

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	☐ Prospectively registered
		☐ Protocol
Registration date 28/09/2007	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 24/01/2018	Condition category Digestive System	☐ Individual participant data
		☐ 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Senior

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Elderly Directorate

Leicester

United Kingdom

LE5 0TD

Sponsor information

Organisation

Funder(s)

Funder type

Government

Funder Name

Leicestershire Partnership NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration