ISRCTN64345887 https://doi.org/10.1186/ISRCTN64345887

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

Submission date 15/08/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 21/11/2008	**Overall study status** Completed	
Last Edited 21/11/2008	**Condition category** Digestive System	

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

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration