

Real world complex intervention research

Recruitment, retention and process evaluation

Jeremy Segrott



DECIPHER

Development and Evaluation of Complex Interventions for Public Health Improvement
A UKCRC Public Health Research Centre of Excellence



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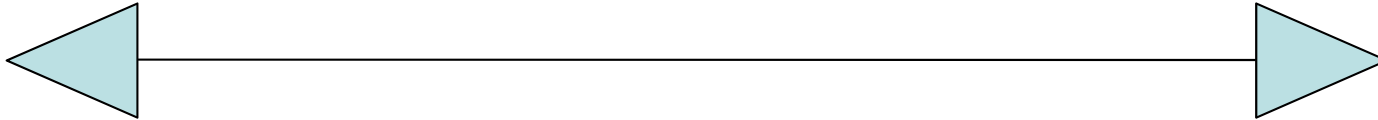
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I love
chocolate

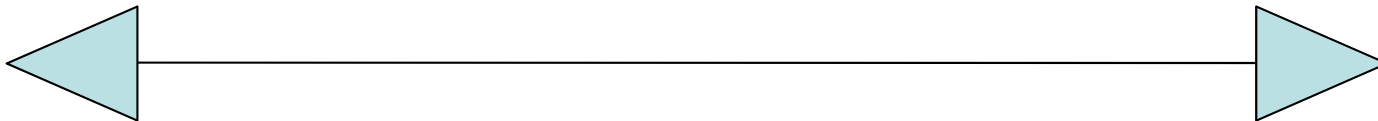


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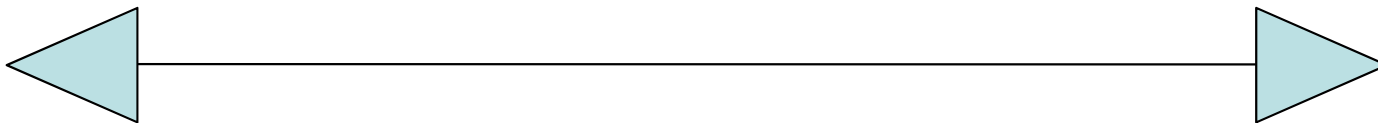
I know a lot
about
conducting
RCTs

I know
nothing
about
conducting
RCTs



In trials of new family/parenting interventions it is perfectly ethical to randomly allocate participants to receive the new intervention or normal care

Randomly allocating participants to receive a new intervention or not as part of a trial is unethical



Session Overview

- ➡ Background: SFP10-14UK trial:
design & process evaluation
- ➡ Challenges
 - ➡ *Aligning research and policy practice timelines*
 - ➡ *Randomisation and random allocation*
 - ➡ *Recruitment*
 - ➡ *Retention*
- ➡ Strategies adopted by the trial team



SFP10-14

- ➡ 7 week family-based substance misuse prevention intervention for families with children aged 10-14
- ➡ Aims to delay substance use initiation (alcohol, tobacco, drugs) and reduce consumption levels in young people by strengthening protective factors
- ➡ Focuses on parenting, family functioning and young people's peer resistance skills
- ➡ Universal prevention intervention for ANY family.
- ➡ Does not address very high needs levels or current substance misuse



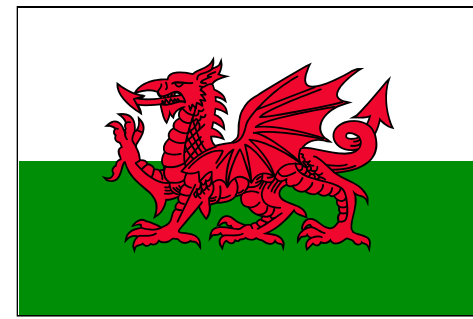
SFP10-14

- ➡ Evidence from US trials that the programme delays and reduces substance use (Spoth, et al. 2001, 2002, 2005)
- ➡ SFP10-14 UK adapted for use in UK, and attracting substantial policy interest
- ➡ Evidence of short term positive outcomes from non controlled studies in relation to family functioning
- ➡ High levels of acceptability
- ➡ Need for evidence on long term effectiveness in the UK

