

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

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<b>Registration date</b> 21/11/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/11/2008	<b>Condition category</b> Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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## 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