The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning:

A qualitative study

And

Clinical Research Portfolio

Volume I

(Volume II bound separately)

Joanne Skeldon (BSc Honours, MSc)

Submitted in partial fulfilment of the requirements for the degree

of

Doctorate in Clinical Psychology

Institute of Health and Wellbeing

College of Medical, Veterinary and Life Sciences

University of Glasgow

September 2015

Contents Page

Volume I

List of Tables

University of Glasgow | Institute of Health & Wellbeing

DECLARATION OF ORIGINALITY FORM

This form **must** be completed and signed and submitted with all assignments.

Please complete the information below (using BLOCK CAPITALS).

Name JOANNE SKELDON.....	
Student Number 2058544S	
Course Name	Doctorate in Clinical Psychology
Assignment Number/Name	Clinical Research Portfolio

An extract from the University's Statement on Plagiarism is provided overleaf. Please read carefully THEN read and sign the declaration below.

I confirm that this assignment is my own work and that I have:

Read and understood the guidance on plagiarism in the Doctorate in Clinical Psychology Programme Handbook, including the University of Glasgow Statement on Plagiarism	☐
Clearly referenced, in both the text and the bibliography or references, **all sources** used in the work	☐
Fully referenced (including page numbers) and used inverted commas for **all text quoted** from books, journals, web etc. (Please check the section on referencing in the 'Guide to Writing Essays & Reports' appendix of the Graduate School Research Training Programme handbook.)	☐
Provided the sources for all tables, figures, data etc. that are not my own work	☐
Not made use of the work of any other student(s) past or present without acknowledgement. This includes any of my own work, that has been previously, or concurrently, submitted for assessment, either at this or any other educational institution, including school (see overleaf at 31.2)	☐
Not sought or used the services of any professional agencies to produce this work	☐
In addition, I understand that any false claim in respect of this work will result in disciplinary action in accordance with University regulations	☐

DECLARATION:

I am aware of and understand the University's policy on plagiarism and I certify that this assignment is my own work**,** except where indicated by referencing, and that I have followed the good academic practices noted above

Signature Date

Acknowledgements

I would like to give an especially big thank you to all the young people who participated in this study. I feel very privileged to have met you all and thank you for sharing your experiences with me. Without you, this study would not have been possible.

I am extremely grateful to my supervisors Dr Kenneth Mullen and Dr Janie Donnan for your invaluable guidance, encouragement and patience over the previous two years. I would also like to thank the Paediatric Cardiology Service at Yorkhill Hospital and Gemma Little for your fantastic support with the recruitment process.

Thank you to my family, friends and fellow classmates for providing much needed advice, encouragement and distraction along the way! Finally, I would like to say a huge thank you to my parents. You have been amazing! Thank you for your continued love and support throughout the course and for always believing in me.

Chapter One: Systematic Review

The prevalence of psychiatric disorders in adults with a diagnosis of neurocardiogenic syncope or unexplained syncope: A quantitative systematic review.

Correspondence to:
Joanne Skeldon
Mental Health & Wellbeing
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
j.skeldon.1@research.gla.ac.uk

Prepared in accordance with the requirements for submission to the British Journal of Health Psychology (Appendix 1).

(Word Count: 9,586, including the main body of text, abstract, references and tables.)

Abstract

Introduction

A number of studies have reported increased prevalence rates of psychiatric disorders in patients with syncope. This paper systematically reviews the evidence concerning the prevalence of psychiatric disorders in patients with a diagnosis of neurocardiogenic (NCS)/ vasovagal syncope (VVS) or unexplained syncope (US). It also reviews evidence relating to difference in prevalence of psychiatric disorders between patients with NCS/VVS and US.

Methods

A systematic literature search was conducted using Ovid MEDLINE, PsycInfo (EBSCO), Web of Science core collections and CINAHL. The quality of each study was assessed using a quality appraisal tool developed specifically for use in this systematic review. This was based upon previously developed appraisal tools. Nine studies met inclusion criteria.

Results

Methodological inconsistencies led to difficulties ascertaining the prevalence of psychiatric disorders in patients with NCS/VVS or US. Overall prevalence varied widely across studies which used a range of assessment methods to identify psychiatric disorders. Although determining an accurate prevalence rate was challenging, examination of the literature suggested higher prevalence rates of psychiatric disorders in patients with NCS/VVS or US compared to matched controls. Furthermore, the findings indicate that prevalence rates of psychiatric disorders in patients with NCS/VVS and US are similar.

Conclusions

Published research indicates that anxiety and depressive disorders are prevalent in patients with NCS/VVS or US. Due to limitations in the current evidence base, further research is necessary. This will allow for firmer conclusions to be drawn regarding the prevalence of psychiatric disorders in patients with NCS/VVS and US.

Keywords: Neurocardiogenic syncope, vasovagal syncope, unexplained syncope, psychiatric disorders, prevalence.

Introduction

Definitions of syncope

Syncope is defined as 'a transient loss of consciousness and postural tone caused by global cerebral hypoperfusion' (Lee et al., 2013 p.583). If first considering syncope in general, there are many causes, including cardiac, orthostatic, metabolic disorders or endocrine diseases, neurological disorders and adverse drug effects (Berkow & Fletcher, 1992). These underlying causes can be divided into four main categories: neurally mediated, cardiac, orthostatic and cerebrovascular (Miller & Kruse, 2005). Neurally mediated syncopes (NMS) are a heterogeneous group of benign autonomic disorders which occur when there is a disturbance in the autonomic nervous system's control of heart rate and blood pressure (McLeod, 2003). NMS can be further divided into the following three groups: reflex syncope, carotid sinus syncope and situational syncope.

The underlying causes for NMS are listed in Table 1.

Table 1. Underlying causes of syncope.

GENERAL CAUSE	CAUSAL SUBCATEGORY	DEFINITIONS
Neurally mediated	Reflex Syncope: Neurocardiogenic syncope/ Vasovagal syncope	A variety of situations including distress, fear and prolonged standing stimulate the vagus nerve, which leads to a sudden drop in heart rate and blood pressure. With a slower heart rate and dilated blood vessels, less blood gets to the brain resulting in syncope.
	Unexplained Syncope	Syncope which occurs without a known medical cause.
	Carotid sinus	The carotid sinus is a part of the major artery supplying blood to the head. Any manoeuvre that causes stimulation of the area, i.e. turning the head, looking up or even a tight collar can cause syncope in people with a diagnosis of carotid sinus hypersensitivity.
	Situational	The temporary loss of consciousness in a particular kind of situation. The situations that trigger this reaction are diverse. For example, coughing, sneezing, defecating, micturition.

This systematic review will focus on neurocardiogenic syncope (NCS) and unexplained syncope (US) which are both forms of reflex syncope. NCS is also commonly known as vasovagal syncope (VVS). Both terms, NCS and VVS, will be used interchangeably to allow for consistency with the term used in each paper reviewed.

Medical investigation and diagnosis of syncope

The initial stage of diagnosis of NCS starts by taking a detailed medical history, followed by a 12 lead electrocardiogram (ECG). In cases where the medical history

and ECG do not identify underlying cardiac difficulties, an upright tilt-table test can help to identify NCS. The tilt table test involves a head-up tilt at 80° for 30 minutes or until the symptoms of syncope appear (e.g., light-headedness, dizziness, nausea). Some individuals will also experience accompanying bradycardia (low heart rate) and hypotension (low blood pressure) (Blount et al., 2004). If symptoms appear, a diagnosis of NCS is given. If no symptoms are induced, a diagnosis of US is given.

Incidence rates of syncope

The literature shows that syncope in general is a common condition with a lifetime incidence rate of 3-39%. It can affect people of all ages, often reoccurring throughout an individual's lifetime (Ganzeboom et al., 2003). Based upon data collected over a 5 year period between 1987 and 1991, the incidence of syncope presenting for medical attention was found to be 125.8 cases per 100, with more females and adolescents reporting symptoms. The majority of syncopal episodes presenting for medical attention are cases of NCS with cardiac syncope being less common (Weiling et al., 2004). Furthermore, it has been estimated that between 20-47% of syncopal episodes remain unexplained, meaning that no specific neurological, cardiology or other medical diagnosis could be identified (Benbadis & Chichokova, 2006; Ventura et al., 2001).

Impact of neurocardiogenic/ vasovagal syncope or unexplained syncope on psychological functioning.

There is a growing body of evidence documenting the prevalence of psychiatric disorders in patients with NCS/VVS or US. A number of studies have reported high rates of anxiety, panic and depression in individuals with recurrent NCS/VVS and

US (Cohen et al., 2000; Rafanelli et al., 2013). Linzer et al. (1991) and Cohen et al. (2000) also reported increased psychological distress in patients with syncope of non-cardiac aetiology when compared to the general population. Furthermore, the frequency and number of recurrent episodes of NCS/VVS and US has been found to impact on psychological functioning. Romme et al. (2011) reported higher levels of anxiety and depression in individuals who experienced at least one recurrent VVS episode within 6 months, compared with those who did not.

Although there is a growing evidence base for the relationship between psychiatric disorders and NCS/VVS and US, a wide variation in the prevalence rates of psychiatric disorders in individuals with NCS/VVS or US has been documented. This review proposes to systematically review literature on the prevalence of psychiatric disorders in adult patients with a diagnosis of NCS/VVS or US. It is hoped that this review can inform syncope assessment approaches to ensure that potential psychiatric disorders are identified, diagnosed and treated appropriately. As documented by Flint et al. (2009), patients with higher levels of psychosocial impairment were less likely to respond to conventional treatment. This could suggest that without appropriate assessment and treatment, psychiatric disorders may maintain and exacerbate syncopal episodes and impair psychological functioning. For these reasons a systematic review exploring the prevalence of psychiatric disorders in patients with NCS/VVS or US was felt to be timely and clinically relevant.

Aim

The aim of this systematic review is to determine the prevalence of psychiatric disorders as reported in the literature, in adults with NCS/VVS or US.

Review Questions

- What is the prevalence of psychiatric disorders in adults with NCS/VVS or US?
- Is there a difference in the prevalence of psychiatric disorders in patients with NCS/VVS or US?

Methods

Searches were carried out using the following electronic databases: Ovid MEDLINE (1946-March week 5, 2015), PsycInfo (EBSCO), Web of Science core collections (1900 –2015) and CINAHL (1981- 2015). A hand search was also carried out using reference lists from relevant journal articles found through the above electronic databases. Where possible, searches were limited to articles published in English. All possible combinations of the following syncope and psychiatric disorder terms were included, with the truncation command (*) utilised on particular search terms to identify all possible word endings.

The following search terms were used:

Syncope OR vasovagal syncope OR neurocardiogenic syncope OR unexplained syncope OR faint* OR drop attack

AND

Mental disorder OR mental health (subheadings: classification, diagnosis) OR mental ill health (stress psychological, depression) OR psychiatric illness (depressive disorder), OR psychiat* OR psycholog*.

Mental health, mental ill health and psychiatric illness were all mapped to mental disorder. Therefore, this term was exploded to include the following search terms:

anxiety, anxiety disorders, somatoform disorders, depression, mood disorders, depressive disorder, stress psychological and suicide.

The database searches yielded 1,341 citations of which 208 were discarded as duplicates. The titles of the remaining 1,133 citations were reviewed and 1,086 were discarded as being irrelevant to the search topic. The abstracts of the remaining 47 articles were examined and using the inclusion and exclusion criteria, a further 30 were discarded. On reading the full text of the remaining 17 articles, eight were excluded for the following reasons: conference paper (Jacques et al., 2012), included cardiac syncope (Kapoor et al., 1995; Linzer et al. 1990; Linzer et al., 1991), the prevalence rates of psychiatric disorders were not stated (Cohen et al., 2000; Flint et al., 2009; McGrady et al., 2001; Romme et al., 2011). The remaining nine articles were deemed suitable to be included in the final review.

Figure 1 outlines the screening process which identified the nine papers eligible for inclusion.

Inclusion criteria

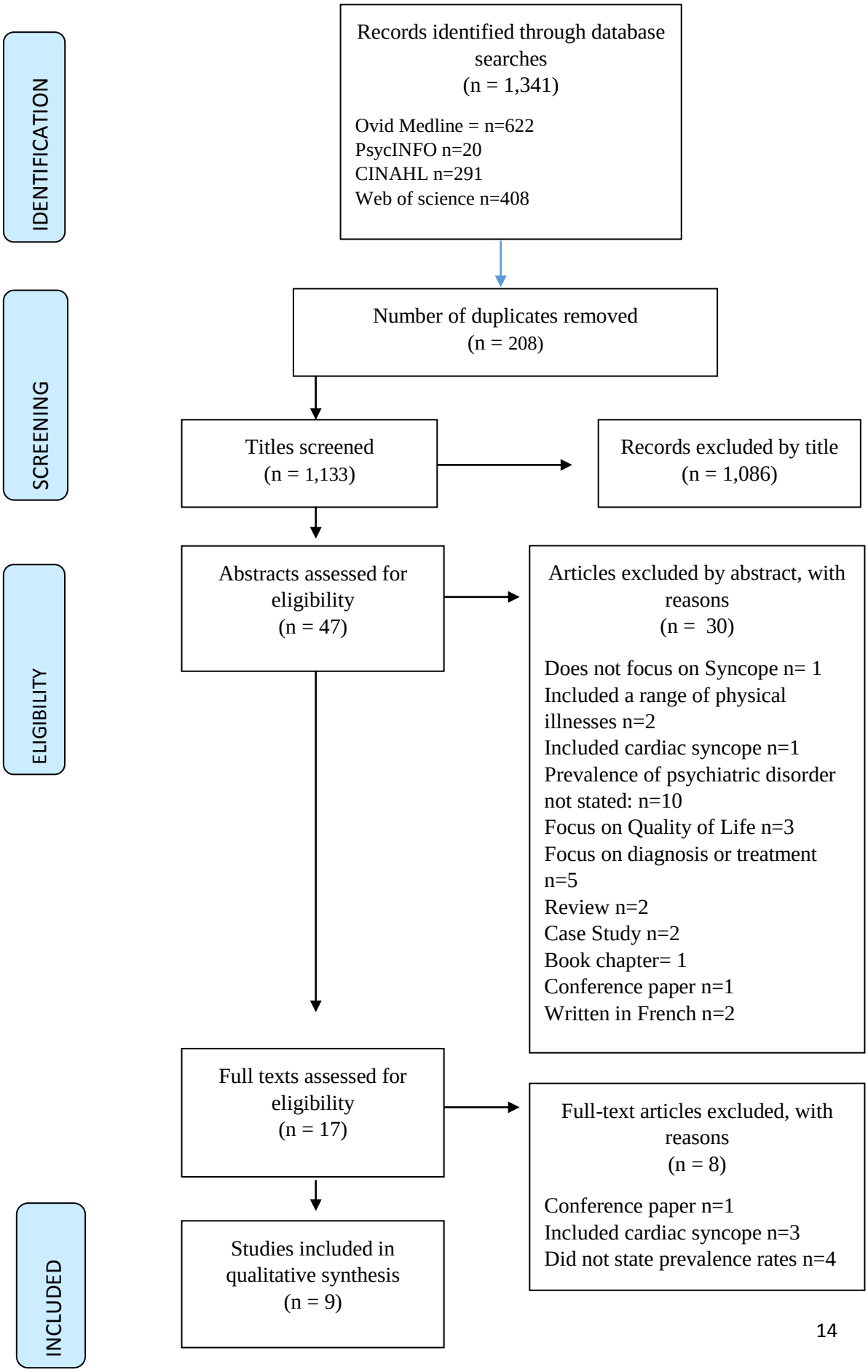
- Includes a diagnosis of neurocardiogenic, vasovagal or unexplained syncope
- States how psychiatric disorder is identified
- States prevalence of psychiatric disorder
- Is published in a peer reviewed journal
- Is published in English
- Studies include adults aged 18 years old and above.

Exclusion criteria

- Studies which include syncope with a cardiac aetiology

- Studies which are published as reviews, conference papers, book reviews, book chapters, case studies or discussion articles
- Studies conducted solely with children aged 17 years old or below and studies conducted solely with older adults aged 60 years old or above.

Figure 1. Screening Process



Quality rating criteria

Due to the reported lack of rigorously designed appraisal tools for non-randomised trials (Jarde et al., 2012), a quality appraisal tool was designed for this review based upon appraisal tools previously developed by Scottish Intercollegiate Guidelines Network (SIGN) and Downs and Black (1998). Downs and Black (1998) developed a checklist for assessing the methodological quality of randomised and non-randomised studies which provides an overall score for study quality and a profile of scores for the quality of reporting, internal validity (bias and confounding variables), power and external validity. Reliability of the subscales varied from good to poor, however, the checklist was found to be highly correlated with existing appraisal tools used for assessing randomised studies. Furthermore, they found little difference in its performance between randomised and non-randomised studies (Downs & Black, 1998). In addition, SIGN guidelines have published methodological checklists for case control studies and cohort studies. The quality appraisal tool used in this review was designed to assess a number of study designs, assessing the quality of the methods, assessment measures, sample, internal and external validity, and reliability of the results and conclusions made. It was designed to evaluate the quality of the evidence presented in each paper using a 2 point rating scale (Appendix 2). A number of items in the quality appraisal tool developed for use in this systematic review were only applicable to case control, cohort designs or cross sectional designs. To allow for comparisons across all studies, scores were converted to percentages. The methodological checklists designed by SIGN state that a study is rated high quality if the majority of the criteria are met, acceptable quality if most criteria are met and low quality if most criteria are not met or there are significant flaws in the research. In line with these recommendations and for the purpose of this

review, fewer than 50% was considered low quality, 50-75% moderate quality and above 75% as high quality. To determine inter-rater reliability, each paper was reviewed by an independent assessor blinded to the previous ratings given by the principal assessor (JS). Any discrepancies in ratings were resolved through discussion resulting in consensus for study ratings. A decision was taken not to exclude any study based on their quality rating. It is recognised that tentative conclusions must be drawn from studies with lower quality ratings. However, due to the limited research and absence of previous systemic reviews in this area, it was felt that all studies should be included to provide an overview of all relevant literature.

Results

A summary of the nine papers reviewed is provided in Table 2. Four of the papers presented research which focused on addressing the review questions (Lee et al., 2013; Rafanelli et al., 2013; Ventura et al., 2001; Weiner et al., 2013). A further five studies stated prevalence rates of psychiatric disorders in individuals with NCS/VVS or US as part of their research (D'Antono et al., 2009; Giada et al., 2005; Gracie et al., 2006; Kouakam et al., 2002; Lerma et al., 2012).

Table 2: An overview of papers presenting prevalence rates of psychiatric disorders in participants with NCS/VVS or US.

Study	Quality Rating Score	Study Design	Region	Sample Characteristics: Size, Age, Gender, Recruitment	Assessment of psychiatric disorders	Assessment of Syncope type	Prevalence of psychiatric disorder	Definition of syncope type
Rafanelli et al. (2013)	92% High	Case-control study	Italy	N= 67 31 male, 36 female Mean Age: 48.4 ±18.8 yrs Age Range: 14-86 Recruitment Site: Emergency department and outpatient clinic in one medical centre.	Psychodiagnostic Structured Clinical Interview for eliciting psychiatric diagnosis (First et al., 1994), in line with Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria (1994). Semi structured interview for the Diagnostic Criteria for Psychosomatic Research (DCPR) (Fava et al.1995). Psychosocial Index (PSI) (Sonino & Fava, 1998). Symptom Questionnaire (Kellner, 1987). Fear Questionnaire (Marks & Mathews, 1979). Kellner's Illness Attitude Scale (Kellner, 1988).	Head Up Tilt Test	**VVS and US** All DSM-IV Criteria 95.5% (n=64) of all participants met criteria for at least 1 DSM-IV/DCPR diagnosis. 86.6% (n=58) of all participants met criteria for at least 1 DSM-IV diagnosis. More participants with VVS compared to US met criteria for depression and generalized anxiety disorder. Raw data not provided.	VVS: 'Sudden transient loss of consciousness associated with a drop in postural tone due to transient global cerebral hypoperfusion and hypoxia'.
Gracie et al. (2006)	89.4% High	Cross Sectional Study	UK	N= 41 14 male, 27 female Mean Age: 54.07 ±18.92 yrs Age Range: Not stated Recruitment Site: One medical outpatient clinic.	The hospital anxiety and depression Scale (HADS), (Zigmond & Snaith, 1983). The syncope functional status Questionnaire (SFSQ), (Linzer et al., 1994). Semi structured interview (Content focused on triggers, thoughts and coping strategies based on the cognitive intrusions questionnaire, dizziness beliefs scale, vertigo coping questionnaire), (Gracie et al., 2006).	Head Up Tilt Test	**VVS** 32.3% (n=9) of participants met criteria for borderline or clinical anxiety. 21.9% (n=14) of participants met criteria for borderline or clinical depression.	VVS: 'Characterised by profound hypotension with or without bradycardia'.

Table 2: An overview of papers presenting prevalence rates of psychiatric disorders in participants with NCS/VVS or US (Continued).

Study	Quality Rating Score	Study Design	Region	Sample Characteristics: Size, Age, Gender, Recruitment	Assessment of psychiatric disorders	Assessment of Syncope type	Prevalence of psychiatric disorder	Definition of syncope type
D'Antono et al. (2009)	84% High	Case control study	Canada	N=104 36 male, 68 female Mean Age: Male, 53 ±12.75 yrs, female 49 ±18.03 yrs. Age Range: Not stated Recruitment Site: Three different medical centres.	Primary Care Evaluation of Mental Disorders (PRIME-MD), (Spitzer et al., 1994) Psychiatric Symptom Index (PSI), (Ilfeld, 1976) Anxiety Sensitivity Index (ASI), (Reiss et al., 1984) The blood and Injury Fear subscale of the Fear Survey Schedule III, (Wolpe & Lang, 1964)	Head up Tilt Test	**VVS** 16.3% (n=7) of participants met criteria for depression. 20.9% (n=9) of participants met criteria for anxiety **US** 27.1% (n=16) of participants met criteria for depression. 40.7% of participants met criteria for anxiety 60% (n=63) of all participants reported clinical levels of psychological distress.	VVS: 'An inappropriate reflex vasodilation and or bradycardia.'
Lee et al. (2013)	79.2% High	Case control Study	Korea	N= 199 total N=176 NMS N=23 US 81 male, 118 female Mean Age: 40.09 ±15.58 yrs Age Range: 16-77 yrs. Recruitment Site: Emergency department and outpatient clinic in one medical centre.	Medical History and physical examination. HADS (Zigmond & Snaith, 1983)	Head Up Tilt Test	**US** 47% (n=11) of participants met criteria for depression 21.7% (n=5) of participants met criteria for anxiety.	US: 'Syncope without apparent trigger and/or lack of prodromal symptoms'.

Table 2: An overview of papers presenting prevalence rates of psychiatric disorders in participants with NCS/VVS or US (Continued).

Study	Quality Rating Score	Study Design	Region	Sample Characteristics: Size, Age, Gender, Recruitment	Assessment of psychiatric disorders	Assessment of Syncope type	Prevalence of psychiatric disorder	Definition of syncope type
Giada et al. (2005)	75% Moderate	Case Control Study	Italy	N= 61 20 male, 41 female Mean Age: 44 ±18 yrs Age Range: Not stated Recruitment Site: Not stated.	Structured interview with a psychologist. Minnesota Multiphase Personality Inventory-2 (MMPI-2) which assess for the following personality traits: Hypochondriasis, depression, hysteria, psychopathic deviance, paranoia, psychasthenia, schizophrenia, mania, social introversion (Hathaway & McKinley, 1989). Diagnosis was made in line with DSM-IV criteria for anxiety disorders, mood disorders, somatisation disorders and personality disorders.	Head Up Tilt Test	**VVS** 71% (n=43) of participants met criteria for at least one psychiatric disorder. This was significantly higher than the control group. ($p<0.001$). 18% (n=11) of participants met criteria for depression. 28% (n=17) met criteria for anxiety. No prevalence rates were reported for personality disorders, however no significant difference was found between the control group and participants with VVS. All psychiatric disorders were reported to be mild to moderate severity.	VVS: 'Syncope with full reproduction of the patient's spontaneous symptoms, associated with a sudden and significant fall in blood pressure and heart rate.'

Table 2: An overview of papers presenting prevalence rates of psychiatric disorders in participants with NCS/VVS or US (Continued).

Study	Quality Rating Score	Study Design	Region	Sample Characteristics: Size, Age, Gender, Recruitment	Assessment of psychiatric disorders	Assessment of Syncope type	Prevalence of psychiatric disorder	Definition of syncope type
Ventura et al. (2001)	72.7% Moderate	Cohort Study	Germany	N= 26 6 male, 20 female Mean Age: 36 ±16 yrs Age Range: 14-83yrs Recruitment Site: One medical outpatient centre.	Psychiatric interview in line with International Classification of Diseases and Related Health Problems (10th edition) (ICD-10) criteria. Symptom Checklist 90 (Derogatis, 1994) Giessen Complaint List (Braehler & Scheer, 1995) Body Image Questionnaire (Clement & Loewe, 1996)	Head Up Tilt Test	**US** 81% (n=21) participants met criteria for 1 psychiatric condition. 46% (n=12) met criteria for major depressive disorder 15% (n=4) panic attacks 12% (n=3) somatisation disorder 8% (n=2) general anxiety 43% (n=9) multiple pathological psychiatric conditions.	Not stated.
Wiener et al. (2013)	54.3% Moderate	Cohort Study	USA	N= 161 59 male, 102 female Mean Age: 61.4 ±25 yrs Age Range: not stated. Recruitment site: One emergency department.	Questionnaires – not identified. Review of past medical history and records.	Head up tilt test	**US** All Major DSM-IV diagnoses included. Excluding attention deficit hyperactivity disorder (ADHD) (which is considered a neurodevelopmental disorder), dementia and learning disability, 31.1% (n=51) of participants met DSM-IV criteria for diagnosis. 16.8% (n=27) met criteria for depression. 6.8% (n=11) met criteria for anxiety.	Not stated.

Table 2: An overview of papers presenting prevalence rates of psychiatric disorders in participants with NCS/VVS or US (Continued).

Study	Quality Rating Score	Study Design	Region	Sample Characteristics: Size, Age, Gender, Recruitment	Assessment of psychiatric disorders	Assessment of Syncope type	Prevalence of psychiatric disorder	Definition of syncope type
Kouakam et al., (2002)	52% Moderate	Case Control Study	France	N= 80 total sample N=40 control group, N=40 experimental group. **Experimental Group**: 14 male, 26 female Mean Age: 42 ±18 yrs Age Range: 18-72 yrs. Recruitment Site: One medical outpatient clinic	Psychiatric Interview to assess for ICD-10 diagnostic criteria, carried out by a psychiatrist (Sheehan et al., 1998). Semi-structured Mini International Neuropsychiatric Interview. Hamilton Anxiety rating scale (Hamilton, 1959). Montgomery and Asberg Scale depression (Montgomery & Asberg, 1979). Stress Coping (Ostell, 1991). General Health Related QoL (GHQ-28) (Goldberg &Williams, 1988).	Head Up Tilt Test	**VVS and US** 65% (n=26) of participants met criteria for anxiety, panic disorder or depressive disorders. **VVS** 12% (n=3) of participants met criteria for depression. 32% (n=8) of participants met criteria for anxiety **US** 20% (n=3) of participants met criteria for depression. 36% (n=4) of participants met criteria for anxiety. The prevalence of psychiatric disorders in participants with syncope was significantly higher than the control group. (p=0.01)	Not stated.

Table 2: An overview of papers presenting prevalence rates of psychiatric disorders in participants with NCS/VVS or US (Continued).

Study	Quality Rating Score	Study Design	Region	Sample Characteristics: Size, Age, Gender, Recruitment	Assessment of psychiatric disorders	Assessment of Syncope type	Prevalence of psychiatric disorder	Definition of syncope type
Lerma et al., (2012)	38.1% Low	Case Control study	Mexico	N= 51 24 male, 27 female Median Age: 17 yrs Age Range: 15-45 yrs. Recruitment Site: One medical outpatient clinic.	Beck Anxiety Inventory (BAI) (Beck et al., 1988) Beck Depression Inventory (BDI) (Beck et al., 1961)	Head Up Tilt Test	**VVS** 45% (n=23) of participants met criteria for depression. 33% (n=17) of participants met criteria for anxiety.	VVS: 'The transitory loss of consciousness secondary to generalize cerebral hypoperfusion due to arterial hypotension with or without a concomitant reduction of heart rate.'

Description of studies and key findings

Relevant findings from each article are described with reference to methodological strengths and limitations.

Overall, variation in definitions and assessment methods of psychiatric disorders were found. These differences are likely to influence reported prevalence rates. Two studies combined psychiatric disorder prevalence rates for participants with NCS/VVS and US (Kouakam et al., 2002; Rafanelli et al., 2013). The prevalence rates of psychiatric disorders found in these studies were higher than studies which reported separate prevalence rates.

Research conducted by Rafanelli et al. (2013) was rated as the highest quality study. This study employed a number of clinician administered and self-report assessment tools which were rated blind. Clinicians administered questionnaires and interviews were completed by a trained psychologist. Information regarding their inter-rater reliability, overall reliability and validity is presented in the paper. A strength of the study includes the recruitment of participants from both a hospital emergency room and an outpatient syncope department, increasing how representative the sample is likely to be of individuals with NCS or US. Rafanelli et al. (2013) reported that 86% (n=58) of participants with VVS or US met criteria for at least one of the following DMS-IV diagnosis: specific phobia, social phobia, general anxiety disorder, depression, panic disorder, somatisation disorder, agoraphobia, histrionic personality disorder and dysthymia. Individual prevalence rates for each disorder are not presented, which is a limitation to the study. However the results show that specific phobia, social phobia, general anxiety disorder and depression were most frequently diagnosed in both groups of participants. It is acknowledged that despite this study receiving the highest quality rating score, the inclusion of DSM-IV criteria for all

diagnoses is likely to increase the reported prevalence rates of psychiatric diagnosis. It is possible that not all diagnoses reported were associated with the pathogenesis of NCS or US.

