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Diet and Exercise for FRAILty: DEFRAIL

Submission date
12/02/2020

Recruitment status
No longer recruiting

Registration date
18/06/2020

Overall study status
Completed

Last Edited
19/07/2023

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Frailty, when the word is used in a medical sense, refers to a condition that is common among older adults and involves a reduced ability to withstand "external stressors" (such as infection or surgery) compared with less frail older adults. We know that frailty is associated with aging (but not inevitable), yet we don't fully understand why some older adults develop it more rapidly than others. There are a number of different ways of assessing frailty, with one of the most commonly used and studied methods being the Fried Frailty Criteria. According to these, an individual is considered frail if they score three or more out of five on tests of weight loss, weak grip strength, slow gait speed, reduced physical activity and self-reported exhaustion (a score of one or two is designated "pre-frail", while a score of zero is "robust"). More recent research has been looking at various blood-tests that are associated with frailty and in the future, may provide a simpler means to identify and assess the condition, either alone or in combination.

Frailty is an issue of significant concern, since being frailer has been shown to increase an individual's risk of falling, being admitted to hospital and even death. For this reason, frailty is increasingly used to identify those most in need of support among our aging population. However, this alone is insufficient to manage the increased demands on the health and social services of a growing frail older population. Thankfully, a number of studies have shown that it may be possible to reverse frailty and the most effective treatment seems to be a combination of resistance exercise (weights or resistance bands) and protein supplementation.

Many of these studies have been carried out in settings that are unrealistic to reproduce in practice, with prolonged interventions facilitated by large research teams. What has not been shown is that the same benefit can be achieved through community-based group exercise programs delivered by people without medical expertise. If it could be demonstrated, then this could provide the foundation to encourage widespread participation in resistance exercise for frail older adults living in the community.

Who can participate?
People aged 65 or older who have a diagnosis of frailty

What does the study involve?
Our study involves the development of a new exercise and nutritional intervention by a group of experts in various related fields (Geriatric Medicine, Exercise Physiology, Physiotherapy, General

Practice), specifically designed to be suitable and safe for people with a range of levels of frailty, followed by its implementation in a clinical trial. The program itself is eight weeks long and involves three one-hour classes per week in a local fitness centre, led by a staff member with experience in delivering exercise training to older adults. Participants will be asked to attend at least two of these three classes each week. A program logbook has been developed to give clear instructions to both instructors and participants to follow. Each class will involve a combination of aerobic, resistance, balance and flexibility work and requires limited equipment (sets of resistance bands and a chair for each participant). A commercially-available protein-supplemented milk product will also be provided for the duration of the study, of which 250ml is to be consumed twice daily. Through this intervention, we aim to demonstrate the beneficial effect of exercise and protein supplementation on frailty in a “real world” setting.

What are the possible benefits and risks of participating?
The benefits of the study include:
1. Social interaction
2. Improvement in frailty status, strength, mobility, mood (potentially)

The risks of the study include:
1. Transient muscle/joint soreness (mild to moderate)
2. Transient fatigue
3. Fall and associated injury (this risk will be minimized as much as possible)
4. Precipitation of cardiovascular event in individuals with known severe cardiovascular disease or several risk factors for cardiovascular disease (while still estimated to be very low risk)

Where is the study run from?
University Hospital Waterford (Ireland)

When is the study starting and how long is it expected to run for?
July 2018 to July 2020

Who is funding the study?
Royal College of Surgeons in Ireland (Ireland) and Glanbia plc (Ireland)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effect of a standardised exercise and nutritional intervention on clinical and biochemical markers of frailty in older adults

Acronym
DEFRAIL

Study objectives
That a novel exercise and nutritional intervention, developed by expert consensus to be feasible for delivery to groups of frail older adults in a community-setting by non-medical professionals, can improve clinical and biochemical markers of frailty

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 07/11/2018, University Hospital Waterford Research Ethics Committee (Dunmore Rd, Waterford, Ireland X91 ER8E; +353 051842026)
2. Approved 15/11/2018, Waterford Institute of Technology (Cork Rd, Waterford, Ireland X91 K0EK; +353 051302000; info@wit.ie), ref: WIT2018REC0002

Study design
Single-centre non-randomised controlled before-and-after intervention trial

Primary study design
Interventional

Secondary study design

Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Frailty

Interventions
The intervention is an eight-week program of multi-component resistance, aerobic, balance, and flexibility) exercise classes, combined with protein supplementation in the form of commercially available protein supplemented milk (Avonmore Protein Milk) at a dose of 250ml twice daily.

