An exploration of mental health and predictors of psychological distress among people with heart failure.

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Foreword

To provide context for this thesis, the major research project was significantly impacted by the COVID-19 pandemic. A major research project to pilot an Acceptance and Commitment Therapy-based group for patients with implantable cardioverter defibrillators had been developed between January 2019 and March 2020. However, major disruptions to NHS services occurring because of the COVID-19 pandemic led to the suspension of group therapies and routine cardiac services, with staff redeployed to other essential services. Due to this, the original planned project could not proceed. As a result, I developed and conducted a new project looking at psychological distress among people with heart failure during COVID-19 (see Appendix 2.6 for proposal). Due to continued COVID-related difficulties (such as research approval delays, charities and clinicians not being able to prioritise research recruitment due to other essential demands, and the long-term suspension of routine face-to-face clinics), the sample size was smaller than planned. In line with guidance from the University of Glasgow, the analysis plan was revised to use appropriate statistical methods for the data collected. Findings are discussed in relation to the limitations of analysis and associated interpretations.

Chapter 1

Predictors of depression among people with heart failure: A systematic review.

Prepared in accordance with the author requirements for the British Journal of Health Psychology (Appendix 1.1).

Abstract

Purpose

Depression is common among people with heart failure (HF) and has been linked with adverse physical health outcomes. Previous research has identified several factors associated with depression in HF. This systematic review synthesises the published prospective longitudinal research examining predictors of depression in patients with HF.

Methods

Five databases (MEDLINE, EMBASE, CINAHL, PsycINFO and Cochrane Library) were systematically searched for relevant published literature from their inception until January 2021. Articles were assessed against eligibility criteria. Included studies were quality assessed using the National Heart, Lung and Blood Institute (NHLBI) quality assessment tool for observational cohort and cross-sectional studies. Narrative synthesis was used to summarise results.

Results

Thirteen studies were included. Demographic factors were investigated in eight studies, clinical factors in ten studies, psychological factors in six studies, and social and spiritual factors in ten studies. There was limited evidence that demographic or clinical factors predicted depression. There was evidence across multiple studies that negative health-related perceptions and lack of satisfaction with social support were independent predictors of subsequent depression.

Conclusions

Further prospective research is needed to clarify the role of predictors identified from single studies, and to increase understanding of mechanisms involved in the development of depression in people with HF. Focusing on modifiable risk factors, such as negative health-related perceptions and lack of satisfaction with social support, may have clinical utility in early identification of at-risk individuals and development of targeted interventions.

Introduction

Heart failure and depression

Heart failure (HF) is a clinical syndrome in which structural and functional defects in cardiac muscle tissue result in the heart being unable to pump blood adequately around the body (Inamdar & Inamdar, 2016). HF is estimated to affect 1-2% of the United Kingdom (UK) population, with prevalence increasing with age (Sutherland, 2010). Average life expectancy is roughly three years following diagnosis (Royal College of Physicians, 2005). Treatment options for HF provide symptomatic relief but are not curative (Inamdar & Inamdar, 2016). Patients with HF often report a significant impact on functional status, reduced quality of life and poor general wellbeing (Sutherland, 2010).

Depression is common among patients with HF (Faris et al., 2002; Maggioni et al., 2016; Westlake et al., 2005; Zahid et al., 2018), with prevalence rates for depression and anxiety disorders higher among people with HF than the general population (Celano et al., 2018). Previous meta-analyses estimate around 21.5% of patients with HF have clinically significant symptoms of depression (Rutledge et al., 2006). Depression has previously been associated with adverse health outcomes in patients with HF including increased risk of mortality at follow-up, greater morbidity, and increased use of healthcare resources (Celano et al., 2018; Cully et al., 2009; Rutledge et al., 2006; Sokoreli et al., 2016).

Factors associated with depression in patients with heart failure

Previous research suggests a number of demographic (e.g., age, gender), clinical (e.g., fatigue, severity of HF) and psychosocial factors (e.g., social support, coping style) are associated with psychological distress and depression among people with HF (Scherer et al., 2007; Trivedi et al., 2009; Yu et al., 2004). However, much of this research has been cross-sectional. Cross-sectional studies are useful in identifying factors associated with depression but are not able to distinguish causal factors. Prospective, longitudinal studies are more informative in identifying potential causal factors which predict subsequent depression. To date, prospective longitudinal research into predictors of depression among people with HF has not been synthesised. The current review seeks to address this gap and provide a clearer account of factors associated with increased risk of depression in people with HF. This could be beneficial for psychological assessment among people with HF and identifying at-risk individuals for enhanced monitoring. Such factors may also indicate potential areas of focus when developing targeted interventions.

Aim

This systematic review aims to provide a synthesis and critical appraisal of the published prospective longitudinal research examining predictors of depression in patients with HF.

Method

Methodology for this systematic review followed the PRISMA statement for conducting and reporting systematic reviews (Page et al., 2021). The review protocol can be found at www.crd.org.uk/prospero (PROSPERO ID: CRD42021227023).

Search strategy

The following five databases were systematically searched for relevant studies: Medical Literature Analysis and Retrieval System Online (MEDLINE) and Excerpta Medica Database (EMBASE) via OVID; Cumulative Index to Nursing and Allied Health Literature (CINAHL) and PsycINFO via EBSCO, and Cochrane Library. Three main concepts of HF, depression and prospective study design were mapped to the most relevant controlled vocabulary using Medical Subject Headings (MeSH) with free-text items added where necessary. The SIGN Observational Studies search filter (Scottish Intercollegiate Guidelines Network, 2020) was adapted for the prospective study design concept. Full search strategies for each database are provided in Appendix 1.2. Databases were searched between their inception date and date of search (22nd January 2021). Backward and forward citation searches of references of included articles were completed to check for any additional relevant studies.

Eligibility criteria

Articles were eligible for review if: 1) research design was prospective/longitudinal; 2) subjects were adult patients who had been diagnosed with HF; 3) data were reported concerning baseline predictors of subsequent depression; and 4) depression was measured using validated outcome measures. Studies looking at mixed cardiac populations (i.e., those where only some participants had HF) and those using data gathered as part of a clinical intervention trial which may have influenced symptoms of depression were excluded. Studies were also excluded if they: 1) utilised a qualitative or mixed methods design; 2) were not published in a peer-reviewed journal (i.e., editorials, dissertations, conference articles); or 3) were not written in English.

Data selection process

Following de-duplication, titles and abstracts of identified studies were screened by the primary reviewer against the inclusion/exclusion criteria. The full texts of potentially relevant articles were then retrieved and assessed against the same eligibility criteria by the primary reviewer.

Data extraction

Data extracted included general study information (author(s), date of publication, country), recruitment and follow-up procedures, key inclusion and exclusion criteria, participant numbers (at baseline and follow-up) and characteristics (gender, age, HF characteristics), depression measure(s) used, predictors investigated, prevalence of depression, data pertaining to the relationship between predictor variables and depression, confounders controlled for and any additional relevant analysis.

Quality assessment

The quality of included articles was assessed using the National Heart, Lung, and Blood Institute (NHLBI) quality assessment tool for observational cohort and cross-sectional studies (National Institutes of Health, n.d.). The NHLBI tools are study-design specific, widely used and were developed by researchers collaborating from organisations such as the Cochrane Collaboration, SIGN, and National Health Service Centre for Reviews and Dissemination (Jorgensen, 2015; National Heart Lung and Blood Institute, n.d.). The observational cohort and cross-sectional studies tool comprises 14 items to assess study quality and risk of bias (see Appendix 1.3). Items were marked 'yes', 'no', or 'other'. Items scored 'other' were coded as either 'cannot determine', 'not applicable' or 'not reported'. Individual item scores were used to guide an overall quality rating of 'good', 'fair' or 'poor'. Two researchers independently rated all included articles using the NHLBI quality assessment tool.

Data analysis and synthesis

Due to heterogeneity across included studies, data were summarised narratively using recommended guidelines for narrative synthesis (Popay et al., 2006). Based on previous studies looking at predictors of depression (Cook et al., 2018; Fisher et al., 2019; Tibubos et al., 2019) and the predictors identified in included studies, results were synthesised and grouped into four broad categories: demographic, clinical, psychological, and social and spiritual predictors. Clinical factors included both factors related to HF and more general physical health factors.

Results

The search identified 5,767 unique records. Of these, 5,700 were excluded based on title and abstract screening. Full-text articles of the remaining 67 records were accessed with 55 excluded following application of the eligibility criteria resulting in 12 included articles. One additional article was identified from backward and forward citation searches of included articles. Therefore, 13 articles were included and are reported in this systematic review. Figure 1 outlines the search results and article selection process (Page et al., 2021).

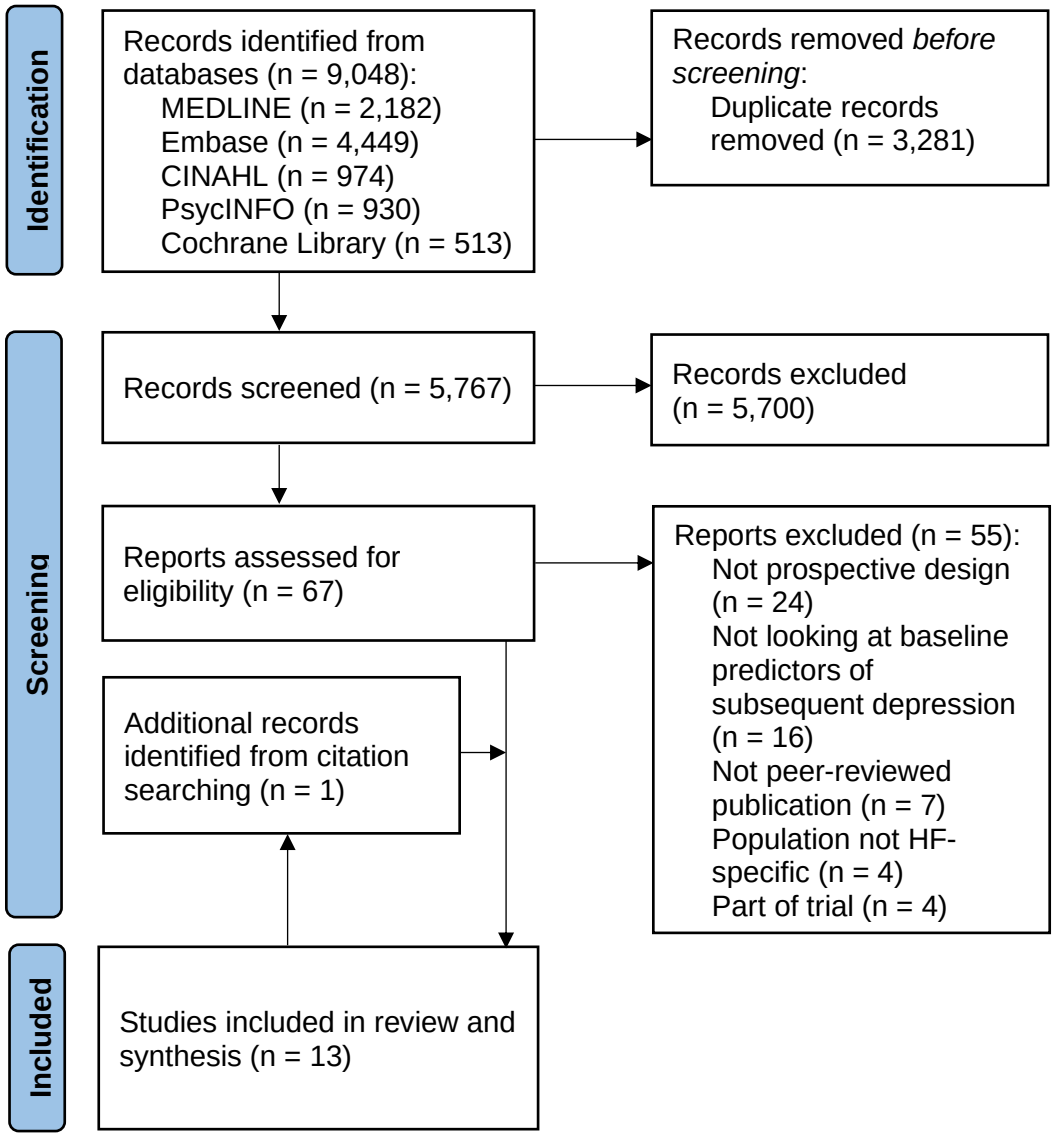

Figure 1*:* PRISMA study selection flowchart.

Study characteristics

Table 1 describes the characteristics of the 13 included studies. Studies were published between 2004 and 2020. Most studies (*n* = 8; 61.5%) were conducted in the United States, with one study conducted in both the United States and Canada. The remaining four studies were conducted in Germany (*n* = 2), the Netherlands (*n* = 1), and Japan (*n* = 1). Mean sample ages ranged from 58.9 to 69.5 years and the average proportion of males was 70.2%. Race was reported in eight studies and participants were mostly Caucasian (75.9%). Eleven studies recruited outpatients, one study recruited patients at discharge, and one study did not explicitly describe their study population. Study participants varied in terms of HF illness severity, as measured by the 4-point New York Heart Association (NYHA) classification system where higher classification indicates greater symptom severity and functional limitations. Six studies had predominately NYHA class I or II participants, two

studies had predominately NYHA class III or IV participants, and two studies only included participants with NYHA class III or IV. Two studies did not report NYHA class. Eight studies reported prevalence of clinically significant depression scores: mean prevalence of scores above the clinical cut off was 19.9% (range 12.9-38.6%).

Most of the included studies (*n* = 12) relied on the following self-report scales to measure the depression outcome: Center for Epidemiological Studies – Depression (CES-D) (*n* = 5); Patient Health Questionnaire-9 (PHQ-9) German version (*n* = 2); Medical Outcomes Study-Depression (MOS-D) (*n* = 1); Beck Depression Inventory (BDI) (*n* = 1); BDI-II (*n* = 1); Hospital Anxiety and Depression Scale-Depression subscale (HADS-D) (*n* = 1); and HADS-D Dutch version (*n* = 1). One study used both a structured clinical interview tool (Structured Clinical Interview for DSM-IV; SCID) and self-report scale (Geriatric Depression Scale; GDS) to measure depression (Turvey et al., 2006). Three studies only recruited participants without depression at baseline, nine studies controlled for baseline depression in statistical analysis and one study did not report whether baseline depression had been controlled for.

Self-report measures were primarily used to assess clinical, demographic, psychological, social and spiritual predictors. Clinical predictors were also assessed through medical record review and/or use of objective physical measurements, such as resting blood pressure, blood sampling and transcranial doppler ultrasonography. Most studies analysed data using either linear (*n* = 8) or logistic (*n* = 3) regression while two studies used structural equation modelling. There was substantial variation in method of analysis and order of entry of predictors into models.

Table 1: Sample characteristics of included studies.

Author (Year), Country	Follow-up (N months)	Study population	NYHA class (%)	Mean age (SD)	Gender (% male)	Race	T1 sample N	T2/T3/T4 sample N (% follow-up)	Dep measure; Caseness cut-off	Dep prevalence
Alosco et al. (2014), United States	12	HF outpatients	II = 84%; III = 16%; IV = 0%	69.5 (9.6)	69%	91% Caucasian	145	100 (69%)	BDI-II; Cut-offs NR	T1) 13% T2) No sig differences
Brouwers et al. (2014), The Netherlands	12	HF outpatients	I/II = 90%; III = 10%	66.7 (8.7)	76%	NR	268	257 (96%)	HADS-D Dutch version; Score ≥ 8	T1) 28% T2) 29%
Carney et al. (2020), United States	6	HF outpatients	NR	68.7 (10.1)	64%	81% Caucasian; 11% Black/ African American; 5% Native American; 1% Other	191	163 (81%)	CES-D; Cut-offs NR	NR
Havranek et al. (2004), United States & Canada	12	HF outpatients without dep at T1	I = 15%; II = 47%; III = 36%; IV = 2%	62.5 (12.3)	75%	73% Caucasian	371	245 (66%)	MOS-D; Score ≥ 0.06	T1) N/A T2) 21%
Lossnitzer et al. (2013), Germany	12	HF patients without dep at T1	II = 66%; III/IV = 34%	62.5 (12.6)	77%	NR	1175	839 (71%)	PHQ-9 German version; Cut -offs NR	T1) N/A T2) 13%
Lossnitzer et al. (2020), Germany	12/24	HF outpatients	I-IV overall mean = 1.69	58.9 (14.2)	74%	NR	NR	NR/446 (NR)	PHQ-9 German version; Score ≥ 9	16%
Park and Lee (2020), United States	6	HF outpatients	NR	68.7 (10.1)	64%	83% Caucasian; 11% African American; 5% Native American; <1% Other	NR	191 (NR)	CES-D; Cut-offs NR	NR

Park et al. (2006), United States	6	HF outpatients	I/II = 76%; III/IV = 24%	65.2 (10)	95%	68% Caucasian; 30% African American; 3% Hispanic/Other	202	163 (81%)	CES-D; Cut-offs NR	NR
Park et al. (2011), United States	3	HF outpatients	III & IV = 100%	66.7 (11.0)	60%	56% Caucasian; 39% African American; 10% Latino; 5% Native American	111	101 (91%)	CES-D; Cut-offs NR	NR
Park et al. (2014), United States	3	111 HF outpatients	III & IV = 100%	66.7 (11.0)	60%	56% Caucasian; 39% African American; 10% Latino; 5% Native American	111	101 (91%)	CES-D; Cut-offs NR	NR
Shimizu et al. (2014), Japan	12	HF patients without dep at discharge	II = 27%; III = 32%; IV = 40%	68.2 (10.6)	66%	NR	178	131 (74%)	HADS-D; Score ≥ 8	T1) N/A T2) 22%
Turvey et al. (2006), United States	2/4/5.5	HF outpatients	I = 5%; II = 34%; III = 60%; IV = 1%	69 (7.0)	49%	99% Caucasian; 1% Native American	83 (32 dep, 51 controls)	NR/NR/32 (100% dep group followed up)	SCID & GDS; Cut-offs NR	T1) 39% T2) 26/32 dep at follow-up (81%)
Wirtz et al. (2010), United States	12	HF outpatients	II = 87%; III = 13% IV = 0%	60.8 (2.5)	87%	NR	NR	30 (NR)	BDI; Score ≥ 10	T1) 0% SCID; BDI NR T2) 27% by BDI

Key: BDI = Beck Depression Inventory; CES-D = Center for Epidemiological Studies – Depression; Dep = depression; GDS = Geriatric Depression Scale; HADS-D = Hospital Anxiety and Depression Scale-Depression subscale; HF = heart failure; MOS-D = Medical Outcomes Study-Depression questionnaire; N = Number; N/A = not applicable; NR = Not Reported; NYHA = New York Heart Association classification; PHQ-9 = Patient Health Questionnaire-9 item; SCID = Structured Clinical Interview for DSM-IV; SD = standard deviation; Sig = significant; T1 = baseline time point; T2 = time 2; T3 = time 3; T4 = time 4; % = percentage

Table 2: Summary of study findings and quality assessment.

