

Pragmatic trials of non-NHS interventions: Experiences from a Randomised Controlled Trial of the Strengthening Families 10-14 UK Programme (SFP10-14 UK)

project



SFP Cymru

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Background

- Pragmatic trials of public health interventions outside the NHS are relatively scarce, much needed and face particular challenges.
 - Funding
 - Trial implementation in professional and organisational cultures unused to randomised trial procedures, Maintaining the counterfactual
 - Recruitment
 - Relevance of findings for and translation into policy and practice

Background to SFP10-14 UK



- Seven week family-focused substance use 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 located in the family
- Also concerned with preventing other problem behaviours
- Focuses on parenting, family functioning and young people's peer resistance skills
- Universal intervention, available to ANY family. Does not address very high needs levels or substance misuse

Background to SFP10-14 UK (cont'd)



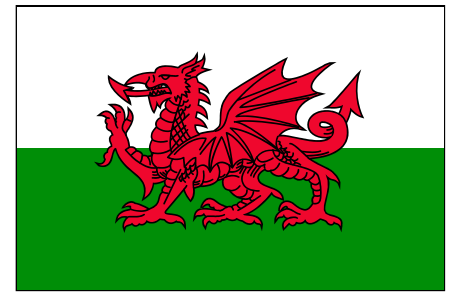
- Evidence from US trials that the programme delays and reduces substance use (Spoth, et al. 2001, 2002, 2005)
- Limitations of previous trials including statistical tests used
- SFP10-14 UK adapted for use in UK, and now attracting substantial policy interest
- Evidence of short term positive outcomes from non controlled studies in relation to family functioning, and high levels of acceptability
- No robust evidence on long term effectiveness of SFP10-14 in the UK



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- Programme running in Cardiff using innovative delivery model (70% of families from the general population, and 30% with some challenges)
- Evaluation of Cardiff SFP conducted on behalf of the WG to examine its potential as a national programme for Wales
- WG involved in trial from outset
 - funded implementation of the SFP in three areas across Wales
 - provided SFP facilitator training to delivery teams
- CU subsequently secured funds from NPRI to extend delivery into 3 further areas and to cover all research costs



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Implementation of the SFP in Wales

Six partnerships identified who were interested in implementing the SFP and willing to do so as part of a trial.

Employed an SFP co-ordinator and admin support, and arranged training of facilitators

A – Flintshire (Barnardo's Cymru)

B – Wrexham (Wrexham BC)

C – Carmarthenshire (Carmarthenshire BC)

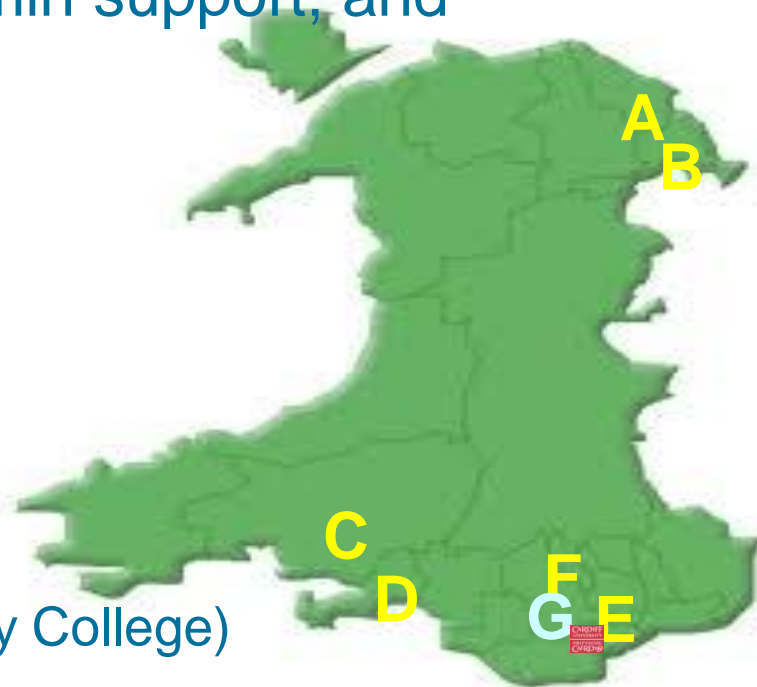
D – Swansea (Swansea Drugs Project)

E –Caerphilly (Drugaid Cymru)

F - Merthyr Tydfil (Merthyr Tydfil CBC)

Additional area recruited in 2011

G - Rhondda Cynon Taf (Tonypany Community College)