Project SFP Cymru trial team

Laurence Moore, Jeremy Segrott, Jo Holliday, Simon Murphy, Heather Rothwell, Claire Thomas, Jonathan Scourfield, Kerry Hood, David Gillespie, Zoe Roberts, David Foxcroft, Ceri Phillips, Ioan Humphries

Project SFP Cymru



- ➡ Evaluation of SFP in Cardiff for Welsh Government to examine potential as a national programme for Wales
- ➡ Welsh Government funding for SFP in three locations
- ➡ Agreed programme funding would be as part of a trial
- ➡ Included training and mentoring to delivery teams
- ➡ Support from Government in trial application process
- ➡ Research team secured funds for research trial and programme delivery in three additional locations

Pragmatic effectiveness trial

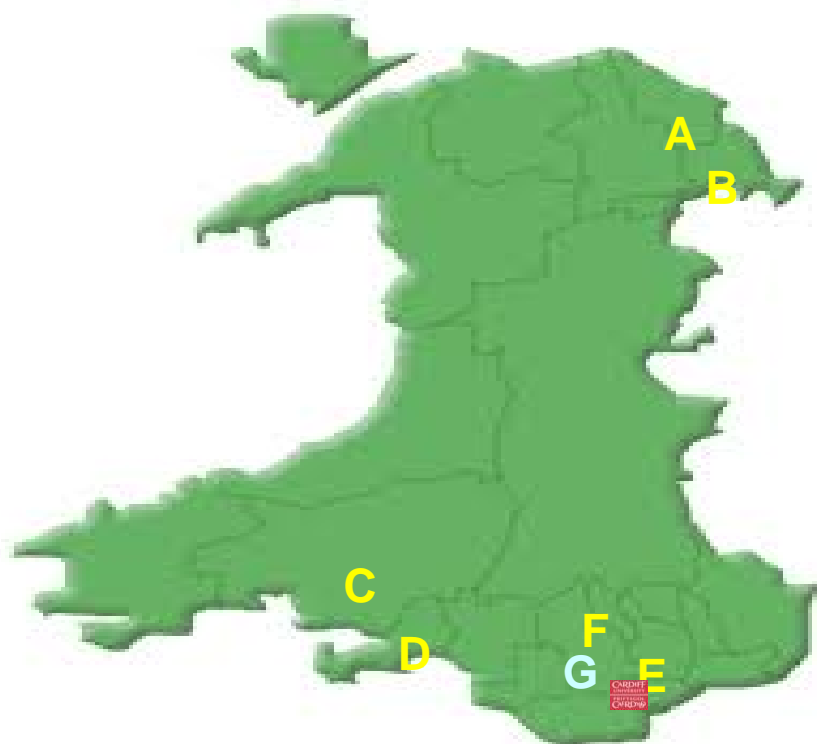
- Efficacy \Rightarrow Effectiveness under real world conditions
- Homogenous groups \Rightarrow variation found in population
- Intervention delivery
 - by organisations that would do so in any future roll out
 - not tightly controlled by research team
- Maximising the external validity of a trial
([Roland and Torgeson, 1998](#); [MacPherson, 2004](#))

Project SFP Cymru

- ➡ **Pragmatic RCT**; families as the unit of randomisation
- ➡ Comparing normal care with normal care + SFP10-14
- ➡ Aims to recruit 756 families
- ➡ Families referred/applied to the programme coordinator & received needs and eligibility assessment
- ➡ Locally embedded fieldworker sent families detailed information about the trial
- ➡ Visited families to seek consent for participation and conduct baseline interviews

Project SFP Cymru

All counties in Wales invited to apply for programme funding as part of the trial



