Methods: In phase 1 of the QRI, generic tips and training were provided to assist recruitment from the outset. In-depth semi-structured interviews were conducted with healthcare professionals, TMG members and sites declining trial participation. Monthly screening logs were scruitinised and recruitment consultations and interviews analysed, using thematic and constant comparative methods. In phase 2, we provided confidential and supportive feedback to recruiters and collaboratively developed and implemented plans to optimise recruitment.
Results: (Recruitment and qualitative data collection is ongoing).
We conducted 12 interviews with surgeons, anaesthetists and research nurses, audio-recorded 9 recruitment consulations and carried out individual and group feedback sessions. Randomisation rates varied between 43 to 100 per cent (randomised/ eligible patients approached). Specific training was given to convey equipoise, to gently explore patient preferences and balance the description of the treatment arms. Despite centres exceeding recruitment targets, accrual may lag due to problems opening the target number of recruitment centres, owing to a sharp decline in the number of planned thoracotomies, a shift away from thoracic epidurals and limited capacity to deliver high-dependency unit nursing care.
Potential relevance and impact
This is the first anaesthesia RCT to embed qualitative methods to optimise recruitment. Findings may be of interest to trialists initiating RCTs when community equipoise challenges clinician preferences for routine local practice.

P-164

Recruitment strategies and screening yields in the Hypertension Approaches in the Elderly: a Lifestyle Study (The HAEL Study)

Daniel Umpierre, Lucas P. Santos, Cíntia Botton
Universidade Federal Do Rio Grande Do Sul, Porto Alegre, Brazil
Trials 2019, **20(Suppl 1):**P-164

Introduction: The identification and recruitment of research participants for clinical trials is a common challenge across studies, being considered a key determinant for adequate trial completion. Since several recruitment strategies may be implemented to enhance recruitment rates, we aimed to describe the recruitment strategies and preliminary results for the Hypertension Approaches in the Elderly: a Lifestyle Study (HAEL).
Methods: The HAEL Study is a 12-week randomised controlled trial (NCT03264443) that aims to assess blood pressure effects of a pragmatic combined training program (1:1 allocation ration) in comparison with a health education program. The sample size will be composed by 184 older adults, divided in two implementation centers. In the two sites, recruitment strategies include five main sources, as follows: press media, word-by-mouth, lists generated by electronic health records, professional referrals, and flyers. Descriptive statistics are used to monitor characteristics of study participants, distribution of sex across sites. Data are expressed as absolute and relative frequencies.
Results: From September/2017 to April/2019, four recruitment waves have been conducted in both, totalizing 289 and 200 monitored screening calls in coordination and field sites, respectively. The screening yields were consistent across site for word-by-mouth (62 [21.4%] of total screenings), flyers (8 [1.6%]), and professional referrals (7 [1.4%]). However, important discrepancy has been observed across sites for press media, which is the source of 154 (53.3%) screenings at the coordination site, and lists generated by electronic health records, which is the source of 104 (52.0%) screening at the field site.
Discussion: The observed discrepancies in recruitment strategies have yielded differences in distribution of women and men in different sites, suggesting that active monitoring of recruitment yields from different sources might be useful to avoid non-random distortions in screened and included subjects.

P-165

What proportion of ethically approved randomised clinical trials can be found in a trial registry?

Benjamin Speich[1,2], Dmitry Gryaznov[2], Viktoria GLoy[2], Kimberly A. Mc Cord[2], Arnav Agarwal[3], Benjamin Kasenda[2], Matthias Briel[2]
[1]Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, United Kingdom, Oxford, United Kingdom; [2]Basel Institute for Clinical Epidemiology and Biostatistics, Department of Clinical Research, University Hospital Basel, University Basel CH-4031 Basel, Switzerland, Basel, Switzerland; [3]Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, Ontario, Canada, Hamilton, Canada
Trials 2019, **20(Suppl 1):**P-165

Background: Randomised clinical trials (RCTs) provide the most trustworthy evidence when evaluating a medical intervention. However, it can be difficult to appraise the true effect of an intervention due to publication bias, i.e. the frequent non-publication of studies with unfavourable results. Clinical trial registries are supposed to give a comprehensive overview of all ongoing RCTs which helps to estimate and control publication bias and to avoid duplication of research. There is little evidence on what proportion of approved RCTs (published and unpublished) was actually registered. This study aimed to close this knowledge gap.
Methods: We had access to a total of 555 RCT protocols that were approved by a research ethics committee in 2012 or 2016 in Switzerland, Canada or Germany. For each RCT we systematically searched if it was registered in a clinical trial registry, and if it was registered before patient enrolment. We present results separately for 2012 and 2016 to assess if there was an improvement over time. In addition, we stratified the analysis by industry and non-industry sponsored RCTs.
Results: From the 555 RCTs, 491 (88%) were registered and 447 (81%) were prospectively registered. We did not find an increase in registrations over time (2012: 91% registered, 81% prospectively registered; n=262; 2016: 88% registered, 81% prospectively registered; n=293). Industry trials seemed to be more often registered (96%; 257 of 269) and prospectively registered (90%; 241 of 269) compared to non-industry RCTs (82% registered; 234 of 286; and 72% prospectively registered; 206 of 286). Data collection on publication status of RCTs approved in 2012 is ongoing and will be present at the conference.
Conclusion: Registration of RCTs is still incomplete, especially for non-industry RCTs. Our study will provide a first estimate of the proportion of unpublished RCTs that can be found in a registry.

P-166

Establishing minimum sample size requirements for stroke rehabilitation randomised controlled trials (RCTs) using the Barthel Index (BI) or modified Rankin Scale (mRS) as outcome measures

Kris McGill[1,2], Jon Godwin[3], Cath Sackley[1], David Gavaghan[4], Marian C Brady[2]
[1]King's College London, London, United Kingdom; [2]NMAHP Research Unit, Glasgow Caledonian University, Glasgow, Scotland; [3]Glasgow Caledonian University, Glasgow, Scotland; [4]University of Oxford, Oxford, United Kingdom
Trials 2019, **20(Suppl 1):**P-166

Introduction: Underpowered trials risk contributing to research waste through the production of inaccurate results. Stroke rehabilitation RCTs can experience recruitment challenges and limited sample sizes. Simulations have been used successfully in other fields to explore sample size adequacy and provide recommendations for future RCTs recruitment targets.
Aim: To examine the adequacy of stroke rehabilitation RCT sample sizes in the context of BI or mRS.