

Randomised controlled trial of the Strengthening Families Programme 10- 14 UK in Wales UK

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Strengthening Families Programme 10-14

- Universal substance misuse prevention intervention
- Delivered to groups of families with children aged 10-14
- Parenting, family functioning & peer-pressure resistance skills
- Weekly sessions of 2.5 hours for seven weeks
- Hour 1: child/parent sessions Hour 2: Family sessions
- Evidence of effectiveness from US trials
- SFP10-14 adapted for use in UK
- Initially targeted at high risk families in UK implementation

Group composition strategy

- Adapted UK programme delivered in Cardiff
- Identified risks from comprising groups with high levels of challenge
- ‘Mixed families’ (70/30) approach: aims to form groups comprised of
 - *Families from General Population with no challenges in a group setting (70%)*
 - *Families who may experience/present challenges in a group setting (30%)*
- Examples of challenges: young person not attending school; ADHD; low literacy skills; learning difficulties
- 70/30 mix aims to maximise fidelity, promote positive group dynamics/behaviour change, and maximise retention
- Terminology: General Population (GP) / Families with Challenges (FWC), 70/30

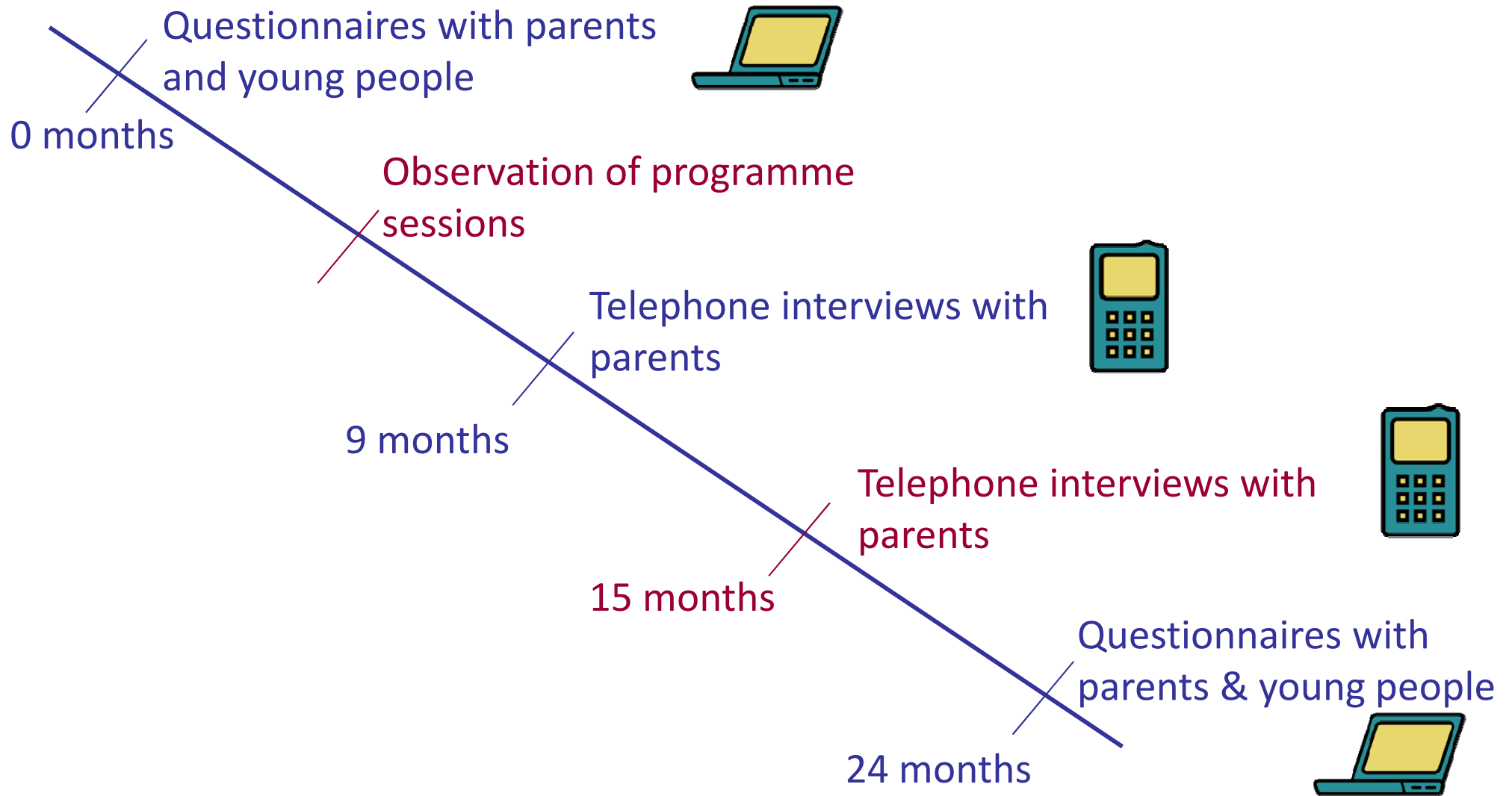
Trial Design

- Pragmatic RCT with families as the unit of randomisation
- Target sample size: 756
- Main follow-up at 24 months (parents and young people)
- Embedded process and economic evaluations
- Comparing normal care with normal care + SFP10-14UK
- SFP10-14 delivered by local government and charities
- Research fieldworkers embedded in programme delivery teams
- Knowledge exchange structures built into trial from outset: strong support from, and partnership with Welsh Government

