



## Why do interventions work in some places and not others: A breastfeeding support group trial<sup>☆</sup>

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### ABSTRACT

In a cluster randomised controlled trial of a policy to provide community breastfeeding support groups in Scotland, breastfeeding rates declined in 3 of 7 intervention localities. From a preliminary study, we expected breastfeeding outcomes to vary and we prospectively used qualitative and quantitative methods to ask why. Ethnographic in-depth interviews, focus groups, observations and survey data were analysed to build seven embedded case studies. A pyramidal model of how primary health service organisations implemented the policy was constructed prior to knowing trial outcomes to minimise bias. Informed by a realist approach, the model explained variation in (a) policy implementation (b) the breastfeeding outcomes, whereas the quantity of intervention delivered did not. In the three localities where breastfeeding rates declined, negative aspects of place including deprivation, unsuitable premises and geographical barriers to inter-professional communication; personnel resources including staff shortages, high workload and low morale; and organisational change predominated (the base model tiers). Managers focused on solving these problems rather than delivering the policy and evidence of progress to the higher model tiers was weak. In contrast, where breastfeeding rates increased the base tiers of the model were less problematic, there was more evidence of leadership, focus on the policy, multi-disciplinary partnership working and reflective action cycles (the higher model tiers). We advocate an ethnographic approach to the design and evaluation of complex intervention trials and illustrate how this can assist in developing an explanatory model. More attention should be given to the complex systems within which policies and interventions occur, to identify and understand the favourable conditions necessary for a successful intervention.

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### Introduction

Public health policy initiatives addressing aspects of parental behaviour are popular with Governments and randomisation to provide more robust evidence is important (Macintyre, 2003). However, often complex intervention trials provide insufficient data on context, development, rationale and implementation processes to be able to explain negative outcomes (Armstrong et al., 2008). Implementation science is a relatively new area of health

services research and a more theoretically informed approach is needed (Eccles, Grimshaw, Walker, Johnston, & Pitts, 2005).

An ecological approach to health promotion policy advocates interventions that change the social environment, with the assumption that these will result in individual behavioural change (McLeroy, Bibeau, Steckler, & Glanz, 1988). This is relevant to a complex bio-psycho-social behaviour like breastfeeding which interfaces primary, secondary health and social care and can be considered liminal (Mahon-Daly & Andrews, 2002). The context of space and place, particularly the public-private interface and tensions between a mother's choice and societal pressures are important (Bailey & Pain, 2001). Hospital cultural and organisational rituals can adversely affect the caring time for breastfeeding (Dykes, 2005), however, how primary care organisation interfaces with breastfeeding has received little attention.

The breastfeeding in groups (BIG) trial (Hoddinott et al., 2009) was not effective at increasing breastfeeding rates and the variation in breastfeeding outcomes could not be explained by the quantity of intervention delivered (Box 1). The trial design (Fig. 1) was guided

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### Box 1. The BIG randomised controlled trial.

**Background:** Scotland has amongst the lowest breastfeeding rates in Europe, with only 44% of babies receiving any breast milk at 6 weeks in 2005. The UK [National Institute of Clinical Effectiveness \(NICE 2006\)](#) endorses the WHO/UNICEF Baby-Friendly Hospital Initiative ten steps to successful breastfeeding yet there is no evidence to support the tenth step which recommends breastfeeding support groups.

**Aim:** To assess the clinical and cost effectiveness of a policy to provide breastfeeding groups for pregnant and breastfeeding women and to evaluate implementation processes.

**Design:** A pragmatic cluster randomised controlled trial implemented largely within existing resources. Fourteen localities (clusters of general practices) with a median of 770 births per annum were randomised to either intervention ( $n=7$ ) or control ( $n=7$ ).

**The intervention:** Localities were asked to double pre-trial breastfeeding group activity, cover main populations and set up a minimum of 2 new groups for 2 years. Control localities did not change group activity. To ensure trial rigour but to take into account differing organisational contexts, some breastfeeding group policy components were fixed, whereas others were flexible. Midwives and health visitors were asked to invite all pregnant women at their 28-week antenatal appointment and at subsequent contacts before and after birth. Fixed characteristics of breastfeeding groups were: weekly meetings; women only; pregnant and breastfeeding women; at least one health professional group facilitator; “woman-centred” with >50% of the meeting time social and interactive. They could be flexible in timing, content and structure. To incorporate aspects of the action research process considered successful in the preliminary study, each locality was asked to hold multi-disciplinary steering group meetings every 6–8 weeks for group facilitators, participants, volunteers and other stakeholders, following the principles of reflective practice.

