

Free School Breakfast Initiative

Laurence Moore, Chris Roberts

- Design issues
- Barriers to policy trials
- Policy Background
- Design and results
- Impact and Reflections

Research design

Efficacy	Explanatory
Effectiveness	Pragmatic
Implementation	<i>Realistic</i>

Efficacy or Effectiveness

(Flay 1986, Glasgow et al 2003)

- Efficacy trial
 - To test whether the treatment does more good than harm when delivered under optimal conditions (max internal validity)
- Effectiveness trial
 - To test whether the treatment does more good than harm when delivered in real-world conditions
 - Allows variability in delivery/receipt/context as would be experienced in real world (+external, - internal validity)

The 2008 MRC Guidance



Developing and evaluating complex interventions: new guidance

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RESEARCH METHODS & REPORTING

Developing and evaluating complex interventions: the new Medical Research Council guidance

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EDITORIALS

New MRC guidance on evaluating complex interventions

Clarifying what interventions work by researching how and why they are effective

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RESEARCH METHODS AND REPORTING, p 979

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It is eight years since the publication of the Medical Research Council's original report on methods for developing and evaluating randomised controlled trials for complex interventions.¹ Although presented as a "discussion document," the MRC framework and its companion paper have often been cited as authoritative guidance on methods. Other people, however, have found the definition of the complexity of interventions narrow and misconceived,² and the suggested phases for developing and evaluating complex interventions as unhelpfully similar to commercial drug evaluation. However, the report can probably be credited with stimulating much of the ongoing debate about appropriate methods and concepts in healthcare evaluation—particularly when

the intervention of interest is hard to define, hard to evaluate (using conventional experimental methods), or just hard to explain.

The MRC has now updated its original report (www.mrc.ac.uk/complexinterventionsguidance) to reflect recent developments in methods and lessons learnt in applying them. The guidance is summarised in the linked article by Craig and colleagues ([doi:10.1136/bmj.e1937](https://doi.org/10.1136/bmj.e1937)).³ It has a broader scope than the original version—it covers observational methods as well as randomised controlled trials and implementation as well as the development and evaluation of interventions; it also has a broader definition of complex interventions beyond the core dimension of having multiple components.

