for the development of a new tool, or instrument, that requires the input of participants before testing it more widely, with the intention of gaining greater insights into the research question. An example of this design is undertaking participant interviews and then developing a new questionnaire with the purpose of understanding a specific issue. This design will appeal to researchers with differing philosophical stances and can be straightforward in its delivery. However, the challenges include the need for a reasonable timeframe to complete both phases and achieving regulatory approval may be difficult, depending on initial results (Creswell & Plano Clark 2018).

3.4.2 Explanatory sequential design

In explanatory sequential design, there are two phases, starting with quantitative data collection, whereby the quantitative results may be further interpreted by the qualitative data (Florczak 2014). Usually, this study design involves the quantitative phase of data gathering, with the qualitative phase afterwards. It may be that the quantitative results guide the development of the qualitative data gathering approach, or that the qualitative findings are used to expand the understanding of the quantitative results. This is a structured and straightforward design, which some researchers may favour, but the challenge is the time required for the two separate stages of data collection and the potential challenges with the potentially separate regulatory authorities' applications in order for a study to begin and be conducted (Creswell and Plano Clarke 2018).

3.4.3 Justification for using a mixed methods approach

This section presents the reasons for the chosen methodology and why it was most suited to this study. From the patient's perspective, it is important for individuals to report their outcomes from invasive treatments (NHS 2018). PROMS following ablation have been demonstrated to be useful and effective (Kotecha *et al*,. 2018). The use of validated questionnaires is a useful way of obtaining information before and after treatment. By involving patients in the treatments that are available, it is envisaged that patient's expectations, and outcomes are improved and enhanced. Nurses are very well placed to research patient's feelings, perspectives, and experiences, and in this study, such information is vital to add to the body of knowledge within the arrhythmia arena. Despite this, there is very little nursing research on AF, and on body mass index effects on quality of life, symptoms, and experiences. To consider quantitative research, in the UK, PROMS in AF ablation are not widely used and this may be for several financial, strategic, and logistical reasons. Regarding value-based healthcare, PROMS are important, a view recently expressed by the British Heart Rhythm Society (BHRS) (Slade 2021). The use of such data enables healthcare researchers to target therapies to those patients that would most benefit (Alliot 2014). In addition, the gap in the current knowledge is the lack of data on the patient's experience of AF, the ablation related to lifestyle factors that may influence their health and the subjective impact and meaningfulness for the individual.

The convergent design was chosen as the most appropriate for this study, as the six-month follow-up questionnaire data were collected around the same time as the six-month interviews. Another reason for this decision is that it fits with Cresswell and Plano Clarke's (2018) definition and explanation of mixed methods in social research and is a popular form of mixed methods design. The philosophical foundation of a convergent design aligns well with pragmatism, which is the chosen methodology within this study. In accordance with current clinical practice and fitting with the pragmatic approach to the research question, the patients travel along their clinical journey in a linear fashion. Therefore, the data collection mirrors the clinical journey, and both sets of data were collected at appropriate time points, reflecting the patient contact points. This study design required the collection of both objective and subjective data, at a time point when patients are experiencing the procedure. The main intention of this design was for the combined qualitative and quantitative data to obtain deeper understandings of the issues. Creswell and Plano Clarke (2018) suggest this design is particularly appropriate for researchers who have limited time for data collection and the research team have experience in both qualitative and quantitative methods, which was the case in this study. The data collection time points at six months make this an efficient study design. Furthermore, the main quantitative tools within this study were readily available, with a plan for a return visit with the intention of collecting qualitative data. From a pragmatic point of view, the timing of data collection required to answer the research question fitted with the study design. At the design phase of the study, the semi-structured interview schedule was developed around the broad topics of AF as a diagnosis, the ablation and lifestyle factors. Additional details on the interview schedule may be found in the methods section. These issues had not been previously researched in a qualitative manner and the questionnaires have not provided enough depth or breadth of subjective enquiry. This study was not just concerning reported numbers from questionnaires, but how much value that patients place on their own health.

The benefit of an interview is that it allows clarity of answers, to otherwise closed questions and an interaction between the interviewer and participant (Cohen 2007). Furthermore, the interview may provide insights into understanding the questionnaire responses that are not able to be articulated beyond the structured format of a written question. The interview allows the interviewer and interviewee to make sense of their individual experiences and allow the storytelling to evolve (Miller & Glassner 2020). At the design stage of the study, the type of interview required consideration. There are basically four types of interviews within qualitative research Rowley (2012). Firstly, structured interviews have predetermined questions and may be similar to questionnaires in their design. Secondly, unstructured interviews, which allow free dialogue over a given period of time. Thirdly, and most commonly, semi-structured interviews, which consist of a topic guide, to frame the interview, but also allow depth of dialogue on the subject matter. Fourthly, focus groups, which are group-based interviews, on a given topic. The advantage of such groups is that a large amount of data may be gathered in one setting. However, they require practical space and a certain degree of skill by the researcher and can be harder to set up.

The semi-structured interview was chosen for this study for a number of reasons. Firstly, this format aligned to the research objectives of wanting to discover personal insights into AF, the ablation and BMI. Being semi-structured allowed a flow from one topic to the next, naturally through the discussion. By undertaking semi-structured interviews in this patient group, the body of evidence in this area would be added to. Finally, my own personal inside knowledge of this patient group over several decades informed me that this is a highly motivated group of individuals, who are, in the main, very keen to discuss their condition. Focus groups, whilst useful, would not be suitable, as what was needed was the individual experiences where people are free to talk rather than seeking a consensus view, or common experiences.

Regarding the interviews, several methods of data analysis were considered, which included thematic analysis, as described by Braun and Clarke (2021). This approach is widely used in the analysis of qualitative data and is a process of organising, understanding, interpreting, and reporting large amounts of data (Nowell *et al*.,2017). One of the advantages of using thematic analysis is that it is relatively straightforward to learn, especially for the novice researcher. Furthermore, it is a flexible form of analysis, which allows the reduction of large amounts of data to more manageable forms. The disadvantages of this method, however, is that there remains relatively little guidance on how to carry it out and the issue of flexibility may in some cases result in inconsistency within the analysis (Nowell *et al*,.2017).

Framework analysis was first developed by Ritchie and Spencer (2003) , originally for the use in social policy. In recent times it has been applied to healthcare research. Its characteristic is the use of a matrix to allow summarisation of the data, whilst maintaining links to the original data that has been gathered. The framework method is useful for research within large teams, where access to the interview data is made less problematic. Furthermore, framework analysis is not affiliated with any particular philosophical or theoretical position, which makes it a flexible way of approaching analysis (Gayle *et al*,. 2013). It is both deductive and inductive, which allows for unexpected finding within the data. Gayle et al (2013) have presented a version of framework analysis that is especially suitable for interview data. It has the advantage of being highly structured, allowing visualisation of the process of analysis from transcription, familiarisation, coding, developing the framework, applying the framework, charting the data to interpreting the data. This idea fits very well with the pragmatic paradigm within this thesis and is appealing to novice researchers, due to the structured nature of the approach.

One of the strengths of this study, from a philosophical standpoint is that it addresses both ends of the methodological spectrum in answering quantifiable data in greater numbers of participants and perspective data in greater detail in smaller numbers. From a methodology perspective this study aims to understand deeper, richer, and broader views from patients with a complex condition undergoing a complex procedure, in the context of a raised BMI. Having two types of data provides unique and new insights that have implications for nursing practice and more widely for patient care in understanding unmet needs.

3.5 Data analysis

Data analysis in mixed methods may be challenging, because combining numbers and words, at a rudimentary level, is not straightforward. The two data sets need to be separately analysed and then brought together to provide deep and meaningful insights to the research question, (Bazely 2018). The data sets may be merged, as in the case of a joint display chart (Clark 2019), or embedded, sometimes referred to as nested (Curry & NunezSmith 2015), in the case of a study with more than one major question. In addition, data analysis may be termed connected integration, which is when one set of data helps inform the other by constructing overall results from the initial results (Curry & Nunez-Smith 2015). Furthermore, data may be transformed, as in the case of applying numerical status to themed codes within qualitative research (Creswell & Plano Clark 2018).

For the purposes of this study, both sets of data were analysed separately. Following this approach, the qualitative findings were used to further explain the quantitative results. Additional detail on this process is discussed in the methods section. It is noteworthy that data synthesis is not an easy option and opinions vary, as there is no consensus on how this should be undertaken.

3.6 Limitations of a mixed methods approach

A number of challenges and limitations exist within this methodology, which require consideration and acknowledgement. Creswell and Plano Clarke (2018) discuss the issue of two different sample sizes, which could potentially result in difficulties in the understanding of the results in applying interview data to the questionnaires. It is potentially difficult to combine the two data sets, which are very different in content. Merging both numbers and words is a mixing of two completely different entities. Creswell and Plano Clark (2018) also acknowledge that there may be problems in understanding the data if the two different methods are not in agreement.

Quantitative data collection presents challenges. These include missing data within questionnaires, depending on how that data is collected or how the questions are presented. The completion of a questionnaire via any means may be challenging for some participants, technically, cognitively, or physically. Qualitative interviews require a description of an individual's experience, and articulation and the ability to communicate are essential. Such abilities may be difficult for some patients, although the same may be stated in the case of questionnaires, where a certain level of comprehension and ability are needed. Moreover, within naturalistic enquiry, Gerrish and Lathlean (2015) argue that a degree of artistry is required by the researcher with the aim of developing the narrative. Such a skill may not be a strength in certain researchers, which means that the data or “life worlds”, which makes creating the narrative a challenge. Equally, the same may be said for the researchers dealing with numerical quantitative data. Doyle et al (2016) propose that mixed methods methodology is limited by the dominance of post-positivism and therefore quantitative enquiry. This suggests a degree of tokenism towards constructivism, in the creation of unique meanings, and qualitative methods.

In order to mitigate these issues, a number of strategies were implemented into the study. Interviewing patients is something I have been undertaking in my clinical role for over 20 years and that experience has helped in creating a dialogue within an interview. The use of an interview schedule is a useful method of guiding the subject matter and including the relevant topics. The experience of the supervisory team in the interview analysis has aided quality assurance within the research process. Further information on this subject may be found in the methods section. Although the number of participants is smaller in the qualitative part of the study, the data aims to provide depth and richness.. The balance of each methodology within mixed methods may present a challenge, as one may dominate over the other. Glogowska (2011) suggests that the challenges within mixed methods methodology are multi-factorial, from the concept, the data gathering and to the synthesis of all data to provide the answers. The challenge is being clear about the relative contribution of data for the overall findings. Each data set needs to be as robust as the other. The issue of understanding both sets of data is an important one, because, as Golgowska (2011) reports, such a process presents a real challenge to the researcher.

Despite these issues, the benefit of using mixed methods to explore and understand this patient group is greater than any potential limitations. As a novice researcher, with previous survey experience and an experienced nurse, used to complex conversations with patients, the limitations within mixed methods were mitigated so that new understandings within this patient group were achieved.

3.7 Summary of methodology

A mixed methods approach will provide new and unique insights into an arena that lacks depth of knowledge. Gelo et al (2008) and Toomela (2008), both reports that quantitative and qualitative research have disadvantages and limitations and therefore, mixed methods research is a solution to the limitations of individual approaches and may provide newer insights and understandings of the patient experience, on many levels. Creswell (2014) suggests that one of the shortcomings of quantitative research is the lack of understanding of the patient's experiences, feelings, or beliefs. Nursing research in general has tended to be of a qualitative nature, as it originates from social sciences (Guba 1961) and medical research has tended to be more quantitative in its methodology. By undertaking a mixedmethods approach, both ends of the philosophical spectrum may be addressed, most importantly, the ability to gain insights into a patient's experiences and thoughts from their own perspective, is an important way forward in enhancing clinical care. Within this local population of patients with an elevated BMI, suffering from AF it is firstly beneficial to obtain quality of life and symptoms information, related to the ablation, but also to ask about their own experiences in more depth and finally to mix the data to obtain novel and deeper insights into their clinical journey.

3.8 Methods

3.8.0 Introduction

This section of the chapter will describe and explain the methods used in this study. The information discussed will include the target population in the quantitative and qualitative phases.

3.8.1 Design

The study used a mixed methods approach, comprising a single-centre, prospective cohort study with an interview study conducted with a sub-sample of respondents to Phase 1. The study protocol may be seen in Appendix 2.

3.8.2 Target population

The study population included those patients with a diagnosis of AF referred to a tertiary centre, specialist arrhythmia clinic, and placed on the waiting list for first time AF ablation. In patients with AF characteristics vary in age, gender, classification of AF (paroxysmal, persistent, or long-standing persistent) and other comorbidities. In clinical practice almost all patients have symptomatic AF, apart from a small sub-group of those with tachycardia cardiomyopathy, requiring ablation to improve heart function. In this study all patients had symptoms related to their AF diagnosis. The inclusion and exclusion criteria developed for the study are presented in table 5 below.

Table 5 Inclusion and exclusion criteria

Inclusion criteria	**Exclusion criteria**
Participant has diagnosis of AF and has been referred for first -time AF ablation	Not eligible for AF ablation
Participant has BMI of 25 or greater	Participant has BMI <25
Participant is willing and able to give informed consent for participation in the quantitative study alone or for both the quantitative and qualitative study	Participant is not willing and unable to give informed consent for participation in the quantitative study alone or for both the quantitative and qualitative study
Male or female, aged 18 years or above.	Male or female under 18 years of age
Participant is eligible for first-time AF ablation	Redo AF ablation
Participant can speak and understand spoken and written English	Participant is not able to understand spoken or written English

3.9 Quantitative methods

The following section will describe the methods used for the quantitative phase of this mixed methods study. The data collection process and tools used will be described.
Following on from this, the method of data analysis will be considered.

Statistical advice was sought from a quantitative researcher, with experience in statistics. Using G*Power computerised software, a power calculation of a sample size of 86 patients was determined sufficient in order to determine, with a moderate effect size, differences in quality of life and symptoms before and after catheter ablation. The sample size represents the total number of first-time ablations (n=200) performed over the study duration. This calculation was based on the number of AF ablations performed in one year in the local hospital and on a moderate effect size determining differences in quality of life and symptoms before and after catheter ablation.

3.9.0 Recruitment

All participants were recruited from an acute NHS hospital trust in the South of England. Participants with paroxysmal, persistent, or long-standing persistent atrial fibrillation that were placed on the waiting list for first-time AF ablation were included for consideration of this study. Those patients that fitted the inclusion criteria were sent a recruitment pack in the postal system, which included an invitation letter, patient information sheet, copy of the questionnaire, a GDPR information sheet and contact details of the researcher. Recruitment started in April 2021, once ethics committee approval was granted, and continued until January 2022 when the final participant was recruited. Patients who were interested in participating in the research were contacted the researcher directly, either by telephone or email and those that did not initially respond were contacted by telephone, by the researcher, approximately a week before the procedure. The main reason for this approach was that, at the time, in the COVID-19 pandemic, the national postal system was not operating with normal efficiency. Previous experience with this patient population appreciated that, in general this is a highly motivated group, who are keen to discuss or inform clinical and research staff on how AF has affected them and hence a follow up phone call was made to initial non-responders. Table 6 presents the numbers of participants recruited.

Table 6 Numbers of participants during recruitment

Recruitment stage	**Numbers of participants**
Identified as eligible and sent invitation letter	90
Declined to participate in quantitative study	2
Number of patients withdrawn after initial baseline, due to cancelled ablation on the day (left atrial appendage thrombus)	3
Total number of participants in quantitative study at baseline	85
Total number of patients lost to follow-up	3
Total number of patients who completed study up to 6 months follow-up	82

3.9.1 Consent process

Eligible participants, identified by the clinical team were sent an invitation letter, about four weeks prior to the ablation, in addition to a detailed participant information sheet and information on General Data Protection Regulation (GDPR) (See in Appendix 3). These documents explained to participants the process of confidentiality and safe storage of data. The contact details of the researcher were given for any additional questions that the patients had hitherto received a detailed patient information sheet, which explained the study process (See Appendix 5). Patients were given the opportunity to discuss study details with the researcher beforehand. individuals may have had.

The patients that agreed to participate in the study were asked to bring the consent form with them, on the day of the procedure. The researcher or a member of the team visited the patient on the ward, answered any questions and completed the written consent form with the patient. Written consent was taken on the day of the ablation, in accordance with GCP guidance and the Declaration of Helsinki (World Medical Association 2001). Patients were given copies of the consent form (see Appendix 4).

3.9.2 Data Collection

Socio-demographic and clinical information on participants was collected at baseline from the patients' medical notes. This information included age, ethnicity, gender, BMI, classification of AF, anti-arrhythmic drugs, alcohol consumption in units per week, cardiac structure & function on echocardiography (Left atrial volume index-LAVI & LV function), baseline ECG rhythm and co-morbidities. Body mass index (BMI) was collected at the three time points within the study. The BMI at baseline was taken from the patient record and the BMI at follow-up was self-reported by the patient. In this study waist circumference was not measured because of the restrictions in place at the time, due to the COVID pandemic The anti-arrhythmic drugs use, and the presence of sinus rhythm (rhythm control) were collected at three and six months from the medical record.

3.9.3 Quantitative tools

Validated questionnaires were used for this study, in keeping with other published work in this patient population. A number of appropriate questionnaires are available and have been widely used in a number of studies (e.g. Dorian *et al.*, 2002, Mohanty *et al,.* 2017). One of the mostly widely used quality of life measures, Short-Form 36 (SF-36) was chosen as suitable for use in this proposed study, as recommended in current guidelines (Alliot *et al.,* 2014). Although the SF-36 is a generic health questionnaire and has been used in several healthcare scenarios, it has also been the most widely used questionnaire in the AF population, despite the fact that it is not listed by the International Consortium, for Health Outcomes Measurement (ICHOM) atrial fibrillation working group (Seligman et al., 2020). Furthermore, I have previous experience in the use of the SF-36 in the AF population (Bygrave *et al*., 1991).

The SF-36 was developed more than 20 years ago for the purpose of allocating health insurance plans to adults in the USA (Bowling 1995). The SF-36 evolved from the Medical Outcomes Study (MOS), which is a quantitative standardised survey, used to measure health-care status (Stewart & Ware 1992). The authors of the SF-36 aimed to develop a short, generic measure of subjective health status that was psychometrically sound, tested for reliability and validity and that could be applied to a wide range of settings. It was initially tested in the USA on >22,000 patients as part of the Rand MOS. The SF-36 has been used, over a number of years and in several health conditions as a subjective measure in healthy subjects to examine ten thousand population norms (Jenkinson et al 1996). Brazier (1992) reported good internal consistency and test-retest reliability, and from a postal survey in Sheffield, good construct validity. Furthermore, Mc Horney et al (1994) performed tests on data completeness quality, test scaling assumptions, estimated internal-consistency reliability testing, which suggests that the SF-36 is suitable for a diverse and wide number of patient populations. For these reasons, this questionnaire was considered suitable for this study in the evaluation of quality of life before and after ablation and may be seen in Appendix 7.

The SF-36 is a self or researcher administered questionnaire that takes approximately ten minutes to complete. It may be used at home, over the telephone or in a face-to-face setting. The SF-36 is a multi-item instrument measuring eight health concepts.

1. Physical functioning, which examines the ability to perform all types of physical activities, without health limitations.
2. Role limitations due to physical health problems, which identifies any issues with daily activities and work because of physical health.
3. Bodily pain
4. Social functioning, which addresses the ability to perform normal social activities without interference from physical or social problems.
5. Mental health (psychological distress and well-being)

6. Role limitations due to emotional problems, which addresses any issues with daily activities due to emotional problems.
7. Vitality, meaning energy or fatigue.
8. General health perceptions, which evaluates personal health.

A symptom score questionnaire that is specific for the AF population was selected, to provide additional understanding of how the ablation has improved, or otherwise, the symptom status of each patient. Two symptom scoring questionnaires were considered. The Atrial Fibrillation Symptom Score (AFSS) has been used widely in a number of studies following ablation and other interventions, such as risk factor management (Patak *et al,.* 2014). The Patient Perception Arrhythmia Questionnaire (PPAQ) is a relatively new, but validated tool, designed to establish, from a quantitative point of view, what the AF symptoms mean to an individual patient, including the loss of workdays and visits to the doctor (Wood *et al*,. 2010). The PPAQ was used in this study, rather than the AFSS mainly because it lends itself directly to the knowledge that is missing in relation to this population. This questionnaire may be seen in Appendix 8. These aspects are exactly those that an arrhythmia nurse would address, in terms of the patient’s treatment trajectory. Although either symptom score would have been suitable, it appears that no study has used the combination of the SF-36 and PPQ in the AF population, which may be providing new insights into this patient group. Moreover, the PPQ has previously been used in a UK based study of ablation patients suggesting it is an appropriate tool to use in this study (Evans *et al*,.2019). The questionnaires were completed on paper at baseline and via telephone at three- and six-months post ablation.

3.9.4 Data Entry

The data from the questionnaires were entered onto a specifically designed database, using SPSS V26 software (IBM 2019). Prior to analysis, the database was prepared as suggested by Pallant (2020). The database was checked for errors in entry. Missing data were entered as a minus one. This process was performed at regular intervals until all data were entered and then the whole database was re-checked at several intervals until analysis began.

3.9.5 Data analysis

Descriptive statistics were produced. The socio-economic characteristics were summarised and presented as means, with standard deviations and percentages, or medians and interquartile ranges (IQR). See Chapter 4 for the findings of the baseline characteristics. The results were assessed for normal distribution. Statistical tests were applied to assess for differences at the three timepoints. Data from the questionnaires were analysed using SPSS V26 software (IBM 2019).

3.9.6 SF-36 scores

SF-36 scores were calculated according to the RAND Corporation scoring instructions. The SF-36 scoring is a two-step process. Firstly, the score numbers were re-coded from original response categories (raw scores) to a re-coded value of 0-100. Each item has five possible responses, but the questions vary in terms of the meaning of a high or a low score, depending on the individual question.

The second part of the scoring process is to average the scores so that the eight domains, or scales are formulated. For example, to create the Pain domain, questions 21 and 22 are averaged. These domain or scale scores are because of averaging the relevant scores for each individual. Once re-coded and the eight domain scores produced the data were assessed for normality of distribution. To test for differences, assumption testing was first carried out. To test if the data were normally distributed, the Shapiro-Wilk alpha values, visual inspection of the QQ plots and box plots was undertaken to check if the data were normally distributed, and any outliers were noted. For data that were not normally distributed median scores, with inter-quartile ranges were calculated and non-parametric tests were applied. To assess for differences in the domain scores at the three time points, in answers with dichotomous variables, the Cochran’s Q test was applied, with pairwise comparisons with a Bonferroni correction. For differences in domain scores at the three time points in questions with more than one answer, the Friedman test was applied, with pairwise comparisons, using a Bonferroni correction. In order to assess for differences in SF36 scores over three time points, in the normally distributed data, a one-way, repeated measures analysis of variance (ANOVA) was calculated, which also provided pairwise comparisons between the three timepoints.

3.9.7 Patient Perception Arrhythmia Questionnaire (PPAQ) scores

Data from the PPAQ were analysed using SPSS V26 software (IBM 2019). The questionnaire responses were entered into the SPSS database. For question 1 (frequency of AF), and 2 (duration of AF) the data were ordinal and assessed for normality of distribution. This assessment revealed that the data were not normally distributed. Descriptive data produced medians with inter-quartile ranges and then compared over the three time points, to determine differences. The Friedman test was used for this purpose, with pairwise comparisons, using a Bonferroni correction.

The symptom question (not given a number on the PPQ) is split into two parts. The first part asked if any of the 19 listed symptoms were present. The second part asked how bothersome each symptom was, on a scale of 0 (not at all bothersome) to 4 (extremely bothersome). The six most commonly reported symptoms in AF were analysed, in accordance with the PPQ originators (Wood *et al*,. 2009). The most commonly reported AF symptoms were "heart flutter, heart skipping, light-headed, fatigue, heart racing and hard to catch breath". Cochran's Q test was used (Cochran 1950), to compare symptom frequencies over three time points, as the responses were dichotomous. Pairwise comparisons were made, using a Bonferroni correction.

The second part of this question regarding "bothersomeness" was reported as frequency of bother for each symptom. The data were assessed for normality of distribution, using Skewness and Kurtosis values and visual inspection of the QQ plots. The Friedman test was used to assess differences in scores over the three time points, with pairwise comparisons, using a Bonferroni correction.

Question 3 relates to the impact of the AF, with ten activities of daily living assessed by impact, on a subscale. The scale ranges from 0 (not at all) to 4 (extremely). These raw scores were transformed to produce subscale scores of 0-100 , as advised by Wood *et al*,.(2009).

- Raw score=total of number for each of the 10 activities SUMMED. Range is 0-40.
- Then equation for 0-100 score =
  (Raw score/40)*100

  (0 is lowest possible raw score and 40 is highest possible raw score)
- Also of note is that a subject must answer at least 80% of the subscale items to receive a total score.

Once the scores were transformed, the data were assessed for normality of distribution, using the Skewness, Kurtosis and Shapiro-Wilk values and visual inspection of the QQ and box plots. The Friedman test was applied to assess for changes at the three time points and pairwise comparisons made, using a Bonferroni correction.

The final part of the PPQ asks about days missed from work and days on which normal activities were reduced. The data were analysed based on those who worked and not those who are retired. The data were assessed for normality of distribution by visual inspection of the QQ plots. The Friedman test was applied to assess for differences at the three time points.

For the days cut down from normal activities, The data were analysed based on those who worked and not those who were retired. The data were assessed for normality of distribution by visual inspection of the QQ plots. The Friedman test was applied to assess for differences at the three time points, with pairwise comparisons, using a Bonferroni correction.

3.9.8 Multiple Regression Analysis

The purpose of multiple regression analysis was to determine the influences on QoL in this cohort. As BMI is central to this thesis, investigating this co-variate is an important part of the research question. However, there are other potential influences on patient reported outcomes after ablation, as seen in other research and guidelines (Hindricks *et al*., 2020, Patak *et al*., 2014). Such influences or predictors include age, gender, type of AF, left atrial volume index and rhythm control post ablation. These variables were based on the literature, not the bivariate analysis.

When using the SF-36, it is not possible to have one composite score to determine an individual's overall QoL, although it is possible to have composite physical and mental health scores. As these scores have limitations and disadvantages, it was decided to use two of the most relevant domains from the SF-36 questionnaire. These are General Health and Vitality. There are several reasons for this. Previous research (Blomström-Lundqvist *et al.,* 2019) has demonstrated that General Health and Vitality are the two domains that are most

influenced when assessing treatment outcomes. Firstly, these two domain scores measure and consider both physical and mental health outcomes. They are the two subscales that are the most accurate within the SF-36 questionnaire, according to its originator, Ware *et al*., (1993). In addition, an essential part of the linear regression process is for the data to be normally distributed. Symptom scores were not used in the model, mainly because there is no single symptom score, and symptoms vary in individuals.

The results of the multivariate analysis quantitative data may be seen in Chapter 4.

3.10 Qualitative phase

The second phase, of the study, which included the interviews, were conducted following the final questionnaires, at around six months post procedure.

3.10.0 Sample Size

A convenience sample of the total number of participants (n=20) were interviewed. The number of interviewees was determined following discussions with supervisors and previously published qualitative research in a similar patient population (McCabe *et al*,.2012). For the purposes of this study, the aim was to interview 15-20 participants. Guest *et al*., (2009) suggest that 12 participants is adequate for interview-based studies. Data saturation has been used for some time to justify sample sizes in qualitative research (Vasileiou *et al*., 2018). Data saturation tends to mean reaching the point in data gathering when no new themes or ideas materialise (Braun and Clarke 2021). However, there appears to be deliberation in recent years over the value of data saturation. Conceptualisation of this approach has been criticised for its lack of clarity (Guest *et al.,*2006). Deciding on data saturation is influenced by factors such as the theory and the meaning that is generated from observing the data and the reliability of the coding process (Braun and Clarke 2021), which makes the issue challenging. The data gathered in interviews and the point at which no new themes are identified is contentious, due several factors, such as homogeneity of the views expressed and the way in which themes are generated and the number of individuals undertaking the analysis. Braun and Clarke (2019) suggest that using data saturation, in some cases may be a tokenistic approach, with less meaning than when originally described. They also argue that quantifying the point at which data collection should stop in qualitative studies is not in line with reflexive thematic analysis and may not be useful. The sample included a fair spread and variation of characteristics, so that a broad range of views were included. This meant that no further interviews were needed, once the number 20 was achieved. It was clear that overall views were homogenous, data saturation had been reached and at this point no further interviews were undertaken. It is important to note that data saturation was deemed to be reached despite only recruiting white British patients, because recruitment from other ethnic groups was not possible from the catchment area for recruitment into the study.

3.10.1 Recruitment and sampling

Although the initial consent to the study included information about interviews, participants were asked again at the six-month data collection point if they wished to take part in the interview. At this point a separate consent form was used for the interviews.

At the design stage of the study, it was decided to use purposive sampling. This type of sampling is sometimes referred to as non-probability sampling, which is designed to select specific cases with the purpose of generating the richest and deepest data (Tashakkori & Tedlie 2003). In this cohort, purposive sampling would have included a variety of ages, BMIs, classifications of AF and genders, so that a range of views and experiences are generated. However, a pragmatic approach was required at the time of study interviews, and convenience sampling was adopted. Patients were asked if they wished to take part in the interviews after completion of the six-month questionnaires, at their convenience.

Convenience sampling is actually a form of purposive sampling, according to Tashakkori & Tedlie (2003), but is useful in recruiting the most easily accessible patients. The limitation in this form of sampling is selection bias and may not always be representative of the more general population. However, the pragmatic approach in this study drove this sampling strategy.

3.10.2 Consent

Patients were asked if they wished to participate in the interviews and were sent an additional consent form, which was completed, in writing, prior to interview. They had hitherto received a detailed patient information sheet, which explained the interview process. Patients were given the opportunity to discuss interview details with the researcher beforehand.

3.10.3 Conduct of interviews

The interview topic guide was informed by the literature and developed by the researcher, following discussions with the supervisory team. In order to enhance the guide and embrace patient involvement, a meeting was arranged with the local hospital Patient Involvement Panel (PIP). The following changes were made to the interview topic guide (changes in italics):

- *Were there* any unexpected results and consequences?
- *Was there* an improvement in QoL and symptoms?
- *Are you aware* of the impact of lifestyle on AF development, progression, and ablation outcomes?
- *Have you made any changes to your health*, eg. smoking, diet, exercise, alcohol?
- *Tell me about your lifestyle, related to* health, exercise.

The final version of the semi-structured interview topic guide was practiced on another arrhythmia nurse.

This approach is in line with the Department of Health Guidance (2009) on public involvement in the research process. The topic guide was reviewed and critiqued by the PIP and a final version was then used within the interview stage of the study.

3.10.4 Telephone interviews

In the design phase of the study, it was decided to adopt telephone, rather than face to face interviews. The main rationale for this approach was for the benefit of the patients. By undertaking telephone interviews, patients would not be required to travel for the interviews. A telephone interview allows flexibility in regard to the time of both interviewer and interviewee and is more convenient than face to face. Cachia and Millward (2011) suggest participants are less likely to drop-out of a study if interviews are via telephone. The literature generally suggests the use of telephones in interviewing is more a matter of convenience than any methodological strengths (Cachia and Millward 2011). However, a pragmatic approach was needed for this study, which was conducted through a global pandemic, whereby travel restrictions were in place and government advice was to stay at home. Whilst the advantages of telephone are clear, there are some limitations using this method of interviewing. The main one is the lack of physical presence within the interview may mean that certain non-verbal cues are missed, particularly when discussing sensitive issues. Even simple non-verbal cues, such as nodding are not possible via the telephone and often result in more verbal cues within the interview. On the contrary, patients may feel safer, within their own space, whilst on the telephone and have the ability to choose their level of privacy. It is worth noting that video interviews were considered for this study, but discounted early on, due to logistical reasons. As many of the interviews were conducted within the hospital environment, albeit in a private office, or room, the ability to use video was limited. I considered using Attend Anywhere, the NHS approved video consulting system. However, local regulations only allow the use of this system for clinical consultations. Other facilities, such as Zoom, or Google meet are not compatible within the hospital environment and IT system. Therefore, for a number of reasons, telephone interviews were chosen as the most applicable, suitable, and pragmatic approach for this method of data gathering.

3.11 Data management

The interviews were digitally audio-recorded. They were immediately to the saved as an audio file in the University's uploaded secure Google Drive. Each recording had no identifiable patient details within them. The first six interviews were transcribed, verbatim, by the researcher, but a decision was made between the researcher and supervisory team to utilise the services of a university approved transcription service, with a non-disclosure agreement in place, for the next 14 patients. The main reason for this was a pragmatic one, with the aim of progressing the study, within the time-frame available.

3.12 Data analysis

As discussed in methodology, framework analysis, according to Gayle *et al*,. (2013) was chosen as the preferred method of data analysis for the interviews within this study. This form of analysis was the chosen method of data analysis, in the early stages of the study.
The structured approach was appealing as a novice qualitative researcher.

3.13 Stages of framework analysis

The stages of framework analysis were followed, as advocated by Gayle *et al*,. (2013). This process took several months and was not linear, but both inductive and deductive in nature.

Gayle (2023) states that the stages of framework analysis are often revisited and refined, whilst moving forwards to the final stage of interpreting the data.

3.13.0 Stage 1) Transcription

The audio recordings were listened to immediately after each interview. The initial six interviews were transcribed, but, due to time pressures, the other 14 were sent to a university approved independent transcription service for verbatim transcription. A nondisclosure agreement was implemented.

3.13.1 Stage 2) Familiarisation

The audio files were listened to, and the transcripts re read, over the next few months. In November 2022 the interview audio recordings and transcripts were reviewed again. In early 2023, the familiarisation process continued over three months, but in the context of also undertaking quantitative analysis. Re-reading and listening to the audio files again gave a deeper insight into the experiences. By doing so, the patient’s voices became so familiar that it was possible to visualise the interview, especially related to context and place. Reading the transcribed interviews and using visual imagery, often sub-consciously, has allowed a deeper understanding of the dialogue. Hearing the individual’s voice enabled a mental image of them as a person, expressing their experiences.

3.13.2 Stage 3) Coding

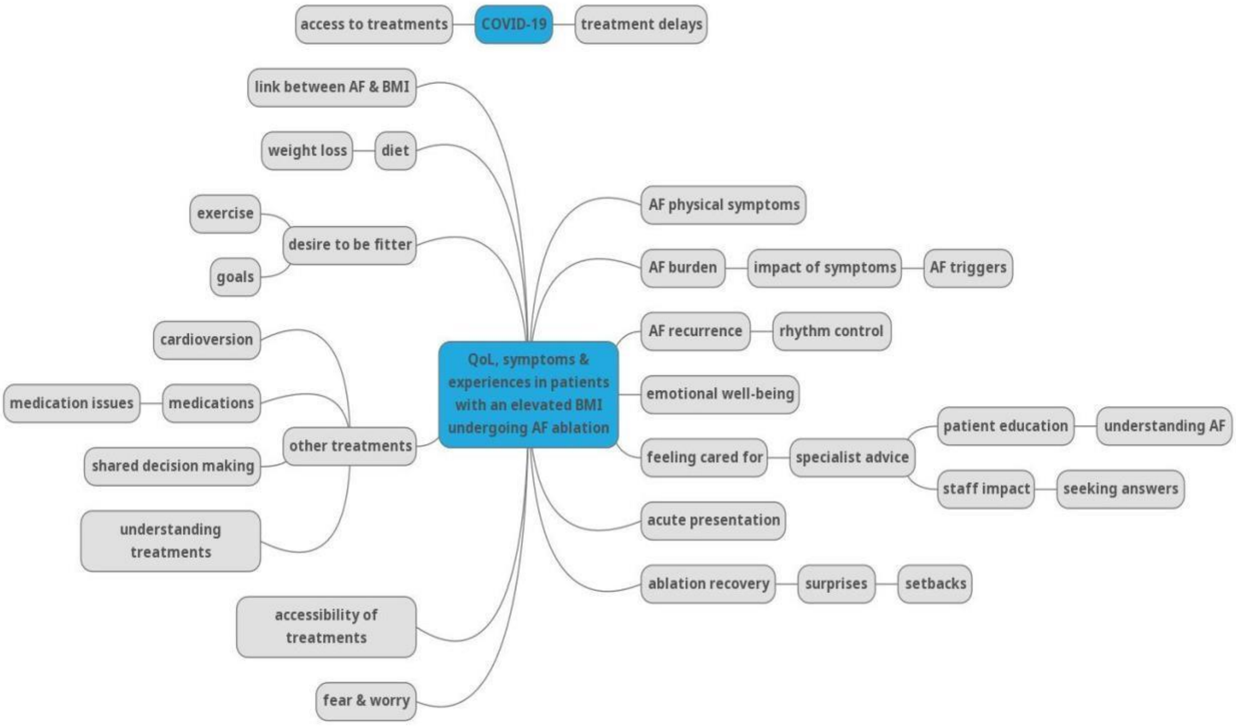
The process of coding was fluid and moved back and forth between familiarisation and applying codes. Deductively having the interview schedule in mind helped frame this part of the analysis. In addition, the interviews tended to flow in a chronological pattern, from AF diagnosis, to treatment, to ablation and the future. Inductively, the patient's voice allowed the expression of feelings, behaviours, and thoughts to assist with the understanding of their individual experiences. The Excel spreadsheet showing the codes may be seen in Appendix 6. The following table 7 shows the codes that developed during the coding process.

Table 7 Initial coding process from the Excel spreadsheet

Life before the ablation	AF diagnosis/uncertainty
	Fear of dying/heart attack/recurrent AF
	Challenges
	Treatment decisions
Life around the time of the ablation	The procedure on the day
	Immediate recovery
	Surprises
	Setbacks
After the ablation	Recovery
	Moving forward
	Hopes for the future
	Lifestyle
	Weight/diet
	Exercise

In addition to the initial codes that developed, a mind map, using software called Mindmup (Mindmup.com) was created to visualise the codes around the central research question. This is displayed below in figure 7.

Figure 7 Mindmap of codes



3.13.3 Stage 4) Developing the analytical framework

This part of the process was fluid and dynamic and involved the grouping codes into categories. Assigning a short phrase to a theme or category, enabled the framework to develop. After several transcripts were coded, the process of development of the framework continued, both inductively and deductively. The initial framework required adjustment and refinement, which is both normal and expected (Gale *et al*,. 2013).

3.13.4 Stage 5) Applying the analytical framework

The framework developed allowing categories to emerge. Summaries of the conversations allowed the categories to develop. An Excel spreadsheet was used, with patient numbers displayed vertically and the themes horizontally, using colour coding for ease of view.

The following categories continued to emerge:

- The presentation of AF as a diagnosis/uncertainty
- Understanding of treatments
- Specialist advice, information & education
- Physical impact of AF
- Mental health consequences of the AF symptoms & diagnosis
- Medication issues and concerns
- Prelude to ablation/shared decision making.
- Impact of ablation on the body/recovery
- Moving forward with life after ablation
- The influence of COVID-19
- Lifestyle factors & modifications

Whilst re-reading transcripts, additional notes were taken, which included thoughts on the following additional categories

- Gratitude to the care team
- Additional treatments such as cardioversion
- The impact of the heart rhythm-AF or sinus rhythm
- The timescale for ablation treatment
- ● Desire to be fitter

3.13.5 Stage 6) Charting data into the framework matrix

Charting involved transferring the data into an Excel spreadsheet. The data were summarised by category from each interview transcript on a separate word document, for ease of interpretation. Once the matrix in Excel was correctly formatted, it was easier to see all the interviews and patients horizontally and vertically displayed on the chart. The dynamic and fluid nature of this type of analysis allowed refinement of the categories. It was at this stage after reviewing the interviews, within the framework and the chart that some of the categories were combined and re-phrased.

3.13.6 Stage 7) Interpreting the data

The final stage of framework analysis involves the interpretation of the data.
The codes, categories, and impressions of the data were all discussed with the supervisory team, who are experienced in qualitative research. This approach is supported by Gale et al (2013), who suggest that this stage may take some time. The aims of the study and the research question were always considered throughout this process. This stage involved periods of reflection, on the interviews and the categories that had emerged, with revisiting the reflective diary. The findings from the questionnaire data provided a useful point of reference on which to view the qualitative data.

The framework analysis, with the final categories and sub-categories may be seen in table 8 below.

Table 8 The categories and sub-categories summarised within the study.

Conceptual Framework	**Categories**	**Summary**	**Subcategories**	**Summary**	**Common across all categories**
QoL, symptoms and experiences in patients with raised BMI undergoing AF ablation	1.Challenge of seeking & receiving a diagnosis of AF	Delays to diagnosis led to frustration & uncertainty. Not knowing why patients felt unwell	1.1 Physical symptoms of AF 1.2 Acute episodes causing concern	Patients described the impact of AF on their body-including QoL & specific symptoms, such as fatigue, or breathlessness. Some individuals presented acutely, some in a dramatic way. Others had delays in reaching a diagnosis, despite multiple attempts. .	6. Impact of Covid-19 The pandemic

	2.Fear & worry	Fear is a common emotion. Fear of dying, fear of a heart attack	2.1 Emotional impact of AF symptoms & diagnosis	The emotional impact of AF including anxiety, depression, fear & panic were discussed.	Affected the access to healthcare & treatments, the perceptions were that waiting lists were longer as a result of COVID-19 and that all staff were not available. Access to primary care was an issue. Frustrations with preparation for the procedure included having PCR tests.
		Lack of understanding & awareness led to some alarmist comments “I was told I needed to be near a defib”		They discussed the mental health benefits of being in sinus rhythm	

	3. Understanding of treatment options	Patients talked eloquently about previous treatments such as cardioversion or medications They discussed anticoagulation issues & the need for it. Generally, the understanding of	3.1 Shared decision making 3.2 Specialist advice & information 3.3 Gratitude to healthcare professionals & feeling cared for	The decision to undergo ablation was discussed in many cases. Shared decision making emerged in the understanding of the risks & benefits of the procedure Being looked after & feeling safe was a common finding	

		treatments was good. Access to specialist care was variable. Some had a seamless route to specialist care whilst others had delays & battles	3.4 Medication issues & concerns	Many patients had issues with medications. Generally, they were familiar with the terminology & knew the names and uses for the drugs. The issues of side-effects & ineffectiveness were often the reasons why ablation was sought as a treatment option.	

	4. Effect on the person from the ablation procedure	Patients talked about the immediate aftereffects of ablation	4.1 Physical & mental recovery 4.2 Obstacles, setbacks & surprises	Patients experienced a number of setbacks, related to the ablation, which included minor complications & AF recurrences Some of the surprises were issues that patient found “daunting”, such as the equipment in the cath lab & the number of staff in the lab on the day of the procedure.	

	5. the interplay between a raised BMI & health	Many were not aware of the link between raised BMI & AF. Weight, diet & exercise were frequently discussed. Some had changed their lifestyle as a result of the AF diagnosis & some had reduced or stopped their usual level of physical activity	5.1 The desire to be fitter & healthier 5.2 Hopes for the future & looking forward	Several mentioned the desire to be better informed about exercise. Hopes & goals for the future were often discussed. The discussions were on the desire to be fitter, to lose weight and to be free of AF.	

3.14 Ethical considerations

This section will explore ethics issues related to this study. Ethics are fundamental to the research process and in addition to the regulatory process that are required to undertake research, the philosophical aspects of ethics were also considered.

Ethical and governance approval was sought and gained from three regulatory bodies. Firstly, from the Faculty Research Ethics Committee (FREC) at Oxford Brookes University (FREC ID: F.02.2019.12), the Health Research Authority (IRAS ID: 275780) and the Research and Development Department at the NHS Hospital (ID:15220-S1001).

3.14.0 Informed consent

Beneficence is a fundamental part of the ethics of healthcare (Kinsinger 2009). Essentially it is the moral obligation of healthcare professionals to do well by their patients and act professionally, by preventing harm and acting fairly. This element of ethics is central to the consent process in any study or procedure.

All staff involved in the consent process within this study and follow-up telephone questionnaires were registered healthcare professionals, either senior doctors, or registered arrhythmia nurses. These staff underwent additional training in Good Clinical Practice (GCP), certified with the National Institute for Health research (NIHR), to ensure a rigorous process throughout the study. The principal investigator delegated certain tasks, on occasions, to a number of the clinical team. These tasks included taking consent, collecting the baseline written questionnaires and undertaking telephone follow-up questionnaires at three and six months at times when the principal investigator was unable to do so. All staff involved were permitted to sign a delegation log, which was stored in the study master file.

3.14.1 Risk of harm to the participant

Potential adverse effects of being a participant were considered and explained within the participant information sheet. The following table 9 highlights the potential issues around risk of harm and how these may be mitigated.

Table 9 Risk of harm and mitigation processes

Potential risk of harm to the participant	**Mitigation processes**
Participant feeling obliged/coerced into the study	Participant informed of choice to not take part, or withdraw
Participant using the session as a clinic appointment/therapy session	Being a nurse allows a professional understanding of the experiences
Negative feelings on issues around weight and BMI	Interviewing patients is using nursing skills
Nurse/researcher giving clinical advice	Look for warning signs –fitting in too well, getting too close, decreased clarity (Colborne et al 2004)
Conflict of roles-nurse/researcher	Including patients that were cared for by other members of the team
Managing expectations of the participant	Patient information sheet to explain the nurse/researcher role
Nurse unable to separate from caring or advocacy	Keeping a reflexive journal

Nurse being unable to help	Contact details of clinical team and researcher

Signposting to relevant agencies, such as the Patient Advice and Liaison Service (PALS), the AF Association (AFA), for confidential support, and the patient's GP were all included within the information provided.

The following section presents the ethical considerations according to qualitative research.

3.14.2 Maintaining rigour

Maintaining rigour in a study is essential, according to Nowell *et al*,. (2017). Rigour means being precise or accurate, which does not align with the concept of qualitative research, which is expansive and flexible (Cypress 2017). Rigour is concerned with the strength of a study design and research question, whilst minimising bias. In quantitative studies reliability and validity are used to maintain rigour and provide reassurance that the research is of sound conduct. The same cannot apply to qualitative research, which is not governed by numbers and statistics. The work of Lincoln and Guba (1985) has assisted with rigour in qualitative research, in the use of the word trustworthiness, which is in some ways equivalent to reliability and credibility. In being trustworthy, the findings may be verified. Several criteria were developed by Guba and Lincoln (1985) in order to demonstrate trustworthiness in a study. These criteria are discussed in relation to this study.

3.14.3 Credibility

Credibility refers to the ability for others to be able to recognize and understand the research findings (Cypress 2017). In this study, a random selection of audio files and transcripts (n=5) were shared with the supervisory team, in order for the process of member checking (Lincoln and Guba 1985). In doing this all the way through the process of analysis, from raw data to final themes, credibility was maintained.

3.14.4 Transferability

Transferability means the ability to reproduce the research in another setting, thus ensuring the data is generalisable to another population (Nowell *et al,.* 2017). In this study, the semistructured interview schedule could be used in other settings and was not specific to one centre. Furthermore, the sampling method created a variety of types of AF, BMI ranges, age, and gender, which was representative of the total sample. The results chapter will present the population and context to help with this issue.

3.14.5 Dependability

Dependability is essentially providing an audit trail of the research, whereby the data make sense, are traceable and there is clear evidence of documentation of the process (Nowell *et al*,. 2017). In this study, there was regular dialogue with the supervisory team, who are all experienced qualitative researchers, in the handling of data materials. Regular discussions enabled refinement of the themes to accurately reflect participants' views.

3.14.6 Confirmability

This process is linked to dependability and ensures that the findings are reached through a robust process (Lincoln and Guba 1985). In this study, the use of framework analysis enabled clarity and visibility due to the structured nature of this method.

