Cochrane Library

Cochrane Database of Systematic Reviews

Massage for promoting growth and development of preterm and/or low birth-weight infants (Review)

Vickers A, Ohlsson A, Lacy J, Horsley A

Vickers A, Ohlsson A, Lacy J, Horsley A.
Massage for promoting growth and development of preterm and/or low birth-weight infants.
Cochrane Database of Systematic Reviews 2004, Issue 2. Art. No.: CD000390.
DOI: 10.1002/14651858.CD000390.pub2.

www.cochranelibrary.com

WILEY

TABLE OF CONTENTS

[Intervention Review]

Massage for promoting growth and development of preterm and/or low birth-weight infants

Andrew Vickers[1], Arne Ohlsson[2], Janet Lacy[3], Angela Horsley[4]

[1]Integrative Medicine Service, Memorial Sloan-Kettering Cancer Center, New York, NY, USA. [2]Departments of Paediatrics, Obstetrics and Gynaecology and Health Policy, Management and Evaluation, University of Toronto, Warkworh, Canada. [3]Paediatrics, Scarborough, Canada. [4]Chilwell, UK

Contact address: Andrew Vickers, Integrative Medicine Service, Memorial Sloan-Kettering Cancer Center, 1275 York Avenue, New York, NY, 10021, USA. vickersa@mskcc.org.

Editorial group: Cochrane Neonatal Group
Publication status and date: Edited (no change to conclusions), published in Issue 1, 2009.

Citation: Vickers A, Ohlsson A, Lacy J, Horsley A. Massage for promoting growth and development of preterm and/or low birth-weight infants. *Cochrane Database of Systematic Reviews* 2004, Issue 2. Art. No.: CD000390. DOI: 10.1002/14651858.CD000390.pub2.

ABSTRACT

Background

It has been argued that infants in Neonatal Intensive Care Units are subject both to a highly stressful environment - continuous, high-intensity noise and bright light - and to a lack of the tactile stimulation that they would otherwise experience in the womb or in general mothering care. As massage seems to both decrease stress and provide tactile stimulation, it has been recommended as an intervention to promote growth and development of preterm and low-birth weight infants.

Objectives

To determine whether preterm and/or low birth-weight infants exposed to massage experience improved weight gain and earlier discharge compared to infants receiving standard care; to determine whether massage has any other beneficial or harmful effects on this population.

Search methods

The following databases were searched: the specialized register of the Cochrane Neonatal Review Group and that of the Cochrane Complementary Medicine Field. Searches were also undertaken of the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library, Issue 3, 2003), MEDLINE, EMBASE, Psychlit, CINAHL and Dissertation Abstracts International (up to July 1, 2003). Further references were obtained by citation tracking, checking personal files and by correspondence with appropriate experts. Data provided in published reports was supplemented by information obtained by correspondence with authors. There were no language restrictions.

Selection criteria

Randomised trials in which infants with gestational age at birth <37 weeks or weight at birth <2500g received systematic tactile stimulation by human hands. At least one outcome assessing weight gain, length of stay, behaviour or development must be reported.

Data collection and analysis

Data extracted from each trial were baseline characteristics of sample, weight gain, length of stay and behavioural and developmental outcomes. Physiological and biochemical outcomes were not recorded. Data were extracted by three reviewers independently. Statistical analysis was conducted using the standard Cochrane Collaboration methods.

Main results

Massage interventions improved daily weight gain by 5.1g (95% CI 3.5, 6.7g). There is no evidence that gentle, still touch is of benefit (increase in daily weight gain 0.2g; 95% CI -1.2, 1.6g). Massage interventions also appeared to reduce length of stay by 4.5 days (95%

CI 2.4, 6.5) though there are methodological concerns about the blinding of this outcome. There was also some evidence that massage interventions have a slight, positive effect on postnatal complications and weight at 4 - 6 months. However, serious concerns about the methodological quality of the included studies, particularly with respect to selective reporting of outcomes, weaken credibility in these findings.

Authors' conclusions

Evidence that massage for preterm infants is of benefit for developmental outcomes is weak and does not warrant wider use of preterm infant massage. Where massage is currently provided by nurses, consideration should be given as to whether this is a cost-effective use of time. Future research should assess the effects of massage interventions on clinical outcome measures, such as medical complications or length of stay, and on process-of-care outcomes, such as care-giver or parental satisfaction.

PLAIN LANGUAGE SUMMARY

Massage for promoting growth and development of premature and low birth-weight infants

In utero, infants are exposed to physical stimulation. This raises the question whether gentle physical massage helps babies born before 37 weeks gestation or weighing less than 2500 grams (5.5 pounds) to develop after birth, and if it can improve their behaviour. The review only included randomized controlled trials, studies in which a group of babies received massage and was compared with a similar group which did not. The authors searched the medical literature and contacted experts and found 14 studies. In most of these studies babies were rubbed or stroked for about 15 minutes, three or four times a day, usually for five or ten days. Some studies also included "still, gentle touch", in which nurses put their hands on babies but did not rub or stroke them. On average, the studies found that when compared to babies who were not touched, babies receiving massage, but not "still, gentle touch", gained more weight each day (about 5 grams). They spent less time in hospital, had slightly better scores on developmental tests and had slightly fewer postnatal complications, although there were problems with how reliable these findings are. The studies did not show any negative effects of massage. Massage is time consuming for nurses to provide, but parents can perform massage without extensive training.

BACKGROUND

It has been argued that infants in Neonatal Intensive Care Units (NICU) are subject both to a highly stressful environment - continuous, high-intensity noise and bright light (Field 1990) - and to a lack of the tactile stimulation that they would otherwise experience in the womb or in general mothering care (Montagu 1978).

A number of workers have suggested that massage both decreases stress and provides tactile stimulation (for an overview of this set of beliefs, see Vickers 1996). Massage has been recommended as an intervention to promote growth and development of preterm and low-birth weight (LBW) infants.

Though massage can be defined as any form of systematic tactile stimulation by human hands, the type of massage typically used in neonatal care is a gentle, slow stroking of each part of the body in turn. For example, Scafidi 1986 describes the infant being placed in a prone position and being stroked "for 1 min periods (12 strokes at approximately 5 seconds per stroking motion) over each region in the following sequence: (1) from the infant's head and face to the neck; (2) from the neck across the shoulders; (3) from the upper back to the waist; (4) from the thigh to the foot to the thigh on both legs and (5) from the shoulder to the hand to the shoulder on both arms". Massage is often combined with other forms of stimulation such as rocking, kinaesthetic stimulation (eg. passive extension/ flexion movements of the arms and legs), talking or eye contact.

A number of non-systematic reviews have been published which support massage interventions in the care of preterm/LBW infants (see, for example, Field 1980.) The only systematic review published is that of Ottenbacher 1987 who concludes that "subjects receiving some form of controlled tactile stimulation performed better on a variety of dependent measures than subjects not receiving intervention". This review is now out of date and is flawed by the inclusion of trials of varying quality (both randomised and non-randomised) which evaluated varying interventions (from massage to non-nutritive sucking). There also appears to be no judgement about the relative importance of different outcomes.

Though the mechanisms by which massage might be of benefit are not fully understood, an explanation in terms of nutrient intake is unlikely. Field 1987 found that massaged infants did not consume or retain more formula than controls, a finding consistent across trials of other forms of supplemental stimulation in preterm infants (Bernbaum 1983, Field 1982) and animal studies (Schanberg 1984). Any increases in weight gain resulting from massage may be due to improved conversion of food into growth. As improved metabolic efficiency has been associated with increased activity levels in both human (Torun 1979, Young 1981) and rat models (Mittelman 1984, Mussachia 1980) such a finding is one explanation as to why massage may improve weight gain. On the other hand, it may be that massage reduces adverse reactions to stress. Scafidi 1990 describes that overt signs of stress, such as facial grimaces and clenched fists, were lower in infants receiving massage than controls. Acolet 1993 reports falls in plasma cortisol following massage, though no differences were reported by Kuhn 1991. In summary, the biological rationale for the use of massage to improve growth and development in preterm/LBW infants is that it may increase metabolic efficiency whilst decreasing stress behaviours.

OBJECTIVES

Our primary question is whether preterm and/or LBW infants exposed to massage experience improved weight gain and earlier discharge compared to those infants receiving standard neonatal care. Our secondary question is whether massage has any other beneficial or harmful effects on this population.

METHODS

Criteria for considering studies for this review

Types of studies

Studies were included in the review if they met criteria for the intervention applied, the patients studied, the methodology used and the outcomes assessed. Only trials in which allocation to different treatments was randomised were included. Trials were excluded if randomisation was known to be unconcealed. If the method of allocation was not stated and randomisation could have been used, attempts were made to contact the author for further information. Cross-over trials were excluded.

Types of participants

Infants with gestational age at birth < 37 weeks OR weight at birth < 2500g.

Types of interventions

Systematic tactile stimulation by human hands. Studies of multimodal interventions of which massage is a part were included.

Types of outcome measures

Trials must have at least one outcome assessing weight gain, length of stay, behaviour or development.

Search methods for identification of studies

The following databases were searched: the specialized register of the Cochrane Neonatal Review Group and that of the Cochrane Complementary Medicine Field. Searches were also undertaken of the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library, Issue 3, 2003, MEDLINE, EMBASE, Psychlit, CINAHL and Dissertation Abstracts International (up to July 1, 2003). Further references were obtained by citation tracking, checking personal files and by correspondence with appropriate experts. Data provided in published reports was supplemented by information obtained by correspondence with authors. There were no language restrictions. Databases were searched using the term 'massage', 'touch' or 'tactile stimulation' with 'infant - newborn', 'infant - premature' and 'infant - low birth weight'.

Data collection and analysis

Inclusion of studies

All retrieved references were first scanned by AV to remove any clearly inappropriate titles. Hard copies of all remaining papers were then obtained. AV read all papers and again removed any for which there was no possibility of eligibility. Inclusion criteria were applied by each reviewer separately. Disagreements about study inclusion were resolved by consensus. All trials excluded from the review were given reasons for exclusion.

Assessment of quality of studies

The methodological criteria used to appraise each paper were concealment of treatment allocation (was treatment allocation concealed until the patient had been unambiguously entered into the trial? could it have been altered after entry?), performance bias (were patients treated similarly in all respects other than the experimental intervention?), blinding of observers (were those assessing outcome blind to treatment assignment?) and exclusions/withdrawals (were there systematic differences in withdrawals from the trial?). Each criterion was graded 'A', 'B' or 'C': 'A' indicates a low risk of bias, where the plausibly postulated bias is unlikely to alter the results seriously; 'C', on the other hand, indicates a high risk of bias, where plausibly postulated bias seriously weakens confidence in the results; a criterion is graded 'B' where it was partially met or where no data are available such that some doubt is raised about possible bias. Each paper was graded independently by at least three reviewers with disagreements resolved by discussion. Methodological assessment was not conducted blind to author, institution, journal of publication or results, as reviewers were familiar with most of the studies. Where studies were reported in different phases, the quality of each phase was assessed separately.

Data abstraction

The following data on the trial participants were extracted by group: dates of recruitment into trial; inclusion and exclusion criteria for gestational age and weight; mean weight and gestational age at birth and at entry by group; sex by group; number of withdrawals; risk factors (eg. exposure to cocaine in utero) and adverse effects. The following data on the trial outcomes were extracted: weight gain, length of stay, behaviour or development; observer blinding (graded A, B or C: see above); the time after start of treatment that the outcome was measured; whether there is evidence that the data were or were not normally distributed; mean and standard deviation/median and inter-quartile range/ number and percentage. If the outcome was sleep/wake state, details were recorded as to the length of time of observation, time elapsed from the end of the intervention to the beginning of the observation period and the criteria for determining sleep/wake state. If the outcome measure was behavioural or developmental but not sleep / wake, Brazleton scale or Bayley scale, the method of assessment was described. If different periods or times of measurement were reported, each was treated as a different outcome. Physiological and biochemical outcomes were not recorded. If an outcome measure was taken from nursing case notes, it was assumed to have been measured unblinded. Details of the intervention given in the treatment and comparison groups were recorded. Reviewers noted any baseline differences which they thought may have affected the result of the trial along with any other comments on the trial data or methodology. Data collection forms were completed by at least three reviewers independently. Attempts were made to contact authors to clarify or provide missing data. Disagreements between reviewers were resolved by consensus. Data collection forms were pilot tested to verify definitions of terms.

Statistical analysis

A grade of 'C' on concealment of treatment allocation was grounds for excluding the trial from the review. All other trials were included. Each reviewer decided independently which outcomes in which trials should be meta-analysed. Disagreements were resolved by consensus. Statistical analyses were conducted using RevMan 4.1.

RESULTS

Description of studies

Our eligibility criteria were liberal: we aimed to include as many trials as possible, even those on infants who only just met criteria for low birthweight or preterm birth. Most of the subjects in the studies we reviewed were very low birthweight (about 1200 - 1600g) and of short gestation (around 30 - 33 weeks). They were usually healthy and medically stable and had been transferred to intermediate or "grower" care before the start of the intervention. Their parents were generally of low socioeconomic status. Trials generally excluded infants with congenital abnormalities, serious pathology (eg. necrotising enterocolitis), histories of maternal drug abuse and those requiring ventilatory assistance or intravenous feeding. One trial had an inclusion criterion which specified a disease state (maternal drug addiction for Wheeden 1993) in addition to preterm birth or low-birth weight.

The interventions used in the trials can be categorised into "massage" and "still, gentle touch." Infants receiving massage were typically rubbed and stroked gently for approximately 15 minutes, three or four times a day. Many massage interventions also included kinaesthetic stimulation consisting of passive flexion/ extension movements of the limbs. Infants assigned to still, gentle touch had nurses place their hands on them gently as they slept. After 15 or 20 minutes, the hands would be removed. No stroking or rubbing motions were used.

Both forms of intervention were usually applied by nurses for 5 to 10 days. An exception was the study by Rice 1977 in which the intervention was applied by mothers for 30 days following discharge.

The outcomes of greatest interest to us were weight gain and length of stay in hospital. We also recorded developmental and behavioural outcomes. The Brazleton 1983 scale is a standard developmental measure which was used in several trials. It is divided into several sub-scales (habituation, orientation, range of state, motor maturity, state regulation, autonomic stability, number of abnormal reflexes and stress behaviours). A higher score is desirable for all sub-scales except the latter two. Many trials reported complex sleep/wake state outcomes (for example, percentage time with facial expressions) which could not reasonably be used in a meta-analysis. The only sleep/wake values we decided to include in statistical analyses were percentage time awake and percentage time in movement.

Some authors attempted to assess longer-term development using the standard Bayley 1969 scales of motor and mental development (higher score optimal). Two authors (Wheeden 1993, Scafidi 1993) assessed postnatal complications using scales such as the Postnatal Complications Scale (higher score optimal), the Newfoundland Scale (lower score optimal) and the Brazy 1985 Scale (lower score optimal).

Full details on the characteristics of each study are given in the table of included studies.

Risk of bias in included studies

There would appear to be five main methodological issues to consider when interpreting the results of this review.

i) Performance bias. We originally intended to assess each trial for performance bias, the degree to which patients were treated similarly in all respects other than the experimental intervention. However, no trial report described manoeuvres to control performance bias. In correspondence, authors stated that while they may not have taken formal steps to ensure that treatment was similar for all infants in a trial, care and treatment is given in the best interests of each patient.

It is our view, however, that clinicians may well be influenced in the care of a neonate by knowledge of group assignment. Differential care may be compensatory, in other words, extra care may be given to those not receiving massage on the grounds that they require extra attention in place of the additional treatment. This would tend to reduce differences between groups. On the other hand, performance bias may exaggerate differences between groups if, consciously or unconsciously, clinicians gave extra care to infants in the massage group because they want to see massage proven as effective. However, it is unclear whether the degree of extra care likely in such circumstances would plausibly lead to differences in weight gain. Furthermore, it is hard to know if it would be feasible to blind clinicians to treatment allocation in a trial of massage for preterm/LBW infants.

ii) Exclusion bias. Most trial reports did not describe any withdrawals or drop-outs. We sought further details from authors directly and obtained confirmation that there were no exclusions for Field 1987, Scafidi 1993, Wheeden 1993 and Harrison 2000. White Traut 1983, White Traut 1986 and Rice 1977 gave adequate information in the trial reports. The low levels of exclusions seemed plausible given the setting of the research. Participants were typically medically stable and transferred to intermediate care ("grower" nurseries) when the trial started. The main reasons for withdrawals in trials of preterm/LBW infants are death, intercurrent illness and transfer to a different institution. Such events are likely to be rare in intermediate care. We concluded therefore that systematic bias due to withdrawals is unlikely to be a problem.

iii) Blinding of weight measurements. No trial described procedures to blind those taking weight measurements. Although weight measurements might be tampered with by a trialist who has knowledge of a subject's treatment assignment, this seems unlikely. Similarly, it does not seem plausible that unconscious bias would explain persisting differences between groups for an outcome, such as daily weight gain, which is objective, precise and measured repeatedly. If weight gain was unconsciously inflated every day, a considerable discrepancy between recorded and actual weight would be apparent by the end of the trial. Nonetheless, poor blinding of the main outcome measure might be considered to be a flaw of the research included in the review.

iv) Blinding length of stay. There are no standardised criteria for discharge of a preterm/LBW infant from hospital. Discharge depends not only on the corrected gestational age and clinical condition of the baby but on the medical and social situation of the family. There are also discharge policies specific to each unit. It is unclear whether a decision to discharge may have been influenced by knowledge of group assignment, especially as parents have a role in determining discharge. In the words of one author White 1976, length of stay data "were seriously compromised by relatively arbitrary decisions regarding medical discharge from the hospital as determined by maternal requests". Only one study (White Traut 1986) explicitly stated that physicians responsible for discharging infants were blind to group assignment, but it is unclear how this blinding was achieved.

v) Types of intervention. We originally expected to find trials in which massage formed part of a multi-modal programme of stimulation. Only two such trials were included. In Rice 1977, cuddling and rocking were used as well as stroking. In Rose 1980, infants received vestibular, auditory and tactile stimulation. However, Rose 1980 did not report any outcomes relevant to the review (see Table of Included Studies) and it did not seem appropriate to analyse Rice 1977 separately just because infants had been cuddled and rocked. On the other hand, we included two trials (M - McCarthy 1992 and Harrison 1996) in which the intervention was a gentle, still touch. This seemed to be a very different type of intervention to the rubbing, stroking and passive movements which provided tactile stimulation in the remaining included studies. As a result, we analysed the results of the two different types of intervention separately. This was not planned in the original protocol.