- A** – Flintshire (Barnardo's Cymru)
- B** – Wrexham (Council Parenting Team)
- C** – Carmarthenshire (Council/Action for Children)
- D** – Swansea (Swansea Drugs Project)
- E** – Caerphilly (Drugaid Cymru)
- F** – Merthyr Tydfil (Council Parenting Team)

Additional area recruited in 2011

G - Rhondda Cynon Taf
(Tonypandy Community College)

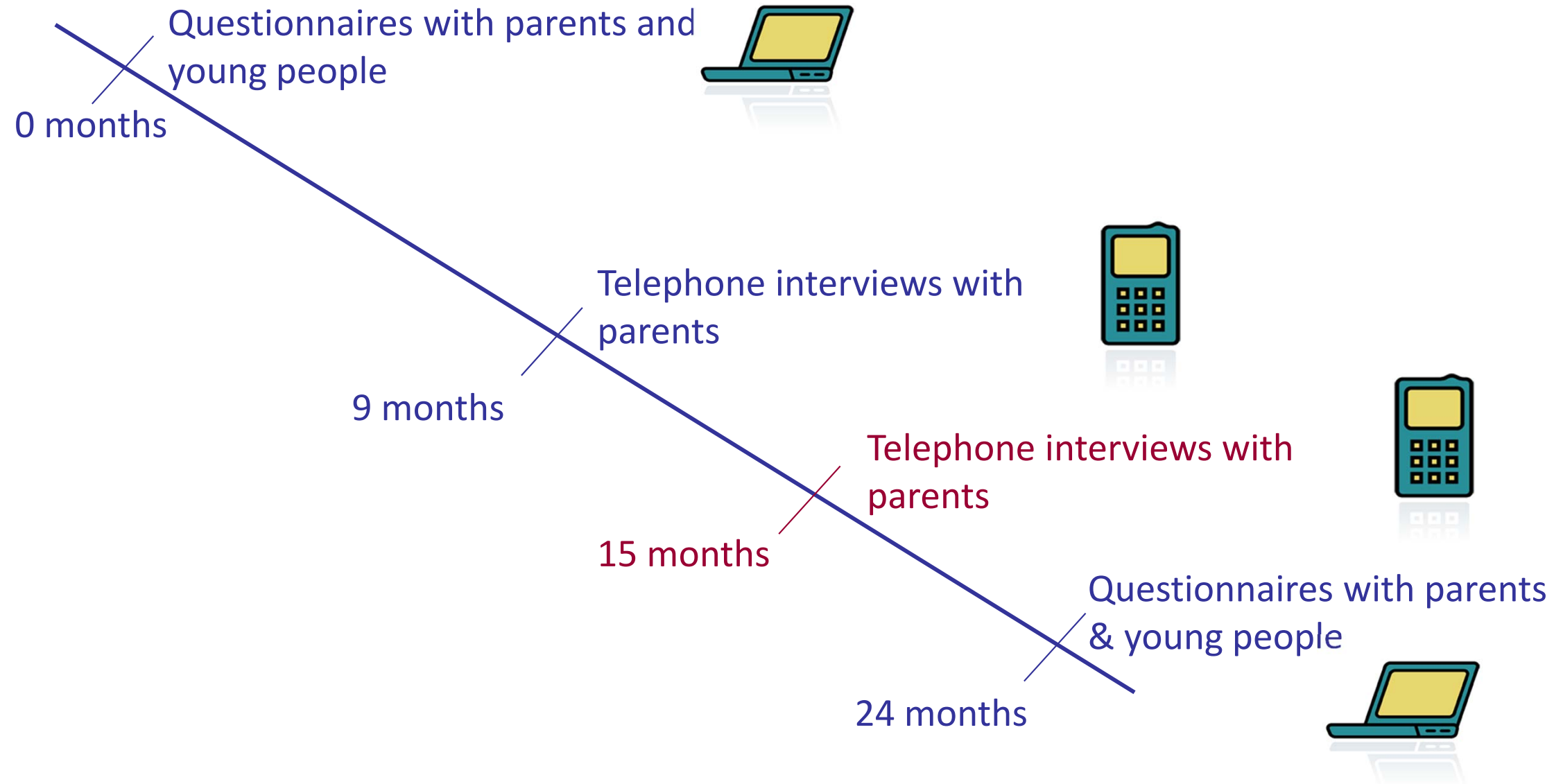
Project SFP Cymru: research questions

- ➡ What impact does the SFP10-14UK have on:
 1. alcohol and drug misuse, and smoking behaviour in adolescents?
 2. school attendance, school performance, and mental health and well being?
 3. protective factors for alcohol & tobacco use/misuse located in the family, e.g. family functioning, parenting and children's peer pressure resistance skills?

- ➡ What are the costs associated with the SFP10-14UK and can it be regarded as efficient use of public funds?

- ➡ How can SFP10-14UK best be implemented and is there variation in delivery and receipt?

Data collection from families



Project SFP Cymru: outcomes

- ➡ Primary outcomes: drinking and drunkenness in the last month
- ➡ Secondary/tertiary outcomes: substance use, family functioning, etc.



Embedded process evaluation

- ➡ Assess implementation (**what** was delivered?)
 - (recruitment processes, adherence, fidelity, receipt, reach) and contextual influences
