

Treating infants for suboptimal breastfeeding, is there a difference between chiropractic care versus multidisciplinary care: A pragmatic randomized comparison trial protocol

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ABSTRACT

Background: Suboptimal breastfeeding is a problematic concern of mothers of newborns in all societies, with huge economic and sociological ramifications. All professionals support breastfeeding, but some professions have set up special clinics to assist these families. Both chiropractors individually providing care and chiropractors within multi-disciplinary clinics have shown some benefit. Since many resources are involved, we propose a randomized clinical comparison trial that may be able to determine whether there are superior benefits to one approach or the other. **Methods:** Randomize mothers and babies who consent to participate to two different treatment arms: (1) chiropractic manual therapy along with advice and (2) chiropractic manual therapy along with midwifery care and routine advice. Maternal report will provide the outcomes at the infant's ages of 6, 12 and 24 weeks. **Discussion:** The purpose of this trial is to investigate the actual difference in effectiveness of chiropractic care alone versus a multi-disciplinary approach. As such, the results should be helpful to determine what resources should be reserved for this population. The purpose of the proposed publication is to receive recommendations from other professionals to strengthen the protocol.

Introduction

The WHO recommends breastfeeding initiation within an hour of birth, exclusively for the first six months and continued alongside appropriate foods up to two years of age and beyond, to achieve optimal health, growth and development.¹ The importance of breastfeeding is undeniable. Only 37% of infants under six months of age are exclusively breastfed.² This is despite the evidence that the meta-analysis performed by Victora et al (2017)² showed increased intelligence along with protection against infections, overweight, diabetes and malocclusions for the breastfed child. If everyone breastfed (who can or can learn), 823,000 annual deaths of children under five years of age could be prevented as well as 20,000 annual deaths in the mothers from breast cancer.²

Breastfeeding education and support, through healthcare professionals and peer counsellors, are thought to be critical in increasing breastfeeding rates and promoting positive outcomes. However, while prenatal education has been shown in one study to improve initiation rates,³ postnatal education was found to have no effect on duration according to a recently updated Cochrane review.⁴ Conversely, breastfeeding support provided by professional or lay/peer supporters, particularly on a face-to-face basis, appears to address some of the issues causing suboptimal feeding thus increasing breastfeeding exclusivity and duration.⁵

Often however, despite support, breastfeeding fails due to the infant's inability to feed. Biomechanical causation, as a result of structural restrictions or birth trauma, can contribute significantly to suboptimal breastfeeding and in these cases, a referral to a musculoskeletal specialist, such as a chiropractor, for structural treatment may be beneficial.⁶

A number of studies have attempted to identify the factors contributing to suboptimal feeding and determine the most effective package of interventions to influence breastfeeding duration.

Background

Difficulty in breastfeeding is a common problem in the newborn population and families seek care both in-hospital and upon release. It afflicts a large percentage of families. To help meet this need on the south coast of England in the UK, a chiropractic teaching University College clinic accepted large numbers of these cases. When the midwifery department of a local University offered to join the program, a multi-disciplinary clinic to manage these cases was also implemented. Both clinics showed positive outcomes collected using the mother's report.^{7,8} Despite the fact that these low-level scientific studies have suggested both multidisciplinary care and chiropractic care of infants may improve breastfeeding outcomes, no clear way forward can be drawn from these reports. A scoping review has found

some evidence for manual interventions for musculoskeletal factors in suboptimal breastfeeding.⁹

Aim and Purpose

The aim of this study is to determine whether there is an advantage to either chiropractic care or multidisciplinary care as an intervention for suboptimal infant breastfeeding (SIB) to improve outcomes and, consequently, the impact on exclusive and enhanced duration of breastfeeding.

The objective is to investigate the following primary research question: “In infants with suboptimal breastfeeding, is there a difference in short- and long-term outcomes, whether they are treated exclusively with chiropractic care versus a multidisciplinary approach of both midwifery and chiropractic care?”

Research Question(s)

The research questions are:

1. Is there a difference in short-term outcomes (in infants aged 6 and 12 weeks) in SIB depending on the type of treatment?
2. Is there a difference in long-term outcomes (in infants aged 24 weeks) in SIB depending on the type of treatment?
3. What is the parental rating of the success of breastfeeding upon initial presentation versus after intervention?
4. Is there a difference in the parental rating of the success of breastfeeding relative to the type of treatment?

Methodology

Study Design: Double blinded randomized comparison trial (with a wait-list control group)

In order to best test the primary research question, the study proposed is a randomized comparison trial with two intervention groups. This particular study design is chosen over a randomized controlled trial to overcome the potentially unethical scenario of a control group of infants experiencing breastfeeding difficulties receiving no care for their complaints. The two types of interventions can be considered ethical because there is a modest amount of evidence to suggest that both approaches have some benefit, but no research that shows that one or the other is more efficacious. As the problem is so vast and egregious, there could be considerable long-term benefits (and huge time and cost savings) if one method or the other were found to be more effective.

