Reflexology for treatment of constipation (Protocol)

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[Intervention Protocol]

Reflexology for treatment of constipation

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The primary objective is to assess the efficacy and safety of reflexology for the treatment of chronic idiopathic constipation.

BACKGROUND

Chronic idiopathic or functional constipation is defined as "an infrequent or incomplete evacuation not caused by disease or medication" (Horton 2004) lasting 6 months or longer and is a common problem in Western populations, affecting 2-27% of adults, with most studies identifying a prevalence of between 12-19% (Higgins 2004). These patients, who are predominantly women, complain of persistent decreased frequency of bowel movements often associated with pain and bloating (Higgins 2004) Chronic idiopathic constipation can result in increased levels of anxiety, depression and poor quality of life (Irvine 2002; Mason 2002; Cheng 2003).

There has been an increase in interest in complementary therapies in recent years with evidence that the use of complementary therapies has grown dramatically in the last 20 years. Reflexology may be one of the most frequently used complementary therapies (Lynn 1996). Reflexology is defined as the use of a sophisticated system of touch, usually on the feet (or hands) (Tiran 2002), whereby a practitioner uses a systematic application of pressure to specific "reflex" points. It has been suggested that reflexology may maintain homeostasis by aiding relaxation and triggering the body's own self-healing capacity (Lett 2000).

Although reflexologists often claim that reflexology may be beneficial for the treatment of constipation there are few studies investigating the efficacy of reflexology for this indication (Eriksen 1995; Yang 1994). Most of these studies are small and non-randomised. A systematic review is required to summarize the available data on the efficacy and safety of reflexology for the treatment of chronic constipation. The aim of this review is to attempt to answer the question: Does reflexology decrease physical or psychological morbidity and symptom distress and improve quality of life in patients with a diagnosis of chronic idiopathic (functional) constipation?

OBJECTIVES

The primary objective is to assess the efficacy and safety of reflexology for the treatment of chronic idiopathic constipation.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials and quasi-randomised trials comparing reflexology for constipation with sham treatment, conventional treatment or no treatment will be considered for inclusion. Controlled before and after studies or interrupted time series studies will also be considered for inclusion. All eligible trials will be included regardless of language and publication type. There will be no language restrictions.

Types of participants

Male or female patients of any age with chronic idiopathic constipation receiving care in a variety of healthcare settings (hospital, community) in treatment or follow-up will be included. Chronic idiopathic constipation can be defined using the Rome I, II or II criteria. Idiopathic constipation according to the Rome III criteria (Longstreth 2006) consists of two or more of the following symptoms for at least 3 months:
1. straining during at least 25% defecations;
2. lumpy or hard stools in at least 25% defecations;
3. sensation of incomplete evacuation for at least 25% defecations;
4. sensation of anorectal obstruction or blockage in at least 25% defecations;
5. manual manoeuvres to facilitate at least 25% of defecations (e.g. digital evacuation, support of the pelvic floor);
6. fewer than 3 defecations per week;
7. loose stools are rarely present without the use of laxatives; and
8. insufficient criteria for a diagnosis of irritable bowel syndrome (IBS).

To avoid missing studies that do not utilize Rome criteria the American College of Gastroenterology Chronic Constipation Task Force definition of chronic constipation will also be utilized. The Task Force defines chronic constipation as, "unsatisfactory defecation characterized by infrequent stools, difficult stool passage or both (Brandt 2005)." Constipation secondary to the use of constipating medication or to conditions such as diabetes mellitus, hypothyroidism, tumour, anal fissure as well as acute constipation will be excluded.

Types of interventions

Studies of reflexology treatment for chronic constipation will be considered for inclusion. Reflexology treatments need to be carried out by a qualified practitioner.

Types of outcome measures

Primary outcomes

The primary outcome measures will be global or clinical improvement as defined by the included studies (e.g. clinical symptoms frequency of defecation, straining, lumpy or hard stools, sensation of incomplete evacuation, sensation of anorectal blockage, manual manoeuvres to facilitate defecation, pain, and bloating).

Secondary outcomes

Secondary outcome measures will include:
- anxiety and depression;
- quality of life;
- need for rescue medication such as laxatives or rectal evacuants;
- transit time measurement (radio-opaque markers), functional recto-anal evaluation (proctoscopy, ano-rectal manometry, defecography) or electromyography;
- cost effectiveness; and
- any adverse events.

Search methods for identification of studies

See: Inflammatory Bowel Disease and Functional Bowel Disorders Group search strategy
The following search strategy will be utilized for this review, using text and keyword/MESH terms in each database:
(reflexology* or (foot* and massage*) or (feet* and massage*) or zone therapy) and (constipation*)
MESH / keyword terms will be modified as necessary for each database. The searches will not be restricted by publication type (i.e. randomised controlled trial).
The following databases will be used to obtain relevant studies for this review. There will be no language or publication type restrictions.
·The Cochrane CENTRAL Register of Controlled Trials
·The Cochrane Complementary Medicine Field
·The Inflammatory Bowel Disease and Functional Bowel Disorders group specialized trials register
·MEDLINE (1966 to present)
·CINAHL (1982 to present)
·British Nursing Index (Jan 1984 to present)
·EMBASE (1980 to present)
·AMED (1985 to present)
·PsychINFO (1989 to present)
·Dissertation Abstracts International (1980 to present)
·Science Citation Index Expanded (SCI-EXPANDED) (1980-present)
·Social Sciences Citation Index (SSCI) (1980-present)
·SIGLE (1980 to present)
Additional Searches
The reference lists of identified randomised clinical trials and review articles will be checked in order to find randomised trials not identified by the electronic or hand searches. Ongoing trials will be searched through the websites www.controlled-trials.com and www.clinicaltrials.gov. Grey literature will be searched through the SIGLE database and other unpublished literature will be obtained through searches of conference proceedings and professional journals.

