ISRCTN93377248 https://doi.org/10.1186/ISRCTN93377248

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

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/01/2018	Digestive System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Lesley Haig

Contact details
Elderly Directorate
Leicestershire Partnership NHS Trust
Towers Hospital
Gipsy Lane
Leicester
United Kingdom
LE5 0TD

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