Sampling, Recruitment and Selection of Participants

Subjects will be recruited from routine intake at the AECC University College Clinic, located on the south coast of England.

Inclusion criteria:

Babies:

- Full term
- Healthy
- Between day 0 and 8 weeks of age
- Any type of birth
- Singleton or twin
- Has been seen by routine medical care (Hospital care, Pediatrician, Midwife, GP and/or Lactation Consultant or health care professional who routinely works with breastfeeding problems) who confirmed a breastfeeding problem.
- Inability to breastfeed fully, effectively and efficiently by mother’s report and corroborated by health care professional

Mothers:

- 18 years of age or older
- English speaking and able to complete survey instruments

Exclusion Criteria:

Babies:

- Premature
- Any sign of illness or known genetic condition
- Admission to NICU for longer than 48 hours

It would be preferable to select only primiparous mothers for this study, as this population is unable to bring to bear any previous breastfeeding experience and therefore cannot “add” to the intervention and bias results. However, current data from the AECC feeding clinic shows that multiparous mothers also encounter difficulty breastfeeding; therefore, these mothers should also be involved in the trial. Their inclusion also enhances the trial size and analysis at the end of the study, along with the pragmatic nature of the study. Thus, this will determine whether there was any statistical difference between the sub-grouping primipara and multipara populations, which will be helpful for future studies.

Upon initial contact with the clinic, mothers will be provided with a validated intake form and information of a trial involving free routine care (although there may be a short wait involved). The inclusion of a waiting list is not an additional treatment arm, but a measure that organically emerges out of necessity. Due to the sheer volume of mothers-infant dyads routinely treated at the AECC clinics, there can be up to a two-week waiting list in order to attend. The use of the waiting list as a control group allows for additional observation and provides the added benefit of determining whether care is indeed effective, or whether it is the act of “doing something” to address the problem. All efforts will be made to see every baby as soon as possible, however.

Mothers consenting to participate will be block randomized at the front reception and entered into either chiropractic care or combined midwifery/chiropractic. Mothers who de-

cline entering the trial will receive routine care as normal. The only difference is that the mothers who decline to enter the trial will incur the expense of treatment. Mothers who drop out of the trial will be followed up and included in their own group (intention to treat analysis).

Prior to treatment, mothers will be asked to complete the informed consent and intake form. The follow-up form will be collected after treatment and again at the ages of 6, 12 and 24 weeks of the infant, in order to compare the maternal ratings of the infant's breastfeeding problem. A few babies who are presented to the clinic later than six weeks of age, will not be included in the data collection at the six week age timeline, but will be included in the older age groups.

Randomization

To minimize selection bias and to ensure participants receive equal probability of allocation into either intervention, participants will be randomized by computer in blocks of 16 to even out presentation to each intervention. Random numbers will be computer-generated and slotted automatically into Clinic Office program which will assign the patient to the interventions.

Blinding

Everyone involved with the trial, who can be, will be blinded. This includes the reception staff, who collects the informed consent and follow-up measures, but will be blinded to actual group assignment; the statistician; the manual therapist and the mothers. Blinding of the manual therapist should be fairly easy to administer at the AECC clinic — by the very nature of its business, it already provides care to mother-infant dyads for a myriad of conditions. Therefore, therapists are able to be blinded to participant's involvement in the trial, as treatment will be routine and commonplace. Each subject will be enrolled and followed up by the research assistant and not anyone working in routine clinic jobs.

Sample size

When estimating a sample size that would achieve a detectable and reasonable effect, data from prior studies relating to treatment of SIB in infants were considered. In a randomized controlled trial by Jolly et al (2012)¹⁰ which consisted of 2,724 participants, the sample size was powered by a 6% increase of initiation as outlined in a study by MacArthur et al (2009).¹¹ In a smaller study conducted by McDonald et al (2010),¹² the trial size of 849 participants was influenced by an already high level of exclusive breastfeeding at six months, as observed by Henderson et al (2003).¹³ Based on previous research therefore, in order to have an 80% chance of identifying a reasonable effect at 0.05 level of significance, a minimum of 850 mothers are required to enter this trial. In light of the effort required to do this study, a 10% overage will be added to the trial size to account for drop-outs.

Recruitment for the trial is unlikely to be arduous. The number of hospital births in the local population are detailed in Table 1.

Location	No. of Births Apr 14 - Apr 15
Royal Bournemouth Birth Centre	290
Poole Hospital	4,400
New Forest Birth Centre	300
Dorset County Hospital	1,850
Salisbury District Hospital	2,300
Princess Anne Hospital, Southampton	5,350
Total Births	14,490

Table 1. Local Hospital Births — April 2014 to April 2015
 Figures taken from www.which.co.uk/birth-choice

Research from Geddes¹⁴ shows that up to 44% of newborns have suboptimal breastfeeding. This would suggest an estimated 6,400 babies eligible for participation in the trial. A pilot study at AECC showed that in one year, AECC accessed approximately 42% of the babies in the local hospitals.⁷

Procedures / Treatments

Participants in this study will be given either chiropractic care (manual therapy) as is routine for this clinic, or multidisciplinary care. The multidisciplinary care arm is a coalescence of midwifery support, which includes advice on attachment and positioning, and manual therapy (mobilization of joints and soft tissue).