Research conducted by Kouakam et al. (2002) was rated as a moderate quality study and assessed for somatisation, panic disorder, anxiety and depressive disorders. The results state that 65% (n=26) of participants with VVS or US met criteria for at least one of the above psychiatric disorders. The study is commended for the use of self-report assessment tools and a clinician administered interview carried out by an independent senior psychiatric physician, who was blinded to the results of the head up tilt test procedure. Diagnosis of psychiatric disorders were obtained in line with ICD-10 criteria, however the study could have further benefited from reporting the reliability and validity of the assessment measures used to provide diagnosis.

What is the prevalence rate of psychiatric disorders in patients with neurocardiogenic/ vasovagal syncope?

Five studies explored the prevalence of psychological disorders in patients with NCS/VVS. Research conducted by Giada et al. (2005), which was rated as moderate quality, included the following DSM-IV diagnoses: anxiety disorders, mood disorders, somatisation disorders and personality disorders. The authors reported 71% (n=43) of participants with VVS met criteria for at least one of the above psychiatric diagnoses. Focusing on specific diagnoses, the study reported 18% (n=11) of participants met criteria for depression, 28% (n=17) met criteria for anxiety and 29% (n=18) met criteria for somatisation disorders. The questionnaires were scored blind by two ‘expert psychologists’. Information on the clinician

administering the MMPI-2 (Hathaway & McKinley, 1989) was not detailed and it is therefore not possible to ascertain whether they were appropriately trained and qualified to do so.

The remaining four studies focused on establishing the prevalence rates of depression and anxiety disorders in participants with VVS (D'Antono et al., 2009; Gracie et al., 2006; Kouakam et al., 2002; Lerma et al., 2012). These studies ranged from high to low quality. Overall, the prevalence of depression ranged from 12% (n=3) (Kouakam et al., 2002) to 45% (n=23) (Lerma et al., 2012). The prevalence of anxiety disorders were found to exhibit greater consistency across the four studies. The overall range was found to be 21% (n=9) (D'Antono et al., 2009) to 33% (n=17) (Lerma et al., 2012). Within this range, Kouakam et al. (2002) reported a prevalence rate of 32% (n=8) for anxiety and 20% (n=5) for panic disorder.

Research conducted by D'Antono et al. (2009) and Gracie et al. (2006) were rated as high quality studies. D'Antono et al. (2009) used a number of clinician rated and self-report assessment tools to identify the following psychiatric disorders: mood disorders, including major and minor depression and dysthymia, and anxiety disorders including panic disorder, generalized anxiety disorder and anxiety disorder not otherwise specified. The PRIME-MD (Spitzer et al., 1994) was used to recognise DSM-IV Axis 1 disorders, however information is not provided on the clinician administering this assessment. A total of 104 participants were recruited from three medical centres across the Montreal region in France. The number of recruitment sites is a strength of the study. The findings revealed that 16% (n=7) of participants with VVS met DSM-IV criteria for a mood disorder and 21% (n=9) met criteria for an anxiety disorder. The study is commended for reporting the internal consistency and validity of the assessment measures used, however it was not possible to

determine whether they were rated blind, which may have resulted in bias in the findings.

Gracie et al. (2006) assessed patients at diagnosis or follow up appointments and found a prevalence rate of 22% (n=9) for depression and 32% (n=14) for anxiety. All participants were recruited from one outpatient clinic and the authors acknowledge that they recruited a convenience sample. This was done to maximise participation, however it may also have resulted in sampling bias and in difficulties in generalizing results. Information on the reliability and validity of the HADS (Zigmond & Snaith, 1983) is not reported and evaluation did not take place at the same time for all participants. It is possible that participant's psychological functioning could have altered between diagnosis and follow up, for example, participants may have felt reassured by their diagnosis. Alternatively, a diagnosis may have increased anxiety and symptoms of low mood. A strength of this study is that a power calculation was performed to determine an appropriate sample size which was adhered to.

It is important to note that the highest prevalence rates for anxiety and depression were documented by Lerma et al. (2012) which was rated the lowest quality of all studies. Therefore, it is possible that studies with a higher quality rating, which found the prevalence rates for anxiety and depression to be lower, are more accurate. Lerma et al. (2012) presented an overall percentage for participants with mild, moderate and severe symptoms, in line with standardised and culturally-normed cut off values for the BAI (Beck et al., 1988) and BDI (Beck et al., 1961). They found that 45% (n=23) of participants with VVS presented with symptoms of depression and 33% (n=17) presented with symptoms of anxiety. The study did not discuss the reliability or validity of the assessment measures used and the clinical rating categories indicating severity of symptoms were not presented. No diagnoses were

given in line with standardised criteria, instead the results report the prevalence of symptoms. It is likely that this contributed to the high prevalence rates reported. Further limitations of the study include a lack of information on the study procedures. Information was not provided on the number of patients asked to participate, full inclusion and exclusion criteria were not stated and no demographic information was provided. Due to the limited information presented in the study, all conclusions must be drawn with caution.

What is the prevalence rate of psychiatric disorders in patients with unexplained syncope?

Five studies investigated the prevalence of psychiatric disorders in patients with US (D'Antono et al., 2009; Kouakam et al., 2002; Lee et al., 2013; Ventura et al., 2001; Weiner et al., 2013). Research conducted by Ventura et al. (2001) and Weiner et al. (2013), which were both rated as moderate quality studies, assessed for all ICD-10 psychiatric disorders and all major DSM-IV psychiatric disorders respectively. Ventura et al. (2001) found 81% (n=21) of participants with US met ICD-10 criteria for at least one psychiatric disorder. Using a range of self-administered and clinician administered assessment tools, 46% (n=12) of participants were reported to meet criteria for depression, 15% (n=4) for panic attacks, 12% (n=3) for somatisation and 8% (n=2) for general anxiety disorder. All psychiatric diagnoses were made by a qualified psychosomatis. The study included data on participant's characteristics including syncope duration, number of syncopal episodes and subsequent bodily injuries. Although these possible confounding variables were identified they were not incorporated into the analysis. Significant differences were noted between

individuals who accepted a psychiatric assessment and therefore consented to participate, compared to those who did not. Those who refused, were older, experienced fewer syncopal episodes over a shorter duration of time and experienced fewer prodromal symptoms. These differences are likely to contribute to the high prevalence of psychiatric disorders found within patients who consented to participate. Furthermore, the sample size was small and the authors acknowledged that participants were a highly selective group, questioning the generalizability of the results.

Weiner et al. (2013) recruited 161 participants from a hospital emergency department and assessed for all major psychiatric disorders. They reported a prevalence rate of 31.1% (n=51). Within this, Weiner et al. (2013) reported a prevalence rate of 16.8% (n=27) for depression and 6.8% (n=11) for anxiety. Overall, there were a number of limitations to this study. These include the potential lack of generalizability of the findings due to recruitment from a single site. This is the only study which solely recruited from a hospital emergency department. It is possible that individuals who presented to emergency departments opposed to outpatient departments have higher levels of distress associated with their symptoms. In addition, limited details about the questionnaires used for assessing psychiatric disorders were provided and difficulties in establishing diagnosis were highlighted due to the use of retrospective analysis of medical history case notes.

Three studies focused on investigating the prevalence of depression and anxiety disorders (D'Antono et al., 2009; Lee et al., 2013; Weiner et al., 2013). These studies ranged from high to moderate quality in accordance with quality assessment rating criteria. The prevalence of depression ranged from 17 % (n=27) (Weiner et al., 2013)

to 47% (n=11) (Lee et al., 2013). Within this range, Kouakam et al. (2002) reported a prevalence rate of 20% (n=3) and D'Antono et al. (2009), reported 27.1% (n=16). This large range is similar to findings in patients with VVS. The prevalence of anxiety ranged from 6.8% (n=11) (Wiener et al., 2013) to 40.7% (n= 24) (D'Antono et al., 2009). Within this range, Kouakam et al. (2002) reported a prevalence rate of 26% (n= 4).

Research conducted by Lee et al. (2013) compared the prevalence of anxiety and depression between patients with NMS and US. Although the study reported that VVS was the most common cause of NMS, the results for participants with VVS were not presented. Therefore, only the prevalence rates of psychiatric disorders in participants with US are included in this review. Symptoms of anxiety and depression were assessed for using the HADS (Zigmond & Snaith, 1983), however information on the reliability or validity of this assessment measure was not included in the study. The findings show a prevalence rate of 33% (n=43) for 'borderline' and 'abnormal' clinical ratings of depression and 26% (n= 47) for 'borderline' and 'abnormal' clinical ratings of anxiety. The study is commended for collating comprehensive data on participant's clinical characteristics including, age, gender, number of syncopal episodes, injury, family history of syncope and medical co-morbidities, excluding cardiac conditions. These variables were analysed in relation to the prevalence of anxiety and depression.

What are the differences in the prevalence rates of psychiatric disorders in participants with neurocardiogenic/ vasovagal syncope or unexplained syncope?

Three studies compared findings between participants with VVS and US (D'Antono et al., 2009; Kouakam et al., 2002; Rafanelli et al., 2013) with contradictory findings. Rafanelli et al. (2013) found a higher prevalence of anxiety, depression and anger in participants with US compared to VVS. Both groups of participants were recruited from the same sites following the same exclusion and inclusion criteria. The groups of participants did not significantly differ on the following socio-demographic variables: age, sex, marital status, occupation and education, or frequency of syncope reoccurrence, family history of syncope and medical comorbidities. No significant differences were found in the distribution of psychiatric diagnoses between the two groups. The findings also highlight that participants with US were found to have significantly lower PSI scores for wellbeing ($p=0.001$) and significantly higher PSI scores for psychological distress ($p=0.018$) compared to participants with VVS. Consistent with these findings, the anxiety and depression subscales on the SQ indicated significantly higher levels of anxiety ($p=0.001$) and depression ($p=0.002$) in patients with US compared to patients with VVS.

Kouakam et al. (2002) reported small differences in the prevalence of psychiatric disorders in participants with VVS or US. The findings indicate that more participants with VVS compared to those with US presented with anxiety disorders (32% v. 26%). In contrast, fewer participants with VVS compared to those with US experienced depression (20% v. 12%). The study presents limited demographic information for both groups of participants with VVS or US and recruitment procedures are not stated, making it difficult to determine if the groups were comparable.

D'Antono et al. (2009) reported that fewer participants with VVS compared to those with US met criteria for mood disorders (16% v. 27%), however in contrast to the findings by Kouakam et al. (2002), fewer participants with VVS met criteria for anxiety disorders (21% v. 41%). No significant group differences emerged on any socio-demographic variables. Kouakam et al. (2002) and D'Antono et al. (2009) did not conduct statistical analysis to determine if the differences between groups were significant.

What is the prevalence rate of psychiatric disorders in patients with neurocardiogenic/vasovagal syncope or unexplained syncope compared to a control group?

Two studies compared prevalence rates to a control group (Giada et al., 2005; Koukam et al., 2002). Lee et al. (2013) compared prevalence rates between participants with US and a sample of the general Korean population, as documented in a previous study (Yun et al., 2007). They acknowledge that a lack of control group is a limitation to the study.

Giada et al. (2005) compared findings from participants with VVS to healthy age and sex matched controls with no history of syncope or pre-syncope symptoms. Findings indicate that the number of participants with VVS who met DSM-IV criteria for mood or anxiety disorders was significantly higher than the control group. No statistically significant differences emerged between groups on socio-demographic variables. A limitation of the study is a lack of details specifying how participants were recruited. Overall, the authors concluded that patients with VVS experience a

higher rate of mild to moderate psychiatric disorders in comparison to healthy controls.

Kouakam et al. (2002) compared findings from participants with VVS or US to patients with arrhythmia with no history of syncope or pre-syncope symptoms. The results showed that significantly more participants with US or VVS met criteria for at least one psychiatric diagnosis compared to the control group, most commonly anxiety and panic disorder. Further analysis revealed that the prevalence of depression was not significantly different between groups. Limited demographic information is provided for both groups and clear inclusion and exclusion criteria are not stated. These factors make it difficult to determine if the control group is accurately matched, whether both groups are representative of their population and whether the findings can be generalized.

Lee et al. (2013) reported no significant differences in prevalence rates between participants with US and the general Korean population. The authors recognise that this contradicts previous findings and concluded that this difference might be accounted for by the infrequent number of syncopal episodes experienced by participants. They also reported that participants recognised syncope as benign, which may have reduced anxiety.

Discussion

The primary purpose of this systematic review was to determine the prevalence rates of psychiatric disorders, in adults with NCS/VVS or US as presented in the literature. It also aimed to address whether there are differences in the prevalence rates of psychiatric disorders between NCS/VVS and US. The papers reviewed

varied in quality from high to low and methodological inconsistencies were found. Overall, the prevalence of psychiatric disorders in patients with NCS/VVS or US ranged significantly across the studies reviewed. Studies which compared prevalence rates of psychiatric disorders to a control group also reported inconsistent findings. The following factors are likely to have influenced these findings.

The definitions of psychiatric disorders differed across studies. Six studies explicitly used DSM-IV criteria (D'Antono et al., 2009; Giada et al., 2005; Rafanelli et al., 2013; Weiner et al., 2013) or ICD-10 classifications (Koukam et al., 2002; Ventura et al., 2001) to establish psychiatric diagnosis. Alternatively, three studies used assessment measures which assessed for symptoms of psychiatric disorders (Gracie et al., 2006; Lee et al., 2013; Lerma et al., 2012). Some differences were found, with the majority of studies using DSM-IV or ICD-10 criteria reporting lower prevalence than those using other assessment measures. DSM-IV and ICD-10 criteria are widely used in mental health services to provide diagnoses. To meet criteria for a particular diagnosis, a number of symptoms must be present over a specified time period. It is possible that this reflects the generally lower prevalence rates reported in studies using these criteria. Studies utilising DSM-IV or ICD-10 criteria allow for the comparison of prevalence rates of psychiatric disorders across studies. However, it is important to consider the value of alternative assessment tools which assess for symptoms, such as the HADS (Zigmond & Snaith, 1983) and the BAI (Beck et al., 1988) and BDI (Beck et al., 1961). In comparison to providing a diagnosis, which typically falls within the domain of psychiatry, these measures are frequently used in clinical practice by psychologists. These assessment tools allow for the identification

of symptoms which although may not reach criteria for diagnosis, may still cause psychological distress.

Furthermore, a number of studies assessed for all DSM-IV or ICD-10 diagnoses compared to other studies which specifically assessed for anxiety and mood disorders. As would be expected, combined prevalence rates for a number of psychiatric disorders were found to be higher than prevalence rates for specific diagnoses. It is possible that studies which assessed for specific psychiatric diagnoses may not capture an accurate picture of the prevalence of all psychiatric disorders present, although it is likely that not all DSM-IV or ICD-10 psychiatric disorders would be associated with the pathogenesis of NCS/VVS or US (Oh & Kapoor, 1997). A number of studies included current and/or previous psychiatric diagnosis in the exclusion criteria. It may be important to note that Rafanelli et al. (2013) and Ventura et al. (2001) did not exclude participants with a previous psychiatric diagnosis and both these studies reported high prevalence rates of psychiatric diagnoses. A range of clinicians including psychiatrists (Kouakam et al., 2002), psychologists (Rafanelli et al., 2013) and psychosomatists (Ventura et al., 2001) administered and interpreted the assessment tools employed across studies. This information was not reported in two studies. (D'Antono et al., 2009; Giada et al., 2005). The different expertise found within these disciplines may have also influenced the interpretation and formulation of participant's difficulties.

In addition to differences in psychiatric diagnosis, assessment and definition, it is possible that a lack of consideration of confounding factors could have contributed towards the variation in prevalence rates documented. Six studies collated additional information on participant's clinical characteristics such as: co-morbid medical conditions; number of syncopal episodes; period of complaint (NCS/VVS or US)

and syncope related trauma (D'Antono et al., 2009; Giada et al., 2005; Gracie et al., 2006; Rafanelli et al., 2013; Lee et al., 2013; Ventura et al., 2001). This data was not consistently included in the analysis across studies. A number of studies controlled for age and gender in the design and analysis, but the findings were contradictory. D'Antono et al. (2009) reported that female gender is associated with increased prevalence rates of depression and anxiety, and Lee et al. (2013) found that female gender and younger age is associated with increased severity of anxiety symptoms. In contrast, Weiner et al. (2013) reported that significantly more males who met DSM-IV criteria for a psychiatric disorder experienced US. The authors note that this finding contradicts previous findings that female gender is related to increased prevalence and severity of anxiety and depressive symptoms (Kapoor et al., 1995; Lee et al., 2013; Romme et al., 2011). Sample size varied across studies from 161 (Weiner et al., 2013) to 23 (Lee et al., 2013), and only one study performed power calculations to establish a suitable sample size (Gracie et al., 2006). In addition, the studies reviewed were conducted in a range of countries and cultures which may impact on the findings, as well as their comparability and generalizability. Although culture was not specifically referred to in the studies included in the review, it is necessary to consider its influence on how mental health difficulties are understood. For example, Lipson et al. (1996) highlighted that mental health difficulties are traditionally considered to be shameful in Korean culture. Beliefs such as these may contribute to the low prevalence rate of psychiatric disorders presented by Lee et al. (2013). Culture can also influence help seeking behaviours. Social stigma and shame may prevent individuals from seeking help and presenting at medical services (Kramer et al., 2002). Although syncope in general has been found to be more common in females (Ganzeboom et al., 2003), it may be important to consider

possible gender differences in health seeking behaviour in individuals with NCS/VVS or US, as the samples recruited for each study reviewed included a higher number of females than males.

There are no known published systematic reviews focusing on psychiatric disorder prevalence in patients with NCS/VVS or US, although two papers reviewed a number of studies investigating the relationship between medically unexplained syncope and psychiatric disorders (Andrighetto et al., 1999; Linzer et al., 1992). Therefore, the results of this systematic review are a first step in establishing prevalence rates of psychiatric disorders in patients with NCS/VVS or US. Taking into consideration the limitations of the papers reviewed, it is difficult to draw meaningful conclusions. Although the findings indicate that patients with NCS/VVS or US experience similar prevalence rates of psychiatric disorders which are greater than those found in matched controls, further research is required to explore the impact of mediating factors on prevalence rates. Such research should employ consistent criteria for psychiatric diagnosis to enable cross-study comparisons.

Limitations of Review

This review aimed to use a comprehensive search strategy to identify all articles relevant to the review questions. Strict inclusion criteria were applied and as such, unpublished studies and those not written in English were excluded. Excluding studies such as these may introduce reporting bias as well as limiting understanding of how this condition may be experienced cross culturally. This review also did not include studies which only reported severity of psychiatric diagnoses or those which focused on the impact of NCS/VVS or US on quality of life. Overall, few prevalence studies were identified which also limits the generalizability of results.

Clinical Implications

Results indicate that individuals who experience NCS/VVS or US have an increased prevalence of mental health difficulties, in particular a more frequent sub-profile of anxiety and depression. Based upon the current evidence, it is challenging to determine whether the presence of psychiatric disorders is the cause or effect of syncopal episodes in patients with NCS/VVS or US. Research has shown that episodes of syncope reoccurrence reduces and in some cases resolves following psychiatric treatment including psychotherapy and medication (Kapoor et al., 1995; Linzer et al., 1990; Ventura et al., 2001). Luzza et al. (2004) suggests that these findings indicate that psychiatric difficulties are causative of US. Benefits of psychological treatment for individuals with NCS/VVS have been reported, indicating that psychological distress may contribute to the maintenance of NCS/VVS symptoms (McGrady et al., 1997; McGrady et al., 2003; Newton et al., 2003; Sabin, 2001). Furthermore, anxiety and depression have been associated with poor prognostic outcomes in a number of long term health conditions. Failure to appropriately assess or treat psychiatric difficulties could worsen prognosis, increasing the risk of syncopal reoccurrence and thus maintaining difficulties (Flint et al., 2009). Health care teams assessing and supporting individuals with syncope should be aware of the potentially increased prevalence rate of mental health difficulties in this population. This knowledge could support multidisciplinary working between medical and psychological services to ensure that individuals with NCS/VVS or US receive appropriate treatment which meets their needs.

Conclusion

There is wide variation in the prevalence rate of psychiatric disorders in patients with NCS/VVS or US. Inconsistencies appear across studies which were rated as high, moderate and low quality. Overall, there were limitations in interpreting the findings of the studies reviewed due to the broad variation in design; methods; participants; assessment and diagnosis of psychiatric disorders; cultural variations and overall methodological quality. Only with further research can firmer conclusions be made regarding an accurate prevalence rate of psychiatric disorders in patients with NCS/VVS or US.

References

American Psychiatric Association. (1994). *Diagnostic and statistical manual of mental disorders. 4th edition.* Washington, DC: APA Press.

Andrighetto, A., G., John, A. B., Barbisan, J. N., & Taborda, J. G. V. (1999). Syncope and it's relation to psychiatric disorders. *Arquivos Brasileiros de Cardiologia, 72*(6), 756-760.

Beck, A. T., Brown G., Epstein, N., & Steer, R. A. (1988). An Inventory for Measuring Clinical Anxiety, Psychometric Properties. *Journal of Consulting and Clinical Psychology, 56*(6), 893-89.

Beck, A. T., Ward, C. H., Mendelson, M., Mock, J., & Erbaugh, J. (1961). An inventory for measuring depression. *Archives of General Psychiatry*, 4(6), 561–71. doi:10.1001/archpsyc.1961.01710120031004

Benbadis, S. R., & Chichkova, R. (2006). Psychogenic pseudosyncope: An underestimated and provable diagnosis. *Epilepsy and Behaviour, 9*(1), 106–110. doi:10.1016/j.yebeh.2006.02.011

Berkow, R., & Fletcher, A. J. (1992). *The Merck manual.* Rahway, NJ: Merck Research Laboratories.

Blount, R. L., Morris, J. A. B., Cheng, P. S., Campbell, R. M., & Brown, R. T. (2004). Parent and Child Psychological Factors in Pediatric Syncope and Other Somatic Symptoms. *Journal of Consulting and Clinical Psychology, 72*(4), 597–604. doi: 10.1037/0022-006X.69.5.51

Braehler, E. I., & Scheer, J. W. (1995). *Giessemer Beschwerdenbogen (GBB).* 2nd Edition, Bern, Goettingen, Toronto, Seattle: Hans Huber.

Clement, V., & Loewe, B. (1996). *Fragebogen zum Koerperbild.* Gettingen: Hogrefe.

Cohen, T. J., Thayapran, N., Ibrahim, B., Quan, C., Quan, W., & Von Zur Muhlen, F. (2000). An Association between Anxiety and Neurocardiogenic Syncope During Head-Up Tilt Table Testing. *PACE, 23*, 837-841.

D'Antono, B., Dupuis, G., St-Jean, K., Levesque, K., Nadeau, E., Guerra, P., Thibault, B., & Kus, T. (2009). Prospective evaluation of psychological distress and psychiatric morbidity in recurrent vasovagal and unexplained syncope. *Journal of psychosomatic Research, 67*, 213-222. doi:10.1016/j.jpsychores.2009.03.012.

Derogatis, L. R. (1994). *Symptom Checklist 90–R: Administration, scoring, and procedures manual(3rd ed.).* Minneapolis, MN: National Computer Systems.

Downs, S. H., & Black, N. (1998). The feasibility of creating a checklist for the assessment of methodological quality of randomised and non-randomised studies of health care interventions. *Epidemiology and Community Health, 52*, 377-384. doi:10.1136/jech.52.6.377

Driscoll, D. J., Jacobsen, S. J., & Porter, C. J. (1997). Syncope in children and adolescents. *Journal of the American College of Cardiology, 29*, 1039–45. doi: 10.1016 S0735-1097(97)00020-X

Fava, G. A., Freyberger, H. J., & Bech, P. (1995). Diagnostic criteria for use in psychosomatic research. *Psychotherapy Psychosomatics, 63*(1), 1-8.

First, M. B., Spitzer, R. L., Gibbon, M., & Williams, J. B. W. (1994). *Structured clinical interview for DSM-IV.* New York: Biometrics Research Department.

Flint, B., Baker, C., Freeston, M., & Newton, J. L. (2009). Level of psychosocial impairment predicts early response to treatment in vasovagal syncope. *Europace, 11*, 231-236. doi: 10.1093/europace/eun332.

Ganzeboom, K. S., Colman, N., & Reitsma, J. B. (2003). Prevalence and triggers for syncope in medical students. *American Journal of Cardiology, 91*, 1006–8. doi: 10.1016/S0002-9149(03)00127-9

Giada, F., Silvestri, I., Rossillo, A., Nicotera, P. G., Mazillo, G. F., & Raviele, A. (2005). Psychiatric profile, quality of life and risk of syncopal recurrence in patients with tilt- induced vasovagal syncope. *Europace, 7*, 465-471. doi: 10.1016/j.eupc.2005.05.008

Goldberg, D., & Williams, P. (1988). A User's Guide to the General Health Questionnaire. Windsor: NFER-Nelson.

Gracie, J., Newton, J. L., Norton, M., Baker, C., & Freeston, M. (2006). The role of psychological factors in response to treatment in neurocardiogenic (vasovagal) syncope. *Europace, 8,* 636-643. doi:10.1093/europace/eul073

Hamilton, M. (1959). The Assessment of anxiety states by rating. *British Journal of Medical psychology, 32*, 50-55.

Hathaway, S. R., & McKinley, J. C. (1989). *Minnesota Multiphasic Personality Inventory-2, test booklet*. Minneapolis, MN: University of Minnesota Press.

Ilfeld, F. W. (1976). Further validation of a psychiatric symptom index in a normal population. *Psychological Reports, 39*, 1215–1228.

Jacques, D., Blommaert, D., Gilain, C., Zdanowicz, N., & Ossemann, M. (2012). Unexplained Syncopes: What place is there for the liaison psychiatrist? Analysis of the first year of the Interdisciplinary Centre of Faintness and Syncopes. *Psychiatria Danubina, 24*(1), 21-24.

Jarde, A., Losilla, J. M., Vives, J., & Rodrigo, M. (2012). Coh: A tool to screen the methodological quality of cohort studies in systematic reviews and meta analysis. *International Journal of Clinical and Health Psychology, 13*(2), 138-146. doi:10.1016/S1697-2600(13)70017-6

Kapoor, W. N., Fortunato, M., Hanusa, B., & Schulberg, H. C. (1995). Psychiatric Illness in Patients with Syncope. *The American Journal of Medicine, 99*, 505-512.

Kellner, R. A. (1987). A symptom questionnaire. *Journal of Clinical Psychiatry, 48*, 269- 74.

Kellner, R., A. (1988). *Abridged manual of the Illness Attitudes Scale*. New Mexico: Department of Psychiatry, School of Medicine, University of New Mexico.

Kouakam, C., Lacroix, D., Klug, D., Baux, P., Marguie, C., & Kacet, S. (2002). Prevalence and Prognostic Significance of Psychiatric Disorders in Patients Evaluated for Recurrent Unexplained Syncope. *American Journal of Cardiology, 98*, 530-535.

Kramer, E. J., Kwong, K., Lee, E., & Chung, H. (2002). Cultural factors influencing the mental health of Asian Americans. *Western Journal of Medicine, 176*(4) 227-231.

Lee, S. H., Park, S., Byeon, K., On, Y. K., Yim, H. R., & Kim, J. S. (2013). Prevalence and Clinical Factors of Anxiety and Depression in Neurally Mediated and Unexplained Syncope. *Yonsei Medical Journal, 54*(3), 583-589. doi: 10.3349/ymj.2013.54.3.583

Lerma, A., Lerma, C., Marquez, M. F., Cardenas, M., & Hermosillo, A. G. (2012). Correlation of syncopal burden with anxiety symptoms score in recurrent vasovagal syncope. *International Journal of Cardiology, 166*(1), 266-267. doi:10.1016/j.ijcard.2012.09.105

Linzer, M., Divine, G., & Mark Estes, N. A. (1992). Medically Unexplained Syncope: Relationship to Psychiatric Illness. *The American Journal of Medicine, 92*(1), 1 S18-S25.

Linzer, M., Felder, B. S., Hackel, A., Perry, A., Varia, I., Melville, M. L., & Krishnan, K. R. (1990). Psychiatric Syncope: A new look at an old disease. *Psychosomatics, 31*(2), 181-188.

Linzer, M., Gold, D. T., Pontinen, M., Divine, G. W., Felder, A., & Brooks, W. B. (1994). Recurrent Syncope as a chronic disease. Preliminary validation of a disease specific measure of functional impairment. *Journal of General Internal Medicine, 9,* 181-186. doi: 10.1007/BF02600121

Linzer, M., Pontinen, M., Gold, D. T., Divine, G. W., Felder, A., & Brooks, W. B. (1991). Impairment of physical and psychosocial function in recurrent syncope. *Journal of Clinical Epidemiology, 44*, 1037–1043.

Lipson, J. G., Dibble, S. L, & Minarik, P. A. (1996). *Culture and Nursing Care: A Pocket Guide*. San Francisco, CA: UCSF Nursing Press.

Luzza, F., Di-Rosa, S., Pugliatti, P., Ando, G., Carerj, S., & Rizzo, F. (2004). Syncope. *Clinical Autonomic Research, 14*, 26-29. doi: 10.1007/s10286-004-0141-y

Montgomery, S. A., & Asberg, M. (1979). A new depression scale designed to be sensitive to change. *British Journal of Medical Psychology, 32*, 382-389.

Marks, I. M., & Mathews, A. M. (1979). Brief standard self rating for phobic patients. *Behaviour Research and Therapy, 17*, 263-267. doi:10.1016/0005-7967(79)90041-X

McGrady, A., Bush, E. G., & Grubb, B., P. (1997). Outcome of Biofeedback-Assisted Relaxation for Neurocardiogeneic Syncope and Headache: A Clinical Replication Series. Applied psychophysiology and biofeedback, 22(1), 63-72. doi: 10.1023/A:1026241826589

McGrady, A. V., Kern-Buell, C., Bush, E., Devonshire, R., Clagett, A. L., & Grubb, B. P. (2003). Biofeedback-Assisted Relaxation Therapy in Neurocardiogenic Syncope: A Pilot Study. *Applied Psychophysiology and Biofeedback, 28*(3), 183-192. doi:10.1023/A:1024664629676

McGrady, A., Kern-Buell, C., Bush, E., Khuder, S., & Grubb, B. P. (2001). Psychological and Physiological Factors Associated with Tilt Table Testing for Neurally Mediated Syncopal Syndromes. *Journal of Pacing and Clinical Electrophysiology, 24*(3) 296-301.