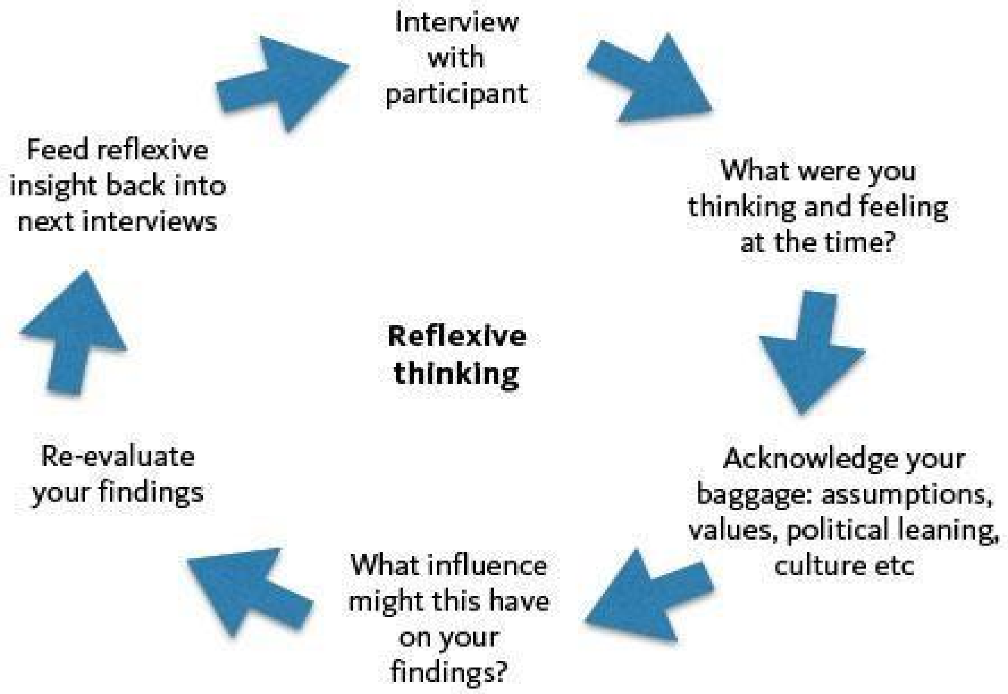
3.14.7 Reflexivity

Reflexivity is concerned with the researcher’s role within the research, in both practice and creation. It involves self-awareness and reflection, which is a less active form of reflexivity (Dowling 2006). Having a degree of epistemological reflexivity means acknowledging the erstwhile assumptions that an individual may have. Such assumptions may be personal, professional, socio-economic, and educational. These assumptions may be related to previous experiences and knowledge. Reflexivity represents an internal and external dialogue that a researcher will be having during the research process (Nowell *et al*,. 2017). The advantage of reflexivity is in the minimisation of bias in the acknowledgment of the role of the researcher within a study (McCabe and Holmes 2009). Although reflexivity may not be commonly acknowledged in published qualitative studies, it is widely noted that reflexivity is challenging (Newton *et al*,. 2011). These authors suggest that reflexivity should also be evident in quantitative research, but this is never apparent. This is despite the view of

McCabe and Holmes (2009) that reflexivity has its roots in both positivist and naturalistic research.

Pragmatism supports philosophical reflexivity, which makes it especially suitable for nursing research (Younas 2020). Rorty (1999) believes that pragmatism provides a sense of utility, which requires reflexivity to function appropriately. Within this research, reflexivity is central to the interview part of the study, mainly because the researcher is an arrhythmia nurse. The arrhythmia nurse is required to assist patients in their understanding of AF and treatments and their practice may be embedded within a clinical service. Assessing patient reported outcomes after catheter ablation may be influenced by the fact that the arrhythmia nurse may be part of the team involved in the ablation procedure and would hope that the outcomes are favourable. It is assumed that undergoing catheter ablation, for rhythm control will have a positive impact on quality of life. It could be argued that if the patient outcomes improve, then the expensive treatments, with certain clinical risks that are offered are worth it. Bias may exist within the expectations and roles of the arrhythmia team, who may well have pre-conceptions of this invasive procedure and the question is if this influences patients in their interaction with the clinical team. The interviews aimed to establish the patient experiences of the procedure and help to interpret the symptoms and QoL outcomes. Arber (2006) recommends the use of a reflexive journal with the purpose of mitigating the issues concerned with reflexivity. Using a reflexive approach, keeping a reflective journal and regular meetings with the supervisory team will all help to maintain rigour during this study. The following diagram from Boscoe (2015) demonstrates the cycle of reflexive thinking, which assists in the process whilst undergoing this type of research.

Figure 8 cycle of reflexive thinking



Being transparent and acknowledging the role as an arrhythmia nurse who is also a researcher is as important as keeping a reflexive journal throughout the process.

The main purpose for adopting a reflexive approach is to minimise bias within, not only the interviews, but the analysis. This issue is further mitigated by the embedded reflective nature of nursing, which is aligned with reflexivity, albeit at a more tempered level.

3.15 Summary

This chapter has presented the philosophical underpinnings and methodology for this study. In addition, the methods used within this study, within a mixed methods approach have been described and presented. The rationale for the particular approaches within the study conduct have been discussed . The subsequent two chapters present the results from both sets of data. The next chapter presents the quantitative results.

CHAPTER FOUR: Questionnaire results

4.0 Introduction

The aim of this study was to explore the quality of life, symptoms, and experiences of patients, all of whom have an elevated BMI and undergo AF ablation. The quantitative findings firstly include the baseline characteristics of the participants. In addition, the descriptive analysis of the two questionnaires used to assess quality of life and symptoms at baseline (before ablation) and at three- and six-months post procedure are presented. The results of the multiple regression analysis, related to vitality and general health from the QoL perspective are presented after the initial quantitative findings.

4.1 Sample overview

In total 90 patients on the waiting list for AF ablation were eligible for the study between 24/04/21 and 18/01/22 and were sent a letter inviting them to participate. Two patients declined to participate. The reasons for this varied but were related to factors in their personal situation at the time, which meant they preferred not to be part of a study. A further three patients were withdrawn on the day of the ablation, due to presence of a left atrial appendage thrombus, resulting in ablation cancellation. Three further patients were lost to follow-up at 3 and 6 months and were withdrawn from the study. Lost to follow-up meant that two of the three patients, although agreed to complete the questionnaires, were not available to do so. The final patient was not contactable, despite a reminder letter and 2 telephone calls. A total of 82 patients completed the study and are included in the analysis (see chapter 3 methods).

4.2 Response rate

There was a 100% response rate to the baseline questionnaires (n=82), which were collected on the day of the ablation procedure. A small number of patients, who were keen to participate, but forgot to bring the questionnaire were provided with another copy and completed it in a timely manner, before the procedure. The follow-up questionnaire response rates were also high at 96.5% for both three and six months, as the questionnaires were conducted via telephone by the research team. Two patients were withdrawn after the baseline questionnaires, as they were lost to follow-up. This was despite being contacted by telephone and appointment letter. Patients were sent a letter with a time and date for the telephone questionnaire to be administered and if the time or date was not convenient, another suitable date was arranged.

4.3 Missing data-

The following data were missing from the patient demographics.

- BMI at 3 months- one participants
- ECG, documenting rhythm at start of the ablation- three participants
- Left atrial volume index (LAVI)- within the medical notes-eight participants.
- Left ventricular ejection fraction (LVEF)-within the medical notes- two participants.

The LVEF missing data was because the echocardiogram report was not available, the images were unavailable, or the report did not quantify the LVEF. The reason for the eight LAVI missing data is either because the images or the reports were unavailable, or the echocardiogram report did not include LAVI. A routine echocardiogram, with left atrial dimensions, is advised in patients with AF as part of routine clinical work-up (NICE 2021, ESC 2020m, Harkness et al 2020). Such data should be available as a matter of routine clinical management.

Missing data within the questionnaires were all at baseline, (M0) at which point the individual patient completed the questionnaire by hand, using pen and paper. The missing values appeared to be random and were only one single question, rather than a whole section of the questionnaire that would affect domain scores.

Dong et al (2013) discuss acceptable levels of missing data, which range from 5-10%. These authors suggest using one or two methods to handle missing data, depending on the type of data. These include multiple imputation, full information maximum likelihood, and expectation-maximization algorithm. These authors applied all three methods in cases where 40-60% of data were missing and concluded the outcomes were similar. In this study the missing items were at baseline, with 40 items (out of 2952), missing at random. This represents 1.4% of the overall number of participant responses and items within the SF-36. Therefore, after statistical advice was sought, it was decided to not use any particular method to manage the data, particularly as the reduction in completed answers would not affect power.

Total missing data from individual questions from the questionnaires were as follows:

- M0-SF-36-40
- M0 PPQ-9
- M3 SF-36-0
- M3 PPQ-2
- M6 SF-36-5
- M6 PPQ-3

M0-baseline, M3-month three, M6-month six.

There were no individuals where composite domain scores were not able to be calculated.

4.4 Statistical guidance

A university appointed quantitative researcher provided advice and guidance for the quantitative analysis, in addition to the supervisory team. Laerd statistics (2015), and Pallant (2020) were used to inform the statistical process.

4.5 Baseline characteristics

The baseline characteristics of the patient cohort are summarised in table 10. The mean age of this cohort was 60.7 years, with 73.2% males. In terms of ethnicity, 96.3% were of White British ethnicity, one patient was Chinese, one Asian and one White Other. Persistent AF represented the majority of patients, with 59.8% of the total sample and 40.2% having paroxysmal AF. Body mass index (BMI) ranged from 25-44 kg/m^2 with the median being 29.5 kg/m^2. Left atrial volume index (LAVI) data were available in 74 of the patients. The values varied widely from 15.5-107.1 ml/m$^{2.}$ The normal range for this measurement is <34ml/m^2 (BSE 2022). Patients with AF often have other related co-morbidities and these additional patient characteristics are displayed in table 1 below. Values are reported as means, medians, or frequencies, with standard deviation, interquartile range, and percentages reported in brackets.

Table 10 Baseline characteristics

Characteristic		Total (n=82)
Age (years) *M(SD)*		60.7 (11.6)
Gender *n(%)*	Female	22 (26.8)
	Male	60 (73.2)
Classification of AF *n(%)*	Paroxysmal AF	33 (40.2)
	Persistent AF	44 (53.7)
	Long standing persistent AF	5 (6.1)
Ethnicity *n(%)*	White British	81 (96.3)
	Asian	1 (1.2)
	Chinese	1 (1.2)
	White other	1 (1.2)
BMI (kg/m^2) *Mdn (IQR)*		29.5, (25.1-38.2)
Alcohol intake units/week M(SD)		7.5 (10.8)

Echocardiogram M(SD)	LAVI (ml/m^2) *	41.4 (20.3)
	LVEF (%)**	54.3 (10)
ECG rhythm at baseline*** *n (%)*	AF	31 (37.8)
	Sinus rhythm	45 (54.9)
	Other	4 (4.9)
Comorbidities *n(%)*	Coronary artery disease	17 (20.7)
	Hypertension	29 (35.4)
	Implantable cardiac device****	
	PPM	9 (11)
	ICD	2 (2.4)
	CRT-D	1 (1.2)
	Dilated cardiomyopathy	1(1.2)
	Hypertrophic cardiomyopathy	2 (2.4)
	Hypercholesterolaemia	8 (9.8)
	Diabetes mellitus	6 (7.3)
	Thyroid disorder history	
	hypothyroidism	4 (4.9)
	hyperthyroidism	16 (19.5)
	Obstructive sleep apnoea	4 (4.9)
	Other past medical history	38 (46.3)

*LAVI n=74, **LVEF n=79, ***ECG n=80 **** PPM-permanent pacemaker, ICDimplantable cardioverter defibrillator, CRT-D- cardiac resynchronisation defibrillator

The following sections describes the findings from the clinical data collected at three time points (sections 4.7-4.9).

4.6 Body mass index (BMI)

The participant's BMI was recorded at baseline, three months and six months follow-up. The baseline data was from the patient record and the follow-up BMI were self-reported numbers. BMI data were not normally distributed, according to visual inspection of QQ plots. Friedman test was conducted to determine whether BMI differed before and after AF ablation at three and six months. There was no significant difference in median BMI, $\chi^2(2)=3.480$, p=0.176, at baseline (Mdn=29.5, IQR 25.1-38.2) compared to M3 (Mdn=30.6, IQR 20.7), and M6 (Mdn=30.2, IQR 21.9). The test statistics for the Friedman test are presented in Appendix 9.

4.7 Anti-arrhythmic drugs

The data recorded was a yes or no answer in relation to whether patients were taking rhythm control drugs or not. The numbers of participants at each time point taking antiarrhythmic drugs were as follows: M0 (49%, n=40), M3 (32%, n=26 and M6 (30 %, n=25). The data were not normally distributed, as determined by visual inspection of QQ plots, Cochran's Q test was applied. It showed a significant statistical difference in the proportion of patients taking anti-arrhythmic drugs at three time points; $\chi^2(2)=18.28$, $p<0.005$

Post hoc analysis using Bonferroni's correction demonstrated a significant difference from M0 to M3 (p=0.037) and M0 to M6 (p< 0.0005), but no significant difference between M3 and M6 (p=0.207). The test statistics for the Cochran's Q test are presented in Appendix 10.

4.8 Rhythm control

Rhythm control usually means absence of the arrhythmia. However, in AF ablation, it conventionally means improvement in quality of life and/or symptoms that do not require a redo procedure. In this study 80.5% (n=66) of participants had rhythm control at M3 and so did not require a redo ablation. This proportion increased to 81.7% (n=67) at M6. In this cohort there were 11% (n=9) who were placed on the waiting list for a redo procedure within the six-month study period. That means that the AF burden was enough to warrant a repeat invasive procedure. One of these patients was listed for a redo within three months of the initial ablation. The questionnaire data on these patients were included for analysis within the total sample.

4.9 Quality of Life scores (QoL) from the SF-36 questionnaire.

Physical Functioning, Role Limitations due to Physical Functioning, Role Limitations due to Emotional Problems, Social Functioning, Pain, Emotional Well-Being.

QoL scores for the eight scales or domains of the SF-36, at three time points are presented in Table 11. A higher score indicates better quality of life. The data were assessed for normality. The Shapiro-Wilk alpha value and visual inspection of the QQ plot revealed that the data were not normally distributed in the physical functioning, role limitations emotional problems, social functioning, emotional well-being, and pain domains. Therefore, non-parametric tests were applied. The Friedman test was conducted in order to assess differences in QoL between time points. The results in these six domains, all significantly improved between the time points ($p<0.0005$). In order to assess for differences between time points, post-hoc comparisons with Bonferroni's correction for multiple tests indicated that there were significant differences between M0 to M3 and M3 to M6 in all domains except pain in timepoints M3-M6 (see table 2). In the pain domain there were no significant differences in the time point M0-M3 and M0-M6.

This study demonstrated at baseline, that median and mean SF-36 scores were lower in all eight domains in patients with AF, compared to population norms. The population norms from the Oxford Healthy lifestyle Survey (Jenkinson et al 1993) are reported as means and (SD) and are presented below.

PF- 88.4 (17.98)

RLP-85.52 (29.93)

RLE- 82.93 (31.76)

SF- 88.01 (19.58)

Pain- 81.49 (21.69)

EWB- 73.77 (17.24)

Within this study six of the domains (PF, RLP, RLE, SF, P & EWB) are reported as medians, due to the data being not normally distributed. This factor makes comparisons difficult. However, the two domains in this study that were normally distributed (GH & V) are lower than the population norms., as follows:

General Health-73.52 (19.90)

Vitality-61.13 (19.67)

The Vitality and General Health scores were normally distributed and therefore Analysis of Variance (ANOVA) was applied to the data. The details are presented below.

4.10 General Health (GH)

A one-way repeated measures ANOVA was conducted to determine whether there were statistically significant differences in GH scores from baseline (M0) to after ablation at M3 and M6. There were no outliers and data were normally distributed, as assessed by box plot and Shapiro-Wilk test respectively ($p<0.005$). The assumption of sphericity was not violated, as assessed by Mauchly's test of sphericity, $\chi^2(2) = 5.95$, $p = 0.051$. General Health scores statistically significantly improved over time, $F\ (2, 162) = 15.381$, $p<0.005$, partial $\eta^2 =.161$.

Post-hoc analysis with Bonferroni's adjustment revealed that GH scores significantly increased from 50.57 at M0 to 60.13 at M3. This was a statistically significant increase of 9.56 (95% CI, −15.382 to 3.740), $p<0.0005$. There was an increase in GH scores from 50.57 at M0 to 61.28 at M6. This was a statistically significant increase of 10.710 (95% CI, −15.685 to 5.734), $p< 0.0005$. Although scores increased from 60.163 at M3 to 61.280 at M6, this was not statistically significant (95% CI, −5.836-3.538), $p = 1$. The QoL scores are displayed in table 2.

4.11 Vitality

A one-way repeated measures ANOVA was conducted to determine whether there were statistically significant differences in Vitality scores from baseline (M0) to after ablation at M3 and M6. There were no outliers and data were normally distributed, as assessed by box plot and Shapiro-Wilk test respectively ($p<0.005$). The assumption of sphericity was violated, as assessed by Mauchly's test of sphericity, $\chi^2 8.30\ (2)$, $p = 0.016$. Therefore, a Greenhouse

Geisser correction was applied (ε – 0.346). Vitality scores improved significantly over time, *F* (1.821, 147.46) = 42.812, p<0.0005, partial $\eta^2 = 0.346$.

Post-hoc comparisons with Bonferroni's adjustment for multiple tests revealed that Vitality scores significantly increased from 36.16 at M0 to 54.27 at M3. This was a statistically significant increase of 19.11 (95% CI, −26.492 to −11.720), p<0.0005. Vitality scores increased from 35.16 at M0 to 58.72 at M6. This was a statistically significant increase of 23.56 (95% CI −30.313 to −16.801), p<0.0005. Although scores increased from 58.720 at M3 to 58.720 at M6, this was not statistically significant (95% CI, −10.019 to 1.116), p=0.162.

Table 11 Median and mean QOL domain scores at each time points

Domain (n=82)	**Timepoint**	**Median score (IQR)**	**Test statistic and pvalue**	**Bonferroni's pairwise p-value**
Physical Functioning	M0	57.8 (95)	$\chi^2(2)=66.77$ p<0.0005*	M0-M3-0.0005*
	M3	85 (85)		M0-M6-0.0005*
	M6	90 (100)		M3-M6-0.593
Role Limitations Physical Functioning	M0	25 (100)	χ^2 (2)=41.80 p<0.0005*	M0-M3-0.0005*
	M3	75.4 (100)		M0-M6-0.0005*
	M6	100 (100)		M3-M6-1.000
Role Limitations Emotional Problems	M0	67 (67)	χ^2 (2)= 47.14 p=0.0005*	M0-M3-0.0005*
	M3	100 (100)		M0-M6-0.0005*
	M6	100 (100)		M3-M6-1.000
Social Functioning	M0	62.6 (100)	$\chi^2(2)$ =60.50	M0-M3-0.0005*

	M3	100 (100)		M0-M6-0.0005*
	M6	100 (100)	P<0.0005*	M3-M6-1.000
Pain	M0	77.5 (90)	$\chi^2(2)$ =6.820 p<0.033	M0-M3-0.355
	M3	90 (90)		M0-M6-0.086
	M6	80 (90)		M3-M6-1.00
Emotional Wellbeing	M0	66 (89.3)	$\chi^2(2)$ =38.375 p<0.0005*	M0-M3-<0.0005*
	M3	84 (72)		M0-M6-<0.0005*
	M6	84 (72)		M3-M6-0.987
		Means scores (SD)		
Vitality	M0	35.1 (20.5)	*F* (1.82,147.5)= 42.8, p<0.0005*	M0-M3-<0.0005*
	M3	54.3 (26.4)		M0-M6-<0.0005
	M6	58.7 (25.0)		M3-M6- 0.162
General Health	M0	50.6 (17.9)	*F* (2,162) = 15.381, p<0.0005*	M0-M3-<0.0005*
	M3	60.1 (24)		M0-M6-<0.0005*
	M6	61.3 (23.6)		M3-M6 - 1

Key-* is a significant p value.

4.12 Patient Perception Questionnaire (PPQ) results

4.12.0 Frequency of AF

The first part of the PPQ assesses the frequency of AF. A score of zero means no AF in the past month and a score of nine means three or more times per day (or persistent AF). Visual inspection of the data on histograms and QQ plots revealed the data were not normally distributed (see Appendix 11), which meant a non-parametric test was undertaken to assess for differences at each time point.

The Friedman test was conducted to determine whether AF frequency scores differed from baseline to three and six-months post ablation. Significant reductions in AF frequency were seen after ablation. Pairwise comparisons were performed, with a Bonferroni correction for multiple comparisons. The frequency of AF decreased significantly between M0 to M3 and M0 to M6. There were no significant differences between M3 and M6, but this was because at both time points the median scores were zero. The results of the Friedman test are presented in table 12 below.

Table 12 PPQ-frequency of AF

Timepoint	Median score (IQR)	Test statistic and p value	Bonferroni pairwise p-value
M0	6 (5)	$\chi^2(2) = 65.133$ $p<0.0005$*	M0-M3-0.0005
M3	0 (5)		M0-M6-0.0005
M6	0 (2)		M3-M6-0.384

Key-* is a significant p value.

4.12.1 Duration of AF

The duration of AF is scored from zero (no AF) to eight (AF longer than one hour), (See Appendix 8 for a copy of the PPAQ). Visual inspection of the data on histograms revealed the data were not normally distributed (see Appendix 12), which meant a non-parametric test was undertaken to assess for differences at each time point.

The Friedman test was conducted to determine whether AF duration scores differed from baseline to three and six-months post ablation. Significant reductions in AF duration were seen after ablation. Pairwise comparisons were performed (SPSS V26), with a Bonferroni correction for multiple comparisons. The duration of AF decreased significantly between M0 to M3 and M0 to M6. There were no significant differences between M3 and M6, but this was because at both time points the median scores were zero. The results of the Friedman test are presented in table 13 below.

Table 13 PPAQ-duration of AF

Timepoint	**Median score (IQR)**	**Test statistic and p value**	**Bonferroni pairwise p-value**
M0	6 (6)	$\chi^2(2) = 49.480$ p<0.0005*	M0-M3-0.0005
M3	0 (4)		M0-M6-0.0005
M6	0 (0)		M3-M6-0.716

Key-* is a significant p value.

4.13 PPAQ Symptoms

The symptom part of the questionnaire has 19 separate symptoms that may be reported by people in any arrhythmia. The following symptoms, as displayed in table 14 are the most commonly reported in AF. The other symptoms which form part of the PPQ may be seen in Appendix 8.

Tests for normality were conducted and found to be not normally distributed. Therefore, non-parametric tests were applied. The assumption tests were met for sample size and therefore a Cochran's Q test was performed. Cochran's Q test demonstrated significant differences in the symptom percentage scores at baseline, compared to post ablation at three and six months timepoints. The following table 14 demonstrates the percentage of symptoms reported at each time point.

Table 14 PPAQ Symptoms at 3 timepoints

Symptom	Timepoint	Frequency of symptoms (%)	χ^{2} (df)	p value	Bonferroni's pairwise p value
Heart flutter	M0	67 (81.7) 32	57.54 (2)	<0.000*	M0-M3 -<0.0005
	M3	(39)			M0-M6- <0.0005
	M6	28 (34.1)			M3-M6-1
Heart skipping	M0	63 (76.8)	60.04(2)	<0.000*	M0-M3-0.0005
	M3	27 (32.9)			M0-M6-0.0005
	M6	21 (25.6)			M3-M6-0.881
Light-headed	M0	62 (75.6)	67.673 (2)	<0.000*	M0-M3-0.0005
	M3	17 (20.7)			M3-M6-0.0005
	M6	21 (25.6)			M3-M6-1.000
Fatigue	M0	74 (90.2)	80.133 (2)	<0.000*	M0-M3-<0.0005
	M3	26 (31.7)			M0-M6-<0.0005
	M6	24 (29.3)			M3-M6-1.000
Heart racing	M0	64 (75.6)	52.128 (2)	<0.000*	M0-M3-0.0005
	M3	27 (32.9)			M0-M3-0.0005
	M6	27(32.9)			M3-M6-1.000

Hard to catch breath	M0	51 (62.2)	42.667 (2)	<0.000*	M0-M3-<0.0005
	M3	19 (23.2)			M0-M6-<0.0005
	M6	19 (23.2)			M3-M6-1.000

Key-* is a significant p value.

Pairwise comparisons were performed using the post hoc Dunn's (1964) test with Bonferroni correction for multiple comparisons. There were statistically significant differences in the individual symptoms between M0 to M3 and M0 to M6. There were no significant differences seen between M3 to M6.

4.14 Symptom bothersomeness scores.

The bothersomeness of symptoms is reported on a scale of 0 (0= not at all) to 4 (4= extremely bothersome) at each time point. The data were not normally distributed, according to the Skewness and Kurtosis values and inspection of the QQ plots (examples of these are seen in Appendix 13). The Friedman test was used to assess differences over three time points.

There was a significant improvement in how bothersome symptoms were from M0 to M3 and M6. At M3 and M6 scores were very low. Pairwise comparisons were performed (SPSS V26), with a Bonferroni correction for multiple comparisons. There were significant differences between M0 to M3 and M0 to M6, but no significant differences between M3 to M6. Table 15 presents the results of the Friedman test.

Table 15 PPAQ Symptoms bothersomeness at 3 timepoints

Symptom	Timepoint	Median score (IQR)	Test statistic-χ^2 (df)	p value	Bonferroni's pairwise p value
Heart flutter	M0	2 (2)	59.168 (2)	<0.0005*	M0-M3 <0.0005
	M3	0 (1)			M0-M6 <0.0005
	M6	0 (1)			M3-M6 = 0.635
Heart skipping	M0	1 (2)	54.607 (2)	<0.0005*	M0-M3 <0.0005
	M3	0 (1)			M0-M6 <0.0005
	M6	0 (0)			M3-M6 = 0.814
Light-headed	M0	2 (1)	56.673 (2)	<0.0005*	M0-M3 <0.0005
	M3	0 (0)			M0-M6 <0.0005
	M6	0 (1)			M3-M6 = 1
Fatigue	M0	2 (3)	74.034 (2)	<0.0005*	M0-M3 <0.0005
	M3	0 (2)			M0-M6 <0.0005
	M6	0 (1)			M3-M6 = 1
Heart racing	M0	2 (3)	50.966 (2)	<0.0005*	M0-M3 <0.0005
	M3	0 (1)			M0-M6 <0.0005
	M6	0 (1)			M3-M6 = 1
Hard to catch breath	M0	1 (3)	39.455 (2)	<0.0005*	M0-M3 <0.0005
	M3	0 (0)			M0-M6 <0.0005
	M6	0 (0)			M3-M6 = 1

Key-* is a significant p value

4.15 Impact of arrhythmia symptoms

The PPAQ also asks how much the arrhythmia impacts on an individual's life. The ten questions related to daily activities are scored from 0 (not at all), to 4, (extremely). The data were not normally distributed, as demonstrated on the Skewness, Kurtosis and ShapiroWilk values, visual inspection of the QQ plots and histograms (examples of this are seen Appendix 14)

Therefore, non-parametric tests were applied. The Friedman tests show significant improvements from M0 to M3 and M0 to M6 in all activities, except the ability to drive a car. There were no significant changes between M3 to M6 in all activities of living. The following Table 16 shows the impact of AF on daily living activities.

Table 16 Impact of AF on daily living

Activity of living	**timepoint**	**Median score (IQR)**	**Test statistic- ⍰^{2} (df)**	**p value**	**Bonferroni's pairwise p value**
Mood	M0	1 (3)	46.909 (2)	<0.0005*	M0-M3 <0.0005
	M3	0 (1)			M0-M6 <0.0005
	M6	0 (1)			M3-M6 = 1
Ability to move	M0	1 (2)	63.731 (2)	<0.0005*	M0-M3 <0.0005
	M3	0 (0)			M0-M6 <0.0005
	M6	0 (0)			M3-M6 = 1
Sleep	M0	1(3)	60.467 (2)	<0.0005*	M0-M3 <0.0005
	M3	0 (0)			M0-M6 <0.0005
	M6	0 (0)			M3-M6 = 1
Work	M0	2 (2)	71.438 (2)	<0.0005*	M0-M3 <0.0005

	M3	0 (1)			M0-M6 <0.0005
	M6	0 (1)			M3-M6 = 1
Recreation	M0	2 (2)	85.602 (2)	<0.0005*	M0-M3 <0.0005
	M3	0 (0)			M0-M6 <0.0005
	M6	0 (0)			M3-M6 = 1
Enjoyment of life	M0	2 (2)	80.027 (2)	<0.0005*	M0-M3 <0.0005
	M3	0 (1)			M0-M6 <0.0005
	M6	0 (1)			M3-M6 = 1
Social activities	M0	1 (2)	53.396 (2)	<0.0005*	M0-M3 <0.0005
	M3	0 (0)			M0-M6 <0.0005
	M6	0 (0)			M3-M6 = 1
Ability to drive a car	M0	0 (1)	16.729 (2)	<0.0005*	M0-M3= 0.127
	M3	0 (0)			M0-M6= 0.362
	M6	0 (0)			M3-M6 = 1
Relationship with partner	M0	1(2)	61.137 (2)	<0.0005*	M0-M3 <0.0005*
	M3	0 (0)			M0-M6 <0.0005
	M6	0 (0)			M3-M6 = 1
Sexual relationship	M0	1 (3)	64.137 (2)	<0.0005*	M0-M3 <0.0005
	M3	0 (0)			M0-M6 <0.0005
	M6	0 (0)			M3-M6 = 0.764

Key-* is a significant p value

4.16 PPAQ Days missed from work and activities, due to AF

The final PPQ questions asks patients in the previous month how many days they took off work and how many days activity was reduced due to the impact of the arrhythmia.

In this cohort 54 out of the 82 participants worked, which represents 65.9% of the total sample. The other 28 participants (34.1%) were retired. Therefore, the analysis of days missed from work only included those that work.

4.17 PPAQ Days missed from work, due to AF.

The data were not normally distributed, as assessed by visual inspection of the QQ and box plots. Therefore, non-parametric tests were used to compare median scores at three time points. The Friedman test showed that there were no significant differences between the three timepoints and therefore pairwise comparisons were not performed because the overall test demonstrated no differences. The analysis of days missed from work are presented in Table 17.

Table 17 Days missed from work due to AF

Timepoint	**Median score (IQR)**	**Test statistic and pvalue**
M0	0 (0)	$\chi^2(2) = 3$
M3	0 (0)	P=0.223
M6	0 (0)	

4.18 PPAQ Days missed from activities due to AF.

The data were not normally distributed, as assessed by visual inspection of the QQ and box plots. Therefore, non-parametric tests were used to compare median scores at three time points. The Friedman test showed that there were significant differences between the three timepoints and pairwise comparisons. Pairwise comparisons, using a Bonferroni correction, revealed that there were significant differences in days cut down in activities from M0-M3 and M0-M6. There were no significant differences between M3-M6. The analysis of days cut down in activities is presented in Table 18.

Table 18 Days cut down from activities due to AF

Timepoint	**Median score (IQR)**	**Test statistic and pvalue**	**Bonferroni pairwise p-value**
M0	2.5 (12)	⍰(2)= 24.850	M0-M3-0.026
M3	0 (2)	P<0.0005*	M0-M6-0.001
M6	0 (0)		M3-M6-1

Key-* is a significant p value.

4.19 Predictors of QoL after ablation

The purpose for assessing predictors of quality of life after ablation is to determine the influences on QoL in this cohort. As BMI is central to this thesis, investigating this co-variate is an important part of the research question. However, there are other potential influences on patient reported outcomes after ablation, as seen in other research and guidelines (Hindricks *et al,.* 2020, Patak *et al,.* 2014). Such influences or predictors include age, gender, type of AF, left atrial volume index and rhythm control post ablation. The results from the two regression models, based on QoL-General Health and Vitality are presented below.

4.20 Model 1, QoL-General Health

A multiple regression model was run to explore predictors of General Health at six months post ablation, with age, gender, classification of AF, BMI at baseline, rhythm control at six months and baseline General Health included as potential predictors. There was linearity as assessed by partial regression plots and a plot of studentized results against the predicted values. The Durbin-Watson statistic of 1.617 demonstrated independence of residuals.

There was homoscedasticity, assessed by visual scrutinization of plotted studentized residuals against unstandardized predicted values. There was no evidence of multicollinearity, as assessed by tolerance values greater than 0.1. There were no studentized residuals greater than 3 standard deviations, no leverage values greater than 0.2, and no values for Cook's distance above 1. The assumption of normality was met, as assessed by a Q-Q Plot (see Appendix 11).

The overall model was significant, *F* (7,66)=.7.292, $p<.0005$, adj R^2 =.376 (see Appendix 9 for statistical significance of the model). General Health score at M0 was a significant predictor of General Health score at M6, such that higher General Health scores at baseline predicted higher General Health scores at six months, controlling for the other predictors in the model, B=0.663, (t=5.398) $p < 0.005$. Regression coefficients for the model are reported in table 19.

Table 19 Regression co-efficients for General Health at 6 months post ablation

General health Age	*B*	95% CI for *B*		*SE B*	t	p value
		LL	*UL*			
	.946	-1.274	3.166	1.112	.851	.398
Gender	-16.513	-67.909	34.883	25.742	-.064	.523
Class of AF	11.806	-37.521	61.133	24.706	.478	.634
BMI at baseline	-3.916	-9.269	1.438	2.681	-1.460	.149
LAVI	.309	-.829	1.447	.570	-.641	.590
Rhythm control at M6	-46.796	-110.132	16.541	31.723	-1.475	.145
Baseline GH	.663	.418	.908	.123	5.398	.0005*

Note: *B*=unstandardized regression coefficient; CI=confidence interval; *LL*=lower limit; *UL*=upper limit; *SE B*=standard error of the coefficient; t=test statistic, * is a significant p value

Key:

Age=years

Gender:1-male, 2=female

Class of AF, 1=PAF, 2=persitent

BMI-in kg/m^2

LAVI- in mls/m^2

4.21 Model 2, QoL-Vitality

A multiple regression was run to predict Vitality at six months post ablation, including age, left atrial volume index, classification of AF BMI at baseline, gender, baseline Vitality and rhythm control at six months as potential predictors. There was linearity as assessed by partial regression plots and a plot of studentized results against the predicted values. The Durbin-Watson statistic of 1.953 demonstrated independence of residuals.

There was homoscedasticity, assessed by visual scrutinization of plotted studentized residuals against unstandardized predicted values. There was no evidence of multicollinearity, as assessed by tolerance values greater than 0.1. There were no studentized residuals greater than 3 standard deviations, no leverage values greater than 0.2, and values for Cook's distance above 1. The assumption of normality was met, as assessed by a Q-Q Plot.

The overall model was significant, *F* (7,66)= 5.758, $p<0.0005$, adj R^2 =.313

Rhythm control at M6 was a significant predictor of Vitality at M6, controlling for the other predictors in the model, B= −111.543, t(−169.445), $p<0.005$, such that achieving rhythm control was associated with increased Vitality scores controlling for other factors in the model. In addition, baseline Vitality scores significantly predicted increased Vitality scores at M6, B=.367, t (2.637), $p<0.005$. However, the width of the 95% confidence interval for the estimate indicates that this finding needs to be interpreted with some caution. Whilst it was observed that an increase in BMI was associated with lower Vitality scores, this was not significant.   Regression coefficients for the model are reported in Table 20.

Table 20 Regression coefficients for Vitality at 6 months post ablation

Vitality	***B***	**95% CI for *B***		***SE B***	**T**	***p value***
		LL	***UL***			
Age	.366	-1.562	2.295	.966	.379	.706
Gender	13.662	-33.213	60.458	23.458	-33.213	.563
Class of AF	-2.746	-48.310	42.817	22.821	-48.310	.905
BMI at M0	-4.510	-9.527	.507	2.513	-9.527	.077
LAVI	.375	-.634	1.385	.506	.742	.461
Rhythm control at M6	-111.543	-169.445	-53.640	.29.001	-169.445	.0005*
Vitality score at M0	.367	.089	.645	.139	2.637	.010

Note: Model= “enter” method is SPSS Statistics, *B*=unstandardized regression coefficient; CI=confidence interval; *LL*=lower limit; *UL*=upper limit; *SE B*=standard error of the coefficient; t=test statistic, * is a significant p value.

Key:

Age- in years

Gender-1=male, 2=female

Class of AF-1=PAF, 2=persistent

BMI- in kg/m2

LAVI- in mls/m^2

4.22 Summary

In this cohort of patients with raised BMI, undergoing AF ablation, a total of 82 individuals completed the baseline, three month and six-month questionnaires. Quality of life scores were calculated at three time points, using the SF-36 questionnaire. All scores improved significantly after ablation, except for pain at M3-M6 when pairwise comparisons were made.

Symptom scores were measured and analysed in several ways, using the Patient Perception Arrhythmia Questionnaire. Firstly, the frequency and severity scores demonstrated significant improvements after ablation. The most frequently reported symptoms were analysed. Significant improvements were seen after ablation. These symptoms are linked to how bothersome each symptom is to the individual. Although the median and mean bothersome scores at baseline were only mild-moderately bothersome, the scores improved significantly after ablation. The impact of arrhythmia scores, which relate to how much the AF affects an individual's lifestyle, all significantly improved after ablation.

The final part of the PPQ asks patients about days off work and days where activity is cut down. The mean and median scores for days off work were low before ablation and did not change afterwards. Regarding activity reduction, there was a significant improvement after ablation.

Multiple linear regression analysis was undertaken in 74 of the participants, to explore predictors of QoL outcomes after ablation (General Health and Vitality domains). The reason for the n=74 is because LAVI was only available in 74 of the participants. Independent variables included age, left atrial volume index, classification of AF, BMI at baseline, gender, baseline Vitality/General Health and rhythm control at six months. Rhythm control at six months control predicted improved Vitality scores at 6 months post ablation and baseline General Health scores predicted improved General Health after ablation. Despite BMI being a specific interest in the study, it did not emerge as a significant predictor.

The next chapter presents the interview findings from the study, whereby 20 participants were interviewed, using a semi-structured guide. The chapter presents analysis of the interviews and how the themes developed, to understand the experiences of those with an elevated BMI undergoing AF ablation

CHAPTER FIVE: Interview findings

5.0 Introduction

This chapter presents the findings from the study interview data. One of the aims of the study was to explore the experiences of patients with AF who have an elevated BMI and undergo ablation. Framework analysis (Gale *et al.*, 2013) was used to analyse the qualitative data. The participant details and socio-demographic characteristics are presented, followed by the findings from the framework analysis. These findings describe the experiences of participants within this study.

5.1 Participants

A total of 20 participants were interviewed at six-months post ablation. Their characteristics are presented in the next section. Participants are identified by their study by their study number.

5.2 Participant characteristics

A total of 24 participants were invited to be interviewed. Four patients declined to be interviewed, citing personal reasons. The 20 participants that were interviewed consisted of 15 men and 6 women, with an age range of 34-82 years and BMI range of 25.1-38.2 kg/m$^{2.}$ Details of participants' demographics are shown in Table 21.

Table 21 Participant characteristics

Interview number	Study number	Sex	Ethnicity	Age	Classification of AF	BMI at baseline
1	**4**	F	WB	52	PAF	38.2
2	**8**	M	WB	61	PERS	33.3
3	**7**	M	WB	39	PERS	26
4	**10**	M	WB	64	PERS	25.5
5	**13**	F	WB	53	PAF	36.1
6	**14**	M	WB	57	PERS	30.3
7	**15**	M	WB	76	PAF	28.7
8	**19**	M	WB	69	PAF	36.1
9	**1**	M	WB	60	PAF	34
10	**25**	M	WB	54	LSPERS	25.6
11	**9**	M	WB	36	PAF	29.7
12	**12**	M	WB	57	PERS	30.3
13	**20**	F	WB	50	PAF	32.3
14	**18**	F	WB	67	PERS	29.5
15	**27**	M	WB	82	PERS	28.2
16	**22**	M	WB	73	PERS	25.1
17	**24**	M	WB	61	LSPERS	35
18	**26**	M	WB	40	PAF	32.3
19	**29**	M	WB	34	PAF	33.1
20	**37**	F	WB	57	PERS	36.4

Key: Sex-m=male, f=female, classification of AF-PAF=paroxysmal AF, PERs=persistent AF, LSPERS=long standing persistent AF, ethnicity=WB=white British

5.3 Interviews

The interviews were guided by a semi-structured topic guide, and were exploring explored? the diagnosis of AF, the ablation procedure and the lifestyle factors which influenced an individual's life and experiences. Interviews ranged from 12 to 30 minutes in duration, the majority of which were over 20 minutes.

5.4 Findings

Four main themes emerged, describing? explaining the experiences of patients with an elevated BMI and who were undergoing AF ablation:

- Personal well-being related to AF.
- Care and treatments
- Interplay of lifestyle and AF
- Living with AF in a pandemic

Each theme consisted of sub-themes, except for living with AF in a pandemic. Participants tended to discuss their experiences sequentially - from being diagnosed with AF, undergoing treatments including ablation, and the relevant lifestyle factors including weight and exercise. Table 22 displays the themes and sub-themes.

Table 22 Themes and sub-themes

Theme 1: Personal well-being related to AF
● emotional impact ● physical effects
Theme 2: Care & treatments
● treatment experiences ● Interactions with healthcare staff
Theme 3: Interplay of lifestyle & AF
● experiences of exercise ● future desires & goals

Theme 4

Living with AF in a pandemic

5.4.0 Theme 1 -Personal well-being related to AF

The interview was commenced by asking the participants about their AF journey. The participants in the main started the interviews by discussing when they were first diagnosed with AF. For some this was associated with an emergency hospital attendance. For others the symptoms were insidious, and it took some time to receive a formal diagnosis, requiring an ECG to be recorded at the time of symptoms to capture any arrhythmia that was present. Participants addressed personal well-being related to AF through an association with physical impact and emotional effects, as described in the sub-themes below.

5.4.1 Emotional impact

The majority of participants described some form of emotional impact from having AF, whether that was related to the physical symptoms, or understanding the long-term implications of such a condition. The emotional impact initially related to the challenge of reaching a diagnosis and seeking answers. For example:

"nobody actually mentioned that I was in AF….it wasn't highlighted to me, but I lost my confidence"

Participant number 7, 39-year-old male.

Some participants described visiting and revisiting healthcare professionals, over a period of time. For some this may be months or even years. Often this was because their symptoms had abated by the time that they were able to receive a clinical appointment. Such challenges led to uncertainty and frustrations.

Once the initial diagnosis of AF was made, whether acutely or not, the resulting emotional impact was expressed by some as fear and worry but also sometimes manifest as changes in mood and personality. Several patients described the anxiety and the negative impact of having AF. For some, it severely influenced their outlook on life and their quality of life. Fear and anxiety were expressed differently in these interviews. Although both are indications of emotional distress, fear is a more biological reaction and anxiety is an emotional anticipation and worry of what might happen.

The youngest patient in the study had symptoms for some years before being diagnosed formally with AF. He found the episodes of symptoms frightening, but each time he reported to a medical professional, the AF had subsided. His description of the AF episodes was aligned with emotional symptoms and was informed, more than once, that the episodes were psychological and not physical.

"I was getting told they thought it was panic attacks".

Participant 29, 34-year-old male.

This resulted in him feeling anxious and fearful with a degree of uncertainty.

For others, the impact of AF emotionally was pervasive, particularly on their sense of personal identity and inner self. The following patient described the emotional effect of AF on her character and sense of self. These feelings initially led to profound anxiety and also lowered her mood.

"I lost a lot of my personality. A lot of my get up and go and I just thought I can't live like this anymore. Because, you know, I felt no disrespect to 70-year-olds, but I felt 20 years older than I was".

Participant 13, 53-year-old female.

The emotional impact of the physical symptoms led to what she felt was a loss of some of her identity and vitality, as a fit and healthy 53-year-old. A similar feeling was expressed by another female in her 50's, who simply noted that having AF, "*took away me*" Participant 4, 52-year-old female.

This feeling of loss of oneself is described by another patient, who had previously maintained an athletic level of physical fitness. AF resulted in him feeling unlike his previous self.

"*always sort of on the edge…..it's as if I'm outside myself*"

Participant 22, 73-year-old male.

Not only did AF interfere with emotional well-being in this cohort, some had distinct anxiety and other psychological conditions that affected their overall quality of life. One of the participants had a challenging time, with several acute and highly symptomatic episodes. A particular healthcare professional suggested that she may have some anxiety and seeking psychological help may help in dealing with the diagnosis of AF. She decided to seek professional advice for her feelings around her diagnosis and described the way that the therapist helped her legitimise her feelings of anxiety.

"So I actually spoke to a counsellor who basically said to me, if you were not suffering from anxiety given the experience you've had, I would think there was something wrong with you".

Participant 20, 50-year-old female.

The feelings of anxiety were commonly discussed in the interviews and in the case of the following participant, the presentation of AF was associated with a change in emotional well-being. He described his feelings, even when in a normal heart rhythm.

"felt absolutely dreadful…and extremely anxious….I was being treated for depression as well"

Participant 19, 69-year-old female.

Several patients, particularly those that had acute episodes of AF, expressed fear. The fear and worry were predominantly a fear of dying, particularly in the case of patients who had yet to receive a diagnosis. Several patients expressed fear of having a heart attack when in AF, or anticipated a heart attack in the future. Many of the participants mentioned heart attack and were familiar with the concept of this medical emergency, but not so familiar with AF, particularly when they were first diagnosed. Fear is often discussed in the context of uncertainty. This could mean uncertainty of mortality, of pain, of feeling unwell, collapse and of treatments that are all part of an acute cardiac presentation. The following participant displayed a similar degree of fear after the ablation, when he presented to his local emergency department with severe chest pain. The pain woke him in the night and was a frightening experience.

"I woke up in the night in severe pain…..I almost called an ambulance….but my wife took me to hospital…. I thought I was having a heart attack"

Participant 9, 36-year-old male.

One patient, when he presented acutely described the fear of dying

"I literally said to my wife as I sat down, I think I'm going to die, that's how bad I felt……….and obviously she was very upset, and I honestly thought I was going to die……..".

Participant 1, 60-year-old male.

The fear and worry of dying also affected his wife who was witnessing the episode in hospital

Fear and worry wasn't just related to AF episodes, but the anticipatory fear that comes with the worry of developing AF again after a treatment, such as medications, cardioversion, or ablation.

This participant described how she felt after her first cardioversion.

"a little bit scared that it was all going to happen again. I was fine, I'm fine, but it was always in the back of my mind"

Participant 4, 52-year-old female.

She describes the troubling worry that comes with the anticipation of AF recurrence. Despite undergoing a rhythm control procedure, the worry for her was the prospect of the AF returning.

Another patient described not only the emotional effect of AF, but the impact on his overall quality of life. Once diagnosed, he felt his life had changed dramatically. Every time he had another episode of AF, his mood was affected. He described the restrictions on his daily life, which had hitherto been full and varied, with lots of travel. The effect of ongoing AF episodes profoundly affected him. He gave a candid account of how he felt during one particularly troublesome episode whilst on holiday.

"But I just thought, you know, it brought me to tears. I was, like, I can't go anywhere, I can't do anything. I'm terrified to get on a plane".

He concluded the interview with the following reflections.

"I wouldn't wish it on my worst enemy. It's really horrendous. So, 'cause it's a condition that feels like it's gonna kill you, acts like it's gonna kill you, but doesn't".

Participant 26, 40-year-old male.

For several patients, it took time to establish the diagnosis of AF. The delays to treatment meant that one participant (participant 8) couldn't explain the feelings of being "*down*". Once the diagnosis of AF was made, he reflected and was able to understand why he had felt generally unwell and low in mood. This is despite seeking answers from several healthcare professionals. He had been feeling unwell and low in mood for some time and had been seeking answers to why he felt this way.

" that was the first time really that I'd had any sort of diagnosis of why I had been feeling pretty low"

Participant 8, 61-year-old male.

It was on reflection that his general decline in mood was related and explained by a diagnosis of AF.

The following participant (25) noted an emotional, not just physical benefit from being in sinus rhythm.

"*I had an overall calmness; I had more clarity of thought*"

Conversely, when the AF recurred, he noted the feeling of emotional stability had disappeared.

"*the feeling of calmness had gone*".

Participant 25, 54-year-old male.

Despite the discussions on negative emotional impact from AF, there was one participant who did not suffer emotionally from AF episodes. He had great insight into his other health conditions and suggested that AF had not affected him emotionally, not caused him any particular fear or concern. He attributed this to his overall character saying

"I'm not a worrier".

Participant 7, 39-year-old male.

Another participant felt that AF was a nuisance , rather than a major emotional strain. He described frustration at the impact of the symptoms but was not overly concerned about the effects of the AF.

"*It didn't feel life-threatening*".

Participant 10, 54-year-old male.

Participants 7 and 10 were the only two participants who did not appear to be particularly affected by anxiety, low mood or worry from the AF diagnosis and symptoms.

There were four other participants that did not mention any particular emotional impact in regard to AF or the treatments, although they were not explicitly asked on this point. As shown in this sub-theme there were a number of emotions related to AF, which ranged from fear, anxiety and worry to stoicism and acceptance. Even in normal rhythm some of the participants' suffered emotionally in the anticipation of the AF returning or changes in mood.

