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Behavioural interventions for dysmenorrhoea (Review)

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[Intervention Review]

Behavioural interventions for dysmenorrhoea

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ABSTRACT

Background

Dysmenorrhoea refers to the occurrence of painful menstrual cramps of uterine origin and is a common gynaecological condition with considerable morbidity. The behavioural approach assumes that psychological and environmental factors interact with, and influence, physiological processes. Behavioural interventions for dysmenorrhoea may include both physical and cognitive procedures and focus on both physical and psychological coping strategies for dysmenorrhoeic symptoms rather than modification of any underlying organic pathology.

Objectives

To determine the effectiveness of any behavioural interventions for the treatment of primary or secondary dysmenorrhoea when compared to each other, placebo, no treatment, or conventional medical treatments for example non-steroidal anti-inflammatory drugs (NSAIDs).

Search methods

We searched the Cochrane Menstrual Disorders and Subfertility Group Trials Register (searched May 2009), Cochrane Central Register of Controlled Trials (CENTRAL on The Cochrane Library, Issue 2, 2009), MEDLINE (1966 to May 2009), EMBASE (1980 to May 2009), Social Sciences Index (1980 to May 2009), PsycINFO (1972 to May 2009) and CINAHL (1982 to May 2009) and reference lists of articles.

Selection criteria

Randomised controlled trials comparing behavioural interventions with placebo or other interventions in women with dysmenorrhoea.

Data collection and analysis

Two authors independently assessed trial quality and extracted data.

Main results

Five trials involving 213 women were included.

Behavioural intervention vs control: One trial of pain management training reported reduction in pain and symptoms compared to a control. Three trials of relaxation compared to control reported varied results, two trials showed no difference in symptom severity scores however one trial reported relaxation was effective for reducing symptoms in menstrual sufferers with spasmodic symptoms. Two trials reported less restriction in daily activities following treatment with either relaxation of pain management training compared to a control. One trial also reported less time absent from school following treatment wit pain management training compared to a control.

Behavioural intervention vs other behavioural interventions: Three trials showed no difference between behavioural interventions for the outcome of improvement in symptoms. One trial showed that relaxation resulted in a decrease in the need for resting time compared to the relaxation and imagery.

Authors' conclusions

There is some evidence from five RCTs that behavioural interventions may be effective for dysmenorrhoea. However results should be viewed with caution as they varied greatly between trials due to inconsistency in the reporting of data, small trial size, poor methodological quality and age of the trials.

PLAIN LANGUAGE SUMMARY

Behavioural interventions for dysmenorrhoea

Dysmenorrhoea is a very common complaint that refers to painful menstrual cramps in the uterus (womb). When the pain is due to a recognised medical condition such as endometriosis it is called secondary dysmenorrhoea. When the pain is of unknown cause it is called primary dysmenorrhoea. Nonsteroidal anti-inflammatory drugs or the contraceptive pill have been used as treatment for period pain but more women are looking for non-drug therapies. Behavioural therapies assume that psychological (the mind) and environmental factors interact with, and influence, physical processes, for example stress might influence period pain. Behavioural therapies focus on both physical and psychological coping strategies for symptoms such as pain rather than focusing on medical solutions for any underlying causes of the symptoms. An example of a behavioural therapy is using relaxation to help a woman cope with painful period cramps. This review found that progressive muscle relaxation with or without imagery and relaxation may help with spasmodic (acute, cramping pain) symptoms of period pain. Also that pain management training and relaxation plus biofeedback may help with period pain in general. The results are not conclusive due to the small number of women in the trials and the poor methods used in some of the trials.

BACKGROUND

Description of the intervention

The aetiology of primary dysmenorrhoea has been the source of considerable debate. Until quite recently, many medical and gynaecological texts ascribed the source of primary dysmenorrhoea as emotional or psychological problems. Dysmenorrhoea was attributed to a variety of ca such as anxiety, emotional instability, a faulty outlook on sex and menstruation, or imitation of the mother's feelings about menstruation (Jeffcoate 1975). It has also been attributed to psychoanalytic principles such as rejection of the feminine role or failure to conceive resulting in a frustrated "weeping" uterus (Ylikorkala 1978). Experimental and clinical research has identified physiological reasons for dysmenorrhoea; the over-production of uterine prostaglandins, which are associated with uterine contractions (Rosenwaks 1980), and the over-production of vasopressin, a hormone that also stimulates the contraction of muscular tissue (Stromberg 1984).

Since the implication of physiological factors in the aetiology of

dysmenorrhoea, conventional treatment has focused on medical therapy. Nonsteroidal anti-inflammatory drugs (NSAIDs), which work as prostaglandin synthetase inhibitors, and oral contraceptive pills, which inhibit ovulation thus reducing myometrial activity, are now considered standard treatments (Dawood 1988; Dawood 1990). The efficacy of these conventional treatments is high, however the failure rate is still around 20 to 25% (Dawood 1985; Henzl 1985). Therefore there is a need for alternatives to the conventional medical treatments.

How the intervention might work

Behavioural interventions have been shown to be effective in managing pain in fields as diverse as osteoarthritis and cancer (Bradley 1998; Syrjala 1995). A recent National Institutes of Health (NIH) Consensus Development Conference also found behavioural and relaxation approaches useful in the treatment of chronic pain (NIH Panel 1996). The behavioural approach assumes that psychological and environmental factors interact with and influence physiological processes. Research has demonstrated that life stress can influence dysmenorrhoea, which lends some evidence to the behavioural approach for this type of disorder (Marini 1978; Siegel 1979). A variety of interventions are labelled as behavioural and it is difficult to provide a single definition. Behavioural interventions are primarily aimed at modifying an individual's behaviour but can also be aimed at modifying thoughts or cognitions in order to subsequently change behaviour. Behavioural interventions for dysmenorrhoea may include both physical and cognitive procedures such as biofeedback, desensitization based procedures, Lamaze exercises, hypnotherapy, and relaxation training (Denny 1981; Lewis 1983). These type of interventions focus on physical and psychological coping strategies for dysmenorrhoeic symptoms rather than modification of any underlying organic pathology. Case studies suggest that behavioural interventions may be effective in treating dysmenorrhoea, although it is difficult to evaluate these types of studies due to small numbers of participants and poor methodology (Denny 1981).

Why it is important to do this review

More and more individuals are seeking alternatives to medical interventions. This review aim to explore the role of behavioural interventions for dysmenorrhoea.

OBJECTIVES

To determine the effectiveness of any behavioural interventions for the treatment of primary or secondary dysmenorrhoea when compared to each other, placebo, no treatment, or conventional medical treatments for example non-steroidal anti-inflammatory drugs(NSAIDs).

METHODS

Criteria for considering studies for this review

Types of studies

Any randomised controlled trials (RCTs) that use behavioural interventions to treat primary or secondary dysmenorrhoea.

Types of participants

Inclusion criteria:
Participants in the trials had to meet these inclusion criteria for the trial to be included in the review

- women of reproductive age;
- women with moderate to severe primary dysmenorrhoea (pain that does not respond well to analgesics, affects daily activity or has a high baseline score on a validated pain scale) or women with secondary dysmenorrhoea of identifiable pathology. Trials where the severity of dysmenorrhoea was not formally assessed were included if the potential participants had sought medical advice for perceived pain;
- women with self-reported dysmenorrhoea in the majority of menstrual cycles.

Exclusion criteria:
If participants in the trial met any of these exclusion criteria the trial was not included in the review

- women with mild dysmenorrhoea (mild pain that responds to analgesics);
- women with irregular/infrequent menstrual cycles (outside of the typical range of a 21-35 day cycle);
- women using an intra-uterine contraceptive device (IUD) or taking oral contraceptive pills (OCP).

Types of interventions

Any RCTs involving behavioural interventions as treatment for primary or secondary dysmenorrhoea versus each other, placebo, no treatment, other types of control groups (e.g.wait lists) or other conventional treatment were considered for inclusion in the review.
A variety of interventions have been labelled behavioural interventions and it is difficult to provide a single, unambiguous definition.
This review included interventions which;

(i) attempt modification of thought and beliefs (cognitions) about symptoms and pain. Examples of interventions would be desensitization based procedures, hypnotherapy, imagery, and coping strategies, and/or
(ii) attempt modification of behavioural (or physiological) responses to symptoms and pain. Examples of interventions would be biofeedback (training that develops an individual's ability to control their autonomic nervous system, for example heart rate), EMG (electromyographic) training (use of a graphic representation of muscle contractions to learn to control them), Lamaze exercises, and relaxation training.
Interventions could include those aimed at reducing the pain of dysmenorrhoea as well as those aimed at improving a participant's ability to cope with dysmenorrhoea. Regardless of the focus of the intervention the same outcome measures were assessed for all included trials.
Exercise as an single intervention was not considered for this review as it is the subject of another review (Bolton 2003).