Article	Predictors tested				Analysis method	Significant findings	Overall quality rating	Identified bias
	Demographic	Clinical	Psychological	Social & spiritual				
Alosco et al. (2014)	Age; Gender	NYHA class; CBF-V; Diabetes; Hypertension; Sleep apnoea	-	-	Hierarchical linear regression	Reduced CBF-V** (β = -.21) predicted higher dep score.	Good	Time period NR; % participated NR; No sample size justification; 31% lost to follow-up
Brouwers et al. (2014)	Age; Gender; Marital status; Educational level	NYHA class; LVEF; BNP; Ischemic aetiology; BMI; Comorbidities; Inflammation markers; Statin; Aspirin	Type D personality	Loneliness	Hierarchical linear regression	Type D personality* (*B* = 1.00 (SE = .52)) & statin use* (*B* = .07 (SE = .49)) predicted dep symptoms. Comorbidity index* (OR = 1.68 [95% CI 1.09-2.60]) & younger age* (OR = .92 [95% CI .85-.99]) predicted clinically relevant levels of dep.	Good	No sample size justification; Some clinical variables self-reported; No repeat exposure assessment
Carney et al. (2020)	Age; Gender, Race	LVEF	-	Belief in afterlife; Belief in God; Religious attendance	Hierarchical linear regression	Younger age** (β = −.24) & increases in belief in God over time* (β = .12) predicted higher dep score.	Good	Time period NR; % participated NR; No sample size justification

Havranek et al. (2004)	Economic burden of healthcare; Health insurance	Diabetes; Hypertension; Alcohol abuse	Perceived health status	Living alone	Multiple logistic regression	Living alone** (*B* = .97, OR = 2.64 [95% CI 1.27-5.54]), economic burden of medical care** (*B* = 1.11, OR = 3.02 [95% CI 1.52-6.14]), lower perceived health status** (*B* = -.02, OR = 1.61 [95% CI 1.16-2.27]) & alcohol abuse* (*B* = .97, OR = 2.64 [95% CI 1.11-6.16]) predicted clinically relevant dep symptoms. Incidence increased with each additional risk factor - 8% with 0 factors, 16% with 1, 36% with 2, 69% with 3.	Good	Time period NR; No sample size justification; 34% lost to follow-up

Lossnitzer et al. (2013)	Age; Gender; Educational level	NYHA class; LVEF; Cardiovascular events; Ischemic aetiology; Blood measures; GP visits; Diabetes; Hypertension; Alcohol; Smoking; Anti-depressant	History of depression; Perceived physical impairment	Living alone	Multiple logistic regression	History of dep** (OR = 4.04 [95% CI 2.37-6.89]), history of resuscitation* (OR = 2.44 [95% CI 1.23-4.81]), smoking** (OR = 2.06 [95% CI 1.08-3.50]), frequent GP visits* (OR = 1.67 [95% CI 1.06-2.63]), NYHA class* (OR = 1.54/class [95% CI 1.05-2.25]), PHQ-9 baseline sum-score** (OR = 1.18/point [95% CI 1.11-1.27]) & perceived physical impairment** (OR = 1.08/-5 points [95% CI 1.03-1.13]) predicted incident dep. Incidence increased with number of independent risk factors: if >3 risk factors then 16% minor dep, 23% major dep.	Good	Time period NR; No sample size justification; 29% lost to follow-up
Lossnitzer et al. (2020)	-	NYHA class, LVEF, NT-prBNP	-	-	Structural equation modelling	N/A - no cross-lagged effects on dep score.	Good	% participated NR; No sample size justification; Loss to follow-up NR; Potential confounders not controlled

Park and Lee (2020)	Age; Gender; Race; Marital status	LVEF; Comorbidities	-	Social support; Religious service attendance; Spiritual peace	Hierarchical linear regression	Spiritual peace** (β = -.22) predicted change in dep symptoms.	Fair	Time period NR; % participated NR; No sample size justification; Comorbidities self-reported; Loss to follow-up NR
Park et al. (2006)	Age; Race	NYHA class	Cognitive appraisals (threat and challenge); Active coping	Number of social supports; Satisfaction with social support	Structural equation modelling	Satisfaction with social support** (β = -.28) & % active coping* (β = -.11) were prospectively related to lower levels of dep. Appraisals of one's illness as threatening** (β = .24) predicted higher levels of dep.	Fair	Time period NR; No sample size justification; Included T2 factors in statistical model so unclear what was predicted by T1 alone
Park et al. (2011)	-	-	-	Religious struggle	Hierarchical linear regression	N/A - Religious struggle did not predict T2 dep score when controlling for baseline dep.	Good	Time period NR; % participated NR; No sample size justification; Fairly short follow-up period

Park et al. (2014)	-	-	-	Forgiveness; Daily spiritual experiences; Religious identity; Public religious practices; Belief in afterlife; Religious social support; Positive religious coping	Hierarchical linear regression	N/A - No religion/spirituality variables predicted T2 dep score when controlling for baseline dep.	Good	Time period NR; % participated NR; No sample size justification; Fairly short follow-up period
Shimizu et al. (2014)	Gender	Ischemic heart disease; 6-min walk test; Hypertension; Diabetes; Knee muscle strength	Perceived functional limitations; Participation restrictions	Social support amount; Satisfaction with social support	Multiple logistic regression	Previous diagnosis of ischemic heart disease** (OR = 3.09 [95% CI 1.15-8.33] , participation restrictions** (OR = .43 [95% CI .26-.70]) & lack of satisfaction with social support** (OR = .48 [95% CI .29-.79]) predicted clinically relevant dep symptoms. Incidence increased with each additional risk factor - 0% with 0 factors, 17% with 1 or 2, 71% with 3.	Good	No sample size justification; 26.4% lost to follow-up

Turvey et al. (2006)	-	-	Perceived physical impairment; Negative attitudes about impairment	Perceived social support	Linear mixed effects models	Negative attitudes about impairment* (*B* = .02 (SE = .01)) predicted dep severity.	Fair	Location & time period NR; 49% participation rate; Potentially underpowered; No repeat exposure assessment; SCID assessors not blinded; Loss to follow-up NR
Wirtz et al. (2010)	-	sICAM-1; CRP; IL-6	-	-	Hierarchical linear regression	sICAM-1* (β = .26) predicted dep scores.	Fair	Time period NR; % participated NR; No repeat exposure assessment; Loss to follow-up NR

Key: BNP = brain natriuretic peptide; BMI = body mass index; CBF-V = cerebral blood flow velocity; CI = confidence interval; CRP = C-reactive protein; dep = depression; GP = general practitioner; IL-6 = interleukin-6; LVEF = left ventricular ejection fraction; N/A = not applicable; NR = Not Reported; NT-prBNP = N-terminal-prohormone B-type natriuretic peptide; NYHA = New York Heart Association classification; OR = odds ratio; PHQ-9 = Patient Health Questionnaire-9 item; QoL = quality of life; SCID = Structured Clinical Interview for DSM-IV; SE = standard error; sICAM-1 = soluble intercellular adhesion molecule 1; T1 = baseline time point; T2 = time 2; % = percentage; * = results significant at $p < .05$; ** = results significant at $p < .01$

Methodological quality

Results from the quality assessment are presented in Table 2. Inter-rater reliability was 86.3% (κ = .65, 95% CI, 0.531-0.774). Discrepancies in scoring between raters mainly arose in relation to whether reporting of recruitment time period was necessary in defining the study population, whether exposure(s) had been assessed more than once over time, and how studies had reported participation and loss to follow-up rates. Discrepancies in scoring were resolved through discussion and are reported in Appendices 1.4 and 1.5.

Quality of included studies varied but was generally good. All studies measured the exposure(s) of interest prior to the depression outcome and had a sufficient follow-up timeframe (minimum 3 months). Exposure and outcome measures were generally well-defined and examined using appropriate methods. Seven studies did not report the percentage of eligible individuals who took part, and one study had a low participation rate (49%). Eleven studies did not provide sample size justifications and one study acknowledged it may have been underpowered. The lack of power calculations may be explained by the exploratory nature of analyses for most included studies. Only five studies reported loss to follow-up of 20% or less: four studies lost more than 20% of participants to follow-up and four did not report loss to follow-up. One study did not control for baseline depression in analysis and one study included follow-up variables in statistical modelling, so it was unclear which baseline factors were independent predictors of subsequent depression. Overall quality of individual studies was considered when interpreting findings as reported below.

Narrative synthesis

Demographic predictors

A summary of predictors tested and study findings are presented in Table 2. From the included studies, there was limited evidence that demographic variables predicted depression among people with HF. Age was assessed as a predictor of depression in six studies, with two finding a significant effect. Younger age predicted higher depression score 6 months later (Carney et al., 2020) and was an independent predictor of clinically elevated depression levels at 12-month follow-up (Brouwers et al., 2014). However, four studies found age was not a significant predictor of depression at 6- or 12-month follow-up (Alosco et al., 2014; Lossnitzer et al., 2013; Park et al., 2006; Park & Lee, 2020). All six studies had similar samples in terms of mean age and four studies were of good quality (two significant, two non-significant) so the reason for disparities in findings is unclear. However, the odds ratio confidence interval for age in the Brouwers et al. (2014) study was close to non-significance (0.85-0.99) and Lossnitzer et al.'s (2013) non-significant finding was from a particularly large sample

size of participants free from depression at baseline. Thus, further investigation is warranted as there is not consistent evidence that younger age is a predictor of depression among people with HF.

Perception of medical care as being a substantial economic burden was also found to be a significant predictor of clinically relevant depressive symptoms at 12-month follow-up (Havranek et al., 2004). However, this study was based in the United States and Canada where healthcare costs may be more likely to result in socioeconomic hardship than countries such as Japan or the UK which have universal healthcare systems. This finding may therefore be specific to North America or to countries with greater healthcare costs for the individual.

No other demographic variables were significant predictors of subsequent depression in the included studies; gender (Alosco et al., 2014; Brouwers et al., 2014; Carney et al., 2020; Lossnitzer et al., 2013; Park & Lee, 2020; Shimizu et al., 2014), race (Carney et al., 2020; Park et al., 2006; Park & Lee, 2020), educational level (Brouwers et al., 2014; Lossnitzer et al., 2013), marital status (Brouwers et al., 2014; Park & Lee, 2020) and health insurance status (Havranek et al., 2004) were all found to be non-significant. Given that non-significant findings for gender were consistently indicated by multiple studies with low risk of bias, gender does not appear to be a significant independent predictor of depression. However, females were underrepresented in all studies which may have skewed results. Further research using representative samples is therefore warranted to clarify whether any demographic variables are independent predictors of depression among people with HF.

Clinical predictors

Clinical predictors were examined in ten of the thirteen included studies, with mixed findings. Five studies evaluated NYHA class (Alosco et al., 2014; Brouwers et al., 2014; Lossnitzer et al., 2020; Lossnitzer et al., 2013; Park et al., 2006), but only Lossnitzer et al. (2013) found NYHA class to be a significant predictor of incident depression at 12-month follow-up. The reason for this variation may be due to differences in the study population as Lossnitzer et al. (2013) only recruited participants free of depression at baseline whereas the other studies used non-selected HF cohorts. One study found reduced cerebral blood flow-velocity (CBF-V) predicted greater depressive symptomatology at 12-month follow-up (Alosco et al., 2014). Other disease severity factors were assessed as possible predictors in five studies, but all were found to be non-significant: left ventricular ejection fraction (LVEF) (Brouwers et al., 2014; Carney et al., 2020; Lossnitzer et al., 2020; Lossnitzer et al., 2013; Park & Lee, 2020), ischemic aetiology (Brouwers et al., 2014; Lossnitzer et al., 2013), brain natriuretic peptide (BNP) (Brouwers et al., 2014), and N-terminal-prohormone B-type natriuretic peptide (NT-

proBNP) (Lossnitzer et al., 2020). Similarly, blood measures, such as haemoglobin, estimated glomerular filtration rate and hyponatremia, did not predict depression (Lossnitzer et al., 2013).

Two studies investigated inflammation markers as possible predictors of depression (Brouwers et al., 2014; Wirtz et al., 2010). Soluble intercellular adhesion molecule (sICAM-1) was found to predict 7-10% of the total variance in depression scores after controlling for confounders at 12-month follow-up in a small sample of 30 HF patients (Wirtz et al., 2010). No other inflammation variables tested (TNFsr1, TNFsr2, TNFα, IL-6, IL-10, CRP) were found to predict depression (Brouwers et al., 2014; Wirtz et al., 2010). Wirtz et al.'s (2010) study was of lower quality than Brouwers et al.'s (2014) which did not include sICAM-1. Therefore, further investigation is needed to confirm whether sICAM-1 is a true predictor of depression.

There was limited evidence that comorbidities predicted subsequent depression. The total number of comorbidities did not predict depressive symptoms at 6-month follow-up (Park & Lee, 2020). However, higher comorbidity index score was an independent predictor of clinically elevated depression levels at 12-months (Brouwers et al., 2014). Compared to Park and Lee (2020), the Brouwers et al. (2014) study was of higher quality, had a longer follow-up period, and used an index score which adjusted for comorbidity weights and age. This suggests comorbidity index score warrants further investigation as a possible predictor of subsequent depression.

Previous diagnosis of ischemic heart disease (Shimizu et al., 2014), history of resuscitation (Lossnitzer et al., 2013) and frequent GP visits (Lossnitzer et al., 2013) were all found to predict incidence of significant depressive symptoms 12-months later. However, diabetes (Alosco et al., 2014; Havranek et al., 2004; Lossnitzer et al., 2013; Shimizu et al., 2014), hypertension (Alosco et al., 2014; Havranek et al., 2004; Lossnitzer et al., 2013; Shimizu et al., 2014), sleep apnoea (Alosco et al., 2014), body mass index (BMI) (Brouwers et al., 2014), 6-minute walk test (Shimizu et al., 2014), and knee muscle strength (Shimizu et al., 2014) did not predict subsequent depression scores. Medication predictors were generally found to be non-significant (Brouwers et al., 2014; Lossnitzer et al., 2013). However, further investigation is warranted regarding statin use which Brouwers et al. (2014) found predicted depressive symptoms at 12-months follow-up.

Two studies investigated lifestyle predictors. Alcohol consumption was non-significant (Lossnitzer et al., 2013) but alcohol abuse was a significant predictor of clinically relevant depressive symptoms at 12-month follow-up (Havranek et al., 2004). Smoking was found to predict incidence of depression 12-months later (Lossnitzer et al., 2013). Both studies were of good quality, but further research is

needed to validate these individual findings and to investigate the cut-off at which alcohol use may become a significant predictor.

Psychological predictors

Psychological predictors were evaluated in six studies. There was evidence that health-related perceptions predicted depression. Lower perceived health status was found to predict clinically relevant depressive symptoms at 12-month follow-up (Havranek et al., 2004). Similarly, appraisals of one's illness as threatening (Park et al., 2006) and negative attitudes about impairment (Turvey et al., 2006) were found to predict higher levels of depression at 6-month follow-up. However, both these studies were of fair quality so further investigation is warranted to validate these findings. Two studies reported on subjective physical impairment with inconsistent findings between the studies. Perceived physical impairment was not a significant predictor of depression score at 6-month follow-up (Turvey et al., 2006) but was an independent predictor of incident depression at 12-month follow-up (Lossnitzer et al., 2013). Compared to Turvey et al.'s (2006) study, Lossnitzer et al. (2013) had a much larger sample size and lower risk of bias so the differences between studies may be due to methodological quality and power rather than length of follow-up. Shimizu et al. (2014) found participation restrictions (i.e., the extent to which individuals feel limited in interpersonal interactions and activities in community life) predicted clinically relevant depressive symptoms at 12-month follow-up, but functional limitations did not. This fits with the other studies suggesting that patient's perceptions of their health may be more closely related to depression than physical health variables.

Other psychological predictors were assessed in three studies. In Lossnitzer et al.'s (2013) study, which only included participants without baseline depression, both previous history of depression and baseline depression score were found to predict incident depression at 12-month follow-up. Type D personality was found to predict depression symptoms at 12-month follow-up (Brouwers et al., 2014). Active coping predicted lower levels of depression at 6-month follow-up, but appraisals of HF as challenging did not prospectively predict depression (Park et al., 2006).

Social and spiritual predictors

Seven studies investigated predictors related to social support, with mixed findings. Havranek et al. (2004) found living alone to be an independent predictor of developing clinically relevant depressive symptoms at 12-month follow-up. However, Lossnitzer et al. (2013) found that whilst living alone was significantly correlated with incident depression in univariate analysis, it lost significance when included in the final regression model. Both studies were of good quality, only included HF patients

without depression at baseline and had similar samples in terms of age, gender and NYHA class. Differences between studies may therefore be due to the specific predictors included in statistical models or the lower proportion of participants living alone in the Lossnitzer et al. (2013) study compared to Havranek et al. (2004) (16.8% compared to 26.5%). Satisfaction with social support was assessed in two studies, with lack of satisfaction with social support found to predict depression scores at 6-month follow-up (Park et al., 2006) and clinically relevant depressive symptoms at 12-month follow-up (Shimizu et al., 2014). However, perceived social support was not a significant predictor (Turvey et al., 2006). This study had a low response rate and small sample size (N=32) so limited statistical power may have led to a type II error. Level of social support (Park & Lee, 2020), number of social supports (Park et al., 2006; Shimizu et al., 2014), and loneliness (Brouwers et al., 2014) also did not predict subsequent depression.

Religion and spirituality variables were assessed in four studies, but there was limited evidence that these variables predicted depression. Two studies found significant results, and these were mixed. Park and Lee (2020) found spiritual peace to be a significant predictor of lower levels of depression, whereas Carney et al. (2020) found increases in belief in God predicted higher depression scores at 6-month follow-up. However, neither of these studies reported their participation rates and Park and Lee (2020) did not report loss to follow-up, making it difficult to determine how representative the samples were. All other religious and spirituality variables investigated were found to be non-significant: e.g., service attendance, belief in afterlife, religious struggle, religious identity (Carney et al., 2020; Park & Lee, 2020; Park et al., 2014; Park et al., 2011).

