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The Malaysian Falls Assessment and Intervention Trial

Submission date
27/10/2012

Recruitment status
No longer recruiting

Registration date
27/11/2012

Overall study status
Completed

Last Edited
06/08/2018

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
About one in three older people over the age of 65 years fall at least once a year. Falling over often leads to loss of confidence and avoidance of activity. Some older people are admitted to nursing homes because of repeated falls. Falls can also lead to severe health problems which include fractures of the hip bone and bleeding in the brain. The older person often becomes very dependent suffering the above consequences. Falls in the older person tend to be due to a few problems rather than just one problem on its own. These problems include heart problems, low blood pressure, side-effects of medications, poor balance, muscle weakness, previous strokes, eyesight and the home environment. To treat falls in the older person, we need to look into the whole person and deal with all the potentially treatable causes. The aim of this study is to find out whether a treatment package which looks into treating multiple possible conditions that increase the risk of falls is an effective method of treating falls in the older population in Malaysia.

Who can participate?
Patients with one fall resulting in physical injuries or two or more falls over the past 12 months from the primary care clinic, geriatric clinic and Accident and Emergency.

What does the study involve?
The patients are approached by a researcher to find out if they are interested in the study. Those who agree to take part are then given an appointment to attend a falls clinic. At the falls clinic, patients are given a medical check-up to find out what may be causing them to fall. This involves taking a history, a physical examination, an ECG heart trace, blood pressure and eye tests. The doctor may also order some blood tests, X-rays and some other tests if required, and ask questions about the psychological effects of falls. After the medical check-up, patients are randomly allocated to one of two groups: the regular treatment or the active intervention group. The regular treatment group continue to receive the treatment planned by the doctors they first saw at the clinic or A&E. They are asked to fill in a falls diary and the researcher contacts them regularly over the next 12 months to find out how they are, and they will be seen again in 12 months for a check-up. If the patient is allocated to the active intervention group, they are given individually-tailored treatment, which is prescribed by the doctor. This can include changes to their medication, heart tests, physiotherapy, and a home visit. The doctor may also

refer the patient to the heart specialist, eye specialist or ENT specialist. If the doctor finds that the patient has a balance problem, he/she is referred for physiotherapy, which involves exercises to strengthen his/her muscles. If the patient has a fall in their own home, an occupational therapist visits them at home to see if we can help make their home safer.

What are the possible benefits and risks of participating?
Participants receive a health check at no charge, and any medical problems identified during health screening are addressed as appropriate. There are no known risks associated with participating in this study.

Where is the study run from?
University of Malaya Medical Centre (Malaysia)

When is the study starting and how long is it expected to run for?
July 2012 to February 2016

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

Who is the main contact?
Dr Maw Pin Tan
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
The Malaysian Falls Assessment and Intervention Trial: a randomized controlled trial

Acronym

MyFAIT

Study objectives
Multifaceted interventions is effective in reducing falls in older Malaysians with a history of previous falls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee, University of Malaya Medical Centre, 20/06/2012, ref: 925.4

Primary study design
Interventional

Study design
Single-centre randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Falls in older people

Interventions
Individually-tailored, multifaceted interventions involving modifiable risk factors of falls:
1. Cardiovascular Assessment and Intervention
2. Medication Review
3. Physiotherapy Prescribed Strength and Balance Exercise Programme
4. Home-hazards Intervention
5. Visual assessment and intervention
6. Others- as required

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Fall recurrence over 12 months follow-up measured with a falls diary. Participants will also receive telephone interviews every 2 months to corroborate the accuracy of the diaries and to improve compliance.

Key secondary outcome(s)
Autonomic measures, gait and balance measures and psychological measures conducted on initial assessment. Follow up visits to be hospital will be conducted at 12 months.

Completion date
02/02/2016

Eligibility

Key inclusion criteria
1. Individuals aged >65 years
2. Two or more falls or one injurious fall over the past 12 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Clinical diagnosis of dementia
2. Inability to stand

Date of first enrolment
10/07/2012

Date of final enrolment
23/12/2014

Locations

Countries of recruitment
Malaysia

Study participating centre
University of Malaya
Kuala Lumpur
Malaysia
50603

Sponsor information

Organisation
University of Malaya Medical Centre (Malaysia)

ROR

https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
University of Malaya (Malaysia) ref: RP-010-2012

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/08/2018		Yes	No
Protocol article	protocol	21/06/2014		Yes	No
Other publications	secondary subgroup analysis	01/03/2018		Yes	No