Types of outcome measures

Primary outcomes

- Pain relief (measured either by visual analogue scale (VAS), other scales, or dichotomous outcomes (i.e. pain relief yes/no)).
- Overall improvement in symptoms (measured by change in dysmenorrhoeic symptoms, either self-reported or investigator-observed treatment effectiveness, or any other similar measures).
- Adverse effects from treatment (incidence of side effects and type of side effects).

Secondary outcomes

- Requirements for medication additional to assigned treatment (measured as a proportion of women requiring analgesics additional to their assigned treatment).
- Restriction of daily life activities (measured as a proportion of women of women who report activity restriction).
- Absence from work or school (measured as a proportion of women reporting absences from work or school, and also as hours/days of absence as a more selective measure).

Search methods for identification of studies

Electronic searches

Electronic searches
We searched the Cochrane Menstrual Disorders and Subfertility Group Trials Register (search updated May 2009) (Appendix 1), MEDLINE (1966 to May 2009)(Appendix 2), Cochrane Central Register of Controlled Trials (CENTRAL on *The Cochrane Library*, Issue 2, 2009)(Appendix 3), EMBASE (1980 to May 2009) (Appendix 4) and PsycINFO (1972 to May 2009)(Appendix 5) for publications which described randomised trials of behavioural interventions in the treatment of dysmenorrhoea.

Searching other resources

The National Research Register (NRR), a register of ongoing and recently completed research projects funded by, or of interest to, the United Kingdom's National Health Service, as well as entries from the Medical Research Council's Clinical Trials Register, and details on reviews in progress collected by the NHS Centre for Reviews and Dissemination, was searched for any trials with dysmenorrhoea or dysmenorrhoea as a keyword. Clinical Trials register, a registry of both federally and privately funded US clinical trials was also searched for the same keywords.
The Cochrane Complementary Medicine Field's register of controlled trials (CISCOM) was also searched for any trials with dysmenorrhoea or dysmenorrhoea in the title, abstract or keyword fields.
The citation lists of relevant publications, review articles, and included studies were also searched.

Data collection and analysis

Selection of studies

The selection of trials for inclusion in the review was performed by two of the review authors (MP and PM) after employing the search strategy described previously. The titles and abstracts of potential trials were checked against the inclusion criteria.

Data extraction and management

Data extraction was performed by two of the review authors (MP and PM) independently. Any discrepancies were to be resolved by a third review author (CF), however this was unnecessary. Included trials were analysed for the following details. This information is presented in the table of characteristics of included studies and provides a context for discussing the reliability of results:
Trial characteristics
1. Method of randomisation
2. Presence or absence of blinding to treatment allocation
3. Quality of allocation concealment
4. Number of participants randomised, excluded or lost to follow up
5. Whether an intention to treat analysis was done
6. Whether a power calculation was done
7. Duration, timing and location of the study
8. Source of participants (i.e. where/how they were recruited)

Characteristics of the study participants

1. Age and any other recorded characteristics of women in the study
2. Other inclusion criteria
3. Exclusion criteria
4. Methods used to define and diagnose study participants

Interventions used

1. Type of behavioural intervention
2. Type of placebo/control
3. Type of behaviour change targeted

Outcomes

1. Methods used to measure pain relief achieved by treatment
2. Methods used to measure overall improvement in dysmenorrhoea
3. Methods used to measure requirements for additional medication
4. Methods used to measure restriction of daily life activities
5. Methods used to measure absence from work or school
6. Information on any other outcomes related to the specific intervention used

Assessment of risk of bias in included studies

Figure 1; Figure 2

All assessments of the quality of trials were performed independently by two of the review authors (MW and HP). Any discrepancies were to be resolved by a third review author (CF), however this was unnecessary. All included trials were assessed for methodological quality with the following list of questions. No formal score was used however the results were used to provide a context in discussing the reliability and validity of results.

Figure 1. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

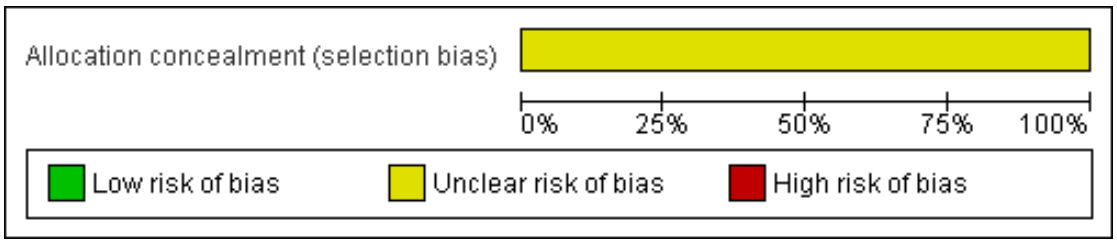
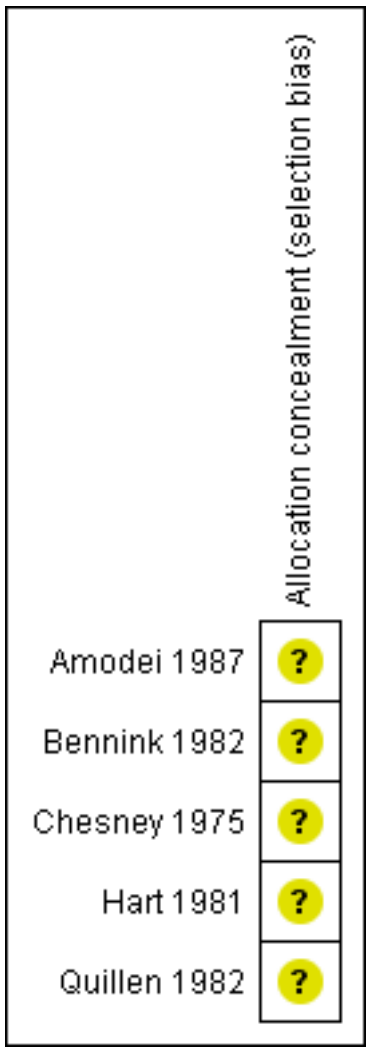


Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Methodological quality assessment questions

- Was the assigned treatment adequately concealed prior to allocation?
- Were the outcomes of patients who withdrew or were excluded after allocation described and included in an 'intention to treat' analysis?
- Were the withdrawals <15% of the study population
- Were the inclusion and exclusion criteria for entry clearly defined?
- Were the treatment and control group comparable at entry?
- Were the subjects blind to assignment status following allocation (if trial design allowed it)?
- Were the treatment providers blind to assignment status (if trial design allowed it)?
- Were the care programmes, other than the trial options, identical?
- Were there any checks to ensure compliance to treatment?
- Were the outcome assessors blind to assignment status?
- Were the outcome measures used clearly defined?
- Were the accuracy, precision, and observer variation of the outcome measures adequate?
- Was the timing of the outcome measures appropriate?
- Were the outcome measures clearly reported?

Additional information on trial methodology or actual original trial data were sought from the authors of four of the included trials

in order to clarify aspects of methodology or when data were unsuitable for inclusion in the meta-analysis (Amodei 1987; Chesney 1975; Hart 1981; Quillen 1982). Replies were not received from any of the authors. Letters were not sent to the other study as recent addresses for the authors could not be located (Bennink 1982).

Measures of treatment effect

Each type of behavioural intervention was analysed separately. Statistical analysis was performed in accordance with the guidelines for statistical analysis developed by the Menstrual Disorders and Subfertility Group. It was intended for outcomes to be pooled statistically. However due to the small number of trials and variety of interventions this was not possible. Heterogeneity between the results of different studies was to have been examined by inspecting the scatter in the data points and the overlap in their confidence intervals and, more formally by checking the results of the chi-squared tests.

A priori, it was planned to perform sensitivity analyses on results to look at the possible contribution of:

(1) differences in methodological quality, trials of high quality only compared to all trials

(2) differences in methods of assessing dysmenorrhoeic pain, use of VAS compared to other scales

However these analyses were not possible as only five trials were included, an inadequate number for these type of analyses.

For dichotomous data (for example, proportion of participants with a specific adverse side effect), results for each study were expressed as an odds ratio with 95% confidence intervals and combined for meta-analysis with RevMan software using the Peto-modified Mantel-Haenszel method.

Continuous differences between groups in the meta-analysis (for example, pain relief on a visual analogue scale) was shown as a weighted mean difference (WMD) and 95% confidence interval. A fixed effects model was used.

Timing of updates

It is the intention of the review authors that no further updates are required for this review.