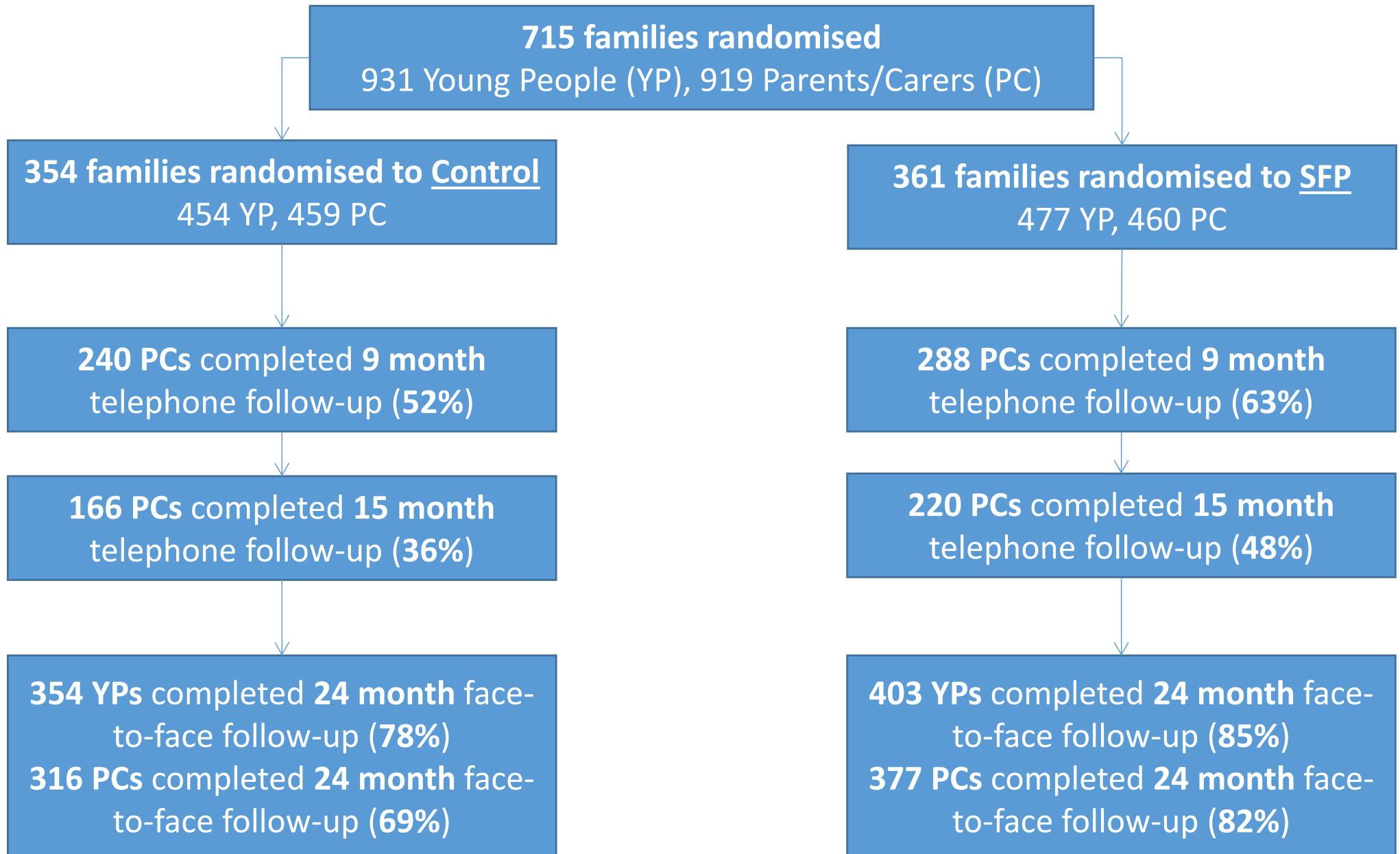
Trial Outcomes

- Primary outcomes: number of occasions that young people report having drunk alcohol and been drunk during the last 30 days, dichotomised as 'never' and '1-2 times or more'
- Secondary outcomes: use of cannabis, weekly smoking, age of alcohol use initiation, frequency of drinking, frequency of different types of alcoholic drinks, drink related problems, and GCSE performance
- Tertiary outcomes: age of initiation of use of drugs and tobacco; family functioning, parenting, and peer pressure resistance skills in young people; wellbeing and stress; and depression.

Data collection from families



Findings: recruitment and retention



Final completion rates (24 months): parents/carers – 75.4%; young people 81.3%

Findings: baseline characteristics

- No differences of major notes between trial arms

Demographic	Young person (YP)	Parent/carer (PC)
Median age (IQR)	12 (10 to 13)	37 (32 to 43)
% Female	46	77
% White British	85	81

Substance use in YPs	%
Ever tried a cigarette	27
Usually smoke > 6 cigarettes a week	5
Had a proper alcoholic drink	31
Been a little bit drunk	17
Been very drunk	7
Tried drugs	5

Substance use in PCs	%
Smoker	52
Never drink alcohol	19
High risk from problematic drinking (AUDIT-C)	34
Used drugs at least once in lifetime	34

Programme attendance

- 361 families were randomised to SFP
- 119 (33%) attended all 7 weeks
- 218 (60%) received the intervention, defined as attending at least 5 sessions without missing more than 1 session in a row
- 74 (20%) did not attend any sessions
- Overall, 287 attended at least 1 session

Process evaluation

