



*Learning from Heart Failure Nurses and Patients: Exploring their Perspectives
in the management of depression and anxiety in primary care settings*

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Introduction

Heart failure (HF) is a complex clinical syndrome manifested by serious and progressive signs and symptoms. It is characterized by inability of the heart muscle to pump enough blood to meet body's blood and oxygen requirements (American Heart Association, 2017). According to the European Society of Cardiology (ESC) (ESC, 2016) heart failure (HF) is a clinical syndrome that results in decreased cardiac output and may be accompanied with high intracardiac pressure during rest or with stress (ESC, 2016). HF induces many changes in a person's life affecting activities of daily living including breathlessness, chest pain and fatigue with limited exercise tolerance affecting their ability to function independently.

With increased life expectancy and an aging population, the prevalence of HF is increasing worldwide. The estimated number of the prevalence of HF cases from 2002 to 2014, increased by 23% in United Kingdom (UK) (Conrad, 2018). As per the hospital diagnoses, estimates show that there are up to 920,000 people living with HF in the UK (British Heart Foundation, 2018). In year 2017-2018 in England, 500,000 people were diagnosed with heart failure (NHS Digital, 2018). Moreover, the ESC published that the prevalence of HF in developed countries is around 1-2 % among adults and is rising up ($\geq 10\%$) among people over 70 years of age. It also indicated that at the age of 55 years, the lifetime risk of developing HF is 33% for males and 28% for females (ESC, 2016).

With the increased prevalence of HF, there is increased cost of HF related healthcare services, as HF hospitalization place a major burden on healthcare services worldwide. The overall management of HF and the frequency of hospital admission leads to increased healthcare expenditure and cost (Farre, 2016; & Lesyuk, 2018). AHA predicted that with the ageing population, this disease may reach epidemic proportions (American Heart Association, 2017). This will increase the healthcare burden as the cost of proving quality care to HF patients is ranked among the leading healthcare expenditures in the US (American Heart Association, 2017). In United Kingdom, the increased utilization of medical services places an extra burden on the NHS budget as it costs more than £2 billion a year (BHF, 2016).

The physiological symptoms of HF such as breathlessness can lead to increased hospitalization. Due to the pathological changes induced in HF, many patients develop depression and anxiety.

Anxiety is unpleasant feelings of unease, worry or fear that many people experience, and cause negative emotions and thinking (Tully *et al.*, 2014). Anxiety is a normal feeling unless it becomes constant or when anxious people fail to control their worries and it starts affecting their daily lives (Wells, 2018b). Symptoms of anxiety can be physical and include restlessness, sleeping difficulties and palpitations (Palacios *et al.*, 2018). For those with HF, they may become anxious due to the activity limiting symptoms of their HF and the associated breathlessness. Anxiety disorder were found to be responsible for adverse outcomes in coronary artery disease but the association between it and HF is less clear (Celona, 2018) and was under-researched. Therefore, in this study anxiety will be explored in HF.

Depression is a common comorbidity in HF due to the pathological similarities between both conditions. With depression, patients are unable to carry out activities of daily living or to function at home or work for at least two weeks (Lesperance & Frasure-Smith, 2000). Depression is considered as a treatable serious medical illness that negatively affects the way people feel, think or even they act, and it can be classified as mild, moderate or severe. Depression may lead to loss of interest in activities, appetite change, changes in sleep pattern, increased fatigue, feeling worthless and hopeless, difficulty in concentration and developing ideas of attempting suicide (Halaris, 2009; Frasure-Smith & Lesperance, 2010). Many HF patients develop depression and the prevalence of depression found to steadily increase from 11% to 42% as the class of New York Heart Association (NYHA) functional status increases from I to IV (Silver, 2010) (i.e. patients become more symptomatic with HF and their prognosis worsens).

The American Heart Association (AHA) (ACCF & AHA, 2013) guidelines on depression and coronary heart disease recommended the consideration of depression as an independent risk factor for poor prognosis in acute coronary syndrome which is known as a leading cause of HF (Lichtman *et al.*, 2014). Also, the AHA HF guidelines considered depression as a common and important comorbidity in HF that can lead to poorer clinical outcomes and poor Health-Related Quality of Life (HRQOL) (ACCF & AHA, 2013).