McLeod, K. A. (2003). Syncope in children. *Archives of Disease in Childhood, 88*, 350-353. doi: 10.1136/adc.88.4.350

Miller, T. H., & Kruse, J. E. (2005). Evaluation of Syncope. *American Family Physician, 72*(8), 1492 – 1500.

Newton, J. L., Kenny, R. A., & Baker, E. R. (2003). Cognitive behavioural therapy as a potential treatment for vasovagal/neurocardiogenic syncope- a pilot study. *Europace, 5*, 299–301. doi:10.1016/S1099–5129(03)00030-8

Oh, J. H., & Kapoor, W. N. (1997). Psychiatric Illness and syncope. *Cardiology Clinics, 15*(2), 269-75.

Ostell, A. (1991). Coping, problem solving and stress: A framework for intervention strategies. *British Journal of Medical Psychology, 64*, 11-24.

Rafanelli, C., Gostoli, S., Roncuzzi, R., & Sassone, B. (2013). Psychological correlates of vasovagal versus medically unexplained syncope. *General Hospital Psychiatry, 35*, 246-252. doi: 10.1016/j.genhosppsych.2013.01.008

Reiss, S., Peterson, R. A., Gursky, D. M., & McNally, R. J. (1984). Anxiety sensitivity, anxiety frequency and the prediction of fearfulness. *Behaviour Research and Therapy, 24*, 2-8.

Romme, J. J. C. M., Van Dijk, N., Go-Schon, I. K., Casteelen, G., Weiling, W., & Reitsma, J. B. (2011). Association between psychological complaints and recurrence of vasovagal syncope. *Clinical Autonomic Research Journal, 21*, 373-380. doi: 10.1007/s10286-0125-7

Rose, M. J., Koshman, M., Spreng, S., Sheldon, R. (2000). The relationship between health-related quality of life and frequency of spells in patients with syncope. *Journal of Clinical Epidemiology 53*, 1209–1216. doi.org/10.1016/S0895-4356(00)00257-2

Sabin, N. (2001). The use of applied tension and cognitive therapy to manage syncope (common faint) in an older adult. *Aging and Mental Health, 5*(1) 92-94. doi: 10.1080/13607860020020690

Sheehan, D. V., Lecrubier, Y., Sheehan, K. H., Amorin, P. J., Weiller, E., Hergueta, T., Baker, R.., & Dunbar, G. C. (1998). The Mini-International Neuropsychiatric Interview (M.I.N.I): The development and validation of a structured diagnostic interview for DSM-IV and ICD-10. *Journal of Clinical Psychiatry, 59*, 22-33.

Sonino, N., & Fava, G., A. (1998). A simple instrument for assessing stress in clinical practice. *Postgraduate Medicine, 74*, 408-410. doi:10.1136/pgmj.74.873.408

Spitzer, R. L., Williams, J. B., Kroenke, K., Linzer, M., deGruy, F. V., Hahn, S. R., Brody, D., & Johnson, J. G. (1994). Utility of a New Procedure for Diagnosing Mental Disorders in Primary Care. The PRIME-MD 1000 Study. *JAMA, 272*(22), 1749-272.

Van Dijk, N., Sprangers, M. A., Colman, N., Boer, K. R., Wieling, W., & Linzer, M. (2006). Clinical factors associated with quality of life in patients with transient loss of consciousness. *Journal of Cardiovascular Electrophysiology 17*, 998–1003. doi: 10.1111/j.1540-8167.2006.00533.x

Ventura, R., Maas, R., Ruppel, R., Stuhr, U., Schuchert, A., Meinertz, T., & Neinaber, C. A. (2001). Psychiatric conditions in patients with recurrent unexplained syncope. *Europace 3*, 311-316. doi: 10.1053/eupc.2001.0182

Weiling. W., Ganzeboom, K. S., & Saul, J. P. (2004). Reflex syncope in children and adolescents. *Heart, 90*, 1094–1100. doi: 10.1136/hrt.2003.022996

Weiner, Z., Shapiro, N. I., Chiu, D. T., & Grossman, S. A. (2013). The prevalence of psychiatric disease in emergency department patients with unexamined syncope. *International Journal of Emergency Medicine, 8*, 427-430. doi: 10.1007/s11739-013-0946-6

Wolpe, J., & Lang, P. J. (1964). A fear survey schedule for the use in behaviour therapy. *Behaviour Research and Therapy, 2*, 27-30.

World Health Organisation. (1992). *International Classification of Diseases. 10th Revision.* Geneva, Switzerland: World Health Organisation.

Yun, Y. H., Kim, S. H., Lee, K. M., Park, S. M., & Kim, Y. M. (2007). Age, sex and co-morbidities were considered in comparing reference data for health-related quality of life in the general and Cancer populations. *Journal of Clinical Epidemiology, 60*, 361-370.

Zigmond, A. S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatra Scandinavia, 67*, 361-370.

Chapter Two: Major Research Project

The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study

Correspondence to:
Joanne Skeldon
Mental Health & Wellbeing
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
j.skeldon.1@research.gla.ac.uk

Prepared in accordance with the requirements for submission to the British Journal of Health Psychology (Appendix 1).

(Word Count: 11,063, including the main body of text, abstract, references and tables.)

Abstract

Introduction

The literature shows that syncope in childhood is common with around one in five children experiencing an episode before the age of 15 years old. Neurocardiogenic Syncope (NCS) is a form of reflex syncope and is the most common form of syncope in children and adolescents. Overall, there is limited research investigating the associations between NCS and health related quality of life (HRQOL) and psychological functioning.

Objective

This project aims to explore young people's experiences of NCS, to gain a more detailed understanding of young people's understanding of their symptoms and diagnosis and the possible impact of NCS on HRQOL and psychological functioning.

Methods

Five adolescents aged 12-17 years old, with a diagnosis of NCS, participated in the study. Semi-structured interviews collected qualitative data which was analysed using Interpretative Phenomenological Analysis.

Results

Analysis of the data revealed the following four overarching themes: uncertainty, self-concept, coping strategies and experiences of medical services. Each theme was divided into a number of sub-ordinate themes and similarities and differences between participant's experiences were identified.

Conclusion

Young people expressed uncertainty in relation to their experiences of NCS, including the uncertainty of the course and prognosis of symptoms. This was found to interrupt a typical adolescent trajectory, influencing young people's development of identity, autonomy and relationships, as well as impacting on current and future opportunities and psychological wellbeing. These findings were consistent with previous research investigating young people's experiences of chronic illness.

Plain English Summary

Investigating the experiences of young people with neurocardiogenic syncope

Introduction

Fainting in childhood is common however can be a symptom of cardiac difficulties which can be potentially serious and/or life threatening. Although this is uncommon it can cause anxiety for families, medical clinicians and for the young person themselves. When individuals frequently faint without any cardiac difficulties it is known as neurocardiogenic syncope or neurocardiogenic fainting. Young people can have numerous investigations to establish the cause of their symptoms, including the implant of a monitoring device called an internal loop recorder. This takes readings of cardiac activity during episodes of fainting, which a cardiologist can analyse to identify cardiac difficulties. Previous research has looked into the links between neurocardiogenic fainting and mental health difficulties. Research has shown that depression and anxiety disorders in children who frequently faint are higher than average (Hyphantis et al., 2012). Research has also shown that young people's experiences of fainting can negatively impact on their quality of life (Anderson et al., 2012). In contrast to adults, relevant data for young people is limited.

Aims

The research aims to investigate young people's experiences of fainting, focusing on the potential impact on their psychological functioning and quality of life.

Methods

Five young people aged between 12 and 17 years old participated in the study. All young people had a diagnosis of neurogardiogenic fainting. Interviews were used to collect data which was analysed using Interpretive Phenomenological Analysis

(IPA). IPA aims to explore the processes which individuals go through to help them understand and give meaning to their experiences.

Main Finding and Conclusions

The results showed that young people experienced uncertainty about their symptoms and diagnosis and this resulted in frustration and anxiety. Fainting can impact on young people's identity, independence and relationships, and their experience of fainting can make them feel different to other young people. Clear communication from clinicians is important and some young people shared that they wanted to be involved in decisions regarding their care. These findings highlight the need for individualised care which meets young people's emotional and physical needs.

Reference List

Anderson, J. B., Czosek, R. J., Knilans, T. K., & Marino, B. S. (2012). The effect of paediatric syncope on health-related quality of life. *Cardiology in the Young, 22*, 583–588. doi:10.1017/S1047951112000133

Hyphantis, T. N., Pappas, A., Vlahos, A., Carvalho, A., Levenson, J. L., & Kolettis, T. M. (2012). Depressive Symptoms and Neurocardiogenic syncope in Children: A 2-year prospective study. *Pediatrics, 130* (5), 906-913. doi: 10.1542/peds.2012-1379

The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study

Introduction

Syncope is defined as 'a transient loss of consciousness and postural tone caused by global cerebral hypoperfusion' (Lee et al., 2013 p.583). The literature shows that syncope in childhood is common with around one in five children experiencing an episode before the age of 15 years old.

Neurocardiogenic syncope (NCS) is a form of neutrally mediated syncope (NMS) and is the most common syncope in children and adolescents (McLeod, 2003). NMS involve changes to heart rate and blood pressure which typically result in symptoms such as nausea, light-headedness and feelings of warmth. These occur directly before a loss of consciousness. Following this, the postsyncopal phase includes symptoms such as nausea, dizziness and confusion. These typically last a few hours following unconsciousness but can continue for days in some cases (Miller & Kruse, 2005). The underlying causes for NMS are listed in Table 1.

Table 1: Underlying causes of syncope.

GENERAL CAUSE	CAUSAL SUBCATEGORY	DEFINITIONS
Neurally mediated	Neurocardiogenic syncope/ Vasovagal syncope	Syncope resulting from a sudden drop in heart rate and blood pressure.
	Carotid sinus	Syncope caused by stimulation to the carotid artery in individuals with a diagnosis of carotid sinus hypersensitivity.
	Situational	The temporary loss of consciousness in a particular kind of situation. The situations that trigger this reaction are diverse. For example, coughing, sneezing, defecating, micturition.

Although NCS is benign, a minority of syncopal episodes are a symptom of underlying cardiac difficulties and as such, may be caused by a potentially serious and/or life threatening condition. Therefore, there are often high levels of anxiety for young people, families and medical clinicians, in particular pre-diagnosis of NCS. Diagnosis can involve a number of investigations including a detailed medical history, an electrocardiogram (ECG) and a head up tilt-table test. Despite such investigation, there are cases where the diagnosis remains unclear. In these cases internal loop recorders can be helpful in establishing an accurate diagnosis. The internal loop recorder is an electrocardiographic (ECG) device, fitted internally which collates ECG data by monitoring cardiac activity. An absence of bradyarrhythmia and/or an absence of tachyarrhythmia accompanying episodes of syncope would indicate a diagnosis of NCS.

Causes of NCS

For individuals who experience NCS, physical and psychological stress may contribute to increased peripheral vascular pooling, or hypotension. This can result in decreased blood flow to the brain exacerbating the symptoms of NCS (Berkow & Fletcher, 1992). It is possible that the recurrent symptoms of NCS increases psychological stress, further exacerbating the symptoms (Henningsen et al., 2003). For example, fear of injury or embarrassment have been found to contribute to anxiety about reoccurrence of syncopal episodes (Gracie et al., 2006). This anxiety can result in individuals avoiding situations in an attempt to limit the anticipated negative outcomes. Avoidance reinforces the belief that NCS is dangerous, in turn maintaining anxiety. Individuals can become hyper vigilant to physical symptoms believed to indicate impending loss of consciousness. Hypervigilance is likely to trigger physical symptoms of anxiety which can be misinterpreted as prodromal signs of syncope. The combination of increased anxiety and hypervigilance may maintain physical symptoms, resulting in actual symptoms of syncope, reinforcing the individual's belief that syncope is dangerous (Gracie et al., 2006). This cycle of psychological distress and NCS can present challenges for clinicians in relation to treatment and management of symptoms, which can be further complicated if patients struggle to accept a lack of cardiac cause for their symptoms (Linzer et al., 1992).

Chronic illness

Chronic illness has been defined as an illness or medical condition which interferes with daily functioning and normal activities over a period of three months or more. Stressors associated with chronic illness include hospitalisation, surgery, pain and

restrictions and limitations on activity, impacting on school attendance and peer relationships (Yozwiak et al., 2011). For many individuals with NCS, their symptoms can resolve following initial treatment including dietary changes, moderate exercise and physical counter pressure manoeuvres (Weiling et al., 2004). However, NCS can become a chronic condition with symptoms persisting throughout an individual's lifetime. For individuals who do not respond to initial treatment, pharmacological intervention or surgery might be considered (Romme et al., 2011). For adolescents who experience chronic NCS, there may be recurrent periods of persistent or difficult to control symptoms, similar to other chronic diseases (Anderson et al., 2012). It is therefore hypothesised that young people may have similar experiences to adolescents with a range of chronic conditions.

The impact of NCS and chronic illness on health related quality of life

Health Related Quality of Life (HRQOL) is a multidimensional construct which has been defined as the extent to which one's usual or expected physical, emotional, and social well-being are affected by a medical condition or its treatment (Cella & Bonomi, 1995). It could be argued that these domains of HRQOL are perceived differently depending on the individual's stage of life. Transitioning from childhood through adolescence into adulthood involves significant changes and previous literature has highlighted the following salient aspects of HRQOL for adolescents: body image; development of self-identity; peer relationships; and autonomy (Frisen, 2006). Previous research has focused on the relationship between NCS and HRQOL in adults and findings have indicated lower HRQOL compared to healthy controls (Linzer et al., 1991; Linzer et al., 1994, Rose et al., 2000; Van Dijk et al., 2006). To

date, there has been one quantitative study which explores the relationship between NCS and HRQOL in children and adolescents (Anderson et al., 2012). Anderson et al. (2012) found that children and adolescents with NCS have lower HRQOL than healthy controls for physical health, psychosocial health, emotional functioning and school functioning. Furthermore, their HRQOL scores are similar to children with a range of chronic health conditions such as asthma, end-stage renal disease, obesity, and structural heart disease.

The relationship between chronic illness and HRQOL among children and adolescents has been explored more extensively. Overall, findings indicate that chronic illness negatively impacts on HRQOL, however some inconsistencies have been reported. Research with children and adolescents with cardiac conditions have shown lower overall HRQOL compared to healthy controls and similar HRQOL to young people with a range of chronic illnesses (Mellion et al., 2014; Spijkerboer et al., 2006; Varni et al., 2007). Coelho et al., (2013) found that adolescents with congenital heart disease presented with lower psychological functioning, however in contrast to previous research, no significant differences were found across other HRQOL domains. Furthermore, increased social support was associated with significantly higher HRQOL. Varni et al., (2007) reported that young people with chronic illness have lower HRQOL than healthy controls, however the findings also indicate substantial differences between chronic conditions on emotional, social, and school functioning.

The impact of NCS and chronic illness on psychological wellbeing

There is some evidence that recurrent NCS can negatively impact on young people's psychological wellbeing. Hyphantis et al., (2012) found that children who experienced NCS were more likely to have clinically depressive symptoms compared to healthy controls. They offered separate counselling to children and their families and after a two year follow up, found a reduction in depressive symptoms with no recurrences of syncope reported. The authors felt these improvements were associated with improvements in child-parent relationships and improved family functioning. Mathias et al. (2000) conducted a case study of a young person diagnosed with NCS who also experienced associated conversion disorder and pseudo-syncope. The authors concluded that symptoms of NCS were exacerbated by a school phobia, depression and family dysfunction. In contrast, Byars et al. (2000) reported no significant differences in psychological adjustment between children with syncope and a control group.

Research with children and adolescents with congenital heart conditions have also provided contradictory findings. Children and young people who received open heart surgery reported no significant differences in psychological functioning compared to healthy controls (Hovels-Gurich et al., 2002). In contrast, Coelho et al. (2013) found the prevalence of diagnosed psychopathology in this population to be 23%, compared to 10% in healthy 5-16 year olds (Green et al., 2005). Overall, it has been estimated that children and adolescents with chronic illness have lower self-esteem (Pinquart, 2012) and are up to four times more likely to experience mental health difficulties (Hysling et al., 2009). A meta-analysis by Lavigne & Faier-Routman (1992) identified potential risk factors for poor psychological functioning and

adjustment. These included pain, frequency of symptoms, lack of control, severity and course of illness and parent perception of illness. As with young people's HRQOL, social support and family cohesion was found to reduce psychological distress and improve adjustment. Lavigne & Faier-Routman (1992) concluded that children with chronic conditions are vulnerable to difficulties in adjustment, however this is dependent on the presence of potential risk factors.

Much of the current evidence base investigating HRQOL and psychological functioning is quantitative in nature, however a growing body of qualitative literature has investigated how young people with chronic illness make sense and derive meaning from their experiences. Common experiences for children and adolescents with chronic illness include school absenteeism, restricted participation in sport and social activities and the frustration of adherence to medication and treatment routines (Gannoni & Shute, 2009). These experiences have contributed to young people expressing a sense of difference to their peers and subsequent experiences of rejection, social isolation and loss of independence (D'Auria et al., 1997; Jamieson et al., 2014; Olsson et al, 2003; Woodgate, 1998).

The inclusion of qualitative research findings is well established in the planning and provision of healthcare (Worrall-Davies & Marino-Francis, 2008) and enables appropriate and effective service development (NHS Executive, 1997). The Department of Health (2007) highlights the need for child-centred service provision, and the Scottish Government's Healthcare Quality Strategy (2010) stresses the need for person-centred care. The United Nations, Convention on the Rights of the Child (2000) also promotes young people's participation in research. There is little research into adolescent's experiences of NCS with no qualitative studies to date.

Therefore a qualitative study investigating young people's experience of NCS would be beneficial in understanding how services can provide holistic care which best meets their medical and psychological needs.

Research Aims and Objectives

Aims

This project aims to explore young people's experiences of NCS: to gain a more detailed understanding of young people's experience of the symptoms, diagnosis and management of NCS.

Objectives

- To gain a more detailed understanding of young people's experience of the symptoms of NCS.
- To explore young people's understanding of the possible physical and psychological triggers for NCS and the possible warning signs or symptoms experienced prior to onset of an episode.
- To explore young people's experience of having an internal loop recorder to monitor their cardiac activity.
- To explore young people's experience of receiving a diagnosis of NCS following this investigation.
- To explore the impact of NCS on young people's HRQOL and psychological functioning.

Method

Participants

Five young people consented to participate in interviews investigating their experience of NCS. This number is suitable for doctorate level research employing Interpretative Phenomenological Analysis (IPA), allowing for a detailed interpretive account of each interview. Due to the nature of IPA, small sample sizes are typically sufficient, with between four to ten participants recommended for a professional doctorate (Smith et al., 2013 p.52). This recommended sample size is consistent with guidance by Collins and Nicolson (2002) who posited that interpretation can be more accurate with smaller sample sizes, as the analysis of large data sets may result in the loss of 'potentially subtle inflections of meaning' (p. 626).

Recruitment criteria stated young people must be aged 12 years and above to participate. Piaget's (1950) developmental stages indicate that children aged 12 years and above transition into the Formal Operational Stage of development and it is at this point that children can start to develop and recognise negative cognitions. Erikson's Psychosocial Stage Model (1963) also proposes that children between 12-18 years old begin to discover their own identity, while negotiating and struggling with social interactions and experience a desire to be accepted by peers. It can be within this stage of development that, depending on experience, adolescents can begin to develop low self-esteem. Furthermore, there can be a rise in somatic symptoms as children develop through adolescence (LaFrance, 2009). Drawing on these developmental theories, young children are likely to experience different emotional responses to NCS. Therefore, the research will focus on exploring adolescent's experiences of NCS.

Participant details are presented in Table 2. Participants have been given pseudonyms to protect anonymity.

Table 2: Participant Information

Participant	**Age**	**Gender**	**NHS Health board**
Steven	15	Male	Greater Glasgow and Clyde
Catherine	16	Female	Fife
Hannah	12	Female	Fife
Kirsty	13	Female	Fife
Tanya	12	Female	Lanarkshire

Inclusion and Exclusion Criteria

Inclusion Criteria:

- Participants must be currently referred to the Paediatric Cardiology Service at the Royal Hospital for Sick Children, Glasgow (RHSC) and have a diagnosis of NCS, after completing a minimum monitoring period of one year using an internal loop recorder.
- The young person is aged between 12-17 years old, inclusive.
- The young person and their parents provide informed consent to participate.
- The young person and their parents speak fluent English.

Exclusion Criteria:

- The young person has a history of cardiac or other medical conditions which may impact on syncope.

- Any young people whom clinicians in the Paediatric Cardiology Service and Paediatric Psychology Service believe to be too physically or mentally unwell to participate.
- The young person has a diagnosis of a learning disability.

Recruitment Procedures

The RHSC is the national centre for cardiology in Scotland and provides specialist care in diagnosis and management of syncope. Therefore, many families across Scotland travel to receive treatment. If there are no identified medical concerns, young people can receive follow up care at the RHSC or at a remote cardiac clinic within their NHS health board. The Consultant Paediatric Cardiologist in the service was asked to identify possible participants based upon the inclusion and exclusion criteria. Potential respondents were posted an information pack about the project including an information sheet and a letter signed by the Consultant Paediatric Cardiologist inviting them to participate in the research. Young people were also sent an opt-in form indicating the best way for the researcher to contact them, for example: by phone, letter or email. After receiving the information pack detailing the research, follow up phone calls were made to young people and their families to discuss participation. These phone calls were made by a Cardiac Liaison Nurse working in the Paediatric Cardiology Service who was known to the young person and their family. Young people and parents who consented to participate were then contacted by phone by the principal investigator. Interviews were arranged at a time and location convenient to the young person and their family. All interviews were held at a NHS site within the young person's health board.

Research Procedures

The research was qualitative in nature. Following informed consent, non-directive semi-structured interviews were conducted by the principal investigator in a private clinic room. Each interview followed an interview schedule based upon the following themes identified within the current literature; social functioning, peer relationships, family functioning, development of sense of self and identity, and autonomy (Frisen, 2006). Interviews lasted between 50 and 180 minutes. The interview schedule followed was flexible to ensure information was collected on individual experiences of NCS in as much detail as possible. All interviews began with an informal discussion designed to help put the young people at ease and build a rapport. Interviews were recorded and transcribed verbatim, identifiers were removed and pseudonyms were given.

Design

All interview data was analysed using Interpretative Phenomenological Analysis (IPA) (Smith et al., 2013). IPA is a qualitative research method which explores the detailed processes which individuals go through to interpret, understand and give meaning to their experiences (Smith et al., 2013). IPA recognises that research is a dynamic process (Smith et al., 1999) and acknowledges that the researcher's own conceptions may influence their interpretation of a participant's account. IPA therefore stresses the importance of the researcher's ability to reflect and analyse (Brocki & Wearden, 2006). IPA has been previously used within health psychology, focusing on the importance of understanding an individual's experience of illness through their perceptions, interpretations and the meaning they attribute to their bodily experiences (Brocki & Wearden, 2006). Based upon this previous literature, IPA was felt to be an appropriate method of analysis to provide detailed

interpretations of young people's experiences of NCS. A systematic review of health psychology literature identified that the majority of research using IPA used interviews to collect the data (Brocki & Wearden, 2006) and the collaborative and dynamic process involved in conducting interviews is in keeping with the methodology of IPA (Smith & Osborn, 2003).

Data Analysis

Analysis was conducted in accordance with the following guidance by Smith et al. (2013). It is recommended that analysis occurs on an individual case basis. Analysis of the data requires fully engaging in the participant's story. The principal investigator immersed themselves in the data by reading and re-reading interview transcripts to ensure familiarity with the content while also reflecting on their own prior conceptions (Smith et al., 2013). Patterns of meaning in the data were then drawn out by a line by line commentary of each transcript. These patterns included the researcher's initial thoughts about the data and what it might mean to the participant to have their thoughts or concerns analysed in relation to their experience. Through this process, the principal investigator made sense of the participant's experience, just as the participant had made sense of their experiences, allowing for the development of a more interpretative account (Smith et al., 2013). Next, all emergent themes were identified, compared and clustered into super and sub-ordinate themes. These were then compared and integrated across interviews to generate a final list of themes. These themes were developed into a framework which demonstrated the relationship between them. Similarities and differences within the data were also identified and a narrative around these were developed linking themes to the current evidence base (Larkin & Thomson, 2012; Smith et al., 2013).

Several steps were taken to ensure rigour and accurate interpretation of the data. Notes were kept to record and inform key decisions in the analysis. The first two interview transcripts were analysed jointly with the project's academic supervisor to corroborate findings and verify the themes identified. The IPA Quality and Evaluation Guide (Smith, 2011) was followed and in line with these guidelines, verbatim quotes are provided to prove evidence of themes.

Ethical Approval

Ethical approval for this study was granted by the NRES East Midlands, Nottingham 2 Committee and the following health board's Research and Development Forums (R&D): NHS Greater Glasgow and Clyde, NHS Ayrshire and Arran and NHS Lanarkshire. Due to initial difficulties with recruitment an amendment was submitted and approved by the NRES East Midlands, Nottingham 2 Committee to include the following health boards to the study: NHS Lothian and NHS Fife. Approval was also granted from the R&D forums for these health boards. (Appendices 6&7)

Reflexivity

Reflexivity is a key feature of IPA. IPA recognises that the principal investigator's perspective can influence the interpretation of participant's narratives (Smith & Osborn, 2003). Care was taken during the analysis to reflect on the principal investigators own experiences and beliefs which may influence interpretations of the participant's narratives. The principal investigator discussed possible themes within the data with the project supervisors to ensure validity and that analysis was not influenced by their own conceptions developed from working in a paediatric psychology service.

Results

Analysis of the data identified the following four super-ordinate themes:

1. Uncertainty
2. Self-concept
3. Coping strategies
4. Experiences of medical services

Super-ordinate themes one and two are made up of three sub-ordinate themes, super-ordinate theme three consists of two sub-ordinate themes and super-ordinate theme four is made up of one sub-ordinate theme, presented in Table 3.

Table 3: Super and sub-ordinate themes.

SUPER-ORDINATE THEMES	**SUB-ORDINATE THEMES**
Theme 1: Uncertainty:	Unpredictability Control Risk and safety
Theme 2: Self-concept	Stigma and normality Autonomy Missed opportunities
Theme 3: Coping strategies	Support Resilience
Theme 4: Experiences of medical services	Communication

Participant quotations are presented in italics and square brackets are used to indicate if material has been omitted or where additional explanatory material has been added.

Theme 1: Uncertainty: *'I mean, if it's not my heart, what the hell's causing this fainting.'* Steven P11: L25

All young people reflected on the uncertain nature of NCS. Young people expressed frustration about the uncertainty of symptoms and diagnosis and experiences were underpinned by a perceived and actual lack of control. Many of these experiences evoked a sense of risk. Three sub-ordinate themes were identified: unpredictability, control and risk and safety.

<u>Unpredictability</u>

Uncertainty about the cause of NCS and the unpredictable pattern of syncopal episodes and prognosis were frequently expressed by young people. This is particularly evident in Kirsty's comment:

> *'I don't know, I could grow out of it but I don't know, maybe I can, maybe I can't, I don't know'.* Kirsty P8: L27-28

All young people provided descriptions of their symptoms. Dizziness, breathlessness, nausea, shaking, blurred vision, increased heart rate and feeling hot were common. A range of potential triggers were discussed including exhaustion, temperature, hunger, exercise and genetic factors. All young people highlighted that triggers were not consistent and this contributed to NCS being unpredictable, as illustrated by Steven's comment:

> *'It [fainting] just chooses its moments. It could be when I wake up, it could be when I do P.E, it could be any time.'* Steven P9: L18-19

Young people expressed that a diagnosis of NCS did not explain their symptoms. They were therefore faced with balancing the relief that there was no cardiac cause,

with the uncertainties associated with their diagnosis. This created tensions in young people's lives. Emotions in response to diagnosis were typically mixed with young people expressing confusion and frustration:

> *'It's hard because I really want to know what's the cause and why it happens'*. Tanya P6: L32

Control

Participant's loss of control was reflected in a number of experiences, including their experience of syncope itself, subsequent injury and the impact on current and future opportunities. Steven and Catherine explicitly spoke about a lack of control over their symptoms. For example, Catherine described the possibility of fainting anywhere, at any time. She articulates a lack of security which conveys a sense of vulnerability and powerlessness attached to her experience:

> *'I feel like I have no control of like anything, I could basically do it [faint] and I could faint anywhere so I feel insecure, like I have no security'.* Catherine P4: L19-22

Similarly, Hannah's description of fainting evoked a sense of powerlessness and lack of control over her body, resulting in fear and distress:

> *'I'd always feel really upset, I didn't like the idea of just dropping to the floor, it just kind of felt like my body had stopped working, I had collapsed, I just didn't like the idea of it, it's quite scary actually'*. Hannah P3: L36-37

Risk and Safety

Many young people identified the potential danger fainting could place themselves in. Catherine spoke about her safety being at risk, giving the example of fainting in

the road. Her narrative illustrates that she does not feel in control of her own safety and the unpredictable nature of NCS appears to heighten the sense of danger and risk:

> *'It is quite frustrating [not having warning signs] because if I'm out and about I don't ken [know] what danger I'm putting myself into like, see if I'm going to cross the road and I faint then that is just, I'll be putting myself in danger, and there's no indication of when it's going to happen so I'm at risk if I'm out and about.'* Catherine P4: L11-17

Fear of injury was highlighted by Steven, Kirsty and Tanya who had experienced previous injuries as a direct result of fainting. Steven, Catherine, Hannah and Tanya highlight that their families help them to feel safe by offering practical support and emotional containment. Hannah spoke about her parents and siblings helping her to relax when she experienced symptoms:

> *'I think they [parents] just wanted to stay with me to make sure I was ok, because they knew how uptight I would get, they were there to help relax me really [ ] just having people around makes me feel more safe.'* Hannah P7: L19-21

Theme 2: Self-concept: *''I was the odd one out, like there was something really wrong with me.'* Catherine P12: L22-23

Self-concept is constructed from a set of beliefs held by the young person about themselves. A number of sub-ordinate themes were identified within this category, all which influenced the development of the young person's self-concept. The sub-ordinate themes are as follows: stigma, autonomy and missed opportunities.