**Primary outcome:** Any breastfeeding at 6–8 weeks.

**Results:** Breastfeeding groups increased from 10 to 27 in intervention localities and remained at 10 groups in control localities. There were no significant differences in breastfeeding outcomes at birth, 7 days and 6–8 weeks comparing 2 trial with 2 pre-trial years. Breastfeeding rates increased in three intervention localities, declined in three and remained unchanged in one. This cannot be explained by the quantity of intervention delivered: number of group meetings or attendances.

by research questions derived from our preliminary study (<http://www.abdn.ac.uk/crh/research/completed/big>). [Blaikie \(2000\)](#) describes four research strategies (inductive, deductive, retroductive and abductive) and argues for a pragmatic attitude given the deficiencies of each. From the outset, we hypothesised that:

(a) localities would differ in baseline contexts and in how they implemented the policy (amount, processes and execution)

(b) changes in both context and intervention implementation would occur during the 2 year trial

(c) outcomes in intervention localities would differ.

In this paper, we ask: why did breastfeeding rates decline in 3 of 7 intervention localities? Our evaluation was informed by a realist approach ([Pawson, 2006](#)) to understanding how the implementation of the policy influenced outcomes. Realist evaluation proposes

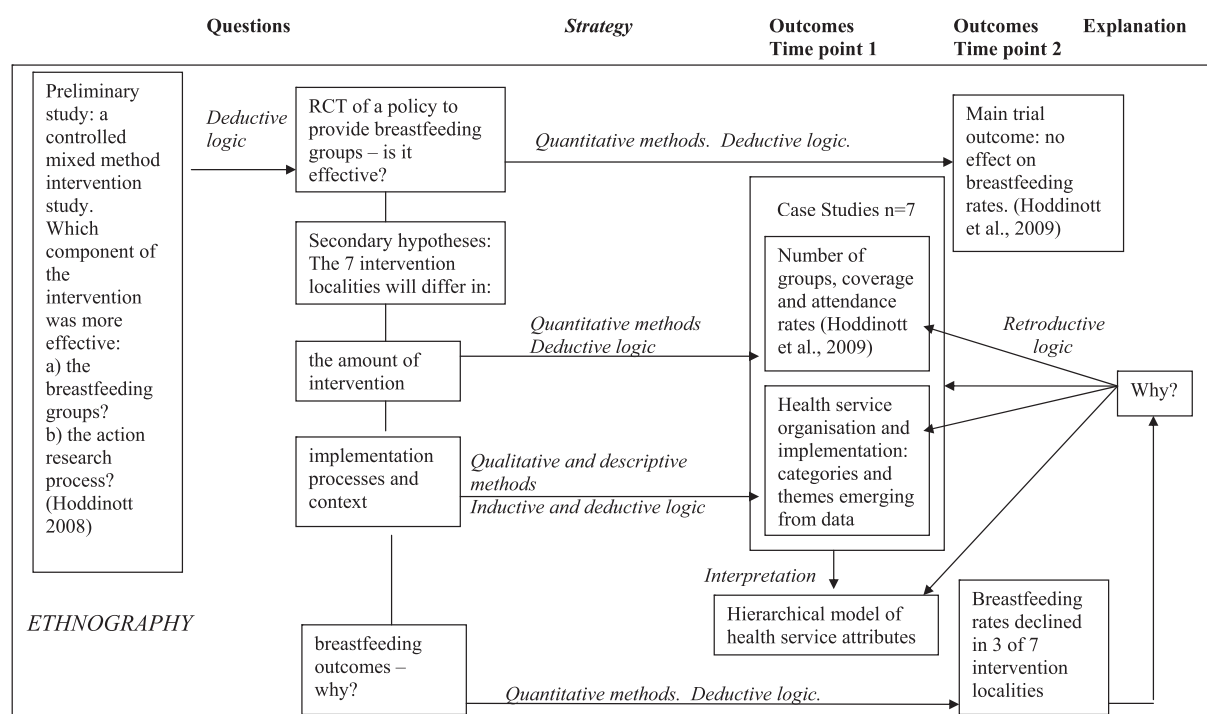


Fig. 1. Trial design and strategy: embedded in ethnography.

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