The two groups will be characterized as (1) chiropractic manual therapy for breastfeeding and (2) chiropractic manual therapy plus midwifery advice for breastfeeding.

Manual therapy has been used in other studies to address and restore full competency in feeding^{7,8,9} in spite of low levels of evidence to support its effectiveness. Studies have found that 3-4 treatments are the mode and mean number of treatments to reach full effect.¹⁵ This study will not place limits on the number of treatments, as each clinician makes these decisions based on the response of the patient. It is anticipated that these numbers may hold true for this study and the costs will be based upon the average of four treatments per infant.

Outcome Measures

Outcome measures are 'no breastfeeding,' 'partial breastfeeding' or 'exclusive breastfeeding.' The definition of exclusive breastfeeding by WHO is where the infant receives only "breast milk without any additional food or drink, not

even water.”¹¹ Outcome measures are recorded by the mother on a daily basis in a breastfeeding diary. These measures are recorded at the time of follow-up, which has been defined as 6, 12, and 24 weeks after the intervention. With the use of the diary, it will be possible to determine the actual method of breastfeeding in each time frame.

The mother will complete the follow-up form at 6, 12 and 24 weeks, which will be an addition to the daily breastfeeding diary, and the answers compared through statistical analysis. Use of other health care professionals’ time will also be collected and mothers asked about any visits to the GP, midwife, health visitor, pediatrician, consultant, lactation consultant or other health care professional. This is important to assess the true costs associated with suboptimal breastfeeding health care. It may also show that there are significant confounding factors in how well or poorly the baby’s breastfeeding commences.

There are no ethical issues in offering this treatment as manual therapy has been found to be safe and a very low risk activity. One chiropractic teaching clinic has tracked approximately 86,000 infant treatments over 20 years without a single adverse event (AECC computerized clinic office). Other studies have also provided evidence that the risks are very low.^{15,16,17}

Fully informed consent will be obtained from the mothers when they report for treatment. It is part of routine clinical care as well as care in this trial.

Drop outs

Drop-out rates will be tracked. The AECC Clinic has demonstrated reasonable follow-up, as seen in the study by Miller et al (2016),⁸ where the response rate achieved was 85% in the cases of suboptimal breastfeeding.

Methods of data analysis

Data will be stored and analyzed using SPSS v. 23 for Windows. Recruitment rates, attrition rates, and overall proportion exclusively breastfeeding, will be calculated with 95% confidence intervals.

An attempt will be made to obtain data on the outcomes measures from subjects who have not completed care or dropped out, in order to perform an intention-to-treat analysis. Their diaries should be very helpful in discerning why they dropped out of the trial. The proportion of mothers totally breastfeeding will be compared between the two groups using the chi-squared test for association or Fisher’s Exact test, as appropriate. Data will be tested for normality although it is anticipated that this data will be non-normally distributed.

Satisfaction levels of the mothers will be compared using

the independent samples t-test or Mann-Whitney U test, whichever is appropriate.

Further statistical analysis will be discussed with a statistician to strengthen and fine-tune the analysis as the trial ensues, as the most appropriate tests for the data and research questions must be utilized.

Descriptive statistics will be used to describe the proportion of mothers totally or partially breastfeeding both at the beginning and end of the treatment, and at 6, 12 and 24 weeks. Any comments made by the mothers on the outcome instruments will be collected over the duration of the trial as well. Any adverse effects of treatment will also be collected.

Resources

Like most randomized trials, it will be necessary to fund this study. These details will be supplied completely in the request for funding with application to funding agencies. At this point, a Research Assistant (RA) will be required, just as in the last RCT done in the AECC clinic to study the colic baby. That funding was supplied by the British Columbia Chiropractic Association.

The additional major cost is for treatment for the babies. The parents of babies who enter the study will not be required to pay, therefore each subject’s individual visits will be paid at the fee of £24/visit (or current fee) by the funding agency. In the last RCT, this was covered by the TAM club. However this trial will be a much larger study, therefore request for fees will be made to the same funding agency. Other incidental requirements such as stationery, printing and copying, travel to train referrers, statistician time, etc, will be added together to determine the final funding requirement.

Strengths / Weaknesses

A strength of this trial is that randomization is a high level method of research as it randomly distributes the biases that can confound any study. However, there can be high drop-out rates which could lessen statistical strength and undermine the initial randomization.

An additional strength is that care is routine at AECC; therefore no special provisions are required. Further, mothers have been found to be very accurate reporters of their infant’s abilities.¹⁷ However, it is possible that there is inaccuracy of maternal recall and this can be a weakness.

Conclusion

A pragmatic design was selected for this study so that the outcomes can more readily be applied to the real-world situation where sub-optimal infant breastfeeding is a serious problem. Suggestions to improve this study before its embarkation are welcome.

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