Stigma

All young people spoke about experiencing felt stigma and the importance of feeling *'normal'*. Kirsty, Hannah and Tanya discussed feeling different to their peers and believed there was something *'wrong'* with them. Stigma was felt by young people in relation to fainting itself, the questions they received about fainting and the internal loop recorder. Kirsty described feeling anxious and embarrassed about strangers seeing her faint:

> *'It maybe makes me abit worried. It was embarrassing, I don't like other people who aren't my friends see me faint.'* Kirsty P4: L18-19

Steven and Catherine described that others did not understand their condition and for both of them, this contributed to experiences of enacted stigmatisation and bullying. Catherine described how other young people at her school *'just made up their own stories'* (P12: L18) about why she faints. These stories suggested she was possessed by spirits. The change in her narrative from the second person, which initially portrayed a sense of distance, to the first person, implies Catherine experienced this stigmatisation personally:

> *'Some folk were like, yeh, like you're possessed or something, like I was possessed.'* Catherine P12: L13-14

Catherine explained that experiences of felt stigmatisation reinforced her belief that she was different to her peers. Catherine creates a powerful image of feeling *'disabled'* due to her experiences of fainting. She spoke of disabled young people attending her school and in her description she likens herself to this group of young people, which in her social world have also been stigmatised. Her narrative was also

characterised by a lack of self-efficacy. To her, the stigma of being '*disabled'* by NCS was associated with not being able to do anything:

> *'It was just the thought in the back of my mind that oh yeh, you're disabled you can't do anything.'* Catherine P7: L7-8

Steven described that his diagnosis of NCS felt like *'another label'* (P19: L49). He described an incident when he felt socially excluded by his peers and it seems that the fear of stigma associated with his experience of NCS contributed to maintaining his social isolation:

> *'That's the main reason why I can't join a football team because I don't want to faint in front of a team of strangers, [ ] just the thought of me fainting in front of people I don't know, I tried to join a team a couple of months back but it didn't work out, [ ] I tried to speak to some of the guys in the team but they didn't want to talk to me back.'* Steven P9: L24-31

Young people's experience of the operation to fit the internal loop recorder also contributed to them feeling different to their peers. The repetition of the word *'unusual'* used by Tanya to describe her experience of having an internal loop recorder highlights this:

> *'It was unusual for me, none of the other kids had it, it felt unusual for me.'*
>
> Tanya P5: L7

Hannah, Kirsty and Steven discussed difficulties in talking to friends about their experience of fainting and in particular, answering questions about fainting. The language used by Steven illustrates the pressure he felt to answer numerous questions when he himself was likely to be feeling uncertain about his experiences or was unwilling to share due to fear of stigma:

'Yeh, loads of questions, like, is it scary, have you done it before, ummm, do you like it, mainly pointless questions. [ ] Like if it was just one question at a time it's fine but if it's like three questions at a time, that's when I just walk away, people are putting a lot of stuff on me at the same time.' Steven P13; L1-4

Catherine explained that she did not feel her experience of fainting impacted on her friendship, however also stated that she felt her friends were cautious when socialising with her, and expressed concerns that she was holding them back:

Interviewer: 'Do you think its [fainting] impacted on your friendships?'

Catherine: *'No, not really, no, my friends are just really cautious when we go out. [ ] I felt to them that I was holding them back.'* P9: L25-26

The young person's narrative creates a sense of difference and uncertainty, possibly emulating how they felt in relation to their experience of fainting, which itself was uncertain and unpredictable, and made them feel different to their peers.

Autonomy

Developing autonomy and independence is a key task during adolescence and is influenced by peer relationships and social context. Steven described embarrassment that his mother had to help explain his diagnosis to others, feeling that he would like to be more independent:

'Embarrassed, yeh I mean like, sometimes I like to cope with situations myself.' Steven P16: L10-11

Hannah articulated not wanting to always have her parents by her side and Catherine's narrative is characterised by annoyance and frustration in relation to

receiving advice from her parents. However, she was also accepting of her parent's reasons behind their behaviour:

> *'It's annoying because I just think that they're nagging but, all the time, but I'm just like, aye I ken [know] but, but they continue to tell me and that, but they're only saying it for my protection basically'.* Catherine P12: L33-37

Missed opportunities

Each young person reflected on the impact of NCS on their life, in particular the inability to take part in activities in the same way as their peers. Catherine described not being allowed to go horse-riding and Hannah and Kirsty described a lack of confidence to participate in sport. Steven, Catherine and Kirsty shared that fainting has disrupted their attendance at school, undermining a typical adolescence trajectory. Having the operation for an internal loop recorder impacted on Steven's stamina and his ability to play football at school:

> *It's kind of lost me my stamina, I mean I worked at it for quite a long time, for me to be fitter than others like me, I managed to catch them up and beat them at cross country and everything, I do my best but when I had that operation, my stamina had been quite low, I couldn't play football, I couldn't manage to get round the defenders a lot so I want to get that stamina back up.'* Steven P14: L47-55

It appears that Steven's football skills and stamina provided him with a sense of self-worth and engaging in football games allowed Steven to make positive social comparisons to his peers. This opportunity was increasingly important in light of negative experiences and stigmatisation which resulted in difficulties in peer

relationships. It is likely that playing football provided Steven with a means of interacting with his peers, reducing feelings of isolation and increasing self-esteem.

The restriction on future opportunities and the impact of this on Catherine's sense of self is illustrated in her concerns about driving due to her diagnosis of NCS. She highlights fears of being left out, left behind and socially isolated from peers:

> *'It makes me feel like I'm left out and that, I just feel left out and I feel that everyone's passing and moving away from me, then I'm going to be left on my own and that without driving'*. Catherine P5: L39-42

Young people reported experiencing a range of emotional distress in relation to their experience of fainting. Fear, anxiety and low mood were frequently described and these difficulties impacted on opportunities to develop autonomy and peer relationships. Catherine described how she felt on receiving her diagnosis:

> *'I was just really sad all the time and I didn't want anyone else to see me at that time, so I would kind of try to avoid my friends'* Catherine P12: L32-34

Theme 3: Coping strategies, *'I just feel I was being a wee hero.'* Steven P16: L46

A range of coping strategies were identified and employed by young people to manage the emotional impact of their experiences. Two sub-ordinate theme were identified; support and resilience.

<u>Support</u>

Peers become increasingly important as young people transition through adolescence and friends were identified as a source of support. Catherine described her friends playing a key role in supporting her at school:

> *'My friends and that were just, they were alright with it, kind of thing, because they were there to support me and like, when I did faint they were there like to do the heart loop monitor for me when teachers were like phoning ambulances and all that so, they were really supportive and they didn't ken [know] what was happening at the start either.'* Catherine P7: L47-54

All young people spoke about the support they received from family members. This was particularly important when young people were faced with hospital procedures and medical appointments. Hannah described feeling distressing by her experience of hospital and the comfort she received from her family:

> *'It wasn't that good, I don't like having jags [injections], I still don't like them, it was awful, but I remember my mum and gran coming to visit me, that was comforting.'* Hannah P5: L6-7

The narratives of Tanya, Steven and Catherine highlight that although they sought support from their family, they also experienced worry in relation to causing distress to others. Tanya's comment highlights this, emphasising a potential shift away from a typical parent child relationship:

> *'I actually think the most difficult thing is family, like worrying about them, worrying about me. It's confusing because I worry in case they get upset because I'm fainting.'* Tanya P8: L29-31

In contrast, Kirsty's experiences of fainting were not discussed with her family, with her stating *'we don't really do that'* (P4: L48). It is interesting to consider her use of the word 'we' opposed to 'I'. It could possibly suggest a lack of family communication and a lack of perceived support from those around her.

Resilience

Kirsty described *'I've just got used to it'* when discussing her experiences of NCS and this mentality was echoed by Catherine, Tanya and Steven. Catherine spoke about not being able to do the things she wanted due to her diagnosis and shared that she may have to change her expectations of her future self. However, it is quite striking from her account that she remains hopeful for her future:

> *'I want to be a paediatric nurse and they said I can't because of the shift work and my sleeping pattern, I'm still hoping I get to be a nurse. It's not really changed my attitude to it, it's just me thinking I need to have a plan B at the same time.'* Catherine P15: L50-57

Hannah explained that following the implant of her internal loop recorder, her symptoms ceased. She identified a number of positive changes since this experience, in particular her ability to participate in sporting activities.

> *'I push myself a lot more now and I feel better for doing it. I'm really a lot more confident to do that, I feel I can push myself a lot more and go a lot faster.'* Hannah P6: L50-52

Theme 4: Experience of medical services, *'I just would have liked to have been included in the medical appointments.'* Tanya P9: L49-50

All young people had a number of experiences of medical services, including travelling in an ambulance and receiving treatment in hospital following an episode of fainting. Hospital admissions were often distressing for young people and as such, young people identified a number of communication preferences. One sub-ordinate theme was identified: communication.

Steven and Hannah spoke about their experiences of going into hospital. Hospital admissions can disrupt daily lives and the hospital environment can feel scary and unpredictable. Hannah's account highlights the distress she felt:

> *'They gave me a jag [injection], to take blood or something, they had me attached to wires and monitors and everything. I got really upset and anxious about it and really scared and I remember just before I went into the operation room I was screaming and crying.'* Hannah P5: L27-29

Communication

Catherine expressed a wish for information to be shared in a timely and honest manner when reflecting on receiving her diagnosis:

> *'I would rather they have told me in February than obviously in the month after so I would rather them tell me up straight than keeping it from me.'* Catherine P14: L45-48

The issue of timing was also raised by Steven who felt angry and upset that he did not have enough time to come to terms with having another operation.

> *'I remember, it was a Friday and I thought it would be a routine check-up but when [doctor] said I'm going back in to get another heart monitor, I was like, ok then, give me a couple of weeks to think about it but then she mentioned Tuesday, and my face just dropped. I just wanted at least time to think about it, to get my head around I'm going to have this thing [internal loop monitor] back in again but I don't think I've been that angry or upset since I've seen [doctor]'.* Steven P13: L43-51

There were times when young people felt that they were not listened to and Catherine's use of the word '*dismissed'* seems to reflect the disempowering nature of her experiences:

> *'They just dismissed me, ummm, I kept on [fainting] like another one that same week, and so they took me back to hospital'*. Catherine P3: L1-3

Tanya felt strongly that she did not want to have the operation to fit an internal loop recorder and felt that her views were not considered in this decision. Tanya went onto describe feeling upset on receiving the diagnosis as she felt that this confirmed that she did not need the internal loop recorder to be fitted for 3 years:

> *'I was quite upset that they practically did that [fit the internal loop recorder] for nothing.'* Tanya P6: L14

Hannah, Catherine and Steven requested more information and involvement in their care and shared that talking about their difficulties with professionals helped to increase knowledge and understanding of NCS. In contrast, Kirsty spoke of lots of appointments and a repetition of information which could be frustrating:

> *'You hear it all the time, I've seen people in [hospital] and [hospital]*. Kirsty P6: L50

Discussion

This research investigated five young people's experiences of NCS. Analysis and interpretation of the interviews elicited four overarching themes: 1) Uncertainty 2) Self-concept 3) Coping strategies 4) Experiences of medical services. Overall, there seemed to be high concordance between experiences, however some differences were expressed, perhaps reflecting how the complexity of experiences and the social

context surrounding them influence the meaning young people create. It is important to note the connectivity of these themes and each theme can be best understood within the context they provide each other. The results of the interviews highlight the significance of the young people's stage of development. This context provides an important framework for understanding young people's experience of NCS. Themes will be discussed in relation to developmental theory (Erikson, 1963; Piaget, 1950) and models of illness behaviour and their implications for clinical practice will be considered.

Leventhal et al.'s (1997) model of illness behaviour examines the relationship between cognitive representations of illness and subsequent coping behaviours. It theorises that an individual's interpretation of the illness is based on how they make sense of their symptoms. Young people described difficulties in understanding their symptoms due to uncertainty, unpredictability and a lack of control. Consistent with previous research, uncertainty has been found to be a fundamental aspect of the narratives of young people with chronic illness (Mador & Smith, 1989). These findings can be understood within Mishel's (1988) model of perceived uncertainty in illness which identified four forms of illness uncertainty: ambiguity about illness, complexity regarding treatment and systems of care, lack of information about diagnosis and seriousness, and unpredictability of the course and prognosis of illness (Mishel, 1988 p.225). Young people's narratives touched on all these factors, in particular the lack of information about diagnosis and the unpredictability of the course and prognosis of NCS. Furthermore, Mishel's (1988) model theorises that successful adaptation to illness depends on the individual's appraisal of the uncertainty. If uncertainty is appraised as risk, as was found in young people's

narratives, this can increase emotional distress. Consistent with previous research with young people with NCS and young people with chronic illness, symptoms of anxiety and low mood were expressed by the young people (Bennett et al., 2015; Hyphantis et al., 2012; Wong & So, 2002). Furthermore, increased illness uncertainty has been associated with increased psychological distress and decreased HRQOL in young people with a variety of chronic illnesses, including diabetes, asthma, cystic fibrosis, cancer, sickle cell disease, and juvenile rheumatic disease (Fortier et al., 2013; Pai et al., 2007).

Leventhal et al. (1997) also posit that illness interpretation is influenced by social context and social interactions. Young people experienced felt stigma and enacted stigma and described grappling with feelings of normality and difference. These results corroborated findings from previous literature on young people's experiences of chronic illness (D'Auria et al., 1997; Nicholas et al., 2011; Olsson et al., 2003). Despite young people striving for normality, they often internalised their experiences, using phrases such as *'what's wrong with me'*. These emphasise the gap between how young people viewed themselves and what they perceived as normal. Consistent with this, young people discussed difficulties in talking to friends about their experience of NCS, possibly linked with feeling of uncertainty about their experiences and also fear identifying themselves as different and experiencing subsequent stigma. These findings are similar to other young people with chronic illness who described weighing up the pros and cons of disclosing their condition and described only telling people who they considered trustworthy. (Berntsson et al., 2007; Nicholas et al., 2011; Woodgate, 1998). For young people with NCS this may be increasingly difficult as they are often unable to hide their symptoms.

Young people also described restrictions on current opportunities due to their experiences of stigma, which negatively impacted on their HRQOL. A similar finding was noted by Anderson et al., (2012). Young people reported missing school which was also likely to contribute to difficulties in developing and sustaining friendships and exacerbate feelings of difference and social isolation. Consistent with previous research, young people withdrew and isolated themselves, which further reduced opportunities to participate in peer activities (Gannoni & Shute 2009; Nicholas et al., 2011; Olsson et al., 2003). The impact of NCS on HRQOL and psychological functioning can be understood within a developmental context. Child development theory posits that as young people transition through adolescence, which is typically characterised by conformity, they begin to become more aware of social difference and being accepted by peers is of paramount importance (Erikson, 1963). Young people's descriptions were cognitive, affective and existential in their focus with narratives touching on the potential pervasiveness of NCS on all aspects of their lives. Episodes of syncope could occur in any domain of young people's lives, for example, home, school and social environments, potentially impacting on all areas of quality of life. This finding differs to young people's experience of other chronic illnesses where the illness does not dominate all aspects of their life (Atkin & Ahmad, 2001).

Despite these experiences young people developed a range of coping strategies and resilience. Some young people expressed a sense of acceptance of their diagnosis which was similar to young people with sickle cell disorders (Atkin & Ahmad, 2001). However, the uncertainty of NCS and associated lack of control made this

coping strategy vulnerable at times. Therefore, a key alternative for coping was drawing on external support from family and friends. Young people described parents as offering emotional and practical support. The results indicate that the emotional support provided by parents was valued, however practical support can become difficult for young people to accept as they develop through adolescence and strive to increase their autonomy and independence. As documented by Christie and Viner (2009) chronic illness during adolescence can prevent the development of independence as well as impact on what has already been achieved. This can create tensions within the child and parental relationship, as the young person fluctuates from seeking support to rejecting it, in relation to their experiences of NCS.

All young people had numerous experiences of medical services and many felt they would have benefited from more information about the condition. Just as young people are developing autonomy and independence in their relationships with parents, this transition is relevant to their experiences of medical services. Young people expressed frustrations at not being included in appointments and not being given options about their care. This is consistent with previous findings where young people valued the opportunity to have increased control over decisions about their care (Shaw et al., 2004). It is likely that this could be particularly empowering when experiencing symptoms and medical procedures which feel out of their control. This might facilitate more predictable experiences of medical services, reinforcing feelings of safety. In contrast, one young person described feeling that they had too many appointments and found that medical clinicians often repeated the same information. Similarly, the contrast between those who wished for more knowledge and interaction with medical clinicians and those who found this challenging, mirrors

inconsistencies reported in previous research about adolescent's confidence to participate in decisions regarding their healthcare (Beresford & Sloper, 2003; Smith & Wallace, 2003).

Limitations

Potential limitations to the study include variations in the number and frequency of syncopal episodes experienced by young people. In addition, the length of time symptoms had been present differed for participants. These factors could contribute to differences in the young person's experiences. Furthermore, all young people who participated were white, English speaking and from the central belt of Scotland. Therefore, these findings cannot claim to represent young people of different ethnic backgrounds, from other areas of the United Kingdom. It could be argued that the sample size is a limitation to the study. However, research literature claims that a sample size of four to ten is suitable for IPA analysis (Smith et al., 2013 p.52). IPA aims to explore the detailed processes which individuals go through to interpret, understand and give meaning to their experiences (Smith et al., 2013). Therefore a sample size of five was felt to be acceptable. Although a small sample size is advocated in IPA research (Smith et al., 2013), it does mean that conclusions must be drawn with caution when generalizing to a wider population.

Clinical Implications

The findings indicate that NCS does impact on young people's psychological wellbeing and HRQOL, as found within the literature with adults with NCS. This may suggest that these difficulties can be pervasive throughout an individual's life. Therefore, it can be argued that there is a role for clinical psychology in providing early intervention to support young people. There is a lack of current research

investigating the efficacy of psychological treatments for NCS with only six published articles presenting data with adults and one with children and young people (Hyphantis et al., 2012). Four studies investigate the efficacy of Cognitive Behavioural Therapy (CBT), including the following strategies: sharing psychological formulations, cognitive structuring of maladaptive beliefs about fainting, graded exposure and using applied tension and relaxation techniques (McGrady et al., 1997; McGrady et al., 2003; Newton et al., 2003; Sabin, 2001). Although these studies highlight the potential benefits of CBT for patients with NCS, the sample sizes are small, including one case study (Sabin, 2001). A systematic review conducted by Bennett et al., (2015) concluded that children with a physical health condition and comorbid anxiety and depression can benefit from CBT interventions. However, these conclusions are tentative due to limited research in this area. Supporting adjustment to diagnosis could be beneficial, promoting adaptive coping strategies which support young people as they transition into adulthood. Previous research has suggested that normalising experiences through group interventions and peer support groups could help reduce social isolation and improve self-esteem (Olsson et al., 2003; Woodgate, 1998). A holistic and collaborative way of working, promoting interventions which provide medical and psychological treatment could be of value to young people and their families.

Future Research

As discussed, research investigating children and young people's experiences of NCS is extremely limited. It is hoped that this study will contribute to the current body of research and provide a foundation for the development of further qualitative studies in this area. Further research into the impact of NCS on psychological

functioning and the efficacy of psychological treatment is necessary to guide the development of appropriate and effective interventions to best meet young people's needs. The literature also suggests that family functioning can impact on young people's experiences of NCS (Blount et al., 2004) and reduced parental physical and psychosocial wellbeing has been shown to consistently predict poorer child adjustment to chronic illness (Barlow & Ellard, 2006). Therefore, it would be important to investigate parent's experiences of their child's diagnosis of NCS to fully understand how to best support young people with NCS and their families.

Conclusion

The findings of this study present an insight into the lived experiences of five young people diagnosed with NCS. The research aimed to develop an understanding of young people's experiences of NCS and the possible impact on HRQOL and psychological functioning. Previous to this research, no known qualitative studies had been conducted with this population. Many of the issues highlighted in the findings are similar to the experiences of chronic illness among young people. Young people are challenged to cope with the uncertainty of their diagnosis and symptoms during a period of their lives when they are expected to negotiate the transition from childhood into adolescence. As such, young people's experiences of NCS are complex and dynamic. Previous research conducted with young people with chronic illness has demonstrated that chronic illness is associated with an increased risk of psychological, psychosocial and emotional difficulties. Chronic illness and uncertainty can make social interactions with family and peers difficult and challenge young people's identity and self-concept. It can also create dependency on

others, making it difficult for young people to develop their own autonomy (Yeo & Sawyer, 2005). Consistent with these findings, the narratives of these young people highlight that similar issues are present for young people with NCS. However subtle differences were evident. Young people with NCS expressed that their diagnosis could remain a source of confusion and uncertainty and their symptoms can be pervasive, impacting on all areas of their lives. This may increase psychological distress which may exacerbate and contribute to the maintenance of symptoms of syncope. This highlights a need for individualised, holistic care to ensure young people's emotional and physical needs are met.

References

Anderson, J. B., Czosek, R. J., Knilans, T. K., & Marino, B. S. (2012). The effect of paediatric syncope on health-related quality of life. *Cardiology in the Young, 22*, 583–588. doi:10.1017/S1047951112000133

Atkin, K., & Ahmad, W. I. U. (2001). Living a 'normal' life: young people coping with thalassaemia major or sickle cell disorder. *Social Science & Medicine, 53*, 615-626.

Barlow, J. H., & Ellard, D. R. (2006). The psychosocial well-being of children with chronic disease, their parents and siblings: an overview of the research evidence base. *Child: Care, Health & Development, 32*(1), 19–31.

Bennett, S., Shafran, R., Coughtrey, A., Walker, S., & Heyman, I. (2015). Psychological interventions for mental health disorders in children with chronic physical illness: a systematic review. *Archives of Disease in Childhood, 100*, 308-316. doi: 10.1136/archdischild-2014-307474

Beresford, B., & Sloper, P. (2003). A causal model of self-care behaviour for adolescents with epilepsy. *Journal of Adolescent Health, 33*, 172-179.

Berkow, R., & Fletcher, A. J. (1992). *The Merck manual.* Rahway, NJ: Merck Research Laboratories.

Berntsson, L., Berg, M., Brydolf, M., & Hellsrom, A. L. (2007). Adolescents' experiences of well-being when living with a long-term illness or disability. *Scandinavian Journal of Caring Sciences, 21*, 419–425. doi: 10.1111/j.1471-6712.2006.00490.

Blount, R. L., Morris, J. A. B., Cheng, P. S., Campbell, R. M., & Brown, R. T. (2004). Parent and Child Psychological Factors in Pediatric Syncope and Other Somatic Symptoms. *Journal of Consulting and Clinical Psychology, 72*(4), 597–604. doi: 10.1037/0022-006X.72.4.597

Brocki, J., & Wearden, A. (2006). A critical evaluation of using interpretive phenomenological analysis (IPA) in health psychology. *Psychology and Health, 21*(1), 87-108. doi:10.1080/14768320500230185.

Byars, K. C., Brown, R. T., Cambell, R. M., & Hobbs, S. A. (2000). Psychological adjustment and coping in a population of children with recurrent syncope. *Journal of Developmental and Behavioural Paediatrics, 21*, 189-197.

Cella, D. F., & Bonomi, A. E. (1995). Measuring quality of life: *Oncology 9*, 47-60.

Christie, D., & Viner, R. (2009). Chronic Illness and transition: time for action. *Adolescent Medicine State of the Art Reviews, 20*(3), 981-987.

Coelho, R., Teixeira, F., Silva, A. M., Vaz, C., Vieira, D., Proenc, C., Moura, C., Viana, V., Areias, J. C., & Areias, M. E. G. (2013). Psychosocial adjustment, psychiatric morbidity and quality of life in adolescents and young adults with congenital heart disease. *Revista Portugesa de Cardiologia, 32*(9), 657-664.

Collins, K., & Nicolson, P. (2002). The meaning of 'satisfaction' for people with dermatological problems: Reassessing approaches to qualitative health psychology research. *Journal of Health Psychology, 7,* 615–629.

D'Auria, J. P., Christian, B.J., & Richardson, L. F. (1997). Through the looking glass: children's perceptions of growing up with cystic fibrosis. *Canadian Journal of Nursing Research, 29,* 99–112.

Erikson, E. H. (1963). *Childhood and society (2nd ed.).* New York: Norton.

Fortier, M. A., Bastila, M. L., Wahi, A., Kain, A., Strom, S., & Sender, L. S. (2013). Illness uncertainty and health related quality of life in children with cancer. *Journal of Pedatric Hematology Oncology, 35*(5), 366-370. doi: 10.1097/MPH.0b013e318290cfdb

Frisen, A. (2006). Measuring health-related quality of life in adolescence. *Foundation Acta Pædiatrica, 96,* 963–968. doi: 10.1111/j.1651-2227.2007.00333

Gannoni, A. F., & Shute, R. H. (2009). Parental and child perspectives on adaptation to childhood chronic illness: A qualitative study. *Clinical Child Psychology and Psychiatry, 15*(1) 39–53. doi: 10.1177/1359104509338432

Gracie, J., Newton, J. L., Norton, M., Baker, C., & Freeston, M. (2006). The role of psychological factors in response to treatment in neurocardiogenic (vasovagal) syncope. *Europace, 8,* 636-643. doi: 10.1093/europace/eul073

Green, H., McGinnity, A., & Meltzer, H. (2005). *Mental health of children and Adolescents in Great Britain, 2004*. London: ONS, The Stationery Office.

Henningsen, P., Zimmermann, T., & Satiel, H. (2003). Medically Unexplained Physical Symptoms, Anxiety and Depression: A Meta-Analytic Review. *Psychosomatic Medicine, 65,* 528-533.

Hovels-Gurich, H. H., Konrad, K., Wiesner, M., Minkenberg, R., Herpertz-Dahlmann, B., Messmer, B. J., & Von Bernuth, G. (2002). Long term behavioural outcomes after neonatal arterial switch operation for

transposition of the great arteries. *Archives of Disease in Childhood, 87*, 506-510.

Hyphantis, T. N., Pappas, A., Vlahos, A., Carvalho, A., Levenson, J. L., & Kolettis, T. M. (2012). Depressive Symptoms and Neurocardiogenic syncope in Children: A 2-year prospective study. *Pediatrics, 130* (5), 906-913. doi: 10.1542/peds.2012-1379

Hysling, M., Elgin, I., Gillberg, C., & Lundervold, A. J. (2009). Emotional and behavioural problems in subgroups of children with chronic illness: results from a large-scale population study. *Child: Health, Care and Development, 35*(4), 527–533. doi:10.1111/j.1365-2214.2009.00967.x

Jamieson, N., Fitzgerald, D., Singh-Grewal, D., Hanson, C. S., Craig, J. C., & Tong, A. (2014). Children's Experiences of Cystic Fibrosis: A Systematic Review of Qualitative Studies. *American Academy of Pediatrics, 133*(6), 1683-1697. doi: 10.1542/peds.2014-0009

LaFrance, W. C. (2009). Somatoform disorders. *Seminars in Neurology, 29*(3), 234–46. doi:10.1055/s-0029-1223875

Larkin, M., & Thomson, A. R. (2012). Qualitative Research Methods. In D. Harper & A. R. Thomson, *Qualitative Research Methods in Mental Health and Psychotherapy. A guide for students and practitioners.* West Sussex: Wiley and Sons.

Lavigne, J. V., & Faier-Routman, J. (1992). Psychological Adjustment to Paediatric Physical Disorders: A Meta-Analytic Review. *Journal of Pediatric Psychology, 17*(2), 133-157.

Lee, S. H., Park, S., Byeon, K., On, Y. K., Yim, H. R., & Kim, J. S. (2013). Prevalence and Clinical Factors of Anxiety and Depression in Neurally Mediated and Unexplained Syncope. *Yonsei Medical Journal, 54*(3), 583-589. doi.org/10.3349/ymj.2013.54.3.583

Leventhal, H., Benyamini, Y., & Brownlee, S. (1997). Illness representations: theoretical foundations. In K. J. Petrie & J. A. Weinman (Eds.) *Perceptions of Health and Illness (pp.19-45).* Amsterdam: Harwood Academic.

Linzer, M., Divine, G., & Mark Estes, N. A. (1992). Medically Unexplained Syncope: Relationship to Psychiatric Illness. *The American Journal of Medicine, 92*(1), 1 S18-S25.

Linzer, M., Gold, D. T., Pontinen, M., Divine, G. W., Felder, A., & Brooks, W. B.

(1994). Recurrent syncope as a chronic disease: preliminary validation of a disease-specific measure of functional impairment. *Journal of General Internal Medicine, 9,*181–186. doi:10.1007/BF02600121 ·

Linzer, M., Pontinen, M., Gold, D. T., Divine, G. W., Felder, A., & Brooks, W. B. (1991). Impairment of physical and psychosocial function in recurrent syncope. *Journal of Clinical Epidemiology 44,* 1037–1043.

Mador, J. A., & Smith, D. H. (1989). The psychological adaptation of adolescents with cystic-fibrosis: The review of the literature. *Journal of Adolescent Health Care, 10*(2), 136–142. doi:10.1016/0197-0070(89)90104-6

Mathias, C. J., Deguchi, K., Bleasdale-Barr, K., & Smith, S. (2000). Familial vasovagal: observation in a case with natural and adopted siblings. *Clinical Autonomic. 10*: 43-45.

McGrady, A. V., Bush, E. G., & Grubb, B. P. (1997). Outcome of Biofeedback-Assisted Relaxation for Neurocardiogenic Syncope and Headache: A Clinical Replication Series. *Applied Psychophysiology and Biofeedback, 22*(1), 63-72. doi: 10.1023/A:1026241826589

McGrady, A. V., Kern-Buell, C., Bush, E., Devonshire, R., Clagett, A. L., & Grubb, B. P. (2003). Biofeedback-Assisted Relaxation Therapy in Neurocardiogenic Syncope: A Pilot Study. *Applied Psychophysiology and Biofeedback, 28*(3), 183-192. doi:10.1023/A:1024664629676

McLeod, K. A. (2003). Syncope in children. *Archives of Disease in Childhood, 88*, 350-353.