The impact of increasing number of independent predictors

Three studies reported on risk of incident depression with increasing number of identified risk factors (i.e., those variables found to be independent predictors of subsequent depression risk) (Havranek et al., 2004; Lossnitzer et al., 2013; Shimizu et al., 2014). Havranek et al. (2004) and Shimizu et al. (2014) had comparable findings with incidence of depression at 0% or 8% with zero risk factors and 71% or 69% with three risk factors, respectively. Similarly, Lossnitzer et al. (2013) reported incidence rates of 16% for minor depression and 23% for major depression when more than three risk factors were present. Thus, whilst the risk factors identified differed between studies, all three studies found cumulative effects, such that incidence of depression increased with increasing number of independent risk factors.

Discussion

This systematic review examined predictors of depression in people with HF. Identifying predictors of depression is of clinical relevance among people with HF given the increased prevalence of depression (Celano et al., 2018; Rutledge et al., 2006) and previously established links with adverse health outcomes (Celano et al., 2018; Cully et al., 2009; Rutledge et al., 2006; Sokoreli et al., 2016). There was little consistent evidence that any demographic or clinical variables reliably predicted depression. Significant predictors were found only in single studies or findings were inconsistent between studies, highlighting the need for further research. Further investigation of these factors (e.g., younger age, comorbidity index score, alcohol use) is needed to clarify their predictive roles.

There was, however, evidence that several psychological factors predict depression among people with HF. Cognitive appraisals associated with health status (e.g., perceptions of one's illness as threatening and negative attitudes about impairment) were found to predict depression in three studies (Havranek et al., 2004; Park et al., 2006; Turvey et al., 2006). This is consistent with Leventhal's Common-Sense Model of illness which posits that individuals develop cognitive and emotional representations of illness threat which directly influence coping responses and thus subsequent outcomes (Leventhal et al., 2003). Negative appraisals of health status may also contribute to ongoing depressive symptomatology with both factors influencing each other in a downwards spiral (Park et al., 2006; Turvey et al., 2006). These negative appraisals are modifiable factors which could potentially be targeted directly in interventions, e.g., through cognitive behavioural therapy (CBT). Previous CBT trials for patients with HF have shown efficacy in reducing depressive symptoms (see review by Celano et al. (2018)). Further research should ascertain the underlying mechanisms and determine whether improvements are due to changes in cognitive appraisals. Screening for negative health-related perceptions may highlight individuals at risk of developing depression who could be targeted by psychological interventions such as CBT.

There was also evidence that lack of satisfaction with social support predicted depression (Park et al., 2006; Shimizu et al., 2014). The construct of social support is multidimensional (Cohen et al., 1985), and findings for other social support variables were generally non-significant. This is consistent with a previous 10-year population-based cohort study by Teo et al. (2013) which found poor quality of social relationships predicted depression, but social isolation did not. Previous research among people with HF has found decreased belonging support to be related to increased likelihood of depression (Graven et al., 2017). Similarly, Heo et al. (2014) found emotional support (i.e., individuals' perceptions of affective support from family, friends and important others) was related to depressive symptoms in people with HF whereas other types of social support were not. Thus,

perceptions of social support appear to be more closely linked with the development of depression. Focusing on satisfaction with social support and improving how connected people feel with those around them may reduce the likelihood of future depressive symptomatology.

There was also good evidence that higher levels of cumulative risk were associated with increased incidence of depression. This suggests the development of depression is multifaceted, and that both individual risk factors and the total number of these should be considered when developing screening methods and understanding depression risk.

Strengths and limitations

A strength of the review is that it focused solely on prospective, longitudinal studies. Such studies are more informative in identifying potential causal mechanisms for the development of depressive symptoms in people with HF. Overall quality of included studies was generally good, and most studies controlled for baseline depression either in study design or analysis methods. There was good evidence for two predictors – negative health-related perceptions and lack of satisfaction with social support – and for a cumulative impact of increasing number of independent predictors on depression risk.

Publication and outcome reporting biases may have resulted in significant findings being more likely to be reported than non-significant results. Included studies were heterogenous and varied in terms of inclusion criteria, length of follow-up and types of depression measures used, making comparisons between studies and interpretation of findings difficult. For instance, there could be differences in significant predictors depending on length of follow-up period. Such nuances warrant further investigation. A previous large representative UK cohort study of newly diagnosed HF patients found mean age of 76.6 and proportion of males to be 51% (Conrad et al., 2019). The sample from included studies in this review was therefore younger and predominantly more male than the wider UK HF population. Most studies were exploratory and sample sizes may not have been large enough to be sufficiently powered. In addition, sampling and attrition biases across studies may be an issue as most studies did not report participation and follow-up rates. Findings from studies with smaller sample sizes warrant future follow-up with appropriately sized representative samples.

Most studies (with one exception) used self-reported measures of depression, and eight studies did not report caseness cut-offs. Self-report measures have previously been found to have weak agreement with clinical interviews for diagnosis of depression (Eaton et al., 2000). This limits validity of prevalence estimates for depression as variation in depression assessment methods and caseness

cut-offs have previously been found to have the biggest impact on reported depression rates in studies of people with HF (Rutledge et al., 2006). In addition, most studies operationalised the dependant variable as depressive symptoms measured on a continuous scale, rather than applying caseness cut-offs for analysis. Predictors of depression score should not be misinterpreted as predictors of depressive disorder.

Implications for future research

Given the significant impact of depression for people with HF, it is apparent more high-quality prospective studies are needed. Further investigation of inconsistencies across studies and predictors identified in single studies is warranted to determine whether these represent true risk factors for the development of depression in people with HF. Adequately powered studies with large sample sizes, more representative samples, and tracking participants at multiple time points for longer follow-up periods are needed to move beyond exploratory findings. This has clinical utility for early identification of at-risk individuals with HF and identifying key modifiable factors which could be targeted by early intervention. HF has become an increasingly heterogenous clinical syndrome with several distinct subtypes and ever-increasing clinical complexity (due to aging populations and advances in cardiovascular treatment) (Iorio et al., 2017). It may be helpful to explore whether predictors of depression differ between subtype groups, or are impacted by related factors, such as time since diagnosis, treatment pathways, and rate of progression of illness. Future studies may also benefit from carefully rationalising caseness cut-offs and use of clinical interview methods.

Identified psychological and social predictors of depression, particularly negative health-related perceptions and lack of satisfaction with social support, highlight potentially modifiable factors which could be targeted by early intervention. It would be beneficial to explore key factors which may influence health-related perceptions and therefore represent areas for intervention, such as information given at time of diagnosis, attitudes of caregivers, communication with health professionals and coping responses. Further research is needed to test whether screening for psychological/social predictors and targeting at-risk individuals with early intervention leads to reduced depressive symptomatology.

Conclusion

This review is the first to systematically identify and synthesise the prospective research evidence investigating predictors of depression in people with HF. The thirteen included studies identified several significant predictors, but these were often detected in single studies and there were inconsistencies across studies. This review found no consistent evidence that any demographic or

clinical variables reliably predicted depression. However, two psychological/social factors were consistent predictors: negative health-related perceptions and lack of satisfaction with social support. Focusing on these potentially modifiable risk factors may allow at-risk individuals to be identified early and supported with targeted interventions. Further prospective research is needed to increase understanding of predictors of depression among people with HF as focus in these areas has the potential to positively impact both psychological and physical wellbeing for people with HF.

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Chapter 2

An exploration of mental health and variables associated with psychological distress among people with heart failure during the COVID-19 pandemic.

Prepared in accordance with the author requirements for the British Journal of Health Psychology (Appendix 1.1).

Plain Language Summary

Title

An exploration of mental health and variables associated with psychological distress among people with heart failure during the COVID-19 pandemic.

Background

In this study, psychological distress is defined as significant symptoms of depression and/or anxiety. In the United Kingdom, rates of psychological distress increased during the COVID-19 pandemic (Shevlin et al., 2020). Before COVID-19, people with heart failure (HF) had higher rates of psychological distress than the general population (Celano et al., 2018). People with HF are at greater risk of becoming unwell and dying from COVID-19. Thus, people with HF might be at greater risk of psychological distress during COVID-19. We looked at rates of psychological distress among people with HF compared to a control group. Psychological distress has also been linked with other factors. For instance, age, gender, having other health conditions, fatigue, and social support. These factors may be linked to psychological distress for HF patients during COVID-19.

Aims

The main aim was to examine rates of psychological distress during COVID-19 among people with HF compared to controls. Another aim was to explore factors related to psychological distress in people with HF.

Methods

Fifty-seven participants (42 with HF and 15 controls) took part in the study. Recruitment was through heart failure organisations and charities across Scotland. These groups shared the study advertisement through social media networks, support groups and routine clinical contact. For the control group, HF participants were asked to pass the study information to 2-3 close friends (known as snowball sampling). To take part, participants filled in an online questionnaire that took 10-15 minutes to complete.

Main findings and conclusions

There were no significant differences in psychological distress in the HF group compared to controls. Overall, 33.9% of participants had significant symptoms of depression and 19.6% had anxiety symptoms. We found higher depression rates and lower anxiety rates than other HF and COVID-19 studies. The snowball sampling method was not able to recruit a control sample that was similarly

sized to the HF group. In the HF group, psychological distress was related to several other variables such as perceived control, loneliness, and having other health conditions. Further research into these factors would be useful for psychological assessment and intervention.

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Abstract

Objectives

People with heart failure (HF) have increased vulnerability to COVID-19 and may be at increased risk of psychological distress. The primary aim of this study was to describe rates of psychological distress among people with HF compared to controls during the COVID-19 pandemic. The study also aimed to investigate other variables potentially associated with psychological distress.

Design

A case-control, cross-sectional design was developed to investigate rates of psychological distress and related variables among people with HF during the COVID-19 pandemic. A feasibility approach was taken to explore use of a snowball sampling method with HF participants to recruit a demographically matched control sample.

Methods

Fifty-seven participants (42 with HF and 15 controls) completed an online questionnaire consisting of several measures (socio-demographic, physical health, COVID-19 related, psychological distress and psychosocial).

Results

Depression prevalence was 33.9% and anxiety prevalence was 19.6%. There were no significant differences in rates of psychological distress in the HF group compared to controls. For the HF group, medium-large effect sizes were found between depressive and anxiety symptoms and several related variables, such as perceived control, loneliness, and presence of other health conditions.

Conclusions

This study extended previous COVID-19 research to a HF population. The study found higher depression rates and lower anxiety rates than previously reported by other HF and COVID-19 studies. Related factors associated with psychological distress warrant further investigation as they may be useful in identifying at-risk individuals and potentially modifiable targets for intervention.

Keywords: heart failure; depression; anxiety; COVID-19

Introduction

Background context: COVID-19 and heart failure

In response to the COVID-19 pandemic, the United Kingdom (UK) government imposed social distancing measures to reduce transmission, protect vulnerable individuals and manage health service demands (Cabinet Office, 2020; McBride et al., 2021). Tiered approaches and 'lockdowns' have been imposed following surges in cases and new virus strains (Public Health England, 2020a; Scottish Government, 2021a, 2021b). People with heart failure (HF) are at increased risk of hospitalisation, poor outcomes, and death from COVID-19 (Bader et al., 2021; Yonas et al., 2020). National guidance emphasised minimising the risk of contracting COVID-19 (Scottish Government, 2020) and high-risk individuals with HF were advised to 'shield' by staying at home and avoiding face-to-face contact (Public Health England, 2020b).

Psychological distress and COVID-19

In line with previous research, psychological distress will be defined as a "state of emotional suffering characterized by symptoms of depression and anxiety" (Drapeau et al., 2012, p. 105). There was increased prevalence of clinically significant levels of psychological distress among the UK population during the first lockdown compared to pre-COVID-19 levels (Kwong et al., 2020; Pierce et al., 2020; Shevlin et al., 2020). For instance, Daly et al. (2020) found population prevalence of mental health problems increased from 24.3% in 2017-2019 to 37.8% in April 2020 and remained elevated in May and June 2020 (34.7% and 31.9% respectively). Population-level evidence from previous infectious respiratory disease outbreaks suggests psychological distress may persist, or even worsen, over time (Gardner & Moallef, 2015; McBride et al., 2021). Bonanno et al. (2008) studied patients with severe acute respiratory syndrome in Hong Kong and found 42% of survivors reported poorer psychological functioning that persisted over time and 13% experienced delayed reactions with initially high psychological functioning which subsequently steeply declined. Thus, some individuals may experience more chronic stress responses during the COVID-19 pandemic and persistent difficulties with depressive and/or anxiety symptoms. Large numbers of population-level, cross-sectional, self-report research studies have provided valuable insights into population-level psychological distress and coping during COVID-19. However, this approach may be less useful for understanding needs of specific subgroups, such as people with HF.

Leventhal's Common-Sense Model of illness posits that when threats are perceived, individuals develop cognitive and emotional representations of these which directly influence coping responses and outcomes (Leventhal et al., 2003). Based on this model, factors such as illness severity, perceived control, and coping style will influence psychological adjustment to health threats, such as COVID-19.

Previous research looking at psychological outcomes following traumatic events, including disease outbreaks, suggests psychological adjustment is influenced by other factors – such as age, gender, education, physical health, trauma exposure, disease fears, social support and coping style (Bonanno et al., 2007; Polizzi et al., 2020; Xu et al., 2011). Gaining better understanding of factors associated with psychological distress and adjustment during COVID-19 may help to inform psychological assessment, build understanding of maintenance and/or remission of psychological distress, and guide interventions to improve mental wellbeing (Holmes et al., 2020).

Heart failure and psychological distress

Prior to COVID-19, prevalence rates for depression and anxiety disorders were higher among people with HF than the general population (Celano et al., 2018). Previous meta-analysis estimated around 21.5% of HF patients had clinically significant depressive symptoms (Rutledge et al., 2006), compared to an estimated UK population prevalence of 7.4% (Arias-de la Torre et al., 2021). Similarly, around 28.8% of HF patients had clinically significant anxiety (Easton et al., 2016), compared to an estimated 7.2% of adults in UK primary care (Martín-Merino et al., 2010). Emerging evidence suggests individuals classed as vulnerable during COVID-19 due to pre-existing health conditions may have experienced higher levels of psychological distress (Pierce et al., 2020; Shevlin et al., 2020), particularly anxiety (Rettie & Daniels, 2020; Westcott et al., 2021), than the general population. This may be due to additional stressors such as increased health- and finance-related anxieties, social isolation and disrupted access to health and social care services (Brooks et al., 2020; Holmes et al., 2020; Scottish Government, 2020). However, studies have tended to include presence of pre-existing health conditions generally within population-level research rather than focusing specifically on these 'vulnerable' groups. Given HF patients have previously been found to have higher rates of psychological distress than the general population, they may represent a particularly at-risk group during the COVID-19 pandemic.

Psychological distress among HF patients has previously been associated with sociodemographic characteristics (such as age, sex and employment status) (Holly & Sharp, 2012; Scherer et al., 2007), number of health problems (Holly & Sharp, 2012; Scherer et al., 2007), greater HF severity (Scherer et al., 2007), fatigue (Yu et al., 2004), avoidant coping and pessimism (Trivedi et al., 2009). Conversely, living with a partner and high levels of social support appear to be protective for HF patients, and increase the likelihood and speed of psychological distress reducing over time (Koenig, 1998; Scherer et al., 2007; Trivedi et al., 2009; Yu et al., 2004). Thus, previous findings in relation to psychological adjustment to disease outbreaks and among HF patients suggest other sociodemographic, health and psychosocial factors may be significantly related to psychological

distress for people with HF during the COVID-19 pandemic. Given that psychological distress can persist or even worsen over time, identifying key related factors may be important as healthcare services move from COVID-19 crisis management into recovery phases.

Aims

The primary aim of this study was to describe rates of psychological distress among people with HF compared to controls during the COVID-19 pandemic. The study also aimed to investigate variables potentially associated with psychological distress.

Hypotheses

Based on previous literature, it was predicted that:

1. Psychological distress would be higher among people with HF compared to controls.
2. Psychological distress would be associated with other variables among people with HF, such as socio-demographic (age, gender, marital status), health (HF severity, shielding status, presence of other health conditions, fatigue) and psychosocial factors (coping style, perceived control, social support, loneliness).

Method

Design

A case-control, cross-sectional design was employed to investigate rates of psychological distress and related variables among HF patients and controls during the COVID-19 pandemic. A feasibility approach was taken to explore using a snowball sampling method with HF participants to recruit a demographically matched control sample.

Participants and recruitment procedure

A total of 57 participants took part: 42 HF and 15 control participants. Participants were eligible if they were aged 18 years or over, able to understand English, and resident in Scotland. Participants also needed the technology and ability to complete the questionnaire online.

HF participants were recruited through the Heart Failure Hub Scotland (HFHS), Scottish Heart Failure Nurse Forum (SHFNF) and three national charities: Cardiomyopathy UK, Chest Heart Stroke Scotland, and British Heart Foundation. These organisations shared the study advertisement through their social media networks and support groups. Through the HFHS and SHFNF, HF clinicians across approved Scottish health boards were also informed of the study and invited to share the study advertisement with HF patients during routine clinical contact.

A snowball sampling method (Goodman, 1961) was used to recruit control participants. Snowball sampling can increase likelihood of recruiting demographically matched samples and has been used in health research for case-control designs (Lopes et al., 1996; Rezaei et al., 2011). HF participants were asked to invite 2-3 close friends not living within the same household to participate as controls.

Ethics

Ethical approval was granted by NHS Greater Glasgow and Clyde (NHSGG&C) West of Scotland Research Ethics Service (WoSRES; Reference: 20/WS/0136) on 26th October 2020 with an amendment to include Golden Jubilee National Hospital granted on 17th December 2020 (Appendix 2.1). NHSGG&C Research and Innovation (R&I; Reference: GN20CA363) agreed to host the research project with approval granted on 11th December 2020 (Appendix 2.2). R&D agreements for the HFHS and SHFNF to share the study with HF clinicians in 11 Scottish health boards were granted between 11th December 2020 and 27th April 2021 (Appendix 2.3).

Procedures

Data were collected between 17th December 2020 and 14th May 2021. Potential participants accessed the webpage provided on the study advertisement (Appendix 2.4). They were provided with an online Participant Information Sheet (Appendix 2.5) and completed short screening questions to ensure eligibility. As responses were anonymised, submission of the questionnaire was deemed to reflect implied consent.

Participants completed an online questionnaire consisting of the measures described below. Control participants did not complete HF-related questions; all other aspects were identical. The question "Do you have heart failure?" was used to differentiate between groups. Participants provided their email address if they were willing to be contacted about future study follow-up. This information was stored securely and separately from the data. Data were anonymised to protect participant confidentiality. Dummy identifiers were assigned to allow linkage for follow-up.

