

Project SFP Cymru: evaluating the impact of the Strengthening Families 10-14 UK Programme on substance misuse

Submission date 03/12/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/02/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/02/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The use of alcohol, tobacco and illegal drugs by young people impacts on their health in the short and long term, and is also associated with anti-social behaviour, crime and dropping out of school. Many of the factors which protect young people from misusing drugs and alcohol, or put them at greater risk of doing so, are linked to family life and parenting. The Strengthening Families Programme 10-14 UK (SFP10-14 UK) aims to strengthen these protective factors (parenting, family communication, and young people's resilience skills) and simultaneously reduce key risk factors that are located within families. Research in the United States has found some evidence that the SFP10-14 delays and reduces substance use (alcohol, tobacco and illegal drugs) by young people. This study will examine whether the results found in the US translate to a UK context. It will identify whether the programme delays or reduces substance use, and collect information that will help with wider implementation of the programme if successful.

Who can participate?

Families with a child aged 10-14.

What does the study involve?

All families are randomly allocated as a family unit to either receive the intervention or to join the control group. For most families, the research will involve each family member completing a questionnaire when we first visit you, and then again two years later. On average this visit will take 1-2 hours and a member of the research team visits the home on both occasions to collect this information. We will also phone parents/carers 9 and 15 months after they join the study to ask some questions about family life and the kinds of support services the family uses. The phone call will last about 30 minutes. If participants attend the Strengthening Families Programme, we may like to observe one or two of the Programme sessions which they attend. This will help us to understand how the Programme is being delivered and received. We will only observe the session if everyone who attends that session agrees. We will also ask about 20 families from each area to take part in focus groups. Families are free to decide whether or not they wish to take part. The questions asked in focus groups conducted with families who attended the programme will be about the SFP and their experience of attending. The questions

asked in focus groups conducted with control group families will be about the kinds of services they use. The focus group will take about an hour for parents and about 45 minutes for young people. Focus groups will be audio taped (if families agree to this) or notes will be taken from which anonymous quotations may be used when we report the results of the research. If participants are happy for us to do so we also like to take a sample of saliva from the child /children at the end of the project which we will test to see how much tobacco smoke they have inhaled over the last few days. We will do this by asking them to place a cotton wool swab in their mouths for a few minutes.

What are the possible benefits and risks of participating?

Each family will receive regular updates about how the research is going and will find out the results from the project as a whole at the end. We hope that the information we will have collected by the end of the trial will help improve the provision of support services for other families and that families views and experiences will help inform future national policy. Families receive goodie bags when they begin taking part in the research. Families who take part in telephone interviews at 9 and 15 month follow-up will be entered into prize draws to win a family treat, and all adults and children who answer the questions at the end of the project (at 2 years) will be given a £10 voucher each as a way of saying thank you for your help. Families allocated to the intervention have the opportunity to attend the 7-week Strengthening Families Programme. There are no risks involved in the trial.

Where is the study run from?

The study is based in seven sites in Wales - Caerphilly, Merthyr, Wrexham, Swansea, Carmarthenshire, Flintshire and Rhondda Cynon Taf. The sites are centrally coordinated in Cardiff.

When is the study starting and how long is it expected to run for?

The study started in September 2009 and is expected to run until December 2014. Recruitment has now finished.

Who is funding the study?

The research is funded by the National Prevention Research Initiative and includes the cost of the delivering the programme in three local areas. The Welsh Government is funding the remaining cost of delivering the programme.

Who is the main contact?

Claire Thomas, Trial Manager
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Study website

<http://www.projectsfcymru.co.uk/>

Contact information

Type(s)

Scientific

Contact name

Prof Laurence Moore

Contact details

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CF10 3BD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2009/1-SPF

Study information**Scientific Title**

Preventing substance misuse: a randomised controlled trial of the Strengthening Families 10-14 UK Programme

Study objectives

Primary objectives:

To ascertain the impact of the Strengthening Families 10-14 UK Programme (SFP10-14 UK) on alcohol and drug misuse, and smoking behaviour in adolescents.

Secondary objectives:

To answer a number of other questions regarding other impacts of the SPF10-14 UK:

1. What impact does the SFP10-14 UK have on school performance, and mental health and well being?
2. What impact does the SFP10-14 UK have on protective factors for alcohol and tobacco use /misuse located in the family, such as family functioning, parenting and young people's peer resistance skills?
3. What are the costs associated with the SFP10-14 UK and to what extent can it be regarded as an efficient use of public funds?
4. How can SFP10-14 UK best be implemented and is there important variation in delivery and receipt?