Effects of interventions

Preterm/LBW infants receiving massage interventions - rubbing, stroking and kinaesthetic stimulation - gained more weight per day than controls (weighted mean difference (WMD) 5.1g, 95% CI 3.5, 6.7). This difference is of low clinical significance. There was, moreover, statistically significant heterogeneity between trials (chi square=11.22, df=5, p=0.047). Infants receiving gentle, still touch without stroking or rubbing experienced no weight gain advantage (WMD 0.2g greater increase in weight per day, 95% CI -1.2,1.6).

Massage interventions decreased length of stay by 4.5 days (95% CI 2.4, 6.5). The meta-analysis of this outcome is strongly influenced (52% of weighting) by one study (White 1976) which had a small sample size (12) and which presented data inconsistently (see Characteristics of Included Studies.) Exclusion of this study in a sensitivity analysis did not have a significant effect on the central estimate but the confidence intervals are widened: mean reduction in length of stay is 5.0 days (95% CI 2.0, 7.9). There is no evidence of a length of stay advantage for infants receiving gentle, still touch.

Massage improved performance slightly on the Brazleton scales for habituation (WMD 0.8, 95% CI 0.5, 1.1), motor maturity (WMD 0.8, 95% CI 0.5, 1.1) and range of state (WMD 0.6, 95% CI 0.2, 0.9). These effects are sensitive to the choice of statistical model: using a random effects model, differences between groups do not reach statistical significance. Moreover, there is extreme statistical heterogeneity (e.g. for habituation, chi square =17.52 df=2, p<0.001). Performance was also improved on orientation (WMD 0.5, 95% CI 0, 1) and state regulation (WMD 0.5, 95% CI -0.1, 1.0), though the lower confidence limit approximates the line of no difference for these two sub-scales. There was no evidence of effect on autonomic stability (WMD -0.1, 95% CI -0.6, 0.3), or on number of abnormal reflexes (WMD -0.6, 95% CI -1.6, 0.4). An apparent error in Wheeden's 1993 study - which reported a standard deviation for this outcome five times larger than other trials - would not change the conclusion of no difference between groups. Stress behaviours were also reduced, though this result was only reported by one study. Evidence was insufficient concerning other developmental scores such as the Bayley scale.

Massage improved postnatal complications as measured by the Littman 1978 Postnatal Complication Scale (WMD 16, 95% CI 11,

21). However, almost all of the weighting (95%) in this analysis comes from one study with a sample of size of 30. Moreover, there is an unexplained discrepancy between the size of the standard deviations in the two studies in the meta-analysis. The effects on the Newfoundland and Brazy 1985 complications scales are hard to judge: there is only one study in each analysis and there appears to be an error in the reporting of standard deviations for the Newfoundland scale.

There was no evidence of an effect of gentle still touch on neonatal morbidity score, days on supplemental oxygen, blood transfusions, activity or behavioural distress cues. Though data for some of these outcomes are non-normal, and possibly should not be meta-analysed, analysis of data from each trial individually gives no reason to change the conclusion of no difference between groups. Gentle, still touch increased days on phototherapy, though given the large number of outcomes, this may be a chance finding. Due to the low number of subjects in the two trials of gentle, still touch (a total of 50), the analyses lack statistical power.

No adverse effects of touch or massage were reported in any study.

DISCUSSION

The nursing literature consulted for this review strongly advocates massage interventions in the care of preterm/LBW infants. This literature is characterised by the use of unsystematic methods of review, leading to the inclusion of non-randomised and uncontrolled trials and even general discussion papers as evidence in support of massage. For example, in a non-systematic review of the literature, Field 1980 includes Solkoff 1975, who does not give any details of the method of treatment allocation and Siqueland 1973, a paper consisting of a short piece of prose which fails to describe experimental methods or present numerical data. Similarly, M - McCarthy 1992 cites Tribotti 1990, an uncontrolled trial, as evidence that "certain types of touch may ... be beneficial to ... preterm infants". Furthermore, studies of interventions such as "mothering", rocking, hammocks and water beds have been cited in reviews which did not start from a focused question and which drew general conclusions about the value of "tactile stimulation". An example is Field 1980, who included all the above interventions in a narrative review; in a subsequent review (Field 1995), one of the citations used to support a statement about "the effects of massage therapy ... on the preterm newborn" was the Barnard 1983 study of rocking waterbeds. Similarly, Ottenbacher 1987 included trials of massage, non-nutritive sucking and non-systematic fondling in a meta-analysis of "tactile stimulation as a form of early intervention." The findings of such reviews are difficult to put into practice because, by including such a disparate range of techniques, they do not specify an intervention which can be implemented in a clinical setting.

This systematic review has excluded much of the research said to constitute the research base of massage interventions in neonatal care. Nonetheless, the kernel of papers of adequate quality which remains seems to suggest, at first, that massage improves weight gain in preterm/LBW infants, albeit by the moderate amount of 5g / day.

One possible explanation for the increase in weight gain might be differential caloric intake between groups. Though we did not enter caloric intake into the meta-analyses - it was not an outcome measure - we did review the data on this variable as an indicator of performance bias. No difference in formula intake was reported by Field 1987, Scafidi 1993 or Wheeden 1993; White 1976 does report significantly increased formula intake. Given that there are 163 patients in trials showing no difference and only 12 in White 1976 one might be tempted to conclude that there is no coherent evidence of differences in caloric intake between groups. As such, massage intervention might be said to lead to increased weight gain without changes in formula intake, suggesting that massage leads to improved conversion of food into growth. However, the picture is slightly more complicated. Not all studies reported caloric intake, raising the possibility of reporting bias. In addition, both White 1976 and Wheeden 1993 report improbable figures for caloric intake: from White's figures, for example, it can be calculated that experimental infants consumed 676 cc of formula per kilogram of body weight per day. Do errors in reporting caloric intake cast doubt on these studies as a whole?

The results for other outcomes are less clear. The data for hospital length of stay are likely to be of great interest to parents, clinicians and purchasers of care. Although a decrease in the length of stay of 4 - 5 days is of considerable value, there must be concerns about bias, particularly, in selective reporting: it is unclear why this outcome was reported in some studies but not others. Only one study (White Traut 1983) pre-specified that length of stay was to be recorded. This raises suspicions that data were reported only if significant effects were found. Indeed, we have some evidence that this is the case. Wheeden 1993 was one of the authors who did not give data for length of stay in the published trial report. When we obtained raw data directly, we found that though there were differences between groups which favoured massage, these did not reach statistical significance. Further evidence of selective reporting comes from White Traut 1999, where data are given for length of stay (which was statistically significant), but not weight gain (where there was no difference between groups), even though both were recorded.

The data for another important clinical outcome, postnatal complications, are based on a small number of subjects. Moreover, there were sometimes unexplained differences in standard deviations between trials.

The improvements on the Brazleton sub-scales are of unclear clinical benefit. It is not known whether small changes on the Brazleton scale are of prognostic significance for longer-term outcome.

Perhaps the most intriguing data comes from 6 month follow-up of Field 1987 which suggests improvements in weight gain and in mental and motor development in preterm/LBW infants receiving massage intervention. Some support for Field's findings is provided by Rice 1977 data for weight at 4 months. Data from Bayley scales are not available from this trial. The number of subjects is very small in these analyses.

This systematic review suggests that massage may improve weight gain in preterm/low birth weight infants and provides some evidence for an effect on length of stay. However, the strength of this conclusion is weak because of important methodologic weaknesses in the contributing trials as noted previously. Caution should be exercised in drawing conclusions from this body of research.

The decision whether to use a treatment depends on comparing the level of evidence and probable degree of benefit with the treatment's cost and potential for harm. We have argued that the evidence base for preterm infant massage is weak and that with the possible exception of length-of-stay, where there were particular concerns about blinding and selective reporting, effect sizes were of minor clinical significance. On the other hand, proponents of preterm infant massage argue that it non-invasive, does not require specialist equipment and can be implemented without undue disruption to routine care procedures. For medically stable infants at least, it seems to have a very low risk of adverse effects. Though somewhat time consuming, massage can be undertaken by those without extensive training, including parents.

When deciding whether massage for preterm infants does more good than harm, both the low cost/potential for harm and the weak evidence-base need to be considered.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence of effectiveness to warrant wider use of preterm infant massage. Where massage is currently provided by nurses, consideration should be given as to whether this is a cost-effective use of time.

Implications for research

Further research is warranted to assess the effects of massage interventions on clinical outcome measures such as medical complications and length of stay. The method for controlling bias in evaluations of length of stay needs to be carefully considered. Selective reporting of outcomes must be avoided. Studies with longer-term follow-up of development are also warranted. Such studies should be conducted at a number of different, independent research institutions. Finally, though it seems reasonable to suppose that massage improves process-of-care outcomes such as care-giver and parental satisfaction, this could be evaluated systematically.

ACKNOWLEDGEMENTS

Claire Smith helped with identifying the primary studies. The Complementary Medicine Field is funded by the Division of Complementary Medicine, University of Maryland at Baltimore School of Medicine and the National Center for Complementary and Alternative Medicine, National Institutes of Health, MD, USA.

REFERENCES

References to studies included in this review

Adamson Macedo 1985 *{published data only}*

Adamson Macedo E. Effects of tactile stimulation on low and very low birthweight infants during the first week of life. *Current Psychological Research Reviews* 1985;**4**:305-8.

Field 1987 *{published and unpublished data}*

Field T, Scafidi F, Schanberg S. Massage of preterm newborns to improve growth and development. *Paediatric Nursing* 1987;**13**:385-7.

* Field TM, Schanberg SM, Scafidi F, Bauer CR, Vega Lahr N, Garcia R, Nystrom J, Kuhn CM. Tactile/kinesthetic stimulation effects on preterm neonates. *Pediatrics* 1986;**77**:654-8.

Scafidi FA, Field TM, Schanberg SM, Bauer CR, Vega Lahr N, Garcia R, Poirier J, Nystrom G, Kuhn CM. Effects of tacktile/kinesthetic stimulation on the clinical course and sleep/wake behaviour of preterm neonates. *Infant Behavior and Development* 1986;**9**:91-105.

Harrison 1996 *{published data only}*

Harrison L, Olivet L, Cunningham K, Bodin MB, Hicks C. Effects of gentle human touch on preterm infants: pilot study results. *Neonatal Network* 1996;**15**:35-42.

Harrison 2000 *{published and unpublished data}*

Harrison LL, Williams AK, Berbaum ML, Stem JT, Leeper J. Physiologic and behavioral effects of gentle human touch on preterm infants. *Research in Nursing and Health* 2000;**23**:435-46.

M - McCarthy 1992 *{published data only}*

Modrcin McCarthy MA. The physiological and behavioral effects of a gentle human touch nursing intervention on preterm infants. *Dissertation Abstracts International* 1993;**54**:1336.

Modrcin-Talbott MA, Harrison LL, Groer MW, Younger MS. The biobehavioral effects of gentle human touch on preterm infants. *Nursing Science Quarterly* 2003;**16**:60-7.

Rice 1977 *{published data only}*

Rice RD. Neurophysiological development in premature nenonates following stimulation. *Developmental Psychology* 1977;**13**:69-76.

Rice RD. The effects of the Rice infant sensorimotor stimulation treatment on the development of high-risk infants. *Birth Defects: Original Article Series (The National Foundation)* 1979;**15**:7-26.

Rose 1980 *{published data only}*

Rose SA, Schmidt K, Riese ML, Bridger WH. Effects of prematurity and early intervention on responsivity to tactual stimuli: A comparison of preterm and full-term infants. *Child Development* 1980;**51**:416-425.

Schmidt K. Rose SA. Bridger WH. Effect of heartbeat sound on the cardiac and behavioral responsiveness to tactual stimulation in sleeping preterm infants. *Developmental Psychology* 1980;**16**:175-84.

Scafidi 1993 *{published and unpublished data}*

Scafidi FA, Field T, Schanberg SM. Factors that predict which preterm infants benefit most from massage therapy. *Journal of Developmental & Behavioral Pediatrics* 1993;**14**:176-80. [MEDLINE: 93340272]

* Scafidi FA, Field TM, Schanberg SM, Bauer CR, Tucci K, Roberts J, Morrow C, Kuhn CM. Massage stimulates growth in preterm infants: a replication. *Infant Behavior and Development* 1990;**13**:167-88.

Solkoff 1969 *{published data only}*

Solkoff N, Yaffe S, Weintraub D, Blase B. Effects of handling on the subsequent development of premature infants. *Developmental Psychology* 1969;**1**:765-8.

Wheeden 1993 *{published and unpublished data}*

Wheeden A, Scafidi FA, Field T, Ironson G, Valdeon C, Bandstra E. Massage effects on cocaine-exposed preterm neonates. *Journal of Developmental & Behavioral Pediatrics* 1993;**14**:318-22.

White 1976 *{published data only}*

White JL, Labarba RC. The effects of tactile and kinesthetic stimulation on premature infants. *Developmental Psychobiology* 1976;**9**:569-77. [MEDLINE: 77069659]

White Traut 1983 *{published and unpublished data}*

White Traut RC. Maternal-infant interaction as a function of maternal stimulation of the premature infant initiated at twenty-four hours of infant age. Unpublished Doctoral Dissertation, Rush University, Chicago 1983.

* White Traut RC, Nelson MN. Maternally administered tactile, auditory, visual, and vestibular stimulation: relationship to later interactions between mothers and premature infants. *Research In Nursing & Health* 1988;**11**:31-9.

White Traut 1986 *{published and unpublished data}*

White Traut RC, Goldman MB. Premature infant massage: is it safe?. *Pediatric Nursing* 1988;**14**:285-9.

White Traut RC, Hutchens Pate CM. Modulating infant state in premature infants. *Journal of Pediatric Nursing* 1987;**2**:96-101.

* White Traut RC, Tubeszewski K. Multimodal stimulation of the premature infant. *Journal of Pediatric Nursing* 1986;**1**:90-5.

White Traut 1993 *{published data only}*

White Traut RC, Nelson MN, Silverstri JM, Patel MK, Kilgallon D. Patterns of physiologic and behavioral response of intermediate care preterm infants to intervention. *Pediatric Nursing* 1993;**19**:625-9.

References to studies excluded from this review

Acolet 1993 *{published data only}*

Acolet D, Modi N, Giannakoulopoulos X, Bond C, Weg W, Clow A, Glover V. Changes in plasma cortisol and catecholamine concentrati ons in response to massage in preterm infants. *Archives of Disease In Childhood* 1993;**68**:29-31.

Adamson-Macedo 1993 *{published data only}*

Adamson Macedo EN, Dattani I, Wilson A, de Carvalho FA. A small sample follow-up study of children who received tactile stimulation after pre-term birth: Intelligence and achievements. Special Issue: Prenatal and perinatal behaviour. *Journal of Reproductive & Infant Psychology* 1993;**11**:165-8.

Adamson-Macedo 1991 *{published data only}*

Adamson Macedo EN. Stroking, emotion and cognition: 11 years on. *Association of Paediatric Chartered Physiotherapists Newsletter* 1991;**60**:6-14.

Adamson-Macedo 1994 *{published data only}*

Adamson Macedo EN, de Roiste A, Wilson A, de Carvalho F, et al. TAC--TIC therapy with high-risk, distressed, ventilated preterms. *Journal of Reproductive & Infant Psychology* 1994;**12**:249-52.

Anisfeld 1983 *{published data only}*

Anisfeld E, Lipper E. Early contact, social support, and mother-infant bonding. *Pediatrics* 1983;**72**:79-83.

Armstrong 1996 *{published data only}*

Armstrong S. Infant/parent interaction analysis and developmental outcome for a high risk premature intervention population: a longitudinal analysis. *Dissertation Abstracts International* 1996;**57**:3688.

Barnard 1973 / 78 *{published and unpublished data}*

Barnard K. The effect of stimulation on the sleep behavior of the premature infant. *In Bately MU (ed): Communicating Nursing Research* 1973;**6**:12-33.

