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CERgAS: multiComponent Exercise and theRApeutic lifeStyle intervention to improve physical function and maintain independent living among urban poor older people

Submission date
15/07/2014

Recruitment status
No longer recruiting

Registration date
27/08/2014

Overall study status
Completed

Last Edited
17/07/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

People around the world are living longer, and this is rapidly changing demographic patterns in societies such as the average lifespan and age. Malaysia, a developing nation, is no exception. The proportion of older Malaysians (aged 60 years and above) is expected to double from 6.3% (1.4 million) in 2000 to 12% (4.9 million) by 2030. As people age, they may become frail, physically disabled and simply not able to do the things they used to be able to do. This can mean that they become more reliant on healthcare in both the short and the long term and this can, in turn, lead to an increase in the cost of public healthcare and services. Frailty is becoming increasingly common with advancing age, resulting in a spiral of physical decline. It leads to weight loss, extreme tiredness, lack of energy, slow movements, loss of muscle and muscle weakness. Frail older people are more likely to fall, become less mobile, become dependent on the help of other people for their day-to-day activities (ADL), become disabled, be admitted to hospital or be admitted to an institution such as a nursing home. Frailty inevitably affects a persons well-being, leads to an increase in individual healthcare costs and can result in death. Since being physically able to enjoy their day-to-day activities (functional status) can be used to assess quality of life among older people, treatments (interventions) that either delay the onset of frailty or make it less severe are likely to be beneficial not only to the elderly people concerned but also their families and society at large. In this study we aim to develop and assess the performance of a six-week multiComponent Exercise and theRApeutic lifeStyle (CERgAS) intervention program aimed at improving the physical capabilities of older people in a poor urban area and ensure that they can continue to live independent lives. This study also hopes to identify the group of older people that will benefit the most from this intervention.

Who can participate?

Older persons aged 60 years and above, residing in a low-cost government subsidized flat in Klang Valley (a cosmopolitan area covering 10 municipalities: Kuala Lumpur, Subang Jaya, Petaling Jaya, Selayang, Shah Alam, Ampang Jaya, Putrajaya and Sepang), independently mobile with a walking speed of <1.24 m/s for females and <1.33 m/s for males, willing and able to

attend a one-hour session twice weekly for 6 weeks, and who do not suffer from unstable cardiovascular disease, other uncontrolled chronic conditions, recent fractures and musculoskeletal diseases.

What does this study involve?
Participants are randomly allocated to either a intervention or control group. Those in the intervention group attend a total of 12 sessions that take place twice a week over a six-week period. These include group exercise sessions and also sessions covering nutrition and oral care. Ongoing support and counselling will be provided through bi-weekly phone calls. People in the control group receive a general health education booklet containing information on a healthy lifestyle.

What are the possible benefits and risks of participating?
Participants will be empowered to adopt a healthy lifestyle with the regular exercise sessions, nutrition and oral care education. It is anticipated that they will improve physically, benefit from better nutrition and that their oral health will improve. While there are no potential risks of participation, any adverse events observed including muscle soreness, pain or injuries will be documented and promptly looked at by a healthcare professional.

Where is the study run from?
The study will take place at 8 randomly selected low-cost government subsidised flats in Klang Valley.

When is the study starting and how long is it expected to run for?
The study will commence in September 2014 and run for 10 months.

Who is funding the study?
The University of Malaya (Malaysia)

Who is the main contact?
Associate Professor Dr Noran Naqiah binti Mohd Hairi
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
MultiComponent Exercise and theRApeutic lifeStyle (CERgAS) intervention to improve physical function and maintain independent living among urban poor older people: a cluster randomised controlled trial

Acronym
CERgAS

Study objectives
A multicomponent exercise and therapeutic lifestyle intervention is more effective than general health education to improve the physical function and maintain independent living among older people in an urban poor setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee, University Malaya Medical Centre (UMMC), 11/07/2014, ref. MEC: 20146-341

Primary study design
Interventional

Study design
Multi-site cluster randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Topic: Elderly, mobility, physical function, exercise, physical activity; Subtopic: health education, therapeutic lifestyle; Disease: Frailty (musculoskeletal)

Interventions
Participants are randomised to:
1. Control arm: Provided with a general health education booklet containing information on a healthy lifestyle. Participants will be advised to maintain their current level of physical activity.
2. Intervention arm: a six-week multiComponent Exercise and theRApeutic lifeStyle (CERgAS) intervention programme comprised of small group exercise sessions, nutrition and oral care education with bi-weekly phone calls to provide ongoing support. The intervention programme will be conducted twice weekly over a duration of six weeks with a total of 12 sessions. Each participant will be provided with a CERgAS kit, a folder containing pamphlets and a DVD on simple home exercises, tips on healthy eating and oral care.