5.4.2 Physical impact

The most common physical impacts of AF were typically symptoms of breathlessness, fatigue, and palpitations. However, some participants mentioned a variety of other physical effects, such as dizziness, episodes of collapse and feeling generally unwell. Some participants didn't describe specific symptoms, but described a general feeling of malaise, or that generally they felt a reduction in their quality of life.

The following example represents a typical participant experience of the physical symptoms associated with AF.

" I suddenly had an incident one evening where I had rapid palpitations…irregular..heartbeat…sweating..the full works, felt dreadful"

Participant number 19, 69-year-old male.
A similar description was given by a younger participant who developed sudden onset symptoms related to an episode of AF, which he had never experienced previously.

"my chest started pounding and my heart started to race quite fast…it felt like it was going out of sync"

Participant number 29, 34-year-old male.

Individuals described how difficult it was to make meanings or sense of symptoms when no diagnosis had been made. One participant had no idea that his symptoms and general wellbeing were related to AF. They felt without prior knowledge of AF as a cardiac condition, it is difficult to understand and explain the reasons for the symptoms they were experiencing.
One participant spoke about the time he was first diagnosed.

"I didn't actually know I had it until I went to a clinic, because I've got a bad knee and I'm having a knee replacement".

This participant was brief in his discussions and didn't elaborate on this point, but mentioned the point at which he was informed of the ECG findings.

His overall reduced well-being was due to the AF and not simply *"getting older"*

Participant number 24, 61-year-old male.

A similar association was described by a female participant in her 50's, She also described the onset of AF symptoms.

"I'd noticed on exercise I would have a strange fluttering sensation in my chest. And I wasn't able to exercise as hard as I used to without feeling very tired, and a bit unwell sometimes, a bit dizzy. Um, but I thought I was just unfit. I thought it was age related."

Participant 20, 50-year-old female.

Feelings of heartbeat awareness were a common finding in this cohort. Participants described palpitations, or awareness of their heartbeat, but often used their own language to depict the feelings and sensations. The following participant, who had other complex cardiac issues was quite clear that his AF related symptoms were different from those other symptoms he had experienced for many years.

"my heart would go into strange rhythms"

In addition to the palpitations, he noted reduction in vitality and effort tolerance, explaining,

"I've got no energy"

Overall, his quality of life was negatively impacted, particularly in terms of physical functioning since AF first occurred. He noted that AF:

"made me feel pretty crap"

Participant 14, 57-year-old male.

The lack of vitality impacted on individual's lives, as illustrated in the following quote:

"it was more debilitating in lots of ways……I used to be really sporty, but surely overtime..I realised I couldn't do as much as I did before..couldn't do it as often…couldn't go to high intensity..and struggled with sleep"

Participant number 13, 53-year-old female.

In addition to the typical physical symptoms and the impact that ensued, other symptoms were discussed, as seen in the following participant:.

"I used to get the shakes a lot..sort of get dizzy….just very weird sensations"

Participant 12, 57-year-old male.

Another active and otherwise healthy participant, felt unwell whilst on holiday and assuming he had a viral illness, visited a local doctor. illness. He was not used to being unwell and had previously lived an active lifestyle, with the challenge for him being the acceptance of a new cardiac diagnosis.

"I couldn't walk up a flight of stairs…. ….well I could, but I would get to the top and have to sit down for five minutes….I felt fairly…very weary and tired without any energy "

Participant number 15, 76-year-old male.
A similar scenario was discussed by a participant who maintained a high level of physical fitness by attending spinning classes three times per week.

"I was having to stop and get my breath back"

Participant 18, 67-year-old female.

It was her inability to function at her usual physical level that made her seek a review with her GP, who diagnosed persistent AF, commenced treatment, and referred her to cardiology.

The symptoms of breathlessness are not only common but may be debilitating for some. One participant, an 82-year-old male, who works full-time in a demanding job, noted a deterioration in his quality of life every time the AF recurred.

"I can track back from the breathlessness side of it I think I've had AF for certainly more than 10 years…….when I used to go walking or even when playing golf….by the time I walked up the fairway I was quite breathless by the time I got to the green……".

Participant 27, 82-year-old male.

Despite his age, he normally played golf regularly and was active in his job, which meant the physical impact of AF was somewhat profound. Once the AF diagnosis was confirmed, his physical symptoms restricted his ability to play golf and go for walks, which had been an important part of his enjoyment of life.

Another younger male participant appeared to have insight into the diagnosis but had never had an ECG during his typical symptoms. When he presented to his GP, he described symptoms, such as chest, shoulder, and arm pains in addition to the typical AF symptoms of fatigue and dyspnoea. He was then sent to the Emergency Department in an ambulance.

"Despite me, despite me saying constantly I haven't had a heart attack. I haven't come in today because I suddenly have the key symptoms, and I'm very concerned".

Participant 25, 54-year-old male.

Participant 25 understood that something wasn't quite right and was confident in the knowledge that he wasn't having a heart attack. His challenge in making sense of his symptoms and obtaining the diagnosis was to gain clinical proof of why he was feeling the way he was. Although he visited his local emergency department, it wasn't because he felt extremely unwell, but because he wanted to have an ECG during symptoms in order to reach a diagnosis. He found the process frustrating because staff didn't understand his reason for attendance and thought he was acutely unwell. He found this a frustrating experience, because he knew something was wrong, but didn't know what the clinical issue was at that time.

The AF symptoms were often associated with advice-seeking and presentation to a clinician in seeking answers. The following participant, with paroxysmal AF described the first time she experienced symptoms:

"I couldn't breathe.. um … I couldn't walk".

Participant number 4, 52-year-old female

These symptoms were unusual for her, particularly as she was used to being active in her work and home life. The impact therein meant that her job became more challenging, physically and she stopped her usual form of exercise and activity.

Even in individuals who had other cardiac conditions, the physical symptoms felt very unpleasant. The following participant, who had an implantable cardioverter defibrillator

(ICD) and was used to previous cardiac symptoms, had never experienced AF previously.

"I could feel the… everything beating it was almost like everything was coming out of your chest and very noticeable erm and even though I didn't necessarily say feel breathless as such.. I felt like I had to take the occasional deep breath almost try and sort of reset things and but erm it just sort of felt like everything was closing in inside. it's quite hard to describe really".

Participant number 7, 39-year-old male.

The limitation in physical activity was widely mentioned in the interviews. It appears that often it is the switch from being in normal rhythm, to suddenly being aware of a cluster of very troublesome symptoms was especially difficult. The following participant describes her first episode of AF.

"I felt very, very unwell…I couldn't even walk half a dozen steps to the front door without having to stop and feel dizzy and nauseous and, and that sort of thing".

Participant number 37, 57-year-old female.

An example of the challenges that occur acutely in the diagnosis of AF, may be seen in the words of the following participant. He had no previous health issues, suddenly developed AF whilst working and managed to return home, before seeking emergency help.

"It's quite horrendous, really…………I was all erm …sweaty and erm and they told me, what we call tachycardic, which I learned at the time. I was losing vision on my peripheral sight. I felt really, really ill, yeah, my wife's going to phone an ambulance".

Participant 1, 60-year-old male.

Clearly, he was very symptomatic. He described the experience as "*horrendous*" and the way he felt resulted in an ambulance bringing him to hospital. The shock and distress at this time was evident from the interview. This participant found the whole experience extremely difficult. He was not aware of AF and had no prior knowledge of what such a diagnosis meant.

On occasions, the participant's used analogies to describe the feelings that came from an AF episode. This patient used a powerful simile to describe her AF symptoms.

"About the six-week post diagnosis point I started having sudden attacks of very fast AF, which was like a firecracker being thrown into my chest".

Participant 20, 50-year-old female.

A different description was mentioned by one participant, who suffered hugely both physically and emotionally during his AF symptoms.

"I could only describe as a cement mixer in my chest".

Participant 26, 40-year-old-male.

The descriptions of physical symptoms and reduced quality of life are the ways in which participants have articulated how the AF made them feel. However, beneath this lies the impact of such symptoms on each person. The words used in the interviews imply how participants have felt in these scenarios. Such descriptions infer the unpleasant corporal sensations that occur in AF. A feeling of a "firecracker" implies heat, drama, and a loud noise. The description by Participant 26, of a "cement mixer" evokes feelings of disorder and churning in the chest. These vivid descriptions come from individuals who were usually fit and healthy. The unexpected and dramatic nature of the physical impact of AF is widely articulated.

5.4.3 Theme 2- Care and management of AF

The second theme of care and management of AF incorporates the sub-themes of AF treatments and healthcare interactions.

Participants frequently discussed the care and management they had received in the context of receiving an AF diagnosis. Participants discussed prior treatments, such as antiarrhythmic medications and the risk and benefits therein, and many reported unwanted side-effects from these potent medications. Aside from cardioversion, which many mentioned, ablation featured highly within the interviews. The interview schedule asked specifically about their experiences of the ablation, which may explain why it featured highly. This portion of the interview included questioning on the education and information that was provided. Some discussed the interactions with staff that included the shared decision-making process that led to undergoing an ablation. Generally, most of the interactions discussed tended to be with the specialist teams, either cardiology or the arrhythmia team.

5.4.4 Treatment experiences

This sub-theme represents a large part of the dialogue in the interviews. All of the participants had a long journey to reach the point of ablation, with many treatments and discussions along the way. All of them appeared to be well-informed about the various treatments and options. Several of the participants discussed the benefit of being in sinus rhythm, whether by drugs, or more commonly by cardioversion.

A participant who had received swift care from her GP and was referred to the specialist arrhythmia team in a timely manner, despite the pandemic, commented on how she benefitted from sinus rhythm and felt, *'immediately better after cardioversion'*

Participant 18, 67-year-old female.

It was common for the participants to undergo a number of cardioversions or medication changes during the months and years leading up to ablation. One participant benefitted from being in sinus rhythm to such an extent that she was prescribed a short course of Amiodarone, the potent anti-arrhythmic used to maintain sinus rhythm post cardioversion.

"I had one cardioversion, that kept me in normal rhythm for about 14 months….then I had another cardioversion, which didn't last for very long….and then I had another cardioversion and that's when they put me on Amiodarone"

"As soon as I started taking the drug…it really made a difference to my quality of life….whilst it's not recommended you stay on it for very long

Participant number 37, 57-year-old female.
This participant spoke with clarity about the treatment process, which spanned a few years. She described the pathway to ablation, understanding the rationale for the other treatments she had undergone.

There were several examples of positive treatment experiences, which were echoed by a number of the participants. The following participant had telephone consultations, due to the pandemic and was highly satisfied with the information he received and the discussions that ensued.

"One of the nurses…answered all my questions and had a really long..detailed appointment on the phone"

Participant 9, 36-year-old male.

The benefit of access to the arrhythmia nurses was echoed by another participant, who understood the main rationale for ablation and long-term rhythm control.

"lets get my heart back on track and get a better quality of life"

"the arrhythmia nurse..went into a lot of detail"

"I was very, very prepared for what was going to happen".

Participant 12, 57-year-old male

Treatment experiences also included discussions around the decision to opt for ablation. Not everyone found this decision an easy one. The following participant's experience was positive in regard to rhythm control. He felt much better in sinus rhythm and was having repeated cardioversions but did not maintain sinus rhythm for long enough to feel any major benefit. He was well informed of the risk and benefits of ablation but did not relish the thought of the invasive nature of the procedure. He discussed the following:

"I was a bit reluctant at first because I didn't like the sound of the procedure".

Participant number 10, 64-year-old male.

On the other hand, another participant in a similar clinical situation had a positive experience in making the decision for ablation, which he found more straightforward and reassured himself with trust in the healthcare team:

"I'd got people doing the procedure who were really, really experienced".

But he was less aware of the so-called *blanking period*, whereby AF recurrence is common in the three months post ablation.

"I hadn't realised that I would go back into AF".

Participant 22, 73-year-old male.

In a similar vein, one participant described his experience of follow-up care, which he felt was lacking in guidance. His desire was to receive more information on exercise and longterm follow-up appointments.

I could've done with a bit more…setting an expectation".

Participant number 25, 54-year-old male.

The access to ablation was discussed as problematic by one participant, who spoke with emotion about her experience. She had been seen by a specialist team in her local hospital, sought advice online and continued to ask for help, as the medications seemed to make matters worse. There seemed to be difficulties in communicating with the specialist team, with barriers to ablation treatment and no clear explanations why this was the case. She felt that there was prejudice against her as an individual with a raised BMI and previous mental health impairment. Additional ways of seeking help and advice was via patient forums on social media. This resulted in a private consultation, with referral to the specialist team at the hospital that performs ablations. This was a positive experience, in reaching shared decisions about the ablation. She described her challenges in opting for ablation.

"I felt that there has been prejudice.. which has created barriers that shouldn't be there".

Participant number 20, 50-year-old female.

Reflecting on the experience her desire was to have been referred sooner to the specialist team and consider ablation at an earlier point, particularly as the AF episodes were having a hugely negative impact on her quality of life.

Access to the ablation referral pathway was variable within this cohort, with some participants feeling satisfied in the journey to ablation, whereas another felt a delay in seeking specialist help and advice.

"I would've wanted it sooner".

Participant number 9, 36-year-old male.

Treatment experiences also included unexpected findings on the day of the ablation procedure. In particular, the environment of the cardiac catheter laboratory led to some anxiety and worry, as explained by the following participant.

"It's quite daunting…there's about 7 or 8 people in there and there's all these flashing machines and that".

Participant number 1, 60-year-old male.

This daunting feeling was further described by another participant:

"When I went into theatre I was surrounded by, like, 15 people….there was all monitor screens..I felt slightly intimidated"

Participant number 4, 52-year-old female.

The recovery from ablation was described by many of the participants. In an otherwise active individual, the following participant mentioned how she spent two weeks in bed recovering from the procedure. She was drained of all energy and was not expecting to feel so dreadful. She described the process as feeling as though she had been,

"hit by a bus"

Participant number 4, 52-year-old female.

A similar use of language was used by another participant:

I had a bruise from the knee up to the groin" "I felt pretty tired….you feel a bit..like you've been hit by a truck"

Participant number 19, 69-year-old male.
One of the most common complications resulting from ablation is groin site bruising and was one of the main issues discussed by participants as part of the ablation recovery.

"the bruising was pretty extensive"

Participant number 8, 61-year-old male.

It is not simply the visual sight of the bruising, which may be extensive and unsightly, but the feeling of being bruised, which hindered recovery.

Vascular complications of bruising and haematoma is something that all patients are informed of before the procedure. Although none of the participants mentioned that these aftereffects were a great surprise, those that were affected in this way felt physically drained as a result. For some, recovery took longer than expected. Complications were not commonly discussed, but one participant suffered a serious complication, which did not result in any long-term issues, but required various follow-up visits.

"they said I had a problem with my diaphragm on the right side collapsed".

Despite the nature of the complication, his overall perception of the procedure was positive, and he didn't appear to have any continuing recovery problems.

Participant number 24, 62-year-old male.

Overall participants spoke eloquently about their treatments for AF, especially ablation, in using appropriate cardiac terminology. Their experiences were generally positive about treatment outcomes, but there were difficulties for some in expectations of treatment or understanding procedural information. Recovery from ablation was unexpectedly traumatic for a few participants, especially as the majority had been otherwise fit and well before the procedure. Generally, it was the maintenance of sinus rhythm that resulted in an increased quality of life in these participants.

5.4.5 Healthcare interactions

Interactions were generally positive, with gratitude shown to the NHS staff.

"I have been extremely impressed with the ..clinical staff"

Participant number 25, 54-year-old male.

Being cared for was mentioned and feeling safe was important:

"I felt very protected and very well cared for"

Participant number 8, 61-year-old male.

Another important component of the ongoing care of these patients is the ability to have a point of access. Although this has always been the case for patients with complex cardiac conditions, it was highlighted during the pandemic, as access to primary care and urgent hospital care was both difficult and challenging.

The following participant required advice after the ablation and his fears were allayed by being able to directly contact the arrhythmia nurse team via telephone.

"being able to contact somebody if there is a problem…which was really great".

Participant number 12, 36-year-old male.

The support delivered by the arrhythmia team was mentioned by another participant, who had found dealing with his AF particularly difficult.

"it was as a result of the support from the cardiac team, who I found were very sympathetic and can't praise enough… for all the support I have had from them…so the AF experience is not so bad"

Participant number 19, 69-year-old male.

Participants recalled conversations with the healthcare staff that they found emotionally rewarding. The following participant felt that AF was extremely challenging to deal with, which affected his in his overall quality of life. He suffered from fear and worry throughout his AF episodes and subsequent treatments. When greeted by the Doctor performing the ablation, he recalled, with emotion in his voice, the Doctor's words:

"*I'll give you your life back today".*

Whilst this kind of language could be perceived as arrogant and superior, this participant felt positive and grateful for the prospect of his life returning to normal. It could be a demonstration of the existence of biomedical hegemony that may exist, and which may make patients feel inferior to the medical profession. Despite this, the participants overall experience of care was very positive, and he placed faith and trust in the healthcare team that performed his procedure.

He reflected on the procedure, which he found stressful in terms of recovery, but he volunteered positive feedback on the ward staff.

"the nurses were absolutely fantastic"

Participant number 1 60-year-old male.

Although the majority of healthcare interactions that were mentioned were favourable, there were indications of more negative nature. The participant that had faced barriers to ablation treatment discussed her sadness and frustration when asking to be referred to an ablation centre.

"I asked for alternative medical interventions and was told there weren't any…..

Participant 20, 50-year-old female.

She hoped that other treatments were available for her troublesome AF, because the impact of the symptoms had completely altered her lifestyle. Eventually she was referred to the specialist arrhythmia team and listed for ablation. She required guidance after the ablation, with ongoing episodes of AF, resulting in a redo procedure. Despite a stormy postprocedure time, involving remote prescribing and several telephone appointments, her overall interactions were highly favourable:

"my experience..has been exceptional…the nurses have been amazing".

Participant number 20, 50-year-old female.

The following participant was happy to openly discuss his overall experiences of having AF, the ablation, and his lifestyle factors. He spoke candidly and with balance about the events surrounding the ablation procedure. His procedural recovery was turbulent and when he presented to the emergency department with a rare gastric complication, he was frustrated with the emergency care team's understanding of the procedure, but also the unavailability of the consultant who performed the ablation.

"I was angry with him".

Participant number 26, 40-year-old male.

His expectation and understanding was that as he had presented acutely with a problem, the cardiologist should have been available to review him and provide guidance to the rest of the team. This issue added to his overall difficulties in recovering physically and emotionally from the ablation procedure.

The interviews demonstrated that interactions with healthcare staff were an important component of communication with this cohort of participants. The experiences highlight the need for clear and accurate communication, but also for individuals to feel safe and cared for.

5.4.6 Theme 3- Interplay between lifestyle and AF

Many of the participants were not aware of the link between lifestyle factors, such as weight and exercise, which meant that some were surprised when asked to discuss it. Those that were aware of the interplay between AF and BMI mentioned consultations with the arrhythmia nurse team about weight and AF in particular. Such discussions are a key part of the role of the arrhythmia nurses in the clinic environment. Not all participants undergoing ablation had contact with an arrhythmia nurse. This theme has two sub-themes of knowledge and understanding of the interplay between lifestyle and AF and the barriers and facilitators to future goals. Participants tended to speak of the matter contained in these sub themes towards the end of the interview and in the context of moving forward after the ablation.

5.4.7 Knowledge & understanding of interplay between lifestyle & AF

Knowledge and understanding of the interplay between lifestyle and AF were generally lacking in this cohort. Whilst a few participants knew about general risks of being overweight or obese, most were not aware of the explicit link between BMI and AF. The majority spoke of their desires to lose some weight and to increase physical activity, which may be seen in the following quote.

"Well hopefully moving forward, I'll lose weight and I will be fitter" Participant number 4, 53-year-old female.

This group of participants were all physically active and did not lead sedentary lives before AF impacted on their lives. In terms of lifestyle most of the discussions focused on weight and exercise, rather than any other cardiovascular risk factors, such as smoking.

The ensuing narrative describes the issues discussed in the context of the sub theme.

The following participant was previously active in the form of running and cycling. Various health issues, unrelated to AF, hindered a return to full cardiovascular exercise. Although he acknowledges that he has become more active since the ablation. This was particularly noticeable when he attended a music festival, which he described as most enjoyable. His wife noted how energetic he was compared to before the ablation.

"I was dancing almost non-stop for 3 hours"

Participant number 7 39-year-old male.

Although he wasn't explicitly aware of the interplay between AF and BMI, he felt that intuitively he knew that a raised BMI is not desirable in the context of ablation.

"I knew being a heavier weight gives you less chance of success".

Participant number 7 39-year-old male.

In a similar vein, a female participant had not been aware of the link between AF and a raised BMI but has educated herself online and as a result made changes to her lifestyle. Weight loss has not been easy or straightforward, but there was a strong focus to improve and lose another 2 stone. She described her progress:

"I've lost nearly 5 stones…I've completed a nutrition course…I am now aware that there is a big link between obesity and AF".

Participant number 20, 50-year-old female.

This change in behaviour was brought about by a combination of the dramatic impact of AF on her quality of life, the realisation that the ablation should result in long term rhythm control and the need for patient involvement in the clinical treatments. She remained motivated even when the AF recurred and she required a second ablation, because she understood the contribution that having a raised BMI was having on her health.

One of the participants described a healthy diet despite having a raised BMI. He admitted he had not made a concerted attempt to lose weight, but was keen on exercise and was physically active, walking his dogs and cycling. He acknowledged that his BMI has a direct relationship to mood but wasn't aware of the link between AF and BMI.

"I have always been very active and very fit…..I'd eat healthily and wouldn't drink… and all types of things that never made any significant difference to the way I felt….but since I can't do any of those things I think it's a direct relationship between how heavy I am and how bad I feel"

Participant number 14, 57-year-old male.

He discussed how his weight would fluctuate, but never within the healthy BMI range. His main focus for treatment was rhythm control, rather than risk factor modifications.

In those that had changed their lifestyles and begun to lose weight, especially prior to ablation, the reason for this was the educational information that had been provided either by the arrhythmia nurses, or via online searches. One participant had been unaware of the link but felt that patients should be informed at the time of their clinic appointments. He suggested that more information on lifestyle would be helpful.

"I think things like that should be pointed out"

Participant number 1, 60-year-old male.

In another case, the link between AF and BMI had not been discussed in clinic, but his own searching for information enabled him to understand the importance of fitness.

"being overweight is going to have more pressure on the heart"

Participant number 12, 39-year-old male.

This participant found that his lifestyle changed when AF first impacted on his physical health. He was used to being physically active at home and in his job in the military. He hadn't considered weight loss *per se,* but was keen to return to running after the ablation.

5.4.8 Barriers & facilitators to future goals.

The interview schedule included questions regarding looking to the future and goals moving forward, in particular the next six months. Clinically a year post ablation is the time at which patients will normally be discharged from the arrhythmia team. The predominant topics of discussion within this sub-theme were around weight loss and exercise. Several facilitators and barriers were discussed. The majority of participants were either interested in increasing their levels of physical fitness, having previously exercised to a moderate level of exercise, but were not athletes (which is a separate AF risk factor).

The barriers to exercise varied between individuals. One participant favoured swimming as her chosen exercise and tended to swim daily, after her ablation. In doing so, she noted how expensive it can be to access the correct facilities:

"I've spent a fortune"

Participant number 4, 52-year-old female.

Whilst she managed to maintain regular swimming once she was in sinus rhythm, doing so had impacted on her finances. Her hopes are to continue to lose weight and become fitter, especially as she is now aware of the link between AF and BMI:

"my goal would be to sort myself out"

Participant number 4, 52-year-old female.

The impact of the coronavirus pandemic meant that the ability to exercise was hindered due to national restrictions. In this case, the participant was fearful of having contact with others, whereas for others, facilities were simply not available.

"I've stopped going swimming because of the COVID thing".

Participant number 19, 69-year-old male.

Another barrier to achieving a higher level of fitness or returning to fitness is the knowledge and confidence to do so. It is a common fear that exertion may cause damage to the heart. In this case there is a desire to be more active, but a need for advice and information on exercise.

"it would be useful to know how much exertion to put on my heart"

Participant number 8, 61-year-old male.

This participant was not alone in requiring advice on physical activity. There is a need for guidance post ablation, in regard to exercise. This issue was mentioned several times towards the end of the interview. The concern is heart safety and how much exercise is appropriate.

" the only problem is I haven't got a programme I can follow……I don't want to overdo it………I need to boost my fitness levels"

Participant number 10, 64-year-old male.

In addition to being concerned about the cardiac effects on exercise, worry about recovery from another health condition had hindered the ability to return to physical exertion. In this case the participant had not restarted exercise and, although she was keen to do so, she required reassurance from her healthcare team that she was safe.

"I'm a bit nervous…I have a bit of trepidation getting back to it".

Participant number 18, 67-year-old female.

This hesitance she felt was a temporary state and she remained motivated to return to her former level of spin classes three times per week.

The factors that facilitated exercise tended to be self-motivation, as seen in a participant who made the decision to get fit before the ablation. He wanted to have the best chance of procedural success by losing a bit of weight and increasing his level of exercise. Reflecting on his experience of AF and the impact it had on his life was a moment of enlightenment in the importance of fitness.

"it made me realise how important fitness and health really is…I decided to get as fit as I possibly could".

At the six months post ablation time point he remained in sinus rhythm and noted a dramatic improvement to his quality of life, both mentally and physically. He concluded the interview with the following comment:

"I feel unbelievably fit and well".

Participant number 22, 73-year-old male.

Self-motivation was felt by one participant who acknowledged the association with BMI and AF and noted weight gain after commencing antidepressants, reduced exercise and COVID. He associated the recurrence of AF with a deterioration in his lifestyle. However, he found the motivation to lose weight and increase fitness around the time of the ablation, mainly because he knew that he would feel better in sinus rhythm. As the recovery from the ablation has been so difficult, with other health issues, his weight has increased. His main concern is the possible recurrence of AF.

"I know there is a link between fitness and atrial fibrillations…..that's a key...the stress and lack of exercise".

Participant number 26, 40-year-old male.

He highlights the association with a positive mindset as a facilitator to risk factor modifications.

One participant discussed making sense of her raised BMI. She wasn’t aware of the link between BMI and AF initially:

“I certainly wasn’t aware that being overweight..impacted”.

Once she had been informed of this link, she used online information to understand the impact of having a raised BMI. She spent some of the interview speaking about her weight issues and felt motivated to achieve her goals of weight loss and increased level of fitness.
“I’m not grossly overweight….but I am quite over, well I am overweight definitely”

Being in sinus rhythm had given her the ability to focus on fitness and she changed her lifestyle accordingly.

“I’m doing aquafit…I try to get half an hour swim”….I’m trying to do 10,000 steps a day”.

She noted that losing weight is her main goal:

“weight loss definitely”.

Despite having the motivation to undertake a moderate amount of physical activity on a daily basis, she acknowledges that weight loss is a challenge:

“and then you’re doing exercise and stuff and then you almost spoil it all by having a KitKat”

Participant number 37, 57-year-old female.

Sometimes self-motivation is not enough to adjust lifestyle factors, such as weight and exercise. One participant described his health journey in a positive manner, whilst reflecting on the enormity of the AF diagnosis and symptoms.

After the ablation he was referred to the health promotion team at the hospital, which he found very beneficial. They set goals and gave sound advice. This included exercise and advice to lose weight. The elevated BMI was noted, and weight loss was acknowledged as a challenge. Setting goals was helpful and having telephone contact with the health promotion team made him feel accountable for his health. In addition to this support, selfseeking measures were undertaken, such as using a fitness app for calorie counting.

"*she was helpful at giving me advice on adjusting to lifestyle"*

Participant number 19, 69-year-old male.

Having external support provided by the hospital teams facilitated the weight loss and motivation that he needed. The health promotion team is an available resource for all patients requiring help, education, and support for a variety of needs, such as weight loss and exercise. However, only one of the participants mentioned this in the interviews.

5.4.9 Theme 4-Living with AF in a pandemic

This research took place during the global coronavirus pandemic and the impact on health services, healthcare professionals and patients was felt widely. The interviews all took place at a time when the UK Government was instructing the population to "stay at home". Those participants that were so unwell at this time of acute presentation needed to attend hospital at a time when the public were discouraged from doing so.

The ablation procedures continued throughout the pandemic, under strict protocols of care. Many of the participants mentioned how COVID-19 affected their lives. Their unique experiences of AF, the ablation and their lifestyle related to the BMI were all in the context of also living in the uncertainty of the pandemic. The following excerpts are from all those who discussed the pandemic within the interviews.

One participant described the ability to increase his level of exercise whilst off work in the midst of the pandemic.

" in fact, I did quite a bit of it during lockdown. And during 2020 as well. That was a good opportunity to get quite a bit in and it was all nice…. and I was furloughed at the time and had the time to do it"

Participant 8, 61-year-old male.

Not everyone had such an opportunity or desire to make healthy choices in the pandemic. In the following individual, the emotional effects of having AF had resulted in weight gain, coupled with low mood. The pandemic magnified those mental health issues and had a negative effect on his health, as he explains.

"And I'd planned to have it done in 2020 and COVID... I needed to lose a bit of weight because I'd put on an awful lot of weight as well. COVID struck, I put on even more weight because I got even more depressed".

Participant 26, 40-year-old male.

Although the semi-structured interview schedule did not specifically ask about the coronavirus pandemic, it has consumed lives since its inception, and it is not surprising that many of the participants discussed some of the effects. The following participant spoke very positively of her overall experience but discussed the negative impact of succumbing to the virus and the effects on her personal health.

"And then everything was going fantastic. I started walking. I started doing hills again….erm… Unfortunately. I got COVID….today I'm having a great day today, …but I went back in hospital about four weeks ago because AF came back. I was told it was due to long term COVID symptoms".

Participant 13, 53-year-old female.

This experience was a difficult time for the participant, who had been making positive progress, since the procedure. She had been free of AF and some months later, COVID-19 affected her whole health and resulted in an AF recurrence. She found this very challenging, and this all resulted in her requiring a second procedure some months later.

The pandemic did not just affect the person physically, life became a real challenge, even for standard everyday practices. Preparing for the ablation procedure is a stressful time under normal circumstances, but during COVID-19, new rules and protocols were required for patients prior to hospital admission. They were obliged to undergo a polymerase chain reaction (PCR) test prior to attending for the ablation. One participant described this impact, which was clearly stressful. Failure to comply with these tests would result in cancellation of the ablation, for which many had waited months.

"That was awful… because the PCR test….. that arrived on the Friday, and I was due to do it on the Sunday….. ahead of going in for the operation on the Tuesday…. And er .. the PCR test was broken in that the fluid that you put the sample in had drained out of the bottle…….". Participant 19, 69-year-old male.

The interviews were all conducted in the midst of the COVID-19 pandemic and have been analysed within that context. The issues around the pandemic are part of usual parlance nowadays and have become immersed in everyone's lives. Participants were positive that the ablation procedures were conducted, despite the restrictions that the pandemic placed upon healthcare services.

5.5 Summary

In summary, 20 patients, with an elevated BMI, ranging from 25.1- 38.5kg/m$^{2\cdot}$. were interviewed by telephone six months post ablation. The semi-structured interview schedule invited individuals to share their experiences of AF, the ablation and their lifestyles related to their elevated BMI.

Framework analysis was used to structure the understanding and volume of the data, using the seven steps as recommended by Gale *et al*., (2013).

Four main themes were identified, with several sub-themes that were linked to the main themes. Once the themes were identified, a narrative was developed to explain the underlying ideas, thoughts, and meanings. This process utilised the expressions of the patients to describe their individual experiences. Such accounts are in the context of a cohort of patients, all of whom have a BMI over 25kg/m$^{2\cdot}$. Most patients described the challenges of living with AF and the difficulties with treatments. Ultimately all participants felt the benefit of being in sinus rhythm and looked positively to the future. Generally, most participants had challenging times when diagnosed with AF, but were positive about their ablation experience, despite several setbacks and minor complications. Some, but not all patients were aware of the link between AF and an elevated BMI. Most patients had a desire to be fitter and healthier and this was the main goal and hope for the future. The impact of the pandemic was apparent throughout the interviews.

CHAPTER SIX: Discussion

6.0 Introduction

The study presented in this thesis has investigated QoL, symptoms, and experiences of patients with an elevated BMI undergoing AF ablation. The initial motivation for the study was an increase in discussions on the impact of increased BMI on AF ablation outcomes that I have had with my MDT of doctors and specialist arrhythmia nurses. In practice, conversations regularly take place both among the MDT and with patients regarding cardiovascular risk factors and how this may affect long-term health. This was considering increasing awareness within the arrhythmia professional community that the evidencebased guidance (Hindricks *et al*., 2021) regarding risk factor modification were developed from an arguably small body of research (Patak *et al*., 2014).

As the numbers of patients diagnosed with AF increases, the demand on tertiary centres performing ablation also rises in terms of increased referrals, longer clinic waiting times and strained ablation waiting list capacity. The decision to undergo AF ablation is a complex one with arrhythmia nurses being at the forefront of these patient interactions and decisionmaking processes. Furthermore, the lifestyle modifications that are recommended for patients with an elevated BMI by the evidence and guidance (Patak *et al*., 2014, Patak *et al,*. 2015, Hindricks *et al.,* 2021) are often negotiated by arrhythmia nurses who are typically the first point of contact for patients in this holistic approach to care. Moreover, recent NHSE (2022), policy unequivocally *mandates* against ablation in those with a BMI of greater than 40kg/m^2 in addition to gathering data on patient QoL and symptoms via questionnaire pre and post procedure. Therefore, it was highly appropriate that the issue of an elevated BMI, QoL, symptoms and experiences in the context of AF ablation was explored by an experienced arrhythmia nurse.

This chapter discusses the main findings from both the quantitative and qualitative research findings presented in this thesis. The literature review results are discussed in the context of the overall study findings, where there are similarities and differences within the literature. I then provide my solutions to the issues that have been identified within the research , based partially on the nursing model of Orem, among other educational and support solutions.

6.1 Main research findings .

The key findings in the context of a raised BMI cohort within this study are as follows:

- QoL improved significantly after ablation.
- Symptoms improved significantly after ablation.
- Rhythm control after ablation was key to the improvements in QoL, symptoms and experiences.
- Four main themes were identified from the interviews, describing the experiences of patients.
    o Personal well-being related to AF o
    Care and management of AF o
    Interplay of lifestyle and AF o Living
    with AF in a pandemic

The interviews provided depth to the patient reported outcomes from the questionnaires. The qualitative data gave examples of the impact of the reduced QoL and the relative increase afterwards. It also highlighted areas of unmet need along the pathway in terms of the anxiety and fear, the frustrations along the support during the shared decision making and even during the aftercare where expectations were not always met. Moreover, topics that were not part of the surveys, such as the interplay between lifestyle and AF and living with AF in a pandemic provided additional understandings of this patient group.

6.1.0 Quality of life improvements after ablation

The surveys revealed significant improvements in the QoL of patients with a raised BMI after ablation. These results align with some of the evidence from the literature review. When considering the interview findings with the survey findings, it was clear that there was parity s. Data obtained from the interviews enabled a greater exploration of AF and the ablation experience, and how perceptions of QOL and symptomology of participants was affected before and after the procedure. The interviews confirmed the survey results in relation to improved QoL and symptoms after ablation. Additionally, the interviews provided knowledge and insights into the patient's experiences that were not evident from the questionnaires how AF negatively impacted physically and psychologically on individuals, especially when first diagnosed. The findings are in line with Cha *et al.,* (2008), who also used the SF-36 to assess QoL, and demonstrated that all BMI groups (lean, overweight, and obese) improved after ablation, with no difference in level of improvement between the groups.

Conversely, Wokhulu *et al.,* (2010) found lower QoL scores, using the SF-36 in those with a BMI of greater than 30 kg/m2, but this was part of multivariate analysis and not by group comparisons within the study design. This *post hoc* analysis performed retrospectively and not included as a predetermined endpoint, suggests less robust results. By contrast Mohanty *et al*., (2011), who also used the SF-36, demonstrated the paradox of QoL improvements in the higher BMI group, with no significant improvement in the comparator group with a normal BMI. Of course, the study reported in this thesis did not have a comparison BMI group, which means it is not possible to draw similarities on this finding.

However, it raises questions regarding the reasons why those with a higher BMI had improved QoL compared to those without. Mohanty *et al.,* (2011) provide some explanations for the obesity paradox, which has been seen in other conditions, such as heart failure. These authors suggest the obesity paradox results may be explained by regression to the mean in QoL scores and the probability that obese patients are more likely to have comorbidities and be on cardioprotective medications. However, very recently, this theory has been discredited by Butt *et al,.* (2023), who have presented a different approach to the measurement of body fat in those individuals with an elevated BMI, but in the context of heart failure. These authors suggest when waist-to height ratios are measured, rather than BMI, mortality and hospitalisation rates are higher in those with more body fat. It is noteworthy that they do not mention QoL. Although the limitations of Butt et *al's.,* (2023) research include lack of data on cardiovascular fitness, variability in individual measurements and the inability to apply results to those with a low BMI, the findings are suggestive that the obesity paradox may not truly exist.

Another explanation for this paradox is that those participants within the Mohanty *et al.,*(2011) study with a normal BMI did not improve significantly after ablation, because they were not as symptomatic as the higher BMI group. This explanation is controversial because it would suggest that patients are not undergoing guideline-based treatment. This means that it is possible that some minimally symptomatic patients underwent ablation and were included in the study. The obesity paradox remains a debatable point, when applied to AF. Liu *et al*., (2020) undertook an exposure-effect meta-analysis of prospective studies to address the relationship between outcomes in AF and BMI. Their findings suggest that those that are underweight tend to have poorer outcomes, although the reasoning is not clear. This issue remains complex and debateable. Additional factors, aside from BMI, such as ageing, cardiovascular fitness (regardless of BMI), biomarker influences, and anticoagulation effects may all be part of this convoluted and challenging clinical situation.

The findings between quantitative and qualitative data were comparable, in the physical domain scores (SF, RLP, P), which were significantly lower at baseline compared to after ablation (at both three and six months). The SF-36 scores significantly improved at both three and six months after ablation, except for pain, which showed a non-significant improvement. Pain was discussed in two scenarios during the interviews. One was in the context of arthritis and awaiting knee replacement, which is clearly unrelated to AF. The second was acute pain related to the femoral venous puncture post ablation. This may explain why pain scores did not improve significantly after ablation. However, whilst not explicit in other interviews, it is possible that these two brief examples of non-AF related pain may be transferable to the whole cohort. Moreover, this is an example of the difficulties in interpreting pain scores within a questionnaire-based study, where there may be no opportunity for an individual explanation. The issue of pain was not evident within the literature review for this study. Physical effects, such as fatigue, breathlessness and reduced exercise tolerance were reported within the questionnaires. The interviews provided additional information concerning the physical experiences of being diagnosed with and having AF. For some participants, the AF was not immediately apparent, due to lack of knowledge about what AF is as a condition. Participants reported an overall feeling of “getting old”, which relates to slowing down and accepting life the way it is, rather than seeking help. There were discussions around particular hobbies or activities, such as cycling or playing golf, which were aspects that gave insights into individual lives. Participants discussed how they were unable to cycle, play golf or go to the gym, for example, as a result of the physical impact of AF. This type of dialogue provides a greater degree of certainty about patient selection for the AF ablation, which is in keeping with clinical guidelines on the issue of rhythm control. It may mean that arrhythmia specialists are able to relate an individual’s personal experiences to the risk and benefits of ablation discussion in order to make the right choices about treatment. This level of understanding means that when undertaking shared decision making with patients there is a deeper level of understanding potentially from both healthcare professionals and patients.

With regard to patient selection for ablation, there is some debate about variability in practice, despite clinical guidance. This may be particularly the case in North America; however, evidence suggests this is also evident in the UK (National Institute for Cardiovascular Research 2022). Different healthcare systems, such as in North America, operate differently which may lead to patients who are otherwise minimally symptomatic, being offered ablation, that may not be in line with a more conservative approach (Masen *et al.,* 2017). In the UK it is common clinical practice to only offer AF ablation once there is a clear demonstration that the AF is causing a negative impact on quality of life with highly bothersome symptoms, which is currently a subjective discussion with the patient and not measured in any formal way (National Institute for Health and Care Excellence 2020). If a patient has minimal symptoms and reports favourable quality of life at the baseline stage, improvements after ablation are not likely to be significant or impactful. This issue is a crucial one, because it relates to the benefit of rhythm control and the importance of shared decision making for ablation. The arrhythmia nurse plays a fundamental role in the decisionmaking process with the patient. Patient selection for ablation is a fundamental part of the role of the arrhythmia nurse and works on multiple levels. The arrhythmia nurse typically assesses symptoms and quality of life verbally, social preferences, emotional state, employment, and level of exercise. This process holistically appreciates the patient perspective to help inform the process and assist to empower the patient to make the decision that is right for them.

In terms of ablation technical outcomes, the success rates in all of the papers in the literature review were lower than those in this study, although success rates were reported at one to two years and not six months. The study in this thesis is some 14 years since the first paper in the literature review and clinical practice has developed in that time. The reasons for higher success in this study is likely to be related to the improvements in operator experience, catheter technology, energy delivery software, 3-D mapping system technological advancements and the passage of time that has allowed additional research in this area. All of the studies demonstrated similar success rates in patients with an elevated BMI, except for Patak *et al.,* (2014), who reported higher procedural success in those individuals who lost >10% of their body weight. It needs to be recognised, however, that all participants in the Patak *et al.,* (2014) study had a BMI ≥ 27kg/m^2. The success rate results suggest that having an elevated BMI does not lead to lower procedural success, despite that being part of perhaps a common view that success rates are lower in those with an elevated BMI. Furthermore, within the study, the six-month ablation success rates were higher than previously published results found in the literature review. However, by contrast, a wider review of the literature on the subject of success rates in the context of a raised BMI suggests that outcomes are worse in those with an elevated BMI. For example, Winkle *et al.,* (2017) addresses the influence of BMI on patient characteristics, long-term ablation outcomes and ablation complications. They concluded that in 2715 patients, co-morbidities are more common in an elevated BMI and persistent AF is more likely. Moreover, a BMI of ≥35kg/ m^2 negatively affects ablation outcomes and a BMI of ≥40kg/ m^2 was related to an increase in minor complications. In addition, Glover *et al,.* (2019) reported that duration of the ablation and radiation dose are higher in those patients with an elevated BMI. Furthermore, a BMI>30kg/m^2 suggests a 1.2-fold increase in AF recurrence at 12 months, compared to patients who are overweight. There are variable results related to AF ablation in the context of a raised BMI and it is worth noting that the patient populations and characteristics vary worldwide. The findings in the study within this thesis suggest that patients have a successful ablation and improve physically and emotionally, despite having an elevated BMI.

The issue of an elevated BMI is central to this discussion and part of current clinical guidance (Hindricks *et al.,* 2021). When considering risk factor modifications in reducing BMI, the two papers in the literature review informing this study that used a lifestyle intervention, demonstrated different results in patient reported outcomes. It is difficult to draw similarities with this current study, as there was no intervention. However, Mohanty *et al.,* (2017), who measured both QoL, with the SF-36 and symptoms with the AFSS, showed significant QoL improvement in the weight loss and exercise group, although symptoms did not change in either the intervention or the control group. The Patak *et al*., (2014) study only measured symptoms, although these scores significantly improved in the RFM intervention group. In the reported study RFM was a comprehensive programme of physician-based interventions, such as weight loss, exercise, alcohol reduction, smoking cessation, and management of co-morbidities. Such resources are not widely available in the NHS in the UK and the depth and breadth of this type of intervention has not been replicated in any other published study.

In terms of gaining a deeper understanding the QoL improvements after ablation in the context of a raised BMI this study, the multiple linear regression provided answers around the influences on QoL post ablation The two domains of General Health (GH) and Vitality (V) were the chosen outcomes for the model and the justification therein is discussed in Chapter 3 (section.3.13.9). The only predictors of improved GH and V were baseline scores for each and rhythm control in addition for Vitality. These findings tie in with the interview discussions around the issue of rhythm control and the main reason for undergoing AF ablation. These findings are useful in the context of patient selection and the shared decision-making process for AF ablation (National Health Service England 2022). Although this study is small, the findings suggest further explanation may be beneficial. This study has demonstrated that as ablation results in long term rhythm control, this naturally leads to increased vitality. This is reinforced within the interviews when participants discussed the positive effects of the ablation and their desire to move forward with their lives. These positive effects mean being able to work, exercise, engage in social relationships and adopt healthy behaviours that reduce cardiovascular disease in the future. By achieving rhythm control and reporting increased Vitality participants also discussed their individual desires for improving fitness levels and returning to some normality of life.

6.1.1 Summary of quality-of-life improvements

A common thread throughout the findings of this study and current clinical practice is the subject of improvements in QoL after ablation. Current clinical practice has hitherto been a non-systematic method of assessing symptom benefit after a rhythm control procedure, such as cardioversion or ablation. Patients are usually asked “do you feel better?”, rather than a more objective measure, such as PROMS. The recently published Clinical Commissioning Policy for AF Ablation (National Health Service England 2022), which mandates for PROMS before and after ablation, with plans to use the AFEQT and the SF-12 questionnaires. Demonstrating improved patient outcomes is important for a number of reasons. Firstly, AF ablation is a procedure with risks, including an overall complication rate of 4.5% and severe complications of 2.4% (Khairy *et al,.* 2023), for a symptom-benefit procedure. Secondly, it would be a futile exercise to undertake an invasive procedure for no particular QoL or symptom benefit, with all the stress that an invasive procedure entails, as demonstrated within the interview discussions. The other issue is the cost of AF ablation. In the current NHS climate of resource allocation, value-based healthcare is an issue (Gray (2017)), particularly related to AF ablation.

Quality of life measurements within this study addressed the physical, psychological, biological, and social aspects of an individual’s life, in accordance with the work of Ware *et al.,* (2000). It is common clinical practice and within the clinical guidelines that the main reason for undertaking AF ablation is to improve overall QoL (Hindricks *et al*.,2020, National Institute for Health & Care Excellence 2021 & National Health Service England 2022). Previous research has demonstrated that AF negatively impacts QoL, compared to populations norms (Dorian *et al.,* 2000). Moreover, the multivariate regression analysis of GH and Vitality demonstrated that it was baseline scores that predicted improved scores post ablation, in addition to rhythm control in the case of Vitality. Assessing the impact of ablation from the SF-36 and the interviews was important, firstly to assess for convergence or divergence within the two groups of data and secondly to seek additional information from the interviews that the surveys did not reveal. Both questionnaires and interviews revealed that patients feel physically and emotionally unwell when suffering from AF and feel much better in sinus rhythm after ablation.

6.1.2 Symptoms

The Patient Perception Arrhythmia Questionnaire (PPAQ) measured frequency and duration of AF, the percentage of six common symptoms, the bothersomeness of those symptoms, the impact of AF and days missed from work and activities. The questionnaire demonstrated the significant improvements in AF symptoms after ablation, which was elaborated on in the interviews. The interviews demonstrated the physical impact of AF symptoms, which were described vividly in some cases, especially at first presentation or in the emergency setting. The questionnaire quantified the symptoms before and after ablation, but it was the interviews that aided deeper appreciations of how these symptoms affected the physical and mental health aspects of the participants' lives and sense of self. The PPAQ results of commonly reported symptoms before ablation were scored as a median of “moderately bothersome”, rather than “extremely bothersome.” Whereas the interviews mentioned a greater detail of not only symptoms, but the overall feeling of how AF impacted on the body. Where the interviews differed from the questionnaires, was how an individual may be affected by AF in a more holistic way, rather than the specifics of one symptom or another. The patients gave vivid descriptions of how the AF made them feel. Such insights are helpful to healthcare professionals in aiding the understanding of the impact that AF has on an individual. However, the interviews revealed information that questions the usefulness of symptom scoring systems.

Patients discussed how AF made them feel in general health terms, or in terms of energy (vitality), or lack thereof. In clinical practice it is common for patients to not refer to individual symptoms, such as “heart flutters” or “palpitations”, but to say that AF makes them feel “generally unwell”, or “terrible”, or “fed up”. This calls into question the true usefulness of capturing patient reported symptom data. The literature review in this thesis demonstrated that when symptom scores were used, there were conflicting results. For example, Mohanty *et al.,* (2017) showed improved QoL in both the intervention and control groups, but symptom scores did not change after ablation in either group. Conversely, Patak *et al.,* (2014) showed an improvement in AF symptom scores after ablation in the intervention group, although they did not measure QoL. Likewise, Wokhulu *et al.,* (2010) demonstrated that symptoms improved, using the MAFSI scores, but this was only in a subgroup of patients later in their study and not the whole cohort.

