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## Editorial

# Global evidence synthesis and UK idiosyncrasy: why have recent UK trials had no significant effects on breastfeeding rates?

Breastfeeding is a highly complex physiological, emotional, social and cultural behaviour, and so, in many ways, it is not surprising that to design and deliver effective behaviour change interventions to improve breastfeeding rates are challenging. The World Health Organization recommends exclusive breastfeeding for 6 months (World Health Organization 2003), and this presents a public health policy challenge, particularly for countries like Britain where less than 1% of women currently achieve this (Bolling *et al*. 2007). Given the diversity of cultures and philosophies underpinning health service systems in different countries, it is unlikely that one generalized intervention will provide a magic bullet to increase breastfeeding. This appears to be the case for the UK, where nine randomized controlled trials reported since 2000 have not significantly improved breastfeeding rates (Morrell *et al*. 2000; Winterburn *et al*. 2003; Graffy *et al*. 2004; Carfoot *et al*. 2005; Lavender *et al*. 2005; Muirhead *et al*. 2006; Wallace *et al*. 2006; Hoddinott *et al*. 2009; MacArthur *et al*. 2009). These trial outcomes differ from the findings of a recent evidence synthesis of international studies reported between 2001 and 2008 (Chung *et al*. 2008) that breastfeeding interventions are more effective than usual care. An earlier synthesis found that additional lay or professional support increases short- and long-term breastfeeding duration and exclusivity (Britton *et al*. 2007). So what is going on? Is it the trial design or execution that is problematic? Is it a particular attribute of UK childbearing women or researchers? Are there factors in the health system or the wider environment that mitigate attempts to intervene to improve breastfeeding outcomes? Is it valid to conclude that breastfeeding interventions are unlikely to be generalized across countries in the developed world? This editorial does not provide definitive answers to these questions; rather, we wish to highlight some key themes that are worth unpicking to make progress in this important area. This is particularly relevant in the current economic climate as the use of finite health service resources will come under increasing scrutiny, and evidence-based breastfeeding care will need to compete with other health improvement behaviours.

The nine UK trials published since 2000 with non-significant breastfeeding outcomes were identified from evidence syntheses and searching trial databases. Most report breastfeeding duration as the primary outcome ranging from hospital discharge until 4 months after birth, with one trial reporting breastfeeding initiation only (MacArthur *et al*. 2009), and in one trial, the primary outcome was general health status, with breastfeeding as a secondary outcome (Morrell *et al*. 2000). We systematically critiqued and extracted thematic data from the nine trial reports and process evaluations linked to three of the trials (Morrell & Stapleton 2000; Crowther *et al*. 2001; Graffy & Taylor 2005; Hoddinott *et al*. 2010a), looking for explanations for the study findings. One of the co-authors (RS) conducted semi-structured telephone interviews with six principal investigators to ask for their perspectives on why their own trial did not improve breastfeeding outcomes (Seyara 2010).

Evidence syntheses tend to focus on who delivers the intervention (professional or lay), whether it is before or after birth or both, whether intervention components are single or multifaceted, and whether the content is either education or support (Britton *et al*. 2007; Gagnon 2007; Chung *et al*. 2008; Dyson *et al*. 2008). In the most recent evidence synthesis for the US Preventive Services Task Force of interventions in primary care (defined as any health service care intervention including hospital care), combining pre- and post-natal components had a larger effect than either alone (Chung *et al*. 2008). Interventions that include lay support in a multi-component intervention *may* be more beneficial than single-component interventions (Chung *et al*. 2008). The careful use of the word *may* in the conclusion reflects

the heterogeneity of the interventions and trial designs included. Thirty-eight randomized controlled trials published between September 2001 and February 2008 (36 trials from developed countries) met the inclusion criteria for this review. Six of the included trials were conducted in the UK (Winterburn *et al*. 2003; Graffy *et al*. 2004; Carfoot *et al*. 2005; Lavender *et al*. 2005; Muirhead *et al*. 2006; Wallace *et al*. 2006), and all reported non-significant changes in breastfeeding duration, although their outcomes have not been combined to assess overall effect.

In an earlier Cochrane systematic review, to assess the effectiveness of support for breastfeeding mothers, 34 trials met the inclusion criteria (Britton *et al*. 2007). Six of the 34 trials were conducted in the UK; three were published since 2000 (Morrell *et al*. 2000; Winterburn *et al*. 2003; Graffy *et al*. 2004), three were published in the 1980s and two of the six trials (Winterburn *et al*. 2003; Graffy *et al*. 2004) were included in the synthesis by Chung *et al*. (2008). The review concluded that combined additional lay and professional support resulted in a significant reduction in the cessation of any breastfeeding before 4–6 weeks (relative risk 0.65, 95% confidence interval 0.51–0.82). All forms of extra support had a larger effect on duration of exclusive breastfeeding than on any breastfeeding.

