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Undertaking multi-centre randomised controlled trials in primary care: learnings and recommendations from the PULsE-AI trial researchers

Kevin G. Pollock¹, Carlissa Dickerson², Manjit Kainth³, Sarah Lawton⁴, Michael Hurst¹, Daniel M. Sugrue², Chris Arden⁵, D. Wyn Davies⁶, Anne-Céline Martin⁷, Belinda Sandler¹, Jason Gordon^{2*}, Usman Farooqui¹, David Clifton⁸, Christian Mullen⁹, Jennifer Rogers⁹, Nathan R. Hill¹, A. John Camm¹⁰ and Alexander T. Cohen¹¹

Abstract

Background Conducting effective and translational research can be challenging and few trials undertake formal reflection exercises and disseminate learnings from them. Following completion of our multicentre randomised controlled trial, which was impacted by the COVID-19 pandemic, we sought to reflect on our experiences and share our thoughts on challenges, lessons learned, and recommendations for researchers undertaking or considering research in primary care.

Methods Researchers involved in the Prediction of Undiagnosed atrial fibrillation using a machine learning Algorithm (PULsE-AI) trial, conducted in England from June 2019 to February 2021, were invited to participate in a qualitative reflection exercise. Members of the Trial Steering Committee (TSC) were invited to attend a semi-structured focus group session. Principal Investigators and their research teams at practices involved in the trial were invited to participate in a semi-structured interview. Following transcription, reflexive thematic analysis was undertaken based on pre-specified themes of recruitment, challenges, lessons learned, and recommendations that formed the structure of the focus group/interview sessions, whilst also allowing the exploration of new themes that emerged from the data.

Results Eight of 14 members of the TSC, and one of six practices involved in the trial participated in the reflection exercise. Recruitment was highlighted as a major challenge encountered by trial researchers, even prior to disruption due to the COVID-19 pandemic. Researchers also commented on themes such as the need to consider incentivisation, and challenges associated with using technology in trials, especially in older age groups.

Conclusions Undertaking a formal reflection exercise following the completion of the PULsE-AI trial enabled us to review experiences encountered whilst undertaking a prospective randomised trial in primary care. In sharing our

*Correspondence:
Jason Gordon
jason.gordon@heps.co.uk

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