The findings on symptoms within this study differ somewhat from the work of Wood *et al.,* (2017). Their study used the same symptom tool (PPAQ) as used in this study, in addition to Canadian Cardiovascular Society’s Severity of AF Scale (CCS-SAF). This study reported that whilst the majority of patients (85%) improved symptomatically at six months post ablation, the recovery rate was much slower than expected. In the Wood *et al* (2017) study, the symptoms reported post ablation included fatigue, anxiety, severe bruising, reduced effort tolerance, sore throat, and high resting heart rate. The interviews in this study found participants mentioned bruising in the groin in the immediate post-procedure recovery period, which was reported as an unexpected finding, despite the opposing comments of being aware of that possibility as a complication. A later paper by Wood *et al.,* (2022), assessed the trajectories of recovery after ablation, using interviews. The narratives that were developed from the analysis in 20 participants revealed three major themes. These are 1) varying speed of resolution of symptoms, 2) presence, frequency, timing, and severity of symptoms and 3) heart rhythm and symptoms between AF episodes. These authors used a novel form of analysis to map the recovery trajectories in these patients, which revealed a shifting, varied and, sometimes prolonged recovery. The study within this thesis demonstrated similar discussions in terms of the desire to return to normal life and physical activity. However, overall, participants in this study were generally positive about the overall benefits of ablation and did not explicitly mention post-ablation fatigue, sore throat, or anxiety. Furthermore, the majority of discussions on symptoms tended to focus on the preablation time period. Whereas the purpose of Wood *et al's.,*(2022) study was to evaluate symptoms and recovery post procedure. It is, nevertheless, difficult to draw similarities with two separate qualitative studies that were conducted in different continents, using different methodologies.

The difficulty in measuring AF symptoms, as opposed to QoL, is that AF is heterogenous disease, meaning that individuals will vary in their reporting of symptoms. In the case of paroxysmal AF, an individual may be in sinus rhythm when completing a questionnaire, and there are cases of patients being unaware of some AF episodes. There is no one single measure of symptoms, as patients present with a variety of different symptoms, such as fatigue, dyspnoea, palpitations or feeling sweaty. All these symptoms give rise to an overall feeling of reduced well-being. Symptom correlation is an important part of current clinical practice as well as the shared decision-making process within the arrhythmia team (Hindricks *et al.,* 2021), National Health Service England 2022). This is where nurses can really make a difference. Symptoms vary and may be inconsistently reported, which is all the more reason to have individualised expert nursing care. Symptoms play a big part in well-being and physical functioning, both of which are factors that affect long term health. Assessing monitoring and managing symptoms there are critical to long term health. This is all within the wheelhouse of the expert consultant nurse.

6.1.3 Summary of symptoms

The assessment of symptoms within this study was demonstrated in the PPAQ and within the narrative from the interviews. Bothersome and unpleasant physical symptoms related to AF were reported in the PPAQ as being moderately bothersome before ablation and not present after ablation. Although the interviews described physical symptoms that correlated with the questionnaires, some of the participants described moments in time when the symptoms were more than moderate. Typically, these symptoms were palpitations, lack of energy, reduced exercise tolerance and breathlessness. Psychological symptoms were discussed in the interviews in detail and included anxiety, fear, and worry. The PPAQ asked more generally about mood, rather than the specific emotional impact from the AF. The symptoms reported within this study correspond to those reported in the literature review, although Mohanty *et al*., (2017) noted that at two years follow-up, the symptom scores did not necessarily correlate with sinus rhythm. In this study symptoms were self-reported and ECG documentation at follow-up, although part of routine clinical practice, was not part of the study. Despite this potential limitation, it is only the presence of symptoms or reduced QoL that drive the process for a redo ablation. If an individual reports ongoing AF symptoms, an ECG would be performed to document what is happening to the heart rhythm at the time of the symptoms and correlate heart rhythm with the patient reported outcomes.

6.2 Rhythm control in the context of an elevated BMI cohort

It is important to consider why patients with an elevated BMI significantly improved in all SF-36 domains, except pain after ablation. One clear reason, based on the literature (Hindricks *et al.,* 2021, Cha *et al*., 2008, Wokhulu *et al*., 2010, Mohanty *et al.,*2011, Patak *et al.,*2014, Mohanty *et al.,* 2017) is the achievement of sinus rhythm, as a result of the ablation procedure. Rhythm control is usually defined as the maintenance of sinus rhythm with medications and/or treatments such as cardioversion or ablation (Han *et al*., 2013). In this study, which centred on ablation as a treatment, rhythm control typically meant improvements in QoL and symptoms that do not require a second ablation procedure. It is common clinical practice to review a patient at three months post ablation and then decide on the need for a second procedure. However, anti-arrhythmic drugs in the management of AF assist in a degree of rhythm control (Hindricks *et al.,* 2021). Each drug may have an influence on patient reported outcomes before or after ablation, because drugs have sideeffects, which vary from one individual to another. Moreover, the fact that these patients are undergoing AF ablation indicates that these drugs have either been ineffective, contraindicated, or caused side-effects. Anti-arrhythmic drugs are defined as those used for rhythm control, rather than rate control (King *et al.,* 2023). These include Amiodarone, Flecainide, Propafenone and Sotalol at class III dose. In persistent AF, rhythm control means being in sinus rhythm as much as possible, to improve symptoms and QoL. However, in paroxysmal AF, rhythm control may mean reduced frequency and/or duration of the selfterminating AF episodes. This study demonstrated that there was a statistically significant decrease in the prescription of anti-arrhythmic drugs after ablation. There was no significant difference in prescribing of anti-arrhythmic drugs between three and six months, which is aligned with common clinical practice, whereby it is commonplace to discontinue these drugs at the first follow-up at three months.

In terms of rhythm control, the results in this study demonstrated that 66 participants (80.5%) at three months and 67 (81.7%) at six months had rhythm control, not requiring a redo procedure. A total of nine participants (11%) were placed on the waiting list for a redo within the six-month study period, and one individual was listed within three months of the first ablation. Not only did most of the sample have rhythm control without requiring a redo ablation, but there was also a significant reduction in the prescribed anti-arrhythmic drugs over the study period, suggesting robust rhythm control. These success rates are a bit higher than the internationally reported rates of successful rhythm control, albeit in a selected cohort. First time success for PAF ablation is about 80% and for persistent AF 67% (McCarthy *et al.,*2022). Such success rates are also higher than the papers published within the literature, bearing in mind that the evidence is conflicting (Patak *et al.,* 2014, Cha *et al.,* 2008). On the one hand, success rates are lower in the elevated BMI group (Patak *et al,.* 2014) and this is a point of discussion during clinic consultations when patients are making decisions about treatment. However, the papers within the literature review within this thesis are from 2008-2017, with no recent evidence that matched the literature review. The timeframe of those papers in the literature review in this thesis was earlier in the development of AF ablation as a treatment and technical procedure. Since that time, success rates have improved globally, due to a number of factors, which have been discussed earlier in this chapter.

It is quite clear that, in this study, rhythm control was a key component in the improved QoL and symptom benefit post ablation. This is in line with the current clinical guidance for the selection of patients undergoing rhythm control treatments, such as ablation or cardioversion (Hindricks *et al.,* 2021). This fits with the current NHSE Clinical Commissioning Policy (2022). The evidence for correct patient selection is evident from the highly significant improvements in QoL and symptom scores within the questionnaire results. The interviews provided additional information on the impact that AF had, both physically and emotionally. The mental health domains of the SF-36 (V, SF, RLE) all improved significantly after ablation. The interviews gave greater insights into how much AF may impact an individual's emotional well-being. The participants discussed the fears and worries that come with a cardiac diagnosis. These negative emotions are not uncommon in the context of AF and such illness perceptions are supported by the work of McCabe and Barnason (2012). These authors recommend that education and the promotion of understanding of AF is a crucial part of clinical practice, and a lack of understanding may lead to worry. The interviews in this study revealed the fear and worry that patients experienced when first presenting with AF, especially in the acute setting. The fear factor was in part related to the uncertainty of the condition and lack of an awareness and understanding of AF, as a condition. The acute symptoms from AF may be very similar to those of a heart attack, which is a significant fear in anyone. The fear of dying was another notable reported form of distress. Not only did these acute presentations result in adverse physical effects, but the psychological impacts were also detrimental and often ongoing, even once sinus rhythm had been achieved. When considering both the questionnaires and the interviews, it became clear that the issue of rhythm control is central to an individual feeling better from both a QoL and symptom perspective.

6.2.0 Summary of rhythm control

It was the ablation treatment that resulted in rhythm control and led to the significant improvements in QoL, and symptoms post ablation. Both sets of data suggest that rhythm control is the key to improvements in general well-being. The interviews gave greater understandings on the fear and worry associated with the symptoms of AF, which the surveys did not. Furthermore, the interviews provided some vivid insights into how the AF impacted on the individual, both physically and psychologically and how much better they felt in sinus rhythm.

6.3 Experiences

In addition to the significant improvements in QoL and symptoms after ablation, despite having a raised BMI, the personal accounts of these participants' experiences were presented. The details of how much AF had impacted mentally and physically and how ablation helped to improve reported outcomes were apparent. The interactions with and expectations of the healthcare professionals featured as a theme from the interviews within the context of the treatments, specifically ablation. The participants talked more about AF and treatments than the interplay of lifestyle and AF, even though the topic guide included all elements. The issue of exercise was commonly discussed and the desire to become fitter was apparent. However, the link between BMI and AF was less apparent and only known about in a small number of participants. The interviews provided some understanding of what it was like to be undergoing treatment within a pandemic. This included the personal impact that COVID-19 had on long-term health perspectives. Discussions involved the frustrations with healthcare access and the general precautions that were required, especially related to the ablation procedure.

6.3.0 Summary of findings

Overall, there was considerable convergence in the findings of the quantitative and qualitative elements of the study. The qualitative data added depth to the quantitative data, Interviews also added to the knowledge gained from the questionnaires, particularly around the decision to consider ablation, the treatments before ablation and the procedure on the day. All of the participants had been within the AF clinical pathway for either many months or years. From the interviews, it was apparent that variation occurred with the access to the specialist arrhythmia team, who are the personnel that hold the key to ablation. The arrhythmia nurses are central to the patient education and decision making about ablation and were mentioned by several of the participants, in a positive manner.

The next sections present a move from results and findings to what these could mean for patients within this clinical pathway.

6.4 The lifestyle factors related to the findings in this study

The combined results of the questionnaires and interviews have drawn together underlying aspects of patient care that directly relate to the role of the arrhythmia nurse. In the analysis of QoL, symptoms and experiences it has become clear that three distinct areas of clinical practice require focus. The subject of an elevated BMI underpins the whole research within this thesis and is a fundamental part of current national policy, as well as an important component of international clinical guidelines (Hindricks *et al.,* 2020). The issue of AF and exercise has emerged as a finding from the interviews specifically and within physical functioning in the SF-36 results. The educational needs of patients and arguably, healthcare professionals, emerged from analysis of the interviews, which suggest that the interplay between AF and BMI is not always communicated at clinical consultations. These three issues, concepts and ideas are discussed in the following sections.

6.5 The problem of an elevated BMI

The cohort of participants in the study all had a BMI of greater than 25kg/m^2. Before the study started, consideration was given to also including patients with a BMI of 25kg/m^2 or less, to compare two groups. However, most patients undergoing AF ablation in this centre had an elevated BMI, meaning a normal BMI group would be much smaller by comparison. This was clear during the screening phase of the study. BMI did not change over the study period, which is not a surprise as the purpose of the study was not to facilitate weight loss. However, it would have been encouraging to see a reduction in BMI with lifestyle modifications post ablation. Furthermore, the interviews suggested that most participants were not aware of the link between AF and BMI. The literature review within this thesis did not contain any qualitative research on this subject, although it was discussed in the wider context within the introduction chapter (Chapter 1).

The issue of BMI was addressed within the interviews, with specific questioning on the knowledge of participants around the link between AF and a raised BMI. individuals were not widely aware of the link between   an elevated BMI and only a few mentioned weight.

Those few individuals that were informed of the link between AF and BMI provided some information on health behaviour changes that had been adopted since being informed. However, the interviews provided less about weight than on exercise experiences. The desire to lose weight was briefly mentioned by a small number of participants and none of them discussed their own sense of self or health in relation to their weight. This is supported by the work of Bates *et al.*, (2022), who conducted 12 interviews with patients with AF and a BMI of greater than 27kg/m^2. One of the identified themes was "broaching the subject". This theme explored patients' understandings of conversations with healthcare professionals about weight and AF. In this cohort, only one individual knew of the link between AF developing and a raised BMI. In this study none of the 12 participants knew that weight loss may be beneficial in symptom benefit in the context of AF. The interviews contained a dialogue on the subject of weight loss, but participants felt unsupported in practical advice and were often not referred to appropriate services to aid weight loss (Bates *et al.*, 2022).

By way of contrast, a cross-sectional study from Belgium addressed the motivation of overweight patients to lose weight with a diagnosis of AF (Delesie *et al.*, 2021). The results demonstrated that 143 participants were recruited to the study and although 75% were motivated to lose weight, 69.9% were aware of the link between AF and weight loss. The authors suggest that these patients need to be better informed about BMI and AF and those more likely to be unaware are females, with lower education, hypertension, living alone, having never lost weight and with a lower, but elevated BMI. The study concluded that the preferred weight loss strategy was a home-based tailored programme, which was reported in over half the cohort. The numbers of participants in this study with knowledge of the link between AF and BMI was much higher overall than the sample in this study. However, what is unclear from Delesie *et al.*, (2021) is the participants prior knowledge before taking part in the trial.

The findings presented within this thesis suggest that there is a lack of knowledge amongst patients related to the interplay of BMI and AF. Although the clinical guidelines state that the third part of AF treatment is the management of co-morbidities, cardiometabolic risk factors and risk factor modification, it appears that these are not being implemented. The guidelines acknowledge the influence on health that an elevated BMI has, and this includes reducing the risk of type II diabetes mellitus, hypertension and hypercholesterolaemia (Hindricks *et al.,* 2021). However, this study and other limited evidence supports the fact that the risk factor modification part of the treatment guidelines is lacking in delivery and application.

Another reason why individuals may not discuss their experiences in relation to their BMI, are the ideas of stigma and weight bias. It is widely accepted that the mass media reinforce weight bias and stigma (Ata & Johnson 2010), and society is driven by social media and images of "the perfect body". Fruh *et al.,* (2016) discuss the issue of obesity stigma and bias in the context of healthcare providers. Although the study within this thesis did not explicitly reveal such bias, the subject was discussed by one of the participants. Fruh *et al,.* (2016) provide advice and guidance to healthcare professionals in the way they approach the issue of a raised BMI. They suggest reducing weight bias in a number of ways, including acknowledging the difficulties, recognising that weight loss may have already been attempted, creating a supportive environment, and acknowledging previous negative healthcare interactions. Bajaj *et al*., (2022) recommend not using the dehumanising labels, such as "obese patient", which tend to reinforce weight stigma. In doing so it is hoped that those individuals with an elevated BMI are more likely to receive and adhere to treatment and be successful in recommended lifestyle adjustments (Baja *et al.,*2022). These issues were considered at the start of this study when it was decided to use the terms "elevated or raised BMI" rather than overweight or obese in the context of the study participants.

The issues around patients with AF and an elevated BMI remain debatable and arguably, unresolved. This is because previous research has varied in results related to success rates and complications. In this cohort patients significantly improved, suggesting that BMI was not a major factor in patient reported outcomes. However, the QoL scores were lower than population norms before ablation, but this is more likely to be related to the AF impact than necessarily the BMI. The range of BMI in this study was from just above healthy range

($25.1kg/m^2$), to almost morbid obesity ($38.2kg/m^2$), which is representative of those patients undergoing AF ablation. However, a study using a comparison outcome in those of normal BMI to overweight and obese individuals may be a useful future direction in order to provide additional evidence to support the care of such patients. Conversely, such a study may simply result in reinforcing the weight stigma problem. Implications for future research and practice are discussed in the next chapter.

6.6 AF and exercise

In this study there was convergence in findings from the questionnaires and interviews related to the subject of exercise. The improvement in physical functioning after ablation, as measured by the SF-36, was significant and this was mirrored within the interviews, with participants' descriptions of exercise. Participants also discussed future fitness goals, and the desire to increase physical activity. Despite this cohort of participants having an elevated BMI, the majority were physically active and mentioned various sporting activities within the interviews. However, what participants felt was lacking in their care was structured advice, information, and education, related to exercise. Clinical guidelines for the management of AF (Kirchoff *et al*., (2020) and National Institute for Health and Care Excellence (2023) both recommend physical activity. There is evidence that some patients with AF avoid exercise, for fear of triggering an episode or worry about causing heart damage (McCabe *et al.,* 2011). Additional research has shown that too much exercise is a risk factor for the development of AF (Lavie *et al.,* 2017). There appears to be a J-shaped curve relationship in those individuals who exercise to an athletic level and those that do not exercise in the risk of developing AF (Zhu *et al.,* 2016). Nielsen *et al,*. (2013) report that AF incidence increases with long term vigorous training or lack of physical activity but is less likely in those who undertake moderate levels of exercise. Ting (2017) notes that athletes have increased inflammatory markers and biomarkers, leading to an increased likelihood of AF. Furthermore, Koone *et al.,* (2020) found that moderate exercise has multiple benefits, in reducing blood pressure, insulin resistance and endothelial function. In the context of an elevated BMI, exercise reduces systemic inflammation and atrial arrhythmogenesis, thus making AF less likely. In the CARDIOFIT study (Patak *et al.*, 2016), which assessed the benefits of physical activity in those with AF and elevated BMI improvements in physical activity boosted weight loss and the greater the level of exercise, the lower the AF burden and higher maintenance of sinus rhythm. These authors suggest that cardiovascular fitness may be offset by the negative effects of an elevated BMI. This suggestion is supported by Liu *et al.,* (2019), who agree that being physically active may offset the negative physical effects of an elevated BMI suggesting that being fitter is more important than the BMI in the context of overall health benefits. Although this point is debatable, Patak *et al.,* (2016) suggest that there is probably a synergistic effect of risk factor modifications, resulting in other benefits, such as structural cardiac changes and biomarker improvements.

Whilst there is evidence for recommending and providing an exercise programme for those with AF, the interviews within this study suggest that such provision at least within the centre where this study took place, is lacking. There is a desire for patients to have guidance and support in either returning to exercise or increasing levels of cardiovascular fitness. This point was highlighted to a greater degree within the interviews, compared to discussions around weight loss. The next section links with these findings in relation to the need for information, education, and support for those with AF.

6.7 Educational needs of patients and the role of healthcare professionals

The need for education, support and information giving is at the cornerstone of any condition. The needs of the patients within this study were demonstrated within the qualitative interviews. Such needs were not always explicit, but often more subtle, particularly in the knowledge of the link between AF and a raised BMI. Most participants were not aware of such a link, but there may be several reasons for this. Firstly, they may not have been informed as part of their clinical journey, despite the management of risk factors and co-morbidities being a recognised part of current clinical guidelines (Hindricks *et al.,* 2020). Secondly, there may be a lack of awareness, or lack of time to discuss, from the clinical team, including the arrhythmia specialists. A recent audit in this centre demonstrated that the link between lifestyle and AF is not always routinely discussed within the outpatient clinic. When such issues are discussed, arrhythmia nurses were more likely to mention a variety of risk factors, consultant cardiologists more likely to mention BMI issues and cardiology registrars the least likely to mention any risk factors (Isaac 2023). Reasons for this are not necessarily lack of knowledge on the part of the healthcare provider, but due to the constraints of a busy out-patient clinic, where the focus is on the immediate medical treatments, such as drugs, cardioversion, or ablation.

The lack of information, education and support for AF patients has been noted in several published papers. McCabe *et al.,* (2011) in her qualitative study found that patients in the US have knowledge deficits, particularly around the nature of AF, the management of symptoms, the trajectory of AF and risk factor modifications. She recommends cardiac rehabilitation classes and information giving to improve the lives of these patients. Those with a good understanding of AF were more accepting of their condition, had fewer negative emotions and fewer symptoms. Taylor *et al.,* (2017) reported that those patients with a good understanding of AF tend to cope with the symptoms better. McCabe *et al*., (2011) indicate that healthcare providers should not assume knowledge. This view is supported by Ferguson *et al.,*(2022), who found that patients have unmet needs in regard to AF information and often seek information via the internet. The problem in doing so is that information may have variable quality and accuracy. These authors recommend a variety of information giving, such as written information, videos, and accessible support, which is tailored to the individual. Currently in the UK cardiac rehabilitation classes are not routinely available for patients with AF.

The interviews within this study revealed the lack of awareness, knowledge, and information, which was the link between AF and BMI. This could be that healthcare professionals are simply not informing patients within the consultation. It could be that the information is not being delivered in a meaningful and understandable way. This was not necessarily the case for other aspects of their care and condition. Generally, the majority felt well-informed about the treatment, in particular the ablation procedure. This contrasts with a study by Withers *et al*., (2015), who interviewed patients undergoing ablation and found there was a lack of support and information, especially regarding the possibility of a redo procedure. Despite this, in this study these patients found that the arrhythmia nurses were an important part of the support required in undergoing ablation. In this study those few that had prior knowledge of the interplay between AF and BMI had been informed at some point in their AF journey. One participant, in particular, had found that the new knowledge was a catalyst to weight loss and improving her overall health in general. She went on to seek additional information online, despite help from her healthcare providers.

Whilst there is wide evidence for patients with AF to be provided with advice, information, and education, in this study the main requirement is around risk factor modifications, such as weight loss and exercise. Arrhythmia nurses are best placed to assist patients in the information giving and support as part of their clinical journey. Furthermore, it may be that other healthcare professionals within the patient's pathway need to be aware of the specific link between AF and BMI. Currently there is no evidence to inform of the knowledge base on RFM in the management of AF. However, in a similar vein, Balin *et al.,* (2017) assessed physicians and patients' knowledge of the benefits of AF ablation and found that there was a general perception that AF ablation improves mortality and reduces stroke risk, neither of which is correct. This was true for patients, who had already been informed of the benefits of AF ablation, and physicians treating those patients. This suggests that there is a knowledge gap generally around the management of AF, including RFM and this is commonly seen in current clinical practice.

The purpose of this study was to understand the QoL, symptoms and experiences of patients with an elevated BMI undergoing AF ablation. This thesis has demonstrated that patients were correctly selected for AF ablation, according to the guidelines. However, the time after the ablation is when there is a gap in the clinical pathway, from a holistic perspective. Patients require knowledge and education on how they may reduce their risk of developing AF in the future, even after a successful ablation. Reduction of the risk of AF involves removing or reducing the substrate that led to the development of AF in the first place. Such substrate modifications include weight loss and exercise, as seen in Patak *et al*., (2014) study. However, there is no standardised approach or model for assisting patients in these behavioural changes after (or ideally before) ablation. An experienced arrhythmia nurse is well-placed to assess, plan and implement care that may complete the care journey. The use of a nursing model could provide a framework on which to move from ablation to lifestyle with this patient group. This solution to the issues discussed earlier in this chapter has the potential to improve long term health outcomes, support patients and address the evidenced based guidance on the management of AF (Hindricks *et al*., 2021)

6.8 Nursing theory & models

Consideration of nursing theory is useful in appreciating the link to nursing practice and is relevant in the study within this thesis. Chinn and Kramer (2004) define theory as "a creative and rigorous structuring of ideas that projects a tentative, purposeful and systematic view of phenomena". They suggest that theory requires a purpose, or reason to make sense of things. Although Florence Nightingale's Notes on Nursing (1859), as discussed by George (2011), guided nursing practice for many years and remains largely influential, she did not refer to her work as nursing theory. The process of theorising has led to the development of grand theories, which are designed to include broad concepts within nursing. Such theories include the work of Peplau (1952), in McKenna and Slevin (2008). The essence of this theory, designed for mental-health nurses, is the concept of interpersonal relationships, or patient-connections. This theory could apply to other specialities of nursing, not solely psychiatry. Middle-range theories are more specific and narrower in scope than grand theories. It is the case that the work of Orem (1980) in McKenna and Slevin (2008), could fit within a middle-range theory, although McKenna and Slevin (2008) state that this model is a grand theory. Middle-range theories appear to be more in line with nursing practice, and issues that interest nurses, such as pain, quality of life, fear, and dignity. This suggests that such theories underpin nursing practice (Cunliffe et al., 2010). Micro, narrow or practice theories are more specific and are related to cause and effect, in the way that if *x* is carried out, *y* will result. Such theories can be very useful, regarding an evidence-based approach to patient care. However, the term "micro-theory" is confusing as it may suggest that the holistic approach is not utilised. Indeed, the terminology "grand, mid and micro" suggests a hierarchy of importance and relevance to nursing, where the reverse is true.

As middle-range theories are more aligned to nursing practice, considering the theory of Orem (2001) has led to a realisation that this theory is a useful framework on which to improve patient care in the context of this thesis. This approach came after further reading, and conversations with a supervisor who had prior knowledge of the use of Orem's model on a cardiac in-patient ward (Walthall 2023). Orem's model was used some years ago on a ward caring for patients undergoing several procedures, including cardiac surgery and ablation. The model was used to plan, implement, and evaluate patient care effectively. A process of reflection resulted in considering how Orem's model may be applied to patients with AF, undergoing ablation in the context of an elevated BMI.

6.9 Orem's model of self-care

Dorothea Orem developed a nursing theory several decades ago, but its legacy makes it applicable to the patient group studied within this thesis. Application of this theory provides a model of nursing care and a potential solution to the issue of lack of knowledge on the link between AF and a raised BMI and changing behaviour to achieve long term health benefits. From a philosophical perspective, Orem's model (1959) stems from the totality paradigm, which is a form of moderate realism (Biggs 2008). This means that the body, mind, and spirit are viewed as separate entities. The beliefs within the totality paradigm are fourfold. Firstly, humans need environmental modifications to meet their desired goals. Secondly, humans are seen as active agents who can undertake self-care. Thirdly, the environment provides the basic survival needs. Fourthly, nursing assists with self-care, and totality is part of the nursing process. Orem's theory is divided into three parts, which are the theory of self-care, the self-care deficit theory, and the theory of nursing systems. The theory of self-care is the way in which humans care for themselves. The self-care deficit theory is the capability of how self-care is performed, and the way in which nurses and nursing is required to assist with self-care. The theory of nursing systems is concerned around the patient/nurse relationship and when self-care is not met in an individual (Younas 2017). Supported selfcare management is the essence of this approach.

Even though Orem's theory has only been used in a small number of research studies, the results are helpful in considering the use of the theory as a solution to helping patients. Khademian et al., (2019) used Orems model within the self-management of hypertension. In this study nurses saw patients as capable of decision-making. This quasi-experimental study included 80 patients who were randomly allocated into control and experimental groups. The experimental group underwent an educational programme over an eight-week period. QoL and health promotion questionnaires (although not clearly defined) were used and demonstrated significant improvements at eight weeks, although not immediately after the intervention. In the context of coronary artery disease, Yildz and Kasikci (2020) assessed the impact of a training program based on Orem's self-care deficit nursing theory. The self-care intervention in this RCT of 109 patients consisted of five home visits and a 45-minute education session. The use of this Orem-based self-care model resulted in significantly increased QoL and self-care agency, with reduced hospitalisations. The framework used within this study, based on Orem's self-care, provided a useful guide for nurses in how to educate and improve the care of patients with coronary artery disease.

Other evidence in the AF population demonstrates that providing patient education to make lifestyle changes has multiple benefits, including improvements in QoL and symptoms (Yaeger *et al.,* 2018), although this was a study that did not use a nursing model. In this study specialist nurses undertook a programme of education, sleep apnoea management and weight loss in patients with obesity and AF. Treatments were monitored monthly, and patient reported outcomes were measured with the SF-36 questionnaire for QoL and AFSS for symptoms. Those enrolled lost significantly more weight than those that declined ($p<0.05$). The QoL and symptom scores improved significantly at six months post intervention.

Having considered the evidence behind Orem's model of self-care and the findings from both the quantitative and qualitative data, it is proposed that the use of Orem's self-care model would provide a framework on which arrhythmia nurses could guide the care of patients with AF undergoing ablation. The results of this study demonstrate a need for advice, support, and education after ablation. However, it may be useful to also consider input before ablation, at the start of the AF clinical journey. The study results demonstrated that once participants were in sinus rhythm, their goals were to improve fitness and physical activity. But they were not generally aware of the link between AF and BMI. The holistic approach of managing stroke risk, symptom control and risk factor modifications would be in line with clinical guidelines (Hindricks *et al.,* 2020). This model also fit with the holistic way in which nurses work and interact with patients. The following figure 9 provides a proposed model of health improvement, which is in line with the clinical guidelines.

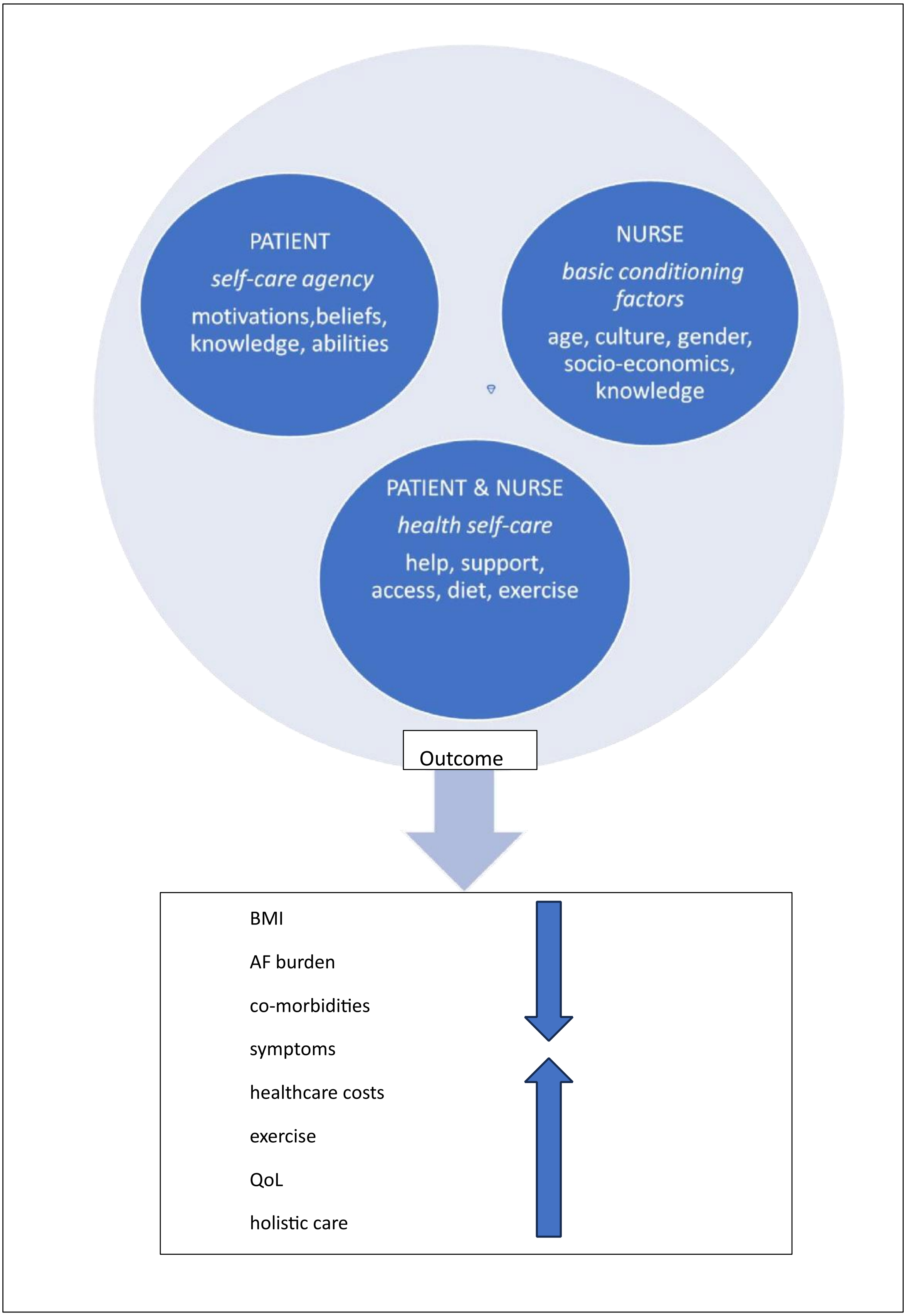


Figure 9 Proposed model of care for patients undergoing AF ablation.

6.10 This model as a solution to the problems of AF and an elevated BMI

This model comprises three positions: the patient, the nurse and both patient and nurse together. From the patient perspective self-care agency is the ability to recognise individual needs, to evaluate available resources and undertake self-care to a preferred outcome (Orem 1991). This concept includes their beliefs, motivations, knowledge, and personal abilities. The nurse requires the basic conditioning factors including the patient characteristics, such as age, culture, gender, educational level, knowledge, and socioeconomic situation (Picket *et al.,* 2014). These are factors that the nurse will consider when engaging with the patient, allowing for the complex influences that make an individual. When the patient and nurse join together in partnership and shared decision-making, the health and self-care component of Orem's model would be applied. In this context, the help, support, and access of care are employed to begin the process of health improvement. It is anticipated within the model proposed here that patient reported outcomes will improve, level of physical activity will increase, co-morbidities, such as hypertension, are managed, BMI will reduce, AF burden will reduce in the long term and a more holistic treatment will ensue. Although much of this care is present in current arrhythmia nurse clinical practice, it is not necessarily evident in the patient interviews and some of the literature (Bates *et al.,* 2022). It is proposed that this model of nursing care will assist these factors. In using Orem's model of self-care, which has a certain simplicity (Gonzalo 2023), it is anticipated that arrhythmia nurse will be able to structure the needs of the patients within the clinic environment. The model will also allow the incorporation of the nurse's interaction with the patient, rather than focussing purely on the medical model of care, such as medicines and treatments.

An example of when the Orem's model may be used is within the needs of patients regarding exercise in the context of AF. Participants in the interviews expressed a need for guidance on exercise and the need to return to physical fitness. One answer to this dilemma is the provision of cardiac rehabilitation (rehab) classes for those with AF. Currently cardiac rehab classes are routinely available for those with coronary artery disease, following an acute coronary syndrome (National Institute for Health and Care Excellence 2015) and in some areas for heart failure (British Association for Cardiovascular Prevention &

Rehabilitation 2023). There is some evidence for the benefits of cardiac rehab in patients with AF. Buckley *et al.,* (2021) noted, in a retrospective study, that cardiac rehab was associated with a 68% all-cause mortality reduction, 44% reduction in hospitalisations and 16% reduction in strokes. This evidence, despite limitations, supports cardiac rehab in the context of AF. Osbak *et al*., (2011) demonstrated significant improvement in QoL and fitness levels in patients with AF who were randomised to exercise training. Furthermore, Risom *et al*,. (2016) undertook an RCT, which compared usual care to cardiac rehab in AF ablation patients and demonstrated improvements in cardiovascular fitness, measured by V02max, but no improvements in QoL. These improvements were seen at four months, but no longterm improvements were assessed as part of the trial. A systematic review undertaken by Giacomantonio *et al.,* (2013), who concluded that moderate intensity physical exercise should be recommended for those with AF and suggests that this is an important area for ongoing research. The provision of cardiac rehabilitation in such patients would go some way to fulfilling the "patient and nurse" component of the proposed model of care for patients undergoing AF ablation. This could apply not only to those with an elevated BMI, but any patient with AF.

The use of Orem's model aligns with the underpinning philosophical beliefs that has driven the research. Orem's model is a pragmatic approach to the care of patients and provides a practical framework for nurses to use in clinical practice (Younas 2017). Pragmatism is at the heart of this thesis and corresponds to the solution in aiding patients to move forward in their clinical journey in a positive way. Strengths of Orem's model include the ability to generalize to a number of nursing scenarios, it may apply to all levels of nursing practice, from novice to expert and is aligned to the theories of health promotion and health improvement (Gonzalo 2023). These concepts are particularly relevant to the patient population within this study and the emerging evidence base for holistic treatment. Furthermore, it addresses the wider health issues of an increasing level of an elevated BMI, which is increasingly prevalent. Although the limitations of the model include possibly a lack of the appreciation of the dynamic changes within health and less appreciation to emotional needs of an individual, modern nursing and medicine are aware of these needs and it is hoped that such components would be incorporated within the three sections of the model.

6.11 Summary and conclusion

This chapter has outlined the main findings from both the questionnaires and the participant interviews. The main issues have been discussed in relation to current clinical practice. The aim of the study; *to explore patient's QoL, symptoms and experiences with an elevated BMI undergoing catheter ablation for atrial fibrillation* has been achieved using a mixed methods approach. The underlying methodology of pragmatism has underpinned the thesis in all aspects and has driven the research process.

The objectives set out in Chapter three have been achieved. The final objective, which is to make practice recommendations will be discussed and explored in the next chapter.

This chapter has discussed the findings and issues identified within the research. In using a nursing model, it is proposed that the care of these patients is enhanced and improved. The model, which could be used after ablation, but may also be introduced earlier in the clinical pathway, is Orem's model of self-care. This model will allow the patient and arrhythmia nurse to work in partnership, particularly related to education on factors, such as BMI, exercise, and education.

New knowledge has been generated through completion of this thesis. Until present, no study using a mixed methods approach exists that addresses the QoL, symptoms in patients undergoing AF ablation in the context of an elevated BMI. The study demonstrates the appreciation of the trajectory from before diagnosis through to the six months post ablation. This study has depicted the patients journey in relation to their outcome measures along the way which has provided insights into their unmet needs, their specific fears and anxieties and the lack of appreciation of lifestyle factors. All of this has enabled an awareness of how nurses may manage and care for these patients to fulfil their specific needs along that trajectory (which wasn't appreciated before). Moreover, to hopefully optimise not just the short-term outcomes (ablation success) but also improve the longterm outcomes associated with improved health behaviours. This new knowledge has been considered within the framework of Orems self-care model, all in the context of an elevated BMI.

The patient reported outcomes of QoL, and symptoms are the crucial aspect of AF ablation selection. Furthermore, PROMS are an essential component of current clinical policy and guidance. The patient experiences of living with AF, the treatments, the interplay of AF and lifestyle, in the context of a global pandemic have provided valuable insights in understanding this patient group.

The next chapter presents conclusions, strengths and limitations, practice, research and policy recommendations and dissemination of the research.

CHAPTER SEVEN: Conclusion

7.0 Introduction

This chapter concludes the thesis that has been presented. The conclusions from the research are discussed, in relation to the overall thesis. The strengths and limitations of the study are presented. This chapter will also include specific and unique recommendations that have been drawn from the results to enhance patient care. The recommendations provided are related to the four pillars of advanced nursing practice.

7.1 Conclusions from the research

Chapter one outlined the problem of AF, which presents a significant clinical challenge to healthcare professionals. The increasing health issue of an elevated BMI was highlighted as a linked challenge in the context of AF. Both health issues are impacting on the finances of healthcare and currently there is no standardised approach to risk factor modification, despite the guidelines. This chapter elaborated on the need to understand more widely the patient's perspectives related to QoL, symptoms and experiences in those with an elevated BMI undergoing AF ablation. The research question, aims and objectives were presented.

Chapter two presented a systematic review of the literature related to the research question. Although a number of papers on patient experiences with AF have been published, there were few related to ablation and none that addressed the entire research question, including the elevated BMI. Therefore, only studies conducted using quantitative methods were found. A systematic approach was used, and the methods adopted in the search strategy were described. A total of five studies were included in the review and as they were variable in study design, a narrative synthesis approach was taken. The chapter presented the similarities and differences within the literature. Differences were seen in the patient reported outcomes following AF ablation, depending on the BMI grouping. Two of the studies (Patak *et al* 2014), Mohanty *et al* 2017) were lifestyle interventional trials that showed patient reported improvements after ablation, but the methods used to demonstrate improvements were different. The conflicting results in the literature and the absence of papers with patient experiences revealed a distinct gap in the literature.

Chapter three combined both methodology and methods for the study within this thesis. Philosophical underpinnings were explored, and pragmatism was chosen as the most appropriate paradigm that fitted with the research question. Pragmatism has been shown to be a common thread throughout this thesis and has driven the research process. To answer the research question, a mixed methods approach was adopted. The convergent design fitted best with the patient's clinical pathway, as the data collection points matched the clinical contact points. Such a study design is congruent with a pragmatic approach to research. The second part of the chapter described the methods that were utilised to carry out the study. This part of the chapter provided descriptions of the study design, conduct, ethical principles, data collection and data analysis. The study was described in two phases, the quantitative phase, with the use of two questionnaires, one (SF-36) on QoL and one (PPAQ) on symptoms. The second phase included the study conduct of the patient interviews, all of which were conducted via telephone at six months post ablation. The processes of data analysis for the quantitative data were described, using SPSS for the statistical analysis. The qualitative data were analysed by a process of Framework Analysis, as described by Gayle et al (2013). Themes were generated from the seven-step analysis process to understand the patient experiences. The study was successful in terms of recruitment and data collection, despite a number of challenges that are common in undertaking a period of research.

The quantitative results were presented in chapter four and the results demonstrated that there were significant improvements in both QoL and symptoms after ablation. A multi regression analysis was provided to understand influences on QoL, specifically General Health and Vitality, according to the SF-36. The results showed that significant predictors of improved SF-36 scores were baseline Vitality scores and rhythm control at six months. For General Health the predictor of significant improvements at 6 months was the baseline scores. These results suggest that BMI did not influence patient reported outcome after ablation, which had been an assumption at the start of the study.

Chapter five demonstrated the qualitative findings from the 20 patient interviews. The semi structured interviews asked participants about their experiences of AF, the ablation, and the lifestyle factors, including BMI. The most surprising finding was the lack of knowledge and awareness of the link between BMI and AF. Lifestyle modifications were not explicitly mentioned as part of AF treatment, but most participants were keen to return to physical activity after ablation. The chapter provided the themes that were generated from the framework analysis, with individual quotes from participants. This was the first study to undertake interviews in this patient group, which gave new knowledge to the needs of patients and the importance of the arrhythmia nurse within the patient's clinical trajectory.

A discussion of the study results and findings was presented in chapter six. This chapter included a discussion on the questionnaires and interviews in this study that used a mixed methods approach. The results were like some of the study within the literature review, but different form others. The literature review results, were contradictory so this is not surprising. This study was much smaller than other large centre studies but has provided information that may apply directly to the UK population of those with AF and an elevated BMI. Furthermore, this study is aligned to the NHSE Clinical Commissioning Policy for AF ablation (2022), which means that the results may be applied nationally and at a policy level. Publication of the results is planned and considered a priority in the dissemination of the work within the study. The final part of the discussion chapter presented a solution in the form of Orem's model of care for the patients undergoing AF ablation, with an elevated BMI. Orem's model focuses on self-care but requires the collaboration of both patient and nurse together in order to facilitate improved outcomes.

7.2 Strengths of the research

There are several strengths to this study. A new exploration of the needs of patients with an elevated BMI undergoing AF ablation was required. This is because the previous evidence, included in the literature review was some years old when AF ablation was developing as a technique and the evidence was conflicting. To date there have been no studies exploring both quantitative and qualitative outcomes from patients undergoing AF ablation, in the context of a raised BMI. This study was started as the NHSE Clinical Commissioning Policy on AF Ablation (2022) was being developed and as a result, provides additional evidence to patient selection, suitability, and experiences in this context. Other strengths are the large sample size, excellent response rate, longitudinal study, mixed methods with interviews adding depth to study. The focus on raised BMI has been valuable as an important group for consideration. The number of patients per year with a normal BMI undergoing first time AF ablation is approximately 50. The fact that the research was nurse led and has recommendations for nursing practice are other strengths. The recruitment in this study was highly successful, bearing in mind that it was conducted through the COVID-19 pandemic. This patient group is well known to an experienced arrhythmia nurse, who understands the needs and desires of patients to have a voice in their clinical journey.

Another strength was the excellent response rate to the questionnaires, which was in part due to the study design, but also due to the motivation of this patient group, to inform us of their physical and emotional issues related to AF. The numbers of participants that were interviewed at six months post ablation was a strength. Those recruited were willing and keen to offer insights into their experiences. The conduct of the interviews worked well, within the technology that was used, and the benefit of the telephone interviews meant that the data collection took place, despite a national pandemic lockdown. The convenience sampling also was successful in recruiting a range of ages, types of AF, gender, and BMI measurements, which was another strength.

7.3 Limitations of the research

This was a single centre study, which naturally only provided the outcomes and views of a limited population. The baseline characteristics of the total cohort of participants were in accordance with this being a representative sample of patients with AF in the hospital. Typically, the mean age, gender balance, type of AF and co-morbidities reflected current clinical practice in this healthcare setting. However, there was no ethnic diversity, the cohort being predominately white British. Those that declined were also White British. The sample of the 20 interview participants was all white British. Whilst this does not represent more diverse views and experiences, it is typical of the demographic in this part of England. The ethnic population of this city is 54% white British (OCC 2023), but the participants came from areas in the South of England, some areas of which are not ethnically diverse. The study was an observational cohort design and not randomised. At the study design stage a consideration for a randomised controlled trial, with a lifestyle intervention was considered.

However, it was felt that such a study would not achieve enough participants in the time available and would need to be multi-centre to achieve sufficient power, which is not pragmatic within the timeframe of a Doctorate. Another limitation in this study was the lack of a normal BMI group, to allow for comparisons in the patient reported outcomes. This factor was considered at the study design stage, but initial scoping of the numbers required revealed that most patients undergoing AF ablation were of a BMI > than 25kg/m^2 and the time required to recruit equal numbers in each group was not practical.

The main limitation of the interview sample was the lack of ethnic diversity. All the 20 interview participants were white British. Whilst this does not represent more diverse views and experiences, it is typical of the demographic in this part of England. The ethnic population of this city is 54% white British (OCC 2023), but the participants came from areas in the South of England, some areas of which are not ethnically diverse.

Another limitation was the potential risk of bias from a single interviewer, which may have led to a degree of impartiality. However, this was mitigated by using a semi-structured interview schedule and my experience over many years of listening and conversing with patients allowed the best possible approach to reducing bias. Conversely being an arrhythmia nurse, may have influenced the responses, a subject discussed in the methods section, when considering bias. Regular supervisory discussions regarding the data assisted in this process. The use of Framework Analysis meant that each stage of this process was transparent, inductive, and deductive.

Whilst the SF-36 was used in this study, based on it being a well-validated questionnaire, widely used in a number of conditions and one I have been most experienced in using, (as explained on page 85), the simplified SF-12 is equally effective as the SF-36 and may well be better to use in any follow-up studies proposed.

The final limitation in this study was the impact of the COVID-19 pandemic which has been discussed throughout this thesis. The restrictions on research at the time of mounting COVD-19 numbers meant that recruitment was delayed for some months. When research was reinstated in the hospital, it became challenging and at one-point, clinical elective work was postponed, meaning recruitment was impossible. The initial study design was for faceto-face interviews at six months, but the pandemic restrictions would not allow such methods. Fortunately, telephone interviews were conducted, which arguably, allowed for a higher number of participants to agree to take part, as such interviews impacted less on their time and travel.

7.4 Potential Impact of the Research

Research impact is becoming an increasingly notable element of research, according to Greenhalgh (2016). The resulting impact of research may influence nursing practice, by developing a deeper understanding of a common heart rhythm condition that may require invasive treatment. Crucially it is the patient's voice that is central to improving the services available. The potential impact of the research includes the implications and recommendations for nursing practice. Using the four pillars of advanced nursing and consultant practice means that the research has potential impact in all aspects of the role, and this can only benefit patient care in the long term. The recommendations from the research are presented below.

7.5 Recommendations for clinical practice

Patients were generally unaware of the link between AF and an elevated BMI, which means there is a gap in the clinical pathway. From a clinical perspective it may help patients if more information is made available at the time, they are seen in the specialist clinic. The following recommendations are provided as potential quality improvements.

- Arrhythmia Nurses to provide more structured, written information on the link between AF and raised BMI
- Arrhythmia MDT to discuss and plan a way of providing structured advice on exercise after AF ablation. This could be in partnership with the Cardiac Rehabilitation team and the health promotion team. These teams are highly skilled in facilitating behavioural change in cardiac patients. It is important for patients to adopt healthier lifestyles and a model of behaviour change will help support this.
- Arrhythmia nurses using an Orem-based model on which to care for patients with AF

7.6 Recommendations for further research

One of the main interview findings was the lack of awareness of the link between BMI and AF. It was not entirely certain why this is and if it was related to not being informed at all. This may be lack of time in the clinic, lack of awareness by the healthcare professional or the information not received in a meaningful manner. Although not mentioned explicitly in the interviews, clinical experience suggests that knowledge may be lacking from the healthcare professional referring patients to the specialist clinic and/or some staff within the clinic. Further research may help in understanding where these gaps lie. The following further research is suggested:

- Questionnaire or interview study on the knowledge base of healthcare providers in the specialist clinic on the link between AF and an elevated BMI.