RESULTS

Description of studies

Results of the search

Thirteen trials were initially identified. Three were excluded (Hubbell 1949; Israel 1985; Lundquist 1947) as they included exercise which is an intervention to be considered by another Cochrane review (Bolton 2003). A further three trials were excluded as their participants were not women with dysmenorrhoea (Pearce 1982; Peters 1991; Van Zak 1994). Two were excluded for failing to mention whether they were randomised (Mathur 1986; Sigmon 1988): data were sought from the authors but no reply was received. Therefore five trials were included in the review (see Included Studies table) (Amodei 1987; Bennink 1982; Chesney 1975; Hart 1981; Quillen 1982).

Types of participants

Three of the included studies categorised the type of dysmenorrhoea as congestive (dull, aching pain) or spasmodic (acute, colicky pain) using the Menstrual Symptoms Questionnaire (Amodei 1987; Bennink 1982; Quillen 1982). These labels were developed as subgroups of primary dysmenorrhoea, although only two of these trials also mentioned excluding organic causes of dysmenorrhoea (Bennink 1982; Quillen 1982). One of these trials also only included women with spasmodic dysmenorrhoea (Bennink 1982). One trial specified women with primary dysmenorrhoea with no other inclusion or exclusion criteria (Hart 1981), and the last mentioned women with menstrual discomfort (Chesney 1975). The trials included women of various ages the overall range was 16 to 44 years of age. Common exclusion criteria were use of oral contraceptives or intrauterine devices and use of additional medication. Three trials mention the source of women; they were all recruited using advertisements from the local community or were college students (Amodei 1987; Bennink 1982; Hart 1981). All trials took place in the USA.

Types of interventions

A number of different behavioural interventions were considered by the five trials. Relaxation by itself or in combination with other treatments was investigated by three trials (Amodei 1987; Bennink 1982; Chesney 1975); other investigated treatments were biofeedback (Bennink 1982; Hart 1981); pain management (Quillen 1982); and coping skills (Amodei 1987). The duration of treatment varied from one to six months.

Types of outcomes

The primary outcome in all five trials was pain, pain relief, or relief of symptoms. This was measured and reported in a variety of ways (see Included Studies table for more details).

Risk of bias in included studies

See Quality Table (Table 1).

Randomisation and allocation concealment

All five trials were stated they were randomised. All received an allocation concealment score of B due to lack of information regarding how randomisation was performed and concealed (Amodei 1987; Bennink 1982; Chesney 1975; Hart 1981; Quillen 1982).

Blinding

One trial (Chesney 1975) reported it was double blind, however blinding status was unclear as the trial only stated that both the treatment providers and women were unaware of the purpose or

hypothesis of the trial and did not state whether they were blind to their treatment assignment. One trial (Amodei 1987) was single blind (therapist only). In the remaining three trials (Bennink 1982; Hart 1981; Quillen 1982) no specific information on blinding was reported.

Inclusion and exclusion criteria

The inclusion and exclusion criteria were clearly defined by all the trials. Many trials used the Menstrual Symptoms Questionnaire to place women in sub-categories of congestive or spasmodic dysmenorrhoea either for inclusion or exclusion, or for diagnostic purposes (Amodei 1987; Bennink 1982; Chesney 1975; Quillen 1982). It is unclear how valid and clinically useful these categories are (Webster 1979). Most of the included trials made no mention of the women excluded from the trial. In one trial of relaxation therapy 7 out of 79 women were excluded, either post recruitment or randomisation (it is unclear which), due to the use of an OCP (Chesney 1975). A trial on pain management training gave specific details on those excluded at recruitment: 14/38 women did not start the trial due to parity, secondary dysmenorrhoea, OCP use, concomitant medication or inability to obtain a physician's statement (Quillen 1982).

Intention-to-treat and withdrawals

None of the published trials stated they performed an intention to treat analysis. Two trials made no mention of withdrawals or dropouts (Amodei 1987; Bennink 1982). One of these trials reported two studies, no mention of withdrawals was made for either study, however in study one the size of the degrees of freedom in the statistical analysis suggested that not all women completed all measures (Amodei 1987). In one trial of relaxation therapy 7/79 women were excluded due to the use of an OCP, then a further 3/72 (4.2%) failed to complete treatment (Chesney 1975). In another study of biofeedback training 3/14 women (21.4%) dropped out of the trial; the authors of the trial stated their reasons for withdrawal as unrelated to the nature of the study (Hart 1981). One trial on pain management had a large number of dropouts from the original 24 women, 8 dropped out during the trial (33.3%) 4 in the control group gave no reason, as did one in the treatment group, one in the group failed to complete treatment due to illness and two had delayed periods. Of those remaining another 8/16 did not complete the 18 month follow-up as they were either not contactable, using oral contraceptives or pregnant (Quillen 1982).

Trial design

Two trials were of factorial design (Bennink 1982; Hart 1981). The other trials did not explicitly state trial design.

Sample size

All trials included in the review were of relatively small sample sizes. Sizes range from 14 to 72 women randomised in each trial.

Baseline comparison of groups

Pre-treatment symptom severity scores (SSS) for the different treatment groups were presented by three trials (Chesney 1975; Hart 1981; Bennink 1982), all of these trials showed no significant differences in baseline scores. Two trials compared Menstrual Symptom Questionnaire (MSQ) scores at baseline and showed no difference (Amodei 1987; Quillen 1982).

Consistency of treatment and compliance to treatment schedules

Trials that involve specific behavioural interventions can be particularly difficult to administer consistently to all the participants in the trial. Only two of the included trials clearly mention attempts to ensure treatment was consistent (Amodei 1987; Hart 1981). One of these trials had a number of therapists providing treatment but gave them a few hours of training and detailed manuals to follow (Amodei 1987). The other trial had weekly meetings for the 10 therapists providing treatment to help maintain consistency and also only used male therapists to try and control for a possible gender effect (Hart 1981). Scheduling problems with this trial meant that not all participants received the same number of treatments, 16 treatments per participant were intended but the actual number of treatments ranged from 9 to 15. The other trials appear to be consistent in their approach to treatment but there was a lack of reported information to clearly assess this consistency. There was no mention of any checks to ensure participants complied to their assigned treatment schedule by two of the included trials (Bennink 1982; Quillen 1982). The other trials used various means to monitor compliance. For the biofeedback trial all the therapy sessions were monitored, although home practice sessions were not monitored (Hart 1981). Two trials that included a relaxation treatment group asked participants to maintain records of relaxation practice (Amodei 1987; Chesney 1975).

Outcome assessment

Four of the included trials used the Symptom Severity Scale (SSS), a 15 point rating scale developed by Chesney 1975, in most cases this scale was well described (Amodei 1987; Bennink 1982; Chesney 1975; Hart 1981). One trial used the Moo's Menstrual Distress questionnaire (MDQ) (Quillen 1982).

Timing of outcome measures was typically the menstruation following treatment although one trial also carried out a follow-up 18 months after treatment, which meant many of the original participants were uncontactable (Quillen 1982).

Outcome measures were usually well reported by the trials. One trial used the MDQ but only reported a small set of the measures, those with large differences between the two groups (Quillen 1982).

Effects of interventions

Five trials of behavioural interventions for dysmenorrhoea met the criteria for inclusion in the review. A number of different interventions were considered by these trials. Relaxation by itself or in combination with other treatments was investigated by three trials (Amodei 1987; Bennink 1982; Chesney 1975); other investigated

treatments were biofeedback (Bennink 1982; Hart 1981); pain management (Quillen 1982); and coping skills (Amodei 1987). The primary outcome in all five trials was pain, pain relief, or relief of symptoms, although this was measured and reported in a variety of ways. Due to the heterogeneity in the considered interventions and outcomes reported statistical pooling would have been inappropriate, even if possible. For this reason, the studies have been analysed separately.

1) Behavioural interventions versus control

Pain relief

One RCT (Quillen 1982) found pain management training was successful in reducing pain compared to a control (pain scale of 0-5, summed means with a minimum score 0, maximum score of 25, treatment mean 2.63, control mean 7.75, reported p-value from trial <0.002). The data from the trial were not suitable for meta-analysis so are described in Analysis 1.1.

Overall improvement in symptoms

Two trials (Bennink 1982; Chesney 1975) reported improvement in symptoms using the Symptom Severity Scale (a 15 item scale of menstrual symptoms, each symptom is scored on a 1-5 point scale, minimum score 15, maximum score 75). Neither trial showed a statistically significant difference between the treatment and control groups for either all women with dysmenorrhoea or women with a specific subtype of dysmenorrhoea (spasmodic or congestive) (see Analysis 1.2 - Relaxation vs control WMD 3.4, 95% CI -11.12, 17.92; Relaxation and biofeedback vs control WMD 1.4, 95% CI -10.82, 13.62; Relaxation and imagery vs control, spasmodic women WMD -0.65, 95% CI -29.52, 28.22; Relaxation and imagery vs control, congestive women WMD -1.55, 95% CI -36.27, 33.17; Relaxation and imagery vs group discussion, spasmodic women WMD -1.0, 95% CI -32.22, 30.22; Relaxation and imagery vs group discussion, congestive women WMD -1.0, 95% CI 37.78, 35.78).