Studies (Marti, 2013; Sherwood, 2011; Nieminen, 2015; Gheorghiade, 2013; Moraska, 2013; Wallenborn, 2013; & Hawkins, 2013) have reported that depression is associated with increased hospitalization and death and worsens clinical outcomes in HF. Depression in HF also found to be closely associated with increased outpatients and emergency department visits

(Moraska, 2013) and of all-cause mortality (Gathright, 2017; Moraska, 2013; Freedland, 2016; & Adelborg, 2016). Moreover, patients with worsening depressive symptoms were found to be at higher risk of death for up to one year following hospital discharge (Freedland, 2016). Studies (Gottlieb, 2004; & Hwang, 2014) also reported that Quality of Life (QOL) scores were significantly worse for HF patients with depression. The evidence clearly showed that depression in HF increases healthcare expenditure and cost (Wallenborn, 2013). Therefore, it is crucial to effectively detect and manage depression in HF that may lead to improvement in QOL and improved life expectancy.

The ESC HF guidelines highlighted the importance of routine depression screening with a validated questionnaire. It also emphasized on initiating treatment for depression for all heart failure patients including the use of psychosocial interventions, pharmacological therapy or exercise training (ESC, 2016).

The National Institute for Health and Care Excellence (NICE) guidelines (NICE, 2016) on heart failure emphasized the importance of treating depression in heart failure but there were no specific treatment options for HF recommended in the document (NICE, 2016). Due to the clinical effects of depression in HF, it is important to effectively assess and treat depression as remission from depression found to improve outcomes (Jiang, 2011). In Southwark and Lambeth, inpatients diagnosed with HF are being assessed for depression. The community-based HF patients are being assessed for anxiety and depression using PHQ-9 and GAD-7. However, the frequency and the process of assessment need to be further explored. The HF community nurses works through the KHP partnership with Guy's and St. Thomas's and King's College Hospital to provide the integrated heart failure service in the local area of Southwark and Lambeth in South London. The integrated heart failure team consists of heart failure specialist community nurses and consultant cardiologist with two pharmacists (Guy's and St Thomas' NHS Foundation Trust, 2019). The service provides specialist care in both the hospital and community with support for GPs on HF diagnosis and management. The aim of the integrated heart failure team in the community is to provide the HF treatment effectively, help patients understand and manage their symptoms and support with lifestyle changes.

Even though, the community HF nurses have extensive role in managing HF patients in the community, their role in assessing anxiety and depression; and providing psychological

treatment need to be further explored. The community-based HF patients who are diagnosed with depression are usually referred for psychological treatment (IAPT or 3DLC). The type of treatment depends on the severity of their depression and the extent to which depression is affecting clients' self-management of HF. So, for persistent and mild to moderate depression or if the depression is not related to HF, the patients will be referred for Improving Access for Psychological Therapies (IAPT) for treatment. While, for moderately severe to severe depression and whose depression affects their management of HF, patients will be seen by the team of 3 Dimensions for Long Term Conditions (3DLC). However, the process of providing treatment and type of therapy offered is not known and need to be further explored.

The London Cardiac Clinical Network (LCCN) in 2017 recommended that all HF services (in hospital and the community) must be knowledgeable regarding the process of referring patients to specialist services including IAPT and should understand the local pathway for referral. Based on this, they recommended that Commissioners must ensure the availability of community services for HF patients that can optimize the medical therapy, provide self-care support, psychosocial support and exercise-based rehabilitation. The LCCN also recommended that secondary care heart failure specialist should have direct access to these services. Support from the LCCN in 2017/18 and 2018/19 reported that follow-up and community care can be improved by enhancing collaboration with the London Mental Health Clinical Network in order to upskill healthcare professionals in IAPT services thus can support people with HF and depression. Also, by promoting an understanding to those working in HF services of local pathways for referral to specialist IAPT services. (LCCN, 2017). This will enable the community HF nurses to be able to provide holistic care which includes physical, mental and social care needs.

Unfortunately, the current literature shows the gap in depression and anxiety assessment and treatment in the community. Therefore, there is a need to assess the process by which community HF nurses assess and manage depression and anxiety. This current study builds on our recent systematic review (phase 1) (Helal, *et al*, submitted) which illustrated that CBT could be effective in improving depressive symptoms in HF, but more studies are needed to build on these findings. The findings from this review will be used in this current study to examine how community HF nurses are assessing, managing and treating depression and anxiety in community-based HF patients. Also, to identify community-based HF patients' views and experiences regarding depression and anxiety assessment and treatment.

Study objectives and purpose

In this current study, online focus group and qualitative telephone/online interviews will be undertaken to explore the community heart failure nurses' and community-based HF patients' views and experiences in managing depression and anxiety; and to assess whether COMPASS a web-based intervention would be useful.

