

# Mechanisms by which fruit and vegetables influence postmenopausal bone health: a randomised controlled trial in a well-characterised population

<b>Submission date</b> 04/04/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/04/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/05/2011	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Helen Macdonald

### Contact details

Osteoporosis Research Unit  
Health Sciences Building  
University of Aberdeen  
Osteoporosis Research Unit  
Foresterhill  
Aberdeen  
United Kingdom  
AB25 2ZD  
+44 (0)1224 559001  
h.macdonald@abdn.ac.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

FSA project number: N05043

## **Study information**

**Scientific Title**

**Acronym**

ADAFVT (Aberdeen Dietary Acidity, Fruit and Vegetable Trial)

**Study objectives**

To test whether fruit and vegetable intake reduces the acidity of a mixed diet and the requirement of bone for buffering, or provide other dietary components important for bone health.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Grampian Research Ethics Committee on 23/12/2002 (ref: 02/0053).

**Study design**

Two year placebo-controlled randomised trial (double blind for potassium citrate arms and single blind for fruit and vegetable arm).

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Prevention

**Participant information sheet**

**Health condition(s) or problem(s) studied**

Low bone mass/risk of osteoporosis

**Interventions**

Minimisation criteria included key genotypes (vitamin D receptor genotype and Apolipoprotein E genotype, smoking and dietary acidity (calculated from protein to potassium ratio)).

Group A: potassium citrate equivalent to 900 g fruit and vegetables (55.5 mEq)  
Group B: potassium citrate equivalent to 300 g fruit and vegetables (18.5 mEq)  
Group C: 300 g of fruit and vegetables  
Group D: placebo

Duration of treatment was two years for each treatment arm.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

1. Bone turnover markers:
  - a. serum N-terminal Propeptide of type 1 collagen (P1NP), measured at baseline, 3, 6, 12, 18 and 24 months
  - b. serum C-terminal telopeptide of type I collagen (CTX), measured at baseline, 3, 6, 12, 18 and 24 months
  - c. urinary free Deoxypyridinoline cross-links (fDPD), measured at baseline, 3, 6, 12, 18 and 24 months; women also posted a fasted urine sample 6 to 8 weeks after the baseline visit

## **Secondary outcome measures**

Bone mineral density change over two years measured by DEXA at baseline and 24 months.

## **Overall study start date**

01/03/2003

## **Completion date**

01/12/2005

# **Eligibility**

## **Key inclusion criteria**

Women aged 55 years to 65 years who had taken part in a longitudinal study (Aberdeen Prospective Osteoporosis Screening Study). Includes:

1. Otherwise healthy women taking other types of diuretics (not potassium sparing diuretics) or hypertension tablets
2. Women on thyroxine treatment provided their thyroid function is stable (as assessed by free Thyroxine [T4] and Thyroid Stimulating Hormone [TSH] levels) and their dose had not changed in the year prior to study entry

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Sex**

Female

**Target number of participants**

260

**Key exclusion criteria**

1. Suffering from severe disease
2. Malabsorption
3. Having difficulties swallowing tablets/capsules
4. Taking oral corticosteroids
5. On or past bisphosphonate treatment (more than a few weeks)
6. Taking Hormone Replacement Therapy (HRT) in the last six months
7. Less than five years past the menopause
8. Currently taking potassium-sparing diuretics
9. Osteoporosis diagnosed from Dual Energy X-ray Absorptiometry (DEXA) scan at baseline visit

**Date of first enrolment**

01/03/2003

**Date of final enrolment**

01/12/2005

**Locations****Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

**Osteoporosis Research Unit**

Aberdeen

United Kingdom

AB25 2ZD

**Sponsor information****Organisation**

Food Standards Agency (UK)

**Sponsor details**

Aviation House

125 Kingsway

London

United Kingdom

WC2B 6NH

[alisdair.wotherspoon@foodstandards.gsi.gov.uk](mailto:alisdair.wotherspoon@foodstandards.gsi.gov.uk)

**Sponsor type**

Government

**Website**

<http://www.food.gov.uk>

**ROR**

<https://ror.org/05p20a626>

## Funder(s)

**Funder type**

Government

**Funder Name**

Food Standards Agency (UK)

**Alternative Name(s)**

The Food Standards Agency, FSA

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## 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				

[Results article](#)

01/08/2008

Yes

No