Mellion, A., Uzark, K., Cassedy, A., Drotar, D., Wernovsky, G., Newburger, J. W., Mahony, J., Mussatto, K., Cohen, M., Limbers, C., & Marino, B. S. (2014). Health-Related Quality of Life Outcomes in Children and Adolescents with Congenital Heart Disease. *The Journal of Paediatrics, 164*(4), 781-788.7

Miller, T. H., & Kruse, J. E. (2005). Evaluation of Syncope. *American Family Physician, 72*(8), 1492 – 1500.

Mishel, M. H. (1988). Uncertainty in illness. *Image- The Journal of Nursing Scholarship, 20*, 225–232. doi: 10.1111/j.1547-5069.1988.tb00082.x

Newton, J. L., Kenny, R. A., & Baker, E. R. (2003). Cognitive behavioural therapy as a potential treatment for vasovagal/neurocardiogenic syncope- a pilot study. *Europace, 5*, 299–301. doi:10.1016/S1099–5129(03)00030-8

NHS Executive. (1997). Priorities and planning guidelines for the NHS: Medium

term priorities. *London:* HMSO.

Nicholas, D. B., Picone, G., & Selkirt, E. K. (2011). The Lived Experiences of Children and Adolescents with End-Stage Renal Disease. *Qualitative Health Research, 21*(2), 162-173. doi:10.1177/1049732310382789

Olsson, C. A., Bond, L., Johnson, M. W., Forer, D. L., & Boyce, M. F. (2003). Adolescent Chronic Illness: A qualitative study of psychosocial adjustment. *Annals of the academy of medicine, 32*(1), 44-50.

Pai, A. L. H., Mullins, L. L., Drotar, D., Burant, C., Wagner, J., & Chaney, J. (2007). Exploratory and confirmatory factor analysis of the child uncertainty in illness scale among children with chronic illness. *Journal of Pediatric Psychology, 32,* 288–296.

Piaget, J. (1950). *The Psychology of Intelligence*. London: Routledge.

Pinquart, M. (2012). Self-esteem of children and adolescents with chronic illness: a meta-analysis. *Child: care, health and development, 39*(2), 153–161. doi:10.1111/j.1365-2214.2012.01397.x

Reid, K., Flowers, P., & Larkin, M. (2005). Interpretative phenomenological analysis: An overview and methodological review. *The Psychologist, 18,* 20–23.

Romme, J. J. C. M., Van Dijk, N., Go-Schon, I. K., Casteelen, G., Weiling, W., & Reitsma, J. B. (2011). Association between psychological complaints and recurrence of vasovagal syncope. *Clinical Autonomic Research Journal, 21*, 373-380. doi: 10.1007/s10286-0125-7

Rose, M. J., Koshman, M., Spreng, S., & Sheldon, R. (2000). The relationship between health-related quality of life and frequency of spells in patients with syncope. *Journal of Clinical Epidemiology 53,* 1209–1216.

Sabin, N. (2001). The use of applied tension and cognitive therapy to manage syncope (common faint) in an older adult. *Aging and Mental Health, 5*(1) 92-94. doi: 10.1080/13607860020020690

Scottish Government. (2010). *The healthcare quality strategy for NHS Scotland*. Edinburgh: Scottish Government.

Shaw, K., Southwood, T., McDonagh, J. (2004). User perspectives of transitional care for adolescents with juvenile idiopathic arthritis. *Rheumatology, 43,* 770–8.

Smith, J. A. (2011). Evaluating the contribution of interpretative phenomenological analysis. *Health Psychology Review, 5*(1), 9-27. doi:10.1080/17437199.2010.510659

Smith, J. A., Flowers, P., & Larkin, M. (2013). *Interpretative Phenomological Analysis. Theory, Method and Research*. London: Sage.

Smith, J. A., Jarman, M., & Osborn, M. (1999). Doing Interpretative Phenomenological Analysis. In M. Murray & K. Chamberlain (Eds.) *Doing interpretative phenomenological analysis. Qualitative health psychology: Theories and methods*. London: Sage.

Smith, J. A., & Osborn, M. (2003). *Interpretative phenomenological analysis. Qualitative psychology: A practical guide to research methods*. London: Sage.

Smith, P. E., & Wallace, S. J. (2003) Taking over epilepsy from the paediatric neurologist. *Journal of Neurology, Neurosurgery & Psychiatry, 74*(1), i37-i41. doi: 10.1684/epd.2011.0409

Spijkerboer, A., Utens, E., De Koning, W., Boggers, A. J. J. C., Helbing, W. A., & Verhulst, F. C. (2006). Health-related quality of life in children and adolescents after invasive treatment for congenital heart disease. *Quality of Life Research, 15,* 663-673. doi:10.1007/s11136-005-3692-z

United Nations. (2000). *Convention on the Rights of the Child.* Retrieved from *http://www.unicef.org/crc/*

Van Dijk, N, Sprangers, M. A., Colman, N., Boer, K. R., Wieling, W., & Linzer, M. (2006). Clinical factors associated with quality of life in patients with transient loss of consciousness. *Journal of Cardiovascular Electrophysiology, 17,* 998–1003. doi:10.1111/j.1540-8167.2006.00533.x

Varni, J. W., Limbers, C. A., & Burwinkle, T. M. (2007). Impaired health-related quality of life in children and adolescents with chronic conditions: a comparative analysis of 10 disease clusters and 33 disease categories/severities utilizing the PedsQL 4.0 Generic Core Scales. *Health and Quality of Life Outcomes, 5*(43), 1-15. doi:10.1186/1477-7525-5-43

Weiling, W., Ganzeboom, K. S., Saul, J. P. (2004). Reflex syncope in children and adolescents. *Heart,* 90, 1094–1100. doi: 10.1136/hrt.2003.022996

Wong, K. T., & So, L. Y. (2002). Syncope in children and adolescents of Hong Kong. *Journal of Paediatric child Health, 38,* 196-198.

Woodgate, R. L. (1998). Adolescents' Perspectives of Chronic Illness. *Journal of Paediatric Nursing*, *13*(4), 210-23.

Worrall-Davies, A., & Marino-Francis, F. (2008). Eliciting children's and young people's views of child and adolescent mental health services: A systematic review of best practise. *Child and Adolescent Mental Health*, *13*(1), 9–15.

Yeo, M., & Sawyer, S. (2005). Chronic illness and disability. *British Medical Journal*, *330*(26), 712-723.

Yozwiak, J. A., Settles, R. E., & Steffens, R. F. (2011). Psychosocial Functioning in Youth with Chronic Illness. In D. R. Patel, D. E. Greydanus, H. A. Omar, & J. Merrick. (Eds.), *Neurodevelopmental Disabilities, Clinical Care for Children and Young Adults.* Springer Science.

Chapter Three: Advanced Clinical Practice 1 - Reflective Critical Account

Developing effective therapeutic relationships

Correspondence to:
Joanne Skeldon
Mental Health & Wellbeing
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
j.skeldon.1@research.gla.ac.uk

Developing effective therapeutic relationships

Abstract

In this reflective account I have used Stoltenberg et al.'s Integrated Developmental Model of Supervision (IDM) (2009) and Gibb's Reflective Cycle Model (1988) to provide an overarching structure to guide my reflections. I have focused on three experiences from different stages in my training, reflecting on the key learning opportunities they provided, supporting me to develop my skills and knowledge as a clinician. These experiences focus on the development of therapeutic relationships with my clients and developing an awareness of my own emotional reactions. I have also discussed how these experiences have taught me to recognise and use my own emotional responses therapeutically to support intervention with the client, develop formulations and promoting multidisciplinary working.

Chapter Four: Advanced Clinical Practice 2 - Reflective Critical Account

Reflections on conducting research in the NHS.

Correspondence to:
Joanne Skeldon
Mental Health & Wellbeing
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
j.skeldon.1@research.gla.ac.uk

Reflections on conducting research in the NHS.

Abstract

I have chosen to reflect on the process of conducting audit and research in the NHS, which I believe has been instrumental in developing my research and clinical skills. I have used Stoltenberg et al.'s Integrated Developmental Model of Supervision (IDM) (2009) to provide an overarching structure to my reflections. I have also found Gibb's Reflective Cycle Model (1988) helpful in guiding my reflections on service development and the role of clinical psychology in driving such changes. While reflecting on my research experiences to date, I discuss three key experiences which have contributed to developing my understanding of clinical psychology as a profession within the context of the NHS. I feel that these experiences have been influential in shaping my professionals identity and fostering my enthusiasm for involving the views of service users in the design and development of services.

Appendices

Systematic Review

Major Research Project

Appendices – Systematic Review

Appendix 1: British Journal of Health Psychology, Author Guidelines

British Journal of Health Psychology
The British Psychological Society
Edited By: Alison Wearden and David French
Impact Factor: 2.776
ISI Journal Citation Reports © Ranking: 2014: 24/119 (Psychology Clinical)
Online ISSN: 2044-8287

Author Guidelines

The aim of the British Journal of Health Psychology is to provide a forum for high quality research relating to health and illness. The scope of the journal includes all areas of health psychology as outlined in the Journal Overview.

The types of paper invited are:

• papers reporting original empirical investigations, using either quantitative or qualitative methods;

• theoretical papers which may be analyses or commentaries on established theories in health psychology, or presentations of theoretical innovations;

• review papers, which should aim to provide systematic overviews, evaluations and interpretations of research in a given field of health psychology; and

• methodological papers dealing with methodological issues of particular relevance to health psychology.

1. Circulation

The circulation of the Journal is worldwide. Papers are invited and encouraged from authors throughout the world.

2. Length

Papers should normally be no more than 5000 words (excluding the abstract, reference list, tables and figures), although the Editor retains discretion to publish papers beyond this length in cases where the clear and concise expression of the scientific content requires greater length.

3. Editorial policy

The Journal receives a large volume of papers to review each year, and in order to make the process as efficient as possible for authors and editors alike, all papers are initially examined by the Editors to ascertain whether the article is suitable for full peer review. In order to qualify for full review, papers must meet the following criteria:

• the content of the paper falls within the scope of the Journal

• the methods and/or sample size are appropriate for the questions being addressed

• research with student populations is appropriately justified

• the word count is within the stated limit for the Journal (i.e. 5000 words)

4. Submission and reviewing

All manuscripts must be submitted via Editorial Manager. You may like to use the Submission Checklist to help you prepare your manuscript. The Journal operates a policy of anonymous peer review. Authors must suggest three reviewers when submitting their manuscript, who may or may not be approached by the Associate Editor dealing with the paper. Before submitting, please read the terms and conditions of submission and the declaration of competing interests.

5. Manuscript requirements

• Contributions must be typed in double spacing with wide margins. All sheets must be numbered.

• Manuscripts should be preceded by a title page which includes a full list of authors and their affiliations, as well as the corresponding author's contact details. A template can be downloaded from here.

• For articles containing original scientific research, a structured abstract of up to 250 words should be included with the headings: Objectives, Design, Methods, Results, Conclusions. Review articles should use these headings: Purpose, Methods, Results, Conclusions.

• Statement of Contribution: All authors are required to provide a clear summary of 'what is already known on this subject?' and 'what does this study add?'. Authors should identify existing research knowledge relating to the specific research question and give a summary of the new knowledge added by your study. Under each of these headings, please provide 2-3 (maximum) clear outcome statements (not process statements of what the paper does); the statements for 'what does this study add?' should be presented as bullet points of no more than 100 characters each. The Statement of Contribution should be a separate file.

• The main document must be anonymous. Please do not mention the authors' names or affiliations (including in the Method section) and always refer to any previous work in the third person.

• Tables should be typed in double spacing, each on a separate page with a self-explanatory title. Tables should be comprehensible without reference to the text. They should be placed at the end of the manuscript but they must be mentioned in the text.

• Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form consistent with text use. Unnecessary background patterns, lines and shading should be avoided. Captions should be listed on a separate sheet. The resolution of digital images must be at least 300 dpi. All figures must be mentioned in the text.

• For reference citations, please use APA style. Particular care should be taken to ensure that references are accurate and complete. Give all journal titles in full and provide doi numbers where possible for journal articles. For example:

Author, A., Author, B., & Author, C. (1995). *Title of book.* City, Country: Publisher.
Author, A. (2013). Title of journal article. *Name of journal, 1,* 1-16. doi: 10.1111/bjep.12031

• SI units must be used for all measurements, rounded off to practical values if appropriate, with the imperial equivalent in parentheses.

• In normal circumstances, effect size should be incorporated.

• Authors are requested to avoid the use of sexist language.

• Authors are responsible for acquiring written permission to publish lengthy quotations, illustrations, etc. for which they do not own copyright. For guidelines on editorial style, please consult the APA Publication Manual published by the American Psychological Association.

• Manuscripts describing clinical trials are encouraged to submit in accordance with the CONSORT statement on reporting randomised controlled trials.

6. Supporting information

Supporting Information can be a useful way for an author to include important but ancillary information with the online version of an article. Examples of Supporting Information include appendices, additional tables, data sets, figures, movie files, audio clips, and other related nonessential multimedia files. Supporting Information should be cited within the article text, and a descriptive legend should be included. Please indicate clearly on submission which material is for online only publication. It is published as supplied by the author, and a proof is not made available prior to publication; for these reasons, authors should provide any Supporting Information in the desired final format.

For further information on recommended file types and requirements for submission, please visit the Supporting Information page on Author Services.

7. OnlineOpen

OnlineOpen is available to authors of primary research articles who wish to make their article available to non-subscribers on publication, or whose funding agency requires grantees to archive the final version of their article. With OnlineOpen, the author, the author's funding agency, or the author's institution pays a fee to ensure that the article is made available to non-subscribers upon publication via Wiley Online Library, as well as deposited in the funding agency's preferred archive. A full list of terms and conditions is available on Wiley Online Library.

Any authors wishing to send their paper OnlineOpen will be required to complete the payment form.

Prior to acceptance there is no requirement to inform an Editorial Office that you intend to publish your paper OnlineOpen if you do not wish to. All OnlineOpen articles are treated in the same way as any other article. They go through the journal's standard peer-review process and will be accepted or rejected based on their own merit.

8. Author Services

Author Services enables authors to track their article – once it has been accepted – through the production process to publication online and in print. Authors can check the status of their articles online and choose to receive automated e-mails at key stages of production. The author will receive an e-mail with a unique link that enables them to register and have their article automatically added to the system. Visit Author Services for more details on online production tracking and for a wealth of resources including FAQs and tips on article preparation, submission and more.

9. Copyright and licences

If your paper is accepted, the author identified as the formal corresponding author for the paper will receive an email prompting them to login into Author Services, where via the Wiley Author Licensing Service (WALS) they will be able to complete the licence agreement on behalf of all authors on the paper.

For authors signing the copyright transfer agreement

If the OnlineOpen option is not selected the corresponding author will be presented with the copyright transfer agreement (CTA) to sign. The terms and conditions of the CTA can be previewed in the samples associated with the Copyright FAQs .

For authors choosing OnlineOpen

If the OnlineOpen option is selected the corresponding author will have a choice of the following Creative Commons Licence Open Access Agreements (OAA):

- Creative Commons Attribution Non-Commercial Licence (CC-BY-NC)
- Creative Commons Attribution Non-Commercial -NoDerivs Licence (CC-BY-NC-ND)

To preview the terms and conditions of these open access agreements please visit the Copyright FAQs and you may also like to visit the Wiley Open Access Copyright and Licence page.

If you select the OnlineOpen option and your research is funded by The Wellcome Trust and members of the Research Councils UK (RCUK) or the Austrian Science Fund (FWF) you will be given the opportunity to publish your article under a CC-BY licence supporting you in complying with your Funder requirements. For more information on this policy and the Journal's compliant self-archiving policy please visit our Funder Policy page.

10. Colour illustrations

Colour illustrations can be accepted for publication online. These would be reproduced in greyscale in the print version. If authors would like these figures to be reproduced in colour in print at their expense they should request this by completing a Colour Work Agreement form upon acceptance of the paper.

11. Pre-submission English-language editing

Authors for whom English is a second language may choose to have their manuscript professionally edited before submission to improve the English. A list of independent suppliers of editing services can be found in Author Services. All

services are paid for and arranged by the author, and use of one of these services does not guarantee acceptance or preference for publication.

12. The Later Stages

The corresponding author will receive an email alert containing a link to a web site. The proof can be downloaded as a PDF (portable document format) file from this site. Acrobat Reader will be required in order to read this file. This software can be downloaded (free of charge) from Adobe's web site. This will enable the file to be opened, read on screen and annotated direct in the PDF. Corrections can also be supplied by hard copy if preferred. Further instructions will be sent with the proof. Excessive changes made by the author in the proofs, excluding typesetting errors, will be charged separately.

13. Early View

British Journal of Health Psychology is covered by the Early View service on Wiley Online Library. Early View articles are complete full-text articles published online in advance of their publication in a printed issue. Articles are therefore available as soon as they are ready, rather than having to wait for the next scheduled print issue. Early View articles are complete and final. They have been fully reviewed, revised and edited for publication, and the authors' final corrections have been incorporated. Because they are in final form, no changes can be made after online publication. The nature of Early View articles means that they do not yet have volume, issue or page numbers, so they cannot be cited in the traditional way. They are cited using their Digital Object Identifier (DOI) with no volume and issue or pagination information. Eg Jones, A.B. (2010). Human rights Issues. *Journal of Human Rights.* Advance online publication. doi:10.1111/j.1467-9299.2010.00300.x

Appendix 2: Systematic Review, Quality Rating Scale

Based upon the SIGN methodology checklist for cohort and case-control studies and Downs and Black's (1998) checklist.

	Question	**Score**
Methodology		
1	Does the study address an appropriate and clearly focused question?	Yes 1 No 0
2	Have the authors developed a clear theoretical framework/ rational for their study	Yes No
3	Are the main outcomes to be measured clearly described in the introduction or methods section?	Yes 1 No 0
4	Does the study provide details of the procedure so the study could be replicated?	Yes 1 No 0
5	Are the two groups being studied selected from source populations that are comparable in all respects other than the factor under investigation?	Yes 1 No 0
Measures		
6	Are the measures used for mental health difficulties standard, valid and reliable?	Yes 1 No 0
7	If Clinicians measures were used, was there evidence that they were appropriately trained to use the measure?	Yes 1 No 0
8	Was syncope type diagnosed in a standard, valid and reliable way? (Includes a head up tilt test)	Yes 1 No 0
9	Does the study clearly define syncope terms?	Yes 1 No 0
10	Was the assessment of outcome made blind to grouping?	Yes 1 No 0
Sample and Internal and external validity		
11	Does the study indicate how many people who were asked took part?	Yes 1 No 0
12	Does the study justify the number of participants used ie power calculations?	Yes 1 No 0
13	Is the sample representative of the entire population from which they were recruited? (Considered representative if they include the entire source population or a random sample or recruit from more than one source ie A&D and outpatient clinics)	Yes 1 No 0
14	Is the inclusion and exclusion criteria stated	Yes 1

		No 0
15	Are the inclusion and exclusion criteria the same for both groups?	Yes 1 No 0
16	Is demographic information included? (Minimum demographic information included should be age, gender and Education)	Yes 1 No 0
17	Is the statistical analysis used appropriate?	Yes 1 No 0
Results		
18	Are the main potential confounders identified? (Confounding variable may be age, gender)	Yes 1 No 0
19	Are confounding variables taken into account in the design and analysis?	Yes 1 No 0
20	Are the main findings of the study clearly described?	Yes 1 No 0
21	Does the study provide estimates of random variability in the data for the main outcomes? (Standard error. Standard deviation or confidence intervals or inter quartile ranges)	Yes 1 No 0
22	Have the characteristics of patients lost to follow up been described?	Yes 1 No 0
23	Have actual probability values been reported for the main outcomes except where the probability value is less than 0.001?	Yes 1 No 0
Discussion		
24	Are the conclusions drawn clearly based upon the results?	Yes 1 No 0
25	Are the limitations of the study considered?	Yes 1 No 0
Total Score:		

Appendices – Major Research Project

Appendix 3: Major Research Proposal

The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study

Abstract

Background

Syncope is defined as 'a transient loss of consciousness and postural tone caused by global cerebral hypoperfusion' (Lee et al., 2013 p.583) and is known more commonly as fainting. The literature shows that syncope in childhood is common with around one in five children experiencing an episode before the age of 15 years old. Neurocardiogenic Syncope (NCS) is the most common form of syncope in children and adolescents and is benign. However, a minority of syncopal episodes are indicative of underlying cardiac difficulties which are potentially serious and/or life threatening. Therefore, there are often high levels of anxiety for young people, families and medical clinicians in relation to syncope, in particular before a diagnosis of NCS can be given.

Previous literature has investigated associations between syncope, which is commonly known as fainting, health related quality of life (HRQOL) and the prevalence of psychiatric conditions (Anderson et al., 2012; Byars et al., 2000; Hyphantis et al., 2012; Lee et al., 2013), however there is a lack of research investigating these factors in young people. In one study, Anderson et al. (2012) explored the relationship between neurocardiogenic syncope (NCS) and HRQOL in children and adolescents and found that children presenting with NCS scored lower on HRQOL measures than healthy controls and in fact had scores similar to children

with a range of chronic health conditions such as asthma, end-stage renal disease, obesity, and structural heart disease (Anderson et al., 2012). Decreased HRQOL is associated with an increased risk of psychiatric, psychosocial and emotional difficulties as well as adverse effects on peer relationships and family functioning (Frisen, 2006). Consistent with these findings, other studies such as that by Hyphantis et al. (2012) have reported a higher prevalence of depression and anxiety disorders in children with NCS compared to healthy controls. Furthermore, factors such as parental psychological distress have been associated with the severity of syncope in young people (Blount et al., 2004). The identification of such factors is crucial for the appropriate clinical management and psychological support of young people with NCS and yet, to date, little is currently known about young people's experiences of NCS and the possible impact on HRQOL and psychological functioning.

Aims

This project aims to explore young people's experience of NCS: to gain a more detailed understanding of young people's experience of the symptoms, diagnosis and management of NCS.

Objectives

- To explore young people's understanding of possible physical and psychological triggers for NCS and the possible warning signs or symptoms experienced prior to onset of an episode.
- To explore young people's experience of having an internal loop recorder to monitor their cardiac activity.

- To explore young people's experience of receiving a diagnosis of NCS following investigation with an internal loop recorder.
- To explore the impact of NCS on young people's HRQOL and psychological functioning.

Based upon the previous literature, the following key issues have been identified and are considered important in understanding the context of young people's experiences: young people's social functioning, peer relationships, family functioning, development of sense of self and identity, and autonomy (Frisen, 2006). Semi structured interview questions will be developed based upon these key issues with the aim of developing a more detailed understanding of young people's experiences of NCS.

Methods

Adolescents aged between 12-18 years old, with a diagnosis of NCS, who are registered with the Paediatric Cardiology Service at Royal Hospital for Sick Children (RHSC), Glasgow will be invited to participate. Semi structured interviews will be used to collect qualitative data which will be analysed using Interpretative Phenomenological Analysis (Smith et al., 2013). It is anticipated that interviews will last approximately 60 minutes. The interview schedule followed for each interview will be flexible to ensure information is collected on individual experiences of NCS.

Applications

Little is currently known about young people's experiences of NCS and the possible impact it may have on HRQOL and psychological functioning. It is hoped that this research will highlight issues, salient to young people which can help guide clinical practice in this area. The finding may help to inform treatment options and provide a

greater understanding of how best to support these young people. In addition, it is hoped that the research will contribute to the current literature on NCS in children and young people and provide a foundation for the development of further qualitative studies in this area.

Introduction and background

Definitions and prevalence rates

Syncope is defined as 'a transient loss of consciousness and postural tone caused by global cerebral hypoperfusion' (Lee et al., 2013 p.583) and is known more commonly as fainting. The literature shows that syncope in childhood is common with around one in five children experiencing an episode before the age of 15 years old. An incidence peak occurs between 15 -19 years old, with females having more than twice the number of incidents than males (Weiling et al., 2004). A study of students averaging 20 years of age showed that 20% of males and 50% of females had experienced at least one syncopal episode in their lifetime (Ganzeboom et al., 2003). The incidence of syncope presenting for medical attention was found to be 125.8 cases per 100,000 based upon data collected over a 5 year period between 1987 and 1991 (Driscoll et al., 1997). They found the incidence was higher for females and for adolescents compared to adults (Driscoll et al., 1997). The majority of syncopal episodes presenting for medical attention are cases of neurocardiogenic syncope (NCS) with cardiac syncope being far less common (Weiling et al., 2004)

Medical investigation and diagnosis of NCS

If we first consider syncope in general, there are many etiologies including cardiac difficulties, metabolic disorders or endocrine diseases, neurological disorders and adverse drug effects (Berkow & Fletcher, 1992). More specifically, neurally mediated syncopes are a heterogeneous group of benign autonomic disorders which occur when there is a disturbance in the autonomic nervous system's control of heart rate and blood pressure. Neurally medicated syncope can be divided into 4 groups including reflex syncope which occur as a result of transient disturbances to heart rate and blood pressure (McLeod, 2003). Neurocardiogenic syncope (NCS) is a form of reflex syncope and is the most common form of syncope in children and adolescents. Although NCS is benign, a minority of syncopal episodes are a symptom of underlying cardiac difficulties and as such, may be caused by a potentially serious and/or life threatening condition, such as Long QT syndrome. Long QT syndrome is an uncommon but serious heart condition which can cause arrhythmia with fatal consequences. Therefore, there are often high levels of anxiety for young people, families and medical clinicians in relation to syncope, in particular before a diagnosis of NCS can be given.

The initial stage of diagnosis of NCS starts by taking a detailed medical history, focusing on identifying the following 'warning signs', all of which might indicate underlying cardiac pathology: syncope during exercise; in relation to loud noise or extreme emotional stress; while supine; and/or a family history of sudden death in individuals under 30 years old. A 12 lead electrocardiogram (ECG) is also essential in identifying cardiac difficulties. In cases where the medical history and ECG do not identify underlying cardiac difficulties, an upright tilt-table test can help to identify

NCS. The tilt table test involves a head-up tilt at 80° for 30 minutes or until the symptoms of syncope appear (e.g., light-headedness, dizziness, nausea) and for some individuals, accompanying bradycardia (low heart rate) and hypotension (low blood pressure) are produced (Blount et al., 2004). Despite such investigation, there will be cases where the diagnosis remains unclear. In cases such as these, internal loop recorders can be helpful in establishing an accurate diagnosis. An internal loop recorder is an electrocardiographic (ECG) device, fitted internally which collates ECG data by monitoring cardiac activity. An absence of bradyarrhythmia and/or an absence of tachyarrhythmia accompanying episodes of syncope would indicate a diagnosis of NCS.

Causes of NCS

For individuals who experience NCS, physical and psychological stress may contribute to increased peripheral vascular pooling, or hypotension. This can result in decreased blood flow to the brain exacerbating the symptoms of NCS (Berkow & Fletcher, 1992). This cycle of events may act to exacerbate the severity of NCS. It is possible that the recurrent symptoms of NCS increases psychological stress in children and adolescents, in turn exacerbating the symptoms of NCS (Henningsen et al., 2003). This vicious cycle of psychological distress and prevalence of NCS can present challenges for clinicians in relation to treatment and management of symptoms, which can be further complicated if patients struggle to accept a lack of cardiac cause for their symptoms (Linzer et al., 1992).

The impact of NCS on health related quality of life

Health related quality of life (HRQOL) is a multidimensional construct which has been defined as the extent to which one's usual or expected physical, emotional, and social well-being are affected by a medical condition or its treatment (Cella and Bonomi, 1995). It could be argued that these various domains of HRQOL are perceived differently depending on the individual's stage of life. Transitioning from childhood through adolescence into adulthood involves numerous significant changes and previous literature has highlighted the following particularly salient aspects of HRQOL for adolescents: body image; development of self-identity; peer relationships; and autonomy (Frisen, 2006).

Previous research has focused on the relationship between NCS and HRQOL in adults and findings have indicated that adults with NCS have a lower HRQOL than healthy controls (Linzer et al., 1991; Linzer et al., 1994; Van Dijk et al., 2006). Research in this area has also identified that adults who experienced more than six syncopal episodes had a significantly poorer perception of their overall HRQOL (SE 1.1 $p<0.001$), rated using the EuroQol (EQ-5D), than adults who had experienced fewer episodes (Rose et al., 2000). In particular they found the prevalence of anxiety or depressive symptoms in individuals with syncope to be 40.8% compared to 19.1% for the general population (Rose et al., 2000). To date, there has only been one study which explores the relationship between NCS and HRQOL in children and adolescents (Anderson et al., 2012). Anderson et al. (2012) found that children presenting with NCS have lower HRQOL than healthy controls and their HRQOL scores are similar to those of children with a range of chronic health conditions such as asthma, end-stage renal disease, obesity, and structural heart disease.

The impact of NCS on psychological wellbeing

Chronic illness has been associated with an increased risk of psychological, psychosocial and emotional difficulties as well as adverse effects on peer relationships and family functioning (Frisen, 2006). As is the case with chronic illness, there is evidence that recurrent NCS can negatively impact on children's and adolescent's psychological wellbeing and family functioning. Hyphantis et al., (2012) found that children who experienced NCS were 2.6 times more likely to have clinically depressive symptoms compared to children who did not experience NCS. They offered children with NCS counselling to address their depressive symptoms, as well as offering counselling to the children's families. At a two year follow up, they found a reduction in depressive symptoms and no recurrences of syncope were reported. The authors felt the improvement in depressive symptoms were associated with improvements in child-parent relationships and improved family functioning. Research by Blount et al., (2004) examined associations between NCS and parental mental health. They found significant associations between 2 out of 10 indicators of mother's psychological adjustment on the Brief Symptom Inventory (BSI) (*r*ss .31, $p<0.05$) and the number of emergency hospital visits (*r*ss .44, $p<0.001$), and 4 out of 10 indicators were positively associated with the frequency of NCS; indicating that poorer psychological adjustment and functioning in mothers was associated with increased severity of NCS in children. These findings suggest the importance of family interactions and relationships in the maintenance of syncope. Furthermore, adolescents are likely to feel that they lack control over syncopal episodes and the unpredictable nature of syncopal episodes could result in physical injury, pain and subsequent psychological trauma. Although research has identified psychological difficulties in adolescents who experience NCS, no research has focused on

adolescent's emotional responses to their experience of syncope. It is hypothesised that adolescents are likely to experience a range of emotional responses including anxiety, embarrassment, increased self-consciousness and low self-esteem.

