

Recruitment by local practitioners to a pragmatic effectiveness trial of the Strengthening Families Programme (SFP10-14) in Wales, UK

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+Presentation overview

- ➔ Background
- ➔ Randomisation
- ➔ Recruitment
- ➔ Strategies adopted by the trial team



+Background

- ☞ Pragmatic trials of public health interventions outside the National Health Service are relatively scarce, much needed and face particular challenges:
 - Funding
 - Professional and organisational cultures unused or opposed to randomised trial procedures (Oakley, et al. 2006)
 - Recruitment
 - Maintaining intervention and control groups
 - Relevance of findings and translation into policy / practice



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+Background to SFP10-14 UK



- ➡ 7 week 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



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+Background to SFP10-14 UK (cont'd)



- ➔ 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



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+Project SFP Cymru

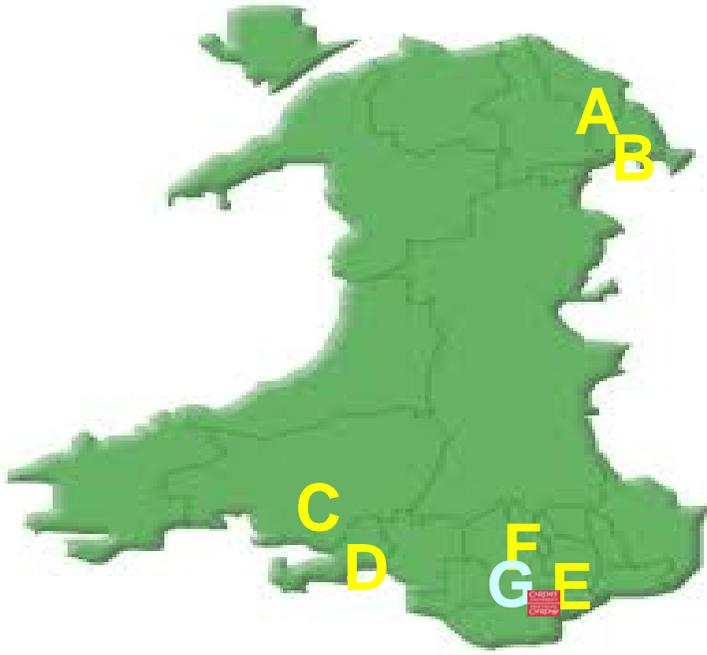


- ➡ Evaluation of SFP in Cardiff for Welsh Government to examine potential as a national programme for Wales
- ➡ Programme offered to mixed groups (70% of families from the general population, and 30% with some challenges)
- ➡ Welsh Government funding for SFP in three locations
 - Agreed that programme 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



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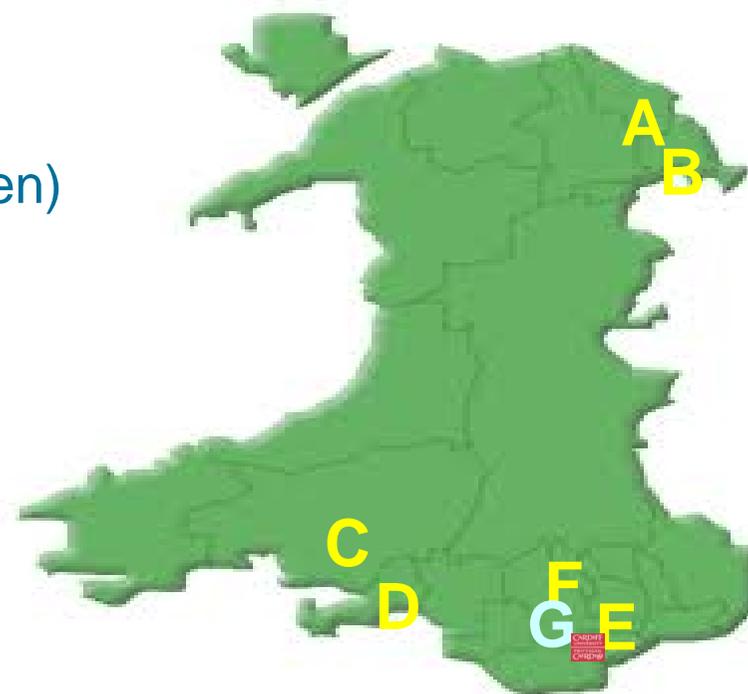
+Implementation of the SFP in Wales

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
(Tonypany Community College)