Measures

Socio-demographic: Information was collected regarding age, gender, ethnicity, area of residence, marital status, and household composition (total number of adults and children under 18 years).

Physical health: HF severity was measured using the self-assigned New York Heart Association (NYHA) classification scale (Holland et al., 2010). The 4-point NYHA scale is widely used to measure

functional status. Higher scores indicate greater symptom severity. Participants were also asked to list any other medical conditions.

Fatigue was measured using the 9-item Fatigue Severity Scale (FSS) (Krupp et al., 1989). The FSS was designed to assess fatigue in chronic health conditions. Scores range from 9-63, with higher scores indicating greater fatigue severity. The FSS has shown good internal consistency (Cronbach's α = .88-.95) and test-retest reliability (*r*=.84) (Whitehead, 2009).

COVID-19: Participants were asked whether they had been advised to shield during COVID-19. COVID-anxiety was measured using the 5-item Coronavirus Anxiety Scale (CAS) (Lee, 2020). Scores range from 0-20, with higher scores indicating greater anxiety. The CAS has shown good internal consistency (α = .80-.93) and appears to measure COVID-anxiety in a similar way regardless of age, gender, or race (Caycho-Rodríguez et al., 2021; Lee et al., 2020). A CAS score ≥9 was used to determine COVID-anxiety caseness (Lee, 2020).

Psychological distress: Depressive symptoms were measured using the 9-item Patient Health Questionnaire (PHQ-9) (Spitzer et al., 1999). Scores range from 0-27 and higher scores indicate greater depression severity. Depression caseness was defined by a cut-off score ≥10 (Lichtman et al., 2008; Meader et al., 2011).

Anxiety symptoms were measured using the 7-item Generalised Anxiety Scale (GAD-7) (Spitzer et al., 2006). GAD-7 scores range from 0-21, with higher scores indicating higher anxiety levels. Anxiety caseness was determined by a cut-off score ≥10 (Ivanovs et al., 2018; Spitzer et al., 2006). Both the PHQ-9 and GAD-7 are well-validated (Kroenke et al., 2001; Rutter & Brown, 2017), recommended in cardiac care for assessment of psychological wellbeing (Scottish Intercollegiate Guidelines Network, 2017), and used routinely within heart failure services.

Psychosocial: Coping style was measured using 6 items from the Brief-COPE questionnaire (Carver, 1997). Consistent with previous HF research (Eisenberg et al., 2012), coping responses were grouped into two overarching categories: approach coping (active coping, positive reframing and acceptance subscales) and avoidant coping (denial, substance use and behavioural disengagement subscales). Higher scores indicate stronger likelihood to adopt the coping style. The Brief-COPE has been validated among participants responding to a range of adversities, including natural disasters and physical conditions (Carver, 1997; Eisenberg et al., 2012).

Perceived control was measured using the 7-item Personal Mastery Scale (PMS) (Pearlin & Schooler, 1978) which assesses the extent to which one believes that they can control life events and circumstances. Scores range from 7-49, with higher scores indicating greater sense of mastery. The PMS is widely used in health research, including cardiac studies (Roepke & Grant, 2011), and has demonstrated acceptable internal consistency (α = .77-.79) (Kempen et al., 1999; Ranchor et al., 2010).

Loneliness was assessed using the 3-item UCLA Loneliness Scale (Hughes et al., 2004). Scores range from 3-9, with higher scores indicating greater feelings of loneliness. The scale has shown acceptable internal consistency (α = .72-.84), and convergent and discriminant validity among community-based populations (Hughes et al., 2004; Rico-Uribe et al., 2016).

Social support was measured using the 7-item ENRICHD Social Support Inventory (ESSI) which comprises items on structural, instrumental and emotional support (Mitchell et al., 2003). Scores range from 8-34, with higher scores indicating greater social support. The scale has demonstrated good internal consistency (α = .86-.88), concurrent and predictive validity, and test-retest reliability within cardiac populations (Mitchell et al., 2003; Vaglio Jr et al., 2004).

Sample size estimation

A previous case control study by Lesman-Leegte et al. (2009) found 39% of elderly HF patients experienced clinically significant depressive symptoms compared to 21% of age- and gender-matched community controls. Based on this study, G* Power (Faul et al., 2009) was used to calculate the sample size required to detect between-group differences in the proportion of cases and indicated a required sample of 90 per group (*N* = 180) (α = .05, β = .80). To the author's knowledge, snowball sampling methods to recruit control participants have not previously been undertaken with HF populations. Participation rates and demographic characteristics of each group were reported to aid sample size estimations for future research.

Adjusted analysis plan

Given increased pressures on NHS services and reduction in routine clinics during the COVID-19 pandemic, it was not possible to meet the recruitment target within the available timescale. Data analysis was therefore modified to use appropriate statistical methods for the sample size achieved.

This paper adheres to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for reporting observational studies (von Elm et al., 2007). PHQ-9, GAD-7 and CAS

scores were dichotomised into caseness according to the clinical cut-offs described above. Following Teymoori et al. (2020) guidance, ordinary mean substitution was used for missing items on measures if less than one third of items were missing. Descriptive statistics were used to summarise feasibility data related to recruitment, missing data, acceptability of follow-up, and baseline characteristics.

For categorical variables, between-group differences were tested using chi-square tests (or Fisher's exact test, FET, if expected frequencies were <5). Given the sample size, exact methods were used to calculate significance levels. Continuous variables were tested using Welch's t-tests as this is robust in the presence of unequal sample sizes and variances (Delacre et al., 2017). Relationships between key variables (e.g., gender, NYHA class, social support) and depression/anxiety scores among the HF group were tested using appropriate non-parametric tests. Confidence intervals and appropriate effect sizes were reported in line with published guidance (du Prel et al., 2009; Kotrlik et al., 2011; Lee, 2016). Bias-corrected and accelerated (BCa) bootstrapping was used to calculate confidence intervals.

Results

Study feasibility

Recruitment was via third party clinicians and organisations passing the study advertisement to potential participants. Therefore, it was not possible to determine number of potential participants approached. Instead, a timeline of recruitment method and number recruited is reported in Figure 1. Four charities initially agreed to support study recruitment. One charity subsequently withdrew involvement due to delays in obtaining approvals. Eleven health boards agreed for the study to be shared with their HF clinicians through the HFHS and SHFNF. Three health boards did not agree: two withdrew due to staff shortages and the need to prioritise large-scale COVID-19 studies; one did not respond to requests for involvement (Appendix 2.3). All participants who decided to take part met the study criteria and completed the survey. The percentage of missing values across all variables was low (0.6%). Forty-six participants (80.7%) agreed to be contacted for follow-up.

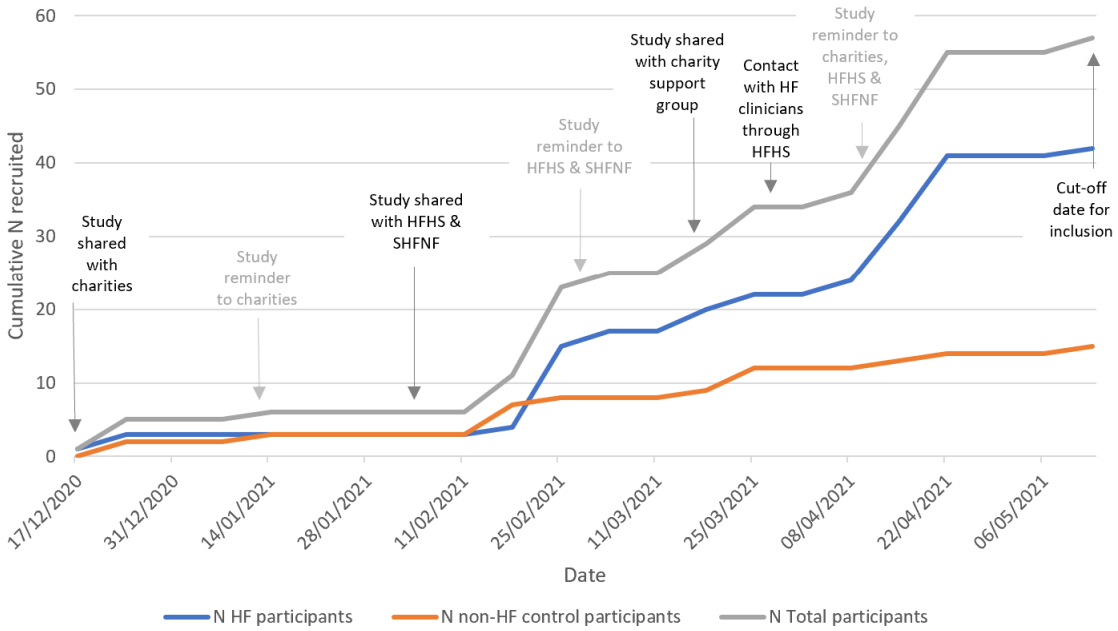

Figure 1: Recruitment Graph

For the snowball sampling method, it was anticipated that asking HF participants to pass on the study details to 2-3 close friends would provide roughly equal-sized and demographically matched samples. Forty-two HF participants (73.7%) and 15 control participants (26.3%) took part. Table 1 shows the demographic characteristics of the total sample and between groups. There were significant gender differences between groups ($\chi^2(1, N = 57) = 6.17$, $p = .013$, $\phi = .33$), with equal numbers of males and females in the HF group but more females in the control group. No control participants were advised to shield, whereas 21.1% of HF participants were advised to shield and 5.3% were unsure ($p = .036$, FET, $V = .36$). There were no significant between-group differences for age ($p = .964$, FET, $V = .17$), ethnicity ($p = .263$, FET, $\phi = .22$), marital status ($p = .262$, FET, $V = .33$), total number of people in the household ($t(22.01) = .47$, $p = .642$, 95% BCa CI [-.61, .97], $d = .15$), area of residence ($p = .899$, FET, $V = .26$), or other health conditions ($\chi^2(1, N = 57) = .68$, $p = .410$, $V = .18$).

Table 1. Descriptive results of demographic variables overall and for each group.

Participant characteristic	Total sample (57)	HF group (42)	Control group (15)	*p value*
Age *n* (%)				.964
18-24	1 (1.8)	1 (2.4)	0 (0.0)	
25-34	6 (10.5)	4 (9.5)	2 (13.3)	
35-44	5 (8.8)	3 (7.1)	2 (13.3)	
35-54	16 (28.1)	12 (28.6)	4 (26.7)	
55-64	15 (26.3)	11 (26.2)	4 (26.7)	
65-74	7 (12.3)	5 (11.9)	2 (13.3)	
75 and over	7 (12.3)	6 (14.3)	1 (6.7)	
Gender *n* (%)				.013
Male	23 (40.4)	21 (50.0)	2 (13.3)	
Female	34 (59.6)	21 (50.0)	13 (86.7)	
Ethnicity *n* (%)				.263
White	56 (98.2)	42 (100.0)	14 (93.3)	
Black, African, Caribbean or Black British	1 (1.8)	0 (0.0)	1 (6.7)	
Marital status *n* (%)				.262
Single (never married)	12 (21.1)	7 (16.7)	5 (33.3)	
Married or civil partnership	22 (38.6)	18 (42.9)	4 (26.7)	
Relationship (living together)	12 (21.1)	10 (23.8)	2 (13.3)	
Relationship (not living together)	1 (1.8)	0 (0.0)	1 (6.7)	
Divorced or separated	8 (14.0)	6 (14.3)	2 (13.3)	
Widowed	2 (3.5)	1 (2.4)	1 (6.7)	
Total number in household *M* [SD]	2.33 [1.19]	2.38 [1.15]	2.20 [1.32]	.642
Area of residence				.899
Ayrshire & Arran	6 (10.5)	5 (11.9)	1 (6.7)	
Fife	4 (7.0)	3 (7.1)	1 (6.7)	
Grampian	2 (3.5)	1 (2.4)	1 (6.7)	
Greater Glasgow & Clyde	25 (43.9)	17 (40.5)	8 (53.3)	
Highland	3 (5.3)	3 (7.1)	0 (0.0)	
Lanarkshire	10 (17.5)	8 (19.0)	2 (13.3)	
Lothian	3 (5.3)	3 (7.1)	0 (0.0)	
Tayside	3 (5.3)	2 (4.8)	1 (6.7)	
Not reported	1 (1.8)	0 (0.0)	1 (6.7)	

NYHA class *n* (%)				-
I	-	6 (14.3)	-	
II	-	14 (33.3)	-	
III	-	19 (45.2)	-	
IV	-	3 (7.1)	-	
Reported other physical/mental health conditions *n* (%)	28 (49.1)	22 (52.4)	6 (40.0)	.410
Advised to shield *n* (%)				.036
Yes	12 (21.1)	12 (28.6)	0 (0.0)	
No	42 (73.7)	27 (64.3)	15 (100.0)	
Unsure	3 (5.3)	3 (7.1)	0 (0.0)	

n = sample size, *M* = mean, *SD* = standard deviation

Between-group comparisons of psychological distress and related variables

Mean scores for depression, anxiety, and COVID-anxiety split by group are shown in Figure 2. Tests of between-group differences in symptoms of psychological distress found a medium effect size for COVID-anxiety ($t(15.98) = -1.64$, $p = .122$, 95% BCa CI [-4.04, .52], $d = -.69$), and small effect sizes for general anxiety ($t(19.24) = -.87$, $p = .393$, 95% BCa CI [-5.34, 2.19], $d = -.29$) and depression ($t(19.34) = -.22$, $p = .831$, 95% BCa CI [-4.93, 4.01], $d = -.31$).

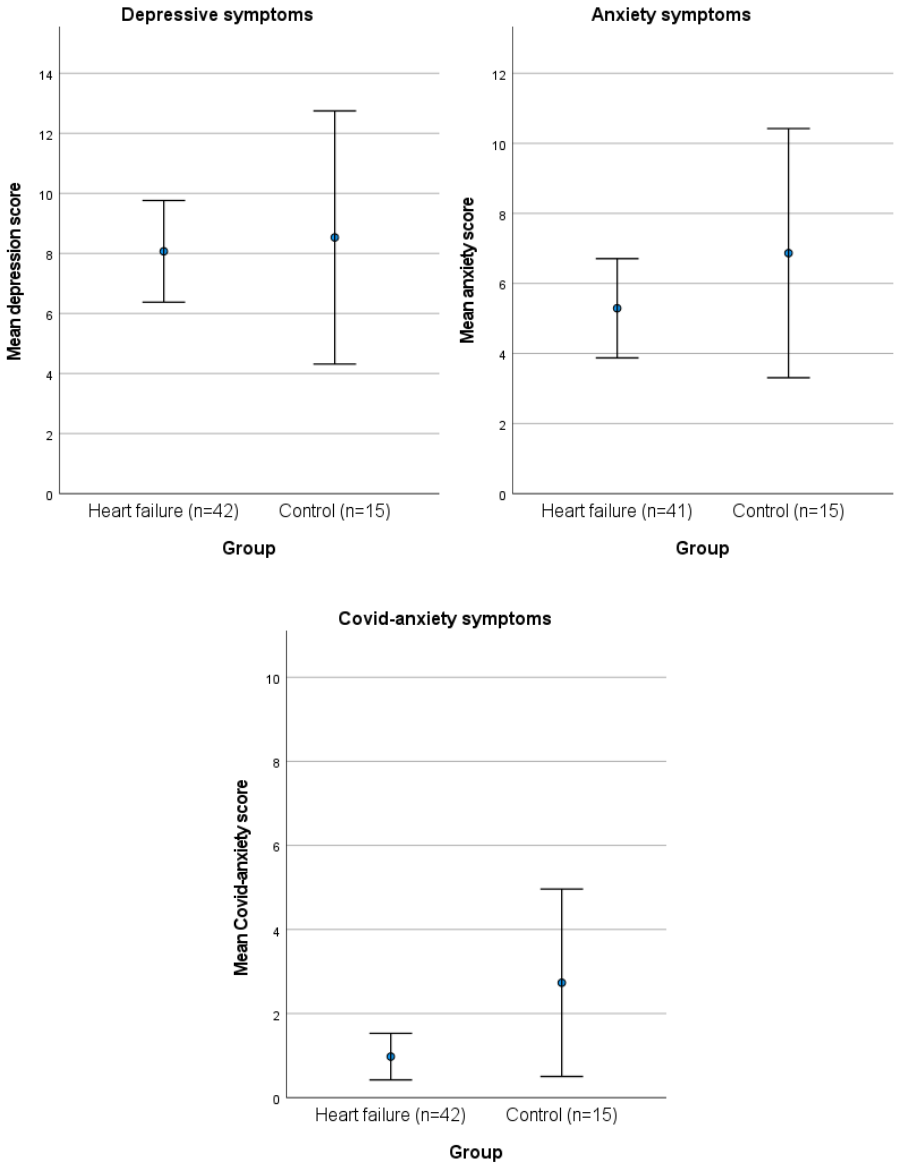

Figure 2: Mean scores and 95% confidence intervals for the psychological distress variables split by group.

Mean scores for the other key variables split by group are shown in Figure 3. Tests of between-group differences for these variables found medium effect sizes for social support ($t(22.80) = 2.03$, $p = .054$, 95% BCa CI [-.10, 10.22], d = .68), avoidant coping ($t(18.77) = -1.68$, $p = .109$, 95% BCa CI [-1.72, .19], $d = -.61$), and fatigue ($t(26.84) = 1.93$, $p = .064$, 95% BCa CI [-.54, 17.87], $d = .56$). A small effect size was found for loneliness ($t(21.61) = -1.00$, $p = .328$, 95% BCa CI [-2.15, .75], $d = -.33$) with negligible effect sizes found for perceived control ($t(21.81) = .45$, $p = .661$, 95% BCa CI [-6.02, 8.29], $d = .15$) and approach coping ($t(27.20) = -.03$, $p = .975$, 95% BCa CI [-1.25, 1.22], $d = -.01$).