Advice gained from personal communication with a Paediatric Cardiologist at the RHSC, Glasgow has indicated that the procedure of fitting an internal loop recorder can have a positive impact on reducing the severity of syncope (McLeod, 2014). It is believed that the internal loop recorder can provide reassurance regarding the absence of underlying serious medical conditions which can reduce patient's anxiety and in turn, reduce the frequency and severity of syncopal episodes. The observation of a reduction or elimination of symptoms after this procedure suggests that underlying emotional and psychological factors are contributing to the adolescent's difficulties (McLeod, 2014).

The inclusion of qualitative research findings from service users in the planning and provision of healthcare is well established (Worrall-Davies & Marino-Francis, 2008) and enables appropriate and effective service development (NHS Executive, 1997). The Department of Health (2007) highlights the need for child-centred service provision, and the Scottish Government's Healthcare Quality Strategy (2010) stresses the need for person-centred care. Yet there is little research into the experiences of adolescents with NCS and no qualitative studies have been identified which explore this. As discussed, previous literature has identified that NCS can negatively impact on adolescent's HRQOL and psychological functioning, however it remains unclear what their understanding of their experience of NCS is, and how

services can provide holistic care which best meets their medical and psychological needs.

Research Aims and Objectives

Aims

This project aims to explore young people's experience of NCS: to gain a more detailed understanding of young people's experience of the symptoms, diagnosis and management of NCS.

Objectives

- To gain a more detailed understanding of young people's experience of the symptoms of NCS.
- To explore young people's understanding of the possible physical and psychological triggers for NCS and the possible warning signs or symptoms experienced prior to onset of an episode.
- To explore young people's experience of having an internal loop recorder to monitor their cardiac activity
- To explore young people's experience of receiving a diagnosis of NCS following this investigation.
- To explore the impact of NCS on young people's HRQOL and psychological functioning.

Based upon the previous literature, key issues have been identified which will guide the research to develop a more detailed understanding of these issues. These are as follows: the impact on young people's social functioning, peer

relationships, family functioning, development of sense of self and identity, and autonomy (Frisen, 2006).

Plan of Investigation

The research will be qualitative. Semi-structured interviews with young people will be conducted and will follow an interview schedule based upon the themes identified within the current literature (Frisen, 2006). It is anticipated that interviews will last approximately 60 minutes. The interview schedule followed for each interview will be flexible to ensure information is collected on individual experiences of NCS. It is anticipated that throughout the process of developing an interview schedule, adaptions and changes will be made as ideas progress (Smith et al., 2013). Therefore, it is planned that the first two interviews will be carried out as pilot interviews to evaluate the interview schedule. Based upon the outcomes from these pilot interviews, further changes to the schedule may be required. The two pilot interviews will be included in the total number of interviews conducted and the interview data will be included in the overall analysis. It is planned the interviews will be conducted face to face, however if a limited number of participants are initially recruited, it may be necessary to recruit from a wider range of health boards, including NHS Lothian and NHS Fife. Due to the geographical distance of these health boards from the RHSC, Glasgow, telephone interviews may be required. Telephone interviews have been employed in previous research studies and it was felt that participants should have this option as attendance at interviews may present as a barrier for young people living outside of Glasgow and in rural regions (Turner et al., 2002). However, certain limitations to telephone interviews must be acknowledged. They can present

challenges in establishing and maintaining rapport with the participant as well as the inability to recognise changes in facial gestures or body language which may add additional information and meaning to data while providing a context for analysis (Kavale, 1996).

Analysis

All interview data will be analysed using Interpretative Phenomenological Analysis (IPA) (Smith at al., 2013). IPA is a qualitative research method which explores the detailed processes which individuals go through to interpret, understand and give meaning to their experiences (Reid et al., 2005). IPA recognises that research is a dynamic process (Smith et al., 2013) and acknowledges that the researcher's own conceptions may influence their interpretation of a participant's account. IPA therefore stresses the importance of the researcher's ability to reflect and analyse (Brocki & Wearden, 2006). IPA has been previously used within health psychology, focusing on the importance of understanding an individual's experience of illness through their perceptions, interpretations and the meaning they attribute to their bodily experiences (Brocki & Wearden, 2006). Based upon this previous literature, IPA was felt to be an appropriate method of analysis to provide a detailed interpretation of young people's experiences and the associated meaning assigned to their experience of NCS. A systematic review of health psychology research identified that the majority of research using IPA used interviews to collect the data (Brocki & Wearden, 2006) and the collaborative and dynamic process involved in conducting interviews is in keeping with the methodology of IPA (Smith & Osborn, 2003).

Analysis will be conducted in accordance with the following guidance by Smith et al. (2013). It is recommended that analysis occurs on an individual case basis focusing on the understanding of each participant. Initially transcripts will be read and re-read to ensure familiarity with the content (Smith et al., 2013). The next stage of analysis requires the researcher to begin to document patterns of meaning in the data which can be drawn out by a line by line commentary. These patterns may also include the researcher's initial thoughts about interpretation of the data and what it might mean to the participant to have their thoughts or concerns analysed in relation to their experience. This allows for the development of a more interpretative account (Smith et al., 2013). Next it is important to begin to organise the initial information drawn from the transcripts to identify themes within the data, all of which will be given a title. These themes can then be developed into a structure or framework which demonstrates the relationship between these themes. At this stage, it is important to identify similarities and differences within the data and develop a narrative around this to guide the reader through the interpretation of the data (Larkin & Thomson, 2012; Smith et al., 2013).

The first two interview transcripts will be jointly analysed with the project's academic supervisor to corroborate findings and verify the themes identified.

Participants

Data received from the Information Services Division (ISD) in the RHSC, Glasgow identified 32 young people aged between 12 and 18 years old inclusive, who are currently registered with the Paediatric Cardiology Service at the RHSC, Glasgow. All participants have a diagnosis of NCS after having their cardiac activity monitored with an internal loop recorder for a minimum period of 1 year. The

RHSC, Glasgow is the national centre for cardiology in Scotland and provide specialist care for the diagnosis and management of syncope in young people and therefore many families across Scotland travel to receive treatment. If a young person experiences an episode of syncope after the internal loop recorder monitor is fitted, medical data from the recorder can be collated by the young person and their family and sent to the Paediatric Cardiology Service at the RHSC, Glasgow for review by a consultant. If there are no medical concerns, young people can receive follow up care at the RHSC, Glasgow or at a remote clinic within their NHS health board. Table 1 identifies the number of young people registered with the Paediatric Cardiology Service at the RHSC, Glasgow across health boards.

Table 1. Number of potential participants

NHS Health Board	Number of young people	Age range
Greater Glasgow and Clyde	8	12-17
Ayrshire and Arran	3	14-16
Lanarkshire	8	12-17
Lothian	2	15-16
Forth Valley	1	13
Tayside	2	16-17
Fife	4	12
Grampian	1	13
Boarders	1	16
Highlands	1	14
Unknown	1	16
Total	32	12-17

Recruitment criteria states young people must be aged 12 years and above to participate. Piaget's (1950) developmental stages indicate that children aged 12 years and above begin to transition into the Formal Operational Stage of development and it is at this point that children may start to recognise negative cognitions. Erikson's Psychosocial Stage Model (1963) also proposes that children between 12- 18 years old begin to discover their own identity, while negotiating and struggling with social interactions and experiencing a desire to be accepted by peers. It can be within this

stage of development that, depending on experience, adolescents can begin to develop low self-esteem. Furthermore, there can be a rise in somatic symptoms as children develop through adolescence. Drawing on these developmental theories, young children are likely to experience different emotional responses to NCS. Based upon this, the research will focus on exploring adolescent's experiences of NCS.

Inclusion Criteria:

- Participants must be currently referred to the Paediatric Cardiology Service at RHSC Glasgow and have a diagnosis of NCS, after completing a minimum monitoring period of 1 year using an internal loop recorder.
- The young person is aged between 12-17 years old, inclusive.
- The young person and their parents provide informed consent to participate.
- The young person and their parents speak fluent English.

Exclusion Criteria:

- The young person has a history of cardiac or other medical conditions which may impact on syncope.
- Any young people whom clinicians in the Paediatric Cardiology Service and Paediatric Psychology Service believe to be too physically or mentally unwell to participate.
- The young person has a diagnosis of a learning disability.

Recruitment Procedures

Young people will be recruited from the Paediatric Cardiology Service based at the RHSC, Glasgow. Meetings have been arranged to provide clinicians in this service with information about this study. The paediatric cardiologist in the service will be

asked to identify possible participants based upon the inclusion and exclusion criteria. Potential respondents will be invited to participate in the research by a letter signed by the consultant paediatric cardiologist which will form part of an information pack on the project. The information pack will also include a letter detailing the research to parents, an information sheet, a stamped addressed envelope, and an opt-in form indicating the best way for the researcher to contact the young person, for example: by phone, letter or email. Young people attending appointments at the RHSC, Glasgow will be provided with the information pack by a cardiac liaison nurse working in the Paediatric Cardiology Service. For young people who are receiving remote care and are not attending the RHSC, Glasgow on a regular basis, information packs will be sent out by post. After receiving the information pack detailing the research, follow up phone calls will be made to all young people to discuss participation. These phone calls will be made by a cardiac liaison nurse working in the Paediatric Cardiology Service who is known to the young person and their family. Young people and parents will be provided with the researcher's contact details should they wish to discuss the project before consenting to participate. It is planned that most interviews will be held at the RHSC, Glasgow for young people within the NHS Greater Glasgow and Clyde (GGC) health board, however to maximise participation and reduce travel time for participants, interviews will also be held at remote cardiac clinics in Crosshouse Hospital in Kilmarnock, NHS Ayrshire and Arran (AA) and if required, Wishaw General Hospital, NHS Lanarkshire for young people based within these heath boards. Initially young people based within NHS GGC and NHS AA will be contacted to participate. If further recruitment is necessary, young people within NHS Lanarkshire will then be invited

to participate. It is planned that interviews will coincide with medical appointments as far as possible to reduce travel time for participants.

Due to the nature of IPA, small sample sizes are typically sufficient, with Smith at al. (2013) recommending between four and ten participants for a professional doctorate. This recommended sample size is consistent with guidance by Collins and Nicolson (2002) who state that interpretation can be more accurate with smaller sample sizes as the analysis of large data sets may result in the loss of 'potentially subtle inflections of meaning' (p. 626). Previous research by Green et al. (2004) investigated illness representations of people with non-epileptic seizures and interviewed nine participants using IPA. Consistent with these numbers, research by Griffiths (2009) using IPA, interviewed nine children investigating their experiences of cancer. In a review of studies using IPA the average number of interviews conducted across 44 studies was 13.5 (Median 13, range, 3-30) (Brocki & Wearden, 2006). As it is not possible to perform sample size calculations for qualitative research, the sample size for the current study has been determined in accordance with the above guidance and it is proposed that seven participants will be recruited.

Health and Safety

All interviews will be conducted on NHS premises within 9am to 5pm working hours. There will be no domiciliary visits. Multidisciplinary clinicians working within the Paediatric Cardiology Service will be present on site and a clinical psychologist working within the Paediatric Psychology Service will also be available should additional advice or supervision be required. Based upon previous research it is anticipated that young people participating may be experiencing mental health

difficulties such as anxiety and low mood and therefore, if appropriate and with consent, referrals can be made to the Paediatric Psychology Service. Written consent will be obtained and participants will be informed that they are not obligated to take part and can withdraw at any time. If there is evidence of distress in a young person the researcher will endeavour to decrease any distress and contact a parent or family member. Please see Appendix 1 for further information.

Ethical Considerations

Ethical approval for this study will be sought from the Integrated Research Application System (IRAS) and the following health board's Research and Development Forums (R&D): NHS GGC, NHS AA and NHS Lanarkshire. Issues of confidentiality will be fully explained prior to interviews commencing. To ensure confidentiality, all identifiable data including names of places and people, will be removed and participants will be assigned pseudonyms to ensure anonymity. Transcripts will be stored on a NHS password protected laptop. Once interviews are transcribed and anonymised, all recordings will be destroyed. Consistent with the University of Glasgow guidelines, all transcribed interview data will be kept for 10 years before being destroyed.

Financial Issues

Please see appendix 2

Timetable

Full proposal Submission	April 14th 2014
Resubmission	July 2014
Submit to R&D	August 2014
Submit to ethics	August/September 2014
Begin participation recruitment	November/December 2014
Data collection	Jan - March 2015
Data transcription	Jan – April 2015
Data analysis	May 2015
Penultimate draft	June 2015
Final draft and submission	July 2015

Applications

The research aims to help develop an understanding of young people's experience of living with NCS and the possible impact on HRQOL and psychological functioning. The research also aims to develop a greater understanding of young people's experience of the stages of investigation and diagnosis and the impact of having an internal loop recorder fitted. As little is currently known about these matters, it is hoped that investigating young people's experiences will highlight issues which may help guide clinical practice. The finding may help to inform treatment options and provide a greater understanding of how best to support these young people. In addition, it is hoped that the research will contribute to the current body of research into NCS in children and young people and provide a foundation for the development of further qualitative studies in this area.

References

Anderson, J. B., Czosek, R. J., Knilans, T. K., & Marino, B. S. (2012). The effect of paediatric syncope on health-related quality of life. *Cardiology in the Young, 22*, 583–588.

Berkow, R., & Fletcher, A. J. (1992). *The Merck manual.* Rahway, NJ: Merck Research Laboratories.

Blount, R. L., Morris, J. A. B., Cheng, P. S., Campbell, R. M., & Brown, R. T. (2004). Parent and Child Psychological Factors in Pediatric Syncope and Other Somatic Symptoms. *Journal of Consulting and Clinical Psychology, 72*(4), 597–604.

Brocki, J., & Wearden, A. (2006). A critical evaluation of using interpretive phenomenological analysis (IPA) in health psychology. *Psychology and Health, 21*(1), 87-108.

Byars, K. C., Brown, R. T., Cambell, R. M., & Hobbs, S. A. (2000). Psychological adjustment and coping in a population of children with recurrent syncope. *Journal of Developmental and Behavioural Paediatrics, 21,* 189-197.

Cella, D. F., & Bonomi, A. E. (1995). Measuring quality of life: *Oncology 9*, 47-60.

Collins, K., & Nicolson, P. (2002). The meaning of 'satisfaction' for people with dermatological problems: Reassessing approaches to qualitative health psychology research. *Journal of Health Psychology, 7,* 615–629.

Driscoll. D. J., Jacobsen, S. J., & Porter, C. J. (1997). Syncope in children and adolescents. *Journal of the American College of Cardiology, 29,* 1039–45.

Erikson, E. H. (1963). *Childhood and society (2nd eds.).* New York: Norton.

Frisen, A. (2006). Measuring health-related quality of life in adolescence. *Foundation Acta Pædiatrica, 96,* 963–968.

Ganzeboom, K. S., Colman, N., & Reitsma, J. B. (2003). Prevalence and triggers for syncope in medical students. *American Journal of Cardiology, 91*, 1006–8.

Green, A., Payne, S., & Barnitt, R. (2004). Illness representations among people with non-epileptic seizures attending a neuropsychiatry clinic: A qualitative study based on the self-regulation model. *Seizure, 13,* 331–339.

Griffiths, M. (2009*). Parent and child experiences of childhood cancer. Using interpretive phenomenological analysis (IPA) approach.* Faculty of Health,

School of Psychology and Counselling; Queensland University of Technology.

Henningsen, P., Zimmermann, T., & Satiel, H. (2003). Medically Unexplained Physical Symptoms, Anxiety and Depression: A Meta-Analytic Review. *Psychosomatic Medicine, 65,* 528-533.

Hyphantis, T. N., Pappas, A., Vlahos, A., Carvalho, A., Levenson, J. L., & Kolettis, T. M. (2012). Depressive Symptoms and Neurocardiogenic syncope in Children: A 2-year prospective study. *Pediatrics, 130*(5), 906-913.

Kavale, S. (1996). *Interviews: An introduction to qualitative research interviewing*. Thousand Oaks, CA: Sage.

Kouakam, C., Lacroix, D., Klug, D., Baux, P., Marguie, C., & Kacet, S. (2002). Prevalence and Prognostic Significance of Psychiatric Disorders in Patients Evaluated for Recurrent Unexplained Syncope. *American Journal of Cardiology, 98,* 530-535.

Larkin, M., & Thomson, A. R. (2012). Qualitative Research Methods. In D. Harper & A. R. Thomson, *Qualitative Research Methods in Mental Health and Psychotherapy. A guide for students and practitioners.* West Sussex: Wiley and Sons.

Lee, S. H., Park, S., Byeon, K., On, Y. K., Yim, H. R., & Kim, J. S. (2013). Prevalence and Clinical Factors of Anxiety and Depression in Neurally Mediated and Unexplained Syncope. *Yonsei Medical Journal, 54*(3), 583-589.

Linzer, M., Divine, G., & Mark Estes, N. A. (1992). Medically Unexplained Syncope: Relationship to Psychiatric Illness. *The American Journal of Medicine, 92*(1), 1 S18-S25.

Linzer, M., Gold, D. T., Pontinen, M., Divine, G. W., Felder, A., & Brooks, W. B. (1994). Recurrent syncope as a chronic disease: preliminary validation of a disease-specific measure of functional impairment. *Journal of General Internal Medicine, 9,* 181–186.

Linzer, M., Pontinen, M., Gold, D. T., Divine, G. W., Felder, A., & Brooks, W. B. (1991). Impairment of physical and psychosocial function in recurrent syncope. *Journal of Clinical Epidemiology 44,* 1037–1043.

McLeod, K. A. (2003). Syncope in children. *Archives of Disease in Childhood, 88,*

350-353.

NHS Executive. (1997). *Priorities and planning guidelines for the NHS: Medium term priorities.* London: HMSO.

Piaget, J. (1950). *The Psychology of Intelligence*. London: Routledge.

Reid, K., Flowers, P., & Larkin, M. (2005). Interpretative phenomenological analysis: An overview and methodological review. *The Psychologist, 18,* 20–23.

Rose, M. J., Koshman, M., Spreng, S., Sheldon, R. (2000). The relationship between health-related quality of life and frequency of spells in patients with syncope. *Journal of Clinical Epidemiology 53*, 1209–1216.

Scottish Government. (2010). *The healthcare quality strategy for NHS Scotland*. Edinburgh: Scottish Government.

Smith, J. A., Flowers, P., & Larkin, M. (2013). *Interpretative phenomological Analysis. Theory, Method and Research.* London: Sage.

Smith, J. A., Jarman, M., & Osborn, M. (1999). Doing Interpretative Phenomenological Analysis. In M. Murray & K. Chamberlain (Eds.) *Doing interpretative phenomenological analysis. Qualitative health psychology: Theories and methods*. London: Sage.

Smith, J. A., & Osborn, M. (2003). Interpretative phenomenological analysis. *Qualitative psychology: A practical guide to research methods*. London: Sage.

Turner, A., Barlow, J., & Ilbery, B. (2002). Play hurt, live hurt: Living with and managing osteoarthritis from the perspective of ex-professional footballers. *Journal of Health Psychology, 7,* 285–301.

Van Dijk, N, Sprangers, M. A., Colman, N., Boer, K. R., Wieling, W., & Linzer, M. (2006) Clinical factors associated with quality of life in patients with transient loss of consciousness. *Journal of Cardiovascular Electrophysiology 17*, 998–1003.

Varni, J. W., Seid, M., & Kurtin, P. S. (2001). PedsQL 4.0: Reliability and Validity of the Pediatric Quality of Life Inventory Version 4.0 Generic Core Scales in Healthy and Patient Populations. *Medical Care, 39(8),* 800-812.

Weiling, W., Ganzeboom, K. S., Saul, J. P. (2004). Reflex syncope in children and adolescents. *Heart, 90,* 1094–1100.

Worrall-Davies, A. & Marino-Francis, F. (2008). Eliciting children's and young

people's views of child and adolescent mental health services: A systematic review of best practise. *Child and Adolescent Mental Health, 13*(1), 9–15.

Appendix 4: Research Equipment, Consumables and Expenses.

RESEARCH EQUIPMENT, CONSUMABLES AND EXPENSES

Item	Details and Amount Required	Cost or Specify if to Request to Borrow from Department
Stationary	77 sheets white paper 57 Envelopes (DL)	£2.50 per 500 £0.39 £6.74 per 500 £0.77 Total Cost: £1.16
Postage	19 initial recruitment packs 19 reminder invite letters 19 self-addressed return envelopes	£0.69 per letter £13.11 £13.11 £13.11 Total Cost: £39.33
Photocopying and Laser Printing (includes cost of white paper)	**Photocopying:** 19 information sheets **Printing:** 19 Parent invite letters 19 young people invite letters 19 Reminder invite letters 1 Information sheet, master copy	£0.05 per sheet £0.95 Total Cost: £0.95 £0.05 per sheet £0.95 £0.95 £0.95 £0.05 Total Cost: £2.90
Equipment and Software	Dictaphone Transcribing aids Laptop	Request to borrow from the University of Glasgow
Miscellaneous		
Total		£44.34

Appendix 5: Health and Safety Form

WEST OF SCOTLAND/ UNIVERSITY OF GLASGOW

DOCTORATE IN CLINICAL PSYCHOLOGY

HEALTH AND SAFETY FOR RESEARCHERS

1. Title of Project	The impact of neurocardiogenic syncope on young people's health related Quality of Life and psychological functioning: A qualitative Study.
2. Trainee	Joanne Skeldon
3. University Supervisor	Dr Kenneth Mullen
4. Other Supervisor(s)	Dr Janie Donnan
5. Local Lead Clinician	
6. Participants: (age, group or sub-group, pre- or post-treatment, etc)	Participants are young people aged between 12-17 years old inclusive. Young people will have a diagnosis of neurocardiogenic syncope after having their cardiac activity monitoring with an internal loop recorder for a minimum period of 1 year. All young people are registered with the Paediatric Cardiology Service at Yorkhill Hospital.
7. Procedures to be applied (eg, questionnaire, interview, etc)	The young people will be invited to participate in semi structured interviews. The interview structure will be flexible in its focus to ensure information is collected on individual experiences of NCS. It is anticipated that interviews will last approximately 60 minutes and it is planned the interviews will be conducted face to face, however if a limited number of participants are initially recruited, it may be necessary to conduct telephone interviews.
8. Setting (where will procedures be	Interviews will be held at Yorkhill Hospital within Glasgow City for young people within the NHS Greater Glasgow and Clyde (GGC) health board.

carried out?) i) General	To maximise participation and reduce travel time for participants out with NHS GGC health board, it is planned that interviews will also be held at remote cardiac clinics in Crosshouse Hospital in Kilmarnock, NHS Ayrshire and Arran (AA) and if required, Wishaw, NHS Lancashire for young people based within these heath boards.
ii) Are home visits involved	No

9. Potential Risk Factors Identified (see chart)	The patient group is not associated with dangerous or unpredictable behaviour. The consultant cardiologist in the Paediatric Cardiology Service and a psychologist in the Paediatric Psychology Service will provide guidance on excluding particular young people who are deemed to be too physically or mentally unwell to participate. This study aims to use interviews to investigate young people's beliefs regarding their experiences of syncope. Interviews have been commonly used within health psychology to investigate individual's understanding of their illness and are not known to be associated with causing a significant amount of distress in participants. The content of the interviews is to explore young people's beliefs regarding their experiences of syncope. Based upon previous research it is anticipated that young people may be experiencing psychiatric symptoms, possibly symptoms of anxiety and low mood.
10. Actions to minimise risk (refer to 9)	Discussions will take place with the Consultant Cardiologist regarding participant suitability before young people are invited to participate to ensure that the exclusion or inclusion criteria are met. All interviews will take place within an NHS facility with access to clinicians in the Paediatric Cardiology Service should advice or support be required. Furthermore, a clinical psychologist working within the Paediatric Psychology Service, will also be available should additional advice or

	supervision be required. If appropriate, referrals can be made to the Paediatric Psychology Service. The limits of confidentiality will be fully explained prior to the interviews commencing.

Participants	
Yes	**No**
This participant sample is not normally associated with dangerous or unpredictable behaviour	This participant sample is associated with impulsive, irrational or unpredictable behaviour, and/or has poor emotional control

Procedures	
Yes	**No**
The procedures in the study are same/similar to those used by clinical psychologists with these participants and are not normally associated with production of significant distress.	These are novel procedures, are not used with this group and by their nature might produce anger, irritability or distress.

Settings	
Yes	**No**
These are clinical or University research settings, or other institutional settings, that participants routinely attend (eg, a school). They have procedures in place to minimise risk to staff and these are thought to be adequate in the context of the proposed study.	A private or other setting where there are not health and safety procedures that are relevant to research or clinical work proceeding without risk

Appendix 6: Ethical Approval Letters

NHS
Health Research Authority

NRES Committee East Midlands - Nottingham 2
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 8839390

14 November 2014

Dr Kenneth Mullen
University of Glasgow, College of Medical, Veterinary and Life Sciences
Mental Health and Wellbeing
Admin Building, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow
G12 0XH

Dear Dr Mullen

Study title:	**The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study.**
REC reference:	**14/EM/1220**
IRAS project ID:	**155898**

Thank you for your letter of 11th November 2014, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

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

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Ms Carolyn Halliwell, NRESCommittee.EastMidlands-Nottingham2@nhs.net.

Confirmation of ethical opinion

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

Conditions of the favourable opinion

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

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

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

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

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

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

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

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

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

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

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

Ethical review of research sites

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

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Covering letter on headed paper [Ethics Covering Letter]	1	11 November 2014
Interview schedules or topic guides for participants [Semi Structured Interview Schedule]	1	10 October 2014
IRAS Checklist XML [Checklist_11112014]		11 November 2014
IRAS Checklist XML [Checklist_23102014]		23 October 2014
IRAS Checklist XML [Checklist_11112014]		11 November 2014
Letters of invitation to participant [Parent Letter]	2	06 November 2014
Letters of invitation to participant [12-15y letter]	2	06 November 2014
Letters of invitation to participant [Child Invitation letter]	1	10 October 2014
Letters of invitation to participant [16-17y letter]	2	06 November 2014
Letters of invitation to participant [16-17y Letter]	2	06 November 2014
Participant consent form [Child Assesnt/ Parent Consent Form]	1	10 October 2014
Participant consent form [Parent Consent Form]	1	06 November 2014
Participant consent form [16-17y Consent Form]	1	10 October 2014
Participant consent form [16-17y Consent Form]	2	06 November 2014
Participant consent form [12-15y Assent Form]	2	06 November 2014
Participant information sheet (PIS) [16-17y Participant Information Sheet]	2	06 November 2014
Participant information sheet (PIS) [16-17y Participant Information Sheet]	1	10 October 2014
Participant information sheet (PIS) [12-15y Participant Information Sheet]	2	06 November 2014
Participant information sheet (PIS) [Child Participant Information Sheet]	1	10 October 2014
REC Application Form [REC_Form_20102014]		20 October 2014
Research protocol or project proposal [Study Protocol]	1	15 September 2014
Research protocol or project proposal [Study Protocol]	2	06 November 2014
Summary CV for Chief Investigator (CI) [Summary CV for Chief Investigator]	1	10 October 2014
Summary CV for student [Summary CV for Student]	1	10 October 2014
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Summary in non technical language]	1	10 October 2014

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

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

14/EM/1220	**Please quote this number on all correspondence**

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

Yours sincerely

[redacted]

Chair

Email: NRESCommittee.EastMidlands-Nottingham2@nhs.net

Enclosures: *"After ethical review – guidance for researchers"*

Copy to: *Dr Karen Bell, Head of Research and Development*

University of Glasgow | College of Medical, Veterinary & Life Sciences

University of Glasgow,
College of Medical, Veterinary and Life Sciences
Mental Health and Wellbeing
Admin Building, Gartnavel Royal Hospital,
1055 Great Western Road,
Glasgow
G12 0XH

NRES Committee East Midlands - Nottingham 2
Royal Standard Place
Nottingham
NG1 6FS
Telephone: 0115 8839390

29th January 2014

Dear NRES Committee,

Study Title	**The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study.**
REC Reference	**14/EM/1220**
IRAS Project ID	**155898**

Thank you for reviewing the above study and offering approval in your letter dated the 14th November 2014.

In order to ensure that enough participants are recruited for the above study we would like to request an amendment to include NHS Lothian and NHS Fife in the study.
All young people invited to participate in the study are registered with the Paediatric Cardiology Service at the Royal Hospital for Sick Children, Glasgow (RHSC). The inclusion of NHS Lothian and NHS Fife in the study will allow us to offer young people living within these health boards the opportunity to meet with the researcher at a NHS base local to them, within the health board they reside. It is hoped that this will increase participation as it reduces potential travel time and expenses for young people wishing to participate in the study.

Many thanks for reviewing this amendment to the study.

Yours Sincerely

[redacted]

Joanne Skeldon
Trainee Clinical Psychologist

[redacted]

Dr Kenneth Mullen
Senior University Teacher

Mental Health and Wellbeing
Gartnavel Royal Hospital
Admin Building
1055 Great Western Road
Glasgow G12 0XH
Tel: +44 (0) 141 211 3920/0607 Fax: +44(0) 141 211 0356
Email: psymed-students@clinmed.ac.uk

NHS
Health Research Authority

NRES Committee East Midlands - Nottingham 2
Royal Standard Place
Nottingham
NG1 6FS

Tel: 0115 883 9435

27 February 2015

Miss Joanne Skeldon
University of Glasgow, College of Medical, Veterinary and Life Sciences
Mental Health and Wellbeing
Admin Building,
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Dear Miss Skeldon

Study title:	**The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study.**
REC reference:	**14/EM/1220**
Amendment number:	**1**
Amendment date:	**13 February 2015**
IRAS project ID:	**155898**

The above amendment was reviewed at the meeting of the Sub-Committee held on 23 February 2015.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Discussion
The Sub-Committee agreed points two and three of the Child Assent Form did not read clearly, and requested the points be re-written.