Whilst it was a positive finding that there were significant improvements in QoL and symptoms post ablation, despite an elevated BMI, further research is recommended on this subject. Further research into how healthcare professionals remove weight stigma without normalising a BMI may help patients to address their own health in a holistic way, rather than treating their heart and not losing weight for health. Further research is recommended:

- Undertake a qualitative study on health behaviours related to the risk factors associated with AF, in particular increased weight and exercise.

- Using an Orem-based interventional study in patients undergoing AF ablation, ideally randomised to those undergoing usual care. An Orem-based model could be a structured educational programme before and/or after ablation, meaning standardised information is provided. This study could be applied to other aspects of AF rhythm control, such as cardioversion and anti-arrhythmic drug treatment.
- Study focussed on diverse groups (which would recruit elsewhere)
- Follow-up studies in the previous bullet points should include a control group of patients with AF who are not overweight or obese, or use a stratified design that includes different classes of BMI
- A study that proposes if the higher prevalence of AF in males may relate to higher waist circumference

7.7 Recommendations for leadership

This research has implications for nursing leadership, not only from the research findings, but the process of undertaking a nursing doctorate. At a local level the following are recommended:

- Work with nursing research leaders within the hospital trust to foster a culture of nursing research.
- Present the research findings to the hospital trust, to raise awareness amongst other teams, when referring to the arrhythmia team. Highlighting nurse-led research outside the heart centre would be helpful in leading and inspiring other nurses to undertake research and for networking opportunities.
- Strengthen and develop nursing research within the arrhythmia team, in the mentoring of those nurses wishing to fulfil the four pillars of advanced practice, in particular, research.

The findings of this research highlight and corroborate the need for PROMS in patients with AF undergoing AF ablation. PROMS are soon to be mandated by NHSE before and after ablation/ However, clinical experience suggests that knowledge and skills on PROMS amongst healthcare professionals within the arrhythmia team are limited. The experience of PROMS within this DNurs has enabled a deeper understanding of the variety of PROMS available in patients with AF and how they may be best delivered. Experience of this research suggests that paper questionnaires have potential challenges and digital applications require knowledge, skill and support.

- Develop a programme of education for the MDT on the use of PROMS in AF that are aligned with the NHSE Clinical Commissioning Policy on AF ablation.
- Lead on the implementation of the Clinical Commissioning Policy on AF ablation within the local hospital trust
- Share the knowledge and experience of PROMS nationally, at BHRS annual meeting.

7.8 Recommendationsfor education

The data from interviews has highlighted the need for increased and enhanced education for patients, especially, and potentially, staff. When patients were first diagnosed with AF, they were fearful and uncertain. Often, they presented to the GP, or urgent care within the hospital. To alleviate fears and provide education in the acute scenario, the following recommendations are suggested:

- Arrhythmia nurses to work with urgent care and primary care to provide educational resources for staff and patients.
- Including primary care and urgent care in the AF Awareness campaign, bi-annually, in collaboration with the AF Association.
- Arrhythmia Team to provide advice to the staff in the Emergency Department on signposting patients once they have received a diagnosis of AF.

7.9 Final reflections

As an arrhythmia nurse, with many years of experience, it was becoming increasingly evident that a raised BMI was becoming more prevalent in patients with AF in my clinical practice. This has been particularly noticeable in the last ten years in this centre and this fits with current clinical evidence. Many of the inter-team discussions on the challenges within clinical practice were related to an elevated BMI. Discussions have primarily focused on patient safety, but also on the efficacy of the ablation procedure. Current clinical practice involves the shared decision-making process on AF ablation, which has become more apparent recently. The survey results clearly demonstrate that patient selection in this centre is appropriate and in line with current clinical guidelines, which is reassuring for both patients and clinicians. The results are that these patients significantly improved after ablation. Of course, this is encouraging and positive and suggests that having a raised BMI should not necessarily preclude ablation.

Having experience of speaking with patients on a daily basis, as part of my professional practice, the interviewing process for the qualitative assessments in this study was aligned to my professional skill set, thereby enabling smooth and effective facilitation of the interviews.

Understanding the lived experiences of this patient group has been highly valuable. This study has reinforced to me the importance of the role of the arrhythmia nurse. Such an individual provides a crucial link in the patient pathway. Often the arrhythmia nurse is the first point of access for patients pre and post ablation. Undertaking this study has reinforced my view of knowing and understanding this patient group. Many times, I was told that recruitment would be difficult. I always felt positive that these individuals would want to share their stories.

Finally, the impact of the pandemic is felt world-wide. Personally, conducting research in the midst of a pandemic has been the greatest challenge. Working full-time in the NHS, during staff redeployment to ICU, family and personal impacts of COVID-19 has been hugely demanding. The positives aspects of such a troubled time has been the gratitude of those within the study, in being listened to as a research participant, the rapid change to remote patient contact and surviving the pandemic as a researcher and a nurse.

This study started with the problems of both AF and an elevated BMI and finishes with a potential solution.

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Appendicies

Appendix 1: Quality appraisal and assessment using the CASP tool for cohort studies

paper	1.did the study address a clearly focused issue	2.was the cohort recruited in an acceptable way ?	3. was the exposure accurately measured to minimise bias?	4. was the outcome accurately measured to minimise bias?	5.a) have the authors identified all important confounding factors?.	5.b) have they taken account of the confounding factors in the design and/or analysis?	6.a) was the followup of subjects complete enoough?	6.b) was the follow up of subjects long enough ?	7. what are the results of the study? *See table*	8. how precise are the results ? *See table*	9. do you believe the results ?	10. can the result be applied to the local population ?	11. do the results of the study fit with other available evidence?	12. what are the implications of this study for practice? *See discussion*
Cha et al (2008)	yes	yes	yes	yes	yes	yes	yes	yes			yes	yes	can’t tell	
Wokhulu et al (2010)	yes	yes	can’t tell	yes	yes	yes	yes	yes			yes	yes	yes	
Mohanty et al (2011)	yes	yes	yes	yes	yes	yes	yes	yes			yes	yes	no	

Patak et al (2014)	yes	yes	yes	yes	yes	yes	yes	yes			yes	yes	yes	
Mohanty et al (2011)	yes	yes	yes	yes	yes	yes	yes	yes			yes	yes	yes	

Appendix 2: Study Protocol

Internal Reference Number / Short title: Atrial Fibrillation ablation Quality of Life (AFab-QoL) Study

Ethics Ref:

Date and Version No: V1.7, 30/10/2020

Chief Investigator: Professor Eila Watson, Oxford Brookes University (OBU)

Investigators: Dr Y Bashir & Dr Helen Walthall, , Angela Griffiths (Principal Investigator),OUHFT, Dr Louise Stayt OBU

Sponsor: Oxford Brookes University

Funder: no funding attached to this study

Principal Investigator Signature:

No conflicts of interest.

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

TABLE OF CONTENTS

SYNOPSIS

This study is a mixed-methods, observational cohort design of patients undergoing catheter ablation for atrial fibrillation (AF). The study aims to assess if body mass index affects quality of life, symptoms and experiences after AF ablation.

Study Title	Does body mass index affect quality of life, symptoms and patient experiences after ablation for atrial fibrillation ?	
Internal ref. no. / short title	Atrial Fibrillation ablation Quality of Life (AFab-QoL) Study	
Study Design	Prospective cohort, mixed methods questionnaire and interviews.	
Study Participants		
Planned Sample Size	n= 86 for quantitative n=20 for qualitative	
Planned Study Period	18 months	
	Objectives	**Outcome Measures**
Primary	To measure quality of life and symptoms, before ablation and at 3- and 6-months following	SF-36 questionnaire Patient Perception Questionnaire
Secondary	To explore patients’ experiences of AF, ablation and lifestyle factors	Semi-structured interviews 6 months post ablation

ABBREVIATIONS

AF	Atrial Fibrillation
CI	Chief Investigator
CRF	Case Report Form

CTRG	Clinical Trials & Research Governance, University of Oxford
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
NHS	National Health Service
NRES	National Research Ethics Service
PI	Principal Investigator
QoL	Quality of Life
PIL	Participant/ Patient Information Leaflet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SOP	Standard Operating Procedure

BACKGROUND AND RATIONALE

Atrial fibrillation (AF) is the most common arrhythmia seen in clinical practice (Camm et al 2010). Previous studies demonstrate that AF may result in high symptom burden and reduced quality of life (Dorian 2000). Rhythm control in the form of catheter ablation has become an established treatment option for AF. Some risk factors are associated with the development and progression of AF, notably, obesity. Emerging evidence suggests that risk factor modification in the management of AF is an important component of the patient pathway.

Prytowsky (2015) reports a dramatic increase in AF burden worldwide, which is also associated with other factors, such as obesity, hypertension and sleep apnoea. Emerging evidence for such factors is seen within key clinical guidelines (Kirchoff et al 2016 and Nalliah et al (2016)), with a focus on obesity. According to the World Health Organisation (2019) obesity is a major global health problem. Epidemiologically, there is an association between obesity and AF, whereby the greater the body mass index (BMI), the higher the risk developing AF (Wang et al 2004).

Evidence demonstrates that long-term rhythm control by AF ablation improves quality of life (Ellis and Reynolds 2012), however, less is known about the impact of obesity on QoL following ablation.

Two systematic reviews have assessed the relationship between AF and QoL following ablation and related to obesity (Ellis and Reynolds 2012, Zhuang et al 2013). Both reviews show that QoL is significantly improved in patients with a BMI of less than 30, although they have limitations. The systematic review by Zhuang et al (2013) only included observational studies, as no randomised controlled trials (RCT) met their inclusion criteria, or, actually existed at that time. Furthermore, in the 12 studies included in their meta-analysis, only 3 of those measured QoL. Ellis and Reynolds' (2012) literature review identified inconsistent results in a number of studies. Cha et al (2008) showed similar QoL improvement in all 3 BMI groups, whereas Wokhlu et al (2010) observed lower QoL scores in obese patients. Mohanty et al (2011) reported significant improvement in overweight and obese groups. A number of factors may explain these confounding results, although comparison between the three groups may be limited by differences in the methodologies of the studies. Other factors may also affect the reported outcomes of AF ablation and these include obstructive sleep apnoea and other conditions associated with obesity (Ellis and Reynolds 2012). These reviews highlight the fact that the impact on QoL following ablation, in those who are obese, is not straightforward and requires further investigation. Furthermore, all studies within the reviews are of a quantitative nature and to date, no qualitative studies exist on the patient experience of AF, the ablation procedure, or knowledge of lifestyle factors in the management of AF.

Aim: To explore if body mass index affects quality of life, symptoms and patient experience following catheter ablation for atrial fibrillation.

OBJECTIVES AND OUTCOME MEASURES

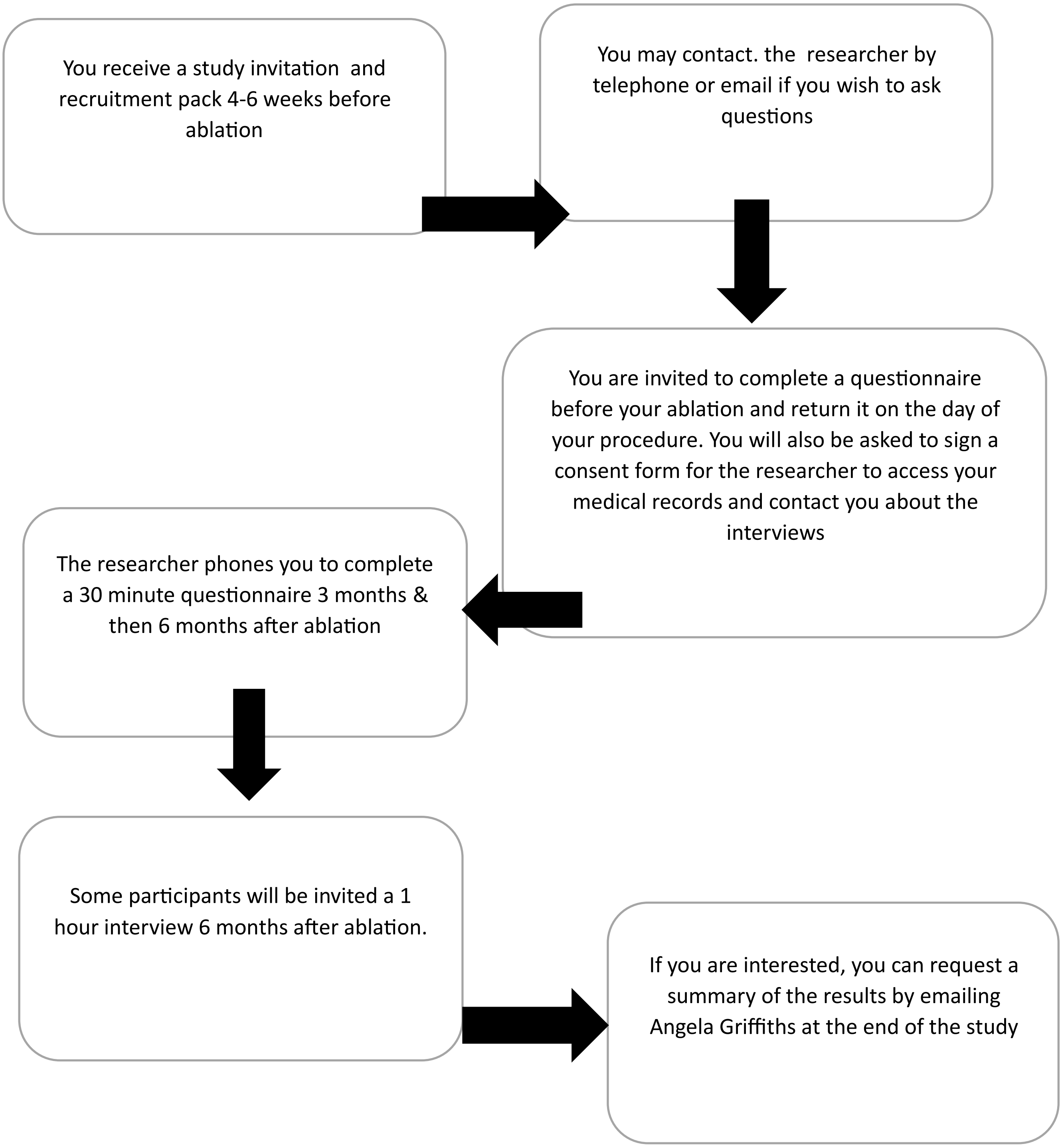
Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Primary Objective To measure quality of life and symptoms, before ablation and at 3- and 6-months following	SF-36 quality of life questionnaire Patient Perception Questionnaire (PPQ)	Baseline-preablation 3 months post ablation 6 months post ablation
Secondary Objective To explore patients' experiences of AF, ablation and lifestyle factors	Semi-structured interviews	6 months post ablation

Tertiary Objectives To establish if body mass index affects a patient's quality of life and symptoms.	SF-36 quality of life questionnaire Patient Perception Questionnaire (PPQ)	Baseline-preablation 3 months post ablation 6 months post ablation

STUDY DESIGN

The proposed study (Atrial Fibrillation ablation Quality of Life (AFab-QoL) Study) is a mixed-methods study in a single centre. It is a prospective cohort study, in consecutive patients who are referred to a tertiary cardiac centre, for AF ablation. Ethical approval will be sought from Oxford Brookes University Health and Life Sciences Faculty Ethics Committee (FREC), Cambridge South Research Ethics Committee (CSREC) and OUHFT Research and Development Department.

Flowchart for the study



You receive a study invitation and recruitment pack 4-6 weeks before ablation

You may contact. the researcher by telephone or email if you wish to ask questions

You are invited to complete a questionnaire before your ablation and return it on the day of your procedure. You will also be asked to sign a consent form for the researcher to access your medical records and contact you about the interviews

The researcher phones you to complete a 30 minute questionnaire 3 months & then 6 months after ablation

Some participants will be invited a 1 hour interview 6 months after ablation.

If you are interested, you can request a summary of the results by emailing Angela Griffiths at the end of the study

PARTICIPANT IDENTIFICATION

Study Participants

Participants with paroxysmal or persistent atrial fibrillation that are placed on the waiting list for first-time AF ablation will be included for consideration of this study.

Inclusion Criteria

Participant has diagnosis of AF and has been referred for AF ablation

Participant has BMI of >25

Participant is willing and able to give informed consent for participation in the quantitative study alone or in both the quantitative and qualitative study

Male or female, aged 18 years or above.

Participant is eligible for first-time AF ablation

Participant may speak and understand spoken and written English

Exclusion Criteria

Participant is not willing and unable to give informed consent for participation in the quantitative study alone or in both the quantitative and qualitative study

Participant has BMI<25

Male or female, under 18 years

Not eligible for AF ablation

Redo AF ablation

Participant is not able to understand spoken or written English

STUDY PROCEDURES

Recruitment

A sample from the total patient population undergoing AF ablation, for the first time, (approximately n=200) per year will be recruited. Following statistical advice and using a power calculation, with GPower software, based on previous studies, for a moderate effect size, a sample of n=86 will be recruited. Participants will be screened, in conjunction with the clinical team, when placed on the waiting list, usually 4 months before the procedure. An invitation to participate letter and recruitment pack, containing an information sheet, consent form and the baseline questionnaires, in addition information regarding data sharing and privacy notice will be sent out at the same time as the admission letter, typically 4-6 weeks prior to ablation. Participants will have the opportunity to contact the Principal Investigator if they have any additional questions.

Participants will be recruited following receipt of the recruitment pack, which they will be asked to bring with them on the day of their admission. They will sign the consent form at home but have the opportunity to ask any additional questions in the 4 weeks before the procedure, or on the day of admission. Questionnaires will be delivered at 3 time points, pre-ablation, as the baseline measure and then at 3 months and 6 months post procedure. The baseline questionnaire will be paper based and the post-procedure questionnaires will be telephone based, which will be digitally recorded. The qualitative arm of the study will include telephone semi-structured patient interviews at 6-months post procedure and will be digitally recorded. It is anticipated that approximately 20 patients will be interviewed as this is the typical amount reported in similar qualitative studies (McCabe et at 2011), however, the aim will be to achieve data saturation (Braun and Clarke 2006), that is when no new themes or findings arise.

An Excel spreadsheet will be kept of patients recruited, with dates of consent, baseline data, such as patient's characteristics on age, gender, body mass index, classification of AF (paroxysmal or persistent) and other co-morbidities will be collected. questionnaire, date of ablation, follow-up dates for telephone questionnaire and interviews., in accordance with data protection strategy at OBU, on the secure Google drive, accessed by the Principal Investigator.

Screening and Eligibility Assessment

All patients on the waiting list for first-time AF ablation with a BMI of > 25, will be eligible, unless they do not give informed consent.

Informed Consent

The participant will personally sign and date the latest approved version of the Informed Consent form before any study specific procedures are performed. There are 2 consent forms, 1 for the quantitative and 1 for the qualitative study. The questionnaire also has a brief consent statement, prior to completion of the questionnaire.

Written versions of the Participant Information and Informed Consent forms will be presented to the participants detailing the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; the known side effects and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as desired, to consider the information, and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study. Written informed consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified experienced and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed consent form/s will be given to the participant. The original signed form will be retained at the study site.

Baseline Assessments

Demographic data: gender, age, BMI, co-morbidities, current medications, electrocardiogram (ECG) and echocardiogram report to determine left ventricular function

Quality of life and symptoms questionnaires

Subsequent Visits

Visit 2: 3 months quality of life and symptoms questionnaire, via telephone

Visit 3: 6 months quality of life and symptoms questionnaire, via telephone

6 month semi-structured patient interviews via telephone

At each visit an eligibility check will be carried out, which means that after baseline, the patients will need to have gone through the ablation procedure, to remain eligible. The interviews will be arranged at a pre-arranged date and time, in accordance to a similar system already in place for routine clinical follow-up.

Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the study at any time. In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including:

Significant protocol deviation

Significant non-compliance with treatment regimen or study requirements

Withdrawal of consent

Loss to follow up

The participant will continue to be under usual clinical care.

Withdrawal from the study will not result in exclusion of the data for that participant from analysis.

Withdrawn participants will be replaced until the desired number of participants is reached.

The reason for withdrawal will be recorded in the case report file (CRF).

Definition of End of Study

The end of study is the date of the last telephone questionnaire and/or telephone questionnaire at 6 months after ablation of the last participant.

STATISTICS AND ANALYSIS

Description of Statistical Methods

SPSS software will be used to analyse the quantitative data and NVivo software for the thematic analysis of the qualitative data. See below for additional detail on analysis.

The Number of Participants

Following statistical advice and using a power calculation, with GPower software, based on previous studies, for a moderate effect size, a sample of n=86 will be recruited, for the quantitative study. For the qualitative study, 20 patients will be recruited. Purposeful sampling, will take place to allow for a range across BMI, age, classification of AF and gender. Participants will be recruited up to data saturation, when no new themes are identified.

Analysis of Outcome Measures

Quantitative data will be analysed using the latest version of SPSS software (IBM 2019). The composite QoL scores and AF symptom scores will be compared from baseline to follow-up, to establish any change following the ablation intervention. Analysis of variance (ANOVA) will be applied at the 3 time points in order to allow for a multivariate analysis, using a p value of 0.5. Comparative statistics will be used to determine any differences between genders, classification of AF and body mass index, as the grouping variable. The qualitative data will be analysed in a convergent manner, in order to provide distinctive types of data, with the same results Creswell (2014), Convergent data analysis will aim to increase the understanding the outcomes of AF ablation, from the patient's reported outcomes and lived experiences. Prior to convergent data analysis, the qualitative data will need to be analysed separately. Thematic analysis has been advocated by Nowell et al (2007), who has provided a contemporary framework on which to analysis themes within a qualitative dataset and this framework will be used. It is anticipated that NVivo software will be used for this purpose (qsrinternational 2019).

DATA MANAGEMENT

Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

Data Recording and Record Keeping

For the baseline questionnaire, on paper, the results will be transcribed into SPSS for data analysis. For the 3- and 6-month telephone questionnaires, data will be directly inputted into an Excel spreadsheet, which will then be uploaded to SPSS for analysis. Each patient will have a unique number identifier, linked to their medical record number and initials.

For the 6-months patient interviews, the data will be digitally recorded via the telephone.

The data will be kept electronically, on the OBU secure Google drive, in accordance with usual data storage arrangements, for a period of 10 years.

Questionnaire response rates will be monitored closely. If it is found that the response rates to Q2 and Q3 are considerably lower, measures will be put in place to try to increase the response. This would all be discussed with the supervisory team and ethics amendment sought if required. It is not anticipated that it will be a problem as the patient group are very motivated. Supervisor's experience also suggests that once patients agree to take part in studies such as these the majority do complete the study and fill in subsequent questionnaires.

QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, Good Clinical Practice (GCP), relevant regulations and standard operating procedures.

ETHICAL AND REGULATORY CONSIDERATIONS

Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice guidance

Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to the Faculty of Health and Life Sciences Research Ethics Committee (FREC) at OBU, Cambridge South Rec, and HRA for written approval.

Reporting

The Principal Investigator shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required) host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

Participant Confidentiality

Oxford Brookes University is the sponsor for this study based in United Kingdom and will act as the data controller for this study.

All information which is collected about the participant during the course of the project would be kept strictly confidential, within the limitations of the law. The results of the study would be reported without mentioning any names or identifying details. We would take every step to ensure anonymity, however, given the small sample size of the project, this cannot be guaranteed. The questionnaires will be linked with a de-identified code and will not be linked to personal data. The digital recordings would be transcribed and transcripts would be pseudonymised. Electronic copies of transcripts, and any personal details would be stored on Oxford Brookes Google Drive. The consent forms, digital recordings, and transcripts would be kept for a minimum of 10 years, in accordance with the Oxford Brookes University Code of Practice for Academia.

The site and the sponsor may also be given access to pseudonymised data for monitoring and auditing purposes. If a participant withdraws from the study, we will keep the information that has already been obtained.

In addition, the researchers will always make every effort to protect anonymity by adopting the following measures:

After giving verbal informed consent to take part over the telephone, the digital consent form completed by the researcher and the audio recording of the informed consent will contain a unique ID number.

The digital recording of the consent will be encrypted and stored in a double password protected University network drive.

All study materials such as notes, audio-digital recordings, will be labelled with a unique code number and not by name.

A single file linking the anonymous code number to name will be stored on a separate password protected location which may be accessed by the principal investigator only. All data will be stored for 10 years.

Expenses and Benefits

As there are no additional visits to normal care, no expenses will be incurred. There will be no costs to the NHS, or OBU.

Other Ethical Considerations

It is possible that completing the questionnaires may result in distress when answering the questions about emotional well-being. This is because patients may be reminded of some unpleasant memories of the time around the procedure, although this may not be the case. It is possible that the interviews may result in emotional upset if bad experiences from the procedure are recalled.

In order to minimise these risks, the Principal Investigator will watch for warning signs of emotional distress and offer to pause or terminate the interview.

There is a small risk of the research team highlighting unmet needs, safeguarding issues and the risk of identification. Processes already in place to protect the participant will allow for these rare possibilities. Unmet needs will be dealt with by liaison with the clinical tea. Safeguarding issues will be dealt with in the standard process adopted by the OUHFT. The Chief investigator has received mandatory training and has many years experience in dealing with any potential safeguarding issues and is fully competent to deal with any potential issues therein. There is a small risk of identification within the study, but the experienced research team is fully competent and able to deal with this small possibility.

The contact details of the Arrhythmia Nurses, the Atrial Fibrillation Association and Patient Liaison and Advice Service (PALS)will be given, for further support and advice.

FINANCE AND INSURANCE

Funding

This study has no funding attached to it.

Insurance

The University has a standard indemnity and public liability policy in place, which would apply in the event of any participant suffering harm as a result of their involvement in the research.

PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

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APPENDIX B: SCHEDULE OF STUDY PROCEDURES

Procedures			
	Visit timing **Day 1**		
	baseline	**3 months**	**6 months**
Informed consent			
Demographics			
Eligibility assessment			
Questionnaire			
Semi-structured interview			
Adverse event assessments			

APPENDIX C: AMENDMENT HISTORY

Amendment No.	**Protocol Version No.**	**Date issued**	**Author(s) of changes**	**Details of Changes made**
1	1.2	20/05/2020	AG	Replacement of obesity to body mass index, throughout & more detail in section 11.4
2	1.3	23/06/2020	AG	Changes to flowchart in section 4, Changes to recruitment and timeline in section 6.1, Changes to CI who is AG, additional text regarding risks in section 11.6,
3	1.4	29/06/2020	AG	Additions to missing data in 8.3
4	1.5	22/09/2020	AG	Edit footer to say "does BMI affect QOL" Changes on flow chart to say would rather than will
5	1.6	22/09/2020		Changes to flow chart format

5	1.7	30/10/2020		Changes to front sheetPI and CI changed from AG to EW, Changes to footer for version number, Page 5-typo after PPQ Inserted CSREC Change to flow chart, 5.2-addition of BMI, 5. 3-addition of BMI, Change to PI, Addition of info on.. 6. 1-addition on qual recruitment, 6.2- add BMI to patient characteristics, 6.2- add brief consent on questionnaire

Appendix 3: GDPR Privacy Notice

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Privacy Notice

Oxford Brookes University (OBU) will usually be the Data Controller of any data that you supply for this research. This means that we are responsible for looking after your information and using it properly. The exception to this is joint research projects where you would be informed on the participant information sheet as to the other partner institution or institutions. This means that they will make the decisions on how your data is used and for what reasons. You can contact the University's Information Management Team on 01865 485420 or email info.sec@brookes.ac.uk.

Why do we need your data?

The aim of this study is to assess patient quality of life, symptoms and experiences of catheter ablation for AF and to establish if body mass influences these outcomes.

OBUs legal basis for collecting this data is:

- You are consenting to providing it to us; and/or,
- Processing is necessary for the performance of a task in the public interest such as research

If the university asks you for sensitive data such as; racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, data concerning health or sexual life, genetic/biometric data or criminal records OBU will use these data because:

- You have given OBU explicit consent to do so; and/or
- Processing is necessary for scientific or research in the public interest.

What type of data will Oxford Brookes University use?

We will use your personal data (your name and contact details) to contact you throughout the study. We will use research data which will include your age, gender, body mass index, other health conditions, medications, all relevant health data that will demonstrate your heart rhythm and function. We will keep a record of the questionnaire you complete and will audio record the interview. The interview will be transcribed into words and we will keep a copy of this without any identifying data related to you

Who will OBU share your data with?

The research team includes researchers from the Oxford Brookes University, who will have access to anonymised data you provide when attending clinic and in interviews and questionnaires; this data will be stored on Google drive. Only the research leads at Oxford Brookes University and will have access to your name and contact details after you reply to the invitation letter included into this recruitment pack.

Will OBU transfer my data outside of the UK?

No

What rights do I have regarding my data that OBU holds?

- You have the right to be informed about what data will be collected and how this will be used
- You have the right of access to your data (until data is pseudonymised)
- You have the right to correct data if it is wrong (until data is pseudonymised)
- You have the right to ask for your data to be deleted (until data is pseudonymised)
- You have the right to restrict use of the data we hold about you
- You have the right to data portability
- You have the right to object to the university using your data
- You have rights in relation to using your data automated decision making and profiling.

Where did OBU source my data from?

The clinical arrhythmia team have sent you this information sheet. Data is sourced from you, the participants, and from your medical file.

Are there any consequences of not providing the requested data?

There are no legal consequences of not providing data for this research. It is purely voluntary.

Will there be any automated decision making using my data?

There will be no use of automated decision making in scope of UK Data Protection and Privacy legislation.”

How long will Oxford Brookes University keep your data?

In line with Oxford Brookes policies data generated in the course of research must be kept securely in paper or electronic form for a period of time in accordance with the research funder or University policy.

Your personal information (name and contact details) will be kept up until three months after the study concludes. Your research data (anonymised information coming from an interview and/or a questionnaire) will be kept for 10 years after the study concludes.

Who can I contact if I have concerns?

In the event of any questions about the research study, please contact the researchers in the first instance (contact details in the study participant information sheet). If you have any concerns about the way in which the study has been conducted, contact the Chair of the Faculty Research Ethics Committee at FREC@brookes.ac.uk. For further details about information security contact the Data Protection Officer at: brookesdpo@brookes.ac.uk or the Information Management team on info.sec@brookes.ac.uk

Appendix 4: Study Consent forms

OXFORD BROOKES UNIVERSITY	Oxford University Hospitals NHS NHS Foundation Trust

Consent form V 1.9/09/11/2020. IRAS project number 275780. FREC ref. 02.2019.12 Principal Investigator: Angela Griffiths

Telephone: 01865 482612. Email: angela.griffiths-2017@brookes.ac.uk

CONSENT FORM FOR THE ATRIAL FIBRILLATION ABLATION QUALITY OF LIFE (AFAB-QOL) STUDY

Participant identification number: *If you agree, please initial box*

1. I confirm that I have read the information sheet dated 6th November 2020 (version 1.12 for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
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 understand and give permission for my medical notes to be accessed by the Principal Investigator where it is relevant to participation in this research	
4. I understand that de-identified study data may be accessed by the sponsor, regulatory authorities where it is relevant to my taking part in this research for audit and monitoring purposes.	
5. I agree to the Principal Investigator contacting my General Practitioner (GP) if necessary to do so during the study in the event of any incidental findings	
6. I agree to complete a baseline questionnaire before ablation and telephone questionnaires at 3 & 6 months after ablation	
7. I agree to take part in this study.	
8. I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	optional

Name of participant	*signature*	*date*
Name of person taking consent	*signature*	*date*

**1 copy for participant; 1 copy for researcher site file; 1 (original) to be kept in medical notes* (if participant is a patient).

OXFORD BROOKES UNIVERSITY	Oxford University Hospitals NHS NHS Foundation Trust

Principal Investigator: Angela Griffiths

Telephone: 01865 482612

Email: angela.griffiths-2017@brookes.ac.uk

Participant identification number:

CONSENT FORM Patient interviews

V1.10/09.11.2020. IRAS number 275780. FREC number F.02.2019.12

Atrial Fibrillation ablation Quality of Life (AFab-QoL) Study.

If you agree, please initial box

9. I confirm that I have read the information sheet dated 6th November 2020 (version1.12) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
10. 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.	
11. I understand and give permission for my medical notes to be accessed by the Principal Investigator, where it is relevant to participation in this research	
12. I understand that de-identified study data may be accessed by the sponsor, regulatory authorities where it is relevant to my taking part in this research for audit and monitoring purposes.	
13. I understand that details, including my age, sex, height and weight, other medical conditions, medications, ECG and results of my heart scan (echocardiogram) will be recorded as part of the study.	
14. I agree to the audio recording of the interview	
15. I agree to take part in this study.	
16. I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	

Signature

Print name

Date

Signature

Print name Date

Appendix 5: Participant Information Sheet

Oxford University Hospitals NHS
NHS Foundation Trust

OXFORD
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UNIVERSITY

Date : 6th November 2020

Version :1.12

FREC ID: F.02.2019.12

IRAS ID 275780

PARTICIPANT INFORMATION SHEET

Atrial Fibrillation ablation Quality of Life (AFab-QoL) Study

You are invited to participate in a Doctoral study about quality of life after atrial fibrillation ablation. You will already have been given information on the ablation procedure by your Arrhythmia Team. Before you decide, it is important for you to understand why the research is being done and what it would involve for you. Please take some time to read this information and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, do please ask us.

What is the purpose of the study?

We would like to find out about quality of life, symptoms and patient experiences after AF ablation, in individuals with a body mass index (BMI) of 25 or over. There is emerging evidence to suggest that lifestyle factors, especially body weight, are an important part of the management of AF. We are keen to find out if certain factors, such as BMI have an effect on how patients feel after ablation for AF. In order to investigate this further, we will select participants with a body BMI of 25 or over, whom we will invite to complete a quality of life and symptoms questionnaire before and after their ablation procedure. We will also invite a smaller number of participants to an interview after the ablation to explore their personal experiences of AF, the procedure and their views on lifestyle factors. Not all of the participants who agree to the interviews will be selected, as this sample will be smaller than those that complete the questionnaires. A range of individuals will be selected for the interview sample. This is a common method for this type of research.

Why have I been invited?

You have been invited to participate because you have symptomatic atrial fibrillation , requiring ablation. You would participate with 85 other participants in the questionnaire part of the study. The questionnaires will be completed before ablation and at 3- and 6- months afterwards. All patients included in this study have a body mass index of 25 or above. The questionnaires and interviews will all be conducted in the English language

Do I have to take part?

Your participation in this study is entirely voluntary. You will not be paid for taking part. You may withdraw from the study at any time, without giving a reason. Participation or withdrawal or not taking part in the study will have no impact on your treatment.

What will happen to me if I decide to take part?

If you agree to take part, you would be given 2 questionnaires before the ablation and at 3 months and 6 months after the procedure. The questionnaires will ask you about your symptoms and quality of life. The questionnaires will take about half an hour to complete each time. The questionnaires will be analysed using statistical software.

A smaller number of patients (up to 20) will also be invited to take part in a telephone interview, 6 months after ablation. The interview will ask participants about their experiences of AF, the ablation procedure and any lifestyle factors that may be linked to AF, such as weight management and exercise. The telephone interview will last approximately 1 hour. The interview will be conducted in English and with your permission and will be audio recorded. The telephone interviews will be transcribed and then analysed, and themes will be explored and identified. You will be asked for your consent for quotations from the interview to be used when the research is disseminated. This is optional. In addition to the questionnaires and interviews, information on your age, sex, BMI, other health conditions, current medications , electrocardiogram (ECG) and echocardiogram (heart scan) report to determine heart function.

Are there any possible disadvantages or risks from taking part?

Your time is needed to take part in the study. It is hoped that the questionnaires will take about 30 minutes to complete and the interviews 1 hour. It is possible that the questionnaires or interview may remind you of stressful experiences. If you become distressed you have the option to stop the questionnaire or interview and withdraw from the study. You may contact the Arrhythmia Nurses, for ongoing support or clinical advice and the Atrial Fibrillation Association, who are a national charity giving advice and psychological support to patients with AF. They may be contacted on 01789-867502, or email: info@afa.org.uk, or www.heartrhythmalliance.org.uk

You may find the Patient Advice and Liaison Service (PALS) helpful. PALS are based at The John Radcliffe Hospital and may be contacted on the telephone on 10865 221473 or email: PALS@ouh.nhs.uk

In the unlikely event that something unexpected, relevant to your care, is found during the study, depending the researcher will discuss this with you and will give you advice on how you can access relevant support. The researcher may ask to contact your clinical team or GP, with your permission to ensure you get the necessary support.

What are the possible benefits of taking part?

Whilst there are no direct benefits, from taking part in the study, there will be the opportunity for you to discuss your feelings, views and experiences of your AF and the ablation procedure. You may feel better for sharing these experiences. It is hoped that understanding more about these issues may improve how patients are informed and prepared for ablation.

Will my taking part in the study be kept confidential?

Oxford Brookes University is the sponsor for this study based in United Kingdom. We would be using information from you 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.

We will need to use information from your medical records] for this research project.

This information will include your initials, medical record number, name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

All information which is collected about you during the course of the project would be kept strictly confidential, within the limitations of the law. The results of the study would be reported without mentioning any names or identifying details. We would take every step to ensure your anonymity. The questionnaires will not contain any identifiable data. We will use a de-identified code which will not be linked to personal data. The interviews will be audio recorded transcribed and transcripts would be pseudonymised. Electronic data would be stored on Oxford Brookes Google Drive. Your personal details will be securely deleted, 3 months after the study has ended. The consent forms, digital recordings, and transcripts would be kept for a minimum of 10 years, in accordance with the Oxford Brookes University Code of Practice for Academic Research.

The site and the sponsor may also be given access to de-identified data for monitoring and auditing purposes. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways 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 personally identifiable information possible.

In addition, the researchers will always make every effort to protect your anonymity by adopting the following measures:

After giving verbal informed consent to take part over the telephone, the digital consent form completed by the researcher and the audio recording of the informed consent will contain your unique ID number. The audio recording will be pseudonymised. The personal details will not be linked to the research data

The OBU storage mechanisms will not link your personal details to the research data that is collected

The digital recording of the consent will be encrypted and stored in a double password protected OBU secure Google drive.

A single file linking your de-identified code number to your name will be stored on a separate password protected location which may be accessed by the principal investigator only.

The study data will be stored for 10 years and personal data will be stored in a separate place for 3 months after the study has ended

Health and care research should serve the public interest, which means that we must demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used? You

can find out more about how we use your information

www.hra.nhs.uk/information-about-patients/

https://www.brookes.ac.uk/it/information-management/gdpr/ or by contacting the information security management office by telephoning 01865 484354 or emailing info.sec@brookes.ac.uk .

What will happen to the results of this study?

The results of this study will be published in a scientific journal and may be presented at conferences. To access a summary of research please email the Principal Investigator after the end of the study.

Feedback to the Arrhythmia Team , in the form of a study report and presentation, will be via the conventional multi-disciplinary team meetings at the OUHFT. The research being undertaken will also contribute to the fulfilment of an educational requirement for a Doctorate in Nursing at Oxford Brookes University.

What if there is a problem?

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, you should contact Kellie Tune, Chair of Faculty Research Ethics Committee at Oxford Brookes University . Email: frec@brookes.ac.uk

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). You may contact our Information Compliance Officer via email at info.sec@brookes.ac.uk or by telephoning 01865 484354.

How have patients and the public been involved in this study?

The Cardiac Directorate Patient Involvement Panel has been involved in reviewing the Participant Information Sheet, consent form, study design and the interview schedule.

Who is organising and funding the study?

The study is organised by Oxford Brookes University. The Chief Investigator of this study is Professor Eila Watson, who is a researcher at Oxford Brookes University. The Principal Investigator is Angela Griffiths, who is a Doctorate in Nursing student at Oxford Brookes University and an Arrhythmia Nurse at The John Radcliffe Hospital. This research is part of Angela's Doctoral studies. No payment will be given for her role in the study. If you wish to know more about any aspect of the study, please contact Angela Griffiths, whose details are found at the end of the document. There is no direct funding attached to this study.

Who has reviewed the study?

All research at the University and in NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by Oxford Brookes Faculty Research Ethics Committee (ref: F.02.2019.12, approved date 07/09/2020), Cambridge South Research Ethics Committee (ref: 275780 date) and Health Research Authority (HRA), (ref:275780 date….)

What should I do if I wish to take part?

If you would like to join this study, pleased complete the paperwork, including the consent form and baseline questionnaire and bring with you on the day of the ablation. If you wish to ask any questions, please contact Angela Griffiths in the following ways:

telephone 01865 482612 email Angela on the following email address:

angela.griffiths-2017@brookes.ac.uk

Finally, we will ask if you are willing to be contacted about other ethically approved research studies for which you may be suitable. By agreeing to be contacted this does not oblige you in any way to participate in any further studies.

Thank you for reading this information and
for the consideration to take part

Appendix 6: Interview Schedule

Oxford University Hospitals NHS
NHS Foundation Trust

OXFORD
BROOKES
UNIVERSITY

Interview Schedule for the Atrial Fibrillation ablation Quality of Life(AFab-QoL) Study Topic Guide

Within the interview I would like to discuss the following topics:

Experiences of AF

Quality of life

Symptoms

Impact on work & daily activities

Expectations of the ablation procedure

Was there adequate information ?

Were there any unexpected results and consequences ?

Was there an improvement in quality of life and symptoms?

Experiences of symptoms post ablation-**tell me about your time in the 6 months after ablation ?**

What was your experience of the blanking period 3 months post ablation ?

Did you need medical interventions, drugs, cardioversion?

Were there any emergency department visits?

What contact did you have with the Arrhythmia Nurses ?

How is your general well-being ?

Health behaviour

Are you aware of the impact of lifestyle on AF development, progression and ablation outcomes ?

Have you made any changes to your health, eg. smoking, diet, exercise, alcohol ?

Tell me about your lifestyle, related to health, exercise ?

It is anticipated that the interview will last between 45-60 mins and will take place on the telephone at 6 months post ablation.[1]

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[1]

Appendix 7: Copy of the SF-36 Questionnaire & the Patient Perception Arrhythmia Questionnaire

Atrial Fibrillation ablation Quality of Life (AFab-QoL) Study

Patient questionnaire Study number:

Date:

Q: What is your gender identity?
A: I identify as (a) man (b) woman (c) other (with option to self-describe) (d) prefer not to say e) prefer to self-describe……………………….(please circle your answer).

Name of Researcher: Angela Griffiths *If you agree, please tick the box*

17. I confirm that I have read the information sheet dated September 2020 (version 1.9) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
18. 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.	
19. I consent to the study	

Atrial Fibrillation ablation Quality of Life(AFab-QoL) Study

SF-36 questionnaire

Choose one option for each questionnaire item.1. In general, would you say your health is:

☐ 1.excellent
☐ 2.very good
☐ 3.good
☐ 4.fair
☐ 5.poor

2. Compared to one year ago, how would you rate your health in general now?

☐ 1.much better than one year ago
☐ 2.somewhat better now than one year ago
☐ 3.about the same
☐ 4.somewhat worse now than one year ago
☐ 5.much worse now than one year ago

The following items are about activities you might do during a typical day.

Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing **several** flights of stairs	1	2	3
7. Climbing **one** flight of stairs	1	2	3
8. Bending, kneeling, or stooping	1	2	3
9. Walking **more than a mile**	1	2	3
10. Walking **several hundred yards**	1	2	3
11. Walking **one hundred yards**	1	2	3
12. Bathing or dressing yourself	1	2	3

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	Yes	No
13. Cut down the **amount of time** you spent on work or other activities	1	2

14. **Accomplished less** than you would like	1	2
15. Were limited in the **kind** of work or other activities	1	2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	yes	no
17. Cut down the **amount of time** you spent on work or other activities	1	2
18. **Accomplished less** than you would like	1	2
19. Didn't do work or other activities as **carefully** as usual	1	2

20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

	1 - Not at all
	2 - Slightly
	3 - Moderately
	4 - Quite a bit
	5 – Extremely

21. How much **bodily** pain have you had during the **past 4 weeks**?

	1	None
	2	Very mild
	3	Mild
	4	Moderate

	5	Severe
	6	Very severe

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

	1	Not at all
	2	A little bit
	3	Moderately
	4	Quite a bit
	5	Extremely

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks**...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6

30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the **past 4 weeks**, how much of the time has **your physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

	1	All of the time
	2	Most of the time
	3	Some of the time
	4	A little of the time
	5	None of the time

How TRUE or FALSE is **each** of the following statements for you.

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

Appendix 8: Patient Perception Questionnaire

1. In the past month, how often on average did your fast heart rhythm occur? (tick one answer only)

9	Three or more times daily
8	Twice daily
7	Daily or almost daily
6	4-5 times a week
5	2-3 times a week
4	About 1 time a week
3	About 2 times in the month
2	About 1 time in the month
1	About 2-4 times a year
0	Not at all

2. In the past month, how long on average did any episodes of the fast heart rhythm last?

(tick one answer only)

0	Not applicable
1	A few seconds
2	About 1-5 minutes
3	About 5-10 minutes
4	About 11-15 minutes
5	About 20-30 minutes

6	About 30-40 minutes
7	About 45 minutes to one hour
8	Longer than one hour

Symptom List

			(b) If present, how much did it bother you? (tick appropriate box on each line)				
(a) Have you had any of these symptoms with your fast heart rhythm in the last 4 weeks? (tick “yes” or “no” on each line)	NO	YES	Not at all	A little bit	Moderately bothersome	Quite a bit	Extremely bothersome
Heart fluttering	0	1	0	1	2	3	4
Heart skipping	0	1	0	1	2	3	4
Blurred vision	0	1	0	1	2	3	4
Pounding feeling in neck	0	1	0	1	2	3	4
Light-headedness/dizziness	0	1	0	1	2	3	4
Headache	0	1	0	1	2	3	4
Passing a lot of urine	0	1	0	1	2	3	4

Sweating	0	1		0	1	2	3	4
Nausea	0	1		0	1	2	3	4
Fatigue/ no energy	0	1		0	1	2	3	4
Loss of appetite	0	1		0	1	2	3	4
Heart racing	0	1		0	1	2	3	4
Trouble concentrating	0	1		0	1	2	3	4
Passing out	0	1		0	1	2	3	4
Hard to catch breath	0	1		0	1	2	3	4
Feeling warm/flushed	0	1		0	1	2	3	4
Chest pressure when heart is racing	0	1		0	1	2	3	4
Trouble sleeping	0	1		0	1	2	3	4
Other:	0	1		0	1	2	3	4

The following questions ask specifically about how your fast heart rhythm has affected your activities. Please go over the activities below and mark how much you were limited due to **your fast heart rhythm** over the past 4 weeks.

3. During the past 4 weeks, how much did your fast heart rhythm interfere with the following things? (tick one box on each line)

	Not at all	A little bit	Moderately	Quite a bit	Extremely
Your mood	0	1	2	3	4
Your ability to walk or move about	0	1	2	3	4
Your sleep	0	1	2	3	4
Your normal work (including both work outside of the home and housework)	0	1	2	3	4
Your recreational activities	0	1	2	3	4
Your enjoyment of life	0	1	2	3	4
Your social activities (like visiting friends or close relatives, going out for dinner, or to the movies)	0	1	2	3	4
Your ability to drive a car	0	1	2	3	4
Your relationship with spouse/partner or boyfriend/girlfriend	0	1	2	3	4

Your sexual relationship with spouse/partner or boyfriend/girlfriend	0	1	2	3	4

4. During the past 4 weeks, how many days did you miss work or school due to your fast heart rhythm? Please circle the words "Not Applicable" if you do not work or are not in school at this time.

   Not applicable days ☐☐

5. During the past 4 weeks, how many days did you cut down on the things you usually do because of your fast heart rhythm?