A less linear model

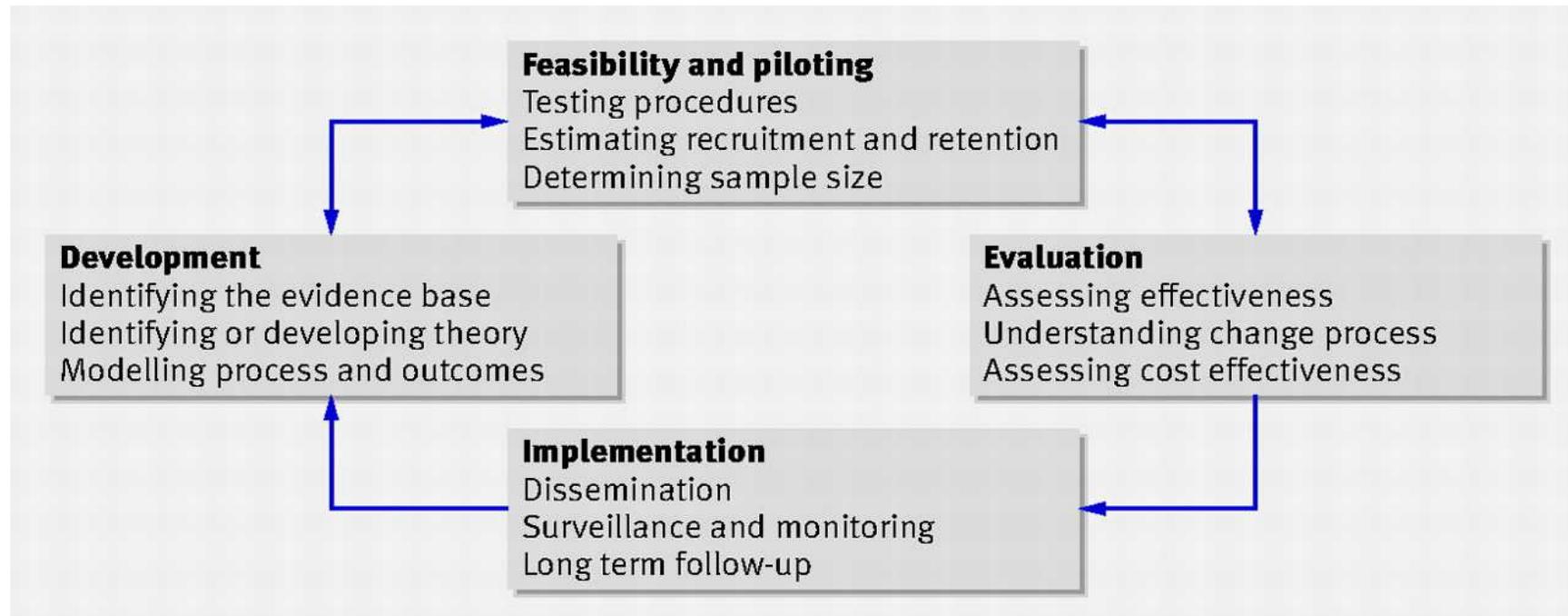


TABLE 1—Distinctive Characteristics of Efficacy and Effectiveness Intervention Studies, Using RE-AIM^{26,27} Dimensions for Program Evaluation

RE-AIM Issue	Efficacy Studies	Effectiveness Studies
Reach	Homogeneous, highly motivated sample; exclude those with complications, other comorbid problems	Broad, heterogeneous, representative sample; often use a defined population
Efficacy or effectiveness	Intensive, specialized interventions that attempt to maximize effect size; very standardized; randomized designs	Brief, feasible interventions not requiring great expertise; adaptable to setting; randomized, time series, or quasi-experimental designs
Adoption	Usually 1 setting to reduce variability; settings with many resources and expert staff	Appeal to and work in multiple settings; able to be adapted to fit setting
Implementation	Implemented by research staff closely following specific protocol	Implemented by variety of different staff with competing demands, using adapted protocol
Maintenance and cost	Few or no issues; focus on individual level.	Major issues; setting-level maintenance is as important as individual-level maintenance

“What are the characteristics of interventions that can (a) reach large numbers of people, especially those who can most benefit, (b) be broadly adopted by different settings (worksite, school, health, or community), (c) be consistently implemented by different staff members with moderate levels of training and expertise, and (d) produce replicable and long-lasting effects (and minimal negative impacts) at a reasonable cost?”

External Validity

- ‘highly unlikely that interventions that are successful in efficacy studies will do well in effectiveness studies or real world application’ Glasgow et al (2003)
- A lot of information on efficacy and very little on effectiveness
 - Call for a moratorium on efficacy trials (Kessler and Glasgow 2011)
 - Development of implementation trials, improvement science

Standardisation

- Assumed that RCTs have to have highly standardised interventions
 - True for explanatory / efficacy trials
- Variability in context / delivery inherent in complex interventions (often welcome in their implementation) so trials unsuited?
- Leads to rejection by many of RCT as a suitable design for the evaluation of complex interventions

Explanatory or Pragmatic

- Explanatory
 - Efficacy
 - Mechanisms
 - Standardised delivery & dose
 - Highly specified inclusion and exclusion criteria
 - Per protocol analysis
- Pragmatic
 - Effectiveness
 - Outcomes
 - 'Black box'
 - Some variation in adherence
 - Less restrictive inclusion/exclusion
 - Intention to treat analysis

Realist Evaluation – Pawson & Tilley

- Purpose of evaluation “as informing the development of policy and practice”
- Experiments can identify the mean effect but this is rarely, if ever, evenly produced
- Mechanism + Context = Outcome
- “what works, for whom, and in what circumstances?” and even better, to also help us to understand “why?”
- Need to develop and continually update program theory

Theory

- Theory of the problem
 - Causal processes
- Intervention theory
 - Key components and their impact
- Program theory
 - How will the intervention bring about change, interact with context

Complexity and variability

- RCTs traditionally require that interventions are standardised and uniformly delivered
 - (efficacy trial)
- Delivery of complex interventions will vary
- Value of efficacy trials limited (poor external validity)
 - Results of efficacy trials not replicated in roll-out
 - Best interventions for demonstrating efficacy (simple, standardised, intensive) least likely to be effective in practice (complex, adaptable, feasible) (Glasgow et al 2003)
 - Do not need to over-standardise interventions, can allow a pragmatic degree of variation (Hawe et al 2004)
- Variations by site / time can be very illuminating for implementation / translation

Process evaluation for implementation

- Which are the important bits?
 - Can I cut this bit out?
 - We don't like that bit and we want to add this
- Will it work here?
 - For this population?
 - In this policy context?
- How should this be disseminated /implemented/supported?
 - Licensing, training, quality assurance, policy support

Realistic Implementation Trials?