- ➡ Interpret trial outcomes (look at outcomes and fidelity)
- ➡ Link implementation and outcome data
- ➡ Help understand programme components, key processes
(Oakley, et al. 2006, Strange, et al. 2006)
- ➡ Develop/refine programme theory/logic models
- ➡ Inform ongoing programme implementation

Group activity 1

- ☞ Which methods would you use to address these research aims?

Aims of the Project SFP Cymru process evaluation

- ☞ Identify key programme content and processes
- ☞ Inform decisions regarding selection of proximal outcomes
- ☞ Evaluate fidelity and completeness of programme delivery
- ☞ Assess trial arm implementation and context
- ☞ Assess participation and reach
- ☞ Evaluate reception and response by families

Methods

- ➡ Literature review to identify key theory and programme processes
- ➡ Researcher observation of programme sessions: 47 from 336 (14%)
 - *Used programme observation schedules + fieldnotes*
- ➡ Observation of facilitator de-brief meetings
- ➡ Facilitator self-report questionnaires on completeness and timing
- ➡ Interviews with programme staff, trainers & Government officials
- ➡ Routine data on recruitment, staffing and programme attendance

Key challenges during the trial

- ➡ Aligning research and practice/policy timelines
- ➡ Randomisation and random allocation:
- ➡ Recruitment
- ➡ Retention