Two further trials (Amodei 1987; Quillen 1982) reported outcomes of symptom severity. The data were not suitable for meta-analysis so are described in Analysis 1.3. One trial reported that relaxation with imagery and relaxation alone (Amodei 1987) were effective treatments for reducing symptom scores compared to a control in menstrual sufferers with spasmodic symptoms yet showed no difference for menstrual sufferers with congestive symptoms (no clear data other than MANOVA F scores were presented in the trial, see Table 0.1.06). The other trial (Quillen 1982) reported that 'general discomfort' was more likely to be relieved by pain management training than a control (scale of 0-5, summed means with a minimum score 0, maximum score of 25, treatment mean 2.75, control mean 8.38, reported p-value from trial <0.002).

Adverse effects

No included trials reported data on adverse effects of treatment.

Requirements for medication additional to assigned treatment

No included trials reported data on requirements for additional medication.

Restriction of daily life activities

Two trials (Amodei 1987; Quillen 1982) reported restrictions in daily life activities as a result of dysmenorrhoea. The data were not suitable for meta-analysis so are described in Analysis 1.4. One trial (Amodei 1987) reported the minutes of rest women needed each day as means. Results reported in the trial showed that women in the relaxation group with spasmodic dysmenorrhoea had a significant decrease in their need for resting time compared to controls (Combined relaxation group - congestives 8 minutes, spasmodics: 42 minutes; Controls - congestives 15 minutes, spasmodics 58 minutes). The other trial (Quillen 1982) reported that interference in daily activities was less likely in the pain management training group compared to a control (scale of 0-5, summed means with a minimum score 0, maximum score of 25, treatment mean 1.63, control mean 4.75, reported p-value from trial <0.002).

Absence from work or school

One trial (Quillen 1982) reported the outcome of absence from work or school as the number of minutes of 'lost time'. Results showed a statistically significant result suggesting that pain management training resulted in less time absent from school or work compared to a control (Analysis 1.5; WMD -313.12, 95% CI -470.69, -155.55).

2) Behavioural interventions vs behavioural interventions

Pain relief

No included trials reported data on pain relief.

Overall improvement in symptoms

Two trials (Bennink 1982; Hart 1981) reported improvement in symptoms using the Symptom Severity Scale (a 15 item scale of menstrual symptoms, each symptom is scored on a 1-5 point scale, minimum score 15, maximum score 75). Neither trial showed a statistically significant difference between the treatment groups (Biofeedback with EMG vs biofeedback with skin temperature training WMD -4.0, 95% CI -9.25, 1.25; Relaxation and biofeedback vs relaxation WMD -2.0, 95% CI 14.93, 10.93). See Analysis 2.1

One trial (Amodei 1987) reported the measurement of symptom severity scores. The data were not suitable for meta-analysis so are described in Analysis 2.2. This trial reported that both relaxation with imagery and relaxation alone were effective treatments for reducing symptom scores in menstrual sufferers with spasmodic symptoms yet showed no difference for menstrual sufferers with congestive symptoms (no clear data other than MANOVA F scores were presented in the trial, see Table 0.1.06). The second experiment reported by this trial compared relaxation and coping skills with coping skills alone. The trial did not report any data for this experiment and reported that 'multivariate analysis failed to demonstrate any significant effects'.

Adverse effects

No included trials reported data on adverse effects of treatment.

Requirements for medication additional to assigned treatment

No included trials reported data on requirements for additional medication.

Restriction of daily life activities

One trial (Amodei 1987) reported the minutes of rest women needed each day as means. Results reported in the trial (Analysis 2.3) showed that women in the relaxation group with spasmodic dysmenorrhoea had a significant decrease in their need for resting time compared to the relaxation and imagery group following two cycles of treatment (Relaxation with imagery group - 44 minutes, relaxation alone 15.7 minutes, no reported p-value). The second experiment reported by this trial compared relaxation and coping skills with coping skills alone. The trial did not report any data for this experiment and reported that 'multivariate analysis failed to demonstrate any significant effects'.

Absence from work or school

No included trials reported data on absence from work or school.

DISCUSSION

The aim of this review was to investigate the effectiveness of any behavioural interventions for the treatment of primary or secondary dysmenorrhoea when compared to each other, placebo, no treatment or conventional medical treatments (e.g. NSAIDs). A meta-analysis combining results from all the trials was not feasible due to differences in the measurement, timing and reporting of outcomes. In addition a number of trials failed to report data on all the outcomes they claimed to measure. This may be a result of trials only reporting 'significant' results and is a form of publication bias that may impact on the overall results of this review. Due to difficulties with the available data results were reported as dichotomous, continuous or descriptive data separately.

Only five relevant trials were identified and included in this review. Interventions included relaxation training with and without imagery, relaxation plus biofeedback, biofeedback with EMG training, and pain management sessions.

The trials in this review had variable quality ratings. None of the trials were clear about how treatment allocation was concealed. Only one of the trials (Chesney 1975) was double blind and one was single blind (Amodei 1987). To be successful in maintaining blinding, the women entering the trial need to be unsure of the treatment being offered. This was unclear in the two trials that mentioned blinding. Double blinding in behavioral interventions is also generally considered impossible, as the treatment provider needs to physically deliver the treatment. As a result, it is probably impossible to perform a true double blind trial of a behavioural intervention although blinding of the participant and outcome assessors should be used if possible. Most of the trials in this review used waiting list controls. An important aspect when using waiting list as controls is the women's previous experience with treatment. Previous treatment of the women was not mentioned in any of the trials in this review.

Women with different levels of severity of dysmenorrhoea were included in the trials and different ways of assessing pain or pain relief were also used. Follow-up length and the timing of outcome assessment also differed.

Overall, the trials in this review had small sample sizes and were of poor methodological quality. Therefore no strong conclusion can be made due to the small size of the trials and other methodological considerations. There were also methodological problems associated with the initial diagnosis of dysmenorrhoea .The use of the Menstrual Symptom Questionnaire (MSQ) to diagnose categories of congestive (dull, aching pain) or spasmodic (acute, colicky pain) dysmenorrhoea are categories that are no longer widely used in experimental trials due to limited validity. There were problems associated with quantifying and grading the pain of dysmenorrhoea in the included trials. The assessment instruments used in quantifying dysmenorrhoea are based on women's self report and as such are subject to obvious bias. In addition all the trials categorised pain using different scales.

Overall there were few withdrawals from treatment, but reporting of adverse events was not conducted by any of the studies therefore it is clear that the data presented in the studies does not reflect a comprehensive assessment of adverse events.

Treatment providers perform behavioural therapies with variation. Treatment is often individually tailored to each participants set of symptoms. Even if this is not the case, different therapists vary the duration of treatment, the frequency of treatments, timing of treatments in the cycle and the number of treatments performed. These are all factors that make it difficult to assess the overall efficacy of behavioural interventions. The impact of these factors on treatment outcome is not clear.

In the trials included in this review, there were many differences in treatment schedules. Many treatments were scheduled during menses, however other trials carried out interventions anytime in the menstrual cycle. These different approaches could affect the measurement of outcomes.

Menstrual pain is highly predictable and has a brief episodic course so seems well-suited to behavioural interventions that can be self-managed. While the trials in this review failed to demonstrate a clear efficacy of behavioural interventions their usefulness should be further evaluated.

AUTHORS' CONCLUSIONS

Implications for practice

There is some evidence from five RCTs that behavioural interven-

tions may be effective for dysmenorrhoea. However results should be viewed with caution as they varied greatly between trials due to inconsistency in the reporting of data, small trial size, poor methodological quality and age of the trials.

Implications for research

The trials included in this study that look at behavioural interventions that are all at least 20 years old therefore more recent trials would be useful. Comparisons with other standard medical treatments such as nonsteroidal anti-inflammatories would also be useful. Any future trials would need to be randomised controlled trials with adequate sample sizes. Objective pain outcome measures such as the visual analogue scale should also be used to standardised outcome trials.