- External validity
 - Nest in implementation; minimise baseline data
- Variation in contexts and implementation
 - Embrace and understand heterogeneity
- Mixed methods
 - Process evaluation inside and outside the black box
- Plan and report sub-group analyses by SES, context, adherence, fidelity.....
- Test and update program models
- Rich data for meta-regression, realist synthesis

Baseline data

- High barrier to entry
- Importance of baseline measures overstated
 - Need a baseline covariate for ANCOVA
 - Can often get this from routine data or a very simple questionnaire
 - Main need is for variables to measure sub-groups / effect modifiers
- Can be sacrificed to increase recruitment / external validity

Barriers to policy trials – government perspective

Key themes:

- Public health policies clearly work and do no harm – why evaluate?
- Policy makers and researchers – two communities?
- Incompatibility of political processes and policy trials.
- Limited knowledge and expertise within government.
- Ethical concerns.
- Prohibitive costs.
- Lack of incentives to champion policy trials.
- Policy maker churn.
- Pejorative use of term experimentation.

(See for example Macintyre, 2011; Roberts *et al.*, 2008; Creegan and Hedges, 2007; Jowell, 2003)

Barriers – political processes

- Rigorous evaluation can be challenging i.e. policy-based evidence versus evidence-based policy – importance of incentives.
- Reluctance to pilot, as ‘big bang’ often preferred.
- Political timetables
 - Short Ministerial tenure – desire for rapid and comprehensive roll-out
 - Sufficiently well developed interventions
 - Adequate time for follow-up
- Language e.g. when policies communicated as being successful prior to evaluation can have ethical implications.
- Technocratic arguments – can ignore evidence but shouldn’t be ignorant of it.
- Arguments generic to an extent but policy trials seen to provide definitive evidence that is harder to ignore.

Barriers – policy/research relationship

- Policy trials associated with discredited linear-rational model of policy process and instrumental impact?
 - Realism versus over-enthusiasm
 - Some instrumental impact can be found
- Two Communities?
 - Limited policy maker understanding of role of policy trials?
 - Limited researcher understanding of political constraints of policy trials?
 - Suggest that this model is exaggerated.
- PHIRN illustrates the potential of interactive model to developing and implementing policy trials.

Barriers – limited knowledge and expertise within government

- *‘Pools of knowledge in a desert of ignorance’* (Comment from senior official in Response to Creegan and Hedges, 2007).
- *‘...it would challenge any academic to come up with a randomised town’* (senior official’s comment cited by Macintyre, 2011, in relation to healthy towns initiative).
- *‘We are about to begin a phase of pilots and testing. That process will be iterative - a process of active and engaged learning - rather than the Schrödinger’s cat model of a black box, when you do a randomised control trial and then come out and look at it at the end of the day’* (Sarah Teather, UK Minister of State for Children, evidence to Education Committee on SEN, 2011).

Barriers – ethical concerns

- Withholding a service frequently raised as an issue – part of ‘stylised critique’ of policy trials (Oakley, 2006).
- Suspicion – UK respondents (Jowell, 2003) not convinced by:
 - Universal use in medicine; or
 - Benthamite argument on individual inequity for societal benefit.
- Exacerbated when:
 - Policies prematurely described as being effective;
 - Decision makers (and stakeholders) convinced of effectiveness;
 - Existing, rather than new service, being trialled.
- Can be politically challenging e.g. use of financial incentives in welfare to work policy.
- *‘It seems perverse to see it as ethical to give or withhold programmes of unknown benefit to 100% of the population, but not to 50%’* (Macintyre, 2011).

Barriers – costs

- Costs seen as prohibitive, particularly in current financial climate.
- Recent push to emphasise that policy trials can be undertaken cheaply using administrative data (e.g. Behavioural Insight Team, 2012; CEBP, 2012).
- Possibly no more expensive than equivalent (quasi-experimental) designs with some form of control.
- Policy trials more efficient at reducing causal uncertainty, so cheaper in long run (Cook, 2002).
- Important to assess cost relative to that of potentially implementing ineffective policy i.e. policy trial as an investment (to save).
 - e.g. US National Job Training Partnership Act trial cost \$50m but annual spend was \$1.8bn (Burtless, 1995).