Project SFP Cymru



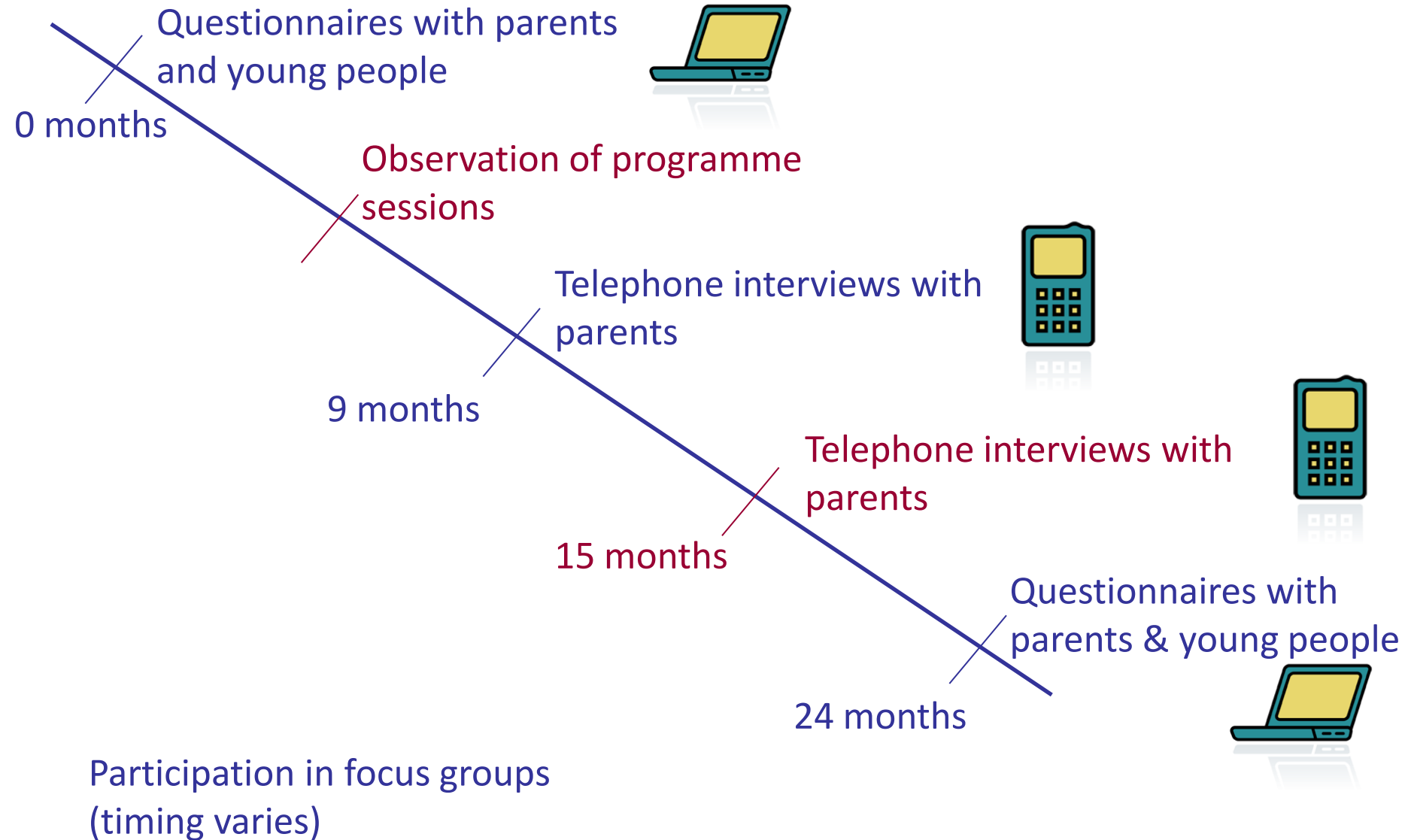
- Pragmatic RCT with families as the unit of randomisation, with embedded process and economic evaluations
- Comparing normal care with normal care + SFP10-14
- Aims to recruit 748 families
- Families are referred/apply to the programme coordinator and receive needs and eligibility assessment
- Locally 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



Progress so far



- Baseline data collection commenced February 2010
- Over 500 families now recruited into the study
- 9 month follow-up data collection commenced October 2010
- 15 month follow-up data collected commenced May 2011
- Logic model developed, and process evaluation data collection well underway
- Promotion of the trial across Wales ongoing
- Work to build strong relationships between trial team, programme delivery staff and potential referrers



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Challenges – Research Vs Practice



- Partnership working
- Concept of a randomised controlled trial relatively unfamiliar in social care setting (both amongst delivery agencies and key referring agencies)
 - Concerns about randomisation
 - Understanding of need for a counterfactual and the importance of maintaining it
 - Translating needs of trial into delivery areas where there may be competing priorities i.e. research vs focus of delivery partner
 - levels of understanding and capacity to adopt new approaches variable

Challenges - Recruitment



- Maintenance of recruitment fidelity
 - More challenging than anticipated
 - Alignment of research and policy timelines (WG funding received before NPRI funding to CU)
 - One of six sites shut July 2011
 - Maintaining momentum (staff changes in programme delivery teams)

Solutions



- Partnership working has been facilitated
 - Engaging early with stakeholder agencies, clearly communicating trial requirements and maintaining open communication channels with delivery teams
 - Using a variety of communication approaches to engage with agencies.
 - Acknowledging competing interests of the research and delivery teams
 - Developing good relationships with key contacts in stakeholder agencies
- 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
 - Increasing knowledge within delivery teams through training, discussion and provision of FAQs

Solutions



- Recruitment levels increased by
 - Securing additional funding from Welsh Government to support programme delivery
 - Opened new site in South Wales
 - Centrally supporting promotional work undertaken by delivery teams
 - Requesting feedback from trial participants through family days run by the research team and the study Public Involvement Officer
- Staff changes
 - Impact minimised by ensuring staff are fully briefed about trial prior to interview and following appointment

Conclusions

- This study has highlighted a number of issues central to the success of pragmatic RCTs:
- Whilst a challenge, partnership working with delivery agencies, national SFP trainers and Welsh Government has been central to the ability of the trial team to address these issues
 - Increased understanding of importance of trials amongst local practitioners and ensured that delivery teams are sufficiently supported in relation to promoting the trial concept to colleagues
 - Increased research team appreciation of challenges faced by delivery teams and their ways of working
 - Facilitated successful funding application to extend programme delivery with aim of increasing recruitment levels

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, Philip Daniels, Kim Sheppard

Fieldworkers: Claire Thomas, Thomas Allan, Gillian Sulley

Swansea University Health Economics Team: Ceri Phillips, Ioan Humphries

Trial Statistician: Zoe Roberts, David Gillespie



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