Rheumatology (2016) 55 (suppl 1): i121.

doi: 10.1093/rheumatology/kew128.020

This article appears in: Rheumatology 2016 Abstracts

147 Successful Strategies Supporting Recruitment, Intervention Delivery and Retention Targets in a Randomized Controlled Trial of a Complex Intervention

Zoe Plummer[1], Celia Almeida[1], Nicholas Ambler[2], Peter Blair[3], Ernest Choy[4], Emma Dures[1], Alison Hammond[5], William Hollingworth[3], John Kirwan[6], Jon Pollock[7], Clive Rooke[8], Joanna Thorn[3], Keeley Tomkinson[3] and Sarah Hewlett[1]

Author Affiliations

1. *[1]Nursing and Midwifery, University of the West of England,*
2. *[2]Pain Management, Southmead Hospital,*
3. *[3]School of Social and Community Medicine, University of Bristol, Bristol,*
4. *[4]Rheumatology, Institute of Infection and Immunity, Cardiff University, Cardiff,*
5. *[5]Health Sciences Research, School of Health Sciences, University of Salford, Salford,*
6. *[6]Academic Rheumatology, School of Clinical Sciences,*
7. *[7]Health and Social Sciences, University of the West of England and*
8. *[8]Academic Rheumatology, Bristol Royal Infirmary, Bristol, UK*

Background: Complex interventions are widely used in modern health care practice and are defined as those having potentially interacting components. Evaluation can be challenging due to difficulties in logistics, standardisation and delivery. In addition, there can be difficulty recruiting to time and to target (particularly in multicentre studies) and minimising attrition and data loss. We report how the RAFT study [a seven-centre randomized controlled trial (RCT) comparing a complex group cognitive-behavioural (CB) intervention with standard care for the reduction of fatigue impact in patients with RA) is implementing successful strategies to meet recruitment, intervention delivery and retention targets. The study requires patients to make a substantial commitment over a 2 year period and for the intervention to be delivered by routine clinical staff trained for this purpose.

Methods: The following strategies were agreed upon during the planning and design phase: Maximising recruitment: Funded research nurse time at all seven sites; mailshot option for approach; recruitment posters for clinics; flexible and pragmatic approach to session attendance; telephone, email and postal contact; newsletter and regular knowledge exchange between the central trial management team and sites; weekly recruitment updates and reviews. Ensuring intervention delivery: Flexible course dates and times set by each site, regular communication with the central

management team to discuss foreseeable issues and preventative actions, provision of real-time clinical supervision and full-time telephone/email support. Minimising attrition and data loss: Primary outcome collection by telephone, ensuring regular personal contact; secondary data collection by postal questionnaire, reducing the number of hospital visits; telephone reminders; partial withdrawal options; personalized letters and thank you cards. Patient involvement: We had a number of acceptability and feasibility consultations with our two patient partners. Both partners had prior experience attending the intervention, were co-applicants on the grant proposal and continue to provide a patient perspective as members of the trial management group.

Results: Our target was to recruit 300 participants with no recent medication changes and a fatigue level ≥6 (on a 1–10 scale where 10 is totally exhausted). During the 2 year recruitment phase, 333 participants were randomized (11% over target). All 28 programmes successfully delivered, with 7/7 sites and 14/15 tutors remaining fully engaged with the study. Retention at 6 months is currently 92.5% (sample size allows for 20% attrition). Data returned by those reaching the 6 month time point are 100% for the primary outcome and 97% for secondary outcomes.

Conclusion: Advanced planning and consistent application of these strategies has ensured success so far. A flexible and pragmatic approach, regular communication between local and central teams, personal contact with participants and extensive patient partner input are key components.

Disclosure statement: The authors have declared no conflicts of interest.