But there are levers as well!

- Research-policy interaction.
- Advocates within and outwith government.
- Independence of evaluation team from policy makers/politicians.
- Outcomes and potential for economic analysis.
- Departure from describing well established problems.
- Ease of presentation of trial findings.
- Body of evidence emerging that policy trials are possible, can estimate outcomes and inform theory/practice i.e. explore 'black box'.

Case study – Primary School Free Breakfast Initiative

BMC Public Health



Study protocol

Open Access

Free breakfasts in schools: design and conduct of a cluster randomised controlled trial of the Primary School Free Breakfast Initiative in Wales [ISRCTN18336527]

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Abstract

Background: School-based breakfast provision is increasingly being seen as a means of improving educational performance and dietary behaviour amongst children. Furthermore, recognition is growing that breakfast provision offers potential as a means of addressing social inequalities in these outcomes. At present however, the evidence base on the effectiveness of breakfast provision in bringing about these improvements is limited.

Methods/Design: This paper describes the research design of a large scale evaluation of the effectiveness of the Welsh Assembly Government's Primary School Free Breakfast Initiative. A cluster randomised trial, with school as the unit of randomisation was used for the outcome evaluation, with a nested qualitative process evaluation. Quantitative outcome measures included dietary habits, attitudes, cognitive function, classroom behaviour, and school attendance. The study recruited 111 primary schools in Wales, of which 56 were randomly assigned to control condition and 55 to intervention. Participants were Year 5 and 6 students (aged 9–11 years) in these schools. Data were collected for all 111 schools at each of three time points: baseline, 4 month and 12 month follow-up. This was achieved through a repeated cross-sectional survey of approximately 4350 students on each of these occasions. Of those students in Year 5 at baseline, 1975 provided data at one or both of the follow-ups, forming a nested cohort. The evaluation also included a nested process evaluation, using questionnaires, semi-structured interviews and case studies with students, school staff, and local authority scheme coordinators as key informants.

- Consider:
 - Policy context
 - Challenges
 - Commissioning process
 - Policy impact

Primary School Free Breakfast Initiative – policy context

- Commitment in Welsh Labour manifesto for 2003 Assembly elections.
- Part of broader policy agenda looking at food and well being.
- Aim to provide all primary school pupils the opportunity of receiving a free, healthy breakfast during the school week by January 2007.
- Plan to roll out in phases:
 - schools in Communities First areas in 9 of the 22 local authorities from September 2004;
 - schools in Communities First areas in the remaining local authorities from September 2005;
 - All other schools across Wales in piecemeal fashion from January 2007.
- Commitment from Minister in plenary to conduct rigorous evaluation.
- Focus on outcomes (eating habits and concentration/behaviour) and process (delivery across schools).

Primary School Free Breakfast Initiative – challenges

- Alignment of research and policy timetables:
 - Policy referred to as a ‘pilot’ but timetable challenging i.e. manifesto commitment to initial roll-out in approximately one year – implications for policy and evaluation design;
 - Desire for quick results meant compromise on follow-up periods;
 - Initial lack of clarity on policy itself may have impacted on recruitment.
- Danger of policy being ‘doomed to success’ rather than ‘learning from failure’ as policy officials wary of publication and potentially hostile press.
- Convincing local authority and school staff of the value of the approach – ‘hands on’ commissioning role required.

Primary School Free Breakfast Initiative – facilitating the policy trial

- Work commissioned by GSR with experience in public health and knowledge of potential of pragmatic policy trials.
- Early and constructive relationship built with policy officials in health and education.
- Model of engagement resulted in roll-out that allowed randomisation of schools within local authorities, with one year waitlist for controls.
- Importance of explaining the randomisation process and benefits of the trial approach to policy officials, local authority coordinators and senior school staff.
- Early process work to inform delivery as far as possible.
- Negotiated budget to allow sufficiently powered study.
- Contractor that understood the methodology suggested and the policy environment.