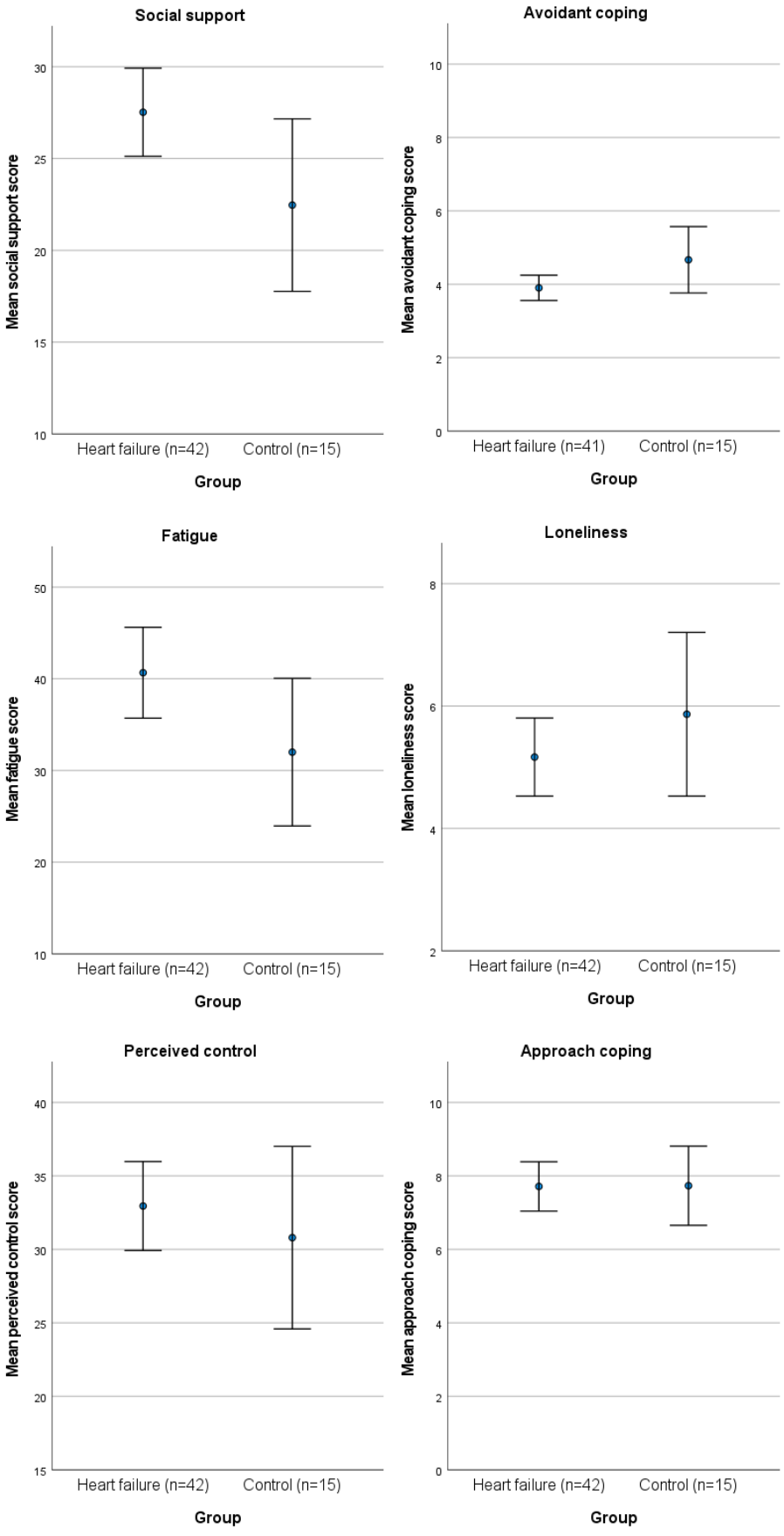

Figure 3: Mean scores and 95% confidence intervals for the other key variables split by group.

Prevalence of psychological distress between groups

Prevalence rates for depression, anxiety and COVID-anxiety are reported in Table 2. Tests of between-group differences in prevalence found a medium effect size for COVID-anxiety caseness (p = .07, FET, ϕ = .32), small effect size for anxiety caseness (p = .14, FET, ϕ = .21), and negligible effect size for depression caseness ($\chi^2(1, N = 57) = .00$, $p = 1.00$, ϕ = .00).

Table 2. Prevalence of psychological distress overall and for each group.

Psychological distress	Prevalence [95% BCa CI]		
	Total sample (56)	HF group (41)	Control group (15)
Depression	33.9% [23.2, 44.6]	34.1% [20.5, 48.6]	33.3% [12.5, 55.6]
Anxiety	19.6% [10.7, 28.6]	14.6% [5.3, 25.7]	33.3% [12.5, 55.6]
COVID-anxiety	3.6% [.0, 8.9]	0% [-]	13.3% [.0, 33.3]

CI = confidence interval

HF group analysis

Relationships between psychological distress and socio-demographic, health, and psychosocial variables were tested for the HF group (see Table 1 for frequencies of categorical variables and Table 3 for relationships between continuous variables).

Table 3. Correlation matrix (r_S) for study variables and depression/anxiety scores in the HF group.

Variable	1	2	3	4	5	6	7	8
1. Depression score	-							
2. Anxiety score	.73**	-						
3. NYHA class	.30	.09	-					
4. Fatigue	.43**	.25	.53**	-				
5. Avoidant coping	.31	.31	-.06	-.11	-			
6. Approach coping	-.03	-.08	-.06	.22	.26	-		
7. Perceived control	-.65**	-.64**	-.15	-.07	-.41**	.28	-	
8. Loneliness	.50**	.35*	.13	.19	.19	-.22	-.32*	-
9. Social support	-.27	-.15	-.21	.15	-.36*	.06	.26	-.67**

N = 40, *p < .05, **p < .01

For depression scores, a negative correlation with large effect size was found for perceived control (r_S = -.65, p < .001, 95% BCa CI [-.81, -.39]). Positive correlations with moderate effect sizes were found for loneliness (r_S = .50, p = .001, 95% BCa CI [.23, .73]) and fatigue (r_S = .43, p = .005, 95% BCa CI [.16, .67]). A medium effect size was also found between presence of other health conditions and depression score (U = 127, z = -2.35, p = .019, r = .36), with depression scores higher among those reporting other health conditions than those who did not report other health conditions (median = 9 and 5 respectively). Medium effect sizes were also found for relationships between depression score and gender (U = 296.5, z = 1.92, p = .055, r = .30), age (H(6) = 4.16, p = .655, ε^2 = .10), shielding status (H(2) = 4.97, p = .083, ε^2 = .12), NYHA class (r_S = .30, p = .058, 95% BCa CI [.03, .56]) and avoidant coping (r_S = .31, p = .050, 95% BCa CI [-.03, .60]), although these were not statistically significant. Small effect sizes were found for relationships between depression scores and marital status (H(4) = 2.56, p = .634, ε^2 = .06) and social support (r_S = -.27, p = .095, 95% BCa CI [-.58, .08]), and a negligible association was found for approach coping (r_S = -.03, p = .838, 95% BCa CI [-.40, .32]).

For anxiety scores, a negative correlation with large effect size was found for perceived control (r_S = -.64, p < .001, 95% BCa CI [-.80, -.36]). A positive correlation with moderate effect size was found for loneliness (r_S = .35, p = .025, 95% BCa CI [.02, .64]). A medium effect size was also found between presence of other health conditions and anxiety score (U = 113, z = -2.55, p = .011, r = .40), with anxiety scores higher among those reporting other health conditions than those who did not report other health conditions (median = 6 and 3 respectively). Medium effect sizes were also found for relationships between anxiety score and marital status (H(4) = 6.91, p = .141, ε^2 = .17) and avoidant coping (r_S = .31, p = .055, 95% BCa CI [-.04, .61]), although these were not statistically significant. Small effect sizes were found for relationships between anxiety scores and gender (U = 272, z = 1.63, p = .104, r = .25), age (H(6) = 2.36, p = .884, ε^2 = .06), shielding status (H(2) = 1.91, p = .384, ε^2 = .05), fatigue (r_S = .25, p = .125, 95% BCa CI [-.08, .57]) and social support (r_S = -.15, p = .342, 95% BCa CI [-.52, .21]). Negligible associations were found between anxiety scores and NYHA class (r_S = .08, p = .590, 95% BCa CI [-.19, .36]) and approach coping (r_S = -.08, p = .638, 95% BCa CI [-.43, .28]).

Discussion

Based on previous literature, Hypothesis 1 predicted that people with HF would have higher rates of psychological distress than controls during the COVID-19 pandemic. However, there were no significant differences in rates of psychological distress among the HF group compared to controls. Hypothesis 2 predicted that psychological distress would be associated with socio-demographic, health, and psychosocial variables in the HF group. Greater levels of depression were found among people who reported lower levels of perceived control, higher levels of fatigue and loneliness, and

presence of other health conditions, with medium-large effect sizes. Moderate effect sizes for relationships between depressive symptoms and gender, age, shielding status, NYHA class and avoidant coping were not statistically significant. Greater levels of anxiety were found among people who reported lower levels of perceived control, higher levels of loneliness, and presence of other health conditions, with medium-large effect sizes. Moderate effect sizes for relationships between anxiety symptoms and marital status and avoidant coping were not statistically significant.

Evaluation and implications

Depression prevalence was higher across both groups (33.9% overall) than previously found in other COVID-19 studies. For example, UK population-based studies from the first COVID-19 lockdown found depression prevalence of 22.1% and 26.1% (O'Connor et al., 2020; Shevlin et al., 2020), consistent across a 6-week period (O'Connor et al., 2020). These studies also used the PHQ-9 with cut-off ≥10 for clinically significant symptoms so differences are not due to measures used. Shevlin et al. (2021) suggest mental health responses to COVID -19 are heterogenous and identified three distinct subgroups of individuals with different trajectories: stability, improvement and deterioration in mental health. Given the later timing of recruitment, it is possible the sample may have been over-represented by the "deterioration" subgroup, with these individuals perhaps more likely to respond to a mental health study than individuals from the "stability" or "improvement" subgroupings.

Anxiety prevalence among the HF group was 14.6%, lower than reported previously (e.g., 28.8% in a meta-analysis by Easton et al. (2016)). Rates of anxiety were higher in the control group (33.3%), although this was not statistically significant. Overall anxiety prevalence was 19.6% which is slightly lower than reported prevalence from early in the COVID-19 pandemic (Daly et al., 2020; O'Connor et al., 2020; Shevlin et al., 2020). Lower anxiety prevalence may be related to the timing of recruitment, although it is unclear why the HF group had lower rates of anxiety in comparison to previous pre-COVID-19 studies. A medium effect size was found for COVID-anxiety in the opposite direction than expected, with 13.3% of controls and 0% of HF participants reporting clinically significant COVID-anxiety. Thus, the perceived threat of COVID-19 and significant changes to healthcare do not seem to have led to increased anxiety among the HF group, with prevalence of both general and COVID-anxiety lower than expected.

Relationships between psychological distress and other related variables were consistent with previous research and with emerging evidence from the COVID-19 pandemic. The medium-large effect sizes found between depressive/anxiety symptoms and perceived control and avoidant coping are in keeping with Leventhal's Common-Sense Model of illness which suggests such factors will

influence psychological adjustment to health threats, such as COVID-19. In addition, loneliness (Creese et al., 2021) and physical multimorbidity (Smith et al., 2020) have been associated with higher levels of poor mental health during the COVID-19 pandemic. These variables warrant further investigation as they may be useful in identifying individuals at-risk of psychological distress and potentially modifiable targets for intervention.

Study strengths and limitations

Our test of the feasibility of using snowball sampling with people with HF resulted in the control group being well-matched on most demographic variables, but sample size (HF group = 42; controls = 15) and gender differed. Reasons for this are unclear as snowball sampling methods have previously been used effectively in health research including with hidden populations such as users of drugs (Lopes et al., 1996). The HF cohort was older than the general population and consequently may have been less likely to share the study online. Similarly, their immediate peers might have unable to access the online questionnaire. Reduced social interactions and shielding measures during COVID-19 may have resulted in decreased opportunities to share the study. HF participants may also have been unwilling to share the study if they had not disclosed HF status to friends. Given the study was explicitly related to HF, some prospective control participants may have chosen not to participate.

Whilst clinicians involved in recruitment were supportive of the study in principle, COVID-related pressures on services negatively impacted on recruitment. The small sample size (particularly for the control group) limits statistical power and results should be interpreted cautiously. Recruitment difficulties also highlight the importance of patient engagement in research and the potential value of including patient and public representatives when designing studies. Medium-large effect sizes were found for some non-significant results suggesting these analyses may have been underpowered and warrant further investigation.

The self-selected nature of the sample may have led to participation bias. A previous representative UK study of newly diagnosed HF patients by Conrad et al. (2019) found mean age of 76.6, whereas most HF participants in this study were aged 35-64 (54.8%). This bias may be partially due to the survey being online as internet use has been found to be lower among older people and those with long-standing illness (Kearns & Whitley, 2019). Given COVID-19 circumstances, an online survey was the most feasible approach but limits generalisability of findings as results may not be representative of the wider HF population. Access to the internet has also been found to be poorer among individuals with mental health problems (Kearns & Whitley, 2019; Too et al., 2020) so individuals most vulnerable to psychological distress during COVID-19 may have been unable to take part.

The self-report nature of HF status is a limitation, as Camplain et al. (2017) previously found low sensitivity of self-reported HF, and poor agreement between self-report and physician-diagnosed HF. HF diagnosis may not be explicitly discussed with patients, leading to lack of knowledge about their HF status (Camplain et al., 2017). Therefore, some eligible individuals may not have taken part due to being unaware of a HF diagnosis. Conversely, some control participants could have had HF but been unaware of this. Self-reported HF was the most feasible option as the survey was anonymous, but may be less reliable than other methods, such as accessing patient records.

This study used widely accepted caseness cut-offs for PHQ-9 and GAD-7 allowing for comparison with other COVID-19 research looking at prevalence of psychological distress. However, there is evidence supporting alternative cut-offs for balancing sensitivity and specificity (e.g., eight for GAD-7 across a range of settings (Plummer et al., 2016) and six for PHQ-9 among cardiac outpatients (Thombs et al., 2008)). Using lower cut-off scores would increase prevalence rates. Further research to validate the PHQ-9 and GAD-7 with HF patients and determine optimal cut-offs for diagnostic accuracy is warranted. Similarly, research using alternative methods such as structured clinical interviews may increase understanding of prevalence rates for depression and anxiety in this population.

This study found low prevalence of COVID-anxiety (3.6%). The CAS is a new measure which has not yet been well-validated, and Lee et al. (2020) found sensitivity of cut-off score ≥9 was below the recommended criterion. A lower CAS cut-off score may be more appropriate for diagnostic accuracy in community-based populations.

Due to the cross-sectional design, it is unknown whether prevalence of psychological distress among HF patients has changed during the COVID-19 pandemic or whether changes have followed the mental health trajectories identified by Shevlin et al. (2021). A longitudinal design was not feasible due to study constraints, but follow-up has been planned with a subsequent project.

Conclusion

This study extended previous research during the COVID-19 pandemic to a HF population. The study found higher depression prevalence (33.9%) and lower anxiety prevalence (19.6%) than previously reported by other HF and COVID-19 studies. There were no significant differences found in rates of psychological distress in the HF group compared to controls. Despite the relatively small sample size, medium-large effect sizes were found in the HF group for relationships between depressive and anxiety symptoms and related variables (such as perceived control, loneliness, and presence of other

health conditions). These factors warrant further investigation as they may be useful in identifying individuals at-risk of psychological distress and potentially modifiable targets for intervention. Planned follow-up should increase our understanding of mental health trajectories and adjustment for people with HF during subsequent phases of the COVID-19 pandemic.

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Appendices

Appendix 1.1: British Journal of Health Psychology Author Guidelines

AIMS AND SCOPE

The British Journal of Health Psychology publishes original research on all aspects of psychology related to health, health-related behaviour and illness across the lifespan including:

- experimental and clinical research on aetiology
- management of acute and chronic illness
- responses to ill-health
- screening and medical procedures
- psychosocial mediators of health-related behaviours
- influence of emotion on health and health-related behaviours
- psychosocial processes relevant to disease outcomes
- psychological interventions in health and disease
- emotional and behavioural responses to ill health, screening and medical procedures
- psychological aspects of prevention

MANUSCRIPT CATEGORIES AND REQUIREMENTS

The types of paper invited are:

- papers reporting original empirical investigations, using either quantitative or qualitative methods, including reports of interventions in clinical and non-clinical populations;
- theoretical papers which report analyses on established theories in health psychology;
- we particularly welcome review papers, which should aim to provide systematic overviews, evaluations and interpretations of research in a given field of health psychology (narrative reviews will only be considered for editorials or important theoretical discourses); and
- methodological papers dealing with methodological issues of particular relevance to health psychology.

Authors who are interested in submitting papers that do not fit into these categories are advised to contact the editors who would be very happy to discuss the potential submission.

Papers describing quantitative research (including reviews with quantitative analyses) should be no more than 5000 words (excluding the abstract, reference list, tables and figures). Papers describing qualitative research (including reviews with qualitative analyses) should be no more than 6000 words (including quotes, whether in the text or in tables, but excluding the abstract, tables, figures and references). In exceptional cases the Editor retains discretion to publish papers beyond this length where the clear and concise expression of the scientific content requires greater length (e.g., explanation of a new theory or a substantially new method). Authors must contact the Editor prior to submission in such a case.

All systematic reviews must be pre-registered. The pre-registered details should be given in the methods section but blinded for peer review (i.e., 'the review was preregistered at [BLINDED]'); the details can be added at proof stage. Registration documents should be uploaded as title page files when possible, so that they are available to the Editor but not to reviewers.

Please refer to the separate guidelines for **Registered Reports**.

COVID-19 Research

The BJHP has received an overwhelming number of COVID-19 related submissions. We can only consider papers that are providing new and novel data on COVID-19. We particularly welcome submissions of intervention studies. Furthermore, rapid peer review for COVID-19 submissions has now ended. COVID-19 papers will now be handled alongside other standard submissions.

PREPARING THE SUBMISSION

Free Format Submission

British Journal of Health Psychology now offers free format submission for a simplified and streamlined submission process.

Before you submit, you will need:

- Your manuscript: this can be a single file including text, figures, and tables, or separate files – whichever you prefer. All required sections should be contained in your manuscript, including abstract, introduction, methods, results, and conclusions. Figures and tables should have legends. References may be submitted in any style or format, as long as it is consistent throughout the manuscript. If the manuscript, figures or tables are difficult for you to read, they will also be difficult for the editors and reviewers. If your manuscript is difficult to read, the editorial office may send it back to you for revision.
- The title page of the manuscript, including a data availability statement and your co-author details with affiliations. *(Why is this important? We need to keep all co-authors informed of the outcome of the peer review process.)* You may like to use this template for your title page.