When asking why a trial has not reported a significant outcome, the initial approach is to assess the methodological quality of the trial and identify shortcomings. In particular, trials may have been inadequately powered to detect small but clinically important differences, given how resistant breastfeeding rates seem to change. In the review by Chung *et al*. (2008), quality assessment included randomization techniques, allocation concealment, clear definitions of outcomes, intention to treat analyses and statistical methods. It graded the quality of two of the UK trials as good (Graffy *et al*. 2004; Wallace *et al*. 2006), one fair (Muirhead *et al*. 2006) and three poor (Winterburn *et al*. 2003; Carfoot *et al*. 2005; Lavender *et al*. 2005). Meeting the sample size requirement was a reported problem in four UK trials (Winterburn *et al*. 2003; Graffy *et al*. 2004; Muirhead *et al*. 2006; Wallace *et al*. 2006), although it is debatable whether this alone explains the observed outcomes. Retrospective self-report of breastfeeding outcomes has potential biases, and blinding women or professionals to allocation is usually not possible when additional support is being provided. Overall, few problems were identified with following up women or with the trial protocol.

After assessing the methodological quality of trials with non-significant outcomes, important aspects of the intervention to consider include identifying the active/inactive/detractive intervention components and the amount, intensity, duration and consistency (sometimes referred to as fidelity) of the intervention. How, where, when and by whom the intervention is delivered may be relevant to effectiveness and how the delivery interacts and fits with existing maternity and community services. Any unanticipated consequences, and any interactions between the intervention and control arms and the overall macro-environmental, social and cultural influences on the trial may be important. Process evaluations often collect mixed qualitative and quantitative data, and can be very illuminating or even explain why a trial has a non-significant effect. For example, a very low proportion of a post-natal support worker's time was spent discussing breastfeeding (Morrell & Stapleton 2000), and over a third of recruits did not receive an educational intervention (Lavender *et al*. 2005) or the intended lay support (Graffy *et al*. 2004).

Considering a woman's breastfeeding journey from pregnancy to the decision to stop breastfeeding, it is useful to reflect on, first, the proportion of the journey that the intervention impacts on, and second, the timing and the intensity of the intervention in relation to outcome measurement. Complying with the evidence synthesis recommendation for interventions to span pregnancy and the post-natal period (Chung *et al*. 2008) is not a guarantee of success, as illustrated by three UK trials (Graffy *et al*. 2004; Muirhead *et al*. 2006; Hoddinott *et al*. 2009). In a recent longitudinal qualitative study, hospital and early days care was identified by women as the time of paramount importance for intense support, where continuity of skilled care is valued (Hoddinott *et al*. 2010b). For interventions where women opt in to additional support after birth (Graffy *et al*. 2004; Muirhead *et al*. 2006), low uptake in the early days at home is likely to reduce

the effectiveness of an intervention. Proactively offered support may be required to overcome this (Graffy *et al*. 2004; Graffy & Taylor 2005). In the Breastfeeding In Groups (BIG) trial, breastfeeding groups were available from pregnancy until breastfeeding ceased, yet few women in pregnancy attended, which was linked to low midwife involvement (Hoddinott *et al*. 2009, 2010a). The median baby age on first attending a group was 36 days, which is probably too close to the 6- to 8-week outcome measurement to impact on breastfeeding rates, as many women will have already stopped and those attending will be those committed to continuing. Unfortunately, a change in government policy withdrew the routinely collected 8-month outcome data before the trial ended. In some trials, the intervention was a single event (Carfoot *et al*. 2005; Lavender *et al*. 2005; Wallace *et al*. 2006), distant from the measurement of breastfeeding duration, which could explain the non-significant findings. It is sometimes assumed that a single dose of intervention will be sufficient, and the 'correct dose' for interventions like positioning and attachment is unknown (Wallace *et al*. 2006). Trials of short, low-intensity, highly focused interventions, which target one component of breastfeeding, are but a drop in the ocean in the whole breastfeeding journey that traverses primary and secondary health care, workplace and social settings, and involve multiple interactions. There is a risk that recognized or unrecognized external factors, for example, media scares or changes in health service organization, might dwarf any effect.