Barnard KE. The effect of stimulation on the duration and amount of sleep and wakefulness in the premature infant. Unpublished doctoral dissertation, University of Washington 1978.

Barnard 1983 *{published data only}*

Barnard KE, Bee HL. The impact of temporally patterned stimulation on the development of preterm infants. *Child Development* 1983;**54**:1156-67.

Benavides-Gonzales *{published data only}*

Benavides-Gonzalez H, Rivera-Rueda MA, Ibarra-Reyes MP, Flores-Tamez ME, Fragoso-Ramirez A, Moran-Martinez N, Fernandez-Carrocera LA. Effects of early multimodal stimulation on preterm newborn infants. *Boletin Medico del Hospital Infantil de Mexico* 1989;**46**:789-95.

Brown 1980 *{published data only}*

Brown JV, La Rossa MM, Aylward GP, Davis DJ, Rutherford PK, Bakeman R. Nursery-based intervention with prematurely born babies and their mothers: are there effects?. *Journal of Pediatrics* 1980;**97**:487-91.

Casler 1965 *{published data only}*

Casler L. The effects of extra tactile stimulation on a group of institutionalised infants. *Genetic Psychol Monogr* 1965;**71**:137-175.

Cody 1995 *{published data only}*

Cody AL. The effects of infant massage on the attitudes and perceptions of mothers who massage their hospitalized premature infants. *Dissertation Abstracts International* 1995;**56**:2858.

Cornell 1976 *{published data only}*

Cornell EH, Gottfried AW. Intervention with premature human infants. *Child Development* 1976;**47**:32.

Crusco 1990 *{published data only}*

Crusco AH. An investigation of tactile/kinesthetic stimulation as an intervention to improve physiological indices of development of preterm infants. *Dissertation Abstracts International* 1990;**51**:979.

de Roiste 1991 *{unpublished data only}*

de Roiste. Aspects of tactile stimulation with infants in intensive and special care baby units. PhD thesis, University of Glasgow, Scotland. 1991.

de Roiste 1993 *{published data only}*

de Roiste A, Bushnell IW. Tactile stimulation and pre-term infant performance on an instrumental conditioning task. Special Issue: Prenatal and perinatal behaviour. *Journal of Reproductive & Infant Psychology* 1993;**11**:155-63.

Eidelman 1994 *{published data only}*

Eidelman AI, Hovars R, Kaitz M. Comparative tactile behavior of mothers and fathers with their newborn infants. *Israel Journal of Medical Sciences* 1994;**30**:79-82.

Ferber 2002 *{published and unpublished data}*

Ferber SG, Kuint J, Weller A, Feldman R, Dollberg S, Arbel E, Kohelet D. Massage therapy by mothers and trained professionals enhances weight gain in preterm infants. *Early Human Development* 2002;**67**:37-45.

Field 1984 *{published data only}*

Field T, Goldson E. Pacifying effects of nonnutritive sucking on term preterm neonates during heelstick procedures. *Pediatrics* 1984;**74**:1012-15.

Freedman 1966 *{unpublished data only}*

Freedman D, Boverman H, Freedman N. Effects of kinesthetic stimulation on certain aspects of development in premature infants. Paper presented at the American Orthopsychiatric Association, San Francisco. 1966.

Freeman 1970 *{published data only}*

Freeman EK. The effects of interpersonal stimulation on growth and development of premature infants. *Dissertation Abstracts International* 1970;**31**:2982.

Gaebler 1996 *{published data only}*

Gaebler CP, Hanzlik JR. The effects of a prefeeding stimulation program on preterm infants. *American Journal of Occupational Therapy* 1996;**50**:184-92.

Garcia 1993 *{published data only}*

Garcia AP, White Traut R. Preterm infants' responses to taste/smell and tactile stimulation during an apneic episode. *Journal of Pediatric Nursing* 1993;**8**:245-52.

Gatts 1995 *{published data only}*

Gatts JD, Fernbach SA, Wallace DH, Singra TS. Reducing crying and irritability in neonates using a continuously controlled early environment. *Journal of Perinatology* 1995;**15**:215-21.

Gorski 1990 *{published data only}*

Gorski PA, Huntington L, Lewkowicz DJ. Handling preterm infants in hospitals. Stimulating controversy about timing of stimulation. *Clinics in Perinatology* 1990;**17**:103-12. [MEDLINE: 90200307]

Groom / McNichol *{published data only}*

Groom GL. The effect of perinatal factors and supplementary stimulation of premature infants upon measures of neonatal cognitive behavior. *Dissertation Abstracts International* 1974;**34**:4663.

McNichol TA. Some effects of different programs of enrichment on the development of premature infants in the hospital nursery. *Dissertation Abstracts International* 1974;**34**:4707-8.

Haselmeyer 1963 *{published data only}*

Hasselmeyer EC. Handling and premature infant behaviour. *Dissertation Abstracts International* 1963;**24**:2874-5.

Hayes 1980 *{published data only}*

Hayes J. Premature infant development: The relationship of neonatal stimulation, birth condition and home environment. *Pediatric Nursing* 1980;**6**:33-6.

Helders 1988 *{published data only}*

Helders PJ, Cats BP, Van Der Net J, Debast SB. The effects of a tactile stimulation/range-finding programme on the development of very low birthweight infants during initial hospitalization. *Child: Care, Health and Development* 1988;**14**:341-54.

Helders 1989 *{published data only}*

Helders PJ. Cats BP. Debast S. Effects of a tactile stimulation/range-finding programme on the development of VLBW-neonates during the first year of life. *Child: Care, Health & Development* 1989;**15**:369-79.

Heller 1991 *{published data only}*

Heller AS. A comparison of the effects of containment and stroking of preterm infants at varying levels of maturity. *Dissertation Abstracts International* 1991;**52**:2793.

Johanson 1992 *{published data only}*

Johanson RB, Spencer SA, Rolfe P, Jones P, Malla DS. Effect of post-delivery care on neonatal body temperature. *Acta Paediatrica* 1992;**81**:859-63. [MEDLINE: 93104625]

Kalscheur 1985 *{published data only}*

Kalscheur JA. Analysis of movement of high-risk premature infants in response to tactile stimulation. *Masters Abstracts International* 1985;**23**:282.

Kassis 1967 *{unpublished data only}*

Kassis NI. Extra-tactile kinesthetic stimulation and the toleration of stress in hospitalised infants. UCLA Nursing Dissertation 1967.

Kattwinkel 1975 *{published data only}*

Kattwinkel J, Nearman HS, Fanaroff AA, Katona PG, Klaus MH. Apnea of prematurity: comparative therapeutic effects of cutaneous stimulation and nasal continuous positive airway pressure. *Journal of Pediatrics* 1975;**86**:588-92. [MEDLINE: 75152998]

Kennell 1974 *{published data only}*

Kennell JH. Maternal behavior one year after early and extended post-partum contact. *Developmental Medicine and Child Neurology* 1974;**16**:172-9. [MEDLINE: 74255541]

Kilgo 1986 *{published data only}*

Kilgo JL. Tactile-kinesthetic stimulation: Effect on the development of preterm infants and the anxiety level of the mothers implementing the stimulation. *Dissertation Abstracts International* 1986;**47**:836.

Koniak-Griffin 1988 *{published data only}*

Koniak Griffin D, Ludington Hoe SM. Developmental and temperament outcomes of sensory stimulation in healthy infants. *Nursing Research* 1988;**37**:70-6.

Koniak-Griffin 1995 *{published data only}*

Koniak Griffin D, Ludington Hoe S, Verzemnieks I. Longitudinal effects of unimodal and multimodal stimulation on development and interaction of healthy infants. *Research in Nursing and Health* 1995;**18**:27-38.

Kramer 1975 *{published data only}*

Kramer M, Chamorro I, Green D, Knudtson F. Extra tactile stimulation of the premature infant. *Nursing Research* 1975;**24**:324-34.

Kuhn 1991 *{published data only}*

Kuhn CM, Schanberg SM, Field T, Symanski R, Zimmerman E, Scafidi F, Roberts J. Tactile-kinesthetic stimulation effects on sympathetic and adrenocortical function in preterm infants. *Journal of Pediatrics* 1991;**119**:434-40.

Leib 1980 *{published data only}*

Leib SA, Benfield G, Guidubaldi J. Effects of early intervention and stimulation on the preterm infant. *Pediatrics* 1980;**66**:83-9.

Ludington 1978 *{published data only}*

Ludington SM. Vaginal and cesarean delivery infants' responses to extra tactile stimulation. *Dissertation Abstracts International* 1978;**38**:4159.

Macedo 1984 *{unpublished data only}*

Macedo EN. Effects of very-early tactile stimulation on very-low birthweight infants - a 2 year follow up study. Doctoral thesis, Bedford College, University of London 1984.

Mansy 1967 *{unpublished data only}*

Mansy G. The effects of extra-tactile stimulation on some aspects of the growth and development of premature infants. UCLA Nursing Dissertation 1967.

Marshall 1990 *{published data only}*

Marshall TM. Holding and rocking the full-term neonate: the immediate and residual effects on behavioural state and heart rate. *Dissertation Abstracts International* 1990;**51**:1015.

Mathai 2001 *{published data only (unpublished sought but not used)}*

Mathai S, Fernandez A, Mondkar J, Kanbur W. Effects of tactile-kinesthetic stimulation in preterms: a controlled trial. *Indian Pediatrics* 2001;**38**:1091-98. [MEDLINE: 21534568]

McCain 1992 *{published data only}*

McCain G. Facilitating inactive awake states in preterm infants: A study of three interventions. *Nursing Research* 1992;**41**:157-60.

McIntosh 1994 *{published data only}*

McIntosh N. Massage in preterm infants. *Archives of Disease in Childhood* 1994;**70**:80.

Millot 1988 *{published data only}*

Millot JL, Filiatre JC, Montagner H. Maternal tactile behaviour correlated with mother and newborn infant characteristics. *Early Human Development* 1988;**16**:119-29.

Morrow 1991 *{published data only}*

Morrow CJ, Field TM, Scafidi FA, Roberts J, Eisen L, Larson S, Hogan AE, Bandstra ES. Differential effects of massage and heelstick procedures on transcutaneous oxygen tension in preterm neonates. *Infant Behavior and Development* 1991;**14**:397-414.

Nelson 1986 *{published data only}*

Nelson D, Heitman R, Jennings C. Effects of tactile stimulation on premature infant weight gain. *Journal of Obstetric, Gynecologic, & Neonatal Nursing* 1986;**15**:262-7.

Nelson 2001 *{published and unpublished data}*

Nelson MN, White-Traut RC, Vasan U, Silvestri J, Comiskey E, Meleedy-Rey P, Littau S, Gu G, Patel M. One-year outcome of auditory-tactile-visual-vestibular intervention in the neonatal intensive care unit: effects of severe prematurity and central nervous system injury. *Journal of Child Neurolology* 2001;**16**:493-8.

Pardew 1983 *{published data only}*

Pardew EM. The effects of infant massage on the interactions between high risk infants and their caregivers. *Dissertation Abstracts International* 1983;**43**:2881.

Powell 1974 *{published data only}*

Powell LF. The effect of extra stimulation and maternal involvement on the development of low birth-weight infants and on maternal behaviour. *Child Development* 1974;**45**:106-13.

Prodromidis 1995 *{published data only}*

Prodromidis M, Field T, Arendt R, Singer L, Yando R, Bendell D. Mothers touching newborns: a comparison of rooming-in versus minimal contact. *Birth* 1995;**22**:196-200.

Rausch 1981 *{published data only}*

Rausch PB. Effects of tactile and kinesthetic stimulation on premature neonates. *Journal of Obstetric, Gynecologic and Neonatal Nursing* 1981;**10**:34-7. [MEDLINE: 81146310]

Rosenfeld 1980 *{published data only}*

Rosenfeld AG. Visiting in the intensive care nursery. *Child Development* 1980;**51**:939-41.

Saigal 1986 *{published data only}*

Saigal S, Watts J, Campell D. Randomized clinical trial of an oscillating air mattress in preterm infants: effect on apnea, growth, and development. *Journal of Pediatrics* 1986;**109**:857-64.

Sampers 1993 *{unpublished data only}*

Sampers JL. The effects of tactile containment on preterm infants in a neonatal intensive care unit. Unpublished: Doctoral dissertation, University of Maryland College Park 1993:Doctoral dissertation, University of Maryland College Park 1993 AAC9425128.

Scafidi 1996 *{published data only}*

Scafidi F, Field T. Massage therapy improves behavior in neonates born to HIV-positive mothers. *Journal of Pediatric Psychology* 1996;**21**:889-97.

Scarr-Salapatek 1973 *{published data only}*

Scarr Salapatek S, Williams ML. A stimulation program for low birthweight infants. *American Journal of Public Health* 1972;**62**:662-7.

Scarr-Salapatek S, Williams ML. The effects of early stimulation on low birthweight infants. *Child Development* 1973;**33**:94-101.

Schaeffer 1982 *{published data only}*

Schaeffer-Jay S. The effects of gentle human touch on mechanically ventilated very short gestation infants. *Maternal Child Nursing Journal* 1982;**11**:199-259.

Scott 1983 *{published data only}*

Scott S, Cole T, Lucas Pl, Richards M. Weight gain and movement patterns of very low birthweight infants nursed on lambswool. *Lancet* 1983;**2**:1014-6.

Siqueland 1973 *{published data only}*

Siqueland ER. Biological and Experiential Determinants of Exploration in Infancy. In: Stone LJ, Smith HT, Murphy LB editor(s). The Competent Infant. London: Tavistock Publications, 1973.

Solkoff 1975 *{published data only}*

Solkoff N, Matuszak D. Tactile stimulation and behavioral development among low-birthweight infants. *Child Psychiatry and Human Development* 1975;**6**:33-7.

Toney 1983 *{published data only}*

Toney L. The effects of holding the newborn at delivery on paternal bonding. *Nursing Research* 1983;**32**:16-9.

Trevathan 1981 *{published data only}*

Trevathan WR. Maternal touch at 1st contact with the newborn infant. *Developmental Psychobiology* 1981;**14**:549-58.

Tribotti 1990 *{published data only}*

Tribotti S. Effects of gentle touch on premature infants. In: Gungenhauser N editor(s). Advances in touch. Skillman, NJ: Johnson & Johnson Inc, 1990.

Uvnas-Moberg 1987 *{published data only}*

Uvnas Moberg K, Widstrom AM, Marchini G, Windberg J. Release of GI hormone in mothers infants by sensory stimulation. *Acta Paediatrica Scandinavia* 1987;**76**:851-860.

Weiss 1991 *{published data only}*

Weiss SJ. Psychophysiologic and behavioral effects of tactile stimulation on infants at-risk from nervous system arousal. *Dissertation Abstracts International* 1991;**51**:4077.

Weiss 1992 *{published data only}*

Weiss SJ. Psychophysiologic and behavioral effects of tactile stimulation on infants with congenital heart disease. *Research in Nursing & Health* 1992;**15**:93-101.

Weiss 1993 *{published data only}*

Weiss S. Predictors of neurobehavioral response during tactile stimulation of infants with congenital heart disease. *Infant Behavior and Development* 1993;**16**:261-4.

White 1964 *{published data only}*

White BL, Castle PW. Visual exploratory behaviour following postnatal handling of human infants. *Perceptual and Motor Skills* 1964;**18**:497-502.

White Traut 1997 *{published data only (unpublished sought but not used)}*

White Traut RC, Nelson MN, Silvestri JM, Cunningham N, Patel M. Responses of preterm infants to unimodal and multimodal sensory intervention. *Pediatric Nursing* 1997;**23**:169-75.

White Traut 1999 *{published data only (unpublished sought but not used)}*

White Traut RC, Nelson MN, Silvestri JM, Patel M, Vasan U, Han BK, Cunningham N, Burns K, Kopischke K, Bradford L. Developmental intervention for preterm infants diagnosed with periventricular leukomalacia. *Research in Nursing & Health* 1999;**22**:131-43.

White-Traut 1998 *{published data only}*

White-Traut R, Powlesland J, Gelhar D, Chatterton R, Morris M. Methodologic issues in the measurement of oxytocin in human neonates. *Journal of Nursing Measurement* 1998;**6**:155-73.

White-Traut 2002 *{published data only}*

White-Traut R, Studer T, Meleedy-Rey P, Murray P, Labovsky S, Kahn J. Pulse rate and behavioral state correlates after auditory, tactile, visual, and vestibular intervention in drug-exposed neonates. *Journal of Perinatology* 2002;**22**:291-299.

Wright 1971 *{published data only}*

Wright L. The theoretical and research base for a program of early stimulation care and training of premature infants. In: Hellmuth J editor(s). The Exceptional Infant: Studies in Abnormalities. Vol. **2**, New York: Brunner/Mazel, 1971:276-304.

References to studies awaiting assessment

Dieter 2003 *{published data only}*

Dieter JN, Field T, Hernandez-Reif M, Emory EK, Redzepi M. Stable preterm infants gain more weight and sleep less after five days of massage therapy. *Journal of Pediatric Psychology* 2003;**28**:403-11.

References to ongoing studies

Dieter 1998 *{unpublished data only}*

Dieter J. Replication of Field 1987.

Additional references

Barnard 1978

Barnard N. Nursing child assessment feeding scale. Seattle, Washington, 1978.

