

Abdominal massage for people with constipation: experiences, effects and cost effectiveness

Submission date 15/08/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/11/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/11/2008	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

Dr Catrine Jacobsson

Contact details

Department of Nursing

Umeå University

Umeå

Sweden

SE-901 87

+46 9 07 86 9162

catrine.jacobsson@nurs.umu.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

The hypothesis is that abdominal massage for people with constipation could decrease the severity of gastrointestinal symptoms, time to defecate, and laxative use, increase number of bowel movements and quantity of faeces, normalise faeces consistency without increased fluid and fibre intake or increased physical activity. The hypothesis is also that abdominal massage will increase health related quality of life and will be a cost effective intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee at the Medical Faculty, Umeå University. Date of approval: 09/02/2005 (ref: Um dnr. 04-132M)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Constipation

Interventions

Age range of the recruited participants: from 36 to 85 years.

The participants in the intervention group had 15 minutes of massage 5 days/week for 8 weeks. The duration of massage and number of assessments were based on experiences from a pilot study and recommendations from experts with experiences with gastroenterological studies. The massage consisted of very gentle strokes with light pressure. The hands and abdomen were massaged (8 and 7 minutes respectively) using a systematic movement pattern to stimulate tactile receptors in the skin. As the effect of the massage was assumed to be different between participants, the use of laxatives was adjusted based on clinical evaluation.

In the control group, the participants continued with the therapy they were using when they joined the study: bulking agents, osmotic laxative, stimulant laxative, enemas, herbal supplements, or increased fibre intake. Except for a first and a concluding appointment, the contact with the control group during the study consisted of letters with questionnaires.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Severity of gastrointestinal symptom measured with Gastrointestinal Symptom Rating Scale
2. Laxative use
3. Health related quality of life measured with EQ-5D
4. Experience of being constipated and having abdominal massage
5. Cost effectiveness of the intervention
6. Participants' experiences of having abdominal massage. Data was collected by interviews.

The assessments were performed on three occasions: at baseline, Week 4 and 8.

Secondary outcome measures

1. Time to defecate
2. Number of bowel movements
3. Quantity of faeces
4. Faeces consistency
5. Fluid and fibre intake
6. Physical activity

The secondary outcomes were self reported in protocols Monday to Friday at baseline, Week 4 and 8.

Overall study start date

24/01/2005

Completion date

26/03/2007

Eligibility

Key inclusion criteria

1. Adults (both males and females) who are constipated, in accordance with Rome II criteria or dependent on laxatives to have sufficient bowel movements
2. Ability to understand and express themselves in Swedish

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Diagnosis of dementia
2. Psychiatric disease
3. Abdominal hernia
4. Known intestinal cancer
5. Recently undergone surgical operation in the abdomen

Date of first enrolment

24/01/2005

Date of final enrolment

26/03/2007

Locations**Countries of recruitment**

Sweden

Study participating centre**Department of Nursing**

Umeå

Sweden

SE-901 87

Sponsor information**Organisation**

Swedish Research Council (Sweden)

Sponsor details

-

Stockholm

Sweden

SE-103 78

Sponsor type

Research council

Website

<http://www.vr.se/2.69f66a93108e85f68d480000.html>

ROR

<https://ror.org/03zttf063>

Funder(s)

Funder type

Research council

Funder Name

Swedish Research Council (Sweden) (Grant ref: K2006-27X-20063-01-3)

Alternative Name(s)

Swedish Research Council, VR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Sweden

Funder Name

Swedish Association of Health Professionals (Sweden)

Funder Name

Ekhaga Foundation (Sweden) (Grant ref: 2006-16)

Funder Name

County Council of Västerbotten (Sweden) (Grant ref: VLL 1178:3 2006)

Funder Name

Senior Centre of Västerbotten (Sweden)

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