The Sub-Committee noted the boxes within the Consent Forms, and requested information be added instructing participants to initial the boxes if in agreement with the statement.

Revised documentation was submitted by the applicant.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper		29 January 2015
Notice of Substantial Amendment (non-CTIMP)		13 February 2015
Participant consent form [for the use of anonymised quotations]	2	23 February 2015

Participant consent form [Child assent form for the use of anonymised quotations]	3	27 February 2015
Participant consent form [Parent consent form for the use of anonymised quotations]	2	23 February 2015
Research protocol or project proposal	3	13 February 2015

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

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

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

14/EM/1220: Please quote this number on all correspondence

Yours sincerely

Dr Frances Game
Chair

E-mail: NRESCommittee.EastMidlands-Nottingham2@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Dr Karen Bell, Head of Research and Development*
Dr Kenneth Mullen
Dr Karen Bell

NHS
Health Research Authority

NRES Committee East Midlands - Nottingham 2

Attendance at Sub-Committee of the REC meeting on 23 February 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Ms Gill Bumphrey	Clinical Trials Pharmacist	Yes	
Dr Frances Game	Consultant Physician	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Lindsey Wallace	REC Assistant

Appendix 7: Research and Development Letters of Approval

NHS Lothian

10th April 2015

Research & Development

Room E1.12
The Queen's Medical Research Institute
47 Little France Crescent
Edinburgh
EH16 4TJ

Tel: 0131 242 3330

Ms Joanne Skeldon

Wishaw General Hospital
50 Netherton Street,
WISHAW
ML2 0DP

Dear Ms Skeldon,

Letter of access for research

This letter should be presented to each participating organisation before you commence your research at that site **NHS Lothian**.

In accepting this letter, each participating organisation confirms your right of access to conduct research through their organisation for the purpose and on the terms and conditions set out below. This right of access commences on 10th April 2015 and ends on 30th September 2015 unless terminated earlier in accordance with the clauses below.

As an existing NHS employee you do not require an additional honorary research contract with the participating organisation(s). The organisation(s) is/are satisfied that the research activities that you will undertake in the organisation(s) are commensurate with the activities you undertake for your employer. Your employer is fully responsible for ensuring such checks as are necessary have been carried out. Your employer has confirmed in writing to this organisation that the necessary pre-engagement checks are in place in accordance with the role you plan to carry out in the organisation(s). Evidence of checks should be available on request to **NHS Lothian**.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving the organisation(s) permission to conduct the project.

You are considered to be a legal visitor to **NHS Lothian** premises. You are not entitled to any form of payment or access to other benefits provided by **NHS Lothian** this organisation to employees and this letter does not give rise to any other relationship between you and **NHS Lothian** or this organisation, in particular that of an employee.

While undertaking research through **NHS Lothian** you will remain accountable to your employer **Ayrshire & Arran NHS Trust** but you are required to follow the reasonable instructions of your nominated manager **NHS Lothian** in each organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by [Insert organisation] or this organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with **NHS Lothian** policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with **NHS Lothian** in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on **NHS Lothian** premises. Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and each participating [Insert organisation] prior to commencing your research role at each site.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

The organisation(s) will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that the organisation(s) accept no responsibility for damage to or loss of personal property.

This letter may be revoked and your right to attend the organisation(s) terminated at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of the organisation(s) or if you are convicted of any criminal offence.

You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

If your circumstances change in relation to your health, criminal record, professional registration or suitability to work with adults or children, or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the organisation that employs you through its normal procedures. You must also inform the nominated manager in each participating organisation.

Yours sincerely

[redacted]

Susan Shepherd
Head of Research Governance

cc: Craig Hannah, HR Officer Crosshouse Hospital, Kilmarnock

Ms Joanne Skeldon
Medical Paediatric Psychology Service,
Ward 1B
Crosshouse Hospital
Kilmarnock
East Ayrshire
KA2 0BE

R&D Department
Corporate Services Building
Monklands Hospital
Monkscourt Avenue
AIRDRIE
ML6 0JS

Date: 19.03.2015
Enquiries to: Lorraine Quinn,
R&D Facilitator
Direct Line: 01236 712445
Email: Lorraine.Quinn@lanarkshire.scot.nhs.uk

Dear Ms Skeldon

Project: [L14113] The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study

Letter of Access (LoA) for a NHS researcher to carry out research

This letter confirms your right of access to conduct research through NHS Lanarkshire* for the purpose and on the terms and conditions set out below. This right of access commences on **19.03.2015** and ends on **31.07.2015** unless terminated earlier in accordance with the clauses below.

> * Note: Independent Contractors (GPs / GDPs) are responsible for the governance arrangements related to any staff working on their premises. If you will be working with an Independent Contractor you should discuss your proposed arrangements with them directly. You are free to copy this letter to individual Practices, which may help facilitate that process; individual practices may also wish to issue their own formal letter confirming your right of access to their premises.

You have a right of access to conduct such research as confirmed in writing in the NHS Lanarkshire R&D Management Approval letter for the above named research project. Please note that you cannot start the research until the Chief Investigator for the research project has received a letter from NHS Lanarkshire giving permission to conduct the project.

While undertaking research through NHS Lanarkshire you will remain accountable to your employer **NHS Ayrshire and Arran** but you are required to follow the reasonable instructions of **Dr Yvonne Vance, Clinical Psychologist** in NHS Lanarkshire or those given on her/his behalf in relation to the terms of this right of access.

You must supply the appropriate member of staff in your Human Resources Department with a copy of this Letter of Access. Your **Employer** must inform **NHS Lanarkshire** if it becomes aware of any issues that impact on your suitability or ability to carry out your agreed research activities within **NHS Lanarkshire**. This includes, but is not limited to, situations where PVG Scheme vetting information, or other Criminal Records information or updates suggests that you may have become unsuitable to do regulated work. Where your **Employer** has issued an honorary NHS clinical contract (e.g. if you are a clinical academic), they will ensure that they have the necessary pass-through or other service agreements in place with the substantive employer (e.g. HEI) to ensure that it is made aware of any relevant issues or PVG Scheme vetting information, or other Criminal Records information or updates. **You must ensure that you make your Employer aware of any such issues**.

Cont/…

It remains the Employer's responsibility to inform NHS Lanarkshire of any relevant issues irrespective of whether you hold a substantive or honorary NHS clinical contract.

You are considered to be a legal visitor to NHS Lanarkshire premises. You are not entitled to any form of payment or access to other benefits provided by NHS Lanarkshire to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by NHS Lanarkshire in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with NHS Lanarkshire policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with NHS Lanarkshire in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on NHS Lanarkshire premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that NHS Lanarkshire accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

NHS Lanarkshire will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in NHS Lanarkshire.

Yours sincerely

Raymond Hamill, Corporate Research & Development Manager

NAME	TITLE	SITE	ROLE
Dr Yvonne Vance	Clinical Psychologist	Paediatric Psychology Service Wishaw General Hospital	Local named contact
Dr Kenneth Mullen	Senior University Teacher	Gartnavel Royal Hospital	Chief Investigator
Dr Karen Bell	Head of R&D	University Hospital Crosshouse	Sponsor Contact
Lorraine Scott	HR Recruitment Manager	Law House, NHSL	HR Contact

Research & Development

Research & Education Centre, Queen Margaret Hospital, Whitefield Road, Dunfermline, KY12 OSU

NHS Fife

Miss Joanne Skeldon
Trainee Clinical Psychologist
University of Glasgow
College of Medical, Veterinary & Life Sciences
Mental Health & Wellbeing
Admin Building, Gartnavel Royal Hospital
1055 Great Western Road
GLASGOW G12 OXH

Date 4 March 2015
Our Ref 15-012 NRS14/PE108 14/EM/1220
Enquiries to Aileen Yell
Telephone 01383 623623 Ext 20940
E-mail aileenyell@nhs.net
Website www.nhsfife.org

Dear Miss Skeldon

Letter of access for research
Project Title : "The impact of neurocardiogenic syncope on young people"

As an existing NHS employee you do not require an additional honorary research contract with this NHS organisation. We are satisfied that the research activities that you will undertake in this NHS organisation are commensurate with the activities you undertake for your employer. Your employer is fully responsible for ensuring such checks as are necessary have been carried out. Your employer has confirmed in writing to this NHS organisation that the necessary pre-engagement check are in place in accordance with the role you plan to carry out in this organisation. This letter confirms your right of access to conduct research through **NHS Fife** for the purpose and on the terms and conditions set out below. This right of access commences on 4 March 2015 and ends on 30 September 2015 unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

You are considered to be a legal visitor to NHS Fife premises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through **NHS Fife**, you will remain accountable to your employer NHS Ayrshire & Arran, but you are required to follow the reasonable instructions of your nominated manager Dr Amanda Wood, R&D Manager or Dr Hilary Maddox in this NHS organisation or those given on her behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation

by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with **NHS Fife** policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with **NHS Fife** in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on **NHS Fife** premises. Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

NHS Fife will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Where applicable, your substantive employer will initiate your Independent Safeguarding Authority (ISA) registration in-line with the phasing strategy adopted within the NHS (as from 26th July 2010 at the earliest). Once you are ISA-registered, your employer will continue to monitor your ISA registration status via the on-line ISA service. Should you cease to be ISA-registered, this letter of access is immediately terminated. Your substantive employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity.

Continued

NHS
Fife

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

If your circumstances change in relation to your health, criminal record, professional registration or ISA registration, or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the NHS organisation that employs you through its normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

[redacted]

Dr Amanda Wood
R&D Manager

cc: Craig Hannah, HR Officer, Ayrshire & Arran (by e-mail)

Coordinator/Administrator: Mrs Joanne McGarry/Mrs Elaine O'Neill
Telephone Number: 0141 211 2142
E-Mail: joanne.mcgarry@ggc.scot.nhs.uk
Website: www.nhsggc.org.uk/r&d

R&D Management Office
Western Infirmary
Tennent Building
1st Floor, 38 Church Street
Glasgow, G11 6NT.

24 November 2014

Miss Joanne Skeldon
NHS Ayrshire and Arran
c/o University of Glasgow
Mental Health and Wellbeing
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow G12 0XH

Dear Miss Skeldon,

NHS to NHS - Letter of Access for Research

As an existing **NHS employee** you do not require an additional honorary research contract with this NHS organisation. We are satisfied that the research activities that you will undertake in this NHS organisation are commensurate with the activities you undertake for your employer. Your employer is fully responsible for ensuring such checks as are necessary have been carried out. Your employer has confirmed in writing to this NHS organisation that the necessary pre-engagement check are in place in accordance with the role you plan to carry out in this organisation. This letter confirms your right of access to conduct research through **NHS Greater Glasgow and Clyde** for the purpose and on the terms and conditions set out below. This right of access commences on **24/11/2014** and ends on **24/10/2015** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

You are considered to be a legal visitor to **NHS Greater Glasgow and Clyde** premises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through **NHS Greater Glasgow and Clyde** you will remain accountable to your employer **NHS Ayrshire and Arran** but you are required to follow the reasonable instructions of your nominated manager **Dr Kenneth Mullen** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with **NHS Greater Glasgow and Clyde** policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with **NHS Greater Glasgow and Clyde** in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on **NHS Greater Glasgow and Clyde** premises. Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and the Board via the **HR Department** prior to commencing your research role at the Board.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

NHS Greater Glasgow and Clyde will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

If your circumstances change in relation to your health, criminal record, professional registration or suitability to work with adults or children, or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the NHS organisation that employs you through its normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

[redacted]

Mrs Joanne McGarry
Research Co-ordinator

cc: Craig Hannah (HR - NHS Ayrshire and Arran)

Administrator: Mrs Elaine O'Neill
Telephone Number: 0141 211 1743
E-Mail: elaine.o'neill2@ggc.scot.nhs.uk
Website: www.nhsggc.org.uk/r&d

R&D Management Office
Western Infirmary
Tennent Institute
1st Floor 38 Church Street
Glasgow, G11 6NT,

24 November 2014

Miss Joanne Skeldon
Trainee Clinical Psychologist
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow G12 0XH

NHS GG&C Board Approval

Dear Miss Skeldon,

Study Title:	**The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study**
Principal Investigator:	**Miss Joanne Skeldon**
GG&C HB site	**Royal Hospital for Sick Children**
Sponsor	**NHS Ayrshire and Arran**
R&D reference:	**GN14NE550**
REC reference:	**14/EM/1220**
Protocol no:	**V2; 06/11/14**

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004

    a. During the life span of the study GGHB requires the following information relating to this site
        i. Notification of any potential serious breaches.
        ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

2. **For all studies** the following information is required during their lifespan.
   a. Recruitment Numbers on a monthly basis
   b. Any change of staff named on the original SSI form
   c. Any amendments – Substantial or Non Substantial
   d. Notification of Trial/study end including final recruitment figures
   e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

[redacted]

Mrs Elaine O'Neill
Senior Research Administrator

Cc:NRSPcc
Karen Bell (NHS Ayrshire and Arran)

NHS
Ayrshire
& Arran

Research & Development
58 Lister Street
University Hospital Crosshouse
Kilmarnock
KA2 0BB

Dr Kenneth Mullen
Senior University Teacher
University of Glasgow
Mental Health and Wellbeing
Admin Building
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Date 19 November 2014
Your Ref
Our Ref AG/KLB/NM R&D 2014AA086

Enquiries to Karen Bell
Extension 25850
Direct line 01563 825850
Fax 01563 825806
Email Karen.bell@aaaht.scot.nhs.uk

Dear Dr Mullen

The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study

I confirm that NHS Ayrshire and Arran have reviewed the undernoted documents and grant R&D Management approval for the above study.

Documents received:

Document	Version	Date
SSI form	Version 3.5	17/10/14 signed
R&D Form	Version 3.5	17/10/14 signed
Protocol	Version 2.0	06/11/14
12-15y assent form	Version 2.0	06/11/14
12-15y letter	Version 2.0	06/11/14
12-15y Participant Information Sheet	Version 2.0	06/11/14
16-17y Consent form	Version 2.0	06/11/14
16-17y Letter	Version 2.0	06/11/14
16-17y Participant Information Sheet	Version 2.0	06/11/14
Parent Consent form	Version 1.0	06/11/14
parent letter	Version 2.0	06/11/14

The terms of approval state that the investigator authorised to undertake this study is: -

- Miss Joanne Skeldon, Trainee Clinical Psychologist, NHS Ayrshire and Arran

With no additional investigators.

The sponsors for this study are NHS Ayrshire and Arran.

This approval letter is valid until 19 January 2016.

Regular reports of the study require to be submitted. Your first report should be submitted to Dr K Bell, Research & Development Manager in 12 months time and subsequently at yearly intervals until the work is completed.

Please note that as a requirement of this type of study your name, designation, work address, work telephone number, work e-mail address, work related qualifications and whole time equivalent will be held on the Scottish National Research Database so that NHS R&D staff in Scotland can access this information for purposes related to project management and report monitoring.

In addition approval is granted subject to the following conditions: -

- All research activity must comply with the standards detailed in the Research Governance Framework for Health and Community Care www.cso.scot.nhs.uk/publications/ResGov/Framework/RGFEdTwo.pdf and appropriate statutory legislation. It is your responsibility to ensure that you are familiar with these, however please do not hesitate to seek further advice if you are unsure.

- Recruitment figures must be submitted to R&D on a monthly basis. If recruitment figures are not received timeously you will be contacted by a member of the R&D team to provide this data.

- You are required to comply with Good Clinical Practice (ICH-GCP guidelines may be found at www.ich.org/LOB/media/MEDIA482.pdf), Ethics Guidelines, Health & Safety Act 1999 and Data Protection Act 1998.

- If any amendments are to be made to the study protocol and or the Research Team the Researcher must seek Ethical and Management Approval for the changes before they can be implemented.

- The Researcher and NHS Ayrshire and Arran must permit and assist with any monitoring, auditing or inspection of the project by the relevant authorities.

- The NHS Ayrshire and Arran Complaints Department should be informed if any complaints arise regarding the project and the R&D Department must be copied into this correspondence.

- The outcome and lessons learnt from complaints must be communicated to funders, sponsors and other partners associated with the project.

- As custodian of the information collated during this research project you are responsible at all times for ensuring the security of all personal information collated in line with NHS Scotland policies on information assurance and security, until the secure destruction of these data. The retention time periods for such data should comply with the requirements of the Scottish Government Records Management: NHS Code Of Practice. Under no circumstances should personal data be stored on any unencrypted removable media e.g. laptop, USB or mobile device (for further information and guidance please contact the Information Governance Team based at University Hospital Crosshouse 01563 825831 or 826813).

If I can be of any further assistance please do not hesitate to contact me. On behalf of the department, I wish you every success with the project.

Yours sincerely

[redacted]

Dr Alison Graham
Medical Director

Enc. UK Amendment leaflet, Guide for researchers v1_06.11.14

c.c.
Dr John Taylor, Associate Clinical Director – Mental Health Services, NHS Ayrshire & Arran
Derek Barron, Associate Nurse Director – Mental Health Services, NHS Ayrshire & Arran
Dr Karen Bell, Head of R&D, NHS Ayrshire and Arran (sponsor contact)
Libby Prentice, Senior Research Advisor, NHS Ayrshire and Arran
Lesley Douglas, Finance, Ailsa Hospital
Information Governance, Ailsa Hospital
NRS Coordinating Centre, Aberdeen

Appendix 8: Participant letters of Invitation

Letter of Invitation for Young People aged 12-15 years old

Dear,

We are writing to invite you to take part in a research project looking at your experiences of fainting. We are interested in finding out your ideas about fainting and why you think this might happen to you. We would like to hear what you think about having an internal loop recorder and how this may have helped you. We are also interested in how your experience of fainting may have changed things in your life or made things difficult for you.

We hope that this study will provide us with information which will help us to understand what it is like for young people like yourself to experience fainting and what things might help you to feel better. This can help us to improve the care you get from people who might be working with you, like doctors, nurses and psychologists.

The research is being carried out by Jo Skeldon, a Trainee Clinical Psychologist at the University of Glasgow. The Cardiac department at the Royal Hospital for Sick Children, Glasgow and the Glasgow Paediatric Clinical Psychology Service are also involved in the research project.

If you would like to participate in the research project you will meet with Jo and she will ask you some questions about fainting. The questions will ask you about things which have helped you, things which might have been difficult for you and what it is like to have an internal loop recorder. You will meet with Jo for about an hour.

If you would like to take part, the information you talk about will be kept private.

There is more information about the research in the participant information sheet. If you have questions about the research or would like to take part, please fill out the form below and send it send it back in the self-addressed pre-paid envelope provided, as soon as possible.

Kind Regards,

Dr Karen McLeod

Consultant Paediatric Cardiologist

Paediatric Cardiology Service, Royal Hospital for Sick Children, Glasgow.

Please tick the box if you would like to find out more information and/or take part in the above research study and give consent for Jo Skeldon to contact you about this ☐

Name:

Address: Telephone Number:

Email Address:

Letter of Invitation for Young Adults aged 16-17 years old

Dear,

We are writing to invite you to take part in a research project looking at your experiences of fainting. The research aims to develop a true understanding of young adult's experiences of fainting, including your experiences of the symptoms, diagnosis and management of fainting. We would like to hear what you think about having an internal loop recorder and how this may have helped you. We are also interested in how your experience of fainting may have changed things in your life or made things difficult for you.

It is hoped that this study will highlight issues which are important to young people and young adults and help us to understand what it is like for young adults like yourself to experience fainting. It is hoped that this will help us to improve the care you get from people who might be working with you, like doctors, nurses and psychologists.

The research is being carried out by Jo Skeldon, a Trainee Clinical Psychologist at the University of Glasgow, Kenneth Mullen, Academic Supervisor at the University of Glasgow and Dr Janie Donnan, Clinical Psychologist in the Glasgow Paediatric Clinical Psychology Service at the Royal Hospital for Sick Children, Glasgow. The Paediatric Cardiology Service at the Royal Hospital for Sick Children is also involved in the research project.

If you would like to participate in the research project you will meet with Jo and she will ask you some questions about fainting. The questions will ask you about things which have helped you, things which might have been difficult for you and what it is like to have an internal loop recorder. You will meet with Jo for about an hour.

If you would like to take part, the information you talk about will be kept private.

There is more information about the research in the participant information sheet. If you have questions about the research or would like to take part, please fill out the form below and send it send it back in the self-addressed pre-paid envelope provided, as soon as possible.

Kind Regards,

Dr Karen McLeod

Consultant Paediatric Cardiologist

Paediatric Cardiology Service, Royal Hospital for Sick Children, Glasgow

---

Please tick the box if you would like to find out more information and/or take part in the above research study and give consent for Jo Skeldon to contact you about this ☐

Name:

Address: Telephone Number:

Email Address:

Letter of Invitation to Parents

Dear,

We are writing to invite your child to take part in a research project looking at their experiences of fainting. The research aims to develop a true understanding of young people's experiences of fainting by discussing their experiences of the symptoms, diagnosis and management of fainting. It is hoped that this research will highlight issues which are important to young people which can help to inform treatment options, improve care and provide a greater understanding of how best to support these young people.

The research is being carried out by Jo Skeldon a Trainee Clinical Psychologist, Kenneth Mullen, Academic Supervisor at the University of Glasgow and Dr Janie Donnan, Clinical Psychologist in the Glasgow Paediatric Clinical Psychology Service at the Royal Hospital for Sick Children, Glasgow. The Paediatric Cardiology Service at the Royal Hospital for Sick Children is also involved in the research project.

If your child would like to participate in the research project they will meet with Jo and she will ask them to answer some questions. The questions will ask about the following topics:

- Your child's understanding of their symptoms and what it was like for them to receive their diagnosis
- What it is like to have an internal loop recorder fitted
- What impact fainting has had on their life, including the possible impact at school and on their relationships
- What might have been difficult about experiencing episodes of fainting

- What might have helped them to cope and manage their experience of fainting

Your child will meet with Jo for about an hour to talk about their experiences of fainting.

If they would like to take part, the information gathered will be confidential and anonymous. Before your child participates in the research they will be asked to sign an assent form stating they are happy to take part. You will also be asked to sign this form stating that you give consent for your child to participate. The form will be completed with Jo, allowing the opportunity for you and your child to ask any questions.

If you and your child would like to know more about this research or if you or your child have any questions please don't hesitate to get in touch with Jo by emailing j.skeldon.1@research.gla.ac.uk. You can also contact an independent person for further information on participating. Contact details are provided in the enclosed participant information sheet.

If your child would like to participate please can they complete the section at the bottom of their letter and return it in the self-addressed pre-paid envelope enclosed as soon as possible.

Kind Regards,

Dr Karen McLeod

Consultant Paediatric Cardiologist

Paediatric Cardiology Service, Royal Hospital for Sick Children, Glasgow.

Appendix 9: Participant Information Sheets

Version Number: 2
Date: 06/11/2014

Participant Information Sheet for Young People aged 12 to 15 years old

Part 1. To give you first thoughts about the project

We are asking if you would join in a research project. Before you decide if you want to join in, it's important to understand why the research is being done and what it will involve for you. So please think about the information on this leaflet carefully. Talk to your family, friends, doctor or nurse if you want to. You can also talk to an independent person working at the University of Glasgow about taking part in the research.

Jo Skeldon, a trainee clinical psychologist is carrying out the research. She will go through the information sheet with you, answer any questions you have and explain anything you feel is unclear.
We think this should take about 15 minutes.

If you agree to take part, we will then ask you to sign a consent form.

What is research?

Research is a way of trying to find out the answer to important questions.

What is the research project is about

The research project aims to ask you about your experiences of fainting. The research will only ask about your experience of fainting and it will not to give you any treatment. You will be asked some questions about your understanding of your symptoms, your ideas about fainting and why you think this might happen to you. Some questions will ask about the following:

- What are your ideas about why you faint?
- What it is like to have an internal loop recorder?
- How have your experiences of fainting changed things in your life?

Version Number: 2
Date: 06/11/2014

Why have I been asked to take part?

You have been asked because you have had an internal loop recorder fitted to help doctors and nurses to understand why you faint. We think it is important to ask young people like you about fainting because it will help us to understand what we can do to best help young people who faint.

Do I have to take part?

No, you don't have to take part. It's your choice whether you take part and you can change your mind. If you decide not to take part, this will not affect the treatment and follow up care you receive from the Paediatric Cardiology Service. It is up to you to decide to join the study. If you do decide to take part:

- You and a parent will each be asked to sign a form to say that you agree to take part.
- You will be given this information sheet and a copy of your signed forms to keep.

What do I need to do to take part in the research?

If you would like to take part you will meet with Jo Skeldon to answer some questions and talk about your experiences. The meeting will last about one hour. You can meet with Jo at the Royal Hospital for Sick Children in Glasgow City Centre or you can choose to meet at either Wishaw Hospital in Lanarkshire or Crosshouse Hospital in Kilmarnock if these are closer to where you live.

What else might happen?

It is unlikely that you will have any difficulties taking part in the research, but sometimes people can find it difficult to talk about their experiences and that's ok.

You can choose not to answer a question if you don't want to. You can also take a break in the meeting and you are free to stop taking part at any time, without giving a reason.

Will my information be kept private?

All the information collected from talking to you will be kept private unless you tell Jo something which makes her worried about your safety or someone else's safety. If this

happens she will talk to you first but she might also need to speak to someone else you know in the Paediatric Cardiology Service.

What you say in the meeting will be recorded. This information will then be written out and your name will removed so others won't know what you have said. All recordings of the interviews will be destroyed once finished with.

What will happen once the research finishes?

All the information will be collected and it will help us see how we can help other young people who faint. We hope to find out information which can help us to develop the treatment options available and improve the care young people receive.

If you would like to find out the results of the research, a summary of the findings will be sent to you once the project has been completed.

Did anyone else check the study is OK to do?

Before any research goes ahead it has to be checked by a research ethics committee.

They make sure that the research is fair. This research has been checked by the research ethics committee called the Integrated Research Application System (IRAS).

This research project has been checked by the research and development departments in Glasgow, Lanarkshire and Ayrshire and Arran.

Where can I get more information about the research?

Contact Details

Independent Person: Dr Sarah Wilson, Senior Lecturer
University of Glasgow, College of Medical, Veterinary and Life Sciences
Mental Health and Wellbeing
Admin Building, Gartnaval Hospital, 1055 Great Western Road, Glasgow
G12 0XH
0141 2113921

Researcher: Jo Skeldon
University of Glasgow, College of Medical, Veterinary and Life Sciences
Mental Health and Wellbeing
Admin Building, Gartnaval Hospital, 1055 Great Western Road, Glasgow
G12 0XH
Email address: j.skeldon.1@research.gla.ac.uk

Version Number: 2
Date: 06/11/2014

Part 2 - more detail – information you need to know if you still want to take part.

What if I don't want to do the research anymore?

Just tell your mum, dad, carer, doctor or nurse at any time if you don't want to take part. They will not be cross or upset with you.

Will anyone else know I'm doing this?

The people in our research team will know you are taking part. The doctors and nurses looking after you in the Paediatric Cardiology Service will also know.

All information collected about you during the research will be kept strictly private.

Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it.

What will happen to the results of the research study?

When the study has finished we will share the findings with the doctors and nurses in the Paediatric Cardiology Service.

Who is organising and funding the research?

Researchers at the University of Glasgow and doctors, nurses and a clinical psychologist at the Royal Hospital for Sick Children, Glasgow are organising this study. They will not get any extra money for doing this research.

The research is being paid for by the University of Glasgow.

If you decide you would like to take part in the research we would like to say thank you for giving your time to come and talk to us. We know that it might also cost you and a family member money to travel to the hospital to meet with the researcher. Unfortunately we cannot cover the cost of your travel but whenever possible we will arrange to meet you at a time when you are travelling to the hospital for another appointment.

Version Number: 2
Date: 06/11/2014

What can I do if I want to make a complaint about the research?

If you are unhappy about something to do with the research you can speak to the researcher and they will try to solve the problem straight away. You can also speak to a member of staff involved in your care, for example, your nurse or doctor in the Paediatric Cardiology Service. If you don't want to talk to someone about the problem yourself, you can tell your parents, who can speak to someone for you.

If you and your parents are unhappy and would like to speak to someone else you can call the NHS Inform helpline on 0800 22 44 88.

A complaint can also be made over the telephone or in writing to your health board. The contact details for your health board are listed below:

- NHS Ayshire and Arran Patient Relations and Complaints Team
  PO Box 13 Eglinton House
  Ailsa Hospital, Dalmellington Road, Ayr, KA6 6AB
  Telephone: 01292 513 620

- NHS Greater Glasgow and Clyde
  E-mail: complaints@ggc.scot.nhs.uk
  Telephone: 0141 201 4500

- NHS Lanarkshire Headquarters Patient Services Department
  Kirklands, Fallside Road, Bothwell, G71 8BB
  Telephone: 01698 858 321

The Patient Advice and Support Service (PASS) offers free information and advice to anyone using the NHS in Scotland. They can help you to provide feedback, concerns or complaints about the NHS. PASS can be contacted by telephone on 0141 7753220 or in any Citizens Advice Bureau in Scotland.

Thank you for reading this – please ask any questions if you need to.

Version Number: 2
Date: 06/11/2014

Participant Information Sheet for Young Adults aged 16 and 17 years old

We are asking if you would like to participate in a research project. Before you decide if you want to take part, it's important to understand why the research is being done and what it will involve for you. So please think about the information on this leaflet carefully. Talk to your family, friends, doctor or nurse if you want to. You can also talk to an independent person working at the University of Glasgow about taking part in the research.

Jo Skeldon, a trainee clinical psychologist is carrying out the research. She will go through the information sheet with you, answer any questions you have and explain anything you feel is unclear.
We think this should take about 15 minutes.

If you agree to take part, we will then ask you to sign a consent form.

