

Official Title: Evaluation of an individualized exercise programme plus behavioural change enhancement strategies for managing general fatigue in community dwelling frail older people: A cluster-randomized controlled trial

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Approved by the Human Subjects Ethics Sub-committee of The Hong Kong Polytechnic University
on 15-Jan-2016

Statistical Analyses:

SPSS version 23.0 will be used to analyse the data. An intention-to-treat analysis will be adopted. Descriptive statistics will be generated for the demographic data. Normality assumptions for the variables will be checked. The baseline characteristics of the participants in the three groups will be compared using ANOVA for the continuous variables, a chi-square test for the categorical variables, and the Kruskal-Wallis test for the ordinal variables. Mixed-effects modelling will be used to measure changes in the outcome assessments across the mid-term programme (at week 8) and the three post-tests (1 week, 6 months, and 12 months after the intervention) among the three groups, followed by the Helmert contrasts test (if any results are found to be significant)(60). Another mixed-effects modelling approach will be used to measure the participants' attendance rate in the weekly exercise sessions and their adherence to the home exercise during the programme and the follow-up period between the EXER and the COMB groups. Any pre-test outcome scores, demographic information, data on health conditions, comorbidity index, health service utilization, dosages of exercise recommended by the physiotherapist, and participation in other exercise programmes during the study period, indicating significant differences between groups, will be treated as co-variates as needed. Multiple imputations will be adopted to manage missing data. A p-value of < 0.05 will be considered statistically significant. Content analysis will be used to analyse the interview data⁶¹. All audio-taped interviews will be transcribed into Chinese by the RA and the transcriptions will be checked for accuracy by the PI using QSR NVivo 11. The revised transcripts will be coded independently by two (Chinese-speaking) Co-Is. The research team will then discuss the identified codes and come to an agreement on them, grouping them into main (sub)categories with the support of verbatim data. The (sub)categories will then be condensed and/or re-organized when deemed necessary. The research team will examine them for consistency, reach a consensus about their meaning and structure, and devise a list of finalized categories. A set of (sub)categories with supporting verbatim data will finally be generated to identify the major strengths and limitations of the combined intervention to come up with improvements for its future use.