Updated 22/09/2014:
Follow Up Length: immediately post-intervention, 3 months, 6 months; Study Entry: Single randomisation only
(previous text: Follow Up Length: 1 month, 3 months, 6 months; Study Entry: Single randomisation only)

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 22/09/2014:
Physical function: 4-meter gait speed

Timepoint(s): Baseline, immediately post-intervention, 3 months and 6 months follow-up

Previous primary outcome measures:
Physical function:
Objective measurements: 4-meter gait speed, grip strength and TUG test
Subjective measurements: Activities of daily living (KATZ-ADL), Lawtons Instrumental Activities of Daily Living (IADL) and physical functioning in SF-12

Timepoint(s): Baseline, immediately post-intervention, 1 month, 3 months and 6 months follow-up

Key secondary outcome(s)
Current secondary outcome measures as of 22/09/2014:
Objective measurements: grip strength and body composition (BIA)

Subjective measurements:
1. Activities of daily living (KATZ-ADL)
2. Lawtons Instrumental Activities of Daily Living (IADL)
3. Physical activity readiness (PAR-Q+)
4. Physical Activity Scale for the Elderly (PASE)
5. Quality of Life (SF-12)
6. Falls Efficacy Scale-International (FES-I)
7. Fear of falling
8. Geriatric Depression Scale (GDS)
9. Cognitive function (Mini Mental State Examination, MMSE)

Timepoint (s): Baseline, immediately post-intervention, 3 months and 6 months follow-up

Previous secondary outcome measures:
1. Physical activity readiness (PAR-Q+)
2. Quality of Life (SF-12)
3. Falls Efficacy Scale-International (FES-I)
4. Fear of Falling
5. Geriatric Depression Scale (GDS)
6. Cognitive function (Mini Mental State Examination, MMSE)

Timepoint(s): Baseline, immediately post-intervention, 1 month, 3 months and 6 months follow-up

Completion date
30/06/2015

Eligibility

Key inclusion criteria
Current inclusion criteria as of 22/09/2014:
Participants will be included if they:
1. Are aged 60 years and above
2. Are residing in a low-cost government-subsidised flat in Klang Valley
3. Are independently mobile with a walking speed of <1.24 m/s for females and <1.33 m/s for males
4. Are willing and able to attend a one-hour session, twice weekly for 6 weeks
5. Do not suffer from unstable cardiovascular disease, other uncontrolled chronic conditions, recent fractures and musculoskeletal diseases

Previous inclusion criteria:
Participants will be included if they:
1. Are aged 60 years and above
2. Are residing in a low-cost government-subsidised flat in Kuala Lumpur
3. Are independently mobile with a walking speed of less than 0.8 m/s
4. Are willing and able to attend a one-hour session, twice weekly for 6 weeks
5. Do not suffer from unstable cardiovascular disease, other uncontrolled chronic conditions, recent fractures and musculoskeletal diseases

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
256

Key exclusion criteria
Current exclusion criteria as of 22/09/2014:
1. Older people who are already involved or participating in any form of structured exercise programme
2. Unable to participate in the 6 weeks multicomponent exercise and therapeutic lifestyle intervention programme
3. Cognitively impaired
4. Have uncontrolled medical condition(s)

Previous exclusion criteria:
1. Older people who are already involved or participating in any form of exercise programme
2. Unable to participate in the 6 weeks multicomponent exercise and therapeutic lifestyle intervention programme
3. Cognitively impaired
4. Have uncontrolled medical condition(s)

Date of first enrolment
01/09/2014

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Malaysia

Study participating centre
Julius Centre University of Malaya
Kuala Lumpur
Malaysia
50603

Sponsor information

Organisation
University of Malaya (Malaysia)

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
University/education

Funder Name
University of Malaya (Malaysia) - Research Grant (RP001A-13HTM)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/02/2015		Yes	No
Abstract results	results presented at the British Geriatrics Society conference	01/07/2017	17/07/2020	No	No