**AB1130-HPR (2016)**

# COGNITIVE THERAPY FOR REDUCING THE IMPACT OF RHEUMATOID ARTHRITIS FATIGUE: SUCESSFUL STRATEGIES FOR MEETING TARGETS IN A COMPLEX HEALTH CARE INTERVENTION

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**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, delivery, recruiting to time and target (particularly in multi-centre studies) and minimising attrition and data loss.

We report how the RAFT study (a 7-centre randomised controlled trial comparing a complex, group cognitive-behavioural intervention with standard care, for the reduction of fatigue impact in patients with rheumatoid arthritis) is implementing successful strategies to meet targets. The study requires patients to make a substantial commitment over a two year period and for the intervention to be delivered by routine clinical staff trained for this purpose.

**Objectives:** To recruit to time and target, ensure intervention delivery, minimise attrition and maximise retention.

**Methods:** Maximising recruitment: Funded research nurse time at all 7 sites, mailshot approach option, recruitment posters, flexible/pragmatic approach to session attendance, telephone, email and postal contact, newsletter and regular knowledge exchange between the central management team and sites, weekly recruitment review. Ensuring intervention delivery: Flexible course dates and times, regular discussions around foreseeable issues and preventative actions, provision of real-time clinical supervision and full-time telephone/email support. Minimising attrition and data loss: Primary outcome collected by telephone ensuring regular personal contact. Secondary data collected by postal questionnaire reducing the number of hospital visits. Telephone reminders, partial withdrawal options, personalised letters and thank you cards. Patient involvement: Acceptability and feasibility consultations with our 2 patient partners. Both have experience of attending the intervention, were co-applicants on the grant proposal and continue to provide the patient perspective as members of the trial management group.

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

**Conclusions:** 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.

**Acknowledgement:** This work is funded by the NIHR HTA commissioned call [project number 11/112/01]

**Disclosure of Interest:** None declared

**DOI:** 10.1136/annrheumdis-2016-eular.1968

**Citation:** Annals of the Rheumatic Diseases, volume 75, supplement 2, year 2016, page 1318

**Session: Miscellaneous forms of clinical care** *(Abstracts Accepted for Publication )*