ACKNOWLEDGEMENTS

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Amodei 1987

Methods	Randomisation method: not stated. Design: factorial Blinding: Single blind, therapists blind to experimental hypotheses and participant assignment Number of women randomised: n= 88 women interviewed and randomised(33 spasmodics and 29 congestives) Number of withdrawals:n= 26 (29.5%) No power calculation or intention to treat analysis performed. Source of funding: not stated Intervention 1:Participants matched on severity of symptoms and randomly assigned to two groups Intervention 2: participant selection same as intervention 1 29 congestives from intervention 1, and 18 additional congestive women recruited. assignment.
Participants	Inclusion: regular cycles, premenstrual or menstrual discomfort for at least two years, women classified as spasmodic or congestive according to Menstrual Distress Questionnaire scores. Exclusion: pregnant, psychological disorders. Age: mean of spasmodic group 20.3, mean of congestive group 30.5. Source of participants: introductory psychology classes, local community. Location: North Carolina, USA.
Interventions	Intervention 1: 1. relaxation training plus imagery (5 individual treatment sessions), n=12 spasmodics 2. relaxation training only (same as above), n=11 spasmodics and 12 congestives. 3. waiting list control (collected data for 3 consecutive menses), n=10 spasmodics and 17 congestives. Intervention 2: 1. coping skills only (“brief training” in behavioral-cognitive skills), n=10 congestives 2. coping skills plus relaxation training, n=8 congestives 3. relaxation only and waiting list groups from experiment 1 were also used in data analysis. Duration: 5 cycles
Outcomes	Symptom Severity Scale Ratings of pain/physical discomfort on 0-100 scale Number of minutes engaged in “resting” behavior Number of doses of analgesia
Notes	

Risk of bias

Bias	Authors’ judgement	Support for judgement

Amodei 1987 (*Continued*)

Allocation concealment (selection bias)	Unclear risk	B - Unclear

Bennink 1982

Methods	Randomisation method: not stated Design: factorial Blinding: no Number of women randomised: n= 15 (randomized comparison between 3 groups (2 treatment and 1 control) Number of withdrawals: none Power calculation: no Intention to treat analysis: no Funding: not stated
Participants	Inclusion: women with spasmodic dysmenorrhoea as indicated by the Menstrual Distress Questionnaire, moderate to severe dysmenorrhoea on Symptom Severity Scale, moderate to severe menstrual cramping. Exclusion: organic disease, use of oral contraceptives, use of medication during study. Age: mean 19.2 Source of participants: volunteer college students Location: Michigan, USA.
Interventions	Intervention 1: relaxation plus biofeedback (n=5) in 5 30 min sessions Intervention 2: relaxation only (n=5) as above but with no feedback Intervention 3: control/no treatment (n=5) told to wait for next menses Duration : at least 3 consecutive menstrual cycles. All subjects received a relaxation/biofeedback type session after initial interview, treatment then began at the next cycle
Outcomes	Daily Intensity Rating: abdominal cramping intensity on a 5 point scale Symptom Severity Inventory EMG (electromyographic) Ratings - graphic representation of muscle contractions
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Chesney 1975

Methods	Randomisation method: not stated Design: not stated Blinding: unclear, trial states that therapist and participants unaware of purpose or hypotheses of trial Number of women randomised: n= 72 (random allocation of women in blocks of 3, women rank ordered according to symptom severity then each block of 3 randomised into the 3 treatments). Number of withdrawals: n= 10 (12.6%)7 excluded due to use of OCP and 3 did not complete Power calculation: no Intention to treat analysis: no Funding: not stated
Participants	Inclusion: women with menstrual discomfort, non parous. Exclusion: OCP use Age: 19.7 years Location: Colorado State University, USA.
Interventions	Intervention 1: behaviour therapy with female undergraduate psychology student: relaxation procedures, deep muscle relaxation exercises, visual imagery taught over 5 sessions Intervention 2: pseudo-treatment (leaderless group discussion): 5 sessions of self-directed group discussion Intervention 3: waiting list: letter asking for symptom questionnaire to facilitate entry into next group. Duration: 5 weeks
Outcomes	Symptom Severity Score scale
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Hart 1981

Methods	Randomisation method: allocation not stated, women randomly assigned by pairs matched on menstrual distress and symptom severity scores Design: 2 x 3 split plot factorial design Blinding: no Number of women randomised: n= 14 (11 analysed, 3 dropouts for reasons unrelated to the nature of the study) Number of withdrawals: n=3 (21%) Power calculation: no Intention to treat analysis: no Funding: not stated
Participants	Inclusion: primary dysmenorrhoea. Age: mean 26.9 Parity: 10/11 women were nulliparous Source: volunteers from adverts at campus and in local newspapers
Interventions	Intervention 1: biofeedback training with EMG training of the frontalis muscle. Intervention 2: biofeedback training with skin temperature training of the frontalis muscle. Treatments began after day 5 of 2nd cycle; 30 minute sessions; 16 sessions over 2 cycles designed but unable to be completed (mean # sessions 12.9); home practice of biofeedback. Duration: 2 months baseline, 2 months biofeedback training, two months follow up data collection. 10 male doctoral students in psychology did training
Outcomes	Symptom Severity Scale administered after each menstrual cycle and for 2 months following treatment cycles
Notes	a LOT of therapists for only 14 patients!

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Quillen 1982

Methods	Randomisation method: allocation not stated, participants blocked into pairs based on symptoms and then each pair randomly assigned to treatment control groups Design: not stated Blinding: not stated Number of women randomised: n=24 Number of withdrawals: 8 (33%) Power calculation: no Intention to treat analysis: no Funding: not stated

Quillen 1982 (*Continued*)

Participants	Inclusion: severe primary dysmenorrhoea, grouped as spasmodic or congestive according to Menstrual Symptom Questionnaire Exclusion: parous, secondary dysmenorrhoea, use of OCP, unwilling to obtain MDs verification of primary dysmenorrhoea, use of prescription drugs for dysmenorrhoea. Location: USA.
Interventions	Intervention: four two hour individual pain management sessions, one week apart between 2nd and 3rd periods for treatment group. Control subjects were not contacted at this same point having been told it was a longitudinal study with longer follow up. Duration: not stated
Outcomes	Pre-treatment: Menstrual Symptom Questionnaire and Menstrual Distress Questionnaire, and with Daily Record of Menstrual Complaints Post treatment: Daily records and Menstrual distress questionnaire completed after 3rd period (THIS IS CONFUSING because it also says controls were not contacted after 3rd period???) After 18 months all subjects who could be contacted completed another set of daily records and a MDQ
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Unclear risk	B - Unclear

OCP= oral contraceptive pill
NSAIDS= non-steroidal anti-inflammatory drugs

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Hubbell 1949	Exercise intervention
Israel 1985	Exercise intervention
Lundquist 1947	Exercise intervention
Mathur 1986	Not randomised
Pearce 1982	Trial investigated at pelvic pain rather than dysmenorrhoea

(*Continued*)

Peters1991	Trial investigated general pelvic pain rather than dysmenorrhoea
Sigmon 1988	Not randomised
Van Zak 1994	Trial investigated premenstrual syndrome not dysmenorrhoea

DATA AND ANALYSES

Comparison 1. Behavioural intervention versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain relief - descriptive data			Other data	No numeric data
2 Improvement in symptoms - measured by Symptom Severity Scale	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 Relaxation vs control	1	10	Mean Difference (IV, Fixed, 95% CI)	3.40 [-11.12, 17.92]
2.2 Relaxation & biofeedback vs control	1	10	Mean Difference (IV, Fixed, 95% CI)	1.40 [-10.82, 13.62]
2.3 Relaxation and imagery vs control - spasmodic dys	1	24	Mean Difference (IV, Fixed, 95% CI)	-0.65 [-29.52, 28.22]
2.4 Relaxation and imagery vs control - congestive dys	1	22	Mean Difference (IV, Fixed, 95% CI)	-1.55 [-36.27, 33.17]
2.5 Relaxation and imagery vs group discussion - spasmodic dys	1	24	Mean Difference (IV, Fixed, 95% CI)	-1.0 [-32.22, 30.22]
2.6 Relaxation and imagery vs group discussion- congestive dys	1	22	Mean Difference (IV, Fixed, 95% CI)	-1.0 [-37.78, 35.78]
3 Improvement in symptoms- descriptive data			Other data	No numeric data
4 Restrictions in activities of daily living - descriptive data			Other data	No numeric data
5 Absence from work or school - continuous data (minutes of lost time)	1	16	Mean Difference (IV, Fixed, 95% CI)	-313.12 [-470.69, -155.55]
5.1 Pain management training vs control	1	16	Mean Difference (IV, Fixed, 95% CI)	-313.12 [-470.69, -155.55]

Comparison 2. Behavioural intervention vs other behavioural intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Improvement in symptoms - measured by Symptom Severity Scale	2	21	Mean Difference (IV, Fixed, 95% CI)	-3.72 [-8.58, 1.15]
1.1 Biofeedback with EMG vs biofeedback with skin temp training	1	11	Mean Difference (IV, Fixed, 95% CI)	-4.0 [-9.25, 1.25]
1.2 Relaxation & biofeedback vs Relaxation	1	10	Mean Difference (IV, Fixed, 95% CI)	-2.0 [-14.93, 10.93]

2 Improvement in symptoms- descriptive data	Other data	No numeric data
3 Restrictions in activities of daily living - descriptive data	Other data	No numeric data

Analysis 1.1. Comparison 1 Behavioural intervention versus control, Outcome 1 Pain relief - descriptive data.

