Short Title: Lifestyle behaviours of women newly diagnosed with heart failure

Full Title: Lifestyle behaviours of women newly diagnosed with heart failure: A quantitative and qualitative approach

Research Protocol

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Background

Heart failure is a condition in which the heart has a reduced function to pump blood during exertion and often at rest [1]. Although the symptoms for heart failure are similar for men and women, there are sex differences in the heart failure etiologies [2]. The incidence of heart failure is greater in men versus women, especially in the younger age groups (45-54 years) [3]. However, it has been reported from 79 years old, women have a greater prevalence than men [4]. This is associated with the age at diagnosis being 5 years older for women compared to men (79.6 vs. 74.8 years) [5]. Men are more likely to present with heart failure with reduced ejection fraction (HFrEF) whereas women are twice as likely to present with heart failure with preserved ejection fraction (HFpEF) [2]. Given their more complex medical profile, men have significantly higher healthcare costs versus women during the first year after diagnosis [6]. The global COVID-19 pandemic has resulted in services and care for patients with heart failure being significantly affected [7]. Our recent review highlighted that patients are continuing to avoid urgent care, which may result in advanced manifestations of cardiac dysfunction and worse prognosis [7].

Physical activity is an important modifiable risk factor in patients with chronic heart failure and is known to improve function and quality of life (QoL) [8]. Although several studies report physical activity in patients with chronic heart failure [9, 10], it appears that no study has evaluated physical activity in women at the time of diagnosis of heart failure and evaluated these lifestyle behaviours by understanding the barriers and facilitators. Women are underrepresented in heart failure studies and treatment guidelines are male-derived due to these disparities in recruitment. Our research will directly address this by evaluating the physical activity levels, sedentary behaviour, sleep and QoL of women newly diagnosed with heart failure and understand the barriers and facilitators to these lifestyle behaviours at the time of diagnosis.

Aim and Objectives:

The aim of the project is to provide evidence for the current lifestyle behaviors of women newly diagnosed with heart failure. The aim will be achieved through the following three objective: (1) assess the physical activity levels, sedentary behavior and sleep of women newly diagnosed with heart failure using objective assessment (2) evaluate the quality of life of women newly diagnosed with heart failure and (3) understand the barriers and facilitators of these lifestyle behaviors of women at the time of their heart failure diagnosis.

Methods/Design

Study Design

A prospective, single-centre, pilot study design will evaluate physical activity, sedentary behaviour, sleep and QoL of women newly diagnosed with heart failure who have been referred to secondary care for specialist review and have attended a heart failure diagnostic clinic at the Royal Victoria Infirmary, Newcastle-upon-Tyne.

Sample size

A total of 40 patients will be recruited into the study.

Eligibility criteria

Inclusion criteria:

- Adult women with a new diagnosis of heart failure after referral to the RVI Heart Failure Diagnostic Clinic run by Drs MacGowan and Bailey;
- Able to walk and perform activities of daily living independently;
- New York Heart Association functional class II-IV;
- Willingness to undertake physical activity monitoring;
- Willingness to participate in a semi-structured interview (this is optional and the participant will be able to participate in the study if they choose not to take part in the interview);
- Ability to read, write and converse in English without the support of an interpreter;
- Able to provide written informed consent.

Exclusion criteria:

- Male;
- Already diagnosed with heart failure;
- Presented with severe symptoms requiring urgent assessment and stabilisation (e.g. breathless at rest, hypotension, confusion);
- Major co-morbidity or other alternative diagnoses of no obvious acute and self-limiting cause (e.g. malignancy, severe respiratory disease, mental health problem);
- Severe physical disability preventing them to function independently;
- Clinically unstable with recent changes in medication;
- Unable to provide informed consent.

Recruitment procedures

Participants will be identified from the Heart Failure Diagnostic Clinics run by Drs MacGowan and Bailey who are part of the research study team and play a vital role in participant recruitment. An information sheet will be given to all patients (women only) after they have

received their diagnosis at the diagnostic clinic appointment. A member of the research study team will attend the Heart Failure Diagnostic Clinics to provide a participant information sheet to eligible patients. The research study team will have an honorary contract with the Newcastle upon Tyne Hospital and sufficient level of competence and permission to assess patients' medical records using computerised system in place. The patient will be given at least 48 hours to read through the participant information sheet. A member of the research team will contact the patient via telephone call to see if they are happy to participate in the study. Research will seek informed and voluntary consent from the participant. A consent form will be attached to the participant information sheet for the patient to complete and return to the research study team via a pre-paid envelope. Consent forms will be signed by the participant and countersigned by a member of the research study team.