On 14/08/2013 the overall trial end date was changed from 31/03/2014 to 31/12/2014.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Full approval pending from the Research Ethics Committee for Wales as of 04/12/2009 (ref: 09 /MRE0953). Provisional opinion given following meeting held on 08/10/2009.

Study design

Single-centre pragmatic randomised controlled effectiveness trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied

Substance misuse

Interventions

Participating families will be randomised to one of two treatment groups:

Control Group (C): Receive usual care with full access to existing services and a minimal information leaflet

Intervention Group (I): Receive the SFP10-14 UK programme in addition to usual care

There will not be a defined programme of usual care, and the existing variation in services available to participants across the six participating areas will continue throughout the trial period. Existing services include some peer education, brief interventions available through primary health care, and more intensive counselling interventions for individuals and families available through Drug and Alcohol Teams (DATs) and voluntary sector counselling services.

The SFP10-14 UK addresses three broad areas: family functioning, including communication between parents and children; strengthening parental skills; and helping young people to develop new skills in relation to resisting peer pressure, stress management, and goal setting. It is designed for delivery to families with children aged 10 - 14 years, and in the Wales adaptation is targeted towards a mix of families with challenges (in relation to child behaviour and family functioning) and families from the general population. Each programme is open to families from a loosely defined and fairly large geographical area. The 'mixed families' approach aims to recruit about 4 families with challenges per group, and 6 - 8 families from the general population. Self referrals come forward from awareness raising in community and educational settings. Families are therefore drawn from the same area facilitating mutual support between sessions and at the end of the programme, but are not from a small or defined community such as a school or local neighbourhood. This recruitment model has worked well and achieved full programmes that have achieved high retention and engagement. The programme comprises seven weekly sessions of two hours and is delivered in a range of community venues by a multi-agency team of trained professionals.

The SFP10-14 UK is a seven week intervention. In each session there is an hour during which parent sessions and young people sessions are conducted separately, followed by a second

combined family hour. Typically, the first hour focuses on skills (e.g. peer resistance for the young people, parenting for the parents), with the second hour designed to enable parents and young people to focus on communication skills, recognise family strengths, and practice skills covered in the first hour.

The last follow-up will be carried out 2 years after baseline.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Number of occasions that young people report ever having been really drunk. All outcomes will be measured at two-year follow-up.

Secondary outcome measures

All outcomes will be measured at two-year follow-up:

1. Reported use of cannabis (ever versus never)
2. Weekly smoking (yes versus no, validated by saliva cotinine)
3. General Certificate of Secondary Education (GCSE) performance (number of GCSEs passed at Grade C or above)

Overall study start date

01/09/2009

Completion date

31/12/2014

Eligibility

Key inclusion criteria

1. Families with a child aged 10 - 14 years, either sex
2. At least one parent/carer and one child are willing to attend the programme together
3. The ability to speak English (help can be provided for parents or children with low literacy levels). Some programmes may also be delivered through the medium of Welsh.
4. Families can self refer to the programme or be referred by a practitioner

Any families deemed eligible to attend the Strengthening Families Programme will be included in the research trial, subject to their giving consent.

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

748 families

Total final enrolment

715

Key exclusion criteria

1. Families with very high needs or challenges (such as serious substance misuse problems or family breakdown)
2. Situations where either a parent or child does not want to attend the programme
3. Families who do not live together e.g. the child/children are in care
4. Parents or children who cannot speak English

Families deemed ineligible to attend the Strengthening Families Programme will not be included in the research trial.

Date of first enrolment

08/02/2010

Date of final enrolment

31/12/2014

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

DECIPHer

Cardiff

United Kingdom

CF10 3BD

Sponsor information

Organisation

Cardiff University (UK)

Sponsor details

30 - 36 Newport Road

Cardiff

Wales
United Kingdom
CF24 0DE

Sponsor type
University/education

Website
<http://www.cardiff.ac.uk/>

ROR
<https://ror.org/03kk7td41>

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) - manages funding from the National Prevention Research Initiative (ref: G0802128)

Funder Name
The Welsh Assembly Government (UK) - cover the costs of implementation and training support during the period to March 2011

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/01/2014		Yes	No

[Results article](#)

results

21/02/2022

23/02/2022

Yes

No