Research Background

- Benefits of breakfast – nutritional adequacy, memory and concentration and obesity (Sjoberg et al. 2003; Rampersaud et al. 2003; Elgar et al. 2005)
- Focus on children – growth/development, improved education and habitual behaviours (Mikkila et al., 2004)
- Breakfast Clubs at School originate in North America- by 2006 9.7 million children attending each day
- Evaluations – suggest improved nutrition and in some cases academic performance and behaviour (Murphy et al, 1998; Shemilt et al, 2004, Crepensek et al, 2006).
- However studies suffer from selection bias or contamination between trial arms - lack of convincing evidence

Policy Background

- Welsh Assembly Government educational pilot initiative to provide the opportunity of free healthy breakfasts for all children in primary schools throughout Wales
- Top 10 Manifesto commitment. Part of a broader policy agenda looking at food and well-being
- £1.5 million available 2004-05
- £3.5 million available 2005-06
- £8.5 million available 2007-08



The Scheme



- Universal provision
- Funding for the breakfasts (25p) - milk based drinks or products, cereal (not sugar coated), fruit and breads.
- Funding for Local Government and school delivery staff.
- Central support and national implementation guidelines.
- Optional for schools and pupils as *“not intending to replace breakfast already provided, it allows all those that, for whatever reason, have not had breakfast, to have one in school”*

Aims of the Scheme

- **To reduce breakfast skipping**
- **To improve diet and nutrition**
- **To improve concentration and behaviour**
- **To assist learning and attainment**



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Mixed Methods Cluster RCT

- **To examine the impact of breakfast provision on a number of key outcomes:**
 - diet
 - breakfast eating habits
 - attitudes towards breakfast
 - cognitive function
 - classroom behaviour
- **To assess differential effects by SES**
- **To explore issues surrounding the implementation of the scheme**
- **To examine the views of providers and users**

RCT Design

- 111 schools, c.5000 students
- School randomised to scheme or 12 month waitlist
- Cluster randomisation of schools stratified by: LEA, school size (><median), free school meal entitlement (><median), Welsh language medium
- Random numbers used to allocate schools within strata, each school with a 50:50 chance of intervention (n= 56) or waitlist (n= 55)
- Quantitative measures at baseline, 6 months and 12 months
- Primary analysis cross sectional comparison at 12 months – Protocol and pre specified analysis (Moore et al, 2007)

Dietary outcome measures

- 24-hour dietary recall questionnaire (target n per school = 40-60) Developed for this study and validated - social gradient in breakfast skipping and quality (Moore et al, 2007)
 - Healthy food items – fruit, bread, milk, cereal
 - Unhealthy food items – sweets, crisps
- Attitudes, norms and intentions regarding breakfast (40-60)
- Individual dietary recall interviews – portion size (6-10) (Lytle et al. 1993)

Educational outcome measures

- Group cognitive tests (40-60) (episodic memory, working memory and selective and sustained attention)
- Individual cognitive tests (6-10) (speed of encoding of new information, sustained attention and psychomotor speed)
- Teacher-completed Strengths and Differences questionnaire (10) (Goodman, 2001)
- Parents questionnaire on breakfast skipping and home routine (35)

Embedded Process Evaluation

- Pilot study of initial 9 LEAs and 46 schools (Roberts and Murphy 2005)
 - develop measures and intervention content /implementation
- LEA co-ordinator interviews (9)
- All intervention schools (56)
 - Teacher co-ordinator questionnaires
 - School records (start up, uptake, attendance)
- All study schools– context questionnaire (111)
- 16 case study intervention schools
 - Staff interviews (81)
 - Pupil interviews (attendees) (c 80)
 - Pupil focus groups (attendees and non attendees) (c 80)
 - Observations

Process Results

- Context – LEA variation in operation and support
- Implementation – few barriers, initial staff recruitment problems only
- Integration – variable e.g. oral health, whole school approach
- Uptake – 41% (700/1693) at least 1 day a week
- Influenced by parental preference, healthy foods, parenting
- Teachers' perceived benefit on classroom

Intervention effects for pupil measures from school-level weighted regression analyses

Variable	Estimate (95% CI)
Percentage of pupils consuming two breakfasts over two days	1% (-2%, 3%)
Parents report proportion of pupils eating breakfast at home 5 days during week	-0.15 (-0.21, -0.10)**
Parents report proportion of pupils eating breakfast provided by school at least 2 days in week	0.19 (0.12, 0.26) **
Healthy food items consumed at breakfast	0.23 (0.09, 0.37) **
Unhealthy food items consumed at breakfast	0.01 (-0.04, 0.06)
Average attitudes towards eating breakfast	0.74 (0.05, 1.43) *
Cognitive ability – word recall - episodic memory	0.11 (-0.13, 0.36)
SDQ – hyperactivity/inattention	0.18 (-0.30, 0.65)