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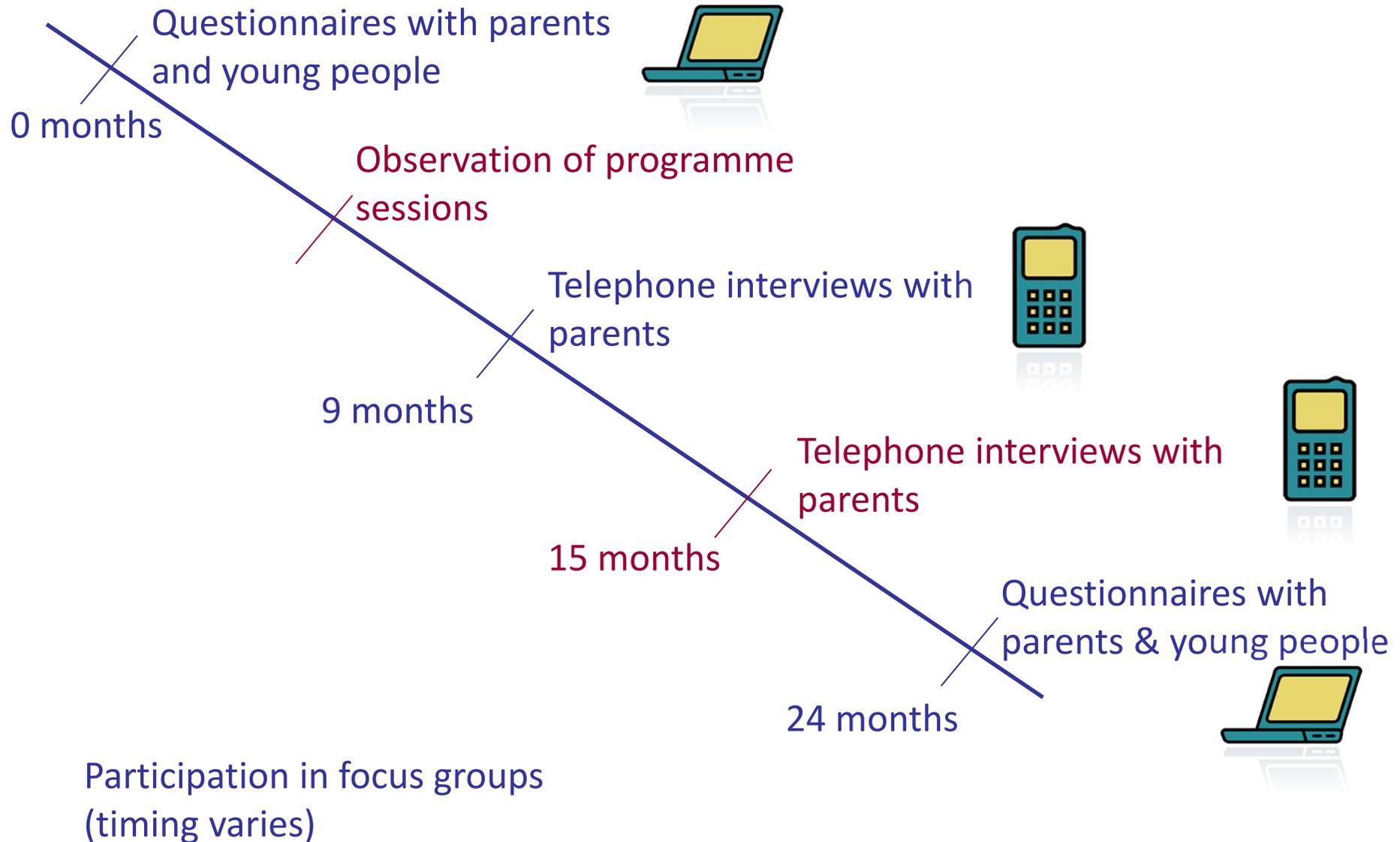
- Pragmatic RCT; families as the unit of randomisation
- Embedded process and economic evaluations
- Comparing normal care with normal care + SFP10-14
- Aims to recruit 748 families
- Families are referred/apply to the programme coordinator and receive needs and eligibility assessment
- Locally embedded fieldworker
 - sends families detailed information about the trial
 - visits families to seek consent for participation and conduct baseline interviews



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+Data collection from families



+Challenges

randomisation and random allocation



- ➡ Delivery agencies / referrers unfamiliar with RCTs
- ➡ Concerns about random allocation
 - Trial seen as imposing ‘rationing’ of programme to only half the families
 - Belief that individual families needed help and that SFP would benefit them
 - Randomisation seen as offering, then taking away programme from families
 - Perception that control group received ‘nothing’
 - Some areas had few services for families with 10-14 year olds
 - Some referrers viewed SFP as crisis intervention



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+Challenges

random allocation and randomisation

- ➡ Some agencies refused to refer families, or stopped doing so in response to allocation to control group
- ➡ Desire to offer control families compensatory programme
- ➡ Translating needs of trial into delivery areas where there may be competing priorities i.e. research vs focus of delivery partner
- ➡ Multiple actors, organisations and structures
- ➡ Levels of understanding and capacity to adopt new approaches variable



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THERE ARE ONLY
TWO TIMES
I FEEL STRESS:
DAY AND NIGHT.

The cartoon depicts a character with a wide-eyed, stressed expression. On the left, the character is shown against a white background with a sun, representing 'DAY'. On the right, the character is shown against a black background with a crescent moon, representing 'NIGHT'. The text above the panels reads 'THERE ARE ONLY TWO TIMES I FEEL STRESS:' and below them 'DAY AND NIGHT.'

+Challenges - Recruitment

- More challenging than anticipated
- Alignment of research and policy timelines
- 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



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+Solutions



👉 Partnership working

- Engaging early with delivery agencies and communicating trial requirements
- Acknowledging competing interests of the research and delivery teams
- Developing relationships with key contacts and opinion shapers
- 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



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+Solutions



👉 Recruitment levels increased by

- Centrally supporting promotional work undertaken by delivery teams
- Employing an educational consultant to develop links between delivery teams and schools
- Securing additional funding from Welsh Government to extend programme delivery
- Opening new site in South Wales
- Requesting feedback from trial participants through family days run by the research team and the study Public Involvement Officer
- Capturing costs and sustainability of recruitment strategies
- Ensuring new delivery staff are fully briefed about the trial prior to interview and following appointment



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+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, analyst, contract manager, lawyer, mediator, fire fighter ...



+Project SFP Cymru research team

Grantholders: Laurence Moore, Jeremy Segrott, Simon Murphy, Jo Holliday, Kerenza Hood, Zoe Roberts, Jonathan Scourfield, David Foxcroft, Ceri Phillips

Cardiff trial team: Laurence Moore, Jeremy Segrott, Jo Holliday, Heather Rothwell, Claire Thomas, Kim Sheppard

Fieldworker: Gillian Sulley

Swansea University Health Economics Team: Ceri Phillips, Ioan Humphries

Trial Statistician: Zoe Roberts, David Gillespie



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