- **Fidelity**: Some variation across trial sites within high overall fidelity
- **Group size**: 84% (n=47) of programmes enrolled 5-12 families
- **Group composition**: 37% (n=21) programmes achieved intended composition (70% families from General Population, 30% families with challenge in group setting)
- Remaining groups also achieved mix of families
- Good adherence to **staffing** levels and delivery of Weeks 1-7 by same staff

Findings: primary outcomes

Outcome	Control %	SFP %	Adjusted odds ratio (SFP vs. Control)	95% CI		p-value
Drunk alcohol in the 30 days prior to 24 month interview	24.6	26.5	1.12	0.72	1.73	0.625
Been drunk in the 30 days prior to 24 month interview	8.3	10.2	1.45	0.83	2.52	0.195

- **No evidence of a between-group difference on either primary outcomes**
 - Conclusions unaltered by:
 - Various pre-planned adjusted analyses
 - Non-receipt of intervention
 - Missing data adjustments
- No strong evidence of differential intervention effects according to pre-planned subgroups
 - Some potential differential effects according to:
 - Baseline parenting skills (as perceived by YP)
 - Family categorisation

Findings: secondary outcomes

- At 24 months, no evidence of a between-group difference on any of the other substance use outcomes
 - Alcohol-related problems in previous 12 months, weekly smoking, cannabis use (ever/last 12 months/last 30 days), time to alcohol/tobacco/drug use initiation (all YP-reported)
- Some borderline evidence of **better** parenting/family-based outcomes for those randomised to SFP
 - Parenting skills (YP and PC perceived), parent-child bonding, family cohesion, family conflict

