ISRCTN71447000 https://doi.org/10.1186/ISRCTN71447000

Promoting physical activity in older Malays with diabetes

Submission date
05/04/2012

Recruitment status
No longer recruiting

Registration date
04/05/2012

Overall study status
Completed

Last Edited
29/07/2015

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 diabetes among older people is becoming a global health problem. Lifestyle intervention such as regular physical activity is a cornerstone in the management of type 2 diabetes. Evidence shows regular physical activity improves glycaemic (blood sugar) and metabolic control. In addition, it reduces the risk of diabetes-related diseases, disability and death. However, compliance to physical activity prescription is poor, especially among older people with type 2 diabetes. Furthermore, older people with diabetes who were less active had poorer glycaemic control than those with higher levels of physical activity. Many strategies have been studied to encourage people with type 2 diabetes to be physically active but few have focused on older people. The strategies include wearable motion sensor devices (pedometer or accelerometer) and peer support. The pedometer/accelerometer increased physical activities (based on step counts in a day) in older people and in people with type 2 diabetes. The accelerometer or pedometer promotes physical activity through personalized visual feedback that involves self-monitoring and the devices are used as a motivational tool. However, little is known about the effects of personalized feedback involving goal setting and planning. There is increasing evidence that peer support through peer mentoring improves diabetes self-management, glycaemic control, self-efficacy and social support. However, most studies focused on younger people. Therefore, this study aimed to find out whether personalized feedback alone or combined with peer support could promote and maintain physical activity when compared to usual diabetes care.

Who can participate?
Patients aged 60 and over with type 2 diabetes who attend the participating primary healthcare clinic .

What does this study involve?
Participants will be randomly divided into three groups. Group 1 will receive usual diabetes care. Group 2 will receive personalized feedback on their physical activity patterns. Group 3 will receive personalized feedback and peer support from peer mentors (older people with type 2 diabetes but with good glycaemic control and physically active). The participants in group 2 and 3 will be encouraged to engage in a walking exercise program for 12 weeks. The personalized feedback includes goal setting and planning. The level of physical activity will be measured using

a pedometer for all groups. Prior to the start of this study, participants will be screened for safety to participate in regular physical activity. Throughout the study, participants will have a total of six visits to the clinic. All participants will undergo health assessments and answer questionnaires on health status on four occasions: at enrolment, week 12, week 24 and week 36. Participants are required to undergo health assessments that include measurements of blood pressure, weight, waist circumference, body fat percentage, time taken to get up from a chair and walk for 6 meters, and distance travelled when walking for 6 minutes. Participants are also required to complete questionnaires and continue with their usual diabetes care by the clinic doctors. Participants will undergo a blood test for sugar and cholesterol during the four visits.

What are the possible benefits and risks of participating?
All participants will receive usual diabetes care, which includes physical activity counselling that may improve their glycaemic control, physical function and health status. It is expected that the feedback and peer support may improve participants' health and physical functions. There should not be any discomfort, risk or harmful effect from this study, as participants will be assessed for safety to participate in physical activity.

Where is the study run from?
The enrolment of this study takes place at a primary healthcare clinic in Shah Alam, Selangor, Malaysia.

When is the study starting and how long is it expected to run for?
The enrolment of study participants was between February 2012 and April 2012 with follow-ups in December 2012.

Who is funding the study?
Monash University (Malaysia).

Who is the main contact?
Dr Sazlina Shariff Ghazali

Contact information

Type(s)
Scientific

Contact name
Dr Shariff-Ghazali Sazlina

Contact details
Jeffrey Cheah School of Medicine
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46150

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Promoting physical activity in sedentary older Malays with type 2 diabetes: a randomized controlled trial

Study objectives
1. The groups receiving personalized feedback on physical activity patterns will demonstrate greater step counts and improvements in clinical parameters and health status than the control group.
2. The groups receiving personalized feedback on physical activity patterns combined with peer supoort will demonstrate greater step counts and improvements in clinical parameters and health status than the groups receiving personalized feedback only and the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Monash University Human Research Ethics Committee, 15/08/2011, ref: CF11/1018-2011000524
2. The Malaysian Ministry of Health Medical Research Ethics Committee, 28/02/2011, ref: NMRR-10-1107-7328

Study design
Three-arm parallel randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Eligible participants are allocated into three groups using a computed random number generator based on blocked randomisation:
1. Control group (receive usual diabetes care)
2. Personalized feedback on physical activity patterns: a structured written feedback on participant's physical activity patterns. The participant's activity patterns will be described based on the calculation of minutes spent walking in a week (obtained from the daily activity diary). The duration achieved will be plotted on a graph. This feedback will be provided as a printed material.
3. Personalized feedback on physical activity patterns combined with peer support: Participants in this group will receive an intervention delivered by peer mentors. The peer mentors will provide structured written feedback on the physical activity patterns. The aim of the peer mentors is to motivate the participants to participate in physical activity and adhere to the activity. A peer mentor is an individual with T2DM for more than 5 years, engaged in regular physical activity, has HbA1c < 8% and lives in the community of the study location.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Pedometer-determined step counts documented in an activity diary measured at enrollment, 12 weeks post intervention, 24 and 36 weeks follow-up.

Secondary outcome measures
1. Glycosylated haemoglobin level (HbA1c)
2. Lipid profile
3. Blood pressure
4. Functional fitness (6-minute walk test)
5. Mobility (timed up and go test)
6. Body composition (body mass index, waist circumference, body fat percentage)
6. General health status (health-related quality of life and psychological wellbeing)
7. Perceived social support
8. Self-efficacy to exercise

Measured at enrollment, 12 weeks post-intervention, 24 and 36 weeks follow-up

Overall study start date
09/04/2012

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Malays aged 60 years and above
2. Diagnosed with type 2 diabetes mellitus (T2DM) at least for 1 year

3. Participating in regular follow up - at least two visits in the last 12 months
4. Sedentary lifestyle
5. No acute medical illness in the last 6 months

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Had recent adjustment in the treatment regime needing increased dose of medication in the last 2 months
2. Presence of cognitive impairment Elderly Cognitive Assessment Questionnaire (ECAQ) < 7
3. Had uncontrolled hypertension (blood pressure ≥ 180/100 mmHg)
4. Presence of coronary artery syndrome
5. Presence of hemiparesis or hemiplegia
6. Has advanced osteoarthritis
7. Presence of psychiatric disorders (such as depression, anxiety, psychosis)
8. Has complications of diabetes such as proliferative retinopathy, renal impairment
9. Presence of uncontrolled respiratory conditions such as asthma or chronic obstructive pulmonary disease
10. Known hearing impairment
11. Known visual impairment (visual acuity worse than 6/12 after optical correction)
12. Lives in residential home

Date of first enrolment
09/04/2012

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Malaysia

Study participating centre
Jeffrey Cheah School of Medicine
Bandar Sunway
Malaysia
46150

Sponsor information

Organisation
Monash University (Malaysia)

Sponsor details
Sunway Campus
Jalan Lagoon Selatan
Selangor Darul Ehsan
Bandar Sunway
Malaysia
46150

Sponsor type
University/education

Website
http://www.monash.edu.my/

ROR
https://ror.org/00yncr324

Funder(s)

Funder type
University/education

Funder Name
Monash University Sunway Campus (Malaysia), ref: M-GPH-MG-68

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	13/07/2015		Yes	No