   ☐☐ days

Patient Perception of Arrhythmia Questionnaire

AF QoL study questionnaire V1.6/30.10.2020. IRAS number 275780. FREC number F.02.2019.12

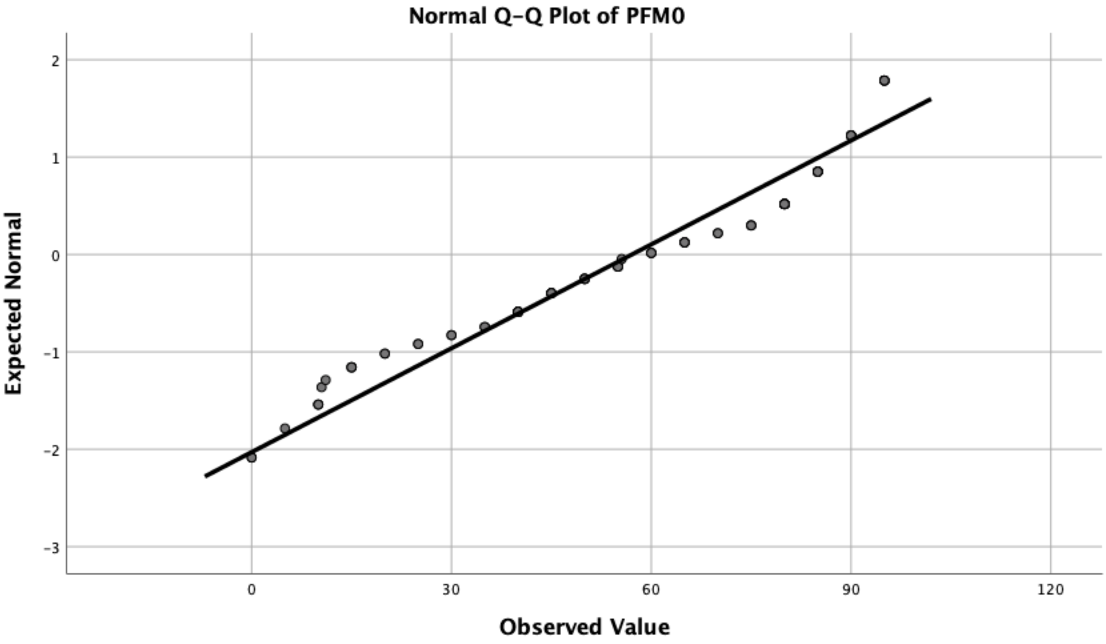
Appendix 9: Test statistics- BMI at three timepoints using Friedman’s test

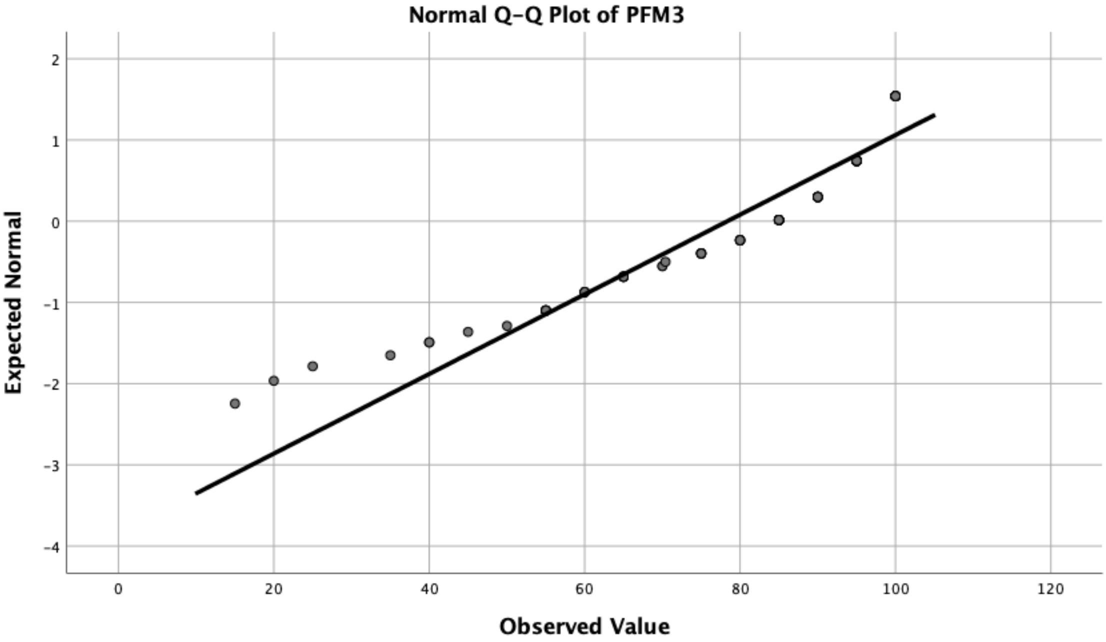
N	81
Chi-Square	3.480
Degrees of freedom	2
p value	<0.176
95% confidence interval	0.071-0.226

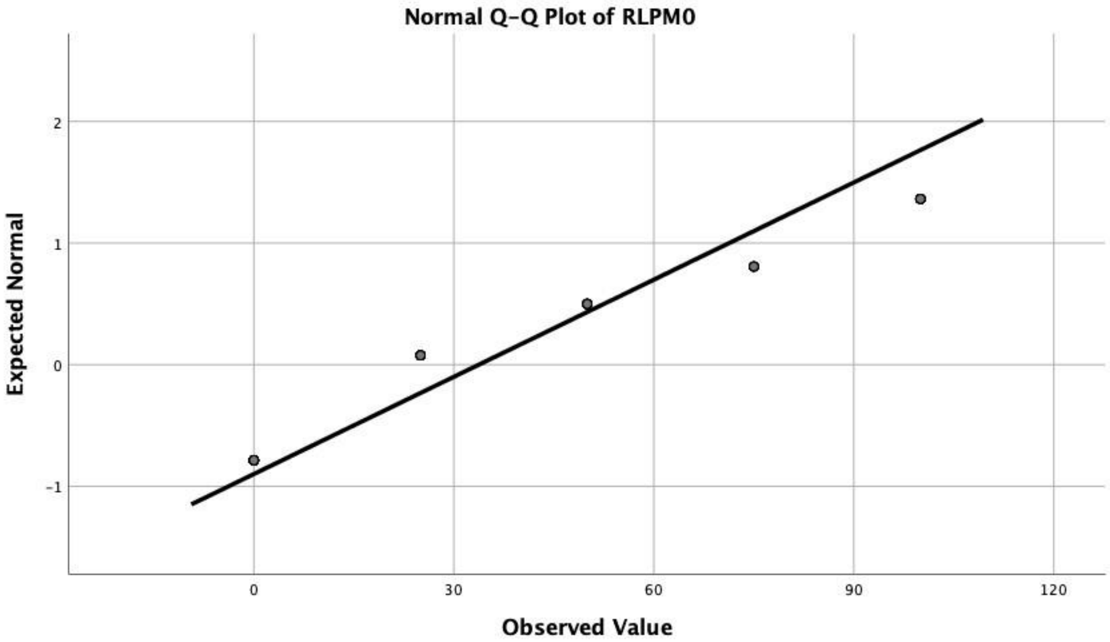
Appendix 10: Test statistics for Anti-arrhythmic drugs using Cochran’s Q test

n	82
Cochran’s Q	18.28[a]
degrees of freedom	2
p value	<.0005 (<0.000082)
95% confidence interval	0-0.036

Appendix 11: QQ Plots for the SF-36 QoL domain scores



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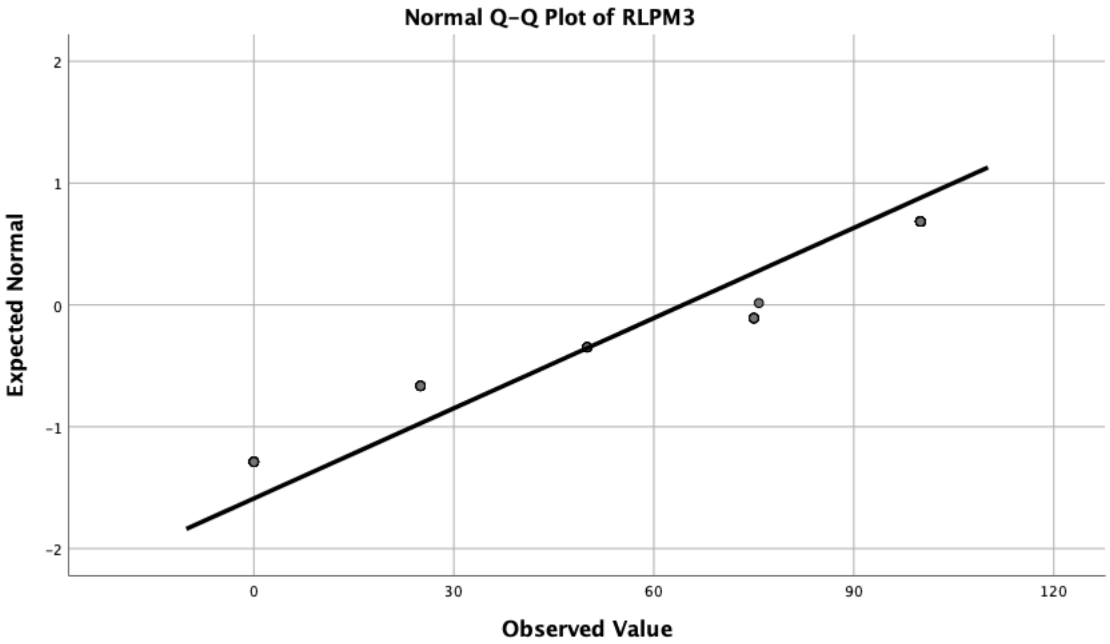
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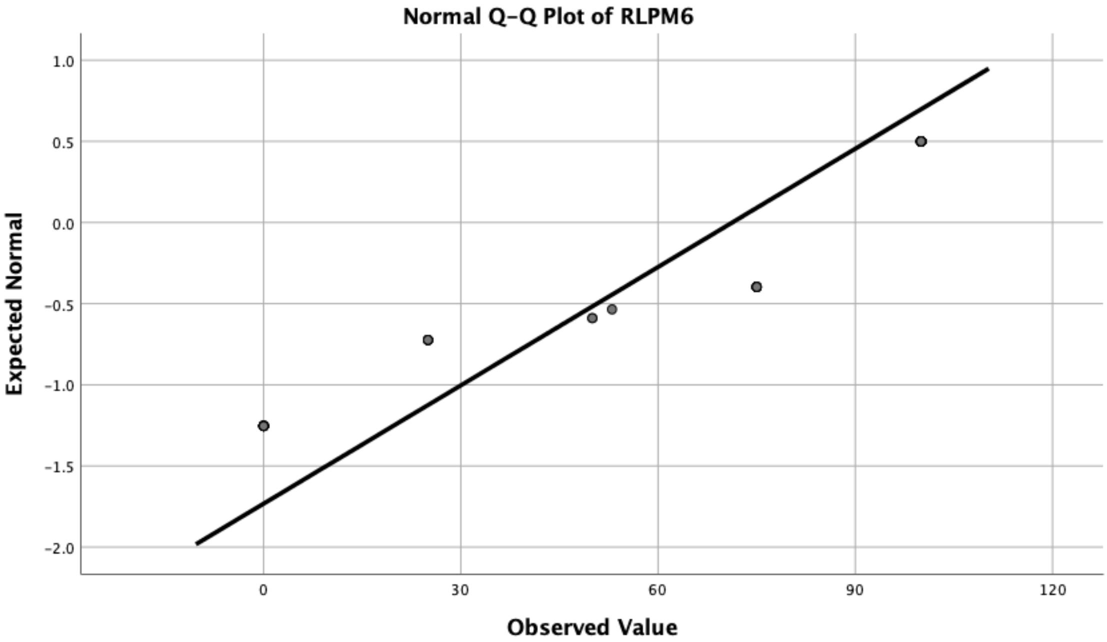
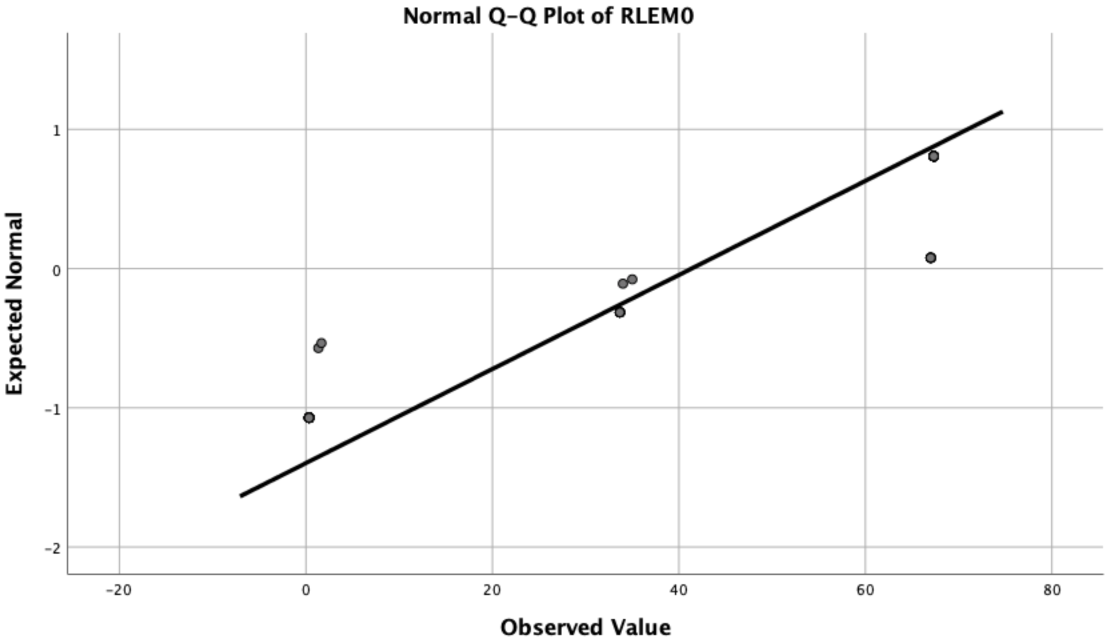

Normal Q-Q Plot of RLPM6
Expected Normal
1.0
0.5
0.0
-0.5
-1.0
-1.5
-2.0
0
30
60
90
120
Observed Value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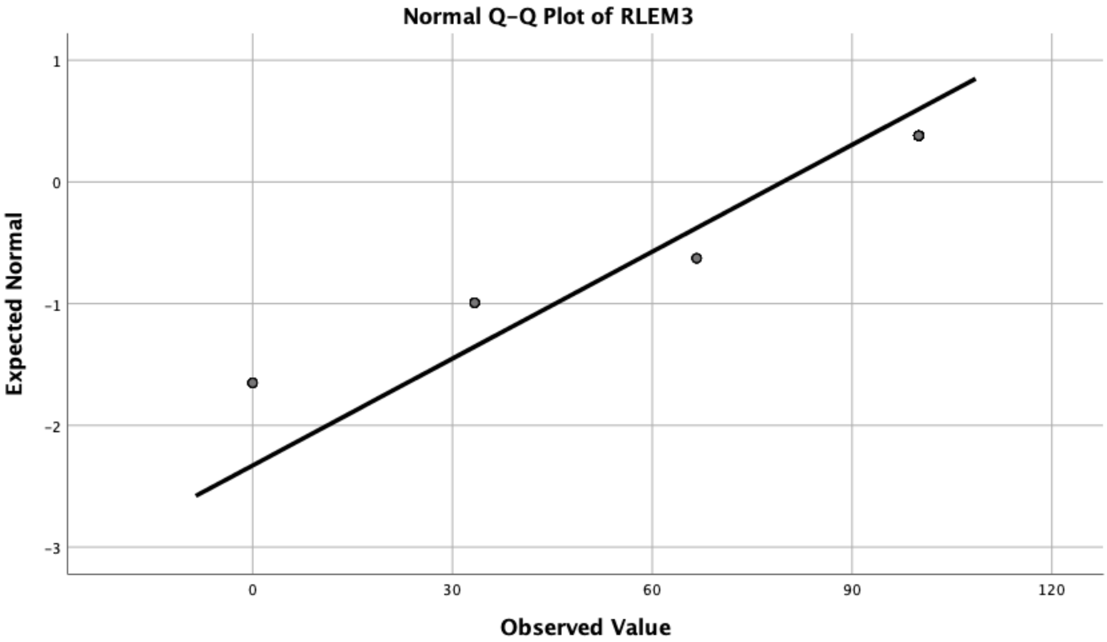
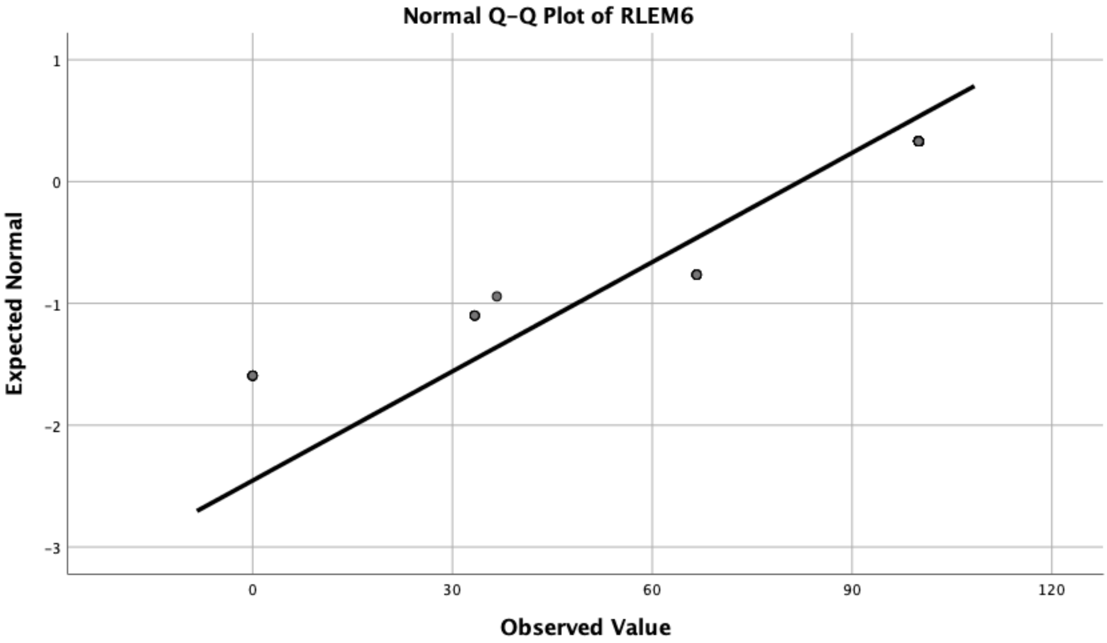
Expected Normal
1
0
-1
-2
-20
0
20
40
60
80
Observed Value


Normal Q-Q Plot of RLEM3
Expected Normal
1
0
−1
−2
−3
0
30
60
90
120
Observed Value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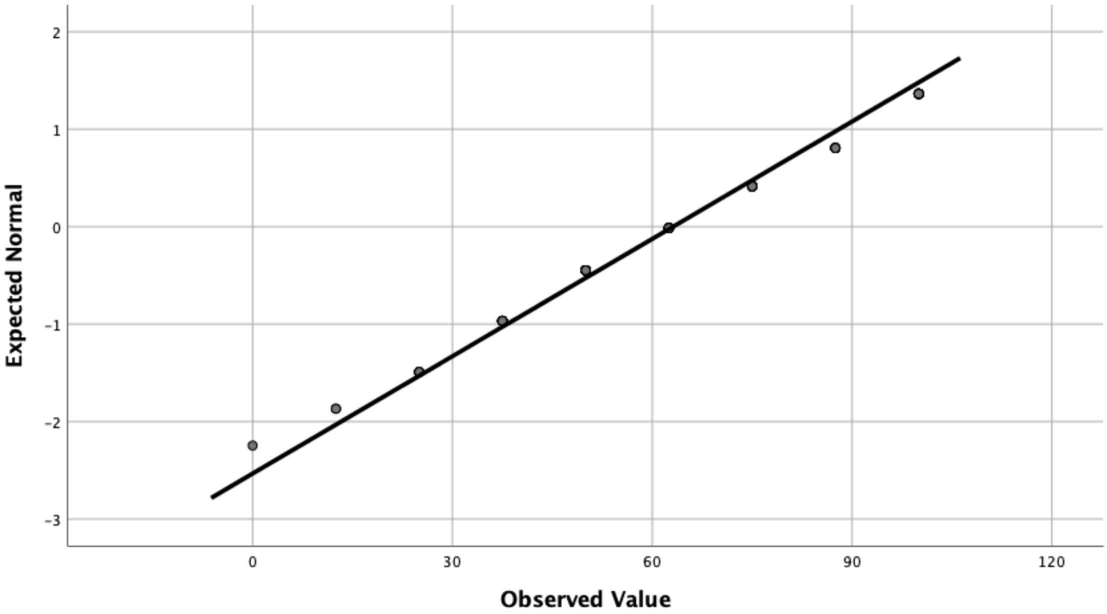
Expected Normal
1
0
−1
−2
−3
0
30
60
90
120
Observed Value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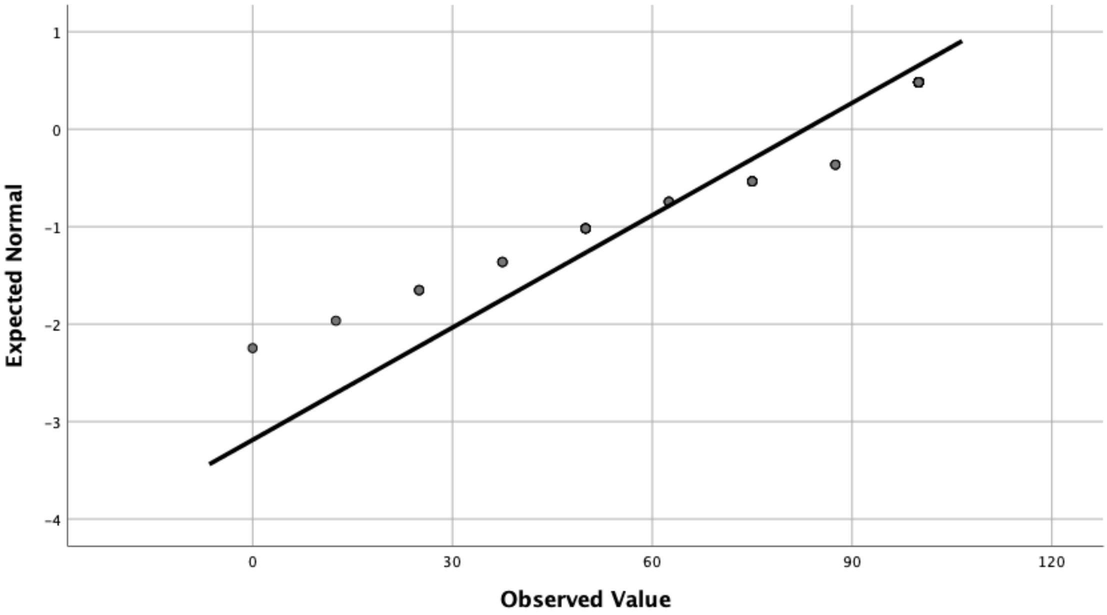
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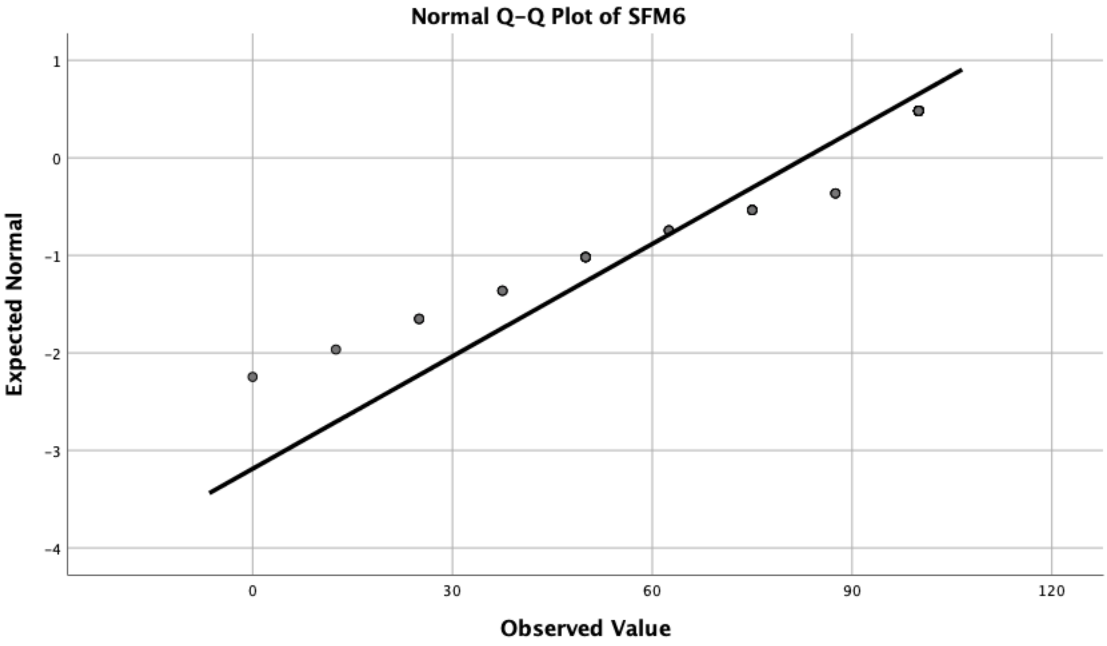
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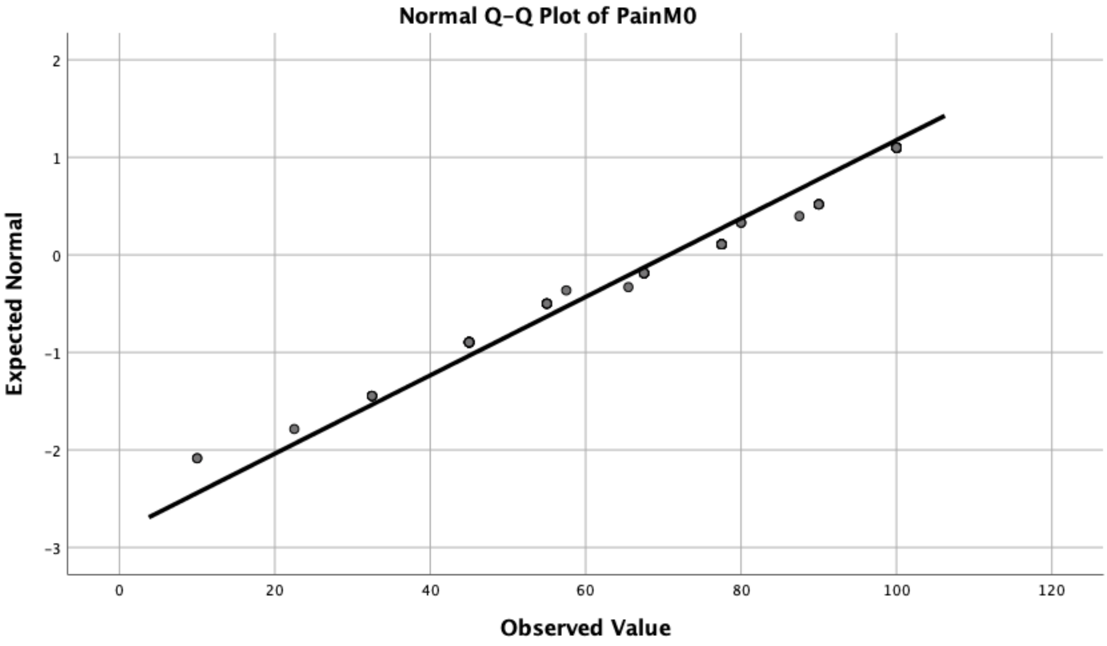
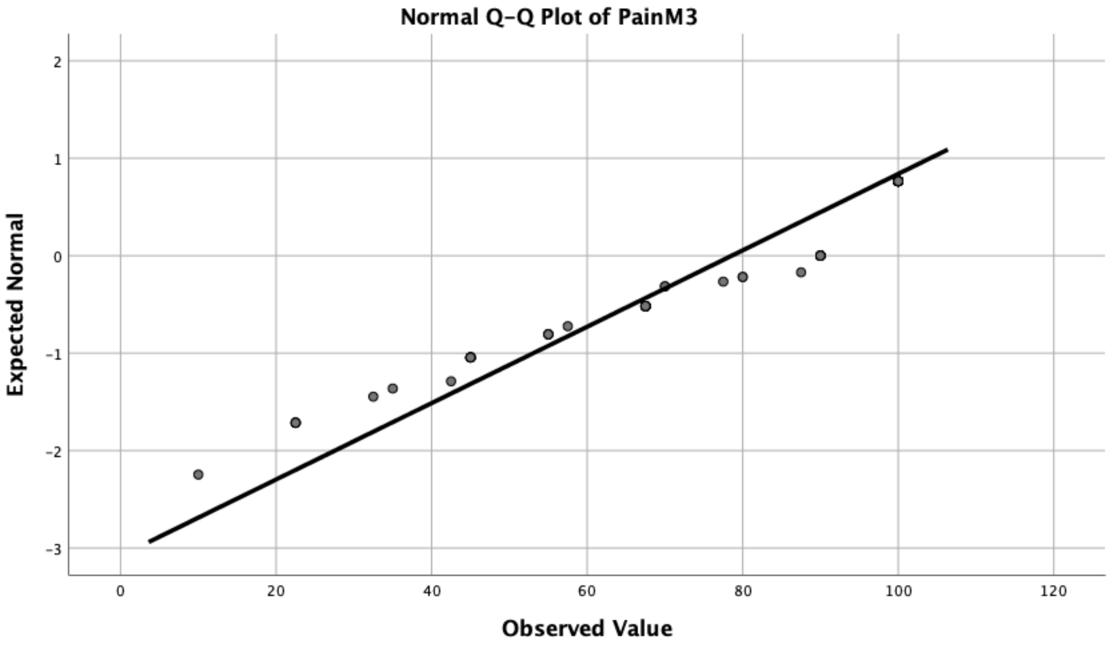
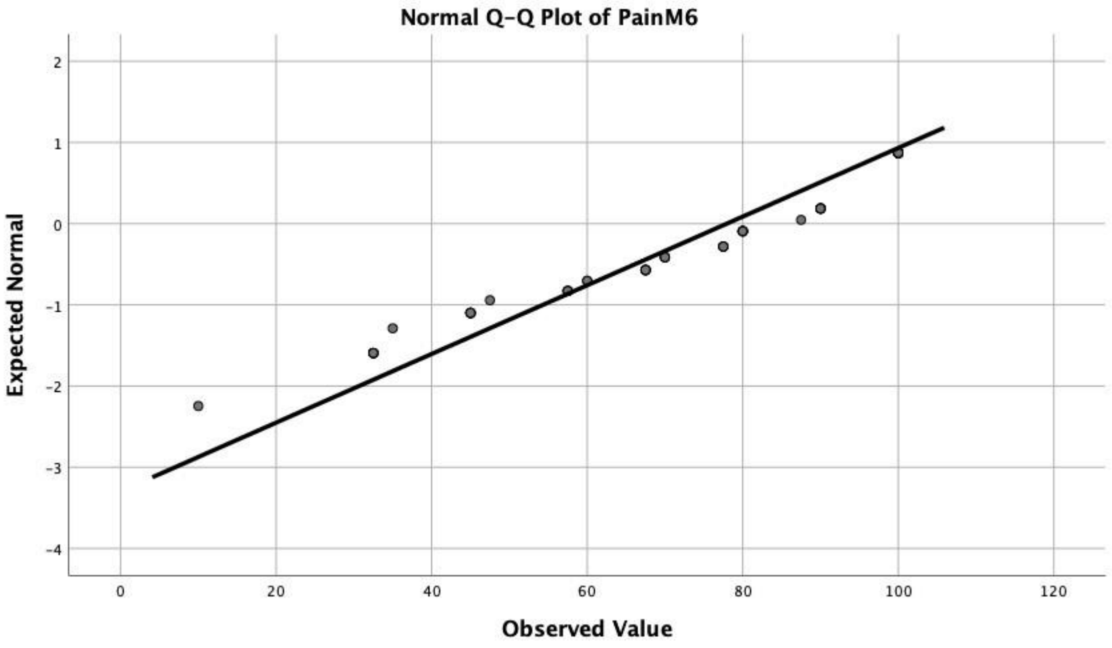
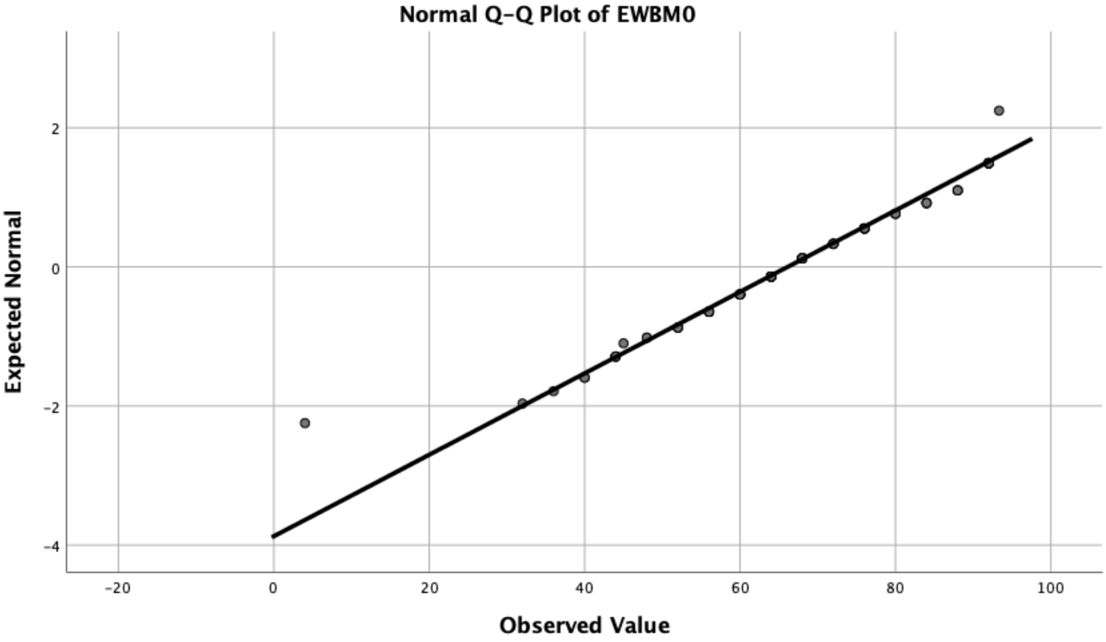
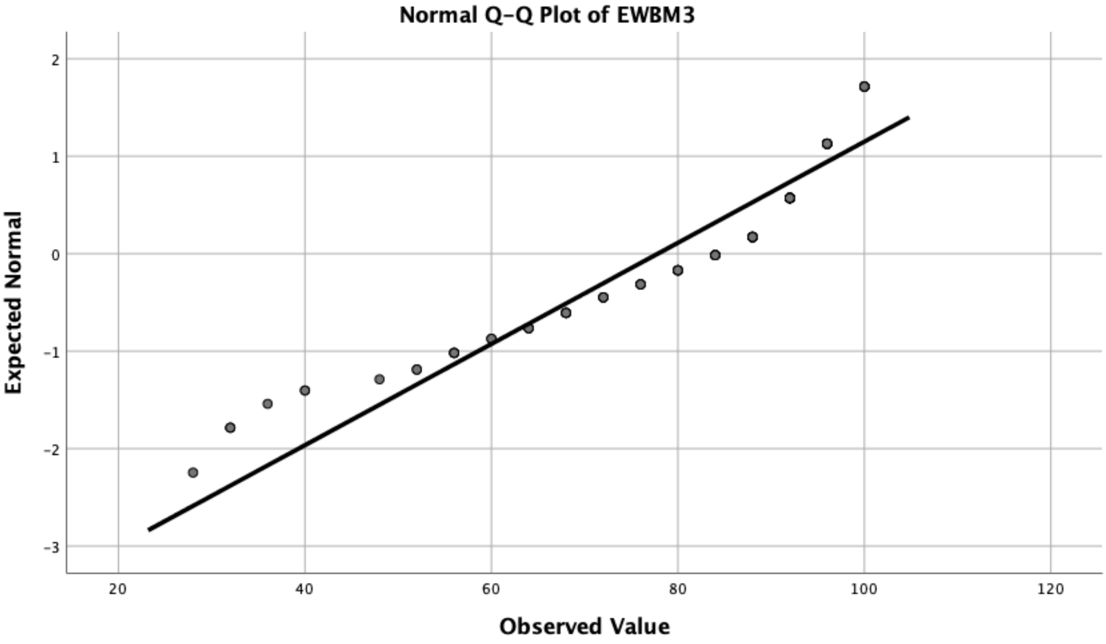
Expected Normal
1
0
-1
-2
-3
-4
0
30
60
90
120
Observed Value


Normal Q-Q Plot of PainM0
Expected Normal
2
1
0
-1
-2
-3
0
20
40
60
80
100
120
Observed Value


Normal Q-Q Plot of PainM3
Expected Normal
2
1
0
−1
−2
−3
0
20
40
60
80
100
120
Observed Value


Normal Q-Q Plot of PainM6
Expected Normal
2
1
0
−1
−2
−3
−4
0
20
40
60
80
100
120
Observed Value


Normal Q-Q Plot of EWBM0
Expected Normal
2
0
-2
-4
-20
0
20
40
60
80
100
Observed Value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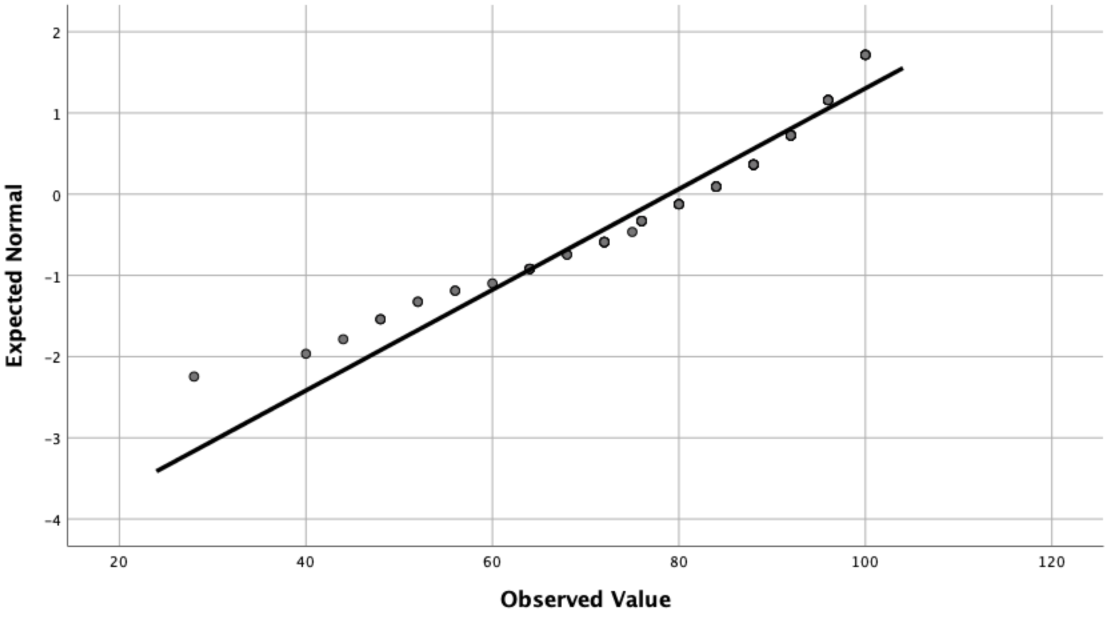
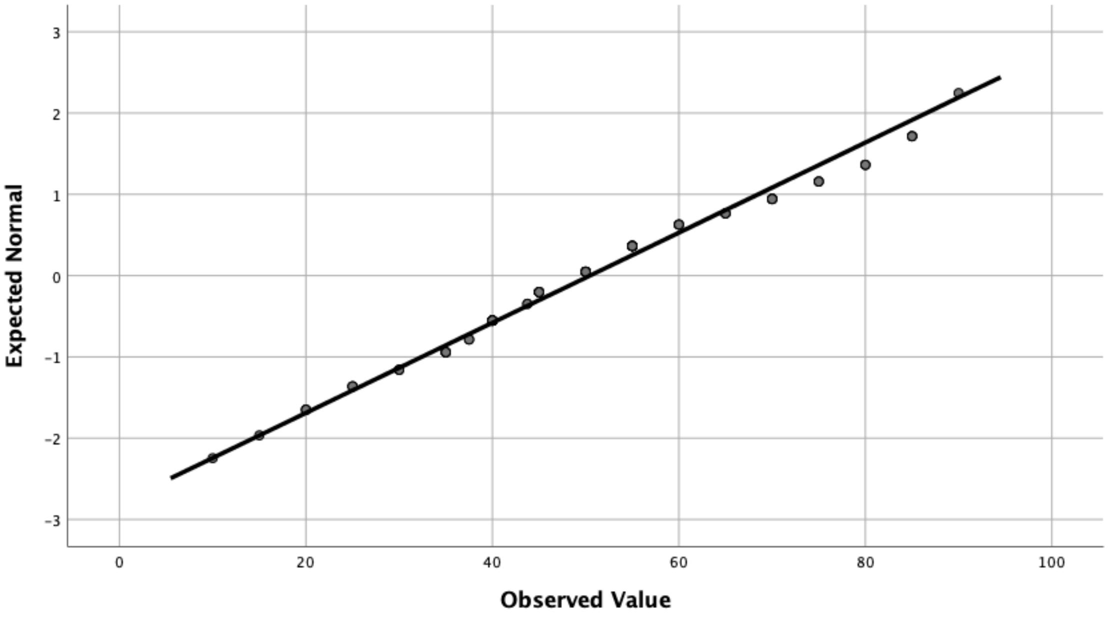
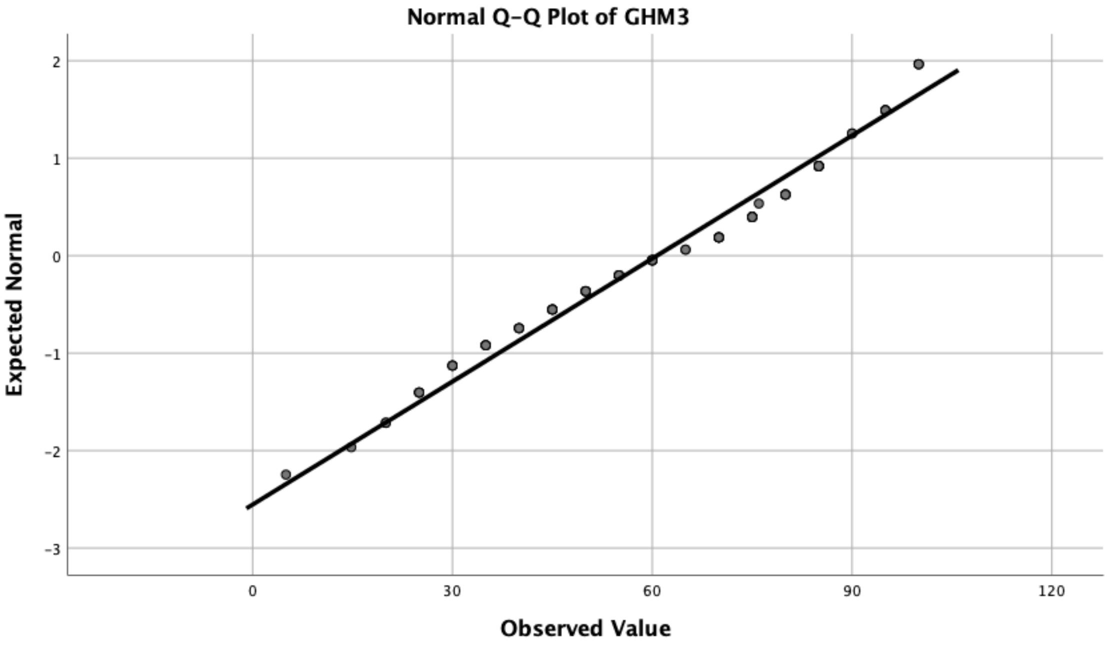
Expected Normal
2
1
0
-1
-2
-3
20
40
60
80
100
120
Observed Value

