

To determine if a peer-education model can improve the management of osteoporosis in community dwelling seniors

Submission date 29/08/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/09/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/09/2013	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Osteoporosis is a condition whereby the bones have lost strength and are at increased risk of fracture. It is well known to be underdiagnosed and undertreated. There are medications available that can significantly reduce the rate of fracturing but they are underused. The decision to treat is usually based on a fracture history and risk assessment, for example by measuring the bone mineral density (a measure of bone strength). The aim of this study was to test an educational model whereby a group of specially educated older peers could educate other seniors about the disease, its assessment and management, and assist them to navigate the healthcare system to get an assessment done and be placed on appropriate treatment by discussing the risk state with their family doctor.

Who can participate?

The study will be conducted in a limited geographic area in London Ontario, consisting of 13 apartment blocks with a high number of seniors. Anyone at or over the age of 65 and who is a resident of that community, can participate.

What does the study involve?

Participants will be randomly allocated to the intervention or the control group. Participants in the control group will receive usual care. Participants in the intervention group will attend a 2-hour education session presented by their peers, following which they will be assigned a monitor who will conduct a fracture risk assessment, encourage the subject to approach their doctor to obtain a bone mineral density (BMD) measurement, and with the result of the fracture risk assessment along with the BMD return to the physician for a final assessment on the need for treatment. The study will assess how many are successful at completing the assessment and being put on the appropriate medication.

What are the possible benefits and risks of participating?

The subjects may benefit from improvement in the management of their risk assessment if appropriate. There are no anticipated risks.

Where is the study run from?

At the University of Western Ontario, London, Ontario, Canada.

When is the study starting and how long is it expected to run for?

The study started in June 2008 and completed in September 2009.

Who is funding the study?

The study is funded by an unrestricted grant from the Alliance for Better Bone Health, an initiative of Procter and Gamble Pharmaceuticals.

Who is the main contact?

Dr Richard Crilly, Department of Medicine, University of Western Ontario.

Dr Marita Kloseck, mkloseck@uwo.ca

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomised trial to determine if a peer-education model can improve the management of osteoporosis in community dwelling seniors

Study objectives

It is hypothesised that an education and mentoring model involving a small group of educated peer-mentors can increase the appropriate assessment and management of osteoporosis in a community of seniors.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Western Ontario Research Ethics Board for Health Sciences, June 8, 2007, Research Number 12835E

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

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

Osteoporosis

Interventions

A small group of six senior volunteers will be educated regarding osteoporosis, its assessment and management. They will then educate their peers regarding the disease and its assessment and management. Each subject is assigned a mentor who will conduct a fracture risk assessment.

The control was "usual care".

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The proportion of subjects who complete the process and receive appropriate management. The outcomes were recorded at baseline and 6 months. This was by patient interview with their mentor who recorded the patient's progress through the system. The nature of the study was a

one on one mentor and patient relationship so progress through the system was continually monitored and advice offered if problems arose. The final assessment was at 6 months.

Secondary outcome measures

No secondary outcome measures

Overall study start date

07/06/2008

Completion date

30/09/2009

Eligibility

Key inclusion criteria

Aged 65 or over, either gender, living within the Cherryhill apartment complex

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

100

Key exclusion criteria

Inability to speak English

Date of first enrolment

07/06/2008

Date of final enrolment

30/09/2009

Locations

Countries of recruitment

Canada

Study participating centre

The University of Western Ontario

London

Canada

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Sponsor information

Organisation

Proctor and Gamble Pharmaceuticals Inc (Canada)

Sponsor details

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Sponsor type

Industry

ROR

<https://ror.org/04rcgpb63>

Funder(s)

Funder type

Industry

Funder Name

An unrestricted grant from the Alliance for Better Bone Health, an initiative of Proctor and Gamble Pharmaceuticals (bought out by Warner Chilcott after the funding) (Canada)

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