Important: the journal operates a double-blind peer review policy. Please anonymise your manuscript and prepare a separate title page containing author details. *(Why is this important? We need to uphold rigorous ethical standards for the research we consider for publication.)*

- An ORCID ID, freely available at https://orcid.org. *(Why is this important? Your article, if accepted and published, will be attached to your ORCID profile. Institutions and funders are increasingly requiring authors to have ORCID IDs.)*

To submit, login at **https://www.editorialmanager.com/bjhp/default.aspx** and create a new submission. Follow the submission steps as required and submit the manuscript.
If you are invited to revise your manuscript after peer review, the journal will also request the revised manuscript to be formatted according to journal requirements as described below.

Revised Manuscript Submission

Contributions must be typed in double spacing. All sheets must be numbered.
Cover letters are not mandatory; however, they may be supplied at the author's discretion. They should be pasted into the 'Comments' box in Editorial Manager.

Parts of the Manuscript

The manuscript should be submitted in separate files: title page; statement of contribution; main text file; figures/tables; supporting information.

Title Page

You may like to use **this template** for your title page. The title page should contain**:**

- A short informative title containing the major key words. The title should not contain abbreviations (see Wiley's best practice SEO tips);
- A short running title of less than 40 characters;
- The full names of the authors;
- The author's institutional affiliations where the work was conducted, with a footnote for the author's present address if different from where the work was conducted;
- Abstract;
- Keywords;
- Data availability statement (see Data Sharing and Data Accessibility Policy);
- Acknowledgments.

Authorship

Please refer to the journal's Authorship policy in the Editorial Policies and Ethical Considerations section for details on author listing eligibility. When entering the author names into Editorial Manager, the corresponding author will be asked to provide a CRediT contributor role to classify the role that each author played in creating the manuscript. Please see the **Project CRediT** website for a list of roles.

Abstract

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. As the abstract is often the most

widely visible part of your paper, it is important that it conveys succinctly all the most important features of your study. You can save words by writing short, direct sentences. Helpful hints about writing the conclusions to abstracts can be found **here**.

Keywords

Please provide appropriate keywords.

Acknowledgments

Contributions from anyone who does not meet the criteria for authorship should be listed, with permission from the contributor, in an Acknowledgments section. Financial and material support should also be mentioned. Thanks to anonymous reviewers are not appropriate.

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.

Main Text File

As papers are double-blind peer reviewed, the main text file should not include any information that might identify the authors.

The main text file should be presented in the following order:

- Title
- Main text
- References
- Tables and figures (each complete with title and footnotes)
- Appendices (if relevant)

Supporting information should be supplied as separate files. Tables and figures can be included at the end of the main document or attached as separate files but they must be mentioned in the text.

- As papers are double-blind peer reviewed, the main text file should not include any information that might identify the authors. Please do not mention the authors' names or affiliations and always refer to any previous work in the third person.
- The journal uses British spelling; however, authors may submit using either option, as spelling of accepted papers is converted during the production process.

References

References in published papers are formatted according to the Publication Manual of the American Psychological Association (6th edition). However, references may be submitted in any style or format, as long as it is consistent throughout the manuscript.

Tables

Tables should be self-contained and complement, not duplicate, information contained in the text. They should be supplied as editable files, not pasted as images. Legends should be concise but comprehensive – the table, legend, and footnotes must be understandable without reference to the text. All abbreviations must be defined in footnotes. Footnote symbols: †, ‡, §, ¶, should be used (in that order) and *, **, *** should be reserved for P-values. Statistical measures such as SD or SEM should be identified in the headings.

Figures

Although authors are encouraged to send the highest-quality figures possible, for peer-review purposes, a wide variety of formats, sizes, and resolutions are accepted.

Click here for the basic figure requirements for figures submitted with manuscripts for initial peer review, as well as the more detailed post-acceptance figure requirements.

Legends should be concise but comprehensive – the figure and its legend must be understandable without reference to the text. Include definitions of any symbols used and define/explain all abbreviations and units of measurement.

Colour figures. Figures submitted in colour may be reproduced in colour online free of charge. Please note, however, that it is preferable that line figures (e.g. graphs and charts) are supplied in black and white so that they are legible if printed by a reader in black and white. If an author would prefer to have figures printed in colour in hard copies of the journal, a fee will be charged by the Publisher.

Supporting Information

Supporting information is information that is not essential to the article, but provides greater depth and background. It is hosted online and appears without editing or typesetting. It may include tables, figures, videos, datasets, etc.

Click here for Wiley's FAQs on supporting information.

Note: if data, scripts, or other artefacts used to generate the analyses presented in the paper are available via a publicly available data repository, authors should include a reference to the location of the material within their paper.

General Style Points

For guidelines on editorial style, please consult the **APA Publication Manual** published by the American Psychological Association. The following points provide general advice on formatting and style.

- **Language:** Authors must avoid the use of sexist or any other discriminatory language.
- **Abbreviations:** In general, terms should not be abbreviated unless they are used repeatedly and the abbreviation is helpful to the reader. Initially, use the word in full, followed by the abbreviation in parentheses. Thereafter use the abbreviation only.
- **Units of measurement:** Measurements should be given in SI or SI-derived units. Visit the Bureau International des Poids et Measures (BIPM) website for more information about SI units.
- **Effect size:** In normal circumstances, effect size should be incorporated.
- **Numbers:** numbers under 10 are spelt out, except for: measurements with a unit (8mmol/l); age (6 weeks old), or lists with other numbers (11 dogs, 9 cats, 4 gerbils).

Appendix 1.2: Search strategy

Searches conducted 22.01.2021

Ovid host MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) 1946 to December 17, 2020 N=2182

1. Depression/

2. exp Depressive Disorder/

3. depress*.tw.

4. 1 or 2 or 3

5. Heart Failure/

6. ((heart or cardiac) adj failure).tw.

7. 5 or 6

8. Epidemiologic Studies/

9. exp Cohort Studies/

10. (cohort adj stud*).tw.

11. cohort analy*.tw.

12. (follow up or follow-up).tw.

13. (observational adj stud*).tw.

14. longitudinal.tw.

15. predict*.tw.

16. 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15

17. 4 and 7 and 16

18. limit 17 to English language

Ovid host EMBASE 1947-Present, updated daily N=4449

1. Depression/

2. exp Depressive Disorder/

3. depress*.tw.

4. 1 or 2 or 3

5. Heart Failure/

6. ((heart or cardiac) adj failure).tw.

7. 5 or 6

8. Epidemiologic Studies/

9. exp Cohort Studies/

10. (cohort adj stud*).tw.

11. cohort analy*.tw.

12. (follow up or follow-up).tw.

13. (observational adj stud*).tw.

14. longitudinal.tw.

15. predict*.tw.

16. 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15

17. 4 and 7 and 16

18. limit 17 to English language

EBSCO host CINAHL N=974

S17	S3 AND S6 AND S15 Limiter: English Language
S16	S3 AND S6 AND S15
S15	S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14
S14	T1 predict* OR AB predict*
S13	TI longitudinal OR AB longitudinal
S12	TI (observational N1 stud*) OR AB (observational N1 stud*)
S11	TI (follow up or follow-up) OR AB (follow up or follow-up)
S10	TI cohort analy* OR AB cohort analy*
S9	TI (cohort N1 stud*) OR AB (cohort N1 stud*)
S8	(MH "Prospective Studies+")
S7	(MH "Epidemiological Research+")
S6	S4 OR S5
S5	TI ((heart or cardiac) N1 failure) OR AB ((heart or cardiac) N1 failure)
S4	(MH "Heart Failure+")
S3	S1 OR S2
S2	TI depress* OR AB depress*
S1	(MH "Depression+")

EBSCO host APA PSYCINFO N=930

S16	S3 AND S6 AND S14 Limiter: English Language
S15	S3 AND S6 AND S14
S14	S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13
S13	T1 predict* OR AB predict*
S12	TI longitudinal OR AB longitudinal
S11	TI observational N1 stud* OR AB observational N1 stud*
S10	TI (follow up or follow-up) OR AB (follow up or follow-up)
S9	TI cohort analy* OR AB cohort analy*
S8	TI cohort N1 stud* OR AB cohort N1 stud*
S7	DE "Cohort Analysis" OR DE "Followup Studies" OR DE "Longitudinal Studies" OR DE "Prospective Studies" OR DE "Repeated Measures"
S6	S4 OR S5
S5	TI ((heart or cardiac) N1 failure) OR AB ((heart or cardiac) N1 failure)
S4	DE "Heart Disorders" OR DE "Angina Pectoris" OR DE "Arrhythmias (Heart)" OR DE "Coronary Thromboses" OR DE "Myocardial Infarctions"
S3	S1 OR S2
S2	TI depress* OR AB depress*
S1	DE "Major Depression" OR DE "Anaclitic Depression" OR DE "Dysthymic Disorder" OR DE "Endogenous Depression" OR DE "Late Life Depression" OR DE "Postpartum Depression" OR DE "Reactive Depression" OR DE "Recurrent Depression" OR DE "Treatment Resistant Depression"

Cochrane Library N=513

#1 MeSH descriptor: [Depression] explode all trees

#2 MeSH descriptor: [Depressive Disorder] explode all trees

#3 (depress*):ti,ab,kw (Word variations have been searched)

#4 #1 or #2 or #3

#5 MeSH descriptor: [Heart Failure] explode all trees

#6 ((heart or cardiac) near/1 failure):ti,ab,kw (Word variations have been searched)

#7 #5 or #6

#8 MeSH descriptor: [Epidemiologic Studies] explode all trees

#9 MeSH descriptor: [Cohort Studies] explode all trees

#10 (cohort near/1 stud*):ti,ab,kw (Word variations have been searched)

#11 (cohort analy*):ti,ab,kw

#12 (follow up or follow-up).ti,ab,kw

#13 (observational adj stud*):ti,ab,kw

#14 (longitudinal):ti,ab,kw

#15 #8 or #9 or #10 or #11 or #12 or #13 or #14

#16 #4 and #7 and #15

Appendix 1.3: NHLBI risk of bias assessment tool

Criteria	Yes	No	Other (CD, NR, NA)*
1. Was the research question or objective in this paper clearly stated?			
2. Was the study population clearly specified and defined?			
3. Was the participation rate of eligible persons at least 50%?			
4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants?			
5. Was a sample size justification, power description, or variance and effect estimates provided?			
6. For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?			
7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?			
8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?			
9. Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?			
10. Was the exposure(s) assessed more than once over time?			
11. Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?			
12. Were the outcome assessors blinded to the exposure status of participants?			
13. Was loss to follow-up after baseline 20% or less?			
14. Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?			

*CD, cannot determine; NA, not applicable; NR, not reported

Quality Rating (Good, Fair, or Poor)	
Additional Comments (If POOR, please state why):	

Appendix 1.4: Final quality assessment ratings agreed by primary and secondary rater

Study	Criteria														Total score
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Alosco et al. (2014)	Y	N	NR	Y	N	Y	Y	Y	Y	Y	Y	NA	N	Y	9/13
Brouwers et al. (2014)	Y	Y	Y	Y	N	Y	Y	Y	Y	N	Y	NA	Y	Y	11/13
Carney et al. (2020)	Y	N	NR	Y	N	Y	Y	Y	Y	Y	Y	NA	Y	Y	10/13
Havranek et al. (2004)	Y	N	Y	Y	N	Y	Y	Y	Y	Y	Y	NA	N	Y	10/13
Lossnitzer et al. (2013)	Y	N	Y	Y	N	Y	Y	Y	Y	Y	Y	NA	N	Y	10/13
Lossnitzer et al. (2020)	Y	Y	NR	Y	N	Y	Y	Y	Y	Y	Y	NA	NR	N	9/13
Park & Lee (2020)	Y	N	NR	Y	N	Y	Y	Y	Y	Y	Y	NA	NR	Y	9/13
Park et al. (2006)	Y	N	Y	Y	N	Y	Y	Y	Y	Y	Y	NA	Y	Y	11/13
Park et al. (2011)	Y	N	NR	Y	N	Y	Y	Y	Y	Y	Y	NA	Y	Y	10/13
Park et al. (2014)	Y	N	NR	Y	N	Y	Y	Y	Y	Y	Y	NA	Y	Y	10/13
Shimizu et al. (2014)	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	NA	N	Y	11/13
Turvey et al. (2006)	Y	N	N	Y	N	Y	Y	Y	Y	N	Y	N	NR	Y	8/14
Wirtz et al. (2010)	Y	N	NR	Y	Y	Y	Y	Y	Y	N	Y	NA	NR	Y	9/13

Key: Y = Yes; N = No; NA = Not applicable; NR = Not reported; highlighted items indicate initial discrepancies between raters

Appendix 1.5: Quality assessment full results and record of discrepancy resolution

Study	Criteria													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Alosco et al. (2014)	Y	N/Y	NR/Y	Y	N	Y	Y	Y	Y	Y	Y	NA	N	Y
Brouwers et al. (2014)	Y	Y	Y	Y	N	Y	Y	Y	Y	N/Y	Y	NA	Y	Y
Carney et al. (2020)	Y	N/Y	NR	Y	N	Y	Y	Y	Y	Y	Y	NA	Y	Y
Havranek et al. (2004)	Y	N/Y	NR/Y	Y	N	Y	Y	Y	Y	Y	Y	NA	N/Y	Y
Lossnitzer et al. (2013)	Y	N/Y	NR/Y	Y	N	Y	Y	Y	Y	Y	Y	NA	N	Y
Lossnitzer et al. (2020)	Y	Y	NR	Y	N	Y	Y	Y	Y	Y	Y	NA	NR	N/Y
Park & Lee (2020)	Y	N/Y	NR	Y	N	Y	Y	Y	Y	CD/Y	Y	NA	NR	Y
Park et al. (2006)	Y	N/Y	Y	Y	Y/N	Y	Y	Y	Y	Y	Y	NA	Y	Y
Park et al. (2011)	Y	N/Y	NR	Y	N	Y	Y/N	Y	Y	Y	Y	NA	Y	Y
Park et al. (2014)	Y	N/Y	NR	Y	N	Y	Y/N	Y	Y	Y	Y	NA	Y	Y
Shimizu et al. (2014)	Y	Y	NR/Y	Y	N	Y	Y	Y	Y	Y	Y	NA	N/Y	Y
Turvey et al. (2006)	Y	N/Y	N	Y	N	Y	Y	Y	Y	N/Y	Y	N	Y/NR	Y
Wirtz et al. (2010)	Y	N/Y	NR	Y	Y	Y	Y	Y	Y	N/Y	Y	NA	NR	Y

Key: Y = Yes; N = No; CD = Cannot determine; NA = Not applicable; NR = Not reported; highlighted items indicate discrepancies between raters (primary rating/secondary rating)

Question	Discussion and agreed outcome
2) Was the study population clearly specified and defined?	Discussed that all discrepancies lay with whether study time period had been reported. Raters agreed that 'time period' was necessary in defining the study population. All studies which did not report 'time period' were kept as a 'no' rating.
3) Was the participation rate of eligible persons at least 50%?	Alosco et al. (2014) – Secondary rater agreed that the study did not report how many participants were initial approached. Rating kept as 'not reported'. Havranek et al. (2004), Lossnitzer et al (2013) & Shimizu et al. (2014) – Primary rater agreed that data was reported on number of eligible participants and participation rate was over 50%. Ratings changed to 'yes'.

5) Was a sample size justification, power description, or variance and effect estimates provided?	Park et al. (2006) – Raters agreed that power had been discussed in the study but that power calculations were not reported. Agreed to change this item to a 'no' rating.
7) Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?	Park et al. (2011) & Park et al. (2014) – Follow-up period was shorter than for other included studies (3 months). Raters decided that 3-month follow-up was a sufficient time frame for depression to develop. Ratings kept as 'yes'.
10) Was the exposure(s) assessed more than once over time?	Brouwers et al. (2014), Turvey et al. (2006) & Wirtz et al. (2010) – Raters agreed that exposure(s) were only assessed at baseline, so rating was kept as a 'no'. Park & Lee (2020) – Method was not entirely clear but raters concluded that it was likely the survey packet was distributed at both time points. Rating was changed to a 'yes'.
13) Was loss to follow-up after baseline 20% or less?	Havranek et al. (2004) – Raters agreed 34% of participants were lost to follow-up, rating kept as a 'no' Shimizu et al. (2014) – Raters agreed 26% of participants were lost to follow-up, rating kept as a 'no' Turvey et al. (2006) – Primary rater agreed that it was unclear whether any participants dropped out as study only reported numbers with complete data. Rating was changed to 'not reported'.
14) Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?	Lossnitzer et al. (2020) – Discussion regarding key potential confounding variables. Raters concluded that baseline depression score was a key potential confounding variable and that this had not been controlled for, rating was kept as a 'no'.

Appendix 2.1: Ethical approval correspondence

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

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West of Scotland REC 1
Research Ethics
Clinical Research and Development
Ward 11
Dykebar Hospital
Grahamston Road
Paisley PA2 7DE

Date 12 October 2020
Direct line 0141 314 0212
E-mail WoSREC1@ggc.scot.nhs.uk

Dear Dr White

Study title: **Psychological, physical, and social wellbeing among people with heart failure during the COVID-19 pandemic: a case control, cross-sectional study.**
REC reference: **20/WS/0136**
IRAS project ID: **285203**

The Research Ethics Committee reviewed the above application at the meeting held on 06 October 2020. Miss Elizabeth Hannaford and Professor Hamish McLeod attended to discuss the application.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

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

Number	Condition
1	As the study was anonymised, the Committee was content to there not being a consent form as completing the questionnaires was implied consent. Please confirm the consent form will not be used and remove reference to it in the PIS.
2	Please remove all reference to a Sub-study and Hypothesis 1 and 2 from the documentation as this has been confirmed to be an error. There is no need to change the IRAS form.
3	As agreed at the meeting, please confirm that a lay summary of the study results will be sent to the charities who advertised the study. This will enable participants to review the results if they wish.
4	In the PIS to make it clear that the snowball sampling is optional, please add "Sending details of the study to close friends is optional"

Number	Condition
5	Please change the first line of the advert to state "We are conducting a study to help us understand the impact of COVID-19 on mental health and wellbeing for people with heart failure and to compare them with people who haven't had heart failure" to make it clear there is a comparison.