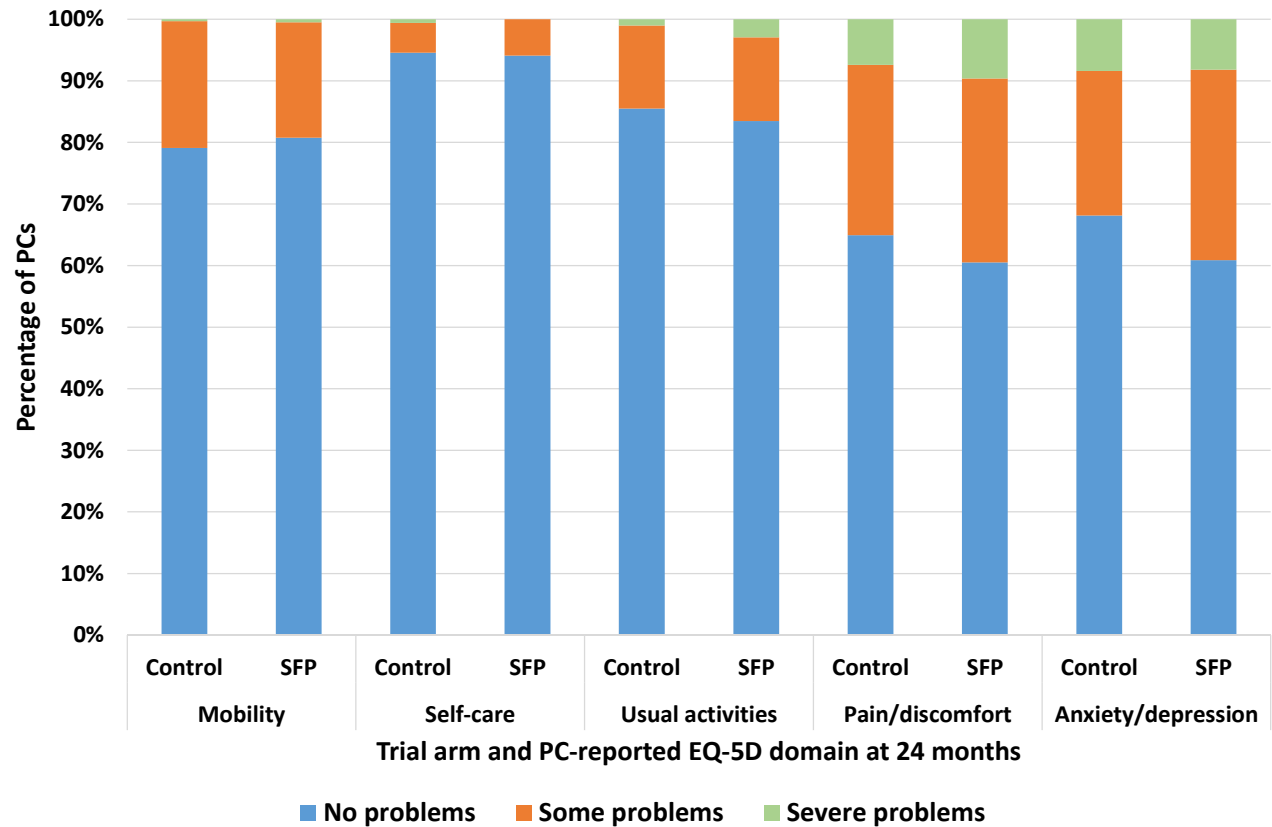
Outcome	Adjusted mean difference (SFP vs. Control)	95% CI		p-value
YP-perceived parenting skills	0.08	0.00	0.16	0.050
PC-perceived parenting skills	0.05	-0.01	0.10	0.097
PC-perceived parent-child bonding	-0.07	-0.15	0.01	0.074
PC-perceived family cohesion	-0.20	-0.44	0.03	0.095
PC-perceived family conflict	-1.70	-3.48	0.08	0.061

Note: for the bonding and cohesion measures, higher scores indicate worse outcomes, and lower scores indicate better outcomes