Part 1: Quantitative Work Package

As part of the standard care and practice in at the Royal Victoria Infirmary (RVI), the following investigations will be performed by specialist NHS staff members:

1) Echocardiography for assessment of cardiac structure and function using non-invasive Doppler ultrasound (30 min).
2) Medical history review, physical examination and interpretation of echocardiography results by a consultant cardiologist, who is also part of the research team, confirming or ruling out heart failure diagnosis (30 min).

Wrist monitor and questionnaires

A total of 40 newly diagnosed heart failure patients will be recruited to the study. Once the research study team has received the participant's postal consent form, a study pack will be posted to the participant, which will include: a wrist monitor, a set of instructions, two validated questionnaires and a pre-paid envelope to return the wrist monitor and questionnaires. By completing this part of the study remotely, the patient will avoid making an additional visit to the hospital at the time of diagnosis.

The participant will be asked to wear the wrist monitor (Actigraph GT3X+) to capture habitual 7-day physical activity, sedentary behaviour and sleep on one occasion. A set of instructions will be posted with the wrist monitor and the research study team telephone contact details will be provided. A follow-up telephone call will be made to the participant to ensure they have received all the information and are happy to complete the questionnaires and 7 day monitoring.

The two validated questionnaires are the Minnesota Living with Heart Failure (MLHF) Questionnaire [11] and the SF-36 [12] and the participant will be asked to complete these prior to completing the 7-day monitoring.

The participant will receive a small padded pre-paid envelope to post the wrist monitor and questionnaires to the research study team at the end of the 7 days monitoring. The wrist monitor data will be processed using the ActiLife software.

The MLHF and SF-36 questionnaires will be posted to the participant at 3 months post-diagnosis to assess any short-term changes in QoL. A pre-paid envelope will be provided to the participant to return the questionnaires to the research study team.

Part 2: Qualitative Work Package

In parallel to the quantitative work package, it is important to clarify what are the barriers and facilitators to these important lifestyle behaviours, i.e. physical activity, sedentary behaviours, sleep and QoL at the time of diagnosis for women. The aim of this work package is to understand what lifestyle behaviours participants currently engage in at the time of diagnosis and how their diagnosis may affect their future lifestyle choices.

One optional semi-structured interviews will be conducted with the participants who provide consent to participate in this part of the study (n=15 or until saturation in findings) once they have completed the quantitative work package. Participants may choose to opt out from this part of the study and this option will be included in the consent form. An interview specific topic guide has been developed on the barriers and facilitators to physical activity, sedentary behaviours, sleep and QoL. Data from the semi-structured interviews will be analysed thematically using an inductive approach [13]. All interviews will be transcribed verbatim. The interviews will be conducted remotely and participants will be given the option to use the zoom platform or receive a telephone call. If the participant becomes distressed or upset from completing the interview (and/or the questionnaires) then we have requested they contact the research study team who will initiate referral to our clinical psychology department at the Freeman Hospital or Royal Victoria Infirmary, Newcastle upon Tyne.

End of the Study

At the end of the study all participants will be provided with information about the study's major findings. This will be communicated by letter mailed to the participants' home address and will also include an invitation to attend a volunteer feedback evening at the Clinical Research

Facility where the overall results of the study will be presented. The study will be considered as completed when participants have completed the proposed clinical procedures.

Data storage

All digital data will be securely stored on the University's Filestore Service and will be pseudonymised with study identification numbers. The data will be accessible only to authorised project staff and backed up daily with a highly available offsite mirror. The audio recordings for the qualitative work package will be destroyed once they have been transcribed.

Data archive and sharing

Research data that supports publications and unpublished data of value at project end will be archived with supporting documentation in data.ncl (https://data.ncl.ac.uk/), Newcastle's Research Data Repository. The datasets will be made public under a Creative Commons licence to ensure credit is given when the data is reused and access provided for at least ten years. Data deposited will also be assigned a persistent identifier (i.e. DOI) that can be included in project outputs, including publications, to detail how and where the data can be accessed. At this stage all study identification numbers will be removed and all data will be anonymised before being archived and shared through the repository. Where there is a risk to data being re-identified the dataset will be archived to make the record findable but access will be controlled and dependent on the future use of the data in question.

Sample size and statistical analysis

The quantitative work package will produce pilot study findings and a recruitment target of 40 patients was chosen, which will adhere to methodological standards for pilot studies [14, 15]. Descriptive statistics of the data variables (physical activity levels, sedentary behaviour, sleep and QoL) will be analysed and compared to age and sex-matched healthy controls. Data (natriuretic peptides (NTproBNP) and left ventricular ejection fraction (LVEF)) from patient's medical records will be exported.

The qualitative work package will involve a purposely selected sample of women with a new diagnosis of heart failure (n=15). This is exploratory work, therefore, an inductive approach to analysis will be made and data saturation of themes will be determined at the analysis stage [16]. Two independent reviewers in the research study team will code and extract segments of the data to identify key themes. Inclusion of supporting quotes from each of the themes will be included in the write up and publication.

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