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

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

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

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

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

Registration of Clinical Trials

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

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

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

You should notify the REC of the registration details. We routinely audit applications for compliance with these conditions.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

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

After ethical review: Reporting requirements

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

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

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

Ethical review of research sites

NHS/HSC Sites

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

Non-NHS/HSC sites (if applicable)

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

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Participant advert]	2.1	21 August 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University of Glasgow Clinical Trials Verification of Insurance]		15 July 2020
IRAS Application Form [IRAS_Form_11092020]		11 September 2020
Other [Screening and contact details request]	2.1	21 August 2020
Other [Snowball sampling request]	1.2	31 July 2020
Other [NHS-NHS confirmation of employment]		03 September 2020
Other [Email of support - BHF]		25 June 2020
Other [Email of support - Cardiomyopathy UK]		17 June 2020
Other [Email of support - CHSS]		24 June 2020
Other [Email of support - Pumping Marvellous]		17 June 2020
Other [Email of support - Scottish Heart Failure Hub]		26 June 2020
Other [Scottish Heart Failure Nurse Forum]		26 June 2020
Participant consent form [Participant Consent Form]	2.1	21 August 2020
Participant information sheet (PIS) [PIS]	2.2	01 September 2020
Research protocol or project proposal [Research protocol]	2.1	21 August 2020
Summary CV for Chief Investigator (CI) [CI CV- Dr White]		
Summary CV for student [Student CV- Elizabeth Hannaford]		20 July 2020
Summary CV for supervisor (student research) [Supervisor CV- Professor McLeod]		29 July 2020
Validated questionnaire [Full questionnaire]	1.5	31 July 2020

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

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

20/WS/0136:	Please quote this number on all correspondence

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

Yours sincerely

Veronika Burgess
Co-ordinator Assistant Research Ethics

On behalf of
Dr Malcolm Booth
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers"

Copy to: Dr Colette Montgomery Sardar
Miss Elizabeth Hannaford
nhsg.NRSPCC@nhs.net

West of Scotland REC 1

Attendance at Committee meeting on 06 October 2020

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Malcolm Booth	Consultant in Anaesthesia and Intensive Care (Chair)	Yes	Chair of Meeting
Dr Katriona Brooksbank	Clinical Trial Manager (Vice Chair)	Yes	
Miss Clodagh Duffy	Pre-Registration Clinical Scientist	Yes	
Dr Ross Fairgrieve	Consultant in Paediatric Anaesthesia and Pain Management	No	
Dr Natasha Fullerton	Consultant Neuroradiologist	Yes	
Mrs Elspeth Fulton	Retired Senior Clinical Research Associate (CRA)	Yes	
Miss Linda Galbraith	Former Management Consultant	No	
Mrs Lynda Hamilton	Retired Manager	Yes	
Dr Peter Hutchison	GP	Yes	
Miss Gemma Kaur	Clinical Pharmacist	Yes	
Mrs Katharine Kilgour	Registered Physiotherapist	Yes	
Dr Derek Manson-Smith	Information Research Consultant (Retired)	Yes	
Mrs Laura Rooney	CRUK Lead Research Nurse	Yes	
Dr Patricia Roxburgh	Medical Oncologist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Kirsty Burt	Senior Co-ordinator
Dr Judith Godden	Scientific Officer

Written comments received from:

Name	*Position*
Dr John D McClure	Statistician

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Miss Elizabeth Hannaford
Trainee Clinical Psychologist
NHS Greater Glasgow & Clyde
Gartnavel Royal Hospital
Admin Building, 1st Floor
1055 Great Western Road
G12 0XH

West of Scotland REC 1
West of Scotland Research Ethics Service
Ward 11
Dykebar Hospital
Grahamston Road
Paisley PA2 7DE
www.nhsggc.org.uk
Date 26 October 2020
Direct line 0141-314-0212
e-mail WosRec1@ggc.scot.nhs.uk

Dear Miss Hannaford

Study title: **Psychological, physical, and social wellbeing among people with heart failure during the COVID-19 pandemic: a case control, cross-sectional study.**
REC reference: **20/WS/0136**
IRAS project ID: **285203**

Thank you for your letter of 20 October 2020. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 12 October 2020.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Participant advert (clean)]	2.2	15 October 2020
Copies of advertisement materials for research participants [Participant advert (track changes)]	2.2	15 October 2020
Participant information sheet (PIS) [PIS (track changes)]	2.3	15 October 2020
Participant information sheet (PIS) [PIS (clean)]	2.3	15 October 2020
Research protocol or project proposal [Research protocol (clean)]	2.2	16 October 2020
Research protocol or project proposal [Research protocol (track changes)]	2.2	16 October 2020
Response to Additional Conditions Met [REC conditions cover letter]		20 October 2020

Approved documents

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

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Participant advert (clean)]	2.2	15 October 2020
Copies of advertisement materials for research participants [Participant advert (track changes)]	2.2	15 October 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University of Glasgow Clinical Trials Verification of Insurance]		15 July 2020
IRAS Application Form [IRAS_Form_11092020]		11 September 2020
Other [Screening and contact details request]	2.1	21 August 2020
Other [Snowball sampling request]	1.2	31 July 2020
Other [NHS-NHS confirmation of employment]		03 September 2020
Other [Email of support - BHF]		25 June 2020
Other [Email of support - Cardiomyopathy UK]		17 June 2020
Other [Email of support - CHSS]		24 June 2020
Other [Email of support - Pumping Marvellous]		17 June 2020
Other [Email of support - Scottish Heart Failure Hub]		26 June 2020
Other [Scottish Heart Failure Nurse Forum]		26 June 2020
Participant information sheet (PIS) [PIS (clean)]	2.3	15 October 2020
Participant information sheet (PIS) [PIS (track changes)]	2.3	15 October 2020
Research protocol or project proposal [Research protocol (clean)]	2.2	16 October 2020
Research protocol or project proposal [Research protocol (track changes)]	2.2	16 October 2020
Response to Additional Conditions Met [REC conditions cover letter]		20 October 2020
Summary CV for Chief Investigator (CI) [CI CV- Dr White]		
Summary CV for student [Student CV- Elizabeth Hannaford]		20 July 2020
Summary CV for supervisor (student research) [Supervisor CV- Professor McLeod]		29 July 2020
Validated questionnaire [Full questionnaire]	1.5	31 July 2020

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

IRAS Project ID: 285203 **Please quote this number on all correspondence**

Yours sincerely

Kirsty Burt
Senior Co-ordinator

Copy to: Dr Naomi White, University of Glasgow
Dr Colette Montgomery Sardar
Lead Nation

Elizabeth Hannaford (PGR)

From: New IRAS Dev <no-reply-iras@hra.nhs.uk>
Sent: 17 December 2020 13:36
To: e.hannaford.2@research.gla.ac.uk
Subject: IRAS 285203. Amendment

IRAS Project ID: 285203
Sponsor amendment reference: GN20CA363Amend1

Thank you for submitting your study amendment. In accordance with the outcome of your completed amendment tool, this amendment requires no further regulatory review. Please now share this amendment with your UK research sites, in accordance with the instructions in your completed amendment tool.

For studies with more than one UK research site, your amendment will now be automatically shared with the R&D offices of any NHS/HSC research sites in Scotland and Northern Ireland, but you should share the amendment by email directly with those Research team/s.

For all NHS research sites in England and Wales, please now share this amendment by email directly with those sites, including both the R&D offices and research teams.

Do not reply to this email as this is an unmonitored address and replies to this email cannot be responded to or read.

Appendix 2.2: NHSGG&C R&D approval

Senior Research Administrator: Kayleigh McKenna
Telephone Number: 0141 314 4000
E-Mail: Kayleigh.mckenna@ggc.scot.nhs.uk
Website: https://www.nhsggc.org.uk/about-us/professional-support-sites/research-innovation

Research & Innovation
Dykebar Hospital, Ward 11
Grahamston Road
Paisley, PA2 7DE
Scotland, UK

23/11/2020

Miss Elizabeth Hannaford,
NHS Greater Glasgow and Clyde
Gartnavel Royal Hospital
1055 Great Western Road
G12 0XH

NHS GG&C Board Approval

Dear Miss Hannaford,

Study Title:	Psychological, physical, and social well-being among people with heart failure during the COVID-19 pandemic: a case control, cross-sectional study
Principal Investigator:	Miss Elizabeth Hannaford
GG&C HB site	Patients homes
Sponsor	NHS Greater Glasgow and Clyde
R&I reference:	GN20CA363
REC reference:	20/WS/0136
Protocol no: (including version and date)	v2.2 dated 16.10.20

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. Researchers must follow NHS GG&C local policies, including incident reporting.

2. **For all studies** the following information is required during their lifespan.
   a. First study participant should be recruited within 30 days of approval date.
   b. Recruitment Numbers on a monthly basis
   c. Any change to local research team staff should be notified to R&I team

d. Any amendments – Substantial or Non Substantial
e. Notification of Trial/study end including final recruitment figures
f. Final Report & Copies of Publications/Abstracts
g. You must work in accordance with the current NHS GG&C COVID19 guidelines and principles.

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,

Kayleigh McKenna
Senior Research Administrator

Appendix 2.3: NHS Board Approvals

NHS Board Approvals for IRAS 285203 GN20CA363

	NHS Board	Board Decision	Date of Board Decision	PIC Agreement Finalised with NHS GG&C	Recruitment Start Approved by Sponsor
1	Ayrshire & Arran	Approved as PIC	03/12/2020	Yes	Yes 11/12/2020
2	Borders	Withdrawn as per email of 18/01/2021			
3	Dumfries & Galloway	Approved as PIC	20/11/2020 (CMS unaware)	Yes	Yes 27/04/2021
4	Fife	Approved as PIC	04/02/2021	Yes 03/02/2021	Yes 04/02/2021
5	Forth Valley	Approved as PIC	21/01/2021	Yes 21/01/2021	Yes 21/01/2021
6	Highland	Approved as PIC	18/12/2020	Yes 25/01/2021	Yes 25/01/2021
7	Grampian	Withdrawn as per email of 19/01/2021			
8	Greater Glasgow & Clyde	Approved as lead board	23/11/2020	Not applicable	Yes 11/12/2020
9	Lanarkshire	Approved as PIC	22/12/2020	Yes 22/12/2020	Yes 05/01/2021
10	Lothian	Approved as PIC	23/11/2020	Yes 03/02/2021	Yes 04/02/2021
11	Orkney	Approved as PIC	14/09/2020	Yes 26/01/2021	Yes 26/01/2021
12	Shetland	No response – re-sent 26/01/2021			
13	Tayside	Not required – not acting as PIC	27/11/2020	Not required	Yes 11/12/2020
14	Western Isles	Approved as PIC 04/03/2021	04/03/2021	Yes 25/03/2021	Yes 25/03/201
15	Golden Jubilee National Hospital	Approved as PIC	12/01/2021	Yes 27/01/2021	Yes 28/01/2021

Appendix 2.4: Study advertisement

Research participants wanted

University of Glasgow

NHS Greater Glasgow and Clyde

We are conducting a study to help us understand the impact of COVID-19 on mental health and wellbeing for people with heart failure and to compare them with people who haven't had heart failure.

We are recruiting participants for an online survey looking at psychological, physical, and social wellbeing during the COVID-19 pandemic among people with heart failure compared to people who do not have heart failure. This study aims to better understand the mental health impact of COVID-19 for people with heart failure and improve healthcare services in future.

Criteria: You need to have a diagnosis of heart failure or have been sent details of the study by a friend who has heart failure. You don't need to have experienced mental health problems to take part, but we welcome participants who have. To take part you must be 18 years old or above, currently reside in Scotland, understand written English and have the technology and ability to access an online survey.

What's involved? Completing an online survey of questions about your wellbeing during the pandemic (about 10-15 minutes to complete). Your answers will be anonymous. If you have heart failure, you will be asked to send details of the study to 2-3 close friends. This is so we can compare wellbeing among people with and without heart failure. We will ask if you are willing to be contacted for future study follow-up.

When? Now! Recruitment is ongoing. For more information about taking part and to complete the survey, please visit: https://glasgow-research.onlinesurveys.ac.uk/heart-failure-survey

If you have any questions, please contact the lead researcher (Elizabeth Hannaford) on e.hannaford.2@research.gla.ac.uk.
This study has been reviewed by the University of Glasgow DClinPsy Programme.
The study is sponsored by NHS Greater Glasgow and Clyde and has received ethical approval from West of Scotland Research Ethics Committee 1 (reference number: 20/WS/0136).

Version 2.2 15.10.2020

Appendix 2.5: Participant information sheet

Version 2.3 15.10.2020

A research project investigating mental health and predictors of psychological distress among people with heart failure during the COVID-19 pandemic.

Participant Information Sheet

We would like to invite you to participate in a research project. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. You should only participate if you want to, choosing not to take part will not disadvantage you in any way. Please take time to read the following information carefully. Talk to others about the study if you wish. You can contact the researcher, Elizabeth Hannaford (e.hannaford.2@research.gla.ac.uk), if there is anything that is not clear or if you would like more information.

What is the purpose of the project?

The purpose of the project is to investigate mental health and wellbeing during the COVID-19 pandemic among people with heart failure compared to individuals who do not have heart failure. We are interested in your psychological, physical, and social wellbeing during the COVID-19 pandemic. Completing this research may help us to understand the mental health impact of a pandemic situation for people with heart failure, and the influence of other factors which are associated with mental health and wellbeing.

Why have I been invited to take part?

You are being invited to participate in this project as you have a diagnosis of heart failure or you have been sent details of the study by a friend. You are eligible to take part if you are aged 18 years old or above, currently reside in Scotland, understand English, and are able to complete an online survey.

Do I have to take part?

No, participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in any way. If you decide to take part, you are free to withdraw at any time and without giving a reason. Withdrawal from the study will not affect the treatment you receive from the NHS or your legal rights in any way. If you do not want data you have already entered to be included, you should withdraw from the study without completing the survey or submitting your survey data. As your responses are anonymous it will not be possible to exclude survey data once you have submitted the survey.

What will happen if I take part?

If you choose to take part, you will be asked to complete an online questionnaire about your psychological, physical, and social wellbeing during the COVID-19 pandemic. This will take approximately 10-15 minutes to complete. If you have heart failure, you will be asked to send on

details of the study to 2-3 close friends who do not live in the same household as yourself. This is so we can compare mental health and wellbeing during COVID-19 among people with heart failure and individuals who do not have heart failure. Sending details of the study to close friends is optional. If you are willing to be contacted about further study follow-up in the future, you will also be asked to provide your name and email address. Providing contact details is optional.

What are the possible benefits and risks of taking part?

You will receive no direct benefit from taking part in this study, although it is hoped that by taking part in this research you will be providing valuable information regarding psychological, physical, and social wellbeing during the COVID-19 pandemic. If you wish, you can also receive a summary report describing the main findings from this study. This is optional, and you do not have to be sent any additional information regarding this study in the future if you do not want to.

There are no major risks involved in taking part in this study. It is important to know that some of the questions you will be asked are related to your current mood and physical health. The questions about your mood are for research purposes only and could not be used to diagnose difficulties. The questions do not require detailed answers (all are multiple choice) but you may find thinking about your mood or physical health stressful or difficult. If you do not feel comfortable answering a question, you can leave it blank and move on to the next one. If you feel distressed during the study and wish to withdraw your participation, you may do so at any point. You may also wish to seek support from your GP, Breathing Space helpline (0800 83 85 87) or Samaritans helpline (116 123, jo@samaritans.org).

Will my information be confidential?

All the information you provide will be treated confidentially. To safeguard your rights, we will use the minimum personally identifiable information possible. If you would like to be contacted for future follow-up of this study, we will ask you to provide your email address. This information will be stored separately from the questionnaire data in a password-protected file and only members of the research team will have access to this information.

What will happen to my data?

NHS GG&C is the sponsor for this study based in Scotland We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Data will be stored on a secure, password protected file on University of Glasgow servers. You will not be identifiable from the data you provide. Your email address will be stored separately from the rest of your data and will not be shared with any third parties. It will only be used for purposes you have explicitly agreed to (i.e. to be contacted for study follow-up in the future or to receive a summary report of the study).

The data will be stored in archiving facilities in line with the University of Glasgow retention policy of up to 10 years. After this period, further retention may be agreed or your data will be securely destroyed in accordance with the relevant standard procedures.

Your rights to access, change or move the information we store are limited, as the data are stored anonymously so cannot be linked to you. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible. You can find out more about how we use your information from Elizabeth Hannaford

Researchers from the University of Glasgow collect, store and process all personal information in accordance with the General Data Protection Regulation (GDPR) (2018).

Your data will form part of the study results that will be published in expert journals, presentations, student theses and on the internet for other researchers to use. Your name will not appear in any publication.

What will happen to the results of the project?

On completion of the full research project, the report will be submitted to the University of Glasgow as part fulfilment of a Doctorate in Clinical Psychology. This will be published on the University of Glasgow's research repository (Enlighten) in 2021. The results will be disseminated within NHS Cardiac services to help inform service delivery. It is hoped that the results will also be published in a relevant academic journal and through other routes to ensure that the general public are also aware of the findings. You will not be identified in any report/publication arising from this study.

Who has reviewed the study?

This study has been reviewed by staff members on the University of Glasgow DClinPsy Programme and approved by West of Scotland Research Ethics Committee 1 (reference number: 20/WS/0136).

Who should I contact for further information?

If you require any further information or have any questions, please feel free to contact a member of the research team.

Researcher: Lizzie Hannaford –

University supervisor: Dr Naomi White – naomi-white@glasgow.ac.uk

University supervisor: Prof Hamish McLeod – hamish.mcleod@glasgow.ac.uk

NHS field supervisor: Dr John Sharp – johnsharp@nhs.net

Alternatively, you can speak to someone who is independent of the study who can answer questions or give advice.

Independent contact: Prof Andrew Gumley – andrew.gumley@glasgow.ac.uk

What if I have a complaint about any aspect of the study?

If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance. You can also contact the Research Director for the DClinPsy Programme, Dr Breda Cullen (breda.cullen@glasgow.ac.uk). The normal NHS complaint mechanisms are also available to you.

Thank you for reading this information sheet and for considering taking part in this research.

Appendix 2.6: Major research project proposal

Title: Mental health and predictors of psychological distress among people with heart failure during the COVID-19 pandemic: a case control, cross-sectional study.

Abstract

Background

Psychological distress is common among people with heart failure (HF). The coronavirus (COVID-19) pandemic is likely to significantly impact on mental health and wellbeing. People with HF have increased vulnerability to COVID-19 and may be at increased risk of psychological distress. Several related factors, such as fatigue and social support, may be predictors of psychological adjustment among people with HF during the COVID-19 pandemic.

Aims

The primary aim of this study is to describe and examine rates of psychological distress and adjustment among people with HF compared to controls during the COVID-19 pandemic. The study will also investigate which variables predict psychological distress among both groups. An exploratory sub-study will track changes in psychological distress more frequently, enabling investigation of daily fluctuations in distress and exploration of potential causal relations among related variables.