Findings: secondary outcomes

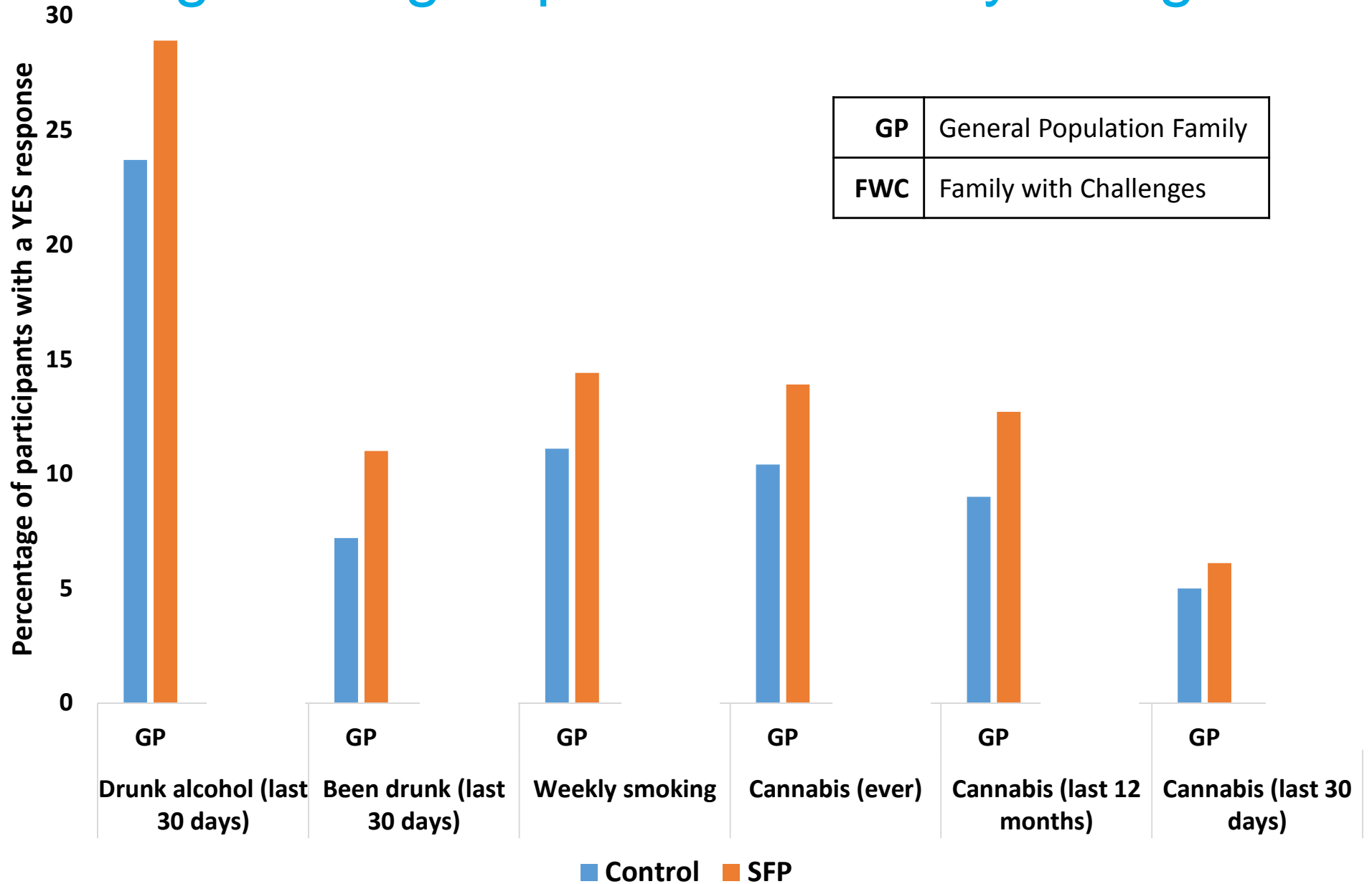
- Some borderline evidence that the odds of reporting full health (using EQ-5D) is **lower** in those randomised to SFP

- **YP-adjusted OR: 0.65 (95% CI: 0.39 to 1.08)**
- **PC-adjusted OR: 0.66 (95% CI: 0.44 to 0.98)**
- Mostly due to differences in the anxiety/depression and pain/discomfort domains

