Methods: We simulated trials with a correlated interim (e.g. brain atrophy) and final outcome (e.g. time to disability progression). Data from earlier PMS trials were used to determine parameters such as the association between the outcomes. We explored different design options, including choices for interim and final outcomes, timing of interim analyses, and stopping rules. Under each scenario, trials were simulated and operating characteristics (sample size, duration, type-I and type-II error rates) graphically displayed.
Timing of Potential Results: Simulations are ongoing and will be completed by August 2019. Simulations have been informed by analysis of two-phase II trials but will be refined with results from ongoing analysis of several larger phase III trials. Preliminary results suggest that multiple interim analyses could be beneficial to better balance the trade-off between stopping ineffective treatments early and the risk of missing effective ones.
Discussion: Designing a MAMS trial presents several complexities. To date simulations are key to inform decisions such as the appropriate outcome and time-point for the interim analyses. The findings will inform the optimum trial design to maximise the chance of identifying effective treatments for PMS and should be instructive in trial design in other neurodegenerative diseases such as dementia.

P-11
Abstract omitted

P-12
Protocol for a pragmatic cluster randomised controlled trial assessing the clinical effectiveness and cost effectiveness of electronic risk-assessment tools for cancer for patients in general practice (ERICA)
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Trials 2019, 20(Suppl 1):P-12

Introduction: Compared with other developed countries, the UK has poorer cancer outcomes. Early cancer diagnosis within general practice has the potential to facilitate improvements. Paper and mouse mat Risk Assessment Tools (RATs) for 18 cancers have been developed to support GPs in identifying cancer. The RATs give precise estimates of the risk of an underlying cancer based on a single symptom or combination of symptoms. Some of the RATs have been converted into electronic versions (eRATs) and embedded into GPs' clinical systems, delivering an automated prompt to consider the possibility of cancer when a patient has at least a 2% risk of cancer. Early pilot work suggests that the eRATs are acceptable to GPs. There is no evidence to date of their clinical- or cost-effectiveness.
Methods: A pragmatic, cluster RCT with 530 practices across England randomised 1:1 to receive either the intervention (access to the eRATs medical device including: lung, oesophago-gastric, kidney, bladder, ovarian, colorectal) or usual practice. There will also be embedded process and health economics evaluations along with a parallel study modelling the impact of eRATs on NHS service delivery. Clinical outcomes will be observed in routinely collected data exported from the cancer registry. The primary outcome will be the proportion of the combined six cancers diagnosed during a 2-year follow-up that were at Stage 1/2 (early – cure likely) versus Stage 3/4 (late – cure not likely) at the time of diagnosis. Ethics approval and trial registration will be sought in the early spring 2019. Practice recruitment is planned to launch in summer 2019 and close in winter 2019.
Results: Results will be available from winter 2023.
Discussion: The results of the RCT will provide a definitive assessment of the clinical- and cost-effectiveness of the six eRATs being studied and report their impact on patient care.

P-13
Testing the Feasibility of a Complex Intervention for Perinatal Mental Health in The Gambia
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Trials 2019, 20(Suppl 1):P-13

Introduction: Perinatal mental health problems affect up to 1 in 5 women worldwide and affect not only the mother but can also have long-term adverse effects on her child. It is thus of high priority to develop new low-cost, low-resource, non-stigmatising and culturally appropriate approaches to reduce symptoms of anxiety and depression perinatally.
Methods: We have worked to test the feasibility of undertaking a stepped wedge trial to examine how group singing could be beneficial in alleviating perinatal mental distress in The Gambia. Women in the intervention participated in weekly singing sessions, led by local Kanyeleng singing groups, for six weeks while the control group received standard care. Symptoms of anxiety and depression were measured using self-report questionnaires. The feasibility of the design was assessed through recruitment, retention and attrition rates of participants, clinic's adherence to the schedule and completeness of data by site. Qualitative interviews and video and audio recordings were used to evaluate the acceptability of the intervention.
Timing of Potential Results: We will have the final results of this trial by the end of May 2019.
Potential Relevance & Impact: When running a trial in a low resource context different challenges are present, such as lack of infrastructure and technology, low literacy rates, and different cultural expectations, as well as affordances, such as high levels of willingness to help and the ability to quickly affect policy. In this presentation, we will discuss how the design of the trial was planned and how the implementation of this design was achieved. This trial's findings will allow us to investigate the use of music as a potential intervention for perinatal mental health in The Gambia as well as discuss different methodological techniques which can be applied to low and middle-income countries.

P-14
Abstract withdrawn

P-15
Abstract omitted

P-16
Move-It 動起來: Digital worksite exercise in China - outcome and process evaluation
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Trials 2019, 20(Suppl 1):P-16

Introduction: Developing strategies to promote exercise is a major health priority in China. Integrating exercise within the working day may benefit employee health, although workplace interventions are less commonplace in China. We evaluate the outcomes and