With the COVID-19 pandemic extra measures were taken to protect HF patients who are considered as clinically vulnerable (shielding). This impacted on patients access to treatment and health care services, community networks and support from family and friends. It is anticipated during the pandemic this has had a deleterious impact on individuals' mental health with increased social isolation, anxiety about care and treatment, and risk of poor outcome if contract COVID-19. This study will explore the impact of COVID-19 on the psychological wellbeing of community-based HF patients.

Research Question

How is depression and anxiety being assessed, managed and treated in community-based HF patients; and what is their views on the use of web-based intervention?

6.1. Aims

To explore community HF nurses' and patients' views and experiences in managing depression and anxiety and to assess whether COMPASS a web-based intervention would be a useful intervention.

Primary objective

To explore community HF nurses' and patients' views and experiences of managing depression and anxiety and to assess whether COMPASS a web-based intervention would be useful.

Secondary objectives

- 1) To conduct online focus groups with community HF nurses (n=5) and qualitative telephone/online interviews with community-based HF patients (n=8) within Lambeth and Southwark NHS Trusts.
- 2) To synthesise the data obtained from online focus groups and qualitative telephone/online interviews using thematic analysis.

3) To understand how depression and anxiety is managed in HF patients and whether web-based intervention would be a useful intervention.

To explore the impact of COVID-19 on community-based HF patients' depression and anxiety level changes to management processes.

Study design

A qualitative methodology will be employed using online focus group and qualitative telephone/online interviews. In this current study online focus group will be undertaken with community HF nurses (n=5) and qualitative telephone/online interviews with community-based HF patients (n=8). Online focus group allows for expression of personal opinions, perspectives and experiences regarding an issue of interest. The synergy of the online focus group allows participants to collectively brainstorm together, add on others' ideas and this may provide rich and large amount of opinions, issues and concepts (Brinkmann, 2015).

Even though qualitative telephone interviews are used less frequently than the traditional face-to-face interviews (Opdenakker, 2006; Sweet, 2002), it can be a useful data collection method (Carr & Worth, 2001, p. 521). The participants of qualitative telephone interviews were found to feel more comfortable being interviewed over the telephone and talking more freely than face to face interviews (Novick, 2008). The qualitative data obtained from telephone interviews were reported to be rich, comprehensive and of high quality (Chapple, 1999; Kavanaugh & Ayres, 1998; Sturges & Hanrahan, 2004; Sweet, 2002). In comparison to face-to-face interviews, the qualitative telephone interviews were less costly (Chapple, 1999), can increase access to different geographically located participants (Sturges & Hanrahan, 2004; Sweet, 2002; Tausig & Freeman, 1988) and is safer for the interviewer (Carr & Worth, 2001; Sturges & Hanrahan, 2004). Qualitative telephone interview also allows more anonymity (Sweet, 2002; Tausig & Freeman, 1988), privacy (Sturges & Hanrahan, 2004), and decrease in social pressure (McCoyd & Kerson, 2006).

Qualitative methodology was deemed the best method to meet the study aims and to understand how community HF nurses are assessing, managing and treating depression and anxiety in community-based HF patients; and what they think of using a web-based Intervention (i.e. COMPASS). Qualitative methods are a useful method to explore the depth of participants' views and opinions related to an issue of interest, and to capture participants' interpretations regarding a concept. Online focus group is useful for the researcher to grasp how those who

take part perceive the process and feel comfortable including experiences and emotions around a particular topic (Barbour, 2005). Barbour (2005) highlights how focus group enables the researcher to observe record and analyse the group's interactions to include this in the presentation of findings.

Subject inclusion criteria

Inclusion criteria for Community-based HF patients:

- 1) Community-based HF patients with clinically established HF diagnosis (confirmed HF diagnosis) in Lambeth and Southwark Boroughs who have mild to moderate symptoms of depression with/without anxiety confirmed by PHQ-9 (5-14) and GAD-7;
- 2) Patients with NYHA class I-III;
- 3) Capacity to provide informed consent; and
- 4) Proficiency in English language so can fully respond to verbal and written material.

Inclusion criteria for Community HF nurses:

- 1) All community-based HF-nurses employed in Lambeth and Southwark Boroughs who are registered with Nursing Midwifery Council (NMC) will be invited to participate in the study;
- 2) Capacity to provide informed consent;
- 3) Community HF-nurses who are actively providing care to community-based HF patients; and
- 4) have access to internet connected computer or device and technology for Microsoft (MS) Teams.

Subject exclusion criteria

8.2.1. Exclusion criteria for community-based HF patients:

1. Community-based HF patients under 18 years of age;
2. Participants who are deemed not to have the capacity to consent;
3. Patients with cognitive impairment or dementia confirmed by medical records; and
4. Community-based HF patients with NYHA class IV.
5. Patients with severe depression and/or having suicidal ideation.