Bayley 1965

Bayley N. Comparisons of mental and motor test scores for ages 1 - 15 monhts by sex, birth order, race, geographic location and education of parents. *Child Development* 1965;**36**:379-411.

Bayley 1969

Bayley N. Bayley scales of infant development. New York: Psychological Corporation, 1969:Psychological Corporation (1969).

Bernbaum 1983

Bernbaum J, Perriera GR, Watkins JB, Peckham EJ. Nonnutritive sucking during gavage feeding enhances growth and maturation in premature infants. *Pediatrics* 1983;**71**:41-5.

Brazleton 1983

Brazleton TB. Neonatal behvaioural assessment scale. London: Spastic International Medical Publications, 1983.

Brazy 1985

Brazy C. Brazy perinatal biological scoring system. Duke University, North Carolina, 1985.

Eisen 1991

Eisen LN, Field TM, Bandstra ES, et al. Perinatal cocaine effects on neonatal stress behavior and preformance on the Brazleton scale. *Pediatrics* 1991;**88**:477-80.

Field 1980

Field T. Supplemental stimulation of preterm neonates. *Early Human Development* 1980;**4**:301-14.

Field 1982

Field T, Ignatoff E, Stringer S, Brennan J, Greenberg R, Widmayer S, Anderson G. Nonnutritive sucking during tube feedings: effects on preterm neonates in an ICU. *Pediatrics* 1982;**70**:381-4.

Field 1990

Field T. Alleviating stress in newborn infants in the intensive care unit. *Clinics in Perinatology* 1990;**17**:1-9.

Field 1995

Field T. Massage therapy for infants and children. *Journal of Developmental & Behavioral Pediatrics* 1995;**16**:105-11.

Littman 1978

Littman D, Parmelee A. Medical correlates of infant development. *Pediatrics* 1978;**61**:470-4.

Minde 1983

Minde K, et al. Effect of neonatal complications in premature infants on early parent-infant interactions. *Developmental Medicine and Child Neurology* 1983;**25**:763-7.

Mittelman 1984

Mittelman G, Valenstein ES. Ingestive behavior evoked by hypothalamic stimulation and schedule-induced polydipsia are related. *Science* 1984;**27**:415-7.

Montagu 1978

Montagu A. Touching: the human significance of the skin. London: Harper & Row, 1978.

Mussachia 1980

Mussachia XJ, Deavers DR, Meininger GA, Davies PP. A model for hypokinesia: effects on muscle atrophy in the rat. *Journal of Applied Physiology* 1980;**48**:479-85.

Ottenbacher 1987

Ottenbacher KJ, Muller L, Brandt D, Heintzelman A, Hojem P, Sharpe P. The effectiveness of tactile stimulation as a form of early intervention: a quantitative evaluation. *Journal of Developmental & Behavioral Pediatrics* 1987;**8**:68-76. [MEDLINE: 86123162]

Schanberg 1984

Schanberg SM, Evoniuk G, Kuhn CM. Tactile and nutritional aspects of maternal care: specific regulators of nutritional aspects of neuroendocrine function and cellular development. *Proceedings of the Society for Experimental Biology and Medicine* 1984;**175**:135-46.

Thoman 1975

Thoman E. Early development of sleeping behaviors in infants. In: Elllis N editor(s). Aberrant development in infancy. Hillsdale, NJ: Erlbaum, 1975:123-38.

Torun 1979

Torun B, Schutz Y, Viteri F, Bradfield RB. Growth, body composition and heart rate/VO2 relationship changes during the nutritional recovery of children with two different physical activity levels. *Bibliotheca Nutritio et Dieta* 1979;**27**:55-6.

Vickers 1996

Vickers A. Massage and aromatherapy: a guide for health professionals. Cheltenham: Stanley Thornes, 1998.

Young 1981

Young VR, Torun B. Physical activity: impact on protein and amino acid metabolism and implications for nutritional requirements. Nutrition in Health and Disease and International Development: symposia from the XII International Congress on Nutrition. New York: Liss, 1981.

References to other published versions of this review

Vickers 1998

Vickers A, Ohlsson A, Lacy JB, Horsley A. Massage therapy for preterm and/or low birth-weight infants. *Cochrane Database of Systematic Reviews* 1998, Issue 3. [DOI: 10.1002/14651858.CD000390]

Vickers 2000

Vickers A, Ohlsson A, Lacy JB, Horsley A. Massage therapy for preterm and/or low birth-weight infants. *Cochrane Database of Systematic Reviews* 2000, Issue 2. [DOI: 10.1002/14651858.CD000390.pub2]

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Adamson Macedo 1985

Methods	Blinding of randomisation: unclear Blinding of intervention: inadequate Complete follow-up: unclear Blinding of outcome measurement: see "Outcomes"
Participants	66 low and very low birthweight infants (defined by the author as <2500g and <1500g respectively) recruited from hospitals in London, UK and the surrounding regions. No inclusion or exclusion criteria described. Mean birthweight and gestational age for massage/control group: 1500/1600g; 32.3/32.0 weeks. Percentage female in massage / control group: 58 / 46%.
Interventions	RISS technique (see Rice 1979). Intervention started within 120 hours of birth. Routine care in control group.
Outcomes	Change in weight from birth to 1 week old assessed unblinded. A number of reflexes (rooting, sucking, hand grasp, crawling, passive arm movement, passive leg movement) were also observed (blinding unclear) at one week. These are not included in the analyses because no data were reported.
Notes	16 infants in the massage group received their first treatment within the first 48 hours; 15 received their first treatment between 49 and 120 hours. The authors compare the change in weight between these two sub-groups and report significantly lower (p<0.03) weight loss in the early intervened group (29.1g; SD44.1) than in the late intervened group (78.1g; SD 70.0g). We attempted to contact the authors for further information about other aspects of the trial but were unsuccessful.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Field 1987

Methods	Blinding of randomisation: adequate, though see discussion. From a fax from Field: "The table [of random numbers] was kept by project co-ordinator who assigned massage person to start massaging infants as soon as they were admitted to intermediate care & only if we had informed consent. The person getting the informed consent did not know which groups the infant would be assigned to. Could [allocation] been altered after entry? No." See also Wheeden 1993, who undertook a study at the same unit and describes a similar randomisation process. Blinding of intervention: inadequate Complete follow-up: adequate Blinding of outcome measurement: see "Outcomes"
Participants	40 preterm infants from the Miami area, recruited when medically stable and admitted to the "grower" nursery. None were receiving supplemental oxygen or intravenous feeding. Inclusion criteria: gestational age < 36 weeks; birthweight <1500g; weight at entry to study 1100-1650g. Exclusions: "congenital heart malformations, gastrointestinal disorders, CNS disturbances, drug addictions and congenital anomalies". Average birthweight, gestational age and weight at entry to the study for massage / control: 1280 / 1268g; 31 / 31 weeks; 1393 / 1385g.
Interventions	The massage intervention consisted of three, 15 minute periods at the beginning of three consecutive hours starting approximately 30 minutes after the first morning feeding. Each session consisted of two, five minute periods of tactile stimulation (stroking) with an intervening five minute period of kinaesthetic stimulation (passive flexion/extension movements of the limbs). Massage was administered for ten consecutive weekdays. Control infants received routine nursery care.
Outcomes	Daily weight gain over course of study (unblinded); all subscales of the Brazleton Neonatal Behaviour Assessment Scale (1983), assessed blindly at end of treatment period; percentage of time "awake" and "in movement", assessed blindly for 45 minutes at end of treatment period and at least 4 hours after the last massage using the criteria of Thoman (1975); length of stay (unblinded). Half of the sample were evaluated at a 6 month follow-up for weight, body length and head circumference centile and the Bayley (1969) mental and motor scales (blinding unclear). The following outcome was relevant

Field 1987 *(Continued)*

	to the review but no data were reported: number of apneic episodes. The following outcomes were not thought relevant to this review: volume intake of formula; caloric intake; number of feedings; percentage of time in the following states: quiet sleep; active sleep; REM sleep; drowsy; inactive alert; active alert; with single limb movement; with multiple limb movement; with head turns movement; with gross body movement; with facial expressions; crying. The following outcomes were not thought relevant to the review and no data were presented: frequency of urination; frequency of stooling; heart rate; body temperature; number of parent visits; number of parent visits with touching; number of parent visits with holding; number of parent visits with feeding; percentage time in behavioural distress.
Notes	Standard deviations for Field (1987) for length of stay; Bayley scales at 6 months and weight at 6 months were calculated, where possible, from t-tests. From the p values, t values were calculated. A pooled standard deviation for both groups was calculated from the t value. Standard deviations for 4 month length and head circumference were not given. They were estimated by multiplying the mean in each group by the ratio of the mean to standard deviation in that group reported in Rice 1976. The author was unable to provide any further raw data.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Harrison 1996

Methods	Blinding of randomisation: adequate Blinding of intervention: inadequate Complete follow-up: unclear Blinding of outcome measurement: see "Outcomes"
Participants	Thirty preterm infants hospitalised in a NICU in Alabama. Inclusion criterion: 26-32 weeks gestation. Exclusion: no congenital abnormalities, no surgery, no paralysis, mother not substance abuser, no contraindication to touch. Age at entry to study between two and six days. Percentage of females in massage/control: 47% / 33%.
Interventions	Fifteen minutes of still, gentle human touch each day for 5 days, starting when the infants were between six and nine days of age. No stroking or massage movements were used. Routine care in the control group.
Outcomes	Daily weight gain; morbidity score on the Neonatal Morbidity Scale (Minde 1983); days on supplemental oxygen; days receiving phototherapy. No details of blinding were given for any of these outcomes. Outcomes relevant to this review but for which data were insufficient for analysis: Brazleton (1983) scales assessed blindly at 36-38 weeks postconceptional age (standard deviations missing). Also reported were caloric intake and percentages of time spent in motor activity, inactive alert state; active alert state; behavioural distress and sleep (categorised as active sleep; quiet sleep; REM sleep; drowsy.) However, the method of data collection for behavioural data was not reported, standard deviations are missing and the values do not add up to 100.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Harrison 2000

Methods	Blinding of randomisation: adequate Blinding of intervention: inadequate Complete follow-up: adequate Blinding of outcome measurement: see "Outcomes"
Participants	84 infants in NICU in Alabama, 27 to 33 weeks gestational age. Exclusion: no congenital abnormalities, no surgery, no paralysis, mother not substance abuser, no contraindication to touch. Age at entry to study between two and six days.
Interventions	Three ten-minute periods of still, gentle human touch each day for 10 days, starting when the infants were between six and nine days of age. No stroking or massage movements were used. Routine care in the control group.
Outcomes	Daily weight gain; Brazleton (1983) assessed at discharge; days on supplemental oxygen; days receiving phototherapy. All assessed unblinded apart from Brazleton.
Notes	We used days on ventilator for days on supplemental oxygen.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

M - McCarthy 1992

Methods	Blinding of randomisation: unclear Blinding of intervention: inadequate Complete follow-up: unclear Blinding of outcome measurement: see "Outcomes"
Participants	20 preterm infants admitted to the University of Tennessee NICU. Inclusion criteria: birthweight < 2000g; gestational age 27 - 32 weeks at birth. Exclusion criteria: congenital abnormality; surgical intervention; haematocrit >0.38
Interventions	One daily session of 20 minutes of still, gentle human touch on days 7 to 16 after birth. Routine care in the control group.
Outcomes	Mean daily weight gain over course of trial; length of stay; number of days of phototherapy; days of supplemental oxygen; number of blood transfusions. No details of blinding were given for any of these outcomes. Caloric intake was recorded but not thought relevant for the review. The following outcomes were not thought relevant to the review and no usable data were presented: percentage of time in quiet sleep, active sleep and crying; heart rate.
Notes	Standard deviations were not reported for any outcome variable. They were therefore estimated from t values. We are attempting to contact the authors for further information.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Rice 1977

Methods	Randomised trial Blinding of randomisation: unclear Blinding of intervention: inadequate Complete follow-up: adequate Blinding of outcome measurement: see "Outcomes"
Participants	30 preterm infants (1 drop out) recruited at a large hospital in Dallas. Mothers were of low socioeconomic status. Average hospital stay of 10 days. Inclusion criterion: Gestational age less than or equal to 37 weeks.
Interventions	The Rice Infant Sensorimotor Stimulation program (RISS). This was administered for 15 minutes, 4 times a day for 30 days starting on day of discharge from hospital. The intervention consists of stroking, followed by rocking, holding and cuddling the infant. Routine care in the control group.
Outcomes	Daily weight gain (blinding unclear), length, head circumference and Bayley motor and mental (1969) scales assessed blindly at four months. No means or standard deviations were given for Bayley scales. Mental Development was said to be significantly better in massaged infants; no difference between groups was found on the psychomotor score. A large number of reflexes were also measured and individual patient data reported. It is unclear how these should be reported in the format of a Cochrane review.
Notes	We attempted to contact the author to obtain data on Bayley scales but were unsuccessful.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Rose 1980

Methods	Blinding of randomisation: unclear Blinding of intervention: inadequate Complete follow-up: adequate Blinding of outcome measurement: see "Outcomes"
Participants	60 preterm infants from the New York area. Inclusion weights: 820 - 2000g. Inlcusion age: 28 - 36 weeks. Exclusion criteria: no major congenital abnormality or maternal drug addiction. Birth weight (g), gestational age (weeks) (presumably: legend of table gives months as unit), postconceptional age at entry to trial (weeks) in massage/control groups: 1577/1574; 32.4/33.7; 37.3/37.2
Interventions	Tactile, auditory and vestibular stimulation given in three, 20 minute periods per day for five days a week for an average of 13 days, starting within the first two weeks of life. Routine care in the control group.
Outcomes	The following outcomes were presented but not relevant for this review: number of parent visits; heart rate; duration of first active sleep, duration of first quiet sleep, duration of first sleep cycle; heart rate during first quiet sleep; behavioural response to tactile stimulation during sleep; time to first quiet sleep in presence or absence of heartbeat sound; duration of first quiet sleep in presence or absence of heartbeat sound. All outcomes were assessed blindly. Quiet sleep defined as 60 seconds with no eye movements, semi-regular respiration, no body movements except isolated jerks/startles.
Notes	Schmidt 1980 involves outcomes on some of the subjects in Rose 1980. On page 176, the authors of the former paper state that "effects ... were examined for preterm infants who had received routine nursing and medical care and for preterms who prior to testing had received intervention emphasizing tactual stimulation" and then references the latter paper. We attempted to contact the authors for further information about other aspects of this trial but were unsuccessful.

Risk of bias

Rose 1980 *(Continued)*

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Scafidi 1993

Methods	Blinding of randomisation: adequate. See Field 1987. Blinding of intervention: inadequate Complete follow-up: adequate Blinding of outcome measurement: see "Outcomes"
Participants	93 preterm infants from an intermediate care unit in Miami. The infants were predominantly from minority backgrounds (only 15% were white). Inclusion criteria: gestational age between 26 and 36 weeks; birth weight between 800 and 1550g; NICU duration less than 60 days; weight at entry to study between 1000 - 1550 g. Exclusion criteria: chromosomal or congenital abnormalities; grades II to IV intraventricular haemorrhages; congenital infection; chronic lung disease; necrotising enterocolitis; CNS infection; substance abuse in mother. Infants were not enrolled until they were considered medically stable and were free from ventilatory assistance, supplemental oxygen, intravenous feeding and intravenous medication. The mean birthweight (g); gestational age (weeks); age at entry to trial (days); and percentage female in massage/control groups: 1197/1211; 30.2/30.4; 15.6/14.5; 54/40. Mean weight at entry to trial for sample as a whole was 1353g. Note: inclusion criteria seem to have been changed during trial (see Discussion).
Interventions	Massage stimulation as described by Field (1987). Routine care in the control group.
Outcomes	Daily weight gain over course of study and length of stay assessed unblinded; all subscales of the Brazleton Neonatal Behaviour Assessment Scale (1983) assessed blindly at the end of the study; postnatal complications on the postnatal complications scale (Littman 1978) and Brazy complications scale (Brazy 1985) (blinding unclear) assessed during the study; number of apneic episodes (no data presented). Outcomes relevant to review but insufficient data for meta-analysis: percentage time in sleep or awake assessed blindly; number of apneic episodes (blinding unclear); sleep/wake state assessed blindly for 45 minutes at on days 1 , 5, 6 and 10 prior to feedings, procedures or stimulation using the criteria of Thoman (1975). Outcomes with usable data but not relevant for this review: volume intake of formula; caloric intake; frequency of urination; frequency of stooling; heart rate; body temperature; total number of parent visits; number of parent visits with touching; number of parent visits with holding; number of parent visits with feeding. Outcomes without usable data and which were not considered relevant for this review: percentage time in each of the following states: crying; quiet sleep; active sleep; REM sleep; drowsy; active alert; active alert; single limb movement; multiple limb movement; head turns movement; with gross body movement; startles; smiles; mouthing; facial grimaces; clenched fists.
Notes	Author informed us that all 40 patients in Scafidi 1990 were included in this paper. Length of stay data for all 1993 subjects were not reported. Only one Brazleton subscale was reported. Attempts to obtain original data from the author were unsuccessful. Standard deviations for weight gain were not given. They were estimated by multiplying the mean in each group by the ratio of the mean to standard deviation in that group reported in Scafidi 1990. Means and standard deviations for orientation on the Brazleton scale are reported separately for "high" and "low" gainers: these values were pooled for each group. No standard deviations were reported for length of stay. These were estimated from a t value given in the text.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Solkoff 1969