Participants are assessed at baseline, then continue with eight weeks of "regular activity" where no specific advice is given. They are assessed again at this point and then commence the eight-week program. They have the final assessment once they finish the program, at approximately 16 weeks. There is no further follow-up after this point

Intervention Type
Mixed

Primary outcome measure
Frailty assessed by Fried frailty criteria comprised of identification of weak grip strength, slow gait speed, excessive weight loss, exhaustion and reduced activity based on pre-determined thresholds at baseline, 8 and 16 weeks

Secondary outcome measures
1. Falls risk as assessed by the Timed Up & Go (TUG) test at baseline, 8 and 16 weeks
2. Functional leg strength assessed by the 30-second sit-to-stand (30STS) test at baseline, 8 and 16 weeks
3. Frailty assessed by Electronic frailty Index (eFI) at baseline, 8 and 16 weeks
4. Body composition assessed by the Bio-electrical Impedance Analysis (BIA) using BodyStat Quadscan 4000 at baseline, 8 and 16 weeks
5. Arterial stiffness assessed by Carotid-femoral Pulse Wave Velocity (cfPWV) using Complior Analyse device & software at baseline, 8 and 16 weeks
6. Cognitive impairment assessed by Montreal Cognitive Assessment (MoCA) by face-to-face interview at baseline, 8 and 16 weeks
7. Depression assessed by the Geriatric Depression Scale Short Form (GDS-SF) by face-to-face interview at baseline, 8 and 16 weeks
8. Quality of life assessed by the CASP-19 quality of life scale by face-to-face interview at baseline, 8 and 16 weeks
9. Pain as assessed by the Pain Numerical Rating Scale (PNRS) by face-to-face interview at baseline, 8 and 16 weeks
10. Frailty assessed through biochemical markers of frailty in serum samples analysed using MagPix Luminex system (CRP, IL-6, IL-8, IL-10, TNF-alpha and IFN-gamma) and standalone ELISA (Cystatin-C) at baseline, 8 and 16 weeks

Overall study start date
09/07/2018

Completion date
12/07/2020

Eligibility

Key inclusion criteria
1. Aged ≥65 years
2. Clinical Frailty Scale (CFS) score of ≥5 as assessed by the multidisciplinary team of a geriatric medicine outpatient clinic

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
24

Total final enrolment
24

Key exclusion criteria
1. Unable to mobilise without the assistance of another person
2. Severe cognitive or sensory impairment that would prevent participation in the intervention, even despite reasonable supports
2. Participation in any research that could impact on the outcome of this study
3. Documented milk-allergy

Date of first enrolment
02/01/2019

Date of final enrolment
13/11/2019

Locations

Countries of recruitment
Ireland

Study participating centre

University Hospital Waterford
Dunmore Road
Waterford
Ireland
X91 ER8E

Sponsor information

Organisation
Royal College of Surgeons in Ireland

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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
University/education

Funder Name
Royal College of Surgeons in Ireland

Alternative Name(s)
Coláiste Ríoga na Máinleá in Éirinn, RCSI

Funding Body Type
Private sector organisation

Funding Body Subtype

Universities (academic only)

Location
Ireland

Funder Name
Glanbia plc

Results and Publications

Publication and dissemination plan
This work forms the basis of a two-year MD, with thesis submission planned for July 2020.
It is also hoped that a number of publications will arise from this project, including a protocol paper (in process), methodology paper (in process) and results paper.

Intention to publish date
02/07/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		13/02/2020	03/07/2020	No	Yes
Protocol article		15/06/2021	19/07/2023	Yes	No