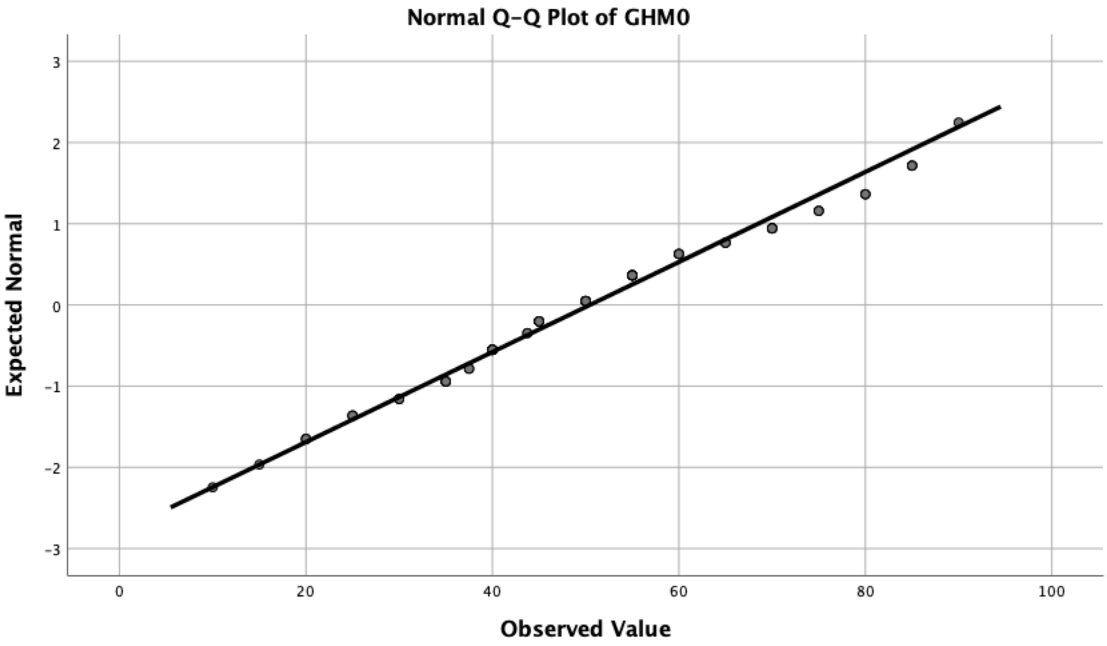


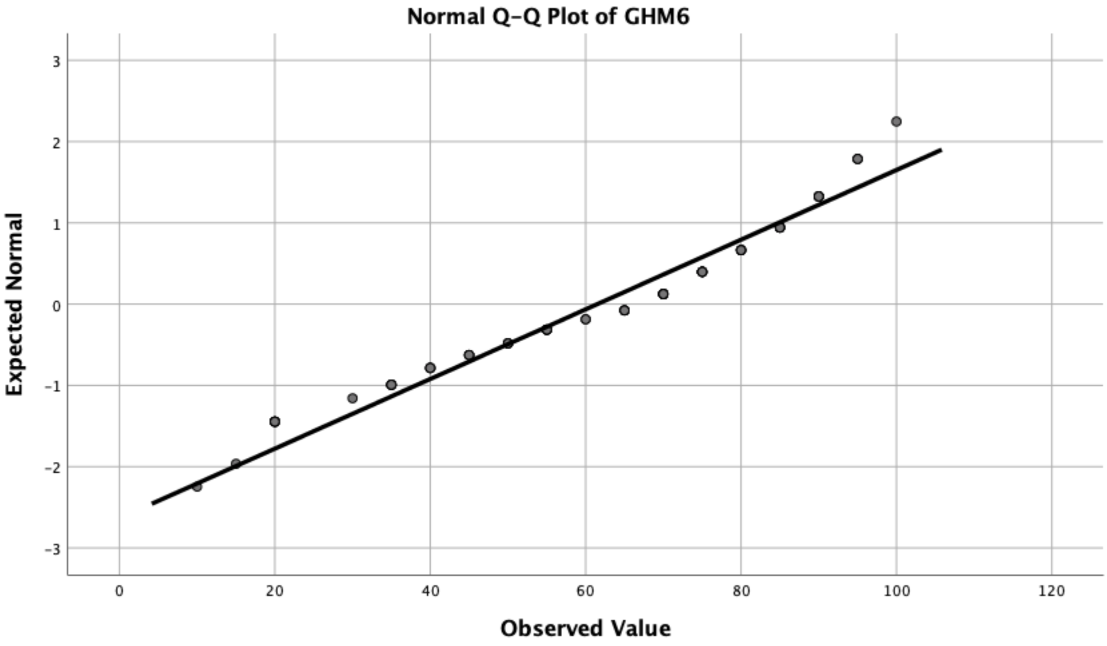
Normal Q-Q Plot of EWBM6

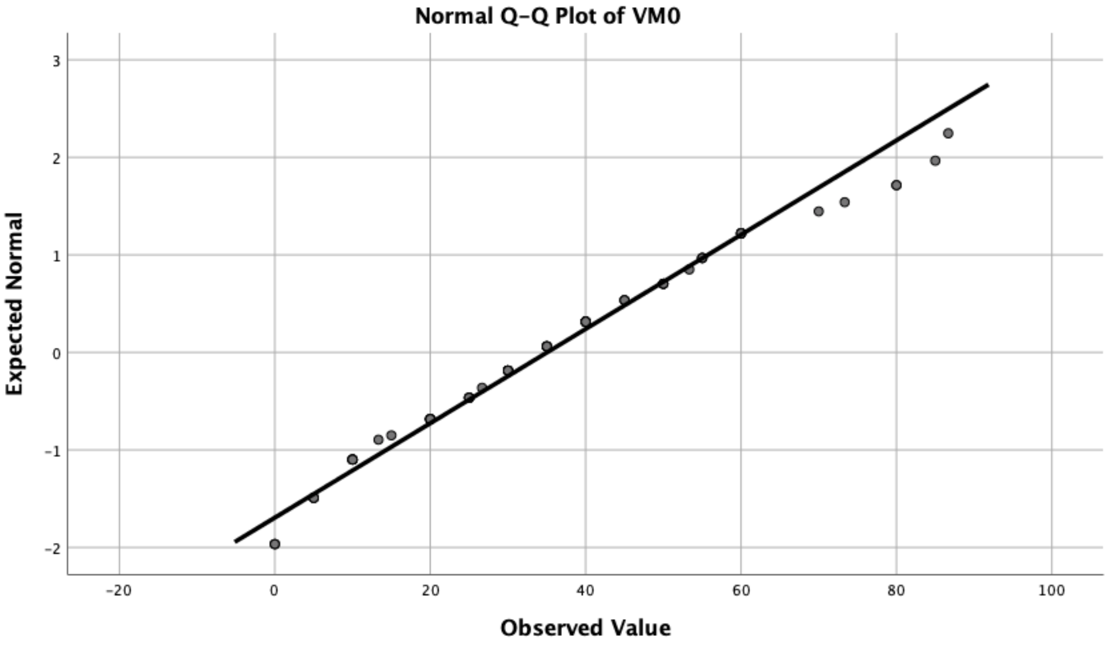


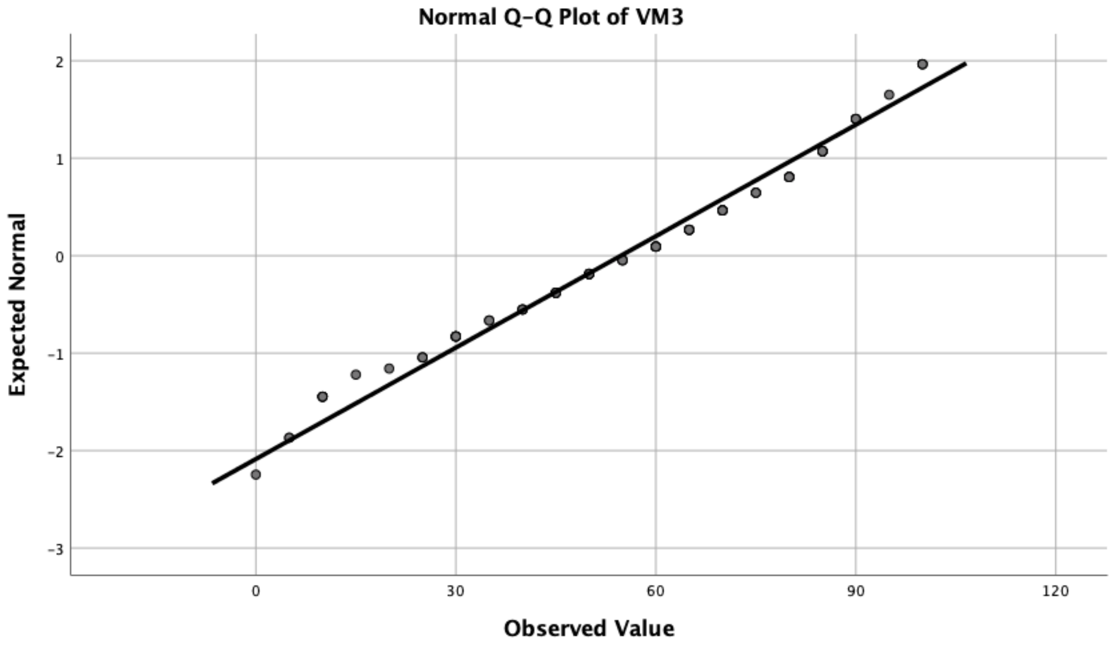
Normal Q-Q Plot of GHM0

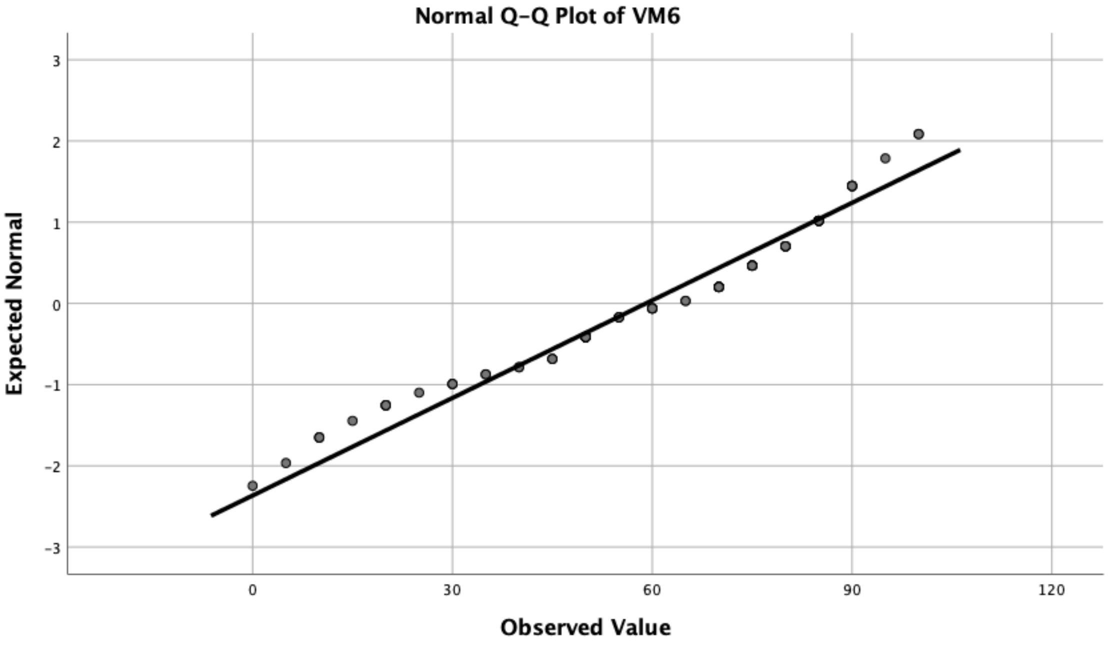

Normal Q-Q Plot of GHM3
Expected Normal
Observed Value
2
1
0
−1
−2
−3
0
30
60
90
120


Normal Q-Q Plot of GHM0
Expected Normal
Observed Value
3
2
1
0
−1
−2
−3
0
20
40
60
80
100


Normal Q-Q Plot of GHM6
Expected Normal
3
2
1
0
-1
-2
-3
0
20
40
60
80
100
120
Observed Value


Normal Q-Q Plot of VM0
Expected Normal
3
2
1
0
-1
-2
-20
0
20
40
60
80
100
Observed Value


Normal Q-Q Plot of VM3
Expected Normal
2
1
0
-1
-2
-3
0
30
60
90
120
Observed Value


Normal Q-Q Plot of VM6
Expected Normal
3
2
1
0
-1
-2
-3
0
30
60
90
120
Observed Value

Appendix 12: General Health. Statistical significance of the model ANOVAa

Model- Gen health	**Sum of squares**	**df**	**Mean square**	***F***	**Sig**
Regression	438967.866	7	62709.695	7.292	$.000^b$
Residual	567619.972	66	8600.303		
total	1006587.84	73			

a. Dependent variable-general health at 6 months post ablation

b. Predictors: (Constant), month 6 rhythm control, LAVI, baseline BMI, age, gender, classification of AF, general score at baseline

Meaning of the ANOVA table

Cell name	**Cell meaning**
F	indicates we are comparing to an F distribution (F-Test)
7 in (7,66)	Indicates the regression (model) degrees of freedom (df)
66 in (7,66)	Indicates the residual (error) degrees of freedom (df)
7.292	Indicates the obtained value of the F-statistic (obtained F value)
p<.0005	Indicates the probability of obtaining the observed F-value if the null hypothesis is true

Appendix 13: Vitality- Statistical significance of the model

ANOVA[a]

Model-vitality	**Sum of squares**	**df**	**Mean square**	***F***	**Sig**
Regression	273218.770	7	39031.253	5.758	.000[b]
Residual	447365.014	66	6778.258		
total	720583.784	73			

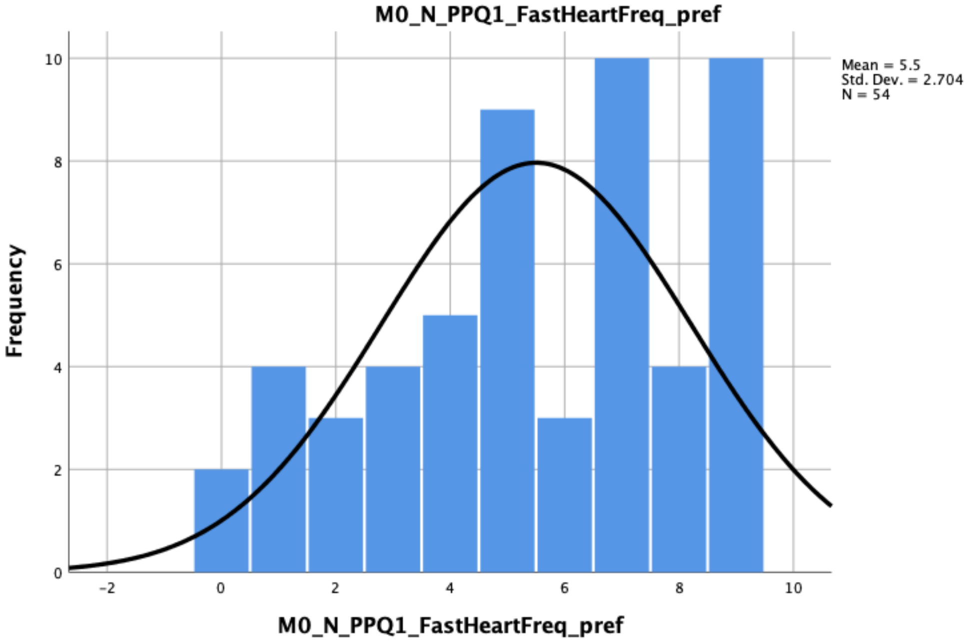
a. Dependent variable-Vitality at 6 months post ablation

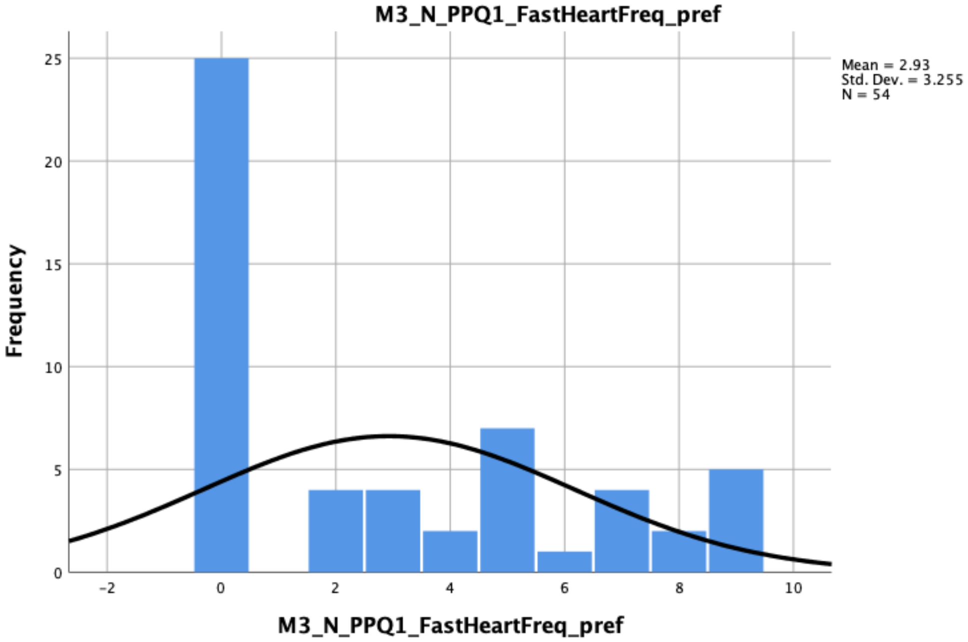
b. Predictors: (Constant), month 6 rhythm control, LAVI, baseline BMI, age, gender, classification of AF, vitality score at baseline

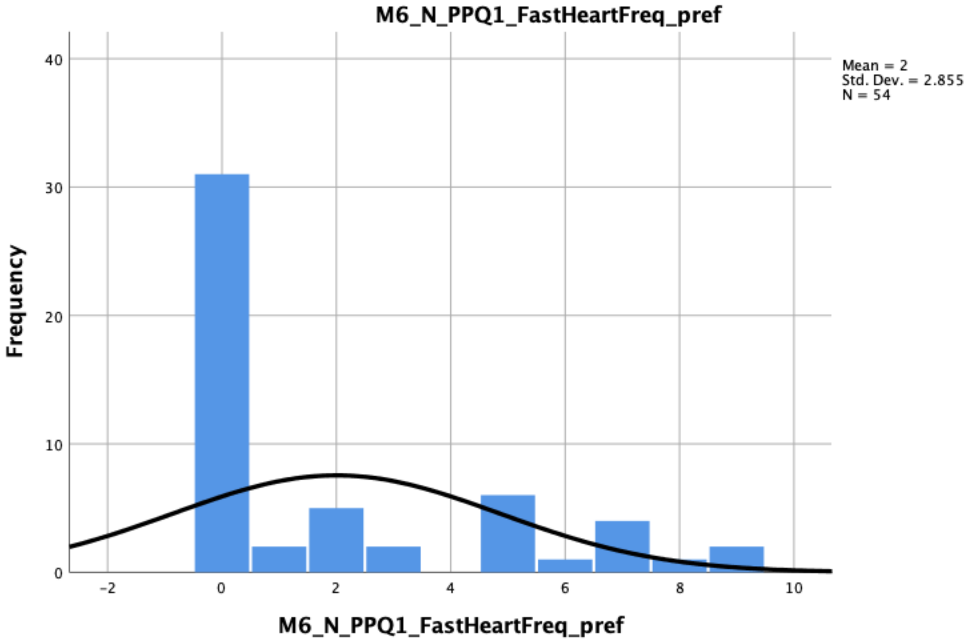
Meaning of the ANOVA table

Cell name	**Cell meaning**
F	indicates we are comparing to an F distribution (F-Test)
7 in (66)	Indicates the regression (model) degrees of freedom (df)
66 in (7,66)	Indicates the residual (error) degrees of freedom (df)
5.758	Indicates the obtained value of the F-statistic (obtained F value)
p<.0005	Indicates the probability of obtaining the observed F-value if the null hypothesis is true

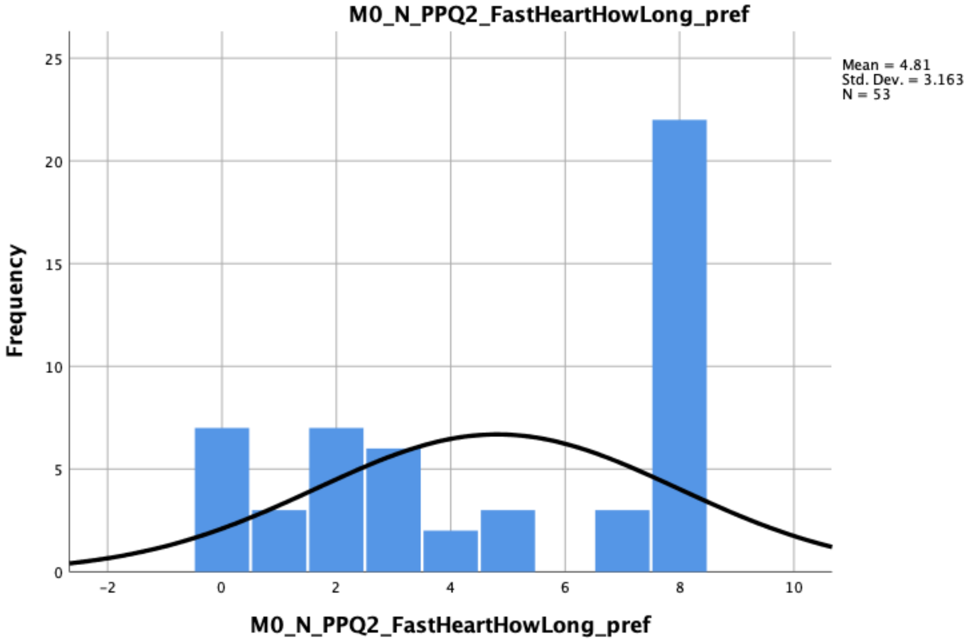
Appendix 14: Examples of histograms on tests for normal distribution on the PPQ Question 1-frequency of AF

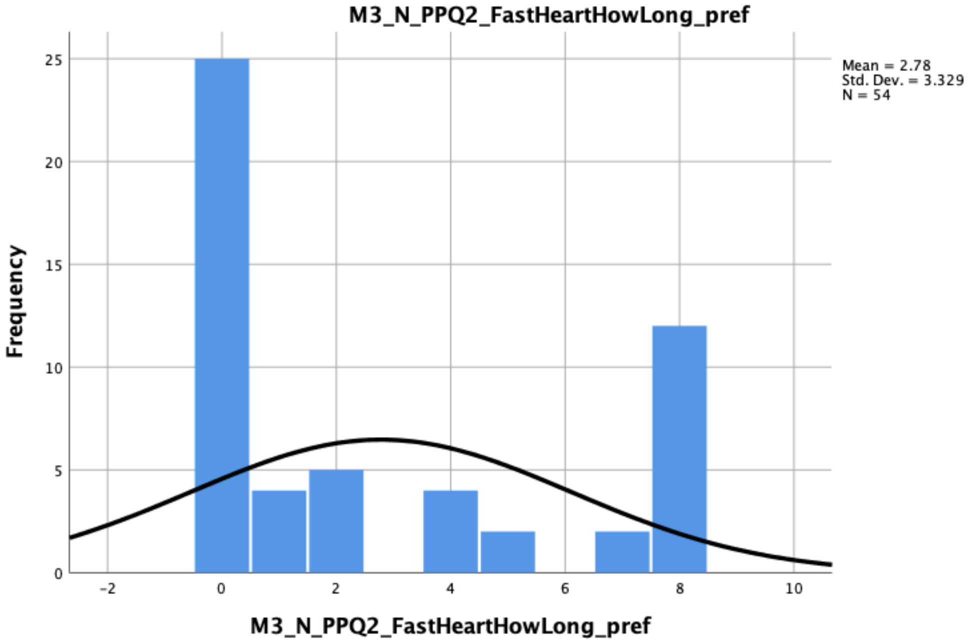


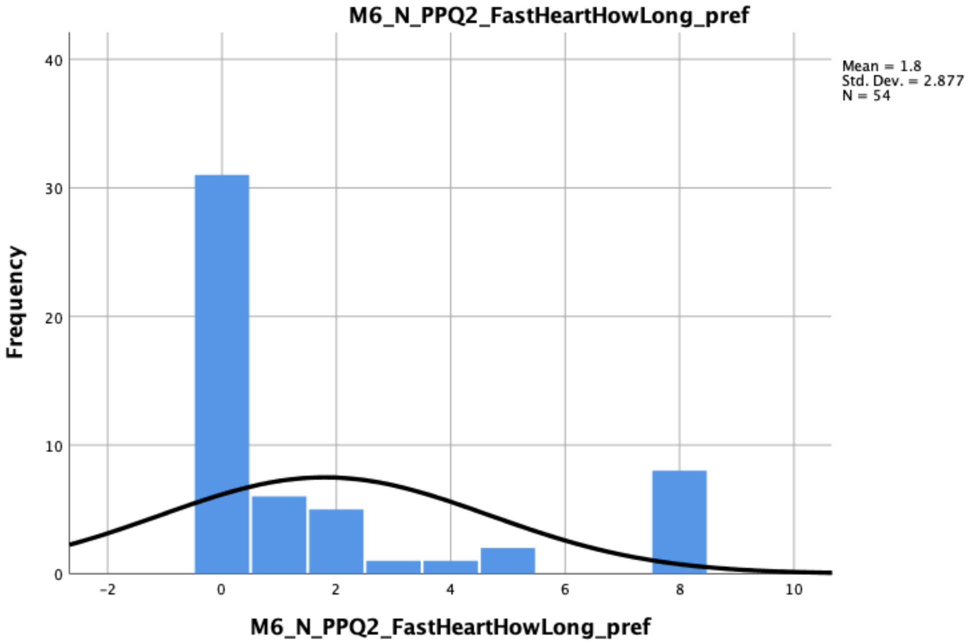



M6_N_PPQ1_FastHeartFreq_pref
Frequency
40
30
20
10
0
-2
0
2
4
6
8
10
M6_N_PPQ1_FastHeartFreq_pref
Mean = 2
Std. Dev. = 2.855
N = 54

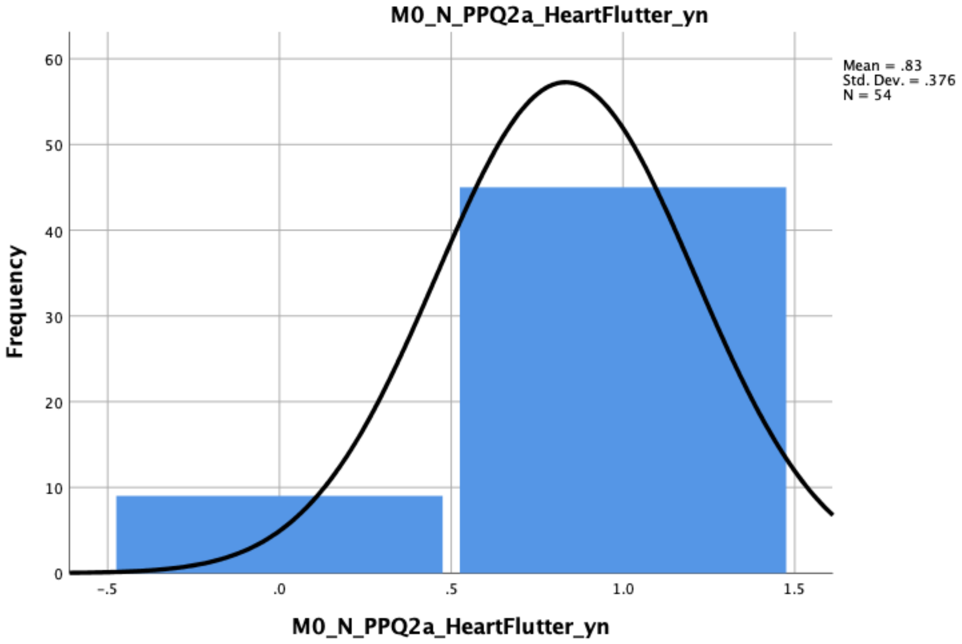
Appendix 15: Examples of histograms on tests for normal distribution om the PPAQ Question 2- duration of AF

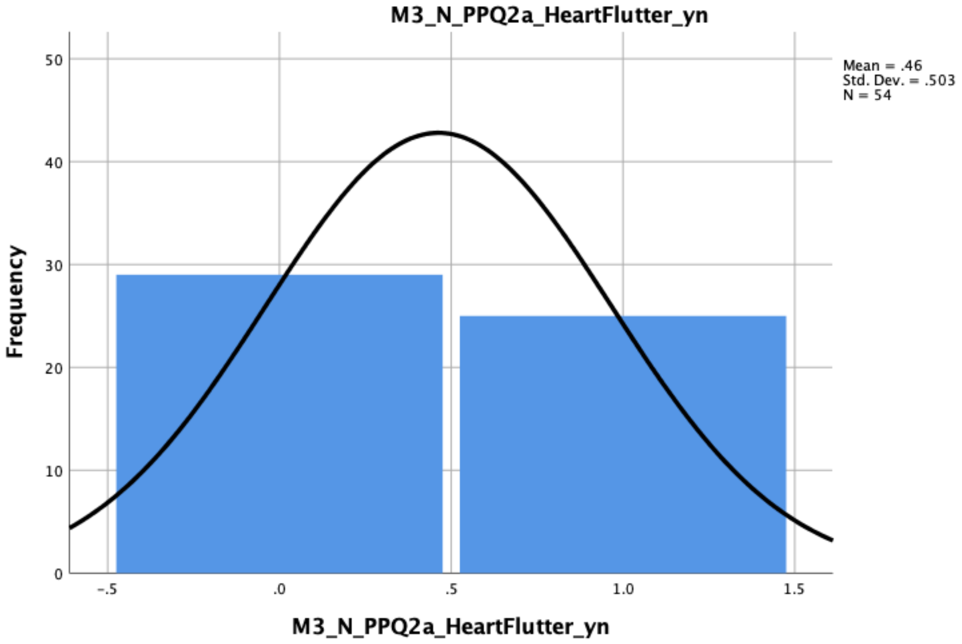


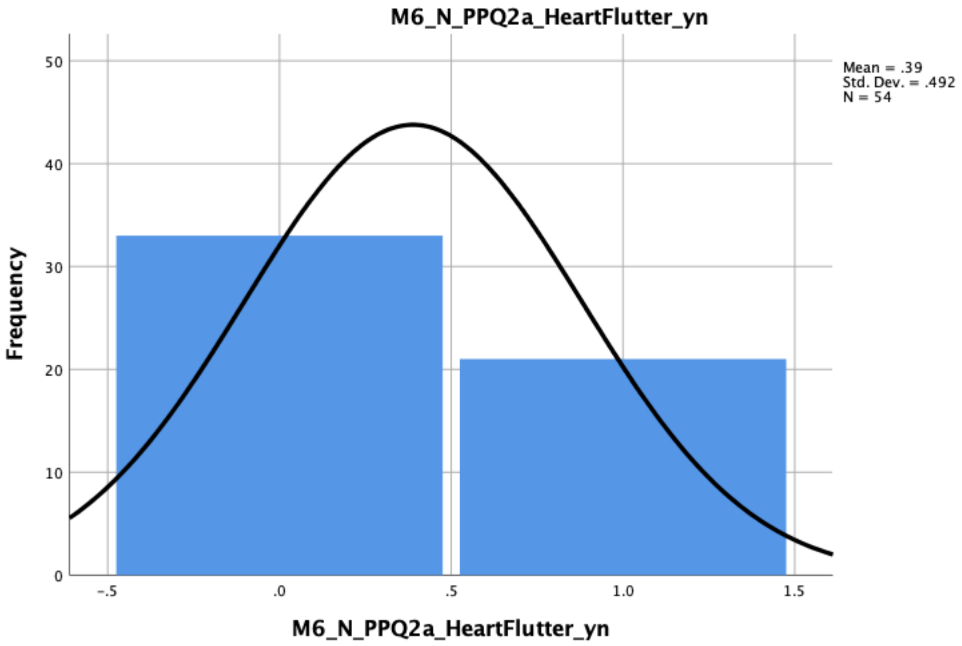

M3_N_PPQ2_FastHeartHowLong_pref
Mean = 2.78
Std. Dev. = 3.329
N = 54
Frequency
25
20
15
10
5
0
-2
0
2
4
6
8
10
M3_N_PPQ2_FastHeartHowLong_pref

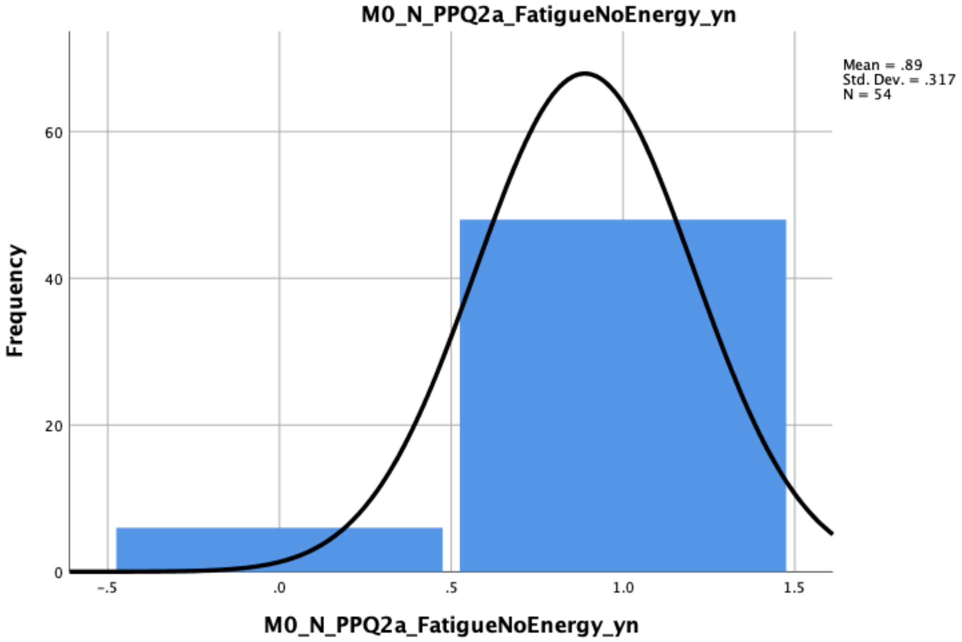

M6_N_PPQ2_FastHeartHowLong_pref
Mean = 1.8
Std. Dev. = 2.877
N = 54
Frequency
40
30
20
10
0
-2
0
2
4
6
8
10
M6_N_PPQ2_FastHeartHowLong_pref

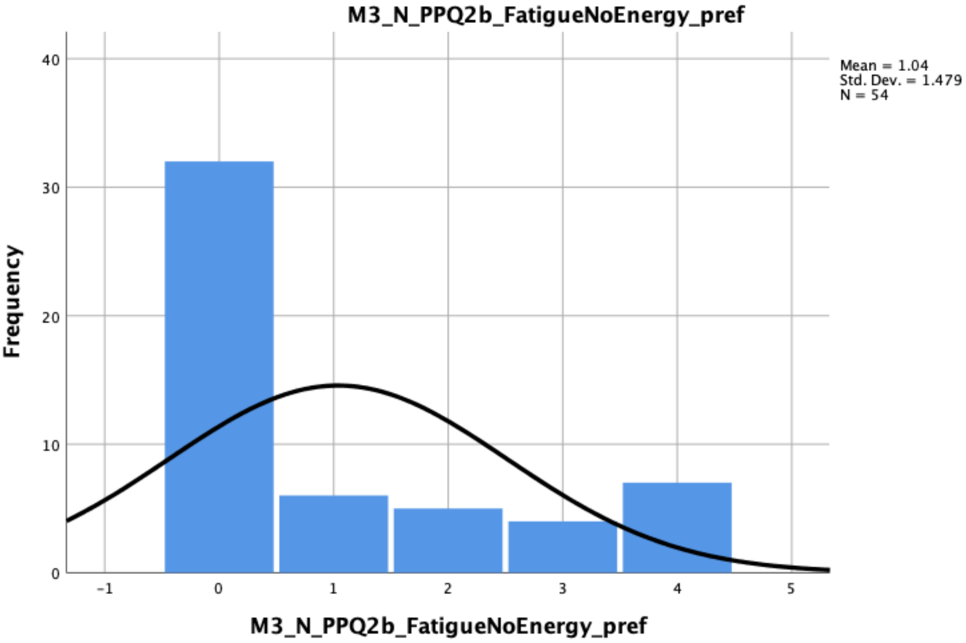
Appendix 16: Examples of histograms for checks on normal distribution from PPAQ symptom questions

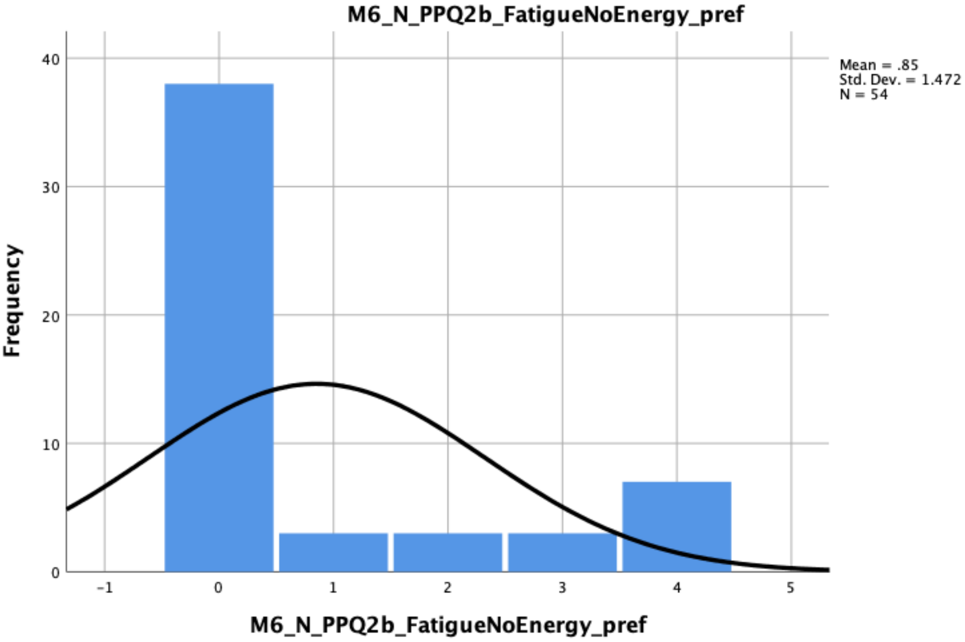


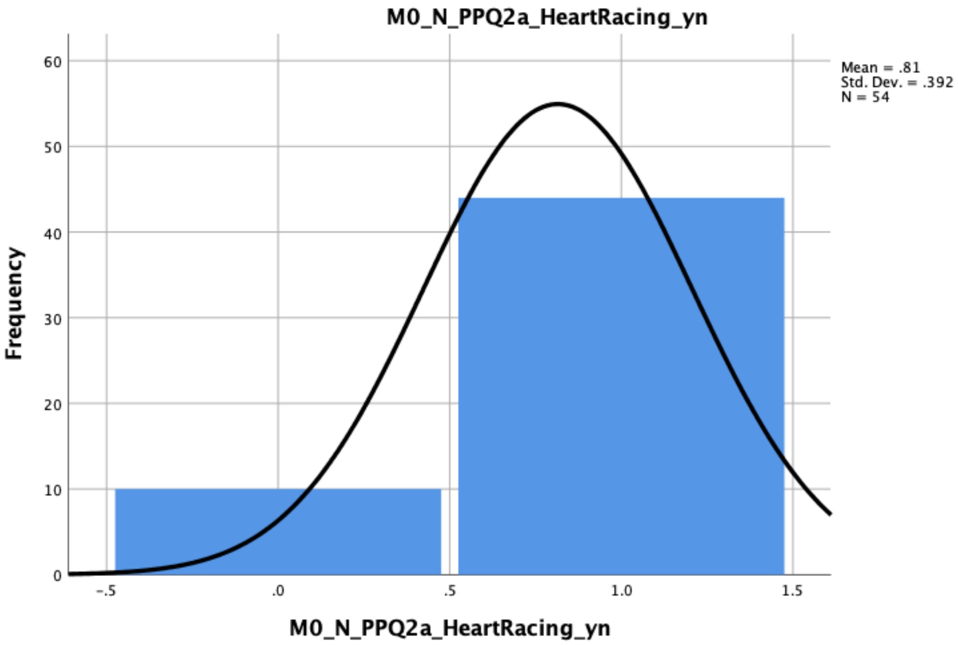


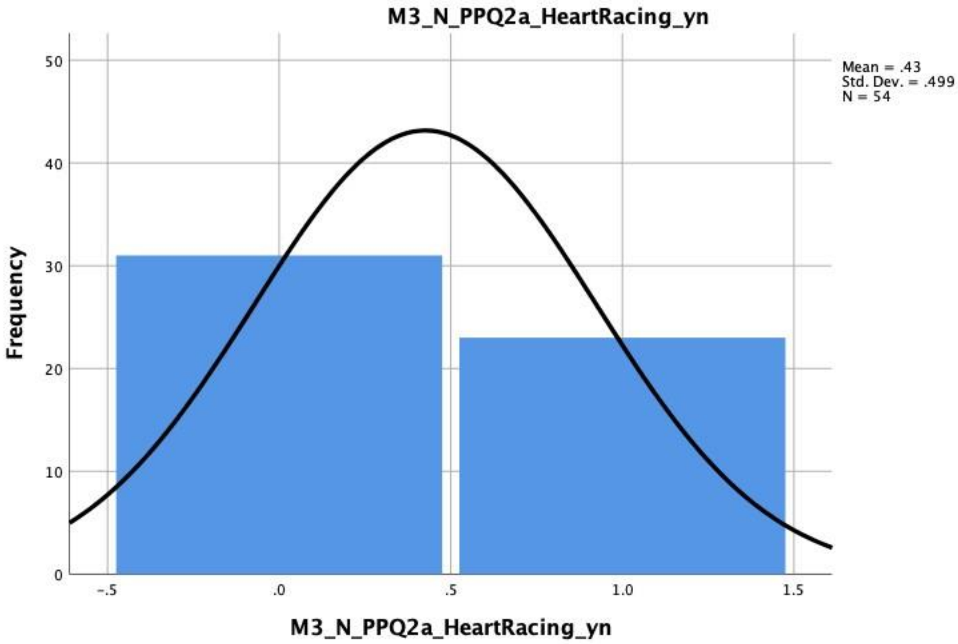

M6_N_PPQ2a_HeartFlutter_yn
Mean = .39
Std. Dev. = .492
N = 54
Frequency
0
10
20
30
40
50
-.5
.0
.5
1.0
1.5
M6_N_PPQ2a_HeartFlutter_yn

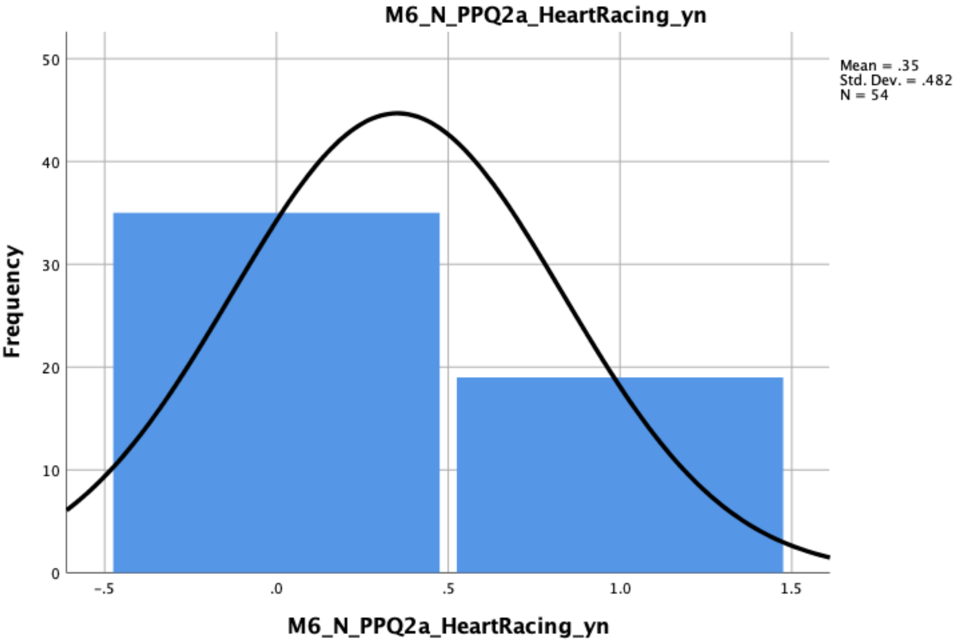

M0_N_PPQ2a_FatigueNoEnergy_yn
Mean = .89
Std. Dev. = .317
N = 54
Frequency
0
20
40
60
-.5
.0
.5
1.0
1.5
M0_N_PPQ2a_FatigueNoEnergy_yn


M3_N_PPQ2b_FatigueNoEnergy_pref
Frequency
40
30
20
10
0
-1
0
1
2
3
4
5
M3_N_PPQ2b_FatigueNoEnergy_pref
Mean = 1.04
Std. Dev. = 1.479
N = 54

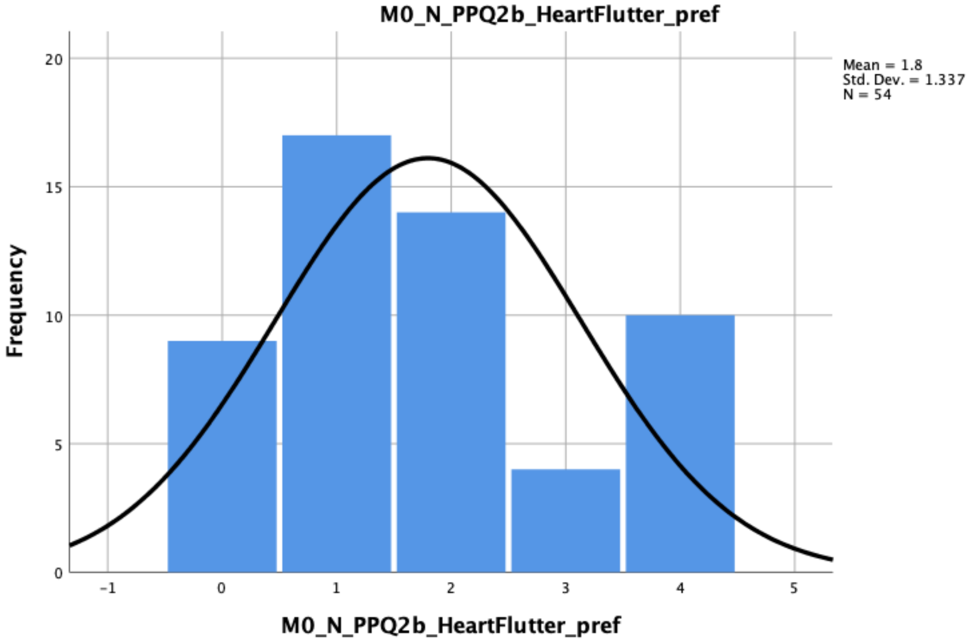

M6_N_PPQ2b_FatigueNoEnergy_pref
Frequency
40
30
20
10
0
-1
0
1
2
3
4
5
M6_N_PPQ2b_FatigueNoEnergy_pref
Mean = .85
Std. Dev. = 1.472
N = 54

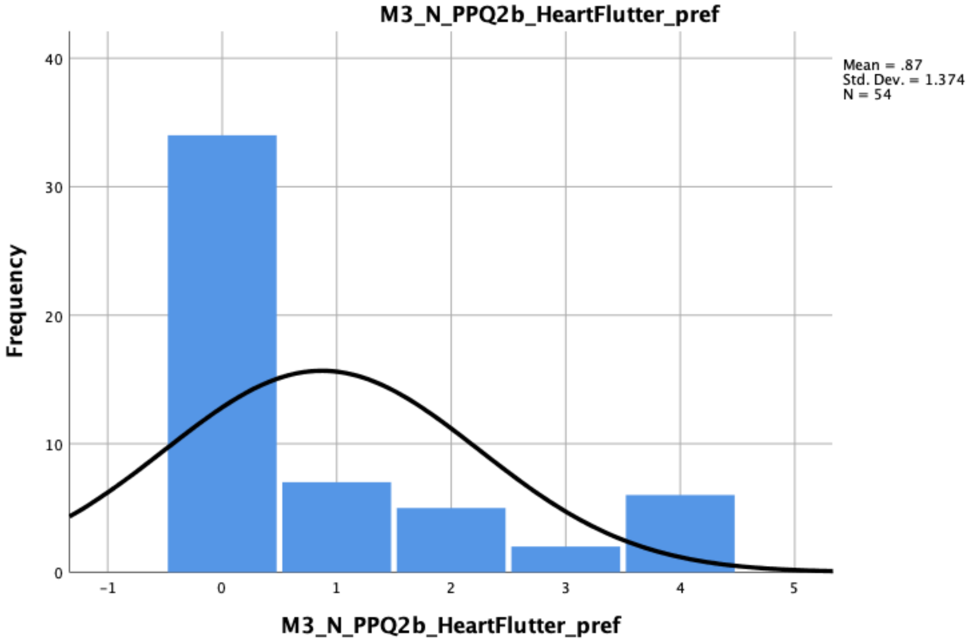

M0_N_PPQ2a_HeartRacing_yn
Mean = .81
Std. Dev. = .392
N = 54
Frequency
0
10
20
30
40
50
60
-.5
.0
.5
1.0
1.5
M0_N_PPQ2a_HeartRacing_yn

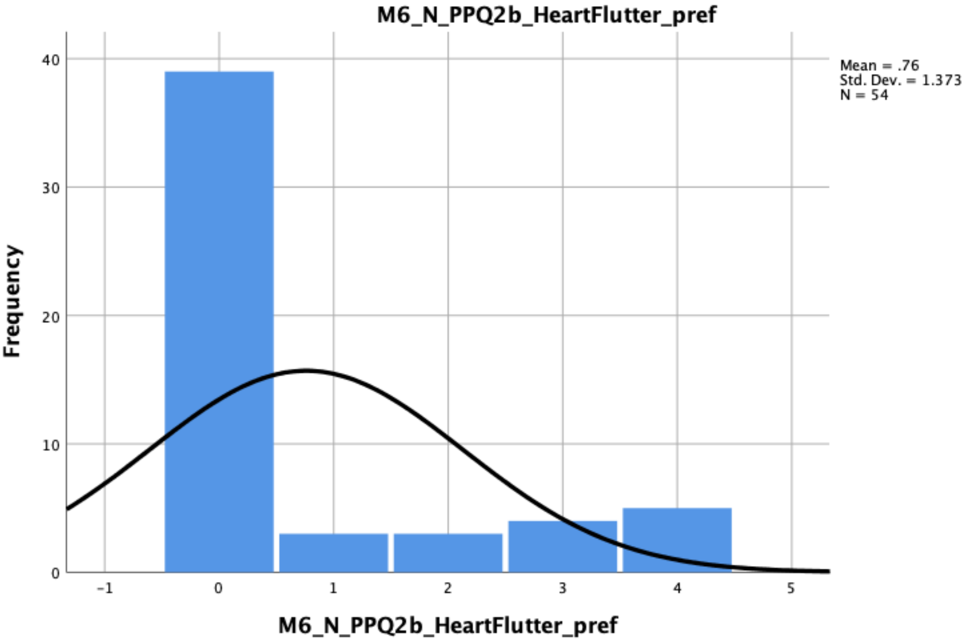

M3_N_PPQ2a_HeartRacing_yn
Mean = .43
Std. Dev. = .499
N = 54
Frequency
0
10
20
30
40
50
-.5
.0
.5
1.0
1.5
M3_N_PPQ2a_HeartRacing_yn