Methods	Blinding of randomisation: unclear Blinding of intervention: inadequate Complete follow-up: unclear Blinding of outcome measurement: see "Outcomes"
Participants	10 preterm infants from the Buffalo, New York area, entered into the trial within 12 hours of birth. Inclusion criteria: birthweight 1190 - 1590g. Birthweight in massage/control group: 1363/1372g.
Interventions	Arms, neck and back were rubbed for 5 minutes every hour for 10 days. The control group received routine care.
Outcomes	Outcomes thought relevant to this review for which no usable data are given: weight gain (blinding unclear); Bayley (1965) motor and mental scales assessed blindly at 7-8 month follow-up; activity level. Outcomes not relevant to this review: temperature; startle responses; crying, frequency of urination and defecation.
Notes	We attempted to contact the authors for further information but were unsuccessful.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Wheeden 1993

Methods	Randomised trial Blinding of randomisation: adequate (though see discussion). From an email from Wheeden: "The list of random numbers was kept in our files in the office -- at time of recruitment, no one knew which number was up next ... no one deciding whether to enter an infant (or approach the parent for consent) had previous access to the list. In no case did the researcher know whether a baby would get massage or not BEFORE entering that child into the trial. I believe Frank [Scafidi] had the list, and a research assistant and myself were primarily responsible for recruitment." Blinding of intervention: inadequate Complete follow-up: unclear Blinding of outcome measurement: see "Outcomes"
Participants	30 cocaine exposed preterm infants from the Miami area. Inclusion criteria: medically stable, birthweight less than 1500g; weight at entry to trial 1000-1650g; gestational age less than 37 weeks; urine or meconium toxicology positive for cocaine or maternal self-report; NICU stay < 50 days. Exclusion criteria: genetic abnormalities; congenital heart malformations; gastrointestinal disturbances; CNS dysfunction; congenital infection or maternal syphilis, herpes, HIV. Mean birthweight (g); gestational age; age at entry to the trial (days); weight at entry (g) for massage / control groups: 1158/1265; 29.7/30.8; 31/25; 1458/1488.
Interventions	Massage stimulation as described by Field (1987). Routine care in the control group.
Outcomes	Average daily weight gain during study (unblinded); Postnatal complications scale (Littman 1978); Newfoundland scale (reference in press at time of publication); all subscales of the Brazleton (1983) scale; Neonatal stress behaviour scale (Eisen 1991). All scales were assessed blindly at end of treatment. No data presented for number of apneic episodes. Data for length of stay (assessed unblinded, data for one subject in the massage group missing) were obtained from the author. Outcomes for which data were reported but which were not considered relevant for this review: volume intake of formula; caloric intake; number of feedings; frequency of urination; frequency of stooling; respiration rate; heart rate; body temperature; total number of parent visits; number of parent visits with touching; number of parent visits with holding; number of parent visits with feeding.
Notes	

Risk of bias

Wheeden 1993 *(Continued)*

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

White 1976

Methods	Blinding of randomisation: unclear Blinding of intervention: inadequate Complete follow-up: unclear Blinding of outcome measurement: see "Outcomes"
Participants	12 preterm infants born at a university hospital in South Carolina. Inclusion criteria: birthweight 1588 - 2041g; gestational age less than 36 weeks; bottle feeding. Exclusion criteria: no gross organic defects. Mean birthweight (g); gestational age (weeks); age at entry to trial (days) and percentage female for massage/control group: 1911/1924; 34.2/34.7; 2/2; 67/50. Mean birthweight for sample at entry: 1890g.
Interventions	Starting within 48 hours, infants in the massage group received 15 minutes of tactile/kinaesthetic stimulation every hour for four consecutive hours. Routine care in the control group.
Outcomes	Weight gain (blinding unclear); length of stay (blinding unclear). The following outcomes were not thought relevant for the review and no usuable data were presented: number of feeds; volume intake of formula; frequency of urination; frequency of stooling; respiration rate; heart rate; body temperature.
Notes	Summary data in the paper were inconsistent (e.g. between graphs and text). Means and standard deviations for daily weight gain and length of stay were recalculated from raw data provided in the original study report.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

White Traut 1983

Methods	Randomised trial with three groups Blinding of randomisation: adequate. See White-Traut 1986. Blinding of intervention: inadequate Complete follow-up: adequate Blinding of outcome measurement: see "Outcomes"
Participants	46 infants from a single institution in Illinois. Data provided on 33 (22 in the two groups in this analysis). Inclusion criteria: gestational age 28 - 35 weeks; birthweight appropriate for age; vaginal delivery; mother 16 years or older and able to speak English. Exclusion criteria: ventilatory assistance; congenital abnormalities suspected or diagnosed.
Interventions	RISS (10 minutes of massage and 5 minutes of rocking - see Rice 1979) given by mothers to their infants four times between 24 and 72 hours following birth. Routine care in the control group. A third group received a "talking only" intervention but these results have been ignored for the purposes of this review.
Outcomes	Weight gain and length of stay (blinding unclear).Two sub-scales of (infant behaviours and mother behaviours) the maternal-infant interaction on the Nursing-Child Assessment Feeding Scale NCAFS (Barnard 1987) assessed blindly. Outcome not thought relevant for this review: type of infant formula.
Notes	Standard deviations for length of stay and NCAFS were obtained from the author.

White Traut 1983 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

White Traut 1986

Methods	Blinding of randomisation: adequate. In an email, White-Traut stated that: "Random assignment of the subjects was conducted after the parents signed the informed consent sheets. The random assignment was not known to the investigator or the parent until after the consent was signed. The sealed envelope was opened immediately prior to starting the protocol. Random assignment to group was never changed after data collection began." Blinding of intervention: inadequate Complete follow-up: adequate Blinding of outcome measurement: see "Outcomes"
Participants	36 preterm infants at an Illinois institution (data provided on 33). Inclusion criteria: birthweight less than 1800g; gestational age 29-35 weeks; medically stable. Exclusion criteria: congenital abnormalities; seizures; supplemental oxygen; enteral nutrition.
Interventions	15 minutes of the RISS technique (see Rice 1979), once a day for ten days or until discharge, starting when the infants reached 1750g. Routine care in the control group.
Outcomes	Weight gain (unblinded); length of hospitalisation assessed blindly. No data were presented for the following outcomes and they were not thought relevant to the review: caloric intake; type and amount of formulat; route of feeding; respiration rate; heart rate; arterial oxygen saturation; body temperature; percentage time in each of the following states: crying; quiet sleep; active sleep; drowsy; inactive alert; active alert.
Notes	Standard deviations for weight gain were obtained from the author. The author was unable to provide standard deviations for length of stay. These were imputed by multiplying the mean in each group by the ratio of the mean to standard deviation in that group in the White Traut 1983 trial.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

White Traut 1993

Methods	Blinding of randomisation: adequate. See White-Traut 1986. Blinding of intervention: inadequate Complete follow-up: unclear Blinding of outcome measurement: see "Outcomes"
Participants	40 infants in the special care nursery of a hospital in Chicago. Inclusion criteria: birthweight less than 1800g; exclusion criteria: medical complications; sepsis; chromosomal disorders; supplemental oxygen.
Interventions	15 minutes of RISS (see Rice 1979) given before late morning feedings once a day for 4 days. Routine care in the control group.
Outcomes	Behavioural state classified as sleep, quite sleep, drowsy, active alert, quiet alert, crying and indeterminate state (blinding unclear). Outcomes not thought relevant to this review: heart rate; arterial oxygen saturation.

White Traut 1993 *(Continued)*

Notes	Author was unable to provide usable data on outcomes.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

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

Study	Reason for exclusion
Acolet 1993	Uncontrolled trial
Adamson-Macedo 1993	Non-randomised trial
Adamson-Macedo 1991	Not a clinical trial
Adamson-Macedo 1994	Uncontrolled trial
Anisfeld 1983	Randomised trial with apparently unconcealed allocation. Excluded because treatment was "extra contact" rather than systematic use of human hands
Armstrong 1996	Unconcealed treatment allocation: allocation was by hospital number
Barnard 1973 / 78	Controlled trial with no mention of method of treatment allocation. Excluded because intervention was a "rocking waterbed" rather than systematic use of human hands.
Barnard 1983	Controlled trial with no mention of method of treatment allocation. Excluded because intervention was a "rocking waterbed" rather than systematic use of human hands.
Benavides-Gonzales	Controlled trial, but no mention of method of allocation: attempts to contact authors have failed so far.
Brown 1980	Randomised trial but no systematic use of touch
Casler 1965	Non-randomised trial
Cody 1995	Non-randomised trial.
Cornell 1976	Not a clinical trial
Crusco 1990	Non-randomised trial
de Roiste 1991	Non-randomised trial
de Roiste 1993	Treatment allocation was probably unconcealed. On pages 157-8, the author states: "subjects were .... assigned to experimental / control conditions depending on how well they matched subjects previously collected on the criteria referred to earlier [gender, birthweight, gestation, Apgar]. Thus if an infant matched a control subject that had no experimental matched then s/he was assigned to the experimental condition or vice versa. Otherwise assignment to group was random". Such a strategy would lead to allocation being unconcealed if recruiting clinicians had access to the minimisation table.

Study	Reason for exclusion
Eidelman 1994	Not a clinical trial
Ferber 2002	Allocation appears to be unconcealed. It is, at any rate, a form of cluster randomization. In a private correspondence, the author stated that: "We used tables of random numbers to select the particular group assigned to a specific room. Of these 4-5 mothers in one particular room, only the 3-4 mothers, those whose infants matched the stratified allocation criteria, were asked to participate in this randomly selected group. All 3-4 approached mothers were asked to participate in the same randomly selected group ... After the director of the NICU presented the study , the mothers were assigned to a particular randomly selected group and then I told them about the study in detail[] and obtained their informed consent."
Field 1984	Randomised trial, but intervention was a "pacifier" (dummy), not human touch.
Freedman 1966	Non-randomised trial
Freeman 1970	Non-randomised trial
Gaebler 1996	Comparison of oral stimulation plus massage to massage alone
Garcia 1993	Randomised trial but used cross-over methodology. Outcome was apnea.
Gatts 1995	Randomised trial, but no massage intervention
Gorski 1990	Not a clinical trial
Groom / McNichol	It appears likely that allocation was unconcealed. From page 25 of McNichol's thesis: "after four infants had been assigned randomly, one to each group, a chart was made indicating which gestational ages and birth weights were represented by these [subjects]. When another [subject] was available, the chart was examined to determine which group(s) did not have a [subject] of the particular gestation and birth weight. A paper with the number of the groups needing such a [subject] was placed in a container and one number was chosen at random. Toward the end of the study, the compositon of each group determined the assignment of the last [subjects]." Groom and McNichol's theses probably consist of data from the same trial. Though there is no direct reference to this in either study: i) the theses were submitted in the same year to the same university ii) the interventions described in each thesis are the same iii) both theses describe recruitment from identical hospitals in Indiana iv) very similar baseline characteristics in each group (eg. the number of males and females in group 1 and 2 in McNichol's thesis are 3/4 and 4/4; in Groom's thesis it is 3/4, 5/4) v) page 102-8 of Groom's thesis and page146-7 of McNichol's give individual patient data for gestational age, sex, race, birthweight and so on. Though the data are not presented well, AV checked 6 patients (the first three from two of the groups) in McNichol's study and found patients with identical or near identical characteristics in Groom's study.
Haselmeyer 1963	Treatment allocation is likely to have been unconcealed. On page 49-51 of the thesis, Haselmeyer describes a minimisation strategy: "[assignment to] the experimental or control section of any individual cell [of the minimisation table] was opposite to the group (X or C) in which the preceding infant had been placed ... placement of ... subjects was made in the order in which they became available". It seems probable that the minimisation table was open so that the recruiting clinician (apparently Haselmeyer) had knowledge of which treatment a subject would receive before recruitment.
Hayes 1980	Randomised trial, however, outcomes were not reported separately for each group. We attempted to contact the author for further information but were unable to do so.
Helders 1988	Controlled trial with insufficient information about method of treatment allocation. Excluded because intervention was a rocking hammock rather than massage.

Study	Reason for exclusion
Helders 1989	Controlled trial with insufficient information about method of treatment allocation. Excluded because intervention was a rocking hammock rather than massage.
Heller 1991	Non-randomised trial
Johanson 1992	Randomised trial but not preterm or low birthweight infants
Kalscheur 1985	Uncontrolled trial
Kassis 1967	Insufficient details of method of treatment allocation. We attempted to contact the authors for further information but were unable to do so.
Kattwinkel 1975	Controlled trial with insufficient information about method of treatment allocation. Excluded because no weight, developmental, behavioural or length-of-stay outcomes. The outcome measure was apnea.
Kennell 1974	Randomised trial with unconcealed allocation (allocation depended on day of delivery). Excluded because not preterm or low birthweight infants.
Kilgo 1986	Insufficient details given about method of treatment allocation. We were unable to contact the authors for further information.
Koniak-Griffin 1988	Randomised trial, but healthy, full-term infants rather than premature or low birthweight
Koniak-Griffin 1995	Randomised trial, but healthy, full term infants, not preterm or low birthweight
Kramer 1975	Unconcealed treatment allocation: on page 327, Kramer states: "after a random start, subjects were alternately assigned to control or experimental groups."
Kuhn 1991	Randomised trial, but biochemical outcomes only.
Leib 1980	Non-randomised trial: first fourteen patients received intervention, second fourteen patients served as controls.
Ludington 1978	Non-randomised trial
Macedo 1984	The analyses mixed data from infants recruited at three hospitals. The exact method of allocation is hard to determine (the author's exact words are reproduced below). At best, some of the subjects came from a randomised trial with unconcealed allocation, but the data from these subjects are mixed in with those from non-randomised comparisons. The author's exact words (page 56-7): "Hospital 1. 12 subjects ... were assigned first to the non-intervention group .... and then to the intervention group." "Hospital 2. 13 subjects ... were randomly assigned to the control group ... and to the experimental group. Footnote: an attempt to have both groups at the same time had failed. Mothers (control group) who observed the responses of the infants (experimental group) declined to be in the control group. The technique was taught to all mothers and fathers and the infants discarded. After discharge of that group we randomly assigned infants to control and experimental groups The experimental infants were discarded. After this group discharge new assignment of the two groups and control infants were discarded." "Hospital 3. 41 subjects ... the first sample (N=8) was divided into the two groups by matching for birthweight and gestational age ... these were allocated to two groups on a quasi-random basis."
Mansy 1967	Allocation appears to be unconcealed (or at the very least, interfered with). On page 22, the author states: "The [code] numbers assigned to the experimental group ... and for the control group [were as follows....] However, at the time of data collection subjects 3 and 4 turned out to be a set of twins. It seemed preferable to the investigator to assign subject 3 to the control group and subject 4 to the experimental group, so that a comparison could be made between them. Subjects 8 and 9 were also a set of twins. Therefore, the investigator assigned subject 8 to the experimental

Study	Reason for exclusion
	group and subject 9 to the control group. When all ten subjects had been discharged, three additional subjects were admitted to the study. Subject 11 was assigned to the control group to match one of the experimental group subjects. Subjects 12 and 13 were a third set of twins. Therefore, subject 12 was admitted to the experimental group to match another subject in the control group, and subject 12 was admitted to the control group...."
Marshall 1990	Insufficient details of method of treatment allocation. We attempted to contact the authors for further information but were unable to do so.
Mathai 2001	Unconcealed allocation: "babies born in weeks starting with an odd-number day were assigned to the test group and those born in other weeks to the control group"
McCain 1992	Randomised trial, but crossover methodology employed.
McIntosh 1994	Not a clinical trial.
Millot 1988	Not a clinical trial
Morrow 1991	Randomised trial, but no weight, behavioural, developmental or length of stay outcomes
Nelson 1986	Randomised trial, but touch stimulation was by a textured underlay rather than by human hands.
Nelson 2001	In an email correspondence, White Traut stated: "a) Random assignment was conducted after informed consent was obtained. A random start was made in a random numbers table. Odd numbers were assigned to the experimental group and even numbers were assigned to the control group. b) The randomization procedure was the same for both studies [White Traut 1999 and Nelson 2001]. The list was held by the person doing the intervention … After informed consent was obtained, the researcher doing the intervention … reviewed the list to determine what group assignment was. c) The PI (me) obtained the consents. One of the research assistants did the intervention. I covered for the intervention if necessary."
Pardew 1983	Randomised trial, but not premature or low birthweight infants.
Powell 1974	Randomised trial, but exact nature of intervention unclear from published report. We attempted to contact author for further information but were unable to do so.
Prodromidis 1995	No systematic use of touch; healthy, term infants.
Rausch 1981	Historical control group
Rosenfeld 1980	Randomised trial, but the intervention was "stroking with different textured materials" rather than use of human hands.
Saigal 1986	Randomised trial, but touch intervention was an oscillating air mattress rather than systematic use of human hands
Sampers 1993	Non-randomised trial
Scafidi 1996	Randomised trial, but infants not low birthweight or preterm
Scarr-Salapatek 1973	Randomised trial with unconcealed allocation. Intervention was general patting, fondling and playing rather than systematic use of touch.

