

The Malaysian Falls Assessment and Intervention Trial

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| Submission date 27/10/2012 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 27/11/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 06/08/2018 | Condition category Injury, Occupational Diseases, Poisoning | <input type="checkbox"/> 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

mptan@ummc.edu.my

Contact information

Type(s)

Scientific

Contact name

Dr Maw Pin Tan

ORCID ID

<http://orcid.org/0000-0002-3400-8540>

Contact details

Department of Medicine

Faculty of Medicine

University of Malaya

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50603

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Study design

Single-centre randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please contact Dr M P Tan, mptan@ummc.edu.my to request a patient information sheet

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/07/2012

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

Age group

Senior

Sex

Both

Target number of participants

300

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)

Sponsor details

c/o Prof Dato Ikram Shah bin Ismail

Lembah Pantai

Kuala Lumpur

Malaysia

59100

Sponsor type

University/education

Website

<http://www.ummc.edu.my>

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, UM

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Malaysia

Results and Publications

Publication and dissemination plan

Article has now been submitted for publication

Intention to publish date**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? |
|------------------------------------|-----------------------------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 21/06/2014 | | Yes | No |
| Other publications | secondary subgroup analysis | 01/03/2018 | | Yes | No |
| Results article | results | 03/08/2018 | | Yes | No |