

Background - FOI 586/19/20 - HELP-AF: A randomised controlled trial assessing home-based support and education for atrial fibrillation patients.

E011/003 'HELP-AF: A randomised controlled trial assessing home-based support and education for atrial fibrillation patients' was an educational study and did not involve clinical intervention. This educational study assessed subjects who had already experienced atrial fibrillation. This research was not conducted by Defence nor were Defence members targeted in this research. Ethical approval was provided by DVA HREC (prior to the establishment of the current committee) and for the purposes of obtaining DVA data. Researchers are not obliged to provide the findings of their research. In accordance with the ethical approval, the DDVA HREC reviewed the 14 serious adverse event reports related to the deaths of the participants during the trial. As this was an educational study and did not involve any clinical interventions, the DDVA HREC concluded that the deaths were not directly related to the study. The serious adverse event reports did not indicate whether any were DVA clients.