Study	Reason for exclusion
Schaeffer 1982	Non-randomised trial.
Scott 1983	Randomised trial, but intervention was a wool underlay rather than systematic touch by human hands
Siqueland 1973	Almost no usable information presented on methods or results
Solkoff 1975	No details given in the paper as to method of treatment allocation. We attempted to contact the author for more information but were unable to do so.
Toney 1983	Randomised trial but healthy, full term infants and no systematic use of touch.
Trevathan 1981	Not a clinical trial
Tribotti 1990	Uncontrolled trial
Uvnas-Moberg 1987	Not a controlled trial
Weiss 1991	Uncontrolled trial
Weiss 1992	Controlled trial (method of treatment allocation unclear) but used crossover methodology.
Weiss 1993	Uncontrolled trial
White 1964	Concealed trial with insufficient information as to method of treatment allocation. Not preterm or low birthweight infants.
White Traut 1997	Randomised trial, but no appropriate weight, behavioural, developmental or length of stay outcomes
White Traut 1999	In an email correspondence, White Traut stated: "a) Random assignment was conducted after informed consent was obtained. A random start was made in a random numbers table. Odd numbers were assigned to the experimental group and even numbers were assigned to the control group. b) The randomization procedure was the same for both studies [White Traut 1999 and Nelson 2001]. The list was held by the person doing the intervention … After informed consent was obtained, the researcher doing the intervention … reviewed the list to determine what group assignment was. c) The PI (me) obtained the consents. One of the research assistants did the intervention. I covered for the intervention if necessary."
White-Traut 1998	Randomised trials (two reported) but not preterm infants.
White-Traut 2002	Randomised trial, but no appropriate weight, behavioural, developmental or length of stay outcomes
Wright 1971	Non-randomised trial

Characteristics of studies awaiting assessment *[ordered by study ID]*

Dieter 2003

Methods	Not known
Participants	Not known
Interventions	Not known
Outcomes	Not known
Notes	

DATA AND ANALYSES

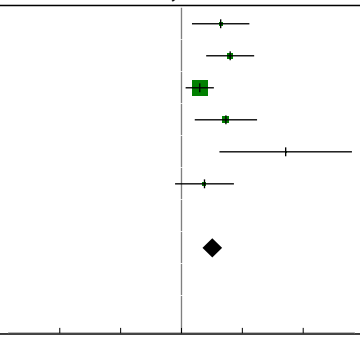
Comparison 1. Massage vs. routine care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Daily weight gain (g/day)	6	274	Mean Difference (IV, Fixed, 95% CI)	5.06 [3.45, 6.67]
2 Length of stay (days)	6	176	Mean Difference (IV, Fixed, 95% CI)	-4.45 [-6.48, -2.43]
3 Brazleton scale: habituation	3	103	Mean Difference (IV, Random, 95% CI)	0.58 [-0.45, 1.60]
4 Brazleton scale: orientation	3	157	Mean Difference (IV, Random, 95% CI)	0.62 [-0.35, 1.59]
5 Brazleton scale: range of state	3	110	Mean Difference (IV, Fixed, 95% CI)	0.56 [0.19, 0.94]
6 Brazleton scale: motor maturity	3	110	Mean Difference (IV, Random, 95% CI)	0.85 [0.17, 1.53]
7 Brazleton scale: state regulation	3	110	Mean Difference (IV, Fixed, 95% CI)	0.48 [-0.07, 1.02]
8 Brazleton scale: autonomic stability	3	110	Mean Difference (IV, Fixed, 95% CI)	-0.13 [-0.57, 0.31]
9 Brazleton scale: number of abnormal reflexes	3	110	Mean Difference (IV, Fixed, 95% CI)	-0.61 [-1.59, 0.37]
10 Stress behaviours	1	30	Mean Difference (IV, Fixed, 95% CI)	-0.70 [-1.32, -0.08]
11 Percentage time awake	1	40	Mean Difference (IV, Fixed, 95% CI)	9.0 [0.75, 17.25]
12 Percentage time in movement	1	40	Mean Difference (IV, Fixed, 95% CI)	7.0 [3.34, 10.66]

Outcome or subgroup title	No. of studies	No. of partici-pants	Statistical method	Effect size
13 Weight at 4-8 month follow-up (mixed units)	2	49	Std. Mean Difference (IV, Fixed, 95% CI)	0.76 [0.17, 1.34]
14 Length at 4-8 month follow-up (cm)	1	29	Mean Difference (IV, Fixed, 95% CI)	1.0 [-1.03, 3.03]
15 Head circumference at 4-8 month follow-up (cm)	1	29	Mean Difference (IV, Fixed, 95% CI)	-0.20 [-0.98, 0.58]
16 Bayley Mental Scale at 6 months	1	20	Mean Difference (IV, Fixed, 95% CI)	12.00 [0.78, 23.22]
17 Bayley Motor Scale at 6 months	1	20	Mean Difference (IV, Fixed, 95% CI)	15.0 [0.98, 29.02]
18 Postnatal Complications Scale	2	70	Mean Difference (IV, Fixed, 95% CI)	16.14 [11.32, 20.96]
19 Brazy postnatal complications scale	1	40	Mean Difference (IV, Fixed, 95% CI)	-0.10 [-0.63, 0.43]
20 Newfoundland postnatal complications scale	1	30	Mean Difference (IV, Fixed, 95% CI)	-1.3 [-1.55, -1.05]
21 NCAFS Infant Feeding Behaviors	1	22	Mean Difference (IV, Fixed, 95% CI)	-4.20 [-7.09, -1.31]

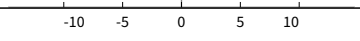
Analysis 1.1. Comparison 1 Massage vs. routine care, Outcome 1 Daily weight gain (g/day).

Study or subgroup	Massage N	Massage Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Adamson Macedo 1985	31	-7.6 (8.9)	35	-14 (10.6)		11.69%	6.44[1.72,11.16]
Field 1987	20	25 (6)	20	17 (6.7)		16.73%	8[4.06,11.94]
Scafidi 1993	50	32 (5.7)	43	29 (5.7)		48.33%	3[0.68,5.32]
Wheeden 1993	15	33 (7.3)	15	25.7 (7)		9.92%	7.3[2.18,12.42]
White 1976	6	18.6 (11.5)	6	1.4 (7.2)		2.19%	17.12[6.23,28.01]
White Traut 1986	17	24.5 (7.5)	16	20.7 (6.7)		11.13%	3.78[-1.05,8.61]
Total ***	**139**		**135**			**100%**	**5.06[3.45,6.67]**
Heterogeneity: Tau^2=0; Chi^2=11.22, df=5(P=0.05); I^2=55.42%							
Test for overall effect: Z=6.15(P<0.0001)							



Analysis 1.2. Comparison 1 Massage vs. routine care, Outcome 2 Length of stay (days).

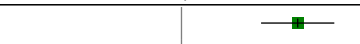
Study or subgroup	Massage N	Massage Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Field 1987	20	18.4 (9.8)	20	24.7 (9.8)		11.15%	-6.3[-12.37,-0.23]
Scafidi 1993	20	19 (7.4)	20	24 (7.4)		19.61%	-5[-9.58,-0.42]
Wheeden 1993	14	13.2 (9)	15	16.5 (11.2)		7.57%	-3.3[-10.67,4.07]
White 1976	6	14.7 (2.2)	6	19 (2.7)		54.22%	-4.33[-7.08,-1.58]
White Traut 1983	11	19.8 (11.7)	11	22.4 (10.8)		4.66%	-2.54[-11.94,6.86]
White Traut 1986	17	32.3 (19.1)	16	34.3 (16.4)		2.8%	-1.96[-14.08,10.16]
Total * **	**88**		**88**			**100%**	**-4.45[-6.48,-2.43]**
Heterogeneity: Tau^2=0; Chi^2=0.83, df=5(P=0.97); I^2=0%							
Test for overall effect: Z=4.3(P<0.0001)							



Favours massage — Favours control

Analysis 1.3. Comparison 1 Massage vs. routine care, Outcome 3 Brazleton scale: habituation.

Study or subgroup	Massage N	Massage Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Field 1987	16	6.1 (0.6)	17	4.9 (0.5)		36.27%	1.2[0.82,1.58]
Scafidi 1993	20	5.3 (1.7)	20	4.4 (0.8)		30.63%	0.9[0.08,1.72]
Wheeden 1993	15	6 (1)	15	6.4 (0.8)		33.11%	-0.4[-1.05,0.25]
Total * **	**51**		**52**			**100%**	**0.58[-0.45,1.6]**
Heterogeneity: Tau^2=0.72; Chi^2=17.52, df=2(P=0); I^2=88.59%							
Test for overall effect: Z=1.1(P=0.27)							



Favours control — Favours massage

Analysis 1.4. Comparison 1 Massage vs. routine care, Outcome 4 Brazleton scale: orientation.

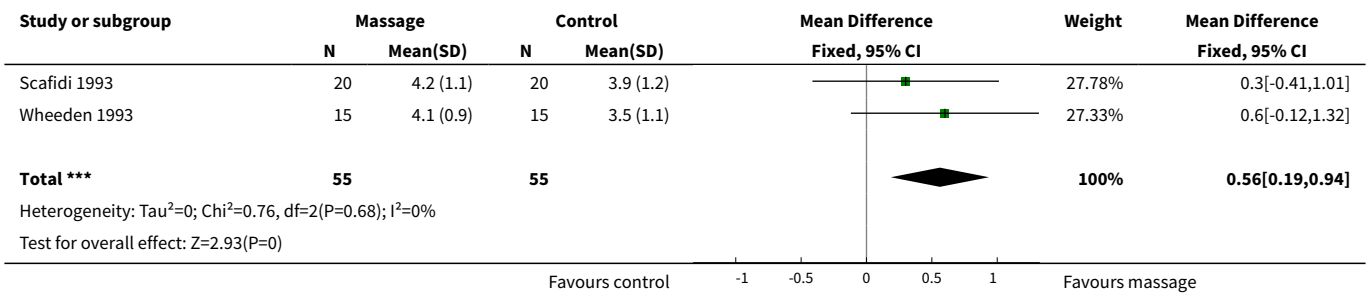
Study or subgroup	Massage N	Massage Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Field 1987	18	4.8 (0.9)	16	4 (1)		39.32%	0.8[0.16,1.44]
Scafidi 1993	50	3.7 (1.9)	43	4 (1.8)		37.27%	-0.25[-0.99,0.49]
Wheeden 1993	15	4.9 (1.5)	15	3.2 (2.4)		23.41%	1.7[0.27,3.13]
Total * **	**83**		**74**			**100%**	**0.62[-0.35,1.59]**
Heterogeneity: Tau^2=0.52; Chi^2=7.49, df=2(P=0.02); I^2=73.31%							
Test for overall effect: Z=1.25(P=0.21)							

Favours control — Favours massage

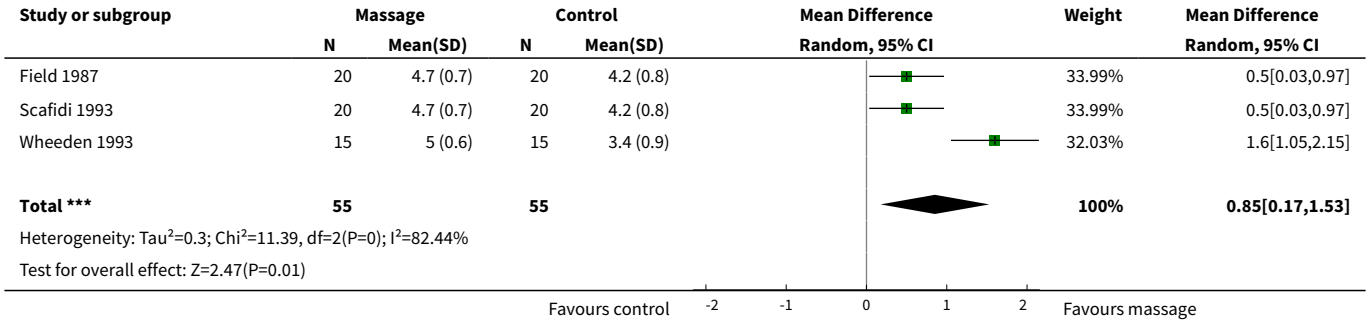
Analysis 1.5. Comparison 1 Massage vs. routine care, Outcome 5 Brazleton scale: range of state.

Study or subgroup	Massage N	Massage Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Field 1987	20	4.6 (0.8)	20	3.9 (1)		44.89%	0.7[0.14,1.26]

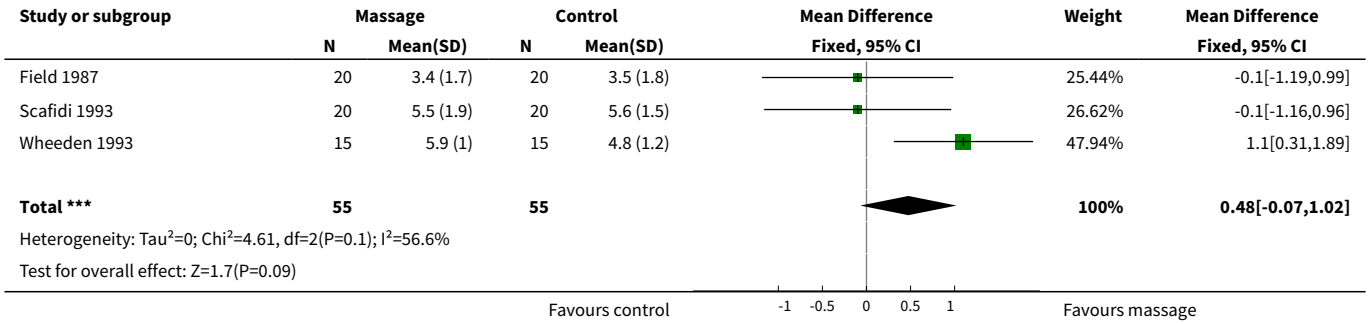
Favours control — Favours massage



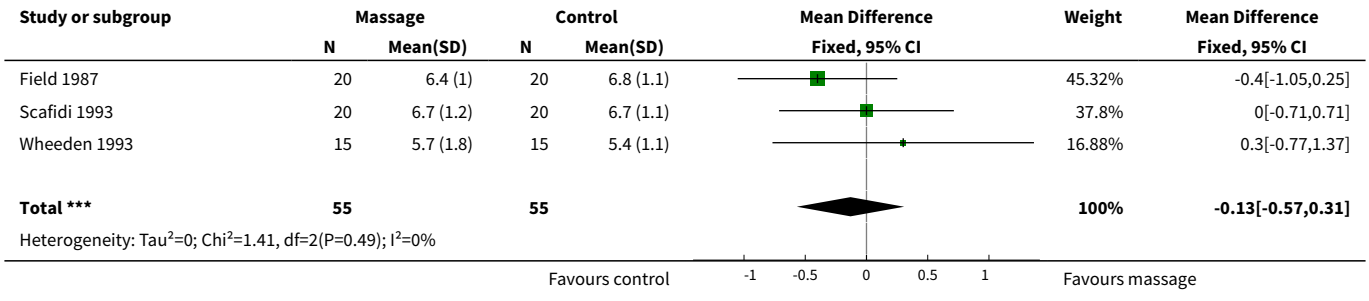
Analysis 1.6. Comparison 1 Massage vs. routine care, Outcome 6 Brazleton scale: motor maturity.



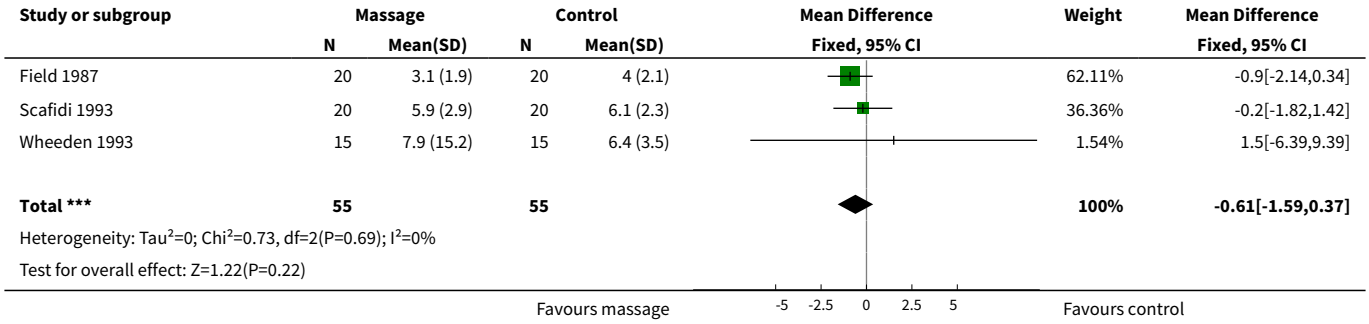
Analysis 1.7. Comparison 1 Massage vs. routine care, Outcome 7 Brazleton scale: state regulation.



