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
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

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

- 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
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
   (Tonypandy Community College)
Project SFP Cymru

- 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
Data collection from families

- Questionnaires with parents and young people
  - 0 months

- Observation of programme sessions
  - 9 months

- Telephone interviews with parents
  - 15 months

- Telephone interviews with parents
  - 24 months

- Questionnaires with parents & young people

- Participation in focus groups (timing varies)
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
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
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
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
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
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

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**Fieldworker:** Gillian Sulley

**Swansea University Health Economics Team:** Ceri Phillips, Ioan Humphries

**Trial Statistician:** Zoe Roberts, David Gillespie
Funding

Project SFP Cymru is funded by the National Prevention Research Initiative (http://www.npri.org.uk)

Funding partners: Alzheimer’s Research Trust; Alzheimer’s Society; Biotechnology and Biological Sciences Research Council; British Heart Foundation; Cancer Research UK; Chief Scientist Office, Scottish Government Health Directorate; Department of Health; Diabetes UK; Economic and Social Research Council; Engineering and Physical Sciences Research Council; Health & Social Care Research & Development Office for Northern Ireland; Medical Research Council; The Stroke Association; Welsh Government; and World Cancer Research Fund

Additional funding for programme delivery is provided by the Welsh Government. Cardiff Drug and Alcohol team provide financial support for recruitment through schools.
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