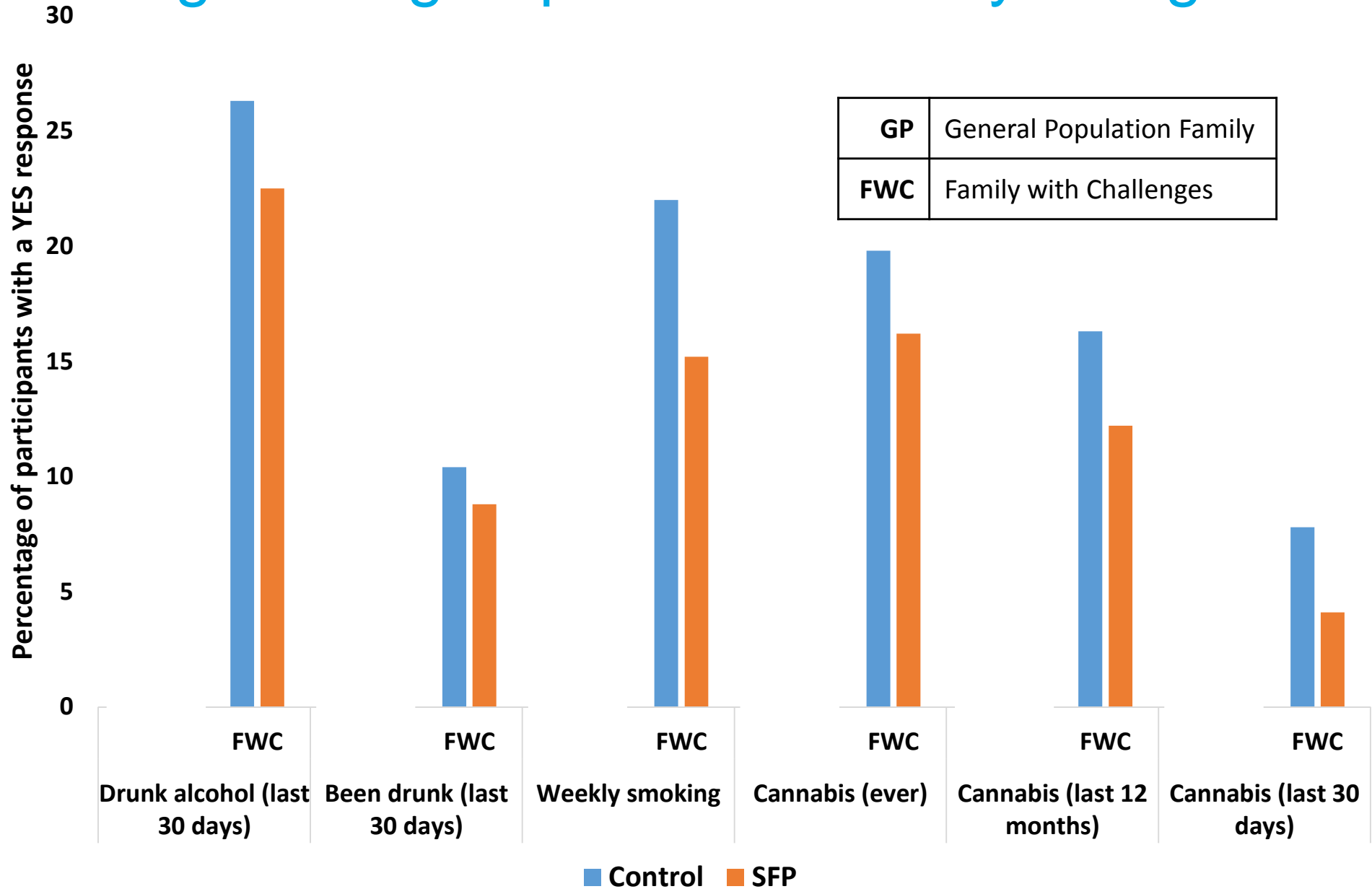


- No evidence of a between-group difference on any of the other secondary outcomes
 - Antisocial and prosocial behaviour of peers, strengths and difficulties, self-efficacy, security/attachment, family expressiveness

