

# The Malaysian Falls Assessment and Intervention Trial

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

Kuala Lumpur

Malaysia

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](mailto: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?
<a href="#">Protocol article</a>	protocol	21/06/2014		Yes	No
<a href="#">Other publications</a>	secondary subgroup analysis	01/03/2018		Yes	No
<a href="#">Results article</a>	results	03/08/2018		Yes	No