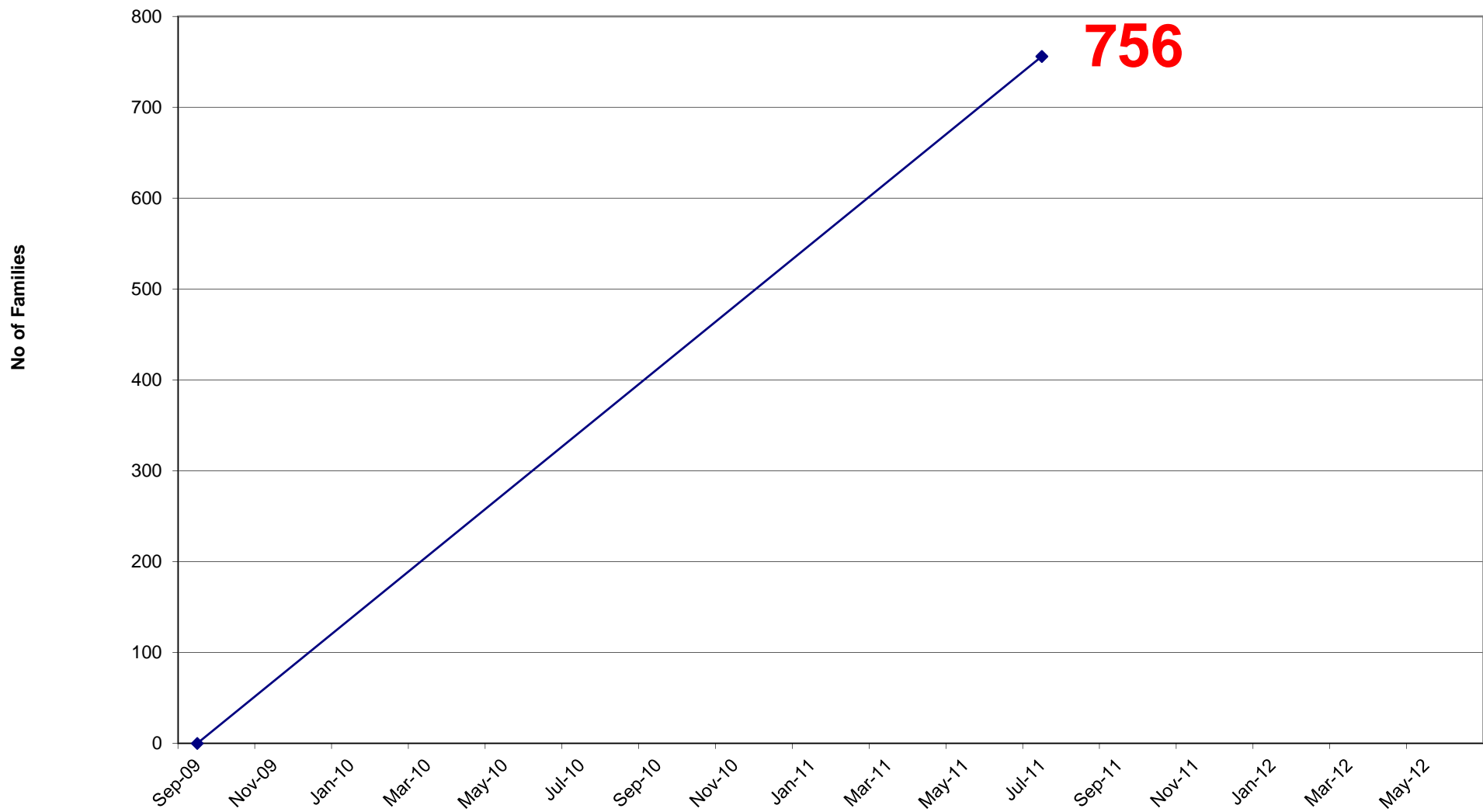


Aligning research and policy / practice

- ➡ Fit between programme funding period and time taken to set up trial
- ➡ Balancing importance of producing evidence on long term effectiveness with 'immediacy' of policy making and key decision points (e.g. strategies or funding)
- ➡ How to sustain programme delivery in the period between trial funding ending and trial results being published