Exclusion criteria for Community HF nurses:

1. Nurses working with inpatients or in the OPD departments; and

2. Nurses who are not employed as community HF nurses.
3. Any community HF nurse who do not have access to internet or online technology.

Study procedures

Subject recruitment

A purposive sampling will be used to capture data from community heart failure nurses and community-based HF patients who meet the inclusion criteria. Participants will be recruited directly by GSTT community HF services in Southwark and Lambeth Boroughs as they have an established community HF service.

Patients recruitment:

Participants will be recruited from Guys and St. Thomas's community-based HF services in Lambeth and Southwark Boroughs through discussion with community HF lead nurse. The invitation letter and participants information sheets will be sent by email to HF lead nurse and community HF nurses and they will be asked to identify community-based HF patients to participate in the study. The information sheets include contact details inviting volunteers to email or phone the researcher. Alternatively, community-based HF patients who are willing to participate can give their contact details to the nurses who will send it over to the researcher. Once this contact is received the researcher will contact possible participants via participant's preferred method (phone, online or email) to offer the opportunity to discuss what would be involved in more details and answer any question. Inclusion criteria (described earlier) will be used to assess eligibility to the study. In addition, the researcher will arrange a time to call back the participants who are not ready to decide regarding participation in the study.

Nurse recruitment:

The community HF lead nurse will be approached by the researcher via telephone/email to allow approaching the community HF nurses. Invitation letter and participant information sheets will be provided by the researcher via email. Participants will be given time to read the information and respond via email or telephone at which further information on the study will be provided and any questions will be answered.

Procedure for online focus groups:

The online focus groups with community HF nurses who consent and meet the eligibility for this study will be conducted by the researcher. The online focus group may take 60-90 minutes

with breaks in between as this time period reported with less participants fatigue (McCoyd and Kerson, 2006). The emphasis will be open-ended form of conversation that can provide opportunities for rich discussions and sharing of personal experiences and interpretations.

The date of the online focus group will be decided according to community HF nurses' preferences. A time will be agreed with their manager when all of the community HF nurses can meet as a group. The PIS and consent form will be sent to all community HF nurses by email. The consent form will be signed ahead of time and gathered online. Similarly, baseline demographic data will be sent and collected online. The community HF nurses will be involved in the online focus group that will be conducted using Microsoft teams. A link to the online focus group will be sent by the researcher to all community HF nurses with the agreed date and time. The online focus group will have a skilled moderator who is the researcher's supervisor (co-investigator). The moderator will moderate the session and will deal with any arising technical issues.

The discussion with community HF nurses will include their perspectives about depression and anxiety assessment and management process and what they think of web-based intervention. Then, the community HF nurses will have a short break. Immediately after the break, a COMPASS team member will join the online focus group and will demonstrate the COMPASS web-based intervention to the community HF nurses. Community HF nurses will be allowed to ask questions regarding COMPASS before the COMPASS team member leaves the online focus group. Once demonstration is complete and the COMPASS personnel has left the online focus group, the researcher will take over and will assess community HF nurses' perspectives regarding COMPASS. The participants will be asked if a similar intervention will be useful to community-based HF patients and which aspects of COMPASS they feel is relevant and important in HF. Issues around potential barriers and facilitators for implementation will also be explored.

Procedure for the Qualitative telephone/online interviews

For the community-based HF patients, qualitative telephone/online interviews will be conducted with each participant at their preferred time and method. Due to COVID-19, the participants will be interviewed in their own home at a time that suits them. Qualitative telephone/online interviews may take 60-90 minutes. The consent form will be sent online to community-based HF patients who have access to the internet and email. Participants who do

not have internet access a recorded consent over the telephone will be obtained. This will be done by the researcher who will read the consent form to the participants and they will be asked for their verbal consent on each statement and their answer will be recorded e.g. Do you agree to...? YES, NO. Once consent is obtained, the researcher will email the community-based HF patients a video link to COMPASS before they engage with qualitative telephone/online interviews. This video link is a demonstration of the COMPASS web-based intervention and the researcher will encourage them to view the video so they can share their views about COMPASS during the qualitative telephone/online interview. For participants who do not have access to email or the internet, the COMPASS will be explained to them by the researcher. They will be encouraged to explore the concept of web-based intervention, what services and resources the clinicians need to consider when introducing web-based interventions to people who do not have access to the internet etc.