The predominant approach in trials is to deliver a 'communication intervention' with precisely defined replicable components to an individual woman with the aim of changing her behaviour. Critics of this approach cite accounts from women of feeling pressurized and of resistance and the risk of deteriorating professional–woman relationships. Five UK trials were embedded within existing maternity and postnatal services with the intervention delivered by existing health service staff, for example, skin-to-skin care after birth (Carfoot *et al*. 2005), hands-off positioning and attachment in hospital (Wallace *et al*. 2006), antenatal education (Winterburn *et al*. 2003; Lavender *et al*. 2005) and breastfeeding support groups (Hoddinott *et al*. 2009). These involve changing health service behaviour, and the assumptions are: that all staff will be highly committed and possess the skills necessary to deliver a consistent intervention, and that this will represent 'value-added time' (Bonuck *et al*. 2009). How a trial integrates with existing care is crucial, with some reporting midwifery ambivalence either about the research or breastfeeding more generally (Morrell & Stapleton 2000; Winterburn *et al*. 2003; Lavender *et al*. 2005), reluctance to work with peer supporters (Muirhead *et al*. 2006; MacArthur *et al*. 2009), contamination between researcher and midwife roles caring for women on labour ward (Carfoot *et al*. 2005), problems with midwife participation (Lavender *et al*. 2005; Hoddinott *et al*. 2010a) and insufficient information transfer about when safe delivery has occurred (Morrell & Stapleton 2000; Graffy *et al*. 2004; Muirhead *et al*. 2006), and these issues were often linked to discourses about high health service staff workload and lack of resources (Wallace *et al*. 2006; Hoddinott *et al*. 2010a). The commissioning and funding body requirements for research protocols can also contribute to implementation problems and tight deadlines, which can impact on trial outcomes.

Arguably, a pragmatic real-life trial can address the theory–practice gap, which can improve the translation of research evidence into practice and sustainability. However, it can increase the risk of a non-significant outcome as contamination between intervention and control group is more likely. This can reduce the amount of difference (Wallace *et al*. 2006), or the consistency or intensity of the intervention delivered may be lower than intended (Carfoot *et al*. 2005; Lavender *et al*. 2005). Researchers seldom evaluate or report whether or how existing care changes during the trial. If the intervention is incorporated into routine care, do staff stop doing something to accommodate the trial, particularly when resources are scarce? For example, in the BIG trial (Hoddinott *et al*. 2009), did running breastfeeding groups with few additional resources lessen the time available for individual breastfeeding support either in clinics or at home? Qualitative interviews with staff did not suggest that individual care suffered; however, it was not measured objectively. Health service staff

might increase their input to control women to meet women's support needs and compensate for the intervention (Bonuck *et al*. 2009). Any actual or potential changes to health care delivery systems that could impact on breastfeeding outcomes should be evaluated as part of the intervention, and this favours cluster randomized controlled trial designs (Lavender *et al*. 2005; Hoddinott *et al*. 2009; MacArthur *et al*. 2009).

An alternative trial model to changing existing health professional behaviour is to provide additional care delivered by people recruited from outside the health service (Morrell *et al*. 2000; Graffy *et al*. 2004; Muirhead *et al*. 2006; MacArthur *et al*. 2009). This can seem attractive, add value and be potentially less disruptive to existing maternity services than trials that require a change of health professional's behaviour. Lay support trials have varying amounts of integration with existing services. For example, programmes can be National Health Service (NHS) designed (Morrell *et al*. 2000; Muirhead *et al*. 2006; MacArthur *et al*. 2009), or designed and managed with a voluntary sector organization like the National Childbirth Trust (Graffy *et al*. 2004). Lower than intended intensity of peer support may explain a non-significant effect (Graffy *et al*. 2004; MacArthur *et al*. 2009). Yet a single-centre trial by Muirhead *et al*. (2006) offered high-intensity peer support in pregnancy and every 2 days for the first 4 weeks with continued availability until 16 weeks, but did not increase breastfeeding rates significantly. Three of the four trials of lay support recruited unselected populations where up to half of the sample did not intend to breastfeed (Morrell *et al*. 2000; Muirhead *et al*. 2006; MacArthur *et al*. 2009), and one recruited women intending to breastfeed who had not previously breastfed for longer than 6 weeks (Graffy *et al*. 2004). As a UK non-randomized intervention study also had a non-significant effect (McInnes *et al*. 2000) and considering evidence synthesis findings (Chung *et al*. 2008), it would seem that lay support alone, particularly in countries where bottle feeding predominates, is not an effective intervention. The jury is still out on whether it is an active ingredient in multifaceted interventions as this has not yet been tested in the UK.