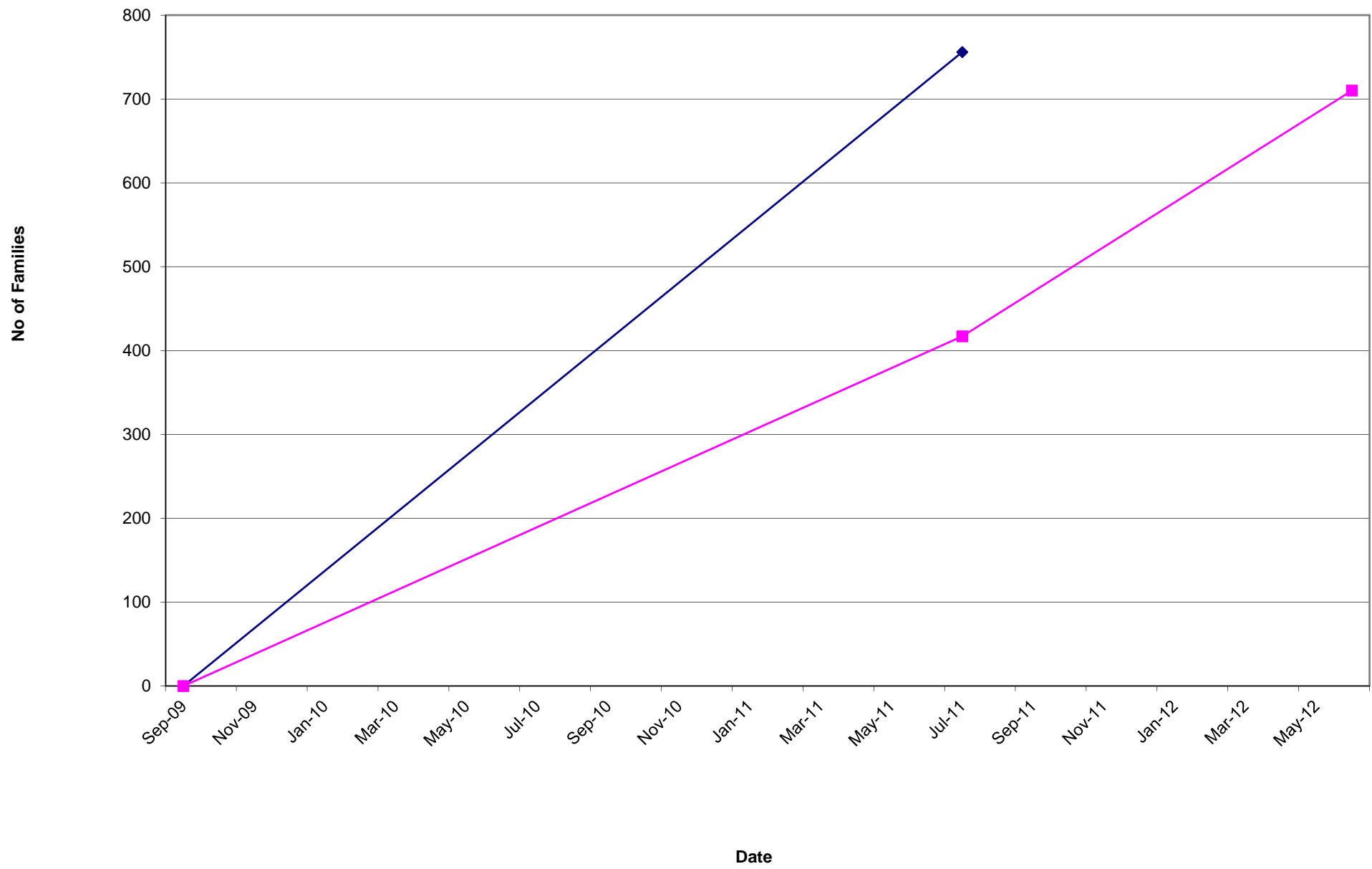
Challenges: randomisation & random allocation

- ➡ Translating needs of trial into delivery areas where there may be competing priorities i.e. research vs focus of delivery partner
- ➡ Organisations unused or opposed to randomised trial procedures
(Oakley, et al. 2006, Rushton and Monck, 2010; Simkiss, et al, 2010)
 - ➡ *Families needed support*
 - ➡ *Normal care varied across different trial areas*
 - ➡ *Impact on families allocated to the control group*
- ➡ Some agencies refused to refer families, or stopped doing so in response to allocation to control group
- ➡ Desire to offer control families compensatory programme
- ➡ Multiple actors, organisations and structures
- ➡ Understanding and capacity to adopt new approaches variable



Sep 2009

**Summer
2011**



Challenges: recruitment

- ➡ More challenging than anticipated
- ➡ Two delivery teams withdrew from the trial
- ➡ Maintaining family applications from the general population sometimes harder than receiving practitioner referrals
- ➡ Randomisation had potential to skew mix of families if recruitment levels were very low
- ➡ Low recruitment levels reinforced practitioners' concerns about the ethics of randomisation
- ➡ Staff changes in programme delivery teams