Pain relief - descriptive data

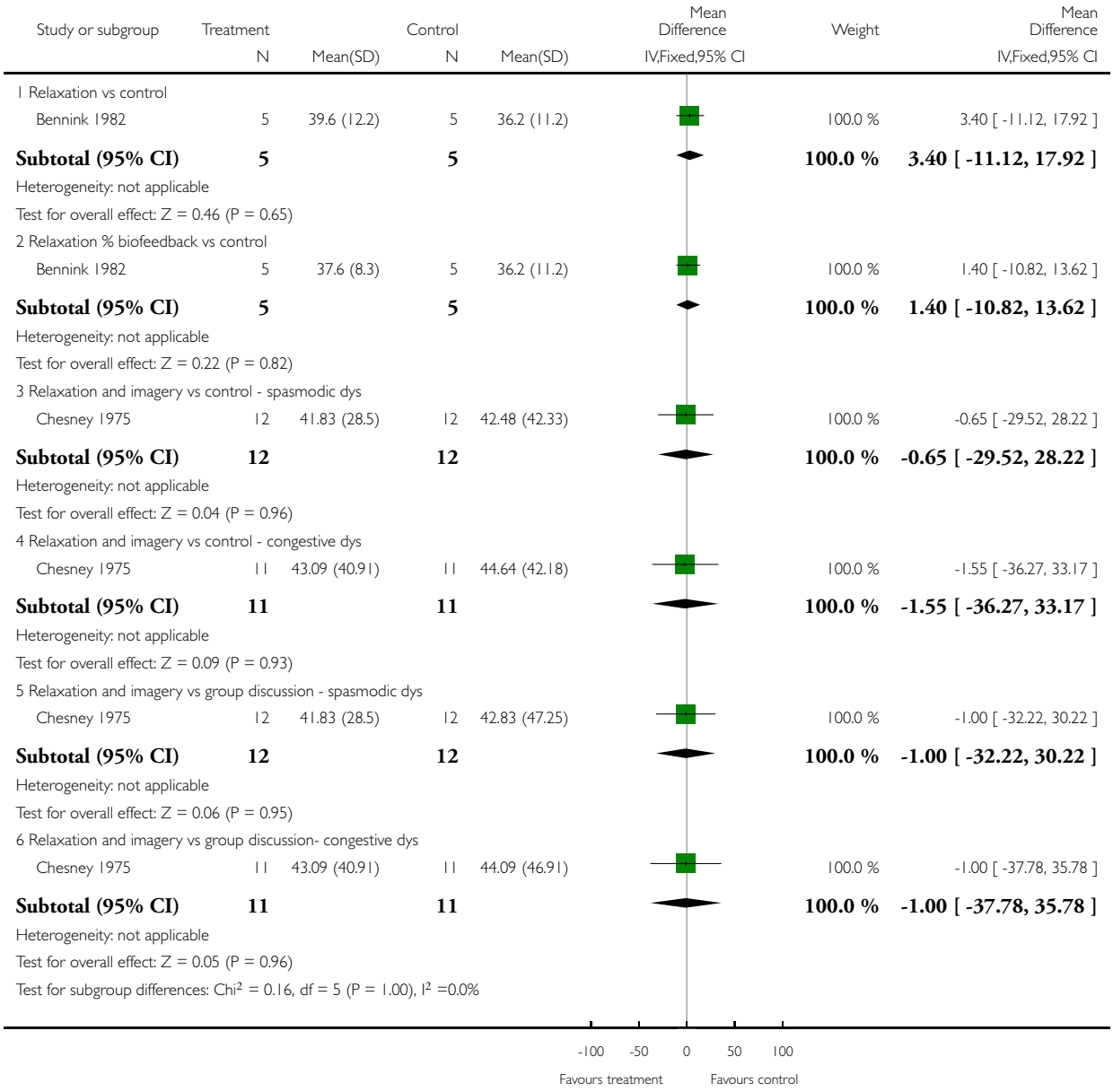
Study	Comparisons	n	Outcome measurement	Data	Conclusions (trial)
Quillen 1982	1) Pain management training 2) Waiting list control	16, 8 in each treatment group	Pain - scale 0-5 (none to exceptionally great). Means and std dev for the sum of responses over 5 days reported for 3 cycles and at 18 month follow-up (min 0-max 25)	Cycle 3 (n=8 in each group): Treatment - 2.63 (1.19) Control - 7.75 (3.15) 18 mth follow-up (n=4 in each group): Treatment - 3.5 (1.73) Control - 8.75 (1.26)	Trial reported that: Following Cycle 3 of treatment all treated women scored significantly lower than controls on all outcome measures (p<0.002)

Analysis 1.2. Comparison 1 Behavioural intervention versus control, Outcome 2 Improvement in symptoms - measured by Symptom Severity Scale.

Review: Behavioural interventions for dysmenorrhoea

Comparison: 1 Behavioural intervention versus control

Outcome: 2 Improvement in symptoms - measured by Symptom Severity Scale



Analysis 1.3. Comparison 1 Behavioural intervention versus control, Outcome 3 Improvement in symptoms- descriptive data.

Improvement in symptoms- descriptive data

Study	Comparisons	n	Outcome measurement	Data	Conclusions (trial)
Amodei 1987	Experiment 1: 1) Relaxation & imagery 2) Relaxation 3) Waiting list control Experiment 2: 1) Coping skills 2) Relaxation and coping skills	Experiment 1: 88 women, 33 spasmodics and 29 congestives completed treatment. Experiment 2: 29 congestives from exp 1, and 18 additional congestive women recruited	No data presented in the trial. MANOVA F scores and p values the only data given.	Experiment 1: MANOVA - 3 treatment x 3 measurement occasions - F (8,116) = 2.62, p <0.01; MANOVA - 2 subject types, congestive and spasmodic x 2 treatments x 3 measurement occasions - F (4,43) = 3.33, p<0.02 and F (4,43) = 4.32, p<0.005	There was some reduction in symptom severity for all experimental positions
Quillen 1982	1) Pain management training 2) Waiting list control	n=16, 8 women in each group	General discomfort measured on scale 0-5, none- exceptionally great. Data reported as means (std dev) of sum of participants responses for five days (min 0- max 25)	Cycle 3 (n=8 women in each group): Treatment - 2.75 (1.04) Control - 8.38 (1.3) 18 month Follow-up (n=4 women in each group) Treatment - 4.25 (1.71) Control - 8.25 (1.26)	Trial reported that: Following Cycle 3 of treatment all treated women scored significantly lower than controls on all outcome measures (p<0.002)

Analysis 1.4. Comparison 1 Behavioural intervention versus control, Outcome 4 Restrictions in activities of daily living - descriptive data.

Restrictions in activities of daily living - descriptive data

Study	Comparisons	n	Outcome measurement	Data	Conclusions (trial)
Amodei 1987	Experiment 1: 1) Relaxation & imagery 2) Relaxation 3) Waiting list control Experiment 2: 1) Coping skills 2) Relaxation and	Experiment 1: 88 women, 33 spasmodics and 29 congestives completed treatment. Experiment 2: 29 congestives from exp 1, and 18 additional congestive women re-	Minutes needing to rest per day - means only reported.	Relaxation group: congestives 28 mins pre-treatment, 8 min post treatment 1, 28 minutes post treatment 2. Spasmodics: 65 mins	Spasmodic relaxation participants showed a significant decrease in their need for resting time

Restrictions in activities of daily living - descriptive data (*Continued*)

	coping skills	cruited		pretreatment, 42 mins post treatment 1, 16 mins post treatment 2 Controls: Congestives - 32 mins pretreatment, 15 mins post treatment 1, 18 mins post treatment 2. Spasmodics - 49 min pretreatment, 58 mins post treatment 1, 95 mins post treatment 2	
Quillen 1982	1) Pain management training 2) Waiting list control	n=16, 8 in each group	Interference in daily activi- ties measured on scale 0-5, none- exceptionally great. Data reported as means (std dev) of sum of participants responses for five days (min 0- max 25)	Cycle 3 (n=8 women in each group): Treatment - 1.63 (1.06) Control - 4.75 (1.91) 18 month Follow-up (n=4 women in each group) Treatment - 2.0 (1.83) Control - 3.25 (2.36)	Trial reported that: Following Cycle 3 of treatment all treated women scored significantly lower than controls on all outcome measures (p<0.002)

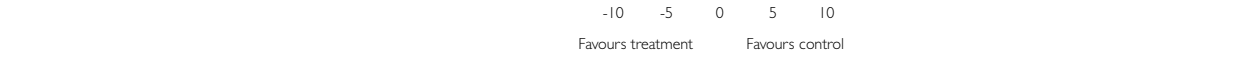
Analysis 1.5. Comparison 1 Behavioural intervention versus control, Outcome 5 Absence from work or school - continuous data (minutes of lost time).