In several trials, the observed breastfeeding rates in both trial arms were higher than baseline pre-trial rates, and this might have diluted the effects of the intervention (Winterburn *et al*. 2003; Carfoot *et al*. 2005; Lavender *et al*. 2005; MacArthur *et al*. 2009). This can be explained by the well-recognized Hawthorne effect, whereby the conduct of research changes the behaviour of health professionals and improves the desired outcome. This might also result from selection bias of the women included or concurrent interventions at the time of the trial (MacArthur *et al*. 2009). Whereas internationally, any intervention group in a trial seems to be more effective than a usual care group (Chung *et al*. 2008), in the UK, both arms of a trial seem to be more effective than not conducting a trial at all. A possible mechanism is provided by qualitative data from health service staff in a breastfeeding group trial, which identified how the trial focused the activities of primary care trusts on breastfeeding and raised the profile in the organization (Hoddinott *et al*. 2010a). With a complex behaviour like breastfeeding that interfaces primary, secondary and social settings, it is unrealistic to expect all other aspects of breastfeeding support to stand still while a trial is being conducted.

The ongoing debate is how to improve breastfeeding rates, particularly as 9 out of 10 UK women who stop in the early weeks after birth report that they would have liked to breastfeed for longer (Bolling *et al*. 2007). Should we continue to tailor interventions towards individual behaviour change? Should we be providing universal interventions or selecting high-risk populations to target? For example, NHS Health Scotland has provided funding for initiatives targeted at disadvantaged women (NHS Health Scotland 2008), and in the United States, education targeted towards disadvantaged women seems effective (Dyson *et al*. 2008). Should we focus on how the health service performs? For example, in Italy, financial penalties are employed if locally set breastfeeding targets are not met (Cattaneo *et al*. 2001). New approaches to behavioural change are being considered in the UK, and a research funding body is currently commissioning research into incentives for breastfeeding (National Institute For Health

Research Health Technology Assessment Programme 2010). There is growing interest in ecological models of behaviour change, which support changing the environment, context or milieu in which behaviour takes place to facilitate the desired behaviour. The most recent evidence for this approach is the success of banning smoking in public places. It may be worth exploring the trials of structural interventions that have been proposed as more effective than individual interventions in other health improvement fields like HIV prevention (Bonell *et al*. 2006). An example of a randomized controlled trial of a structural intervention to improve breastfeeding is the Promotion of Breastfeeding Intervention Trial of implementing the first nine steps of the Baby Friendly Hospital Initiative conducted in Belarus (Kramer *et al*. 2001). Given the reported difficulties with the integration of trials into existing maternity services, a more participatory approach involving front-line health professionals and service users in trial design and implementation is recommended (NIHR Service Delivery and Organisation Programme 2011). Longer duration, multifaceted and more intense interventions might be effective, but cost-effectiveness will also be important. Some argue for turning attention away from the health service to address wider attitudes towards breastfeeding through education in schools, media campaigns, marketing of infant formula, or legislation on maternity and paternity leave. However, in our view, this should not absolve the health service from change and progress towards finding effective interventions, as there is evidence that the support needs of some women are not currently being met (Hoddinott *et al*. 2010b). Interventions aimed at both the health and social systems with substantial improvement in the quality of research methods are recommended by the European Union blueprint for action to protect, promote and support breastfeeding (*European Union Project on Promotion of Breastfeeding in Europe* 2008).

In conclusion, breastfeeding intervention trials are complex, and a highly reductionist approach to testing a relatively small, short, single intervention seems less likely to succeed than a multi-component, multi-dose intervention that spans a greater proportion of the breastfeeding journey. Generalizability across developed countries cannot be assumed for complex interventions, as the context in which the intervention is delivered matters, and this is likely to apply to other health improvement behaviours. Absence of evidence for a particular intervention is not the same as evidence of absence of an effect, not only for methodological quality issues, but also because the intervention may need to be combined with other interventions to be effective. We would argue that drawing a nihilistic conclusion from UK research is not warranted. Trials with inadequate sample size and methodological weaknesses cannot be considered to have given an intervention a fair test (Moher *et al*. 1994). On balance, the problem of non-significant outcomes appears to be related to the choice of intervention and how it is delivered rather than the trial design. In particular, UK trials have often tested single education or support components, which were found to be ineffective in the most recent evidence synthesis (Chung *et al*. 2008). New approaches to trials are needed with designs informed by theory and methodological guidelines for complex interventions (Craig *et al*. 2008). Trials should meet the Consolidated Standards of Reporting Trials quality criteria (Consort group 2011), assess cost-effectiveness and have rigorous process evaluations (Oakley *et al*. 2006) to assist in explaining trial outcomes. Randomized controlled trials provide the gold standard evidence required to inform both policy and practice, and relying on potentially biased non-randomized interventions would be likely to hinder rather than hasten progress. As concluded by others who have critiqued the evidence for improving breastfeeding outcomes (Renfrew *et al*. 2007), the current paucity of high-quality research to inform UK breastfeeding policy and practice needs to be addressed.

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## Conflicts of interest

PH conducts trials aiming to improve breastfeeding rates.

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