Challenges: retention

- ➡ Became the key challenge!
- ➡ Interviews with parents and children
- ➡ Difficult to maintain contact with 700+ families
- ➡ Families **lost to follow-up**
 - ➡ Participants had moved house & were untraceable
 - ➡ Difficulty in arranging interviews
 - ➡ Multiple cancellations
- ➡ **Refusals:**
 - ➡ Unhappiness with the research process
 - ➡ Other issues going on
 - ➡ Just not interested / no reason given

Group activity 2

How would you address our four key challenges?

Group 1: aligning research and policy/practice timelines

Group 2: randomisation and random allocation

Group 3: recruitment

Group 4: retention



Solutions: randomisation and random allocation

Partnership working

- ➡ Early engagement with delivery agencies
- ➡ Acknowledging and understanding competing interests of the research and delivery teams
- ➡ Developing relationships with key contacts and opinion shapers
- ➡ Support from delivery teams / national trainers acted as advocates for the trial

Knowledge about trials addressed by

- ➡ Undertaking information days for local practitioners to provide details of trial and answer questions and concerns
- ➡ Offering to visit local practitioners and discuss the trial with staff
- ➡ Using a variety of communication approaches
- ➡ Learning how to present the trial and programme

Solutions: recruitment

- ➡ Supported promotional work done by delivery teams
- ➡ Employing an educational consultant to develop links between delivery teams and schools
- ➡ Funding from Welsh Government to extend programme delivery
- ➡ Opened new research site in South Wales
- ➡ Feedback from trial participants
- ➡ Information on sustainability of recruitment strategies
- ➡ Ensuring new delivery staff are fully briefed about the trial prior to interview and following appointment