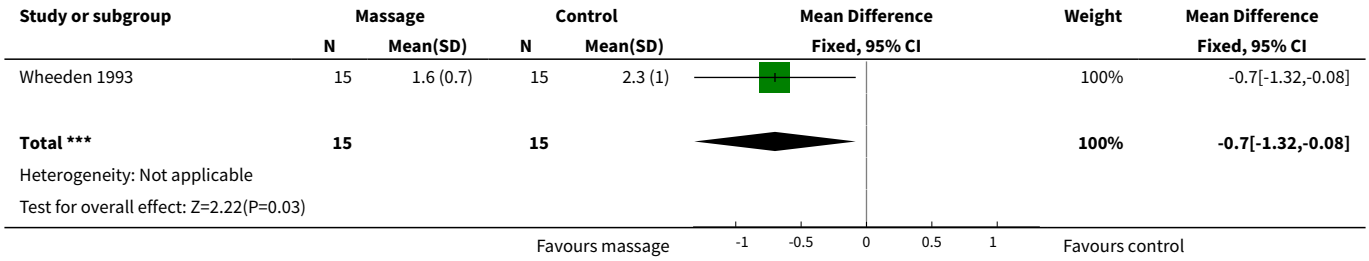
Analysis 1.8. Comparison 1 Massage vs. routine care, Outcome 8 Brazleton scale: autonomic stability.



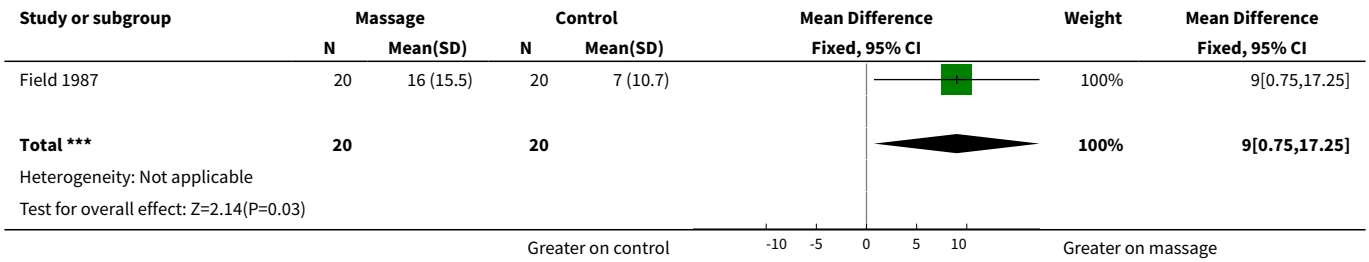
Analysis 1.9. Comparison 1 Massage vs. routine care, Outcome 9 Brazleton scale: number of abnormal reflexes.



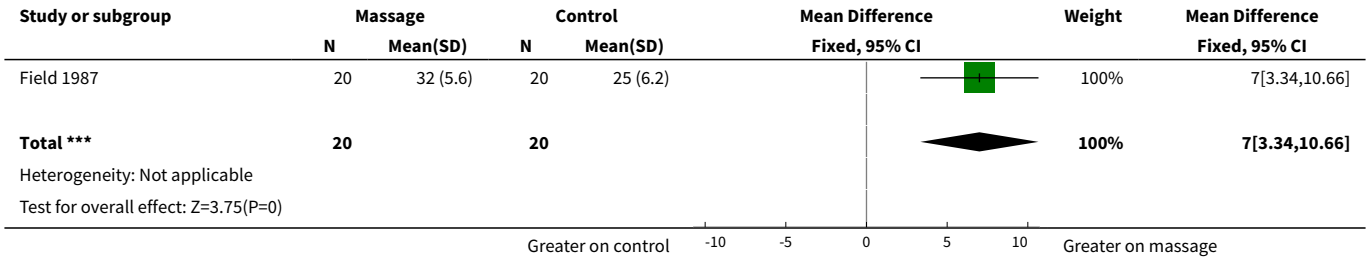
Analysis 1.10. Comparison 1 Massage vs. routine care, Outcome 10 Stress behaviours.



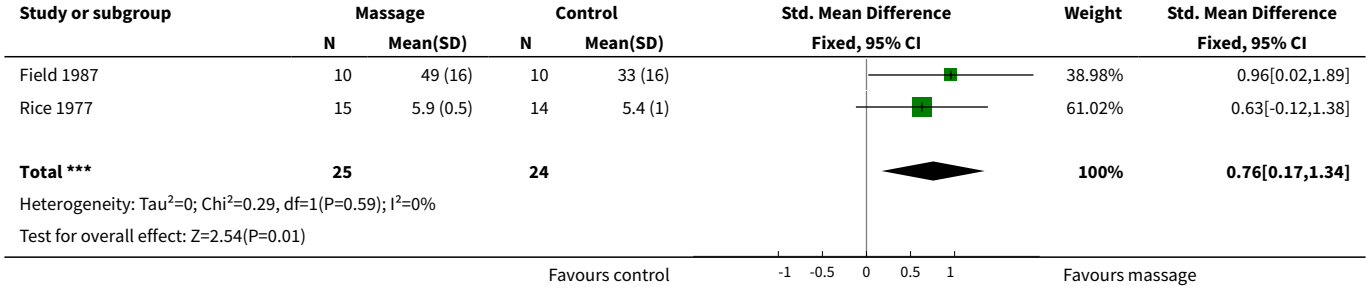
Analysis 1.11. Comparison 1 Massage vs. routine care, Outcome 11 Percentage time awake.



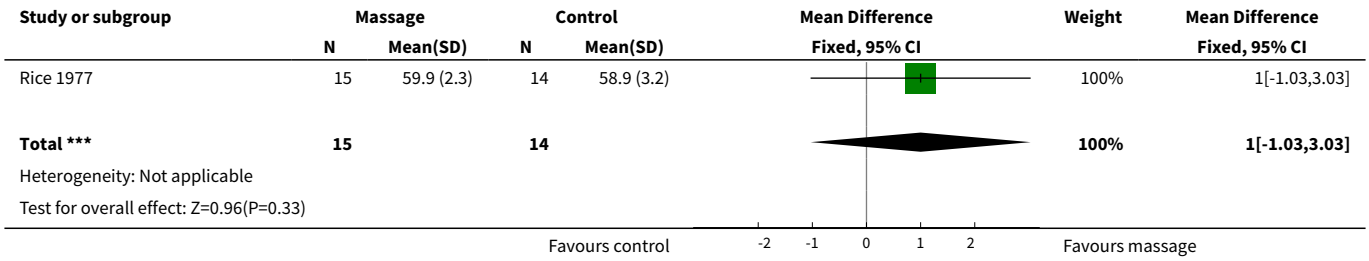
Analysis 1.12. Comparison 1 Massage vs. routine care, Outcome 12 Percentage time in movement.



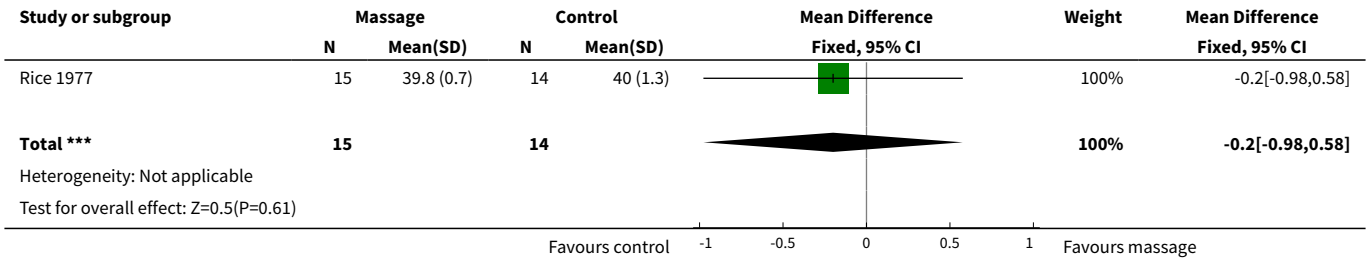
Analysis 1.13. Comparison 1 Massage vs. routine care, Outcome 13 Weight at 4-8 month follow-up (mixed units).



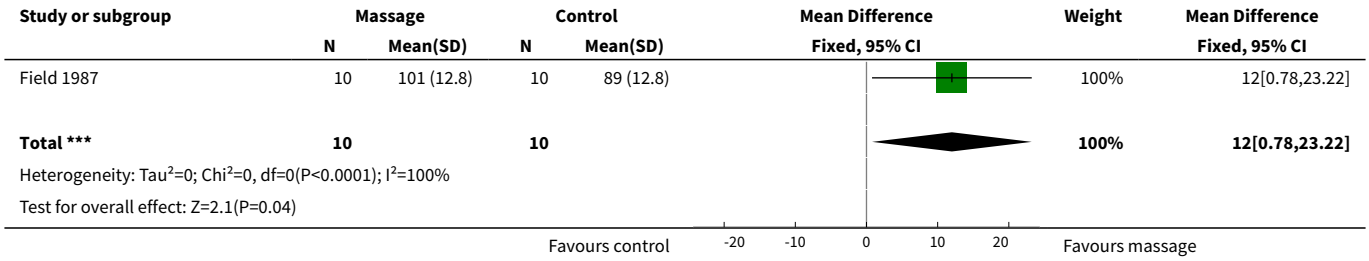
Analysis 1.14. Comparison 1 Massage vs. routine care, Outcome 14 Length at 4-8 month follow-up (cm).



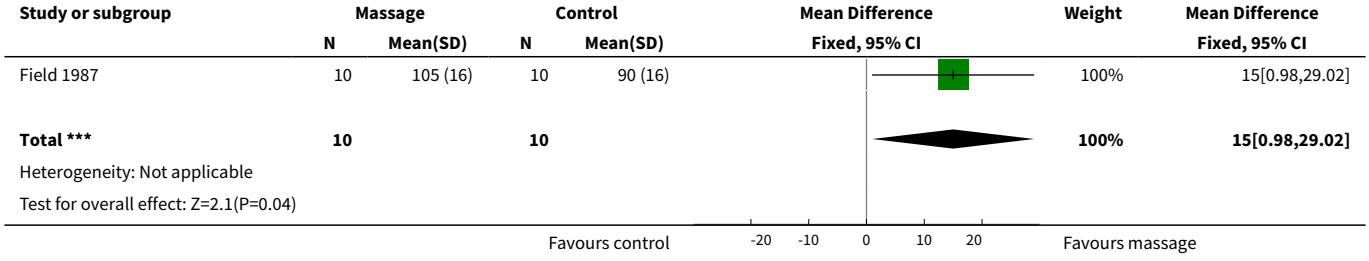
Analysis 1.15. Comparison 1 Massage vs. routine care, Outcome 15 Head circumference at 4-8 month follow-up (cm).



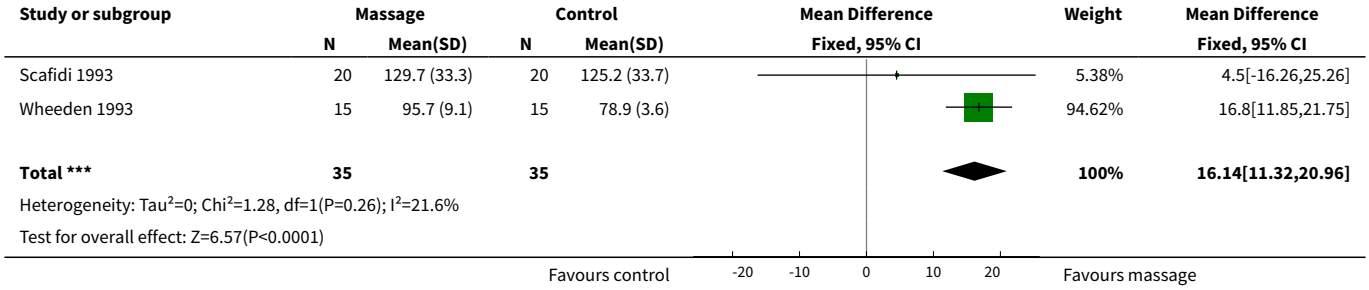
Analysis 1.16. Comparison 1 Massage vs. routine care, Outcome 16 Bayley Mental Scale at 6 months.



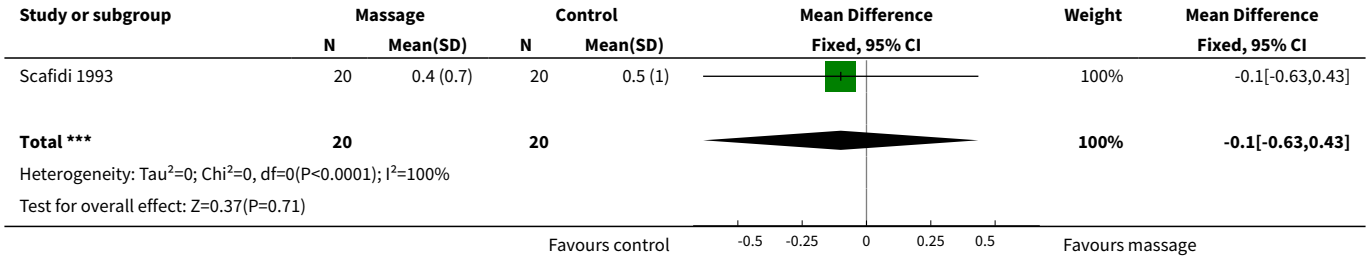
Analysis 1.17. Comparison 1 Massage vs. routine care, Outcome 17 Bayley Motor Scale at 6 months.



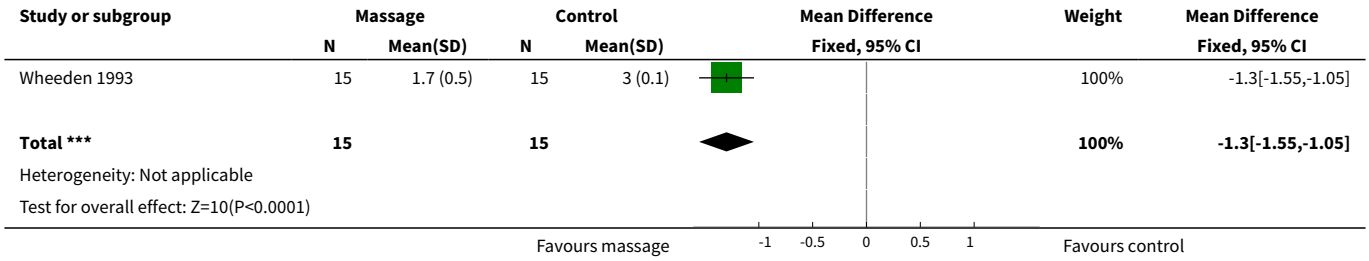
Analysis 1.18. Comparison 1 Massage vs. routine care, Outcome 18 Postnatal Complications Scale.



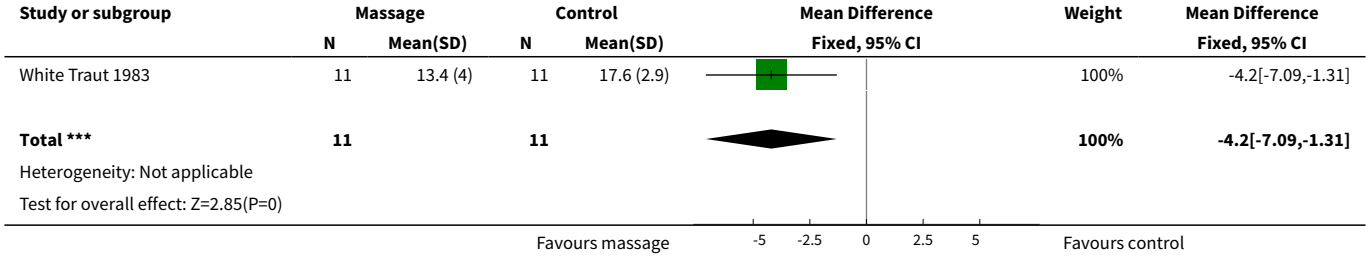
Analysis 1.19. Comparison 1 Massage vs. routine care, Outcome 19 Brazy postnatal complications scale.



Analysis 1.20. Comparison 1 Massage vs. routine care, Outcome 20 Newfoundland postnatal complications scale.



Analysis 1.21. Comparison 1 Massage vs. routine care, Outcome 21 NCAFS Infant Feeding Behaviors.



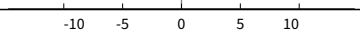
Comparison 2. Gentle touch vs. routine care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Daily weight gain (g/day)	3	134	Mean Difference (IV, Fixed, 95% CI)	0.21 [-1.22, 1.64]
2 Length of stay (days)	2	104	Mean Difference (IV, Fixed, 95% CI)	-0.87 [-10.05, 8.30]
3 Neonatal morbidity score	1	30	Mean Difference (IV, Fixed, 95% CI)	-0.10 [-0.79, 0.59]
4 Days on supplemental oxygen	3	134	Mean Difference (IV, Fixed, 95% CI)	-0.67 [-2.46, 1.12]
5 Days of phototherapy	3	134	Mean Difference (IV, Fixed, 95% CI)	1.07 [0.33, 1.81]
6 Number of blood transfusions	1	20	Mean Difference (IV, Fixed, 95% CI)	-0.5 [-1.52, 0.52]
7 Change in time in movement	2	50	Std. Mean Difference (IV, Fixed, 95% CI)	-0.26 [-0.82, 0.30]
8 Change in behavioural distress	1	20	Mean Difference (IV, Fixed, 95% CI)	-6.2 [-18.35, 5.95]

Outcome or subgroup title	No. of studies	No. of partici-pants	Statistical method	Effect size
9 Brazleton scale: habituation	1	84	Mean Difference (IV, Fixed, 95% CI)	-0.38 [-1.09, 0.33]
10 Brazleton scale: orientation	1	84	Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.66, 0.70]
11 Brazleton scale: range of state	1	84	Mean Difference (IV, Fixed, 95% CI)	0.41 [0.06, 0.76]
12 Brazleton scale: motor maturity	1	84	Mean Difference (IV, Fixed, 95% CI)	0.10 [-0.23, 0.43]
13 Brazleton scale: state regulation	1	84	Mean Difference (IV, Fixed, 95% CI)	-0.47 [-1.25, 0.31]
14 Brazleton scale: autonomic stability	1	84	Mean Difference (IV, Fixed, 95% CI)	0.20 [-0.36, 0.76]

Analysis 2.1. Comparison 2 Gentle touch vs. routine care, Outcome 1 Daily weight gain (g/day).