Methods

The study will use a case-control, cross-sectional design. Participants with HF and controls will complete an online questionnaire consisting of several measures (socio-demographic, physical health, COVID-19 related, psychological distress and psychosocial). An exploratory sub-study will follow a small number of participants with HF in greater depth for one week using daily Ecological Momentary Assessment.

Applications

The study will increase understanding of the mental health impact of a pandemic situation among a vulnerable group, namely people with HF. Identifying predictors of psychological distress may help to inform clinical assessment and development of interventions to improve mental wellbeing.

Introduction

Since January 2020, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) which causes coronavirus disease 2019 (COVID-19) has spread rapidly across the world. In the UK, the first case of COVID-19 was diagnosed in January 2020 and community transmission has since led to a rapid increase in cases (see McBride et al. (2020) for timeline). This has resulted in extraordinary changes to life and working practices in the UK. Schools, restaurants, and non-essential shops have been closed, and people have been told to stay at home and avoid non-essential travel and contact with others (Public Health England, 2020a).

Whilst research is still emerging, people with heart failure (HF) could be particularly vulnerable to COVID-19 as they may have reduced cardiovascular functional reserve and the COVID-19 infection may precipitate a myocardial infarction or increase metabolic demand (Tan and Aboulhosn, 2020). They have therefore been advised to be particularly careful in trying to minimise the risk of contracting COVID-19 (Pumping Marvellous, 2020; Scottish Government, 2020). In addition, particularly high-risk individuals with HF have been advised to 'shield' by staying at home at all times and avoiding all face-to-face contact for at least twelve weeks (Public Health England, 2020b). Reduced social contact and worries about practical issues such as finances, obtaining food supplies and accessing medical care are likely to have an additional impact on mental health. Consequently, Holmes et al. (2020) argue research investigating the mental health impact of the COVID-19 pandemic and how this can be mitigated should be an immediate priority, including the impact for vulnerable groups, such as people with HF.

Prior to the COVID-19 pandemic, psychological distress had previously been found to be common among patients with HF (Holly and Sharp, 2012). In line with previous research, this study will define psychological distress as a 'state of emotional suffering characterized by symptoms of depression and anxiety (Drapeau et al., 2012). Previous research looking at prevalence rates for depression and anxiety disorders among people with HF have found them to be higher than in the general population (Celano et al., 2018). Previous meta-analyses estimate around 21.5% of patients with HF have clinically significant symptoms of depression (Rutledge et al., 2006) and 28.8% have clinically significant levels of anxiety (Easton et al., 2016). Psychological distress among patients with HF is associated with adverse health outcomes including increased mortality, morbidity and use of healthcare resources (Celano et al., 2018; Holly and Sharp, 2012). Vulnerable groups, such as people with HF, may also be at increased risk of psychological distress during the COVID-19 pandemic due to factors such as increased health- and finance-related anxieties, social isolation and disrupted access to health and social care services (Brooks et al., 2020; Holmes et al., 2020; Scottish Government, 2020). Thus, people with HF may represent an at-risk group for psychological distress during the COVID-19 pandemic.

Evidence from previous outbreaks of infectious respiratory diseases suggests psychological distress may persist, or even worsen, over time (Brooks et al., 2020; Gardner and Moallef, 2015; McBride et al., 2020). As lockdown restrictions begin to lift, some individuals may experience a more chronic stress response with persistent difficulties with symptoms of low mood and/or anxiety. Previous research looking at psychological outcomes following traumatic events, including disease outbreaks, suggests psychological adjustment is influenced by a number of factors – such as age, gender, education, income change, physical health, level of trauma exposure, fear of the disease, social support and coping style (Bonanno et al., 2007; Polizzi et al., 2020; Xu et al., 2011). Initial reports from research into COVID-19 among the general population suggest that symptoms of depression and anxiety spiked after lockdown restrictions were introduced, and that higher rates of anxiety and depression were associated with a number of factors, including presence of an underlying health condition (COVID-19 Psychological Research Consortium (C19PRC), 2020). The network approach to mental health posits that psychopathology arises from, and is maintained by, networks of causally connected and interacting symptoms (Borsboom, 2017; Fried and Cramer, 2017). Fried et al. (2020) used dynamic network models to investigate mental health during the initial stages of the COVID-19 pandemic and identified negative reinforcing cycles of loneliness, mental health problems and COVID-19 related worries.

Holmes et al. (2020) suggest that COVID-19 related research should investigate underlying mechanisms and possible predictors of psychological distress and adjustment. This may help to inform both our understanding of maintenance and/or remission of psychological distress and the development of interventions to improve mental wellbeing (Holmes et al., 2020). For people with HF, research suggests specific factors are associated with increased risk of psychological distress and reduced likelihood of psychological adjustment over time. Leventhal's Common-Sense Model (CSM) of illness posits that when a threat is perceived, individuals develop cognitive and emotional representations of this which directly influence coping responses and subsequent outcomes (Leventhal et al., 2003). Based on this model, factors such as severity of illness, perceived control and coping style influence psychological adjustment to health threats, such as the current COVID-19 pandemic.

Psychological distress has previously been associated with sociodemographic characteristics (such as age, sex, and employment status) (Holly and Sharp, 2012; Scherer et al., 2007), number of physical and emotional problems (Holly and Sharp, 2012; Scherer et al., 2007), greater severity of HF (Scherer et al., 2007), fatigue (Yu et al., 2004), avoidant coping and pessimism (Trivedi et al., 2009). Conversely, living with a partner and high levels of social support appear to be protective for patients with HF, and increase the likelihood and speed with which psychological distress reduces over time (Koenig, 1998; Scherer et al., 2007; Trivedi et al., 2009; Yu et al., 2004). Thus, previous findings in

relation to psychological adjustment to disease outbreaks and among people with HF suggest that a number of sociodemographic, health and psychosocial factors may be significant predictors of psychological distress for people with HF during the COVID-19 pandemic.

Aims

The primary aim of this study is to describe and examine rates of psychological distress and adjustment among people with HF compared to controls during the COVID-19 pandemic. The study will also investigate which variables predict psychological distress among both groups. An exploratory sub-study will track changes in psychological distress more frequently, enabling investigation of daily fluctuations in distress and exploration of potential causal relations among related variables.

Hypotheses

1. Assuming COVID-19 restrictions are prolonged for vulnerable individuals, psychological distress will be higher among people with HF compared to controls.
2. Psychological distress will be associated with a number of variables among people with HF and controls, such as socio-demographic (age, gender, marital status, household composition), COVID-19 (anxiety, shielding), health (presence of HF, HF severity, total number of physical and emotional problems, fatigue) and psychosocial factors (coping style, perceived control, social support, loneliness).

Plan of Investigation

Participants and recruitment procedure

Participants diagnosed with HF will be recruited through links with the Heart Failure Hub Scotland and national advocacy groups, such as Cardiomyopathy UK, Pumping Marvellous and Chest Heart Stroke Scotland. Individuals with HF will be invited to take part in the study through advertising within these services via social media networks and email databases where individuals have given permission to be contacted about relevant research. Through the HF Hub Scotland, HF clinicians will be informed of the study and invited to support recruitment. This may involve HF nurses being invited to pass on study information to patients. A snowball sampling method (Goodman, 1961) will be used to recruit control participants. Snowball sampling has previously been used effectively in health research for case-control designs (LOPES et al., 1996; Rezaei et al., 2011) and has the advantage of increasing the likelihood of recruiting demographically matched samples. Participants with HF will be asked to pass on details of the comparison survey to 2-3 close friends who do not live within the same household; these individuals will be used as controls. Potential participants will be provided with an information sheet and complete a set of short screening questions to ensure they meet the inclusion/exclusion criteria.

Inclusion and exclusion criteria

Participants will be aged 18 or over, able to understand English and resident of the UK. Participants must have the technology and ability to complete the questionnaire online. Participants who wish to take part in the exploratory sub-study will need to have access to a smartphone using Android or iOS operating systems for the SEMA3 software.

Measures

Questionnaire

Socio-demographic: Information will be collected regarding age, gender, ethnicity, area of residence, marital status, and household composition (number of adults and children under 18 years).

Physical health: Participants will be asked to report any medical conditions. HF severity will be measured using the self-assigned New York Heart Association classification scale (SA-NYHA) (Holland et al., 2010). The 4-point NYHA scale is used worldwide in clinical and research practice to measure functional status, with higher scores indicating greater symptom severity and limitations to functioning.

Fatigue will be measured using the 9-item Fatigue Severity Scale (FSS) (Krupp et al., 1989). The FSS was designed to assess fatigue in chronic health conditions. Higher scores indicate more severe fatigue. The FSS has demonstrated good psychometric properties for research into a variety of chronic health conditions (Whitehead, 2009).

COVID-19: The 5-item Coronavirus Anxiety Scale (CAS) will be used to assess COVID-related anxiety. Higher scores indicate greater anxiety, with CAS scores ≥9 indicative of dysfunctional levels of anxiety (Lee, 2020). Participants will also be asked whether they have been advised to shield at home during COVID-19.

Psychological distress: The 9-item Patient Health Questionnaire (PHQ-9) (Spitzer et al., 1999) will be used to measure symptoms of depression. Scores range from 0-27 and higher scores indicate greater severity of depression. Symptoms of anxiety will be measured using the 7-item Generalised Anxiety Scale (GAD-7) (Spitzer et al., 2006). GAD-7 scores range from 0-21 with higher scores indicating higher levels of anxiety. Both the PHQ-9 and GAD-7 are well-validated (Kroenke et al., 2001; Rutter and Brown, 2017), recommended in cardiac care for assessment of psychological wellbeing (Scottish Intercollegiate Guidelines Network (SIGN), 2017) and used routinely within heart failure services.

Psychosocial: Coping style will be measured using 6 items from the Brief-COPE questionnaire (Carver, 1997). Consistent with previous research among patients with HF (Eisenberg et al., 2012),

coping responses will be grouped into two overarching categories – approach coping (active coping, positive reframing, and acceptance subscales) and avoidant coping (denial, substance use and behavioural disengagement subscales). Higher scores indicate a stronger likelihood to adopt the coping style. The Brief COPE has been validated among participants responding to a wide range of adversities, including natural disasters and physical conditions (Carver, 1997; Eisenberg et al., 2012).

Perceived control will be measured using the 7-iten Personal Mastery Scale (PMS) (Pearlin and Schooler, 1978) which assesses the extent to which one believes that one can control life events and circumstances. Higher overall scores indicate a greater sense of mastery. The PMS has strong structural validity (Pearlin and Schooler, 1978) and has previously been used in cardiac-related research (Roepke and Grant, 2011).

Social support will be measured using the 7-item ENRICHD Social Support Inventory (ESSI). The ESSI was developed by identifying items predictive of mortality in cardiovascular patients and comprises items on structural, instrumental, and emotional support (Mitchell et al., 2003). Individual items are summed with higher scores indicating greater social support. The scale has demonstrated concurrent and predictive validity and test-retest reliability within cardiac populations (Mitchell et al., 2003; Vaglio Jr et al., 2004).

Loneliness will be assessed using the 3-item UCLA Loneliness Scale (Hughes et al., 2004). Scores range from 3-9 with higher scores indicating greater feelings of loneliness. The scale has shown satisfactory internal consistency, and convergent and discriminant validity among community-based populations (Hughes et al., 2004; Rico-Uribe et al., 2016).

Ecological Momentary Assessment (EMA)

The EMA will include 10 items to assess psychological wellbeing, health-related stress, and COVID-19 stress. Participants will be asked how often, over the last three hours, they have experienced specific symptoms of depression and anxiety using a modified version of the PHQ-4 (Kroenke et al., 2009). Six items adapted from Fried et al. (2020) related to tiredness, loneliness, social interaction, physical health concerns of self and family/friends, and COVID-19 related pre-occupation will also be included.

Design

The study will take a case-control, cross-sectional design to investigate rates of psychological distress and related variables among people with HF and controls during the COVID-19 pandemic. An exploratory sub-study will follow a small number of participants with HF in greater depth four times per day for a week, allowing changes in psychological wellbeing and COVID-19 or health-related

stress to be tracked through EMA (Shiffman et al., 2008). There may also be potential for longitudinal follow-up in future.

Research procedures

Participants will be asked to complete an online questionnaire consisting of the measures described above. The questionnaire will take an estimated 10-15 minutes to complete. Control participants will not be asked to complete HF-related questions; all other aspects of the questionnaire will be identical. Participants will be asked to provide an email address if they would be willing to be contacted about future study follow-up.

Participants with HF will be asked if they would also be willing to take part in an exploratory EMA sub-study. Previous EMA research suggests that studies assessing highly variable constructs, such as mood, should be measured multiple times per day (Kirtley et al., 2019) and that completion rates tend to decline over time (Ono et al., 2019; Rintala et al., 2020). In line with Fried et al. (2020), participants will therefore be asked to complete the EMA survey of psychological wellbeing and health/COVID-19 related stressors four times daily. To reduce participant burden, participants will be asked to complete these surveys for one week only and surveys will take under two minutes to complete. Participants will receive a push notification prompt asking them to complete the EMA survey at set times of the day (noon, 3pm, 6pm and 9pm). Participants will have 60 minutes to respond to the prompt before it expires.

Data analysis

Descriptive statistics will be used to summarise participant characteristics and study variables. Psychological distress will be defined by caseness (i.e., whether clinically significant symptoms of anxiety and/or depression are present). For hypothesis 1, in line with Lesman-Leegte et al. (2009), between-group differences in dichotomised depressive and anxious symptoms will be analysed using chi-square test. For hypothesis 2, in line with Scherer et al. (2007), logistic regression analyses will be used to identify predictors of psychological distress among both people with HF and controls. Stepwise backward elimination will be used to remove variables with $p>0.05$ as the level for removing effects.

For the exploratory sub-study, slopes of the EMA variables will be investigated to explore whether items changed over time. Following Fried et al. (2020), two-step multilevel vector auto-regression will be used to estimate dynamic network models with all variables at a given timepoint regressed on variables of the previous assessment. The network models will be visualised in graphs containing nodes (variables) and edges (statistical relationships) with stronger relations indicated by thicker edges.

Justification of sample size

A previous case control study by Lesman-Leegte et al. (2009) found that 39% of elderly patients with HF experienced clinically significant depressive symptoms compared to 21% of age- and gender-matched community controls. In addition, research suggests that rates of psychological distress have increased during the COVID-19 pandemic in the general population with 27.75% of participants reporting clinically significant symptoms of depression and/or anxiety (Shevlin et al., 2020). Based on Lesman-Leegte et al.'s (2009) study, G* Power (Faul et al., 2009) was used to estimate sample size for between-group effects and indicated a required sample of 90 per group (N = 180) ($\alpha = 0.05$, $\beta = 0.80$).

Guidelines from Bujang et al. (2018) on logistic regression in clinical research suggest that a rule of thumb of 10 events per variable (EPV) is appropriate for logistic regression using stepwise analysis. They propose a sample size formula of $n = 100 + xi$ (where x is EPV and i represents number of independent variables). With 14 possible predictors, this study would therefore need a minimum of 240 participants. Previous research looking at predictors of psychological distress among patients with HF, Scherer et al. (2007) investigated 16 variables longitudinally and found that four factors (baseline distress, emotional problems, social support and NYHA classification) independently predicted distress at follow-up. Using this paper, G* Power (Faul et al., 2009) was used to estimate sample size for logistic regression with multiple covariates ($\alpha = 0.05$, $\beta = 0.95$, assumed event rate at baseline = 0.3). This indicated a required sample size of between 89 and 263 based on odds ratios between 0.54 and 5.51 (as found in Scherer et al. (2007)). Using the more conservative estimate, this study will therefore aim to recruit 263 participants.

As far as the researchers are aware, EMA studies among people with HF have not previously been undertaken. Given the exploratory nature of this sub-study, all participants with HF will be invited to take part. Participation and compliance rates for EMA will be described to aid sample size estimations for future research.

Settings and Equipment

Data collection will occur through an online questionnaire hosted through the JISC Online Surveys tool which is compatible for both computer and smartphone devices. EMA data will be collected by participants downloading the SEMA3 smartphone app. Equipment required will be an encrypted computer to store data and access to SPSS and R software for data analysis.

Health and safety issues

Participants will be asked questions related to their current mood and a range of other psychological variables. There is a risk that this may be difficult and cause distress for some individuals. Potential

participants will be fully informed of this in the participant information sheet before they agree to participate. They will be told that questions which relate to their mood are for research purposes only and are not diagnostic. Participants will be informed that if they feel distressed during the study and wish to withdraw their participation, they may do so at any point. In addition, participants will be advised that they may wish to contact their GP, Breathing Space or the Samaritans if feel they require further assistance. No practical risks are anticipated as data collection will take place online.

Ethical issues

Participation in the study will be voluntary and there will be no cost, reimbursement, or compensation for taking part. Potential participants will be given the opportunity to contact the researcher if they have questions about taking part in the study. Participants will also be told they are free to withdraw from the study at any time and can leave questions blank if desired. Participants will complete the questionnaire online so will not provide written consent to participate. Instead, potential participants will be asked to complete an online consent page to confirm they consent to take part in the study.

Participants will be asked to provide an email address if they would be willing to take part in the EMA sub-study or future study follow-up. This information will be stored securely and separately from the data collected and no other personal identifiable data will be collected. Once collected, data will be anonymised to protect participant confidentiality. Dummy identifiers will be assigned to allow linkage with follow-up data. Data will be processed and stored in accordance with the General Data Protection Regulation (2018) and NHS GG&C policies. Participants will be informed of this before taking part.

The study will recruit participants through links with the Heart Failure Hub Scotland and national advocacy groups. Since the project will constitute an NHS research project, ethical approval will be sought from the NHS ethics committee.

Timetable

Final proposal – May 2020
Final approved proposal and ethics application – June 2020
Data collection – Summer 2020
Data analysis and write-up – Autumn 2020 – Spring 2021
Final MRP submission – July 2021
Viva – September 2021

Practical Applications

The study will increase understanding of the mental health impact of a pandemic situation, specifically COVID-19, among a vulnerable group, namely people with HF. It will help to clarify whether this

population represents an at-risk group in need of additional targeted mental health support. Reducing psychological distress is particularly pertinent among people with HF given the previously established link between distress and poor health outcomes. Identifying predictors of psychological distress may help to inform clinical assessment in terms of key factors related to risk of distress. The study may be useful in informing the development of interventions to improve mental wellbeing. For instance, interventions which focus on increasing social support or help people with HF to manage fatigue may reduce psychological distress and improve adjustment. Future longitudinal follow-up may also increase our understanding of maintenance and/or remission of psychological distress among people with HF during disease outbreaks.

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