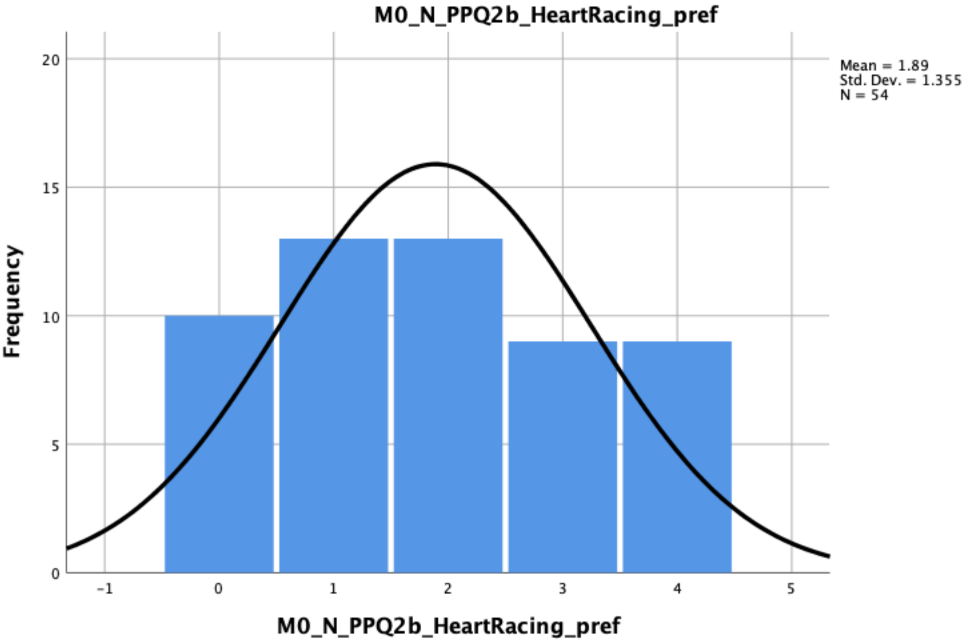

M6_N_PPQ2a_HeartRacing_yn
Frequency
50
40
30
20
10
0
-.5
.0
.5
1.0
1.5
M6_N_PPQ2a_HeartRacing_yn
Mean = .35
Std. Dev. = .482
N = 54

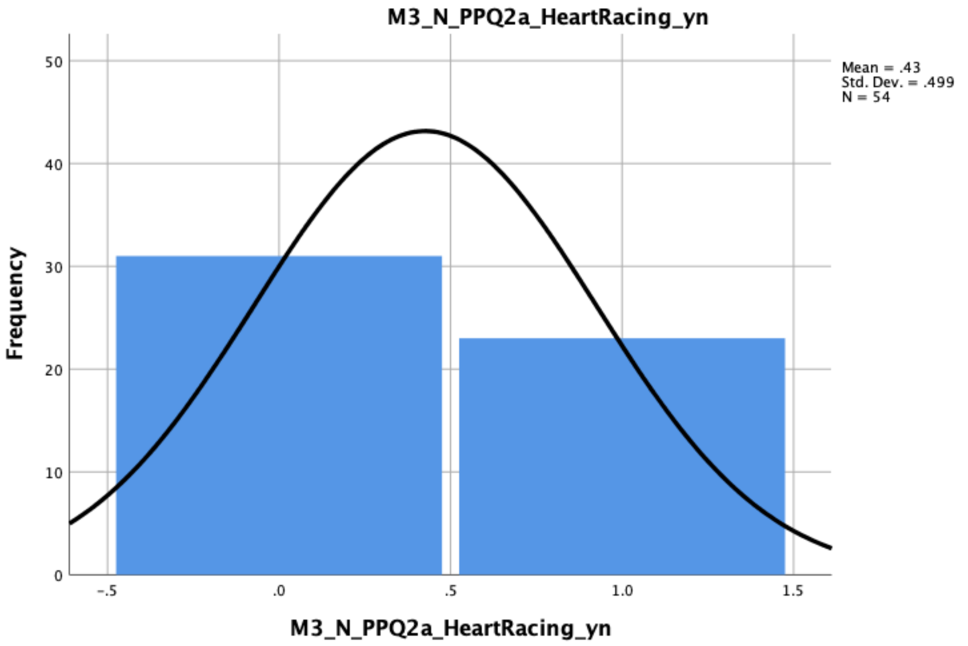
Appendix 17: Examples of histograms for tests of normal distribution on symptom bothersomeness

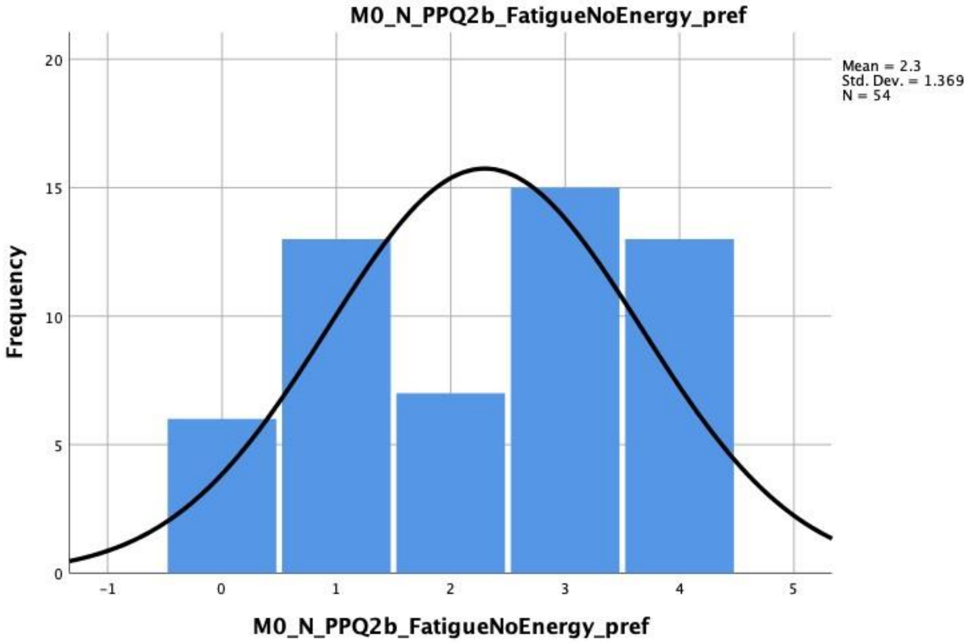


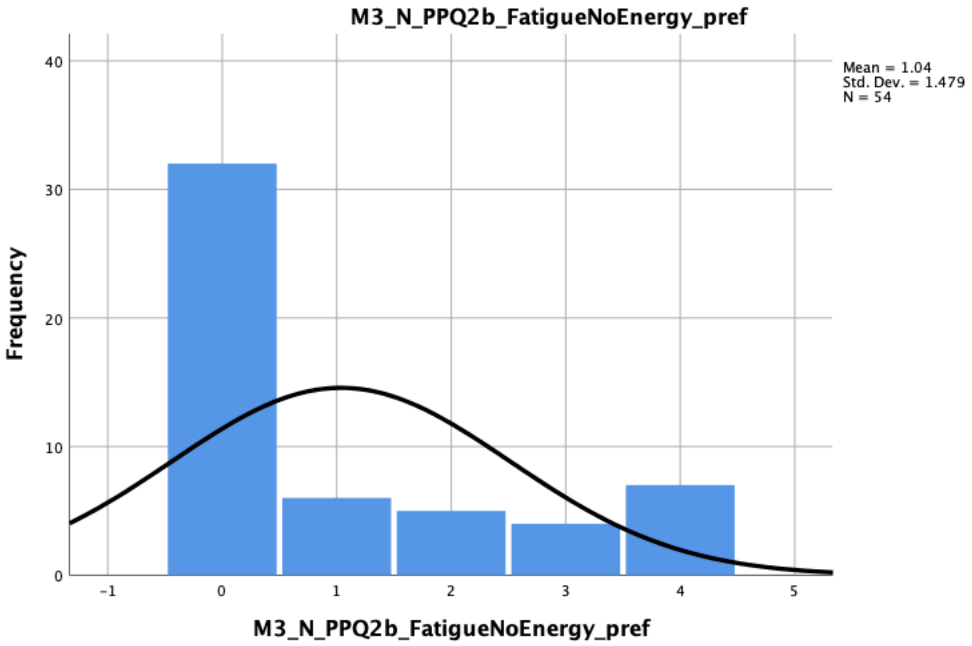


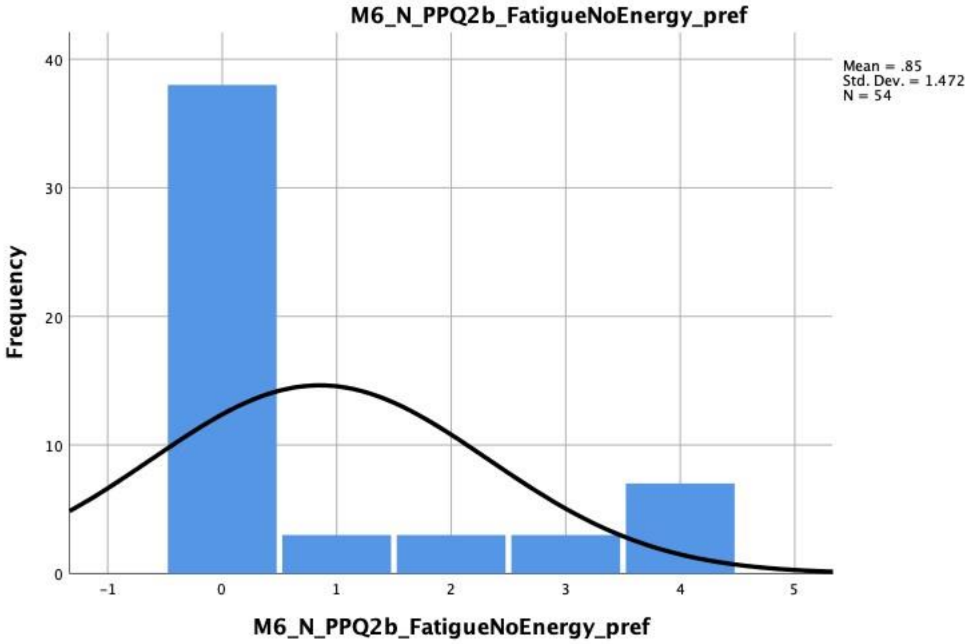

M6_N_PPQ2b_HeartFlutter_pref
Frequency
40
30
20
10
0
-1
0
1
2
3
4
5
M6_N_PPQ2b_HeartFlutter_pref
Mean = .76
Std. Dev. = 1.373
N = 54


M0_N_PPQ2b_HeartRacing_pref
Frequency
20
15
10
5
0
-1
0
1
2
3
4
5
M0_N_PPQ2b_HeartRacing_pref
Mean = 1.89
Std. Dev. = 1.355
N = 54

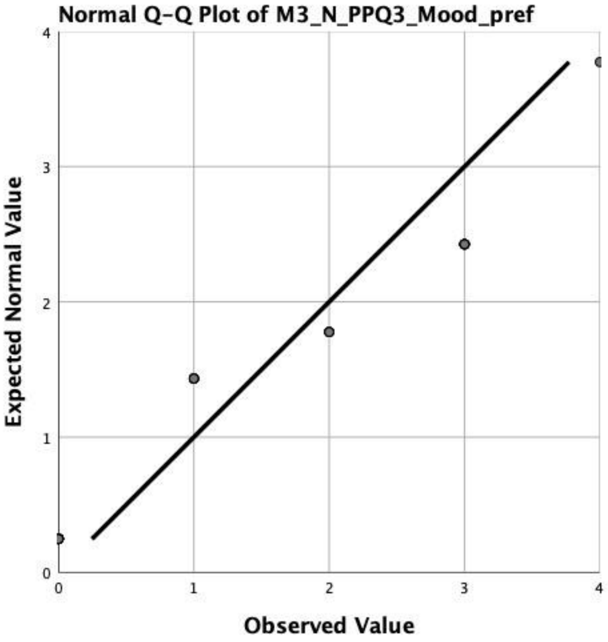

M3_N_PPQ2a_HeartRacing_yn
Mean = .43
Std. Dev. = .499
N = 54
Frequency
50
40
30
20
10
0
-.5
.0
.5
1.0
1.5
M3_N_PPQ2a_HeartRacing_yn

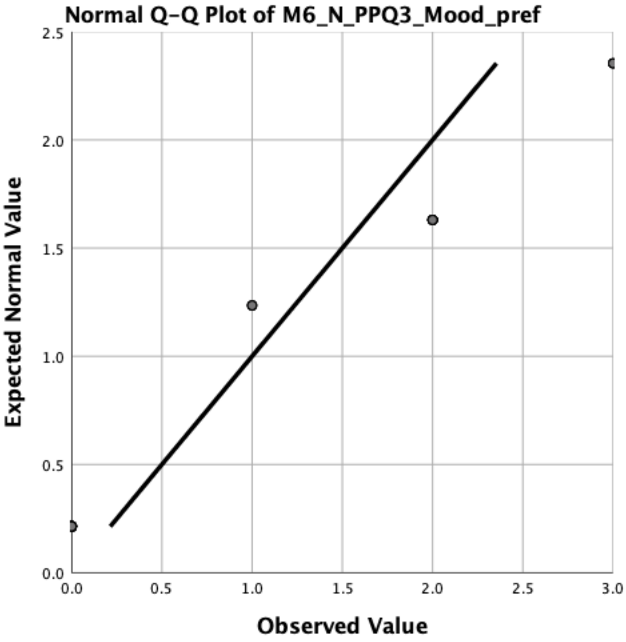

M0_N_PPQ2b_FatigueNoEnergy_pref
Mean = 2.3
Std. Dev. = 1.369
N = 54
Frequency
20
15
10
5
0
-1
0
1
2
3
4
5
M0_N_PPQ2b_FatigueNoEnergy_pref

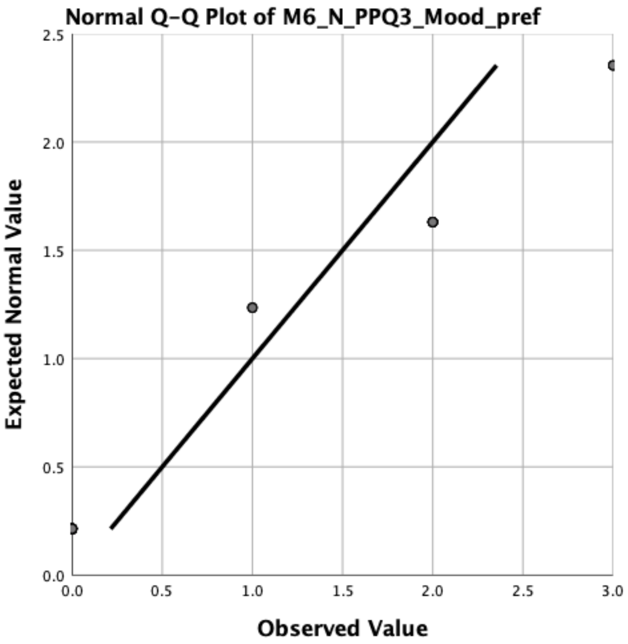

M3_N_PPQ2b_FatigueNoEnergy_pref
Mean = 1.04
Std. Dev. = 1.479
N = 54
Frequency
0
10
20
30
40
-1
0
1
2
3
4
5
M3_N_PPQ2b_FatigueNoEnergy_pref

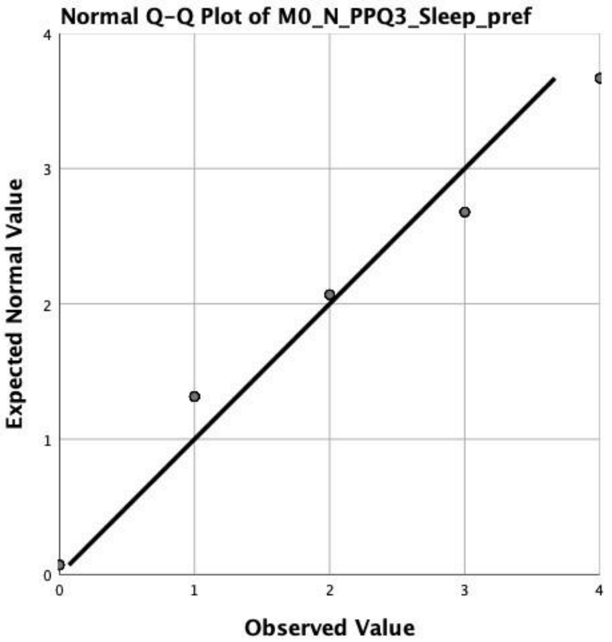

M6_N_PPQ2b_FatigueNoEnergy_pref
Mean = .85
Std. Dev. = 1.472
N = 54
Frequency
0
10
20
30
40
-1
0
1
2
3
4
5
M6_N_PPQ2b_FatigueNoEnergy_pref

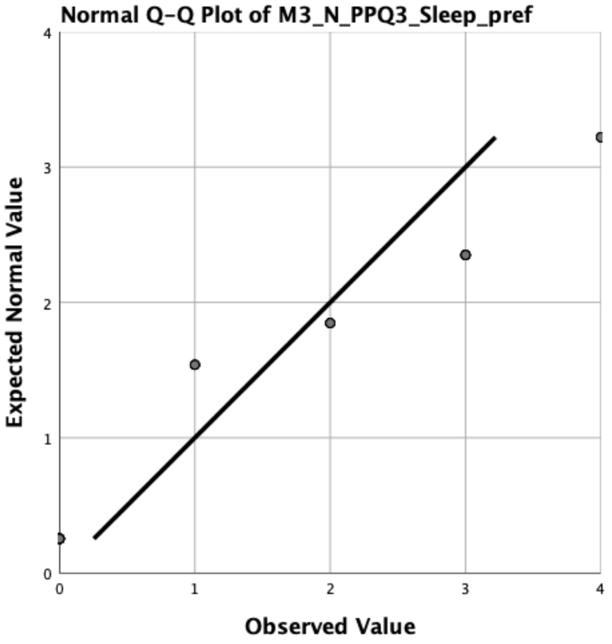
Appendix 18: Examples of QQ plots for tests for normal distribution on symptom impact

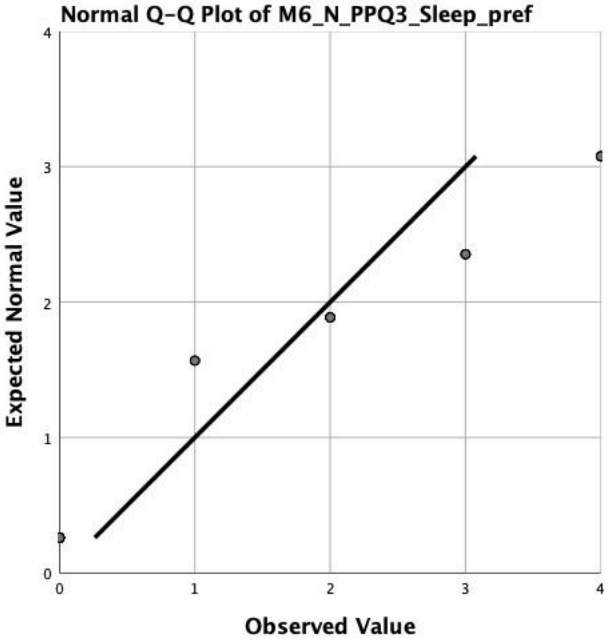


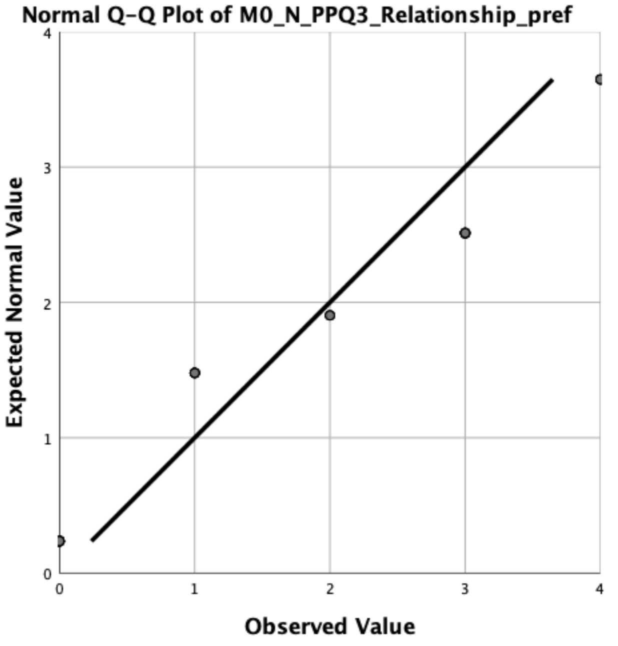



Normal Q-Q Plot of M6_N_PPQ3_Mood_pref
Expected Normal Value
Observed Value
0.0
0.5
1.0
1.5
2.0
2.5
3.0

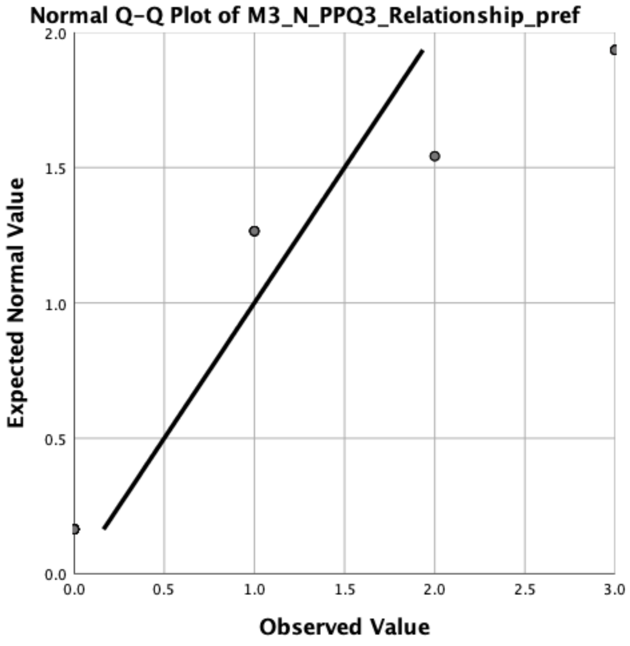

Normal Q-Q Plot of M0_N_PPQ3_Sleep_pref
Expected Normal Value
Observed Value
0
1
2
3
4


Normal Q-Q Plot of M3_N_PPQ3_Sleep_pref
Expected Normal Value
Observed Value
0
1
2
3
4
0
1
2
3
4

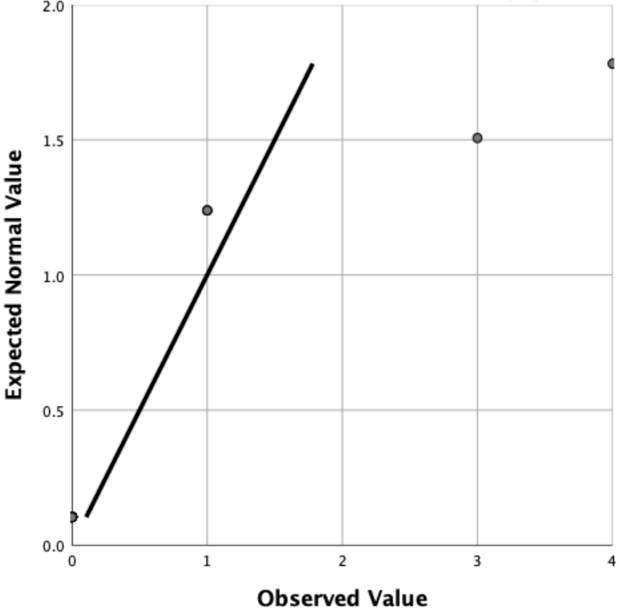

Normal Q-Q Plot of M6_N_PPQ3_Sleep_pref
Expected Normal Value
Observed Value
0
1
2
3
4
0
1
2
3
4



Normal Q-Q Plot of M0_N_PPQ3_Relationship_pref



Normal Q-Q Plot of M3_N_PPQ3_Relationship_pref



Normal Q-Q Plot of M6_N_PPQ3_Relationship_pref

Appendix 19: Example of initial codes from 3 of the interviews

PATIENT 1

1.Fear, shock 2.

Variation in heart rate

3.Became unwell.

4.Needed help.

5.Being informed what was wrong

6.becoming unwell

7. needing emergency care
8. impending doom and fear
9. family affected by AF
10. abnormal body behaviour
11. medical treatment that didn't work

12.drama of treatment

13. restoration of normal rhythm
14. being given treatment

(where is SDM?)

15. treatment preferences
16. normality of heart rhythm
17. tests that are ordered
18. AF recurrence
19. emergency presentation
20. dissatisfaction with healthcare
21. assumptions of desire to be treated

14. being given treatment

(where is SDM?)

22. pressure on NHS

14. being given treatment

23. violent act

14. being given treatment

24. impact of treatments

25. views on medicines

26. patient empowerment

27.desire for rhythm control

22. pressure on NHS

28.

29. story of death personal bereavement

30. finality of death

31. expectation of ablation

32. SDM in understanding treatments

33. mis-information in the consequences of a condition

34. clinical team understanding the anxiety

35. body invasion

36. stress of cancellation

7. under estimation of impact of cancellation

38.staff understanding the impact of AF

37. empathy with nurse

38. perception of clinical area

39. feeling overwhelmed

40. understanding significance of a cardiac condition

41. significant prospect of treatment

42. displaying gratitude to team

43. description of procedure

44. embarrassment of revealing body

45. biomedical hegemony

46. uncomfortable nature of a procedure

47. Painful consequence of ablation
48. Painful consequence of ablation
49. Painful consequence of ablation
50. trust in the researcher
51. urgency of having full bladder
52. After effects of ablation
53. the British way
54. dietary needs
55. consequences of the ablation
56. fear of fainting
57. dealing with a medical emergency
58. desire to go home and constraints of complications
59. use of dark humour
60. gratitude to staff

    And positive feedback
61. hygiene and manners are important
62. impact of ablation
63. desire to recover
64. recovering from an invasive procedure
65. time to recover
66. role in the workplace
67. focus on the heart
68. lack of energy
69. making sense of high BMI
70. contempt towards the person
71. pride in financial standing
72. treatment required and not given
73. not comprehending medical treatments
74. type of work
75. desire to lose weight

76.ability to exercise

75. desire to lose weight
76. fitness plans
77. expectation of sinus rhythm
78. misinformation about medicines
79. seeking healthy advice
80. risk factor modifications
81. recognising impact of Covid
82. not wishing to be a bother to NHS
83. need for easier access to specialist team
84. confirming grief
85. expectations of specialist team
81. recognising impact of COVID
82. gratitude to NHS staff
83. choice to not stay on meds
84. mis-information of medications and the effects

82. gratitude to NHS staff

Patient 4

1.illness perception

2. dramatic impact of AF

3.acute stress

4. incapacity
5. falling apart
6. hope for cure

7.redcued effort tolerance

8. loss of self

3. acute stress

9.immediate relief from symptoms

9.immediate relief from symptoms

9.immediate relief from symptoms

10. benefit of SR

11. motivation to be fitter & healthier

12. AF recurrence

13. expectations of ablation

14. receiving information expectations of ablation

13.

15. recovery form ablation

15. recovery from ablation

16. physical impact of AF

17. medical instructions

10. benefit of SR

18. cost of being healthier

19. impact of BMI on health

20. emotional health

21. perceptions of BMI

22. stoicism

23. COVID impact

23. COVID impact

23. COVID impact

23. COVID impact

23. COVID impact

24. desire to be fitter

25. understanding RFM

26.aware of own body

27. lack of education

28. prejudices

29. perception of saying the right thing

30. benefit of weight loss

31.self-perception of AADs

32. benefit of being on a drug to maintain SR
33. other healthcare professionals perceptions of AAD
34. Dr Google
35. delivery of patient information
36. awareness of heterogeneity of AF symptoms
37. having a point of contact
38. feeling cared for by arrhythmia nurses

10. benefit of SR

37. desire to lose weight
38. desire to be fitter
39. gratitude to staff
40. unexpected part of the ablation
41. concern about procedure
42. frightening thought of procedure
43. need to be informed
44. expectations of recovery
45. access to information
46. passive patient
47. future goals

47.future goals

10. benefit of SR

Patient 7

1.Physical impact of AF

2. lack of information

2. lack of information

2.physical impact of AF

2. physical impact of AF

2. physical impact of AF
3. understanding of medications
4. COVID imapct
5. acute stress and physical effects
6. understanding of acute episode
7. self-awareness
8. reaching a decision about ablation
9. SDM
10. delivery of information
11. unexpected consequence of ablation
12. physical recovery from ablation
13. benefit of SR
14. feeling emotionally recovered
15. understanding of complications
16. medical advice
17. effects of medications
18. tuning out of AF symptoms
19. active lifestyle
20. impact of AF on ability to exercise
21. negative impact of AF on fitness
22. dramatic improvement in symptoms

23.confidence to exercise in SR

24. knowledge of RFM & lifestyle factors

25.lifestyle knowledge

26. long term advice and education

27. (positive) impact of AF

28. future goals

29. surprises from the ablation procedure

30. use of humour

31. unexpected part of the ablation

32. recovery once home

Patient 8

1.Feeling unwell

2. being diagnosed

3. acute presentation

4. insidious symptoms

2. being diagnosed

5. benefit of being in SR

6.understanding the treatments

3. benefit of SR

7. emotional pressure in life

8. emotional well-being

9. emotional imapct

10. association of AF with mental health

11.treatment choices

12. side effects from AADs

13. emotional impact of AF recurrence

14. patient education for treatment options

15. QoL impact from AF

16. emotional and physical effects of AF

17. loss of vitalty

18. satisfaction with telemed

19. feeling informed

19. AF recurrence effects

20. hopes for treatment

20. nervous of the procedure

21. positive feedback

22. being cared for

23. physical after effects

24. physical recover

25. expectations of ablation

26. AF recurrence

27. positive feedback about care

28. mental health

29. linking mental health with heart

30. awareness of need to exercise

31. desire to lose weight

32. link between BMI and AF

3.satisfied with treatment

34. association of meds with health

35. considering exercise

36. seeking guidance on exercise

37. seeking reassurance

38. prior knowledge of BMI link with AF

39. importance of prompt diagnosis

39. importance of prompt diagnosis

40. gratitude to NHS team

41. learning the cardiac language

42. importance of patient education

43. aftercare needs

44. importance of follow up

45. desire to know plans going forward

46. uncertainty of plans

46. uncertainty of plans

46. uncertainty of plans

Appendix 20: Reflective diary Patient interviews for the AFabQoL Study

1)Patient number 4 11/11/21

I felt nervous at the start and excited to engage with the patients.

I felt that I may have been so keen to do the interview that I may have rushed her at the start. The background to her AF could have been explored in greater detail.

She was keen to discuss the lifestyle factors and the ablation experience, which was encouraging and left me feeling enthusiastic about future interviews.

I felt I had a good rapport with her. The difficulties I found were as an arrhythmia nurse and being a researcher, I couldn't clarify some of the medical terms that she used, for example, her comments about heart failure were factually incorrect and if I had been in nurse mode, I would have explained matters more clearly to her.

7/11/22-familiarisation stage

Effects of AF= "I felt I lost me"

- Ablation-intimidated by number of people in cath lab, recovery-longer than expected
- COVID impact
- Lifestyle- weight & exercise
- Patient information-Amiodarone, ablation discharge information-didn't read,
- Positive about her care
- Next 6 months-lose weight and be fitter

2)Patient number 8 16/11/21

I was looking forward to this interview because he has been so keen to engage.

He talked openly but was generally positive about his overall experiences.

He talked about his mental health, and I felt true empathy with him. I thought about this afterwards and realised how much the nurse in me is hard to separate from the researcher.

7/11/22-familiarisation stage

- Diagnosis of AF- via GP, grateful, didn't realise how ill he was ● Amiodarone-side effects
- Ablation-felt protected, groin hurt
- Lifestyle-weight, depression, goal to take less meds, increase exercise, useful to know what to do, delay to diagnosis

3)Patient number 7 19/11/21

I found this patient very easy to interview. He was quite open and honest about his AF. He had other cardiac issues, which he was able to separate from the AF symptoms and impact. I reflected on how he has allowed life to be as normal as possible, with work and young children, besides his cardiac issues. He seemed very relaxed and I remember thinking that I would not be so chilled about such health issues, if I were in his position.

7/11/22-familiarisation stage

Noisy audio. Patient has an ICD, which he referred to as his device.

- Unexpected-bruising in groin, area that needed shaved, after effects from the GA ● Exercise- delayed by series of events

4)Patient number 13 10/12/21

This patient was so easy to have a dialogue with that the interview felt very natural, like a conversation. She talked a lot about her feelings and her self-motivation to lose weight and deal with her mental health concerns. I found myself really interested in what she had to say and truly interested in her conversation about meditation and yoga. Her positivity, despite recently having COVID, really shone through. As she is a similar age to me, I felt a real sense of commonality and I felt that she enjoyed the interview.

7/11/22-familiarisation stage

- Diagnosis-as an emergency presentation
- Symptoms-insomnia as AF always nocturnal
- Lifestyle-never mentioned initially meditation, yoga
- Effects of AF on personality
- Ablation-decided on a positive mind set, kindness of staff
- COVID infection-

5)Patient number 10 16/12/21

I found this interview a bit stressful, only because the patient's mobile phone signal kept dipping and it wasn't always easy to hear what he was saying. His main focus was the need for a structured exercise programme. He demonstrated how much benefit he had gained form the procedure, but wanted more from the service in terms of long-term benefit. He explained that he had retired in the pandemic and was a bit lost in terms of activities and routine and I felt that he seemed a bit unmotivated to try new things.

7/11/22-familiarisation stage

- Initially cautious about ablation
- Ablation recovery- exercise requirements
- Lifestyle- previously has cardiac rehab that was helpful, desire to increase fitness, wished to have a structured exercise programme, cut down on alcohol ● COVID impact- on going to the gym

6)Patient number 14 30/12**/21**

My main reflection on this patient's experience is that he has some other serious health issues. He was being very helpful in giving me the context of his other cardiac issues. But, although interesting, I felt a bit impatient in wanting to reach the discussion about AF. I repeatedly kept thinking what an awful time this patient had with so many health issues. I noted he had amazing insight into all the complex cardiac problems that he had. Despite this he was able to articulate how AF makes him feel. The ablation made him feel like he "had been beaten up", which made me think about the impact of the procedure.

7/11/22-familiarisation stage

- Complex heart history before AF
- Immediate time before ablation was stressful & unpleasant
- Ablation recovery- felt "battered and bruised". Unexpected-arm and leg bruising. Longer recovery-especially mentally
- Lifestyle-weight loss, diet

7)Patient number 15 30/12/21

This patient was very happy to participate and had a very relaxed style. I reflected on how positive he was about the whole ablation experience. I found that although he was aware of the general health advice about diet and exercise, he seemed less clear about the direct link with AF and lifestyle factors. I felt that I needed to prompt him a bit on that and explore further. Having said that, his lifestyle is quite active, he mentioned cycling and his dog, which he walks daily. Although the interview was a bit shorter than the others, I felt he covered a lot of salient points and moved quite naturally onto the next point on the interview schedule, with fewer prompts.

7/11/22-familiarisation stage

- AF diagnosed on board a ship
- Unpredictable episodes, triggers-alcohol
- Ablation recovery-groin site "kicked like a donkey", 1 episode of AF
- He sounded positive about the ablation

8) Patient number 19

4/1/22

This patient was very engaging and happy to chat. I found him open and honest, particularly about his mental health. I felt that the conversation flowed very naturally, and he didn't require many prompts. He has embraced the support that is available for patients and seems motivated to change his lifestyle, particularly exercise.

It struck me that the need to be seen as an individual is an important and interesting one. I reflected on his point about this and can see why patients don't always feel that care is individualised. I had to bring myself out of clinical mode for the rest of the interview, and park any thoughts of how our service may improve.

8/11/22-familiarisation stage

- Diagnosed as an emergency. Arrhythmia team very important for support and advice
- Affected mental health-anxiety and depression
- Cath lab-daunting-equipment
- Recovery-took much longer, bruised groin, "hit by a truck"
- Support after the ablation-helped mental health
- Lifestyle modifications-very difficult without support. Health promotion team really helped. Diet and exercise. Amazed with lack of awareness
- Listed for a redo
- COVID impact-has hindered exercise

9)Patient number 1 6/1/21

This interview was interesting, he described the way he was diagnosed in quite an emotive way. I felt real empathy for the awful time he had. He seemed very open and easy to talk to. He talked a bit about how he first presented to the Emergency Department and was clearly quite unwell at the time. I recall thinking about the importance of communication with patients and some of the things we say can be taken literally, or sometimes negatively and dramatically.

8/11/22-familiarisation stage

- Presented as an emergency, felt he was going to die
- Brother dies-felt very anxious
- In the cath lab-daunting-machines
- Recovery-after effects-swollen hands, bleeding groin, fainted after going to the loo, 3 weeks off work
- Lifestyle modifications-wasn't aware of link between weight and AF

10)Patient number 25 7/1/21

This patient was very keen to be interviewed. He was relaxed and open, which I appreciated. I reflected on how his AF was initially diagnosed, which was in the Emergency Department of his local hospital. I recall thinking how the diagnosis of AF is often a challenge. His comments about being "manhandled" in the procedure made me wonder why he had post procedural discomfort in his arms and legs. As an arrhythmia nurse, I am aware that patients are not moved, other than from the lab table to trolley. I reflected on why he could have felt physically “battered”. I was interested to hear about the psychological effects of AF, rather than physical. He articulated this well. I noted that he found being part of the study helpful for his ongoing care. At this point my VPN dropped out and I had to pause the recording. He acknowledged that being part of the study meant that there was the opportunity to discuss what to do for him clinically. However, he was aware of my role as a researcher and that I needed to refer him back to the clinical team. My mind drifted as he mentioned lack of clarity about post ablation care. I kept thinking about service improvement and then had to bring my mind back to the present, as a researcher. I felt a real sense of pride when he gave positive feedback about the care that he had received.

8/11/22-familiarisation stage

- Diagnosed by GP with typical symptoms and sent to ED
- Expectations of recovery-needed more guidance
- Ablation recovery- “battered”, groin-painful
- Felt calm afterwards, in normal rhythm, both mentally and physically
- More inclined to exercise in normal rhythm
- Not clear when to call the team
- Benefit of being in the study
- Lifestyle modifications-no targeted advice on exercise, work
- Need for guidance on long term plan for treatment

11)Patient number 9 11/1/21

I was immediately interested to hear of this patient’s experience, as he is in the armed forces. I reflected on my experience of dealing with patients with AF in the military and how they seem to have delays to treatment, despite having access to military medical teams. He recognised the psychological impact of AF. He demonstrated the negative impact on quality of life that AF has had on him. I noted that he reported chest pain after the procedure, which is not mentioned as a complication following ablation. He told me about a recent COVID infection, which I felt true empathy for. My mind wandered to thinking about the pandemic and how hard it has been for everyone. I reflected on how patients need support with getting back to normal life after ablation. Overall, I found it easy to be in the researcher role with this patient.

8/11/22-familiarisation stage

- Delay to diagnosis
- Medication side effects
- Impact on work-depressed
- Ablation-pain 1 week after, in the chest
- COVID infection as getting back to fitness

12)Patient number 12 11/1/21

This patient was very positive about the interaction with the arrhythmia team. I noted that he reported dyspepsia post procedure, which was an unexpected consequence. He seemed to have had regular contact with the arrhythmia nurses, and I reflected on how much better that is for patients. I was interested to hear that he underwent gastric bypass and had lost about 60kgs. He seemed to have taken the lifestyle advice very seriously. I felt pride in the team, of which he was very positive, especially the arrhythmia nurses.

8/11/22-familiarisation stage

- Very positive about his experience
- Ablation recovery-unexpected sore throat
- Aware of need to lose weight, had gastric bypass

13)Patient number 20 13/1/21

The thing I reflected on the most in this interview was the enormity of the impact of AF on her as an individual. She described the AF as "a firecracker in her chest". The delay to seeking ablation treatment was clearly an issue for her and she expressed real concern about how difficult it was to get referred to the specialist team. I could understand her frustrations, especially the barriers to treatment. I reflected on the fact that although my role in the interview was that of a researcher, my experience as an arrhythmia nurse meant that I completely understood the issues that she discussed, in particular the effects of the medications. I found her very open and easy to talk to. I felt she had great insight to her diagnosis and lifestyle factors and although motivated, she was finding it all so difficult. I was acutely aware of some of the people that she mentioned in the interview, but my professional training enabled me to remain impartial. I was constantly aware of how I came across in the interview in maintaining the patient/researcher relationship. She was very balanced in her views and gave very positive views on the team at the time of the ablation. I recall feeling pride in the service and the way in which the nursing team treated her with kindness and empathy. I was interested to hear that being in the study was motivating for her, in terms of weight loss, as the 3 & 6 month follow-up provided realistic goals**. 8/11/22-familiarisation stage**

- Medication effects
- COVID impact-no review
- Mental health impact
- AF impact on QoL is huge
- Delay to specialist referral
- Use of patient support group
- Second ablation experience- positive
- Wasn't aware of link between lifestyle and AF, but then lost 30kgs
- Benefit of the study-incentive to lose weight

14)Patient number 18 14/1/21

The main thoughts I kept having during this interview was around how the patient was diagnosed and how effective her GP was. She presented with breathlessness and her GP immediately diagnosed the problem. I recall thinking that she was so fortunate to have such a proactive GP. The other thing that I thought of during the interview is how active this patient like to be and how much AF has limited that. She had been doing online spinning classes and I thought how impressive that was and how motivated she seemed. She was also very happy to be involved in the study and sounded so positive.

8/11/22-familiarisation stage

- Early GP diagnosis
- Positive experience
- Seen quickly
- Diagnosed with colon ca
- Very positive

15)Patient number 27 27/1/22

This patient was very helpful and keen to be involved in the study. I was humbled by his insights into the mortality risk of the procedure. I reflected on the decision-making process that patients go through. I reflected on his concerns about his hypertension, which made me think about how difficult life has been for patients in the pandemic. His reports of his extremely high blood pressure made me feel very anxious for him. However, he sounded very organised and had matters in hand. I had to remind myself that my role in this context is that of a researcher, not a clinical nurse. I was aware that he is 82 years of age but was impressed by the fact he is not retired and continues to work. In regard to lifestyle factors, I was surprised to hear that he had never been informed about the link between AF and weight.

8/11/22-familiarisation stage

- Positive experience
- Active and working aged 82
- Unexpected part of the ablation-number of people in the cath lab

16)Patient number 22 1/2/22

This patient was very enthusiastic to be involved in the study. I reflected on how well informed he was about AF treatments. He was very positive about his experience. I thought about how incredibly active this patient is and how committed to exercise he is. He competes nationally in his chosen sport. He gave some useful insights on the psychological impact of AF.

8/11/22-familiarisation stage

- Well informed about the procedure
- Some ongoing AF
- Very high level of fitness (national racket ball)
- AF affected him mentally-diet and weight deteriorated

17) Patient number 24 3/2/22

This patient was very happy to participate in the interview, but I felt was less chatty than some of the other patients. I felt I needed to ask more than listen, as some of the answers were a bit brief. He gave some useful insights into how his AF was diagnosed and how it has impacted on his career in the police force. I recall thinking how his knee issues (waiting for a knee replacement), seemed to bother him a lot. His other health problems seem to be compounding his overall health.

8/11/22-familiarisation stage

- Diagnosis-when waiting for knee op
- Ablation recovery-ok, but had complication
- Later found to have a separate cardiac issue
- No awareness of lifestyle link

18) Patient number 26 4/2/22

I found this patient a challenge to interview. He had a lot to report, was highly articulate and had some negative experiences. He described the AF as “a cement mixer in his chest”. He showed real insight into the effects of AF and the mental health impact on it. I noted he was negative about the health care teams, which I found difficult and had to find strength to rise above and remain very professional. He admitted how angry he was after the procedure. A lot of his frustrations were around obtaining the AF diagnosis, despite extensive investigations. He was very open and honest about his experiences, and I reflected on how much support patients post ablation require. My role as an arrhythmia nurse enabled me to understand the technical and medical terms that he used, but his anger and negative views made it easier for me to be within the researcher role. If I had been in a clinical consultation, within my arrhythmia role, I was aware that I would have addressed his complaints from a professional standpoint. Some of his comments I found patronising, although I could see that he was trying to be helpful. What I found positive from him, was that he spoke to me as a researcher, not as an arrhythmia nurse. I ended the interview feeling emotionally drained and reflected that this was the most challenging interview so far.

8/11/22-familiarisation stage

- Noted the impact of stress
- Delay to diagnosis
- Awful post ablation recovery-migraines, pericarditis, gastric dysmotility
- Keen to get fit but left with other issues

19) Patient number 29 4/2/22

I reflected that this patient had difficulties in reaching a diagnosis of AF, like many of the others. I noted that treatment options had not been discussed in detail previously, until he saw the specialist team. He was helped by increased information by the clinical team. He was very positive about his ablation experience. The discussion about lifestyle was interesting because some of the information he had been given was not correct. I noted he was in his 20’s when diagnosed.

10/11/22-familiarisation stage

- Delay to diagnosis
- Patient info re ablation-positive
- Ablation recovery-“new lease of life”
- Exercise
- Would have liked more knowledge early on

20) Patient number 37 22/2/22

This patient was extremely keen to be interviewed. I reflected on how she had a lot to say in detail about her experience. I thought how this patient wanted to do the right thing and would have benefited from very clear discharge advice. I had to remind myself that this was of interest as a researcher, but not something I could solve as an arrhythmia nurse in this context. I admired her candour and openness. I liked the discussion about her sweet tooth and like of chocolate. She was keen to have support and advice on diet and weight loss and I was able to refer her to the correct team, as I maintained my research mode.

10/11/22-familiarisation stage

- Diagnosed by GP after severe symptoms
- Positive experience of ablation
- Care on ward- not satisfactory, discharge not positive ● Lifestyle-unaware of link, but active

Reflections on the interviews 22/2/22

Overall, my reflections on the patient interviews are summarised as follows:

- The impact on COVID-19, in regard to access to specialist services and treatments
- Overwhelmingly positive experiences of the ablation procedure
- The patients were all very keen to speak about their experiences
- As the interviewer I found all, but one, easy to interview
- At the end of the interviews, it occurred to me that I hadn’t asked anyone about the questionnaires and if there was anything that wasn’t included that then came out in the interviews.

8/11/22

Reflecting on the interviews, I considered my role in the interviews, my behaviour, and the rapport with the patients. I have positive reflections on my role in the interviews, as I had been nervous about conducting them. I reflected on how I listened much more than I would do in a clinical consultation. I also reflected again on patient 26, who showed real insight and understanding of all the issues that he had related to the AF and the ablation.

Stages of framework analysis Familiarisation

November2021-February 2022, I listened to audio recordings immediately after each one. I transcribed 6 of the transcripts (the first 5 then a later one), but I had to be pragmatic and sent the others to Way With Words, for verbatim transcription. I then read through the transcripts over the next few months, on and off.

November 2022- I re-listened and re read the interviews audios and transcripts.

The framework started to develop after discussions with LS.

- Life before ablation
- Life around the time of ablation
- After the ablation

22/11/22

After spending several days on the first 3 stages of framework analysis, additional themes seemed to emerge- physical impact of AF symptoms, medication issues and concerns, decision-making for the ablation procedure, physical aspects after the procedure, unexpected aspects of the ablation, moving forward with life and lifestyle factors.

After supervision, however, it became apparent that the codes or categories were not emerging organically, but more in a process-driven way. Following these discussions, rereading the transcripts and annotating accordingly, themes of a more mindful nature began to emerge. The following themes seemed to emerge

- The presentation of AF as a diagnosis
- Specialist advice, information & education
- Physical impact of AF
- Mental health consequences of the AF symptoms & diagnosis
- Medication issues
- Prelude to ablation
- Impact of ablation on the body
- Moving forward with life after ablation
- The influence of COVID-19
- Lifestyle factors & modifications

Whilst re-reading transcripts, additional notes were taken, which included thoughts on the following additional themes, or even sub-themes

- Gratitude to the care team
- The importance of the ECG in the management of AF, from patient perspective
- Additional treatments such as cardioversion
- The impact of the heart rhythm-AF or sinus rhythm
- The timescale for ablation treatment

Appendix 21: Written permission for the use of AF ablation figure on page 16

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Cardiology appointments: 01752 439233

For outstanding results, please contact the secretary on the telephone number above. If the secretary has not responded within 48 hours, please contact the Clinical Admin Manager on 01752 432908.

Mrs Angela Griffiths
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Oxford University Hospitals NHS Foundation Trust
Headington
OX3 9DU

25/04/2024

Subject: Use of Carto3 images in Doctorate in Nursing (DNurs)

Dear Angela,

I give permission for you to include the images provided to you in your DNurs thesis titled 'Quality of life, symptoms and experiences of patients with an elevated BMI undergoing AF Ablation'. Images are taken from the Biosense Webster Carto3. Catheters in the image are Biosense Webster diagnostic catheters Webster CS™ and Octaray™, and the therapeutic catheter QDot Micro™. You may recreate the images in a suitable format for your DNurs purposes.

Yours Sincerely,

Bradley Porter

Dr Bradley Porter
Consultant Cardiologist & Electrophysiologist