Review: Behavioural interventions for dysmenorrhoea

Comparison: 1 Behavioural intervention versus control

Outcome: 5 Absence from work or school - continuous data (minutes of lost time)

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Pain management training vs control							
Quillen 1982	8	80.63 (87.61)	8	393.75 (209.84)		100.0 %	-313.12 [-470.69, -155.55]
Total (95% CI)	**8**		**8**			**100.0 %**	**-313.12 [-470.69, -155.55]**
Heterogeneity: not applicable							
Test for overall effect: Z = 3.89 (P = 0.000098)							
Test for subgroup differences: Not applicable							

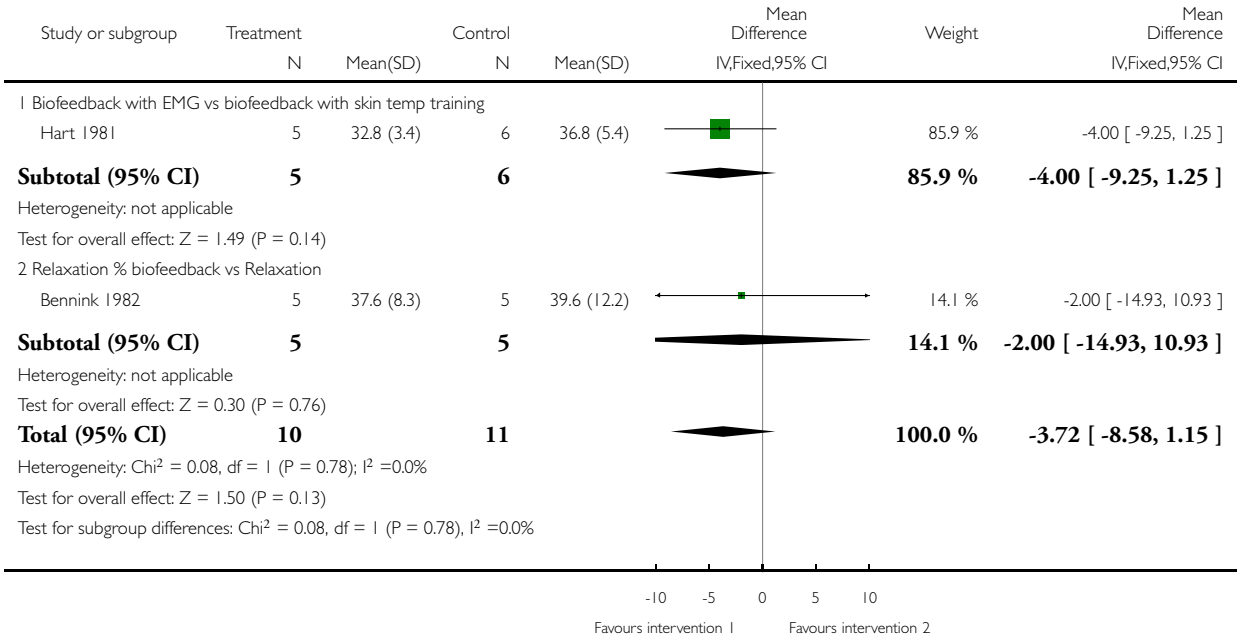


Analysis 2.1. Comparison 2 Behavioural intervention vs other behavioural intervention, Outcome 1 Improvement in symptoms - measured by Symptom Severity Scale.

Review: Behavioural interventions for dysmenorrhoea

Comparison: 2 Behavioural intervention vs other behavioural intervention

Outcome: 1 Improvement in symptoms - measured by Symptom Severity Scale



Analysis 2.2. Comparison 2 Behavioural intervention vs other behavioural intervention, Outcome 2 Improvement in symptoms- descriptive data.

Improvement in symptoms- descriptive data

Study	Comparisons	n	Outcome measurement	Data	Conclusions (trial)
Amodei 1987	Experiment 1: 1) Relaxation & imagery 2) Relaxation 3) Waiting list control Experiment 2: 1) Coping skills 2) Relaxation and coping skills	Experiment 1: 88 women, 33 spasmodics and 29 congestives completed treatment. Experiment 2: 29 congestives from exp 1, and 18 additional congestive women recruited	No data presented in the trial. MANOVA F scores and p values the only data given.	Experiment 1: MANOVA - 3 treatment x 3 measurement occasions - F (8,116) = 2.62, p <0.01; MANOVA - 2 subject types, congestive and spasmodic x 2 treatments x 3 measurement occasions - F (4,43) = 3.33, p<0.	There was some reduction in symptom severity for all experimental positions

Improvement in symptoms- descriptive data (*Continued*)

				02 and F (4,43) = 4. 32, p<0.005	

Analysis 2.3. Comparison 2 Behavioural intervention vs other behavioural intervention, Outcome 3 Restrictions in activities of daily living - descriptive data.

Restrictions in activities of daily living - descriptive data

Study	Comparisons	n	Outcome measurements	Data	Conclusions (trial)
Amodei 1987	Experiment 1: 1) Relaxation & imagery 2) Relaxation 3) Waiting list control Experiment 2: 1) Coping skills 2) Relaxation and coping skills	Experiment 1: 88 women, 33 spasmodics and 29 congestives completed treatment. Experiment 2: 29 congestives from exp 1, and 18 additional congestive women recruited	Minutes needing to rest per day - means only reported.	Experiment 1: Relaxation with imagery group - 44 minutes, relaxation alone 15.7 minutes, no reported p-value). Experiment 2: no data reported. Trial reported that multivariate analysis failed to demonstrate any sig. effects	Spasmodic relaxation participants showed a significant decrease in their need for resting time

ADDITIONAL TABLES

Table 1. Quality table

Study ID	Randomisation method	Design	Allocation score	Blinding	ITT analysis	Power calculation	Withdrawals	Funding
Amodei 1987	Not stated	Factorial	B	Single (therapist)	No	No	26 (29.5%)	Not stated
Bennink 1982	Not stated	Factorial	B	No	No	No	None	Not stated
Chesney 1975	Not stated	Not stated	B	Double	No	No	10 (12.6%)	Not stated
Hart 1981	Not stated	Factorial	B	No	No	No	3 (21.4%)	Not stated
Quillen 1982	Not stated	Not stated	B	No	No	No	8 (33%)	

APPENDICES

Appendix 1. MDSG search terms

MW527 MDSG Search string 15.05.09
Keywords CONTAINS “dysmenorrhoea” or “dysmenorrhoea” or “Dysmenorrhea-Symptoms” or “menstrual cramps” or “menstrual pain” or “pain-dysmenorrhea” or “pelvic pain” or Title CONTAINS“dysmenorrhoea” or “dysmenorrhoea” or “Dysmenorrhea-Symptoms” or “menstrual cramps” or “menstrual pain” or “pain-dysmenorrhea” or “pelvic pain”
AND
Keywords CONTAINS “behavioral coping strategies” or “behavioral therapy” or “cognitive behavioral therapy” or “cognitive approaches” or “cognitive coping strategies” or “coping strategies” or “Relaxation Techniques” or “Psychological therapies” or “psychological therapy” or “psychophysiological” or “psychosocial therapy” or “Psychotherapy” or “biofeedback” or “electromyography” or Title CONTAINS “behavioral coping strategies” or “behavioral therapy” or “cognitive behavioral therapy” or “cognitive approaches” or “cognitive coping strategies” or “coping strategies” or “Relaxation Techniques” or “Psychological therapies” or “psychological therapy” or “psychophysiological” or “psychosocial therapy” or “Psychotherapy” or “biofeedback” or “electromyography”