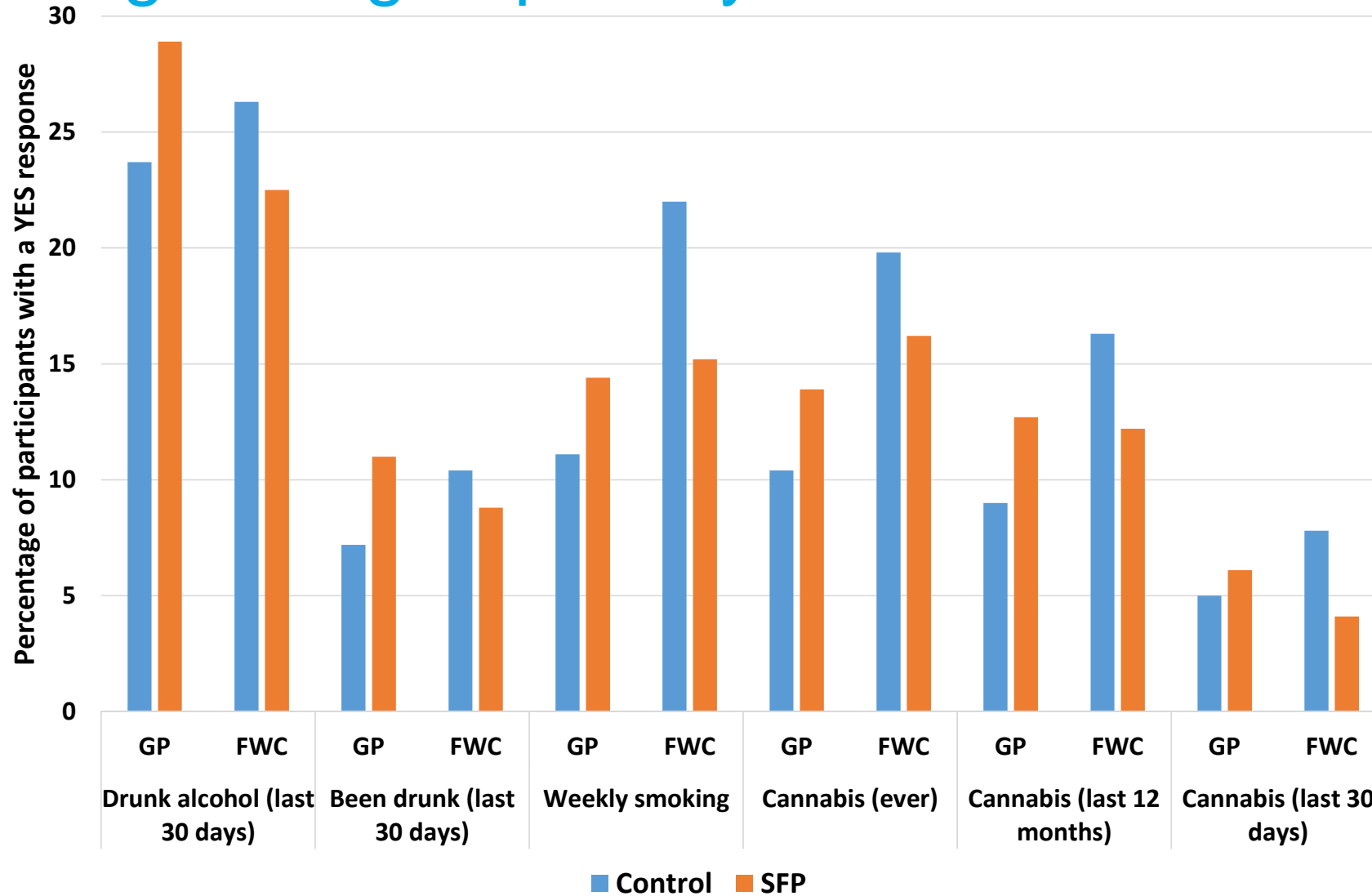
Findings: sub group effect of family categorisation



Findings: sub group effect of family categorisation



Findings: subgroup analyses



Outcome	FWC x SFP Adjusted mean difference	95% CI		p
SDQ	-2.39	-3.94	-0.84	0.003

Summary

- Challenging trial conducted with high follow-up rates over 2 years
- Pragmatic trial, good fidelity of programme delivery, although groups sometimes small and variable composition
- No evidence of any differences on any of the young person reported substance use outcomes at 24 months
- Some evidence that SFP had:
 - a positive effect on **parenting skills, parent-child bonding, family cohesion, and family conflict** (small differences, not statistically significant)
 - a negative effect on **health-related quality of life in young people and parents at 24 months** (though small differences) - mostly driven by differences in levels of **anxiety or depression**
- No evidence of differences in terms of antisocial and prosocial behaviour, behavioural difficulties, self-efficacy, security/attachment, and family expressiveness
- Some evidence to suggest that SFP may have been beneficial for **families with challenges**, but harmful for **general population families**

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