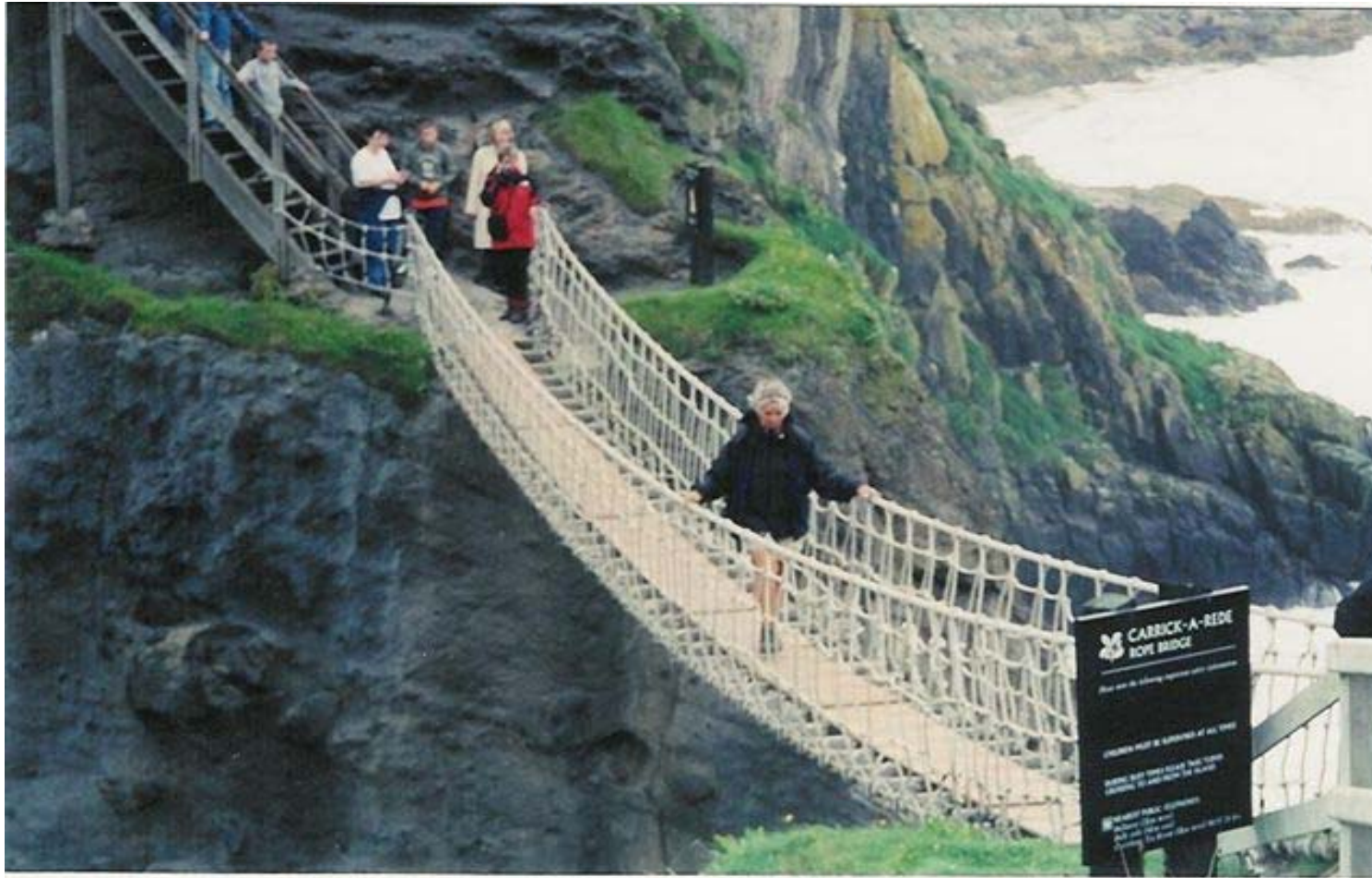
Solutions: retention

- ➡ Good systems for monitoring retention and progress through the trial
- ➡ Help from local practitioners
- ➡ Engagement with families through schools; used former teachers with local knowledge
- ➡ Increases in incentives provided to participants
- ➡ Newsletters to key in regular contact with participants
- ➡ We became detectives ...
- ➡ *Dyfal donc a dyr y garreg*
- ➡ Current completion rate for young people at 24m= 77.9%

Solutions: aligning research and policy/practice timelines

- ➡ Involvement key policymakers right from the start of the trial helped build relationships and mutual understanding
- ➡ Thinking about what information we could provide to key stakeholders:
 - ➡ Recruitment and retention
 - ➡ Programmes delivered and families engaged by it
 - ➡ Findings from process evaluation
 - ➡ Information about ongoing programme delivery in trial areas

Communication



Building Social Capital

- ☞ “features of social organization such as networks, norms, and social trust that facilitate coordination and cooperation for mutual benefit” (Putnam 1995)
- ☞ “... an instantiated informal norm that promotes co-operation between two or more individuals.” (Fukuyama, 2001)
- ☞ Norms and values influence the extent to which external relationships are positive
- ☞ Bonding social capital relates primarily to one’s immediate social group or network
- ☞ Bridging capital: connections with other networks
(Newman and Dale, 2005; Granovetter, 1973)
- ☞ Requires building a ‘radius of trust’ between organisations

Conclusions

- ➡ Partnerships with policy and practice have been central
- ➡ Process of building relationships and social capital
- ➡ Re-thinking how we describe the design and value of our research
- ➡ Maintaining the external validity of the trial has meant working with a complex set of organisational structures
- ➡ Running the trial has required a range of skills – statistician, interviewer, analyst, contract manager, lawyer, mediator, fire fighter ...

Acknowledgements

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- ☞ Programme delivery teams; Cardiff SFP team
- ☞ Research participants
- ☞ Referrers and other collaborators

Contact details

segrottj@cardiff.ac.uk

Project website: <http://www.projectsfpccymru.co.uk>

DECIPHER website: <http://www.decipher.uk.net/>



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