


processes of a video and web-based worksite exercise intervention for sedentary office workers in China.

**Methods:** Participants were recruited from an insurance information technology service organisation with sites in two major cities in China. A theoretically informed digital workplace intervention (Move-It ) involving a 10-minute Qigong exercise session (video demonstration via website) was delivered twice a day at set break times during the working day for 12 consecutive weeks. The outcome study was a cluster-randomised wait-list control trial with outcomes assessed in two groups (intervention, n = 143; wait-list control, n = 73). Process evaluation was conducted using the RE-AIM framework: reach, effectiveness, adoption, implementation and maintenance. Data from employee exercise logs, six focus groups with employees and managers, and analysis of documents including employee profiles and promotional materials were examined.

**Results:** Employees' physical activity increased from baseline to post-intervention in both the intervention and control group, though the magnitude of change failed to reach statistical significance. There were no changes in job performance or weekday sitting hours. Process evaluation showed that the intervention had wide reach and was successfully marketed to all employees with good uptake. The participatory approach increased perceived organisational support and enhanced adoption. The intervention was implemented broadly as planned, with employee enthusiasm for long-term maintenance but no concrete plans in place at study sites.

**Discussion:** Qigong worksite exercise intervention can be successfully delivered to sedentary office workers in China using video and web-based platforms and may increase physical activity although further outcome trials are required. The study highlights the complexity of conducting health research in real-world organisational settings.

#### P-17

##### Improving engagement in a health app: considerations in designing a Micro-Randomised Trial

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*Trials* 2019, **20(Suppl 1)**:P-17

**Introduction:** Health systems are undergoing a digital revolution, with recent developments seeing therapeutic apps emerging as prescribed treatments. However, a common barrier to the therapeutic app's effectiveness is sustaining user engagement. One feature to increase user engagement is with push notifications, which are messages sent to the user from the app.

This research focuses on Drink Less, a digital therapeutic app which is a complex intervention that aims to help users reduce harmful and hazardous alcohol drinking. The app includes five different therapeutic components and sends a daily push notification at 11am.

**Methods:** Observational data comprises of 25,083 users of 1,108,102 sessions between May 2017 and January 2019. We are exploring patterns of use and engagement with the app through descriptive statistics, graphical summaries and cluster analyses. Results from this exploratory analyses will inform the design of a Micro-Randomised Trial (MRT) which aims to understand the effect of new push notifications as time-varying treatments. The MRT objective is to optimise the delivery of notifications to increase user engagement by tailoring the message content and timing of delivery to baseline characteristics. Following the randomisation of a notification, our outcome will be time spent on the app (seconds) during the next hour.

**Timing of potential results:** Exploratory analyses of current patterns of use will be finalised at the end of May 2019. The Micro-Randomised Trial protocol will be finalised by the end of August 2019. Potential relevance and impact

The results will be generalizable to other behaviour change therapeutic apps. This reflects good practice of learning from real world use and brings transparency to the app-developing process which is often considered a 'black-box'. To date, this will be the largest Micro-Randomised Trial undertaken, providing insights to shared experiences, challenges and solutions of clinical trials for developing digital therapies.

#### P-18

##### Issues with missing data in trials of complex interventions: Using therapy non-compliance, we demonstrate a framework for assessing how to deal with the potential bias caused by missing data, a systematic way of determining which pre-/post-randomisation variables predict missingness in final outcomes and assess the need for multiple imputation

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**Introduction:** The ACTIB trial [1] followed 558 participants randomly assigned to either telephone delivered CBT (TCBT), web-based CBT (WCBT) in addition to treatment as usual (TAU) or TAU alone. Binary compliance was defined differently for TCBT and WCBT and not assessed for TAU. Therapy non-compliance (primary outcome completion) was for TCBT, WCBT and TAU respectively; 16% (73%), 31% (67%) and undefined (70%).

**Methods:** We intended to analyse the primary outcomes using longitudinal linear mixed modelling, a method robust to missing data assuming that the mechanism driving missingness was missing at random (MAR), and valid if all potential predictors of missingness have been collected pre-randomisation and incorporated into the analysis model.

Non-compliance with therapy, determined by an independent statistician, was found to be predictive of missing data in both therapy arms (Fisher's exact tests  $p < 0.001$ ) invalidating the MAR assumption. We therefore employed MI to accommodate MAR process which includes a post-randomisation variable predicting missingness.

We used a three-step framework (described in detail in [1]);

1. Assess empirically what baseline variables predict missingness using a stepwise forward selection procedure to identify important predictors

2. Empirically assess whether post-randomisation variables predict primary outcome missingness, e.g. therapy compliance. If true then do step 3,

3. Use MI including all variables identified in steps 1 and 2 in the imputation step of the procedure.

**Results:** Imputation resulted in more conservative trial arm differences comparing therapy arms individually with TAU. The attenuation was more pronounced in the WCBT arm which imputed more missing values. This suggests that MI analyses allowing non-compliance to predict later drop can help remove missing data biases.

**Discussion:** MI can be used where post-randomisation variables such as compliance predict missing outcomes. Variables allowed to drive missingness under a MAR assumption should be assessed systematically.

#### P-19

##### Outcome selection and reporting for innovative surgical procedures and devices: a review of current practice in IDEAL/ IDEAL-D studies to inform the development of a core outcome set

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**Introduction:** Evaluation and reporting of innovative surgical procedures and devices has historically been poor. Development of a core outcome set (COS); generic domains to be measured and reported in all studies of surgical innovations, may help to improve safe and transparent evaluation for their introduction into clinical practice. Methods for identifying outcomes for COSs for effectiveness studies are well established, however, these are unlikely to encompass outcomes relevant to innovation.