Appendix 2. MEDLINE search strategy

Database: Ovid MEDLINE(R) <1950 to May Week 2 2009>
Search Strategy:
---
1 dysmenorrh$.tw. (2934)
2 dysmenorrhea/ (2505)
3 painful menstrua$.tw. (65)
4 pelvic pain/ (2282)
5 menstrua$ cramp$.tw. (76)
6 (menstrua$ adj3 pain$).tw. (597)
7 pelvic pain.tw. (3827)
8 or/1-7 (8244)
9 Complementary Therapies/ (10571)
10 “Biofeedback (Psychology)”/ (5238)
11 DESENSITIZATION, PSYCHOLOGIC/ (1427)
12 (behavioural adj5 therapy).tw. (1231)
13 Behavior Therapy/ (19972)
14 Cognitive Therapy/ (9156)
15 PSYCHOTHERAPY/ (35506)
16 Psychotherapy, Rational-Emotive/ (165)
17 (psychotherap$ adj5 techniqu$).tw. (497)
18 Hypnosis/ (7481)
19 hypnotherapy.tw. (718)
20 Lamaze.tw. (103)
21 EMG.tw. (18329)
22 relax$.tw. (86594)
23 Desensiti$.tw. (20034)
24 hypnosis.tw. (5189)
25 electromyograh$.tw. (7)
26 image$.tw. (208453)
27 biofeedback.tw. (3918)
28 or/9-27 (409682)
29 8 and 28 (301)
30 randomized controlled trial.pt. (270500)
31 controlled clinical trial.pt. (79176)
32 randomized.ab. (180480)

33 placebo.tw. (115211)
34 clinical trials as topic.sh. (143058)
35 randomly.ab. (130974)
36 trial.ti. (78769)
37 (crossover or cross-over or cross over).tw. (42715)
38 or/30-37 (640944)
39 (animals not (humans and animals)).sh. (3278689)
40 38 not 39 (593527)
41 40 and 29 (29)
42 (2005$ or 2006$ or 2007$ or 2008$ or 2009$).ed. (2994237)
43 42 and 41 (15)
44 from 43 keep 1-15 (15)

Appendix 3. CENTRAL search strategy

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <2nd Quarter 2009>
Search Strategy:
---
1 dysmenorrh$.tw. (518)
2 dysmenorrhea/ (262)
3 painful menstrua$.tw. (6)
4 pelvic pain/ (162)
5 menstrua$ cramp$.tw. (15)
6 (menstrua$ adj3 pain$).tw. (121)
7 pelvic pain.tw. (313)
8 or/1-7 (893)
9 Complementary Therapies/ (133)
10 "Biofeedback (Psychology)"/ (606)
11 DESENSITIZATION, PSYCHOLOGIC/ (260)
12 (behavioural adj5 therapy).tw. (427)
13 Behavior Therapy/ (2296)
14 Cognitive Therapy/ (2249)
15 PSYCHOTHERAPY/ (1012)
16 Psychotherapy, Rational-Emotive/ (19)
17 (psychotherap$ adj5 techniqu$).tw. (20)
18 Hypnosis/ (250)
19 hypnotherapy.tw. (68)
20 Lamaze.tw. (9)
21 EMG.tw. (1333)
22 relax$.tw. (4995)
23 Desensiti$.tw. (824)
24 hypnosis.tw. (501)
25 electromyograh$.tw. (3)
26 image$.tw. (5234)
27 biofeedback.tw. (953)
28 or/9-27 (18096)
29 8 and 28 (23)
30 limit 29 to yr="2005 -Current" (9)
31 from 30 keep 1-9 (9)

Appendix 4. EMBASE search strategy

Database: EMBASE <1980 to 2009 Week 19>
Search Strategy:
---
1 Controlled study/ or randomized controlled trial/ (2899215)
2 double blind procedure/ (72374)
3 single blind procedure/ (8152)
4 crossover procedure/ (21275)
5 drug comparison/ (81258)
6 placebo/ (126465)
7 random$.ti,ab,hw,tn,mf. (438069)
8 latin square.ti,ab,hw,tn,mf. (1130)
9 crossover.ti,ab,hw,tn,mf. (36587)
10 cross-over.ti,ab,hw,tn,mf. (12303)
11 placebo$.ti,ab,hw,tn,mf. (177798)
12 ((doubl$ or singl$ or tripl$ or trebl$) adj5 (blind$ or mask$)).ti,ab,hw,tn,mf. (118808)
13 (comparative adj5 trial$).ti,ab,hw,tn,mf. (16000)
14 (clinical adj5 trial$).ti,ab,hw,tn,mf. (608295)
15 or/1-14 (3434891)
16 nonhuman/ (3221437)
17 animal/ not (human/ and animal/) (14488)
18 or/16-17 (3225137)
19 15 not 18 (2029152)
20 dysmenorrh$.tw. (2221)
21 dysmenorrhea/ (3676)
22 (painful adj5 menstruat$).tw. (44)
23 pelvic pain/ (4775)
24 or/20-23 (8360)
25 Alternative Medicine/ (12599)
26 relaxation.tw. (51779)
27 biofeedback.tw. (3378)
28 DESENSITIZATION/ (8581)
29 desensitization.tw. (13901)
30 Cognitive Therapy/ or Behavior Therapy/ (27717)
31 Cognitive Therapy/ (16130)
32 PSYCHOTHERAPY/ (37185)
33 emotive therapy/ (19)
34 rational-emotive therapy.tw. (93)
35 psychotherapeutic techniques.tw. (130)
36 Hypnosis/ (6515)
37 hypnotherapy.tw. (593)
38 Lamaze.tw. (28)
39 EMG.tw. (16057)
40 or/25-39 (159424)
41 19 and 24 and 40 (121)
42 limit 41 to yr="2008 -Current" (17)
43 from 42 keep 1-17 (17)

Appendix 5. psycINFO search strategy

Database: PsycINFO <1806 to May Week 2 2009>
Search Strategy:
---
1 dysmenorrh$.tw. (250)
2 dysmenorrhea/ (137)
3 painful menstrua$.tw. (13)
4 pelvic pain/ (0)
5 menstrua$ cramp$.tw. (11)
6 (menstrua$ adj3 pain$).tw. (133)
7 pelvic pain.tw. (256)
8 or/1-7 (608)
9 Complementary Therapies/ (0)
10 "Biofeedback (Psychology)"/ (0)
11 DESENSITIZATION, PSYCHOLOGIC/ (0)
12 (behavioural adj5 therapy).tw. (1188)
13 Behavior Therapy/ (11284)
14 Cognitive Therapy/ (10253)
15 PSYCHOTHERAPY/ (33451)
16 Psychotherapy, Rational-Emotive/ (0)
17 (psychotherap$ adj5 techniqu$).tw. (3168)
18 Hypnosis/ (5827)
19 hypnotherapy.tw. (1948)
20 Lamaze.tw. (77)
21 EMG.tw. (4791)
22 relax$.tw. (14181)
23 Desensiti$.tw. (4646)
24 hypnosis.tw. (12145)
25 electromyograh$.tw. (0)
26 image$.tw. (57858)
27 biofeedback.tw. (4391)
28 or/9-27 (143657)
29 8 and 28 (72)
30 limit 29 to yr="2005 -Current" (3)
31 from 30 keep 1-3 (3)

WHAT'S NEW

Last assessed as up-to-date: 3 August 2009.

Date	Event	Description
25 August 2011	Amended	Minor edits: study numbers and search dates corrected, analyses renumbered and linked, duplicate data in analysis tables deleted
9 February 2011	Review declared as stable	The findings of this review have been deemed to be stable, therefore this review will no longer be updated

HISTORY

Protocol first published: Issue 3, 2000

Review first published: Issue 3, 2007

Date	Event	Description
4 August 2009	New search has been performed	Review updated, no new studies identified
6 November 2008	Amended	Converted to new review format.
1 April 2007	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Michelle Proctor: Took the lead in writing the protocol and review, developed initial objectives, selection criteria, methods and background. Developed and performed search strategy. Performed independent data extraction and methodological quality assessment.

Patricia Murphy: Contributed to background section, selection criteria and initial extraction of information from included trials.

Helen Pattison: Helped develop quality assessment criteria, and performed independent methodological quality assessment, commented on drafts of the protocol and review.

Jane Suckling: Contributed to drafts of the review.

Cindy Farquhar: Initiated and conceptualised the protocol, commented on drafts of the review.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- University of Auckland, School of Medicine, Auckland, New Zealand.

External sources

- Princess of Wales Memorial Trust Fund administered by the Mercia Barnes Fund, New Zealand.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Title changed to remove 'primary and secondary' dysmenorrhoea from the title.

NOTES

The findings of this review have been deemed to be stable therefore this review will no longer be updated

INDEX TERMS

Medical Subject Headings (MeSH)

Adaptation, Psychological; Behavior Therapy [*methods]; Biofeedback, Psychology; Dysmenorrhea [psychology; *therapy]; Imagery (Psychotherapy); Randomized Controlled Trials as Topic; Relaxation Therapy

MeSH check words

Female; Humans