Socio-economic Status

- Baseline:
 - Free school meal entitlement associated with:
 - + Unhealthy items, breakfast skipping
 - Healthy items, attitudes towards breakfast
 - Associations with breakfast skipping and healthy items mediated by attitudes
- Programme effects:
 - Healthy items and attitudes improved more in higher FSM schools

Conclusions - Intervention

- Support for the free healthy breakfast scheme as a **dietary** not **educational** intervention.
- The intervention **did** improve the quality of children's breakfasts - fruit, grains and wholemeal bread and promoted positive attitudes to eating breakfast.
- Reduced inequalities in healthy items and attitudes
- **Did not** reduce breakfast skipping - students more likely to eat breakfast in school and less likely to eat it at home
- **Did not** impact on cognitive abilities and classroom behaviour despite teacher perceptions. Although possible ceiling effects? and changed teacher perceptions = changed reality
- May require further work in developing the **reach** of scheme amongst breakfast skippers

Design issues

- CRT, consent, opt-out consent
 - Universal intervention
 - High sample coverage, response rates
- One year waitlist
 - Dangerous! – limit follow-up, concede equipoise
- Repeated cross-section – power & validity at school level
 - Embedded cohort – additional effect modifiers, biased sample
- Outcomes
 - Valid/sensitive at group level
 - Data linkage for longer term educational outcomes
- Flexible implementation
 - Pilot limited learning curve problems

Conduct issues

- Recruitment and randomisation of schools easier than expected
 - Many schools in equipoise
- Not recruited if not in equipoise (unwilling to be randomised)
- MoU signed by school heads prior to randomisation – no dropout
- Not all schools per protocol. Analysed ITT

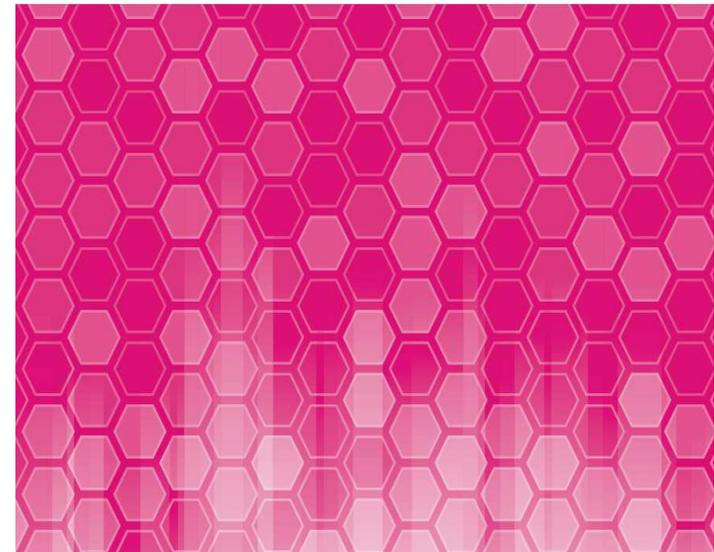
Primary School Free Breakfast Initiative – research impact

- Protocol paper and outcomes published and disseminated widely (Moore et al., 2007 and Murphy et al., 2010).
- Study cited elsewhere e.g. similar intervention and study design in New Zealand (Murchu et al., 2010).
- Availability of a free breakfast at school level did result in nutritional benefits e.g. quality of breakfast consumed.
- Policy continued and remains in place today.
- However, a change in government could possibly see a different policy direction despite the availability of this research.
- See HM Treasury (2011) *The Magenta Book* – this study is included as a short case study on the use of RCTs in government research (page 105).



The Magenta Book

Guidance for evaluation



Gwasanaethau Gwybodaeth a Dadansoddi

Knowledge and Analytical Services

Random reflections from a researcher working within government

- Current focus in government of picking the low hanging fruit but don't underestimate the complexity of conducting policy trials.
- Policy officials will not always understand the implications of planned roll-out for study design so early engagement is key.
- 'Winning hearts and minds' is critical but can be time consuming.
- Serendipity is important but so are formal structures to maximise the chance of sustaining ways of working beyond individual relationships.
- Need for pragmatism to work around the numerous political and operational challenges.