Study or subgroup	Still, gentle touch N	Still, gentle touch Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Harrison 1996	15	16.4 (2.9)	15	16.9 (3.2)		42.91%	-0.47[-2.65,1.71]
Harrison 2000	42	16.8 (3.1)	42	16.2 (5.6)		54.97%	0.57[-1.36,2.5]
M - McCarthy 1992	10	23.3 (11.2)	10	18.5 (11.2)		2.12%	4.8[-5.02,14.62]
Total ***	**67**		**67**			**100%**	**0.21[-1.22,1.64]**
Heterogeneity: Tau²=0; Chi²=1.35, df=2(P=0.51); I²=0%							
Test for overall effect: Z=0.29(P=0.77)							

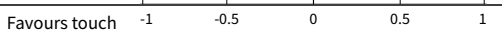


Analysis 2.2. Comparison 2 Gentle touch vs. routine care, Outcome 2 Length of stay (days).

Study or subgroup	Still, gentle touch N	Still, gentle touch Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Harrison 2000	42	45.6 (20.5)	42	47 (25.4)		86.4%	-1.39[-11.26,8.48]
M - McCarthy 1992	10	49 (28.4)	10	46.6 (28.4)		13.6%	2.4[-22.48,27.28]
Total ***	**52**		**52**			**100%**	**-0.87[-10.05,8.3]**
Heterogeneity: Tau²=0; Chi²=0.08, df=1(P=0.78); I²=0%							
Test for overall effect: Z=0.19(P=0.85)							

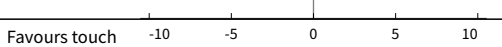
Analysis 2.3. Comparison 2 Gentle touch vs. routine care, Outcome 3 Neonatal morbidity score.

Study or subgroup	Still, gentle touch N	Still, gentle touch Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Harrison 1996	15	1.9 (0.8)	15	2 (1.1)		100%	-0.1[-0.79,0.59]
Total ***	**15**		**15**			**100%**	**-0.1[-0.79,0.59]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.29(P=0.77)							



Analysis 2.4. Comparison 2 Gentle touch vs. routine care, Outcome 4 Days on supplemental oxygen.

Study or subgroup	Still, gentle touch N	Still, gentle touch Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Harrison 1996	15	1 (3.1)	15	4.7 (12.8)		7.25%	-3.67[-10.32,2.98]
Harrison 2000	42	4 (5.4)	42	4.5 (4.5)		71.85%	-0.53[-2.64,1.58]
M - McCarthy 1992	10	3.2 (4.5)	10	3.3 (4.5)		20.9%	-0.1[-4.02,3.82]
Total ***	**67**		**67**			**100%**	**-0.67[-2.46,1.12]**
Heterogeneity: $Tau^2=0$; $Chi^2=0.88$, df=2(P=0.64); $I^2=0\%$							
Test for overall effect: Z=0.73(P=0.46)							

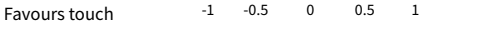


Analysis 2.5. Comparison 2 Gentle touch vs. routine care, Outcome 5 Days of phototherapy.

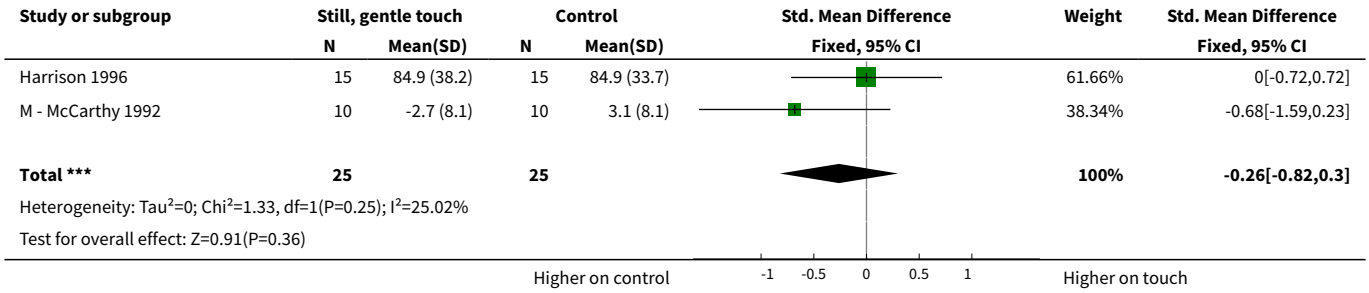
Study or subgroup	Still, gentle touch N	Still, gentle touch Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Harrison 1996	15	6.3 (1.9)	15	4.6 (2)		28.31%	1.67[0.27,3.07]
Harrison 2000	42	5 (3.6)	42	4.5 (3.4)		24.24%	0.5[-1.01,2.01]
M - McCarthy 1992	10	1.8 (1.2)	10	0.8 (1.2)		47.44%	1[-0.08,2.08]
Total ***	**67**		**67**			**100%**	**1.07[0.33,1.81]**
Heterogeneity: $Tau^2=0$; $Chi^2=1.27$, df=2(P=0.53); $I^2=0\%$							
Test for overall effect: Z=2.82(P=0)							

Analysis 2.6. Comparison 2 Gentle touch vs. routine care, Outcome 6 Number of blood transfusions.

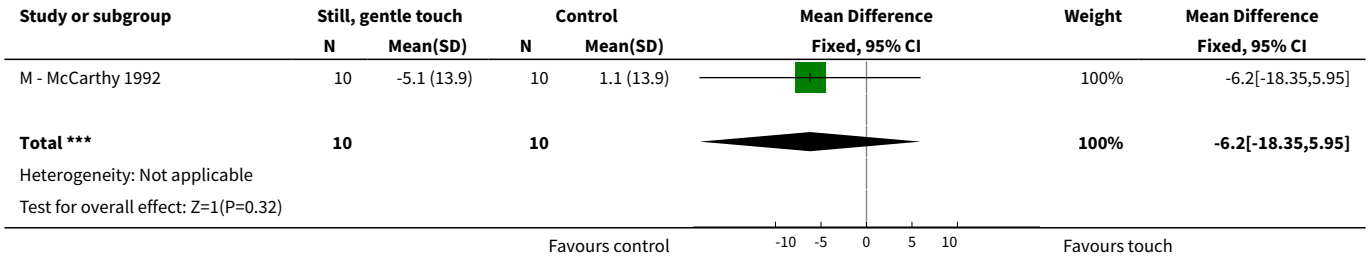
Study or subgroup	Still, gentle touch N	Still, gentle touch Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
M - McCarthy 1992	10	0.5 (1.2)	10	1 (1.2)		100%	-0.5[-1.52,0.52]
Total ***	**10**		**10**			**100%**	**-0.5[-1.52,0.52]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.96(P=0.34)							



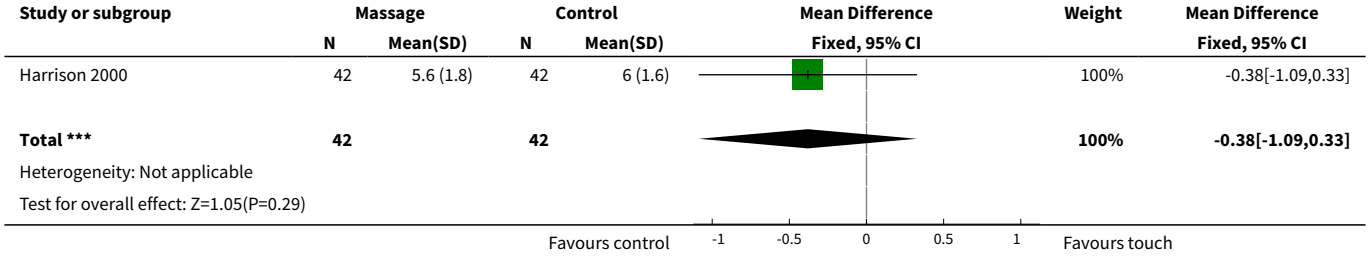
Analysis 2.7. Comparison 2 Gentle touch vs. routine care, Outcome 7 Change in time in movement.



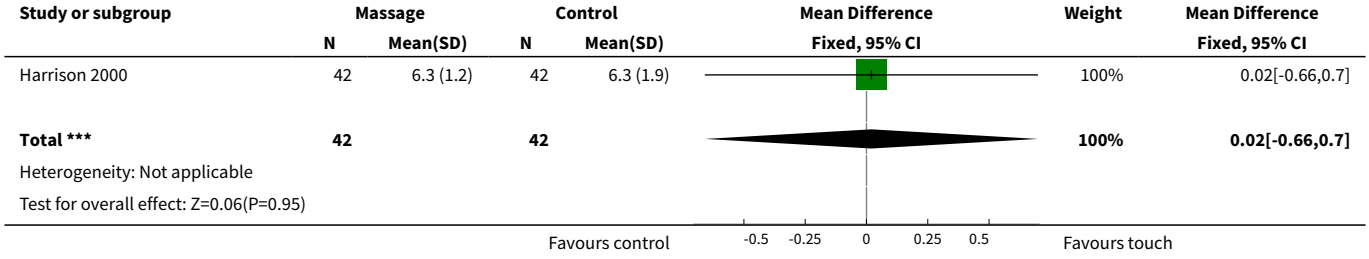
Analysis 2.8. Comparison 2 Gentle touch vs. routine care, Outcome 8 Change in behavioural distress.



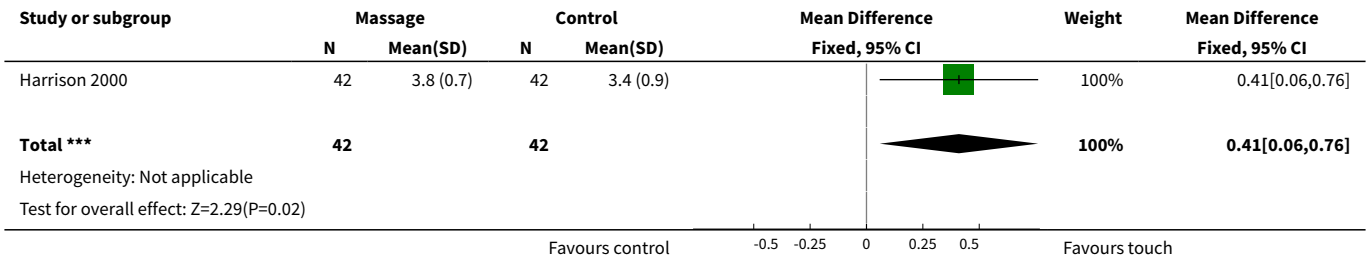
Analysis 2.9. Comparison 2 Gentle touch vs. routine care, Outcome 9 Brazleton scale: habituation.



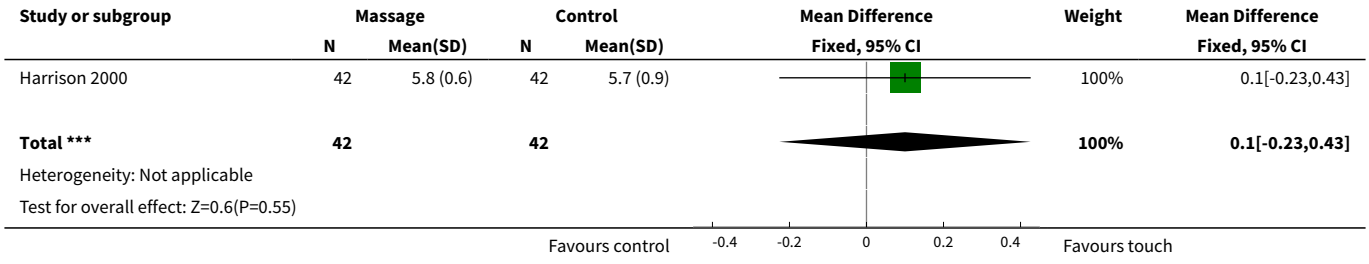
Analysis 2.10. Comparison 2 Gentle touch vs. routine care, Outcome 10 Brazleton scale: orientation.



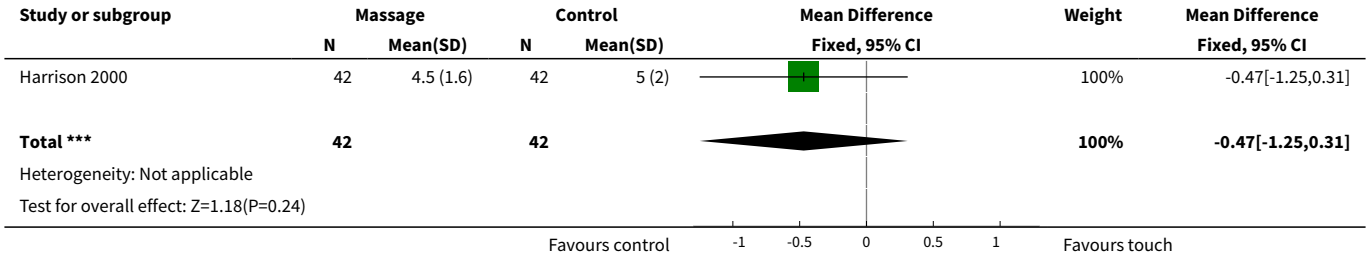
Analysis 2.11. Comparison 2 Gentle touch vs. routine care, Outcome 11 Brazleton scale: range of state.



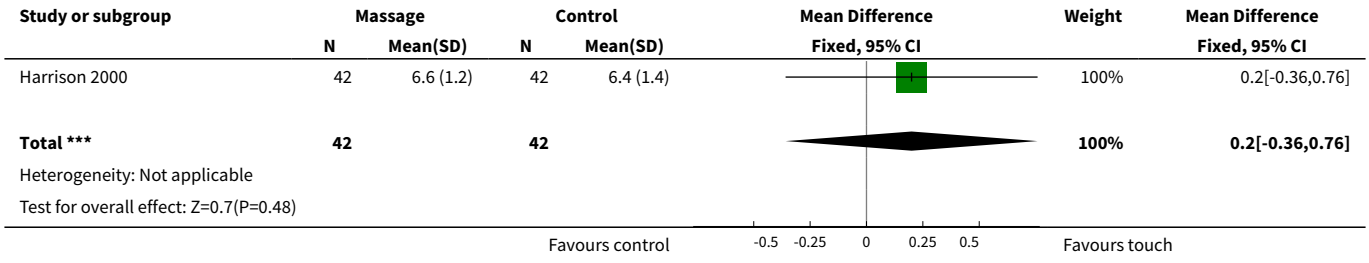
Analysis 2.12. Comparison 2 Gentle touch vs. routine care, Outcome 12 Brazleton scale: motor maturity.



Analysis 2.13. Comparison 2 Gentle touch vs. routine care, Outcome 13 Brazleton scale: state regulation.



Analysis 2.14. Comparison 2 Gentle touch vs. routine care, Outcome 14 Brazleton scale: autonomic stability.



WHAT'S NEW

Date	Event	Description
28 October 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 4, 1997
Review first published: Issue 3, 1998

Date	Event	Description
8 January 2004	New search has been performed	This is an update of "Massage for promoting growth and development of preterm and/or low birth-weight infants" published in The Cochrane Library, Issue 2, 2000 (Vickers 2000). We added a new trial examining still, gentle touch. This shrank the confidence intervals somewhat, confirming that this intervention is unlikely to have an important impact on weight gain. We removed a trial (White Traut 1999) previously classified as "allocation concealment unclear". In Email contact with the author, the method of randomization was made clear. We determined that allocation was unconcealed and that the review did not, therefore, meet our eligibility criteria. Exclusion of this trial had no impact on the results or conclusions of the review. We located several more studies that were all excluded for using unconcealed allocation.
8 January 2004	New citation required but conclusions have not changed	Substantive amendment

DECLARATIONS OF INTEREST

None

SOURCES OF SUPPORT

Internal sources

- Department of Paediatrics, Mount Sinai Hospital, Toronto, Ontario, Canada.

External sources

- Rescue: the foundation for the brain injured infant, UK.

INDEX TERMS

Medical Subject Headings (MeSH)

*Infant Care; *Massage; Infant, Low Birth Weight [*growth & development]; Infant, Premature [*growth & development]; Physical Stimulation; Weight Gain

MeSH check words

Humans; Infant, Newborn