At the start of the qualitative telephone/online interviews, rapport will be established with the participant in person (Burke & Miller, 2001; Carr & Worth, 2001) and predeveloped interview script will be used to introduce the study at the beginning of the interview (Burke & Miller, 2001). The discussion with community-based HF patients will include their perspectives about depression and anxiety assessment and management process and what they think of web-based intervention. Then, the participants will be asked about using web-based intervention for the management of depression and anxiety in general and about COMPASS intervention in specific if they have viewed the video. The participants will be asked if they think that a web-based intervention will be applicable to them and if they feel that it can be useful in HF. Also, the community-based HF patients will be asked to identify the potential barriers and facilitators for implementation of any web-based intervention.

Data to be collected

The demographic form will be sent to community HF nurses and they will be asked to complete and return this via email to the researcher before the online focus group.

The demographic form will also be emailed to community-based HF patients and they will also be asked to complete and return this via email to the researcher before the qualitative telephone/online interview. For community-based HF patients who do not have email access, the researcher will read the information required from the baseline demographic form and will ask them to provide an answer before the interview starts.

Data handling and record keeping

Data collection will include note taking, digital encrypted Dictaphone and remarking participants' nonverbal cues when possible. The online focus groups using encrypted Microsoft (MS) teams with community HF nurses will be audio recorded using digital encrypted Dictaphone. The qualitative telephone/online interviews with community-based HF patients will be in a private room and will be audio-recorded using digital encrypted Dictaphone. The participants will be assured that privacy and confidentiality will be maintained, as the researcher will be sitting alone in a private room during the interview.

Field notes on the group interactions and processes will also be transcribed by the researcher. Thematic analysis assisted by N-vivo 12 will be used to allow the development and 'saturation' of themes and categories.

An online consent form will be sent to community HF nurses which will be signed prior to the scheduled online focus group. For community-based HF patients, the consent form will be recorded at the start of the interview, and the participant will be asked whether they agree with each statement read by the researcher e.g. Do you agree to...? YES, NO.

All the online collected consent forms, participants personal data and qualitative data recordings and transcripts will be encrypted before they are uploaded to a secure and encrypted cloud storage area provided by KCL and will only be accessible by researcher and the two co-investigators. Once the study has been completed, the recordings will be destroyed by deleting them from the encrypted and password protected file sharing cloud.

Sample size:

This study will include five Community HF nurses and eight community-based HF patients, 13 in total (n=13). A total of five community HF nurses (n=5) will be recruited for the online focus group and eight community-based HF patients (n=8) will be recruited for the qualitative telephone/online interviews. Online focus group can vary in size but tend to average between 6 to 8 but it is recommended to reduce the number to 4-5 participants for online focus group. Smaller group size (around six) are advised where the topic is controversial, where the participants have considerable knowledge or are likely to have strong views on the subject. The qualitative telephone interviews will include eight community-based HF patients.

DATA ANALYSIS:

The qualitative data from online focus group will be entered into a computer-assisted qualitative data analysis package (NVivo 12). The verbatim transcription will be conducted for the audio data obtained from online focus group. Coding will be based on the research questions as well as emerging themes. Field notes on the online group interactions and processes will also be transcribed. The qualitative data from qualitative telephone interviews will be transcribed using NVivo 12. Data Coding will be done, and emerging themes will be identified.

Thematic analysis will be used to analyse the themes. Final categories and themes will be determined using a consensus approach to resolve any differences in interpretation. The data will be managed using NVivo 12 to organise the ongoing analysis, themes and categories.

Ethical considerations

An application to NHS R&D and IRAS is currently under preparation for submission. The community HF nurses will email the consent form to the researcher before the online focus group takes place. The community-based HF patients will send the consent form either via email if they have internet access or they will be consented verbally and recorded at the beginning of the qualitative telephone/online interview.

During recruitment of the participants, the researcher will discuss the purpose of the study and the criteria for participation. The researcher will assure all the participants that anonymity will be provided, and they can withdraw at any time. Participants will also be informed that no harm will result from taking part in the study or even by refusing to participate. It is not anticipated that participation in the study will be stressful. However, before the online focus group or qualitative telephone/online interviews commences, it will be explained to all participants that they do not have to answer any questions they do not wish to or that make them uncomfortable. In addition, the online focus group will be co-facilitated by the co-investigator who is a mental health lecturer with extensive experience in clinical mental health practice and psychological therapy.

Moreover, it will be clearly explained to all participants that all data will be pseudo-anonymised during transcription and that data will be stored securely under a study number whereas

comments quoted in any reports, results, published papers or feedback will not be linked to any individual.

Reporting and dissemination

The study will be published in a peer-reviewed scientific journal.

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