Determined feasibility of chair-based physical activity interventions, aimed at improving various aspects of health and wellbeing in geriatric populations with pre-existing frailty, within a hospital ward setting.

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Background
Frailty is a common and clinically significant condition within geriatric populations, the latter predominantly due to its association with adverse health outcomes such as hospitalisation, disability and mortality (Fried et al. 2001, Rodriguez-Mañas, Fried 2013). Physical activity and exercise interventions have been proposed as potentially offering the best form of treatment for frail older adults (Theou et al. 2011).

However, to date there is a surprising, but evident, lack of interdisciplinary research pertaining to this area, with the majority of studies focusing on the impact of physical activity interventions on functional capacity (Giménez-Garriga et al. 2014), or reductions in the rate of cognitive decline (Ngando et al. 2015). Recently research has begun to move towards the examination of physical activity intervention with relation to holistic health examining physiological, cognitive, social and emotional health and functional capacity (Tarazona-Santabalbina et al. 2016).

This present study will assess the feasibility and efficacy of physical activity interventions, aimed at improving multidimensional health, in the form of short duration (2 weeks), intensive (5–6 days per week), chair-based physical activity interventions within a hospital ward setting.

Protocol

Aims and Objectives

**Primary Aim:** Assess the feasibility of a future clinical trial in this setting, which aims to assess the impact of chair-based physical activity interventions on the multidimensional health of frail geriatric populations.

**Secondary Aim:** To assess the efficacy of the interventions on the primary dependent variables of the proposed future clinical trial within this setting.

Participant population / Sample size

The study will recruit ~ 50 older adults (BMI) with pre-existing frailty, meeting at least 3 of the criteria of the Fried frailty phenotype (Fried et al. 2001).

A convenience sample will be utilized, with participants recruited from the Harborne ‘living lab’ ward of the Queen Elizabeth Hospital Birmingham.

Key Eligibility Criteria

**Inclusion criteria:** All participants will be required to be:
- temporary residents within the Harborne ‘living lab’ ward of the Queen Elizabeth Hospital Birmingham, Edgbaston, Birmingham, United Kingdom.
- 65 years of age
- frail according to the fried frailty phenotype criteria (Fried et al. 2001)
- have the capacity to speak and read in English.
- Anticipated by their care team to remain on the ward for ~ 14 days post enrolment into the study. This will be advised by the patients care team.

**Exclusion criteria** will exclude participants who are/ have:
- currently taking part in any other clinical trial which could potentially have an impact upon the findings of the present study
- currently terminally ill with life expectancy less than the duration of the study
- severe sensory impairment which would profoundly impact on their capacity to undergo the interventions, even once adaptations have been made.

**Trial Design**

- Feasibility Study
- Interventional, randomized, independent measures (between participants) research design.
- A variation of the stepped wedge design / rolling recruitment will also be utilized. The interventions will be run multiple times over several months in order to maximise the potential sample size due to the constraints of the setting a short-stay ward (~ 3 weeks), with ~ 25 patients on the ward at any given time.
- Participants will be randomised (stratified block randomisation) into one of the two physical activity interventions.

**Independent variables**

- Physical activity intervention 1: Move It Or Lose It (MIOI)
- Physical activity intervention 2: HUR resistance equipment training (HURT)

**Potential Implications of the research**

- Most immediate implication of the research will be the assessment of the feasibility of the proposed future clinical trial within this setting which will allow for a more impactful, informative and robust understanding of the efficiency of the specifically adapted chair-based physical activity interventions on the multidimensional health of frail geriatric populations within a hospital ward setting.
- Frailty can also have an enormous impact on an individual’s life, in addition to the lives of their loved ones, and even society as a whole (Theou et al. 2013). As such, if these current interventions prove feasible and if the limited efficacy testing proves positive, this could be the potential for where an implication; more importantly the implementation of chair-based physical activity for older adults with frailty, in order to improve their health, not only from a physiological perspective, but also potentially a psychological, cognitive, emotional and social health, and functional capacity perspective, as well as benefitting their lives.

**Methods of Qualitative Data collection**

- Semi-structured interviews with participants
- Focus groups with intervention implementers and study support staff

Qualitative data analysis will take the form of Interpretative Phenomenological Analysis

Potential dependant variables

**Physical**

- Acute: Short Physical Performance Battery (SPPB)*
- Functional:
  - Controlled, individually limited, slow, unsteady gait
  - Deterioration / recovery rate of physical activity level
  - Dynamic balance tasks
  - C-reactive protein (CRP)
  - Interleukin-6 (IL-6)
  - Inflammatory cytokines
  - Tumor Necrosis Factor Alpha (TNFα)
  - Inflammatory markers

**Social**

- Interpersonal Support Evaluation List (ISEL)
- PSQI (Pittsburgh Sleep Quality Index)
- Physical Activity Scale for the Elderly (PASE)

**Analytical methods**

- **Qualitative data analysis**
  - Data transcription
  - Data familiarisation (multiple readings)
  - Development of coding and category system
  - Analysis of themes
  - Development of research hypothesis
  - Conceptualisation of findings

- **Quantitative data analysis**
  - Product correlations between socio-demographic variables and changes in the secondary dependent variables

**Main dependent variables**

- **Secondary dependent variables**
  - Physiological variables
  - Functional variables
  - Psychological / Emotional dependent variables
  - Social variables

**Interventions**

- **Move It Or Lose It (MIOI)**
  - An established chair-based physical activity programme for older adults.
  - Exercises performed will related to strength, balance, aerobic capacity and flexibility.
  - Aimed to increase functionality and independence in older adults.

- **HUR Resistance Training Intervention**
  - Specially adapted resistance training machines for older adults.
  - Comfortable, easy to use, pneumatics
  - Allow to load to be increased in increments of 100 grams - similar to the weight of a small apple (very appropriate for the population)

**Methods of Analysis**

- **Primary dependent variables:** Based on an inductive process, utilising Interpretative Phenomenological Analysis (Thematic analysis). Two researchers will be employed to analyse the data in order to increase triangulation form the data analysis perspective.

**Secondary dependent variables:**

- 2x2-way independent measures ANOVA’s will be carried out on all secondary dependent variables
- Pearson-product correlations between socio-demographic variables and changes in the secondary dependent variables.

**References**