

Welcome to REACH-HFpEF Newsletter 05 (February 2024)

NIHR REVIEW – November 2023

We were very pleased to announce at the end of 2023 NIHR HTA agreed our extension to continue recruitment to 520 patients. We project this will mean **recruitment will continue until May 2025**. We are in the process of submitting our variation to contract to the NIHR and will be in touch with local R&Ds regarding this trial extension.

* **231 participants now randomised!**

TRIAL UPDATE

- **Our recruited trial patient cohort looks representative of NHS practice** – as you will be aware, RCTs are often criticised as not reflecting real world practice. With >200 patients now recruited, we are in a good position to check our representativeness. ‘Eye-balling’ our baseline data so far it looks as though we are very representative of UK heart failure. We will be formally assessing this over the next couple of months ahead of preparing our next TSC and DMC reports. More to follow...
- **Good data collection stats** – our statistician *Katie Dudman* has recently checked our data completion rates. For our primary outcome (the MLWHF questionnaire) we’ve got 100% completion at baseline, 91% at 4 months 93% at 12-months follow up (data at October 2023). We look to have similar high completion percentages for secondary outcomes. Well done to the site research/data collection teams...keep up the great work!
- **Variable REACH-HF facilitator contacts** – we have also had a chance to look at facilitator contact logs for participants who have completed the intervention. Across all patients and sites we have a mean of ~6 contacts per patient which indicates a good average level of patient contact with the intervention team. We would anticipate 2 face-to-face contacts (in the home or clinic) with patients (and their caregiver, where appropriate) at the start and end of their REACH-HF intervention and 2-3 telephone calls during the intervening 12 weeks (so about 4-5 contacts per patient in total). **Please continue to record all contacts on the contact log via the eCRF as this will be used as part of the trial analysis.**
- **Event adjudication** – our trial adjudication committee chaired by *Dr Paco Leyva* will be beginning their review of hospitalisations and deaths to assess HF-relatedness in the next month or so. **Site PI’s: please make sure your local review of SAEs is up-to-date.** Please contact the trial management team if you need any guidance navigating the eCRF.
- **Welcome Royal Free!** – we welcome our 20th site, Royal Free London NHS Foundation Trust who got their green-for-go in January 2024 and are led by their local PI, *Dr Ameet Bakhai*.
- **Process Evaluation** – The process evaluation team are happy to report that 10 facilitators are now taking part in the evaluation, across 6 sites, and with good geographical spread. These facilitators are helping to collect valuable data, which is enabling us to build an understanding of what might be working in their setting, and the patients that they work with, as well as how it might be working. With so many different sites taking part in this big trial, there may well be variations in how the REACH-HF intervention is being delivered. It is therefore important to know how these variations impact on patient outcomes and the services themselves. **The PE team are always keen to speak to more facilitators, so if you are interested in taking part, please get in touch with the trial team management team or email - s.b.vanbeurden@exeter.ac.uk**

Your experiences of REACH-HFpEF

✿ The Optimisation of Exercise Fidelity sub-study – an update from the team ✿



Mohammad Jarallah



Colin Greaves

Our sub-study aims to assess the quality of exercise in a sub-sample of 86 participants within the REACH-HFpEF trial, recruited from the intervention group at 18 sites over 12 months. To do this, we are providing patients in the intervention group with Fitbit watches to record their heart rate during their chair-based or walking exercise. The data comes back to us through a study smartphone (that we also provide) and we look for the presence of warm-up and warm-down activities, as well as the number of minutes spent working at 40-70% of the maximum heart rate (which is calculated from their age, resting heart rate and adjusted for use of beta-blockers using a validated formula). We are also video recording a small sample of their exercise sessions to look at other aspects of the exercise, such as safety and quality of movement.

Between August 2023 and January 2024 we have sent invites to twenty-eight participants, of which four have been consented, two have completed the sub-study and two are awaiting the start of their intervention. Two further participants withdraw after consenting. Recruitment is steadily progressing and, with the first couple of participants now completed the intervention, we know that the measurement procedures are working well.

Although it is still early days, the study is progressing well and expected to finish collecting data around July or August 2024.

We would like to take this opportunity to thank all the NHS staff, the CTU team and the Chief Investigators and a special thank you to the participants for giving their valuable time and effort to make this sub-study work.



CONTACT US:

REACH-HFpEFproject@glasgowctu.org with any questions for the trial management team.