Study Title

The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study.

What is the research project is about

The research project aims to ask you about your experiences of syncope, which is also known as fainting. The research will only ask about your experience of fainting and it will not offer you any treatment. You will be asked questions about your understanding of your symptoms, your ideas about fainting and why you think this might happen to you. Some questions will ask about the following:

- What are your ideas about why you faint?
- What it is like to have an internal loop recorder?
- How have your experiences of fainting changed things in your life?

Version Number: 2
Date: 06/11/2014

Why have I been asked to take part?

You have been asked because you have had an internal loop recorder fitted to help doctors and nurses to understand why you faint. We think it is important to ask young adults like you about fainting because it will help us to understand what we can do to best support other young adults who faint.

What would taking part in the research involve?

If you would like to take part you will meet with Jo Skeldon to answer some questions and talk about your experiences. The meeting will last about one hour. You can meet with Jo at the Royal Hospital for Sick Children in Glasgow City Centre or you can choose to meet at either Wishaw Hospital in Lanarkshire or Crosshouse Hospital in Kilmarnock if these are closer to where you live.

What are the possible benefits of taking part?

It is hoped that the information gathered from discussing individual's experiences of fainting will help us see how we can best support other young people and young adults who faint. We hope to find out information which can help us to develop the treatment options available and improve the care young people and young adults receive.

What are the possible disadvantages of taking part?

It is unlikely that you will have any difficulties taking part in the research, but sometimes people can find it difficult to talk about their experiences.

You can choose not to answer a question if you don't want to. You can also take a break in the meeting and you are free to stop taking part at any time, without giving a reason.

Do I have to take part?

No, you don't have to take part. It's your choice whether you take part and you can change your mind. If you decide not to take part, this will not affect the treatment and follow up care you receive from the Paediatric Cardiology Service. If you do decide to take part:

- You will be asked to sign a consent form to say that you agree to take part.
- You will be given this information sheet and a copy of your signed consent form to keep.

What will happen if I don't want to carry on with the research?

If you don't want to take part anymore you can tell Jo and you can leave the meeting at any time. You can also tell a family member or your doctor or nurse if you change your mind at any time before the interview takes place.

How will my information be kept confidential?

All the information collected from talking to you will be kept confidential unless you disclose something which raises concerns about your safety or someone else's safety. If this happens Jo will talk to you first but she might also need to speak to someone else you know in the Paediatric Cardiology Service.

What you say in the meeting will be recorded. This information will then be written out and your name will removed so others won't know what you have said. All recordings of the interviews will be destroyed once finished with. All information will be stored securely in a locked filing cabinet on an NHS site.

What will happen to the results of this study?

All the information collected will be analysed and it is hoped that the results will help us see how we can support other young people and young adults who faint. We hope to find out information which can help us to develop the treatment options available and improve the care for other people like you receive. When the study has finished we will share the findings with medical practitioners in the Paediatric Cardiology Service.

If you would like to find out the results of the research, a summary of the findings will be sent to you once the project has been completed.

Who is organising and funding the research?

Researchers at the University of Glasgow, healthcare practitioners in the Paediatric Cardiology Service and a clinical psychologist in the Paediatric Psychology Service at the Royal Hospital for Sick Children, Glasgow are organising this study. They will not get any extra money for doing this research.

The research is being paid for by the University of Glasgow.

If you decide you would like to take part in the research we really appreciate you giving your time to come and talk to us. We also recognise that it might cost you money to travel to the

hospital to meet with the researcher. Unfortunately we cannot cover the costs of your travel but whenever possible we will try to arrange to meet you at a time when you are travelling to the hospital for another appointment.

How have patients and the public been involved in this study?

A summary of the research project has been reviewed by a mental health, service user and carer group called CUSP. Clinicians working at the University of Glasgow's often work closely with this group of service users and carers. The group were asked to offer feedback on the research questions, research design and accessibility of the information provided to members of the public.

Who has reviewed this study?

Before any research goes ahead it has to be checked by a research ethics committee.

They make sure that the research is fair. This research has been checked by a research ethics committee called the East Midlands Research Ethics Service.

This research project has been checked by the research and development departments in Glasgow, Lanarkshire and Ayrshire and Arran.

Where can I get more information about the research?

Contact Details

Independent Person: Dr Sarah Wilson, Senior Lecturer
University of Glasgow, College of Medical, Veterinary and Life Sciences
Mental Health and Wellbeing
Admin Building, Gartnaval Royal Hospital, 1055 Great Western Road, Glasgow
G12 0XH
0141 2113921

Researcher: Jo Skeldon
University of Glasgow, College of Medical, Veterinary and Life Sciences
Mental Health and Wellbeing
Admin Building, Gartnaval Royal Hospital, 1055 Great Western Road, Glasgow
G12 0XH
Email address: j.skeldon.1@research.gla.ac.uk

What can I expect from the consent process?

Before taking part in the research you will be asked to sign a consent form stating the following:

- you understand the research
- you know you can stop taking part in the research at any time
- you are happy to take part in the research

This form will be completed with Jo and all the information on the form will be discussed to ensure that any questions you might have will be answered.

Involvement of other healthcare practitioners

Only the people in our research team and the medical practitioners looking after you in the Paediatric Cardiology Service will know that you are taking part in the research. All information collected about you during the research will be kept strictly private.

Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it.

What can I do if I want to make a complaint about the research?

If you are unhappy about something related to the research you can speak to the researcher and they will try to resolve the difficulty straight away. You can also speak to a member of staff involved in your care, for example, your nurse or doctor in the Paediatric Cardiology Service.

If you are still unhappy and would like to speak to someone else you can call the NHS Inform helpline on 0800 22 44 88.

You can also make a complaint over the telephone or in writing to your health board. The contact details for your health board are listed below:

- NHS Ayshire and Arran Patient Relations and Complaints Team
  PO Box 13 Eglinton House
  Ailsa Hospital, Dalmellington Road, Ayr, KA6 6AB
  Telephone: 01292 513 620

- NHS Greater Glasgow and Clyde
  E-mail: complaints@ggc.scot.nhs.uk
  Telephone: 0141 201 4500

- NHS Lanarkshire Headquarters Patient Services Department
  Kirklands, Fallside Road, Bothwell, G71 8BB
  Telephone: 01698 858 321

The Patient Advice and Support Service (PASS) offers free and confidential information and advice to anyone using the NHS in Scotland. They can help you to provide feedback, concerns or complaints about the NHS. PASS can be contacted by telephone on 0141 7753220 or in any Citizens Advice Bureau in Scotland.

Thank you for reading this – please ask any questions if you need to.

Appendix 10: Consent Forms

Version Number: 2
Date 06/11/2014

Patient Identification Number:

Young Person Assent Form

Title of project: The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study.

Name of researcher: Jo Skeldon, Trainee Clinical Psychologist

Please circle your answer

Has somebody explained this project to you?	Yes/No
Do you understand what this project is about?	Yes/No
Have you asked all the questions you want?	Yes/No
Have you had your questions answered in a way you understand?	Yes/No
Do you understand it's OK to stop taking part at any time?	Yes/No
Do you understand that you will be asked to meet with the researcher once for around 1 hour to talk about your experiences of fainting.	Yes/No
Is it ok for the researcher to speak to the doctors, nurses and psychologists who might be involved in your care and treatment.	Yes/No
Do you understand that the information you provide will be anonymised which means that your name, the names of others and the names of places will be changed to keep the information private.	Yes/No
Do you understand that you will be provided with a summary of the research findings once the project is competed?	Yes/No
Do you understand that the interview will be recorded?	Yes/No
Are you happy to take part?	Yes/No

Version Number: 2
Date 06/11/2014

If any answers are no or you don't want to take part, don't sign your name!

If you do want to take part in the research please sign your name below.

Name of Participant	Date	Signature

Name of Person taking assent	Date	Signature

Version Number: 2
Date: 06/11/2014
Participant Identification Number:

CONSENT FORM

Title of Project: The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study.

Name of researcher: Jo Skeldon, Trainee Clinical Psychologist

Please initial box

1. I confirm that I have read the information sheet dated 06/11/2014 (version 2) for the above 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 that I will be asked to meet with the researcher for around 1 hour to talk about my experiences of fainting. ☐
4. I understand that the information I provide will be anonymised and confidential. ☐
5. I understand that I will be provided with a summary of the research findings once the study is completed. ☐
6. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Version Number: 1
Date: 06/11/2014
Participant Identification Number:

CONSENT FORM

Title of Project: The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study.

Name of researcher: Jo Skeldon, Trainee Clinical Psychologist

Please initial box

1. I confirm that I have read the information sheet dated 06/11/2014 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my child's participation is voluntary and that they are free to withdraw at any time without giving any reason, without their medical care or legal rights being affected. ☐

3. I understand that my child will be asked to meet with the researcher for around 1 hour to talk about their experiences of fainting. ☐

4. I understand that the information provided will be anonymised and confidential. ☐

5. I understand that my child will be provided with a summary of the research findings once the study is completed. ☐

6. I understand that the interview will be recorded ☐

7. I give consent for my child to take part in the above study. ☐

Version Number: 1
Date: 06/11/2014

Name of Parent	Date	Signature
Name of Person taking consent	Date	Signature

Appendix 11: Consent and Assent Forms for the Use of Anonymised Quotations

Version Number: 3
Date: 27/02/2015

Child Assent Form for the Use of Anonymised Quotations

Title of project: The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study.

Name of researcher: Jo Skeldon, Trainee Clinical Psychologist

When the study has finished all the information collected will be written up in a document called a thesis. Some of what you say in the interview might also be included in the document. When something you say is written in a document it is called a quotation. Quotations will not have your name in them so others won't know what you have said. We will share the findings with the doctors and nurses in the Paediatric Cardiology Service. The findings may also be shared with others by publishing the information we find.

Do you understand that any quotations will be anonymised which means that your name, the names of others and the names of places will be changed to keep the information private.	Yes/No
Do you understand that the researcher may use what you have said in your interview as quotations in the thesis and in reports about the research.	Yes/No
Do you understand that this research may be published in a scientific journal and quotations from your interview may be used.	Yes/No

Name of Participant	Date	Signature
Name of Parent/Carer	Date	Signature
Name of Person taking consent	Date	Signature

Version Number: 2
Date: 23/02/2015

Consent Form for the Use of Anonymised Quotations

Title of project: The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study.

Name of researcher: Jo Skeldon, Trainee Clinical Psychologist

Contact Address: College of Medical, Veterinary and Life Sciences
Mental Health and Wellbeing
Admin Building
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow, G12 0XH

When the study has finished all the information collected will be written up as a thesis which will be submitted for the Doctorate in Clinical Psychology qualification at the University of Glasgow. Some quotations of what you say in the interview might also be included in the document. All quotations will be anonymised so others won't know what you have said. We will share the findings with the doctors and nurses in the Paediatric Cardiology Service. The findings may also be shared with others by publishing the information we find.
Please read the following statements. If you are in agreement with the statement please initial the box.

I understand that all names, references to places and anything that could identify me will be anonymised or removed from my interview transcript. ☐

I give consent to the researcher to use extracts from my interview transcripts in reports about the research. ☐

I understand that this research may be published in a scientific journal and I give consent for the researcher to use extracts from my interview transcript for this purpose. ☐

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

Version Number: 2
Date: 23/02/2015

Parent Consent Form for the Use of Anonymised Quotations

Title of project: The impact of neurocardiogenic syncope on young people's health related quality of life and psychological functioning: A qualitative study

Name of researcher: Joanne Skeldon, Trainee Clinical Psychologist

Contact Address: College of Medical, Veterinary and Life Sciences
Mental Health and Wellbeing
Admin Building
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow, G12 0XH

When the study has finished all the information collected will be written up as a thesis which will be submitted for the Doctorate in Clinical Psychology qualification at the University of Glasgow. Some quotations of what your child says in the interview might also be included in the document. All quotations will be anonymised. We will share the findings with clinicians in the Paediatric Cardiology Service. The findings may also be shared with others by publishing the information we find.
Please read the following statements. If you are in agreement with the statement please initial the box.

I understand that all names, references to places and anything that could identify my child will be anonymised or removed from their interview transcript. ☐

I give consent to the researcher to use extracts from my child's interview transcripts in reports about the research. ☐

I understand that this research may be published in a scientific journal and I give consent for the researcher to use extracts from my child's interview transcript for this purpose. ☐

_____	_____	_____
Name of Parent/Carer	Date	Signature
_____	_____	_____
Name of Researcher	Date	Signature

Appendix 12: Semi Structured Interview Schedule.

Semi Structured Interview Schedule

Notes for the interviewer:

This interview schedule is aimed to be used as a guide to facilitate a comfortable interaction with the participants. It is hoped that this will support the young person to provide a detailed account of their experience of fainting. The questions aim to be open, expansive and to not make assumptions about the participant's experiences. The schedule will be flexible to allow the researcher to follow the participant's lead on their reflections on their experience. Should the interview discourse stall, the questions will aim to provide prompts to encourage the conversation to develop as required.

The researcher will aim to build rapport with the participants using a warm and curious manner and acting as an active listener. Prior to commencing the interview the researcher will inform the participant that they are interested in their experiences and that there are no right or wrong answers. Throughout the interview the researcher may reflect information shared, back to the participant to ensure that they understand the participant's experience from their own perspective.

Introduction

I would like to start by saying thank you very much for meeting with me today. My name is Jo Skeldon and I'm a Trainee Clinical Psychologist and I'm carrying out some research. Research is a way of finding the answer to important questions. We would like to find out more about your experiences of fainting and any changes it may have made to your life. You will be asked some questions about your understanding of your symptoms, your ideas about fainting and why you think this might happen to you. I am also interested in hearing about your experience of having an internal loop recorder fitted. As you have experienced fainting and have had an internal loop recorder fitted, I would like to spend some time talking to you. There are no right or wrong answers and I would like to hear about your personal experiences and your thoughts. If you don't want to answer a question, that's ok, and you can take a break whenever you like.

Before we start, I would like to talk through the consent form. This will make sure you understand everything and I can answer any questions you might have.

What we talk about will be private unless you tell me something which makes me worried about your safety or someone else's safety. If this happens I will talk to you first but I might also need to speak to someone else you know in the Paediatric Cardiology Service.

During our meeting I want to make sure I am listening carefully to what you are telling me. To help me to remember everything we talk about I would like to record it. No one apart from the research team will hear the tapes and they will be kept in a

locked filing cabinet at the University of Glasgow. Is it ok for me to record our conversation?

Interview Questions

1. Opening Questions

I wonder if you could tell me a little about when you first came to see someone in the Paediatric Cardiology Service?

Can you remember why it was that you came to see someone?

- How old were you?

How long had you experienced difficulties with fainting before you were seen in the Paediatric Cardiology Service?

Can you tell me a little bit about the first time you fainted?

- When did it first start?

Can you tell me a little bit about your experience of fainting since that first time?

- Has it changed since it first started?

2. Possible triggers for NCS

Can you tell me about a time when you fainted?

- When was this?
- Where did it occur?
- How did you feel?
- Is this usual or can it be different each time you faint?

Are there triggers/warning signs that you notice before you faint?

- Are their physical signs or psychological changes you notice?
- Are they always the same triggers/warning signs?

3. Young people's experience of the symptoms of NCS.

Can you tell me about why you think you experience fainting?

What kind of symptoms do you experience?

What do you think causes the symptoms?

4. Young people's experience of having an internal loop recorder

Can you explain to me what it was like to have the medical appointment to find out why you were fainting?

- Can you tell me what it was like to come into hospital for the appointment?

What was it like to have an internal loop recorder fitted?

What have been the effects of having the internal loop recorder on your symptoms?

- Did you have concerns about the investigations?

What were other people's reactions to your symptoms and the medical appointments?

5. Young people's experience of receiving a diagnosis of NCS.

Can you tell me what it was like to receive the diagnosis of fainting without cardiac difficulties?

- Do you think receiving your diagnosis has had an effect on you?

Was this possible explanation for your symptoms discussed with you and your family before the internal loop recorder was fitted?

Has your understanding of your symptoms changed?

Have there been things that have helped you to understand your diagnosis?

- Is there anything that you think could have been done differently?

6. The possible impact young people's HRQOL

Has fainting changed things in your life?

- Have there been positive and/or negative changes

Can you tell me how it affects your relationships?

- What have the reactions of your friends and family been like?

Have other people helped you and how have they helped?

Would you like things to be different?

7. The possible impact on young people's psychological functioning.

Has fainting impacted on how you feel?

- Has it changed your mood?
- Are there things you're concerned about related to your experience of fainting?
- Do you have any concerns for the future?

8. Sense of self, identity and autonomy

Have your symptoms of fainting changed the way you think or feel about yourself?

- In what ways?

How do you think others see you?

- Parents, friends, school teachers, anyone else?
- Do you think this is different/ has this changed since your diagnosis?

Do you think receiving your diagnosis has had an effect on you?

Is there anything else about your experience of fainting you would like to talk about? Has there been anything we have missed, which you think is important to tell me about your experience of fainting?

I would like to thank you for giving me your time for this interview. Do you have any questions for me?

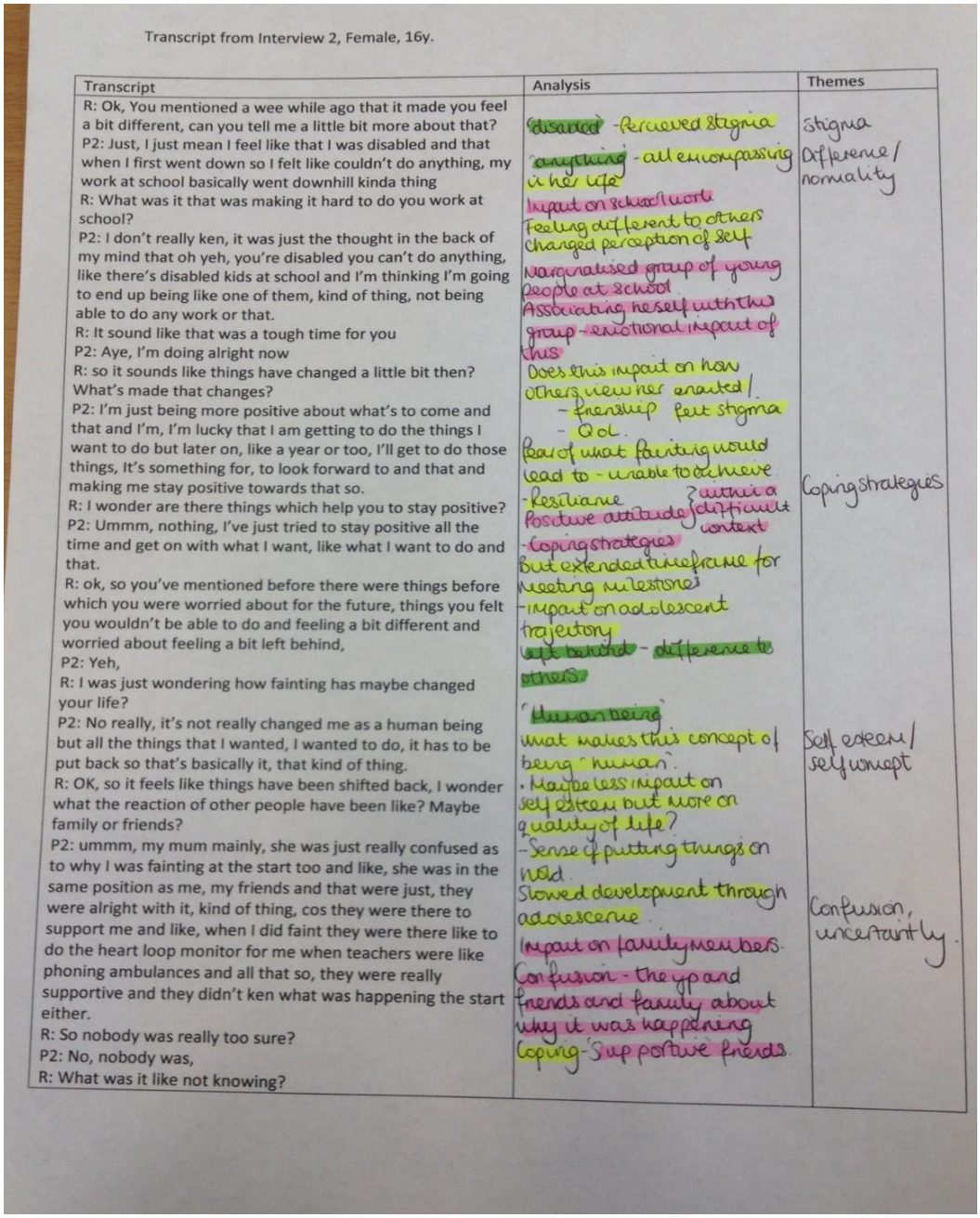
A summary of all the findings will be available once the research has finished. If you would like a summary it can be sent in the post to you.

Possible additional probes:

- Can you tell me more about that
- What did you think/feel about that
- Can you give me an example

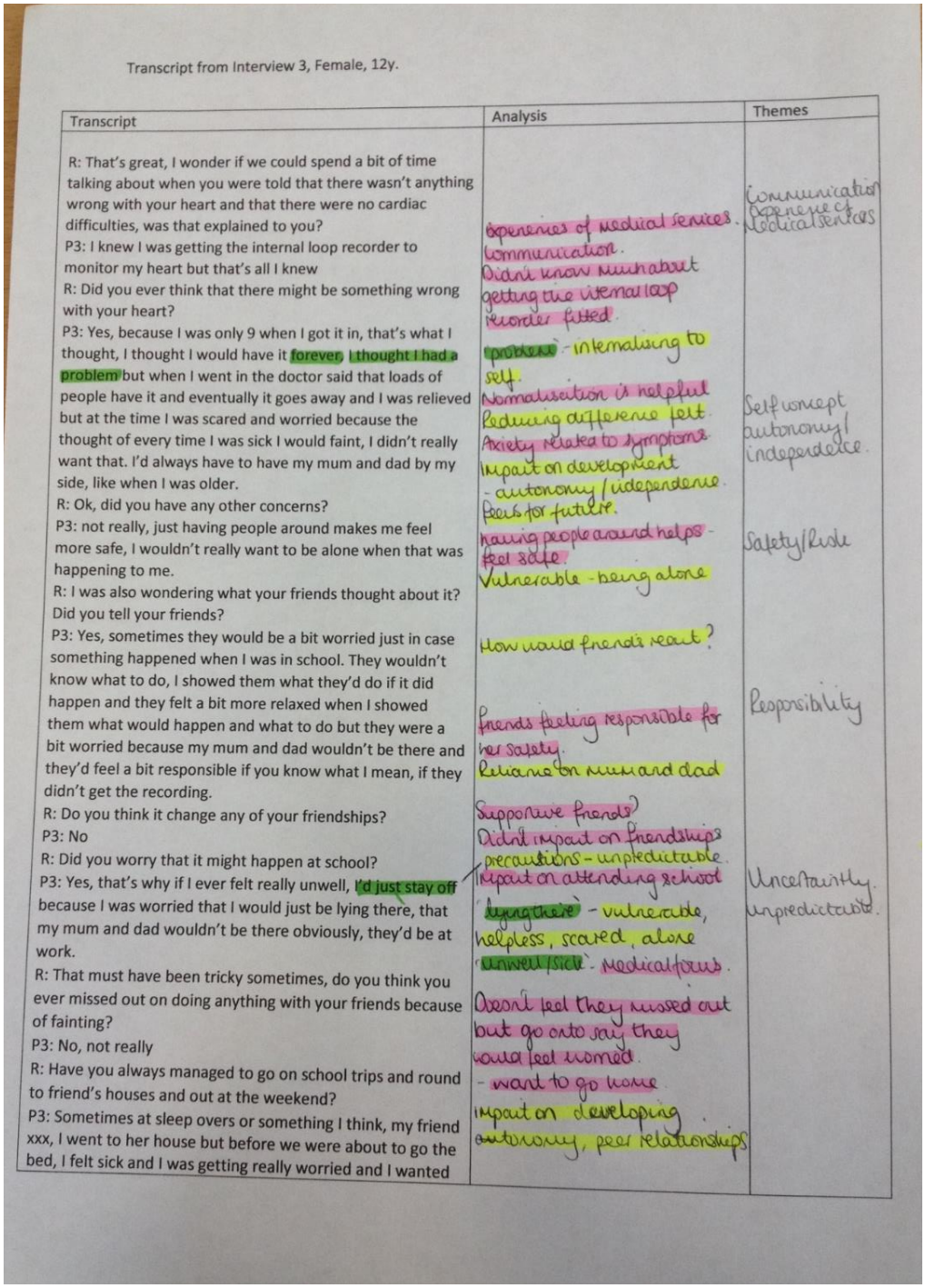
Appendix 13: Sample extract of analysis process

Linguistic comments are highlighted in green, descriptive comments in pink and conceptual comments in yellow.



Transcript from Interview 2, Female, 16y.

Transcript	Analysis	Themes
R: Ok, You mentioned a wee while ago that it made you feel a bit different, can you tell me a little bit more about that? P2: Just, I just mean I feel like that I was disabled and that when I first went down so I felt like couldn't do anything, my work at school basically went downhill kinda thing R: What was it that was making it hard to do you work at school? P2: I don't really ken, it was just the thought in the back of my mind that oh yeh, you're disabled you can't do anything, like there's disabled kids at school and I'm thinking I'm going to end up being like one of them, kind of thing, not being able to do any work or that. R: It sound like that was a tough time for you P2: Aye, I'm doing alright now R: so it sounds like things have changed a little bit then? What's made that changes? P2: I'm just being more positive about what's to come and that and I'm, I'm lucky that I am getting to do the things I want to do but later on, like a year or too, I'll get to do those things, It's something for, to look forward to and that and making me stay positive towards that so. R: I wonder are there things which help you to stay positive? P2: Ummm, nothing, I've just tried to stay positive all the time and get on with what I want, like what I want to do and that. R: ok, so you've mentioned before there were things before which you were worried about for the future, things you felt you wouldn't be able to do and feeling a bit different and worried about feeling a bit left behind, P2: Yeh, R: I was just wondering how fainting has maybe changed your life? P2: No really, it's not really changed me as a human being but all the things that I wanted, I wanted to do, it has to be put back so that's basically it, that kind of thing. R: OK, so it feels like things have been shifted back, I wonder what the reaction of other people have been like? Maybe family or friends? P2: ummm, my mum mainly, she was just really confused as to why I was fainting at the start too and like, she was in the same position as me, my friends and that were just, they were alright with it, kind of thing, cos they were there to support me and like, when I did faint they were there like to do the heart loop monitor for me when teachers were like phoning ambulances and all that so, they were really supportive and they didn't ken what was happening the start either. R: So nobody was really too sure? P2: No, nobody was, R: What was it like not knowing?	'disabled' - Perceived stigma 'anything' - all encompassing in her life Impact on school work Feeling different to others Changed perception of self Marginalised group of young people at school Associating herself with this group - emotional impact of this Does this impact on how others view her enacted/ - friendship felt stigma - QoL. Fear of what fainting would lead to - unable to achieve -Resilience ? within a Positive attitude difficult context -Coping strategies But extended timeframe for meeting milestones -Impact on adolescent trajectory Left behind - difference to others 'Human being' What makes this concept of being 'human'. • Maybe less impact on self esteem but more on quality of life? -Sense of putting things on hold. Slowed development through adolescence. Impact on family members. Confusion - the ypand friends and family about why it was happening Coping - Supportive friends.	Stigma Difference / normality Coping strategies Self esteem / self concept Confusion, uncertainty.



Transcript from Interview 3, Female, 12y.

Transcript	Analysis	Themes
R: That's great, I wonder if we could spend a bit of time talking about when you were told that there wasn't anything wrong with your heart and that there were no cardiac difficulties, was that explained to you?		
P3: I knew I was getting the internal loop recorder to monitor my heart but that's all I knew	Experience of medical services. Communication. Didn't know much about getting the internal loop recorder fitted.	Communication/ Experience of Medical Services
R: Did you ever think that there might be something wrong with your heart?		
P3: Yes, because I was only 9 when I got it in, that's what I thought, I thought I would have it forever, I thought I had a problem but when I went in the doctor said that loads of people have it and eventually it goes away and I was relieved but at the time I was scared and worried because the thought of every time I was sick I would faint, I didn't really want that. I'd always have to have my mum and dad by my side, like when I was older.	'problem' - internalising to self. Normalisation is helpful Reducing difference felt Anxiety related to symptoms Impact on development - autonomy / independence. Fears for future.	Self concept autonomy/ independence.
R: Ok, did you have any other concerns?		
P3: not really, just having people around makes me feel more safe, I wouldn't really want to be alone when that was happening to me.	having people around helps - feel safe Vulnerable - being alone	Safety/Risk
R: I was also wondering what your friends thought about it? Did you tell your friends?		
P3: Yes, sometimes they would be a bit worried just in case something happened when I was in school. They wouldn't know what to do, I showed them what they'd do if it did happen and they felt a bit more relaxed when I showed them what would happen and what to do but they were a bit worried because my mum and dad wouldn't be there and they'd feel a bit responsible if you know what I mean, if they didn't get the recording.	How would friends react? Friends feeling responsible for her safety. Reliance on mum and dad	Responsibility
R: Do you think it change any of your friendships?	Supportive friends?	
P3: No	Didn't impact on friendships	
R: Did you worry that it might happen at school?	precautions - unpredictable.	
P3: Yes, that's why if I ever felt really unwell, I'd just stay off because I was worried that I would just be lying there, that my mum and dad wouldn't be there obviously, they'd be at work.	Impact on attending school 'lying there' - vulnerable, helpless, scared, alone 'unwell/sick' - Medical focus.	Uncertainty. Unpredictable.
R: That must have been tricky sometimes, do you think you ever missed out on doing anything with your friends because of fainting?	Doesn't feel they missed out but go onto say they would feel worried. - want to go home	
P3: No, not really		
R: Have you always managed to go on school trips and round to friend's houses and out at the weekend?	Impact on developing autonomy, peer relationships	
P3: Sometimes at sleep overs or something I think, my friend xxx, I went to her house but before we were about to go the bed, I felt sick and I was getting really worried and I wanted		