

The effect of vibration therapy on bowel stimulation in elderly patients with dementia - a pilot study

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/01/2018	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0081063466

Study information

Scientific Title

The effect of vibration therapy on bowel stimulation in elderly patients with dementia - a pilot study

Study objectives

To examine the claim that vibration, when used regularly over a period of months can help to restore normal bowel function to persons needing medical intervention for severe constipation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled cross-over pilot study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

Digestive System: Constipation

Interventions

Randomised controlled cross-over trial over twelve months. Vibration therapy will be administered via vibration pads and the effects assessed for each participant for six months with the intervention in place, and six months when it is not offered. Vibration therapy will involve patients using the pads 3 times a week for 40 minute sessions.

Group 1: Vibration for 6 months then no intervention

Group 2: No intervention, then vibration for 6 months.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Frequency of bowel movement
2. Enema/laxative use for participants
3. Recording of adverse effects

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/02/2000

Completion date

14/12/2005

Eligibility

Key inclusion criteria

Long-stay elderly patients (at least 20) on selected ward/nursing home areas who have moderate to severe dementia and who have constipation requiring regular laxative therapy.

Participant type(s)

Patient

Age group

Senior

Sex

Not Specified

Target number of participants

20

Key exclusion criteria

1. Failure to give consent
2. Withdrawn if therapy too distressing
3. Withdrawn if too ill to continue

Date of first enrolment

01/02/2000

Date of final enrolment

14/12/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Elderly Directorate
Leicester
United Kingdom
LE5 0TD

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Leicestershire Partnership NHS Trust (UK)

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