



Determining the 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



Doody P., Whittaker A.C., Lord J.M.
School of Sport, Exercise and Rehabilitation Sciences
College of Life and Environmental Sciences
University of Birmingham

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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 2015).
- 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 (Giné-Garriga et al. 2014), or reductions in the rate of cognitive decline (Ngandu 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 multi-dimensional 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 multi-dimensional 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 (≥65) 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:

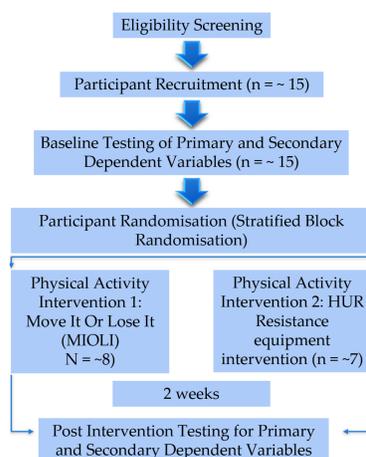
- temporary residents within the Harborne 'living lab' ward of the Queen Elizabeth Hospital Birmingham, Edgbaston, Birmingham, United Kingdom.
- ≥ 65 years of age
- frail according to the fried frailty phenotype criteria (Fried et al. 2001)
- have the capacity to speak and read in English.
- Anticipated 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 wedged 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 (MIOLI)	Physical Activity Intervention 2: HUR resistance equipment training (HUR)
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Potential Implications of the research

Most immediate implication from a research prospective is the assessment of the feasibility of the proposed future clinical trial within this setting which will allow for a more intricate, informative and robust understanding of the influences of the specially 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 individuals life, in addition to the lives of their loved ones, and even society as a whole (Theou et al. 2011). As such, if these current interventions prove feasible and if the limited efficacy-testing proves positive, this research has the potential to have far reaching implications; most importantly the advancement of short term care within a geriatric ward setting, 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 benefiting the lives of their loved ones.

Interventions

Move It Or Lose It (MIOLI)



- 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, pneumatic
- Allow to load to be increased in increments of 100 grams – similar to the weight of a small apples (very appropriate for the population).

Dependent Variables

Primary Dependent variables: Relate to the eight primary areas of focus of feasibility studies (Bowen et al. 2009).

Primary areas of focus for feasibility studies (Bowen et al. 2009)		
Acceptability	Practicality	Expansion
Demand	Adaptation	Limited-efficacy testing
Implementation	Integration	

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

Secondary Dependent variables related to multi-dimensional health:

Physiological	Functional
Physiological Dependent Variables (Blood samples)	Functional Dependent Variables
Cortisol	Hand grip strength*
Dehydroepiandrosterone-sulphate (DHEAS)	Leg power output
Serum cortisol : DHEAS ratio	Short Physical Performance Battery (SPPB)*
C-reactive proteins (CRP)	Katz Index of Independence in Activities of Daily Living (Katz ADL) *
Inflammatory Cytokines:	Fried Frailty Phenotype*
Interleukin 6 (IL-6)	
Tumor Necrosis Factor alpha (TNFα)	
Interferon gamma (IFNγ)	
	Psychological
	Psychological / Emotional Dependent variables
	Geriatric Depression Scale (GDS)*
	Hospital Anxiety Depression Scale (HADS)*
Cognitive	
Cognitive Dependent Variables	
Standardized Mini - Mental State Examination (SMMSE)*	
Social	
Social Dependent Variables	
Interpersonal Support Evaluation List (ISEL-12) *	* PANINI toolkit items

Methods of Analysis

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

Secondary Dependent variables:

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

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