Data collection and analysis

Selection of studies

Two authors (SW & CN) will independently review potentially relevant studies to determine if they meet the pre-specified inclusion criteria. Any disagreement between authors will be resolved by consensus and if necessary by consultation with the third author.

Data extraction and management

A standardized data extraction sheet will be developed to record data on: study quality, study setting, participants (age and sex; how diagnosis was confirmed; inclusion and exclusion criteria), interventions (type of reflexology, administration, duration, regimen of controlled intervention), outcome measures, attrition, intention to treat analysis, duration of follow-up and the type and number of any reported adverse events. Two authors (SW & CN) will independently extract the data from each study. Any disagreement will be resolved by discussion and consensus with a third author (JG).

Assessment of risk of bias in included studies

The full text of all 'eligible' studies will be obtained for independent review by both authors. The methodological quality of each study will be assessed and where necessary the study authors will be contacted for missing data or clarification of the published data. The Cochrane risk of bias tool (Higgins 2008) will be used to assess the quality of randomised controlled trials. Factors to be assessed include:

1. sequence generation (i.e. was the allocation sequence adequately generated?);
2. allocation sequence concealment (i.e. was allocation adequately concealed?);
3. blinding (i.e. was knowledge of the allocated intervention adequately prevented during the study?);
4. incomplete outcome data (i.e. were incomplete outcome data adequately addressed?);
5. selective outcome reporting (i.e. are reports of the study free of suggestion of selective outcome reporting?); and
6. other potential sources of bias (i.e. was the study apparently free of other problems that could put it at a high risk of bias?).

A judgement of 'Yes' indicates low risk of bias, 'No' indicates high risk of bias, and 'Unclear' indicates unclear or unknown risk of bias. Disagreements will be resolved by consensus. Study authors will be contacted when insufficient information is provided to determine risk of bias. A validated instrument (Downs 1998) will be used for measuring the quality of non-randomised studies.

Measures of treatment effect

The extracted data from the original studies will be used to construct 2 x 2 tables (e.g. clinical improvement versus no improvement for reflexology versus sham). The relative risk (RR) with 95% confidence intervals (95% CI) will be calculated for each outcome. The number needed to treat (NNT) and risk difference (RD) will be calculated where appropriate. An intention-to-treat analysis will be used. For continuous variables, the weighted mean difference (WMD) or standardised mean difference with 95% CI will be calculated.

Dealing with missing data

The authors of the included studies will be contacted to obtain any missing data.

Assessment of heterogeneity

Heterogeneity will be assessed using the chi-square test (a P value of 0.10 will be regarded as statistically significant). The I^2 statistic will be used to estimate the degree of heterogeneity. This measure describes the percentage of total variation across studies that results from heterogeneity rather than chance. A value of 25% is considered to indicate low heterogeneity, 50% moderate heterogeneity and 75% high heterogeneity (Higgins 2003). Sources of heterogeneity will be investigated using a graphic display. The log RR and its 95% confidence interval (CI) will be calculated and plotted for each trial. These plots will be examined to identify any possible outliers as well as to explore any trends in outcome due to differences in methodology, patient population or treatment regimes.

Assessment of reporting biases

Potential publication bias will be investigated using the funnel plot or other corrective analytical methods (Egger 1997). A linear regression approach to measure funnel plot asymmetry on the natural logarithm scale of the odds ratio will be used.

Data synthesis

Data will be analysed using Review Manager (RevMan 5.0.21). Data from individual trials will be combined for meta-analysis if the interventions, patient groups and outcomes are sufficiently similar (to be determined by consensus). Data will not be pooled for meta-analysis if a high degree of heterogeneity is detected (i.e. $I^2 \geq 75\%$). A fixed effects model will be used to pool data in the absence of heterogeneity. A random effects model will be used if significant heterogeneity is detected. The pooled RR and 95% CI will be calculated for dichotomous outcomes. For continuous outcomes the pooled WMD or SMD and 95% CI will be calculated as appropriate.

Subgroup analysis and investigation of heterogeneity

If a sufficient number of randomised trials are identified, the following subgroups analyses will be performed:

1. treatment duration (less than six weeks or more than six weeks); and
2. duration of disease (less than 5 years, 5 to 10 years, more than 10 years).

Sensitivity analysis

A sensitivity analysis will be carried out to determine if the findings from the primary analysis are changed by incorporating different trials in the analysis. This will be done by varying the inclusion criteria and repeating the analysis with the new data set. In addition, the effect of including randomised controlled trials reported only in abstracts and in languages other than English will be examined. Furthermore, if a sufficient number of randomised trials are identified, a sensitivity analysis to explore the influence of trial quality on effect estimates will be performed.

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* *Indicates the major publication for the study*

HISTORY

Protocol first published: Issue 4, 2009

DECLARATIONS OF INTEREST

None known

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Internal sources

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External sources

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