

Steps towards alcohol misuse prevention programme (STAMPP): a school and community based cluster randomised controlled trial

Submission date 23/09/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/11/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/01/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Adolescence is a period when young people increasingly begin to experiment with alcohol, and as they get older they increase their consumption both in terms of the amount and frequency of use. Alcohol misuse among adolescents occurs in most countries worldwide, although the UK reports some of the highest levels in the EU. Consequences of heavy alcohol use in young people are extensive and adversely impact upon health, educational achievement, societal cohesion, criminality, welfare and well-being. There are clear geographic differences in the burden alcohol places on the population, and these are closely associated with other major indicators of ill health and health inequalities. Indeed, differences in alcohol use are thought to be one of the major determinants of health and social inequalities. Given the prevalence of underage drinking in the UK, the reported problems, costs and harms associated with this behaviour, and the lack of a robust UK evidence base for alcohol prevention we wish to investigate how well a school based alcohol education curriculum with parental training components will work in reducing hazardous levels of drinking and alcohol related harms in school children in Northern Ireland and Glasgow/Inverclyde Local Authorities.

Who can participate?

Participants are male and female children aged 13 and 14 attending post-primary schools in Northern Ireland and Glasgow/Inverclyde Local Authorities. Children with special educational needs will participate at the discretion of their teachers as the intervention materials have not been adapted for this group of children.

What does the study involve?

The treatment to be tested is an adapted version of the School Health and Alcohol Harm Reduction Project (SHAHRP), which was developed in Australia, with the addition of a parental component designed to help parents set rules around alcohol in the family home. The combined treatment is called STAMPP - Steps Towards Alcohol Misuse Prevention Programme (STAMPP). One set of schools will receive STAMPP, the other will receive their usual school alcohol education. Parents of children who receive alcohol education as normal will not be invited to receive any type of intervention.

Phase 1 of STAMPP is delivered when pupils are in the second year of post-primary education (aged at least 13 on 01/09/2012), coinciding with the onset of alcohol use for many children, and phase 2 a year later, when alcohol use becomes more established. Phase 1 consists of six sessions (with 16 activities) and phase 2 consists of four sessions (with 10 activities). Each lesson uses skills-based activities and individual and small group discussions to emphasise the identification of alcohol-related harm and the development of harm reduction strategies. Interactive involvement is a key feature of the sessions. Based on previous work it is likely that changes in alcohol use associated with the classroom curriculum are influenced by changes in self efficacy, self regulation, and time perspective and orientation, whereby the skills developed in the sessions enable children to make more accurate decisions on the likely immediate short and long term consequences of different types of alcohol use, and to develop (and adhere to) personal and group strategies to reduce harm experienced by the recipients' own and others' alcohol use. These changes will be reinforced and supported by changes in family based skills. Parents receive an intervention comprising a short standardised presentation delivered by a trained facilitator at school parent evenings. The presentation includes information on alcohol prevalence in young people, corrects parents' (under)estimates of youth drinking, and highlights the importance of setting strict family rules around alcohol. The presentation is followed by a brief discussion on family rules, and followed up by a leaflet providing a summary of the key information from the evening.

The classroom intervention is delivered by specially trained teachers. Teacher training will be conducted in the school setting and include an introduction to the concepts involved in harm reduction, rehearsal of delivery of each of the sessions in that intervention phase, and awareness of raising of potentially difficult issues/areas around alcohol. Additionally, teachers will be provided with a support pack which includes detailed lesson plans, and alcohol information sheets. The parental component is delivered by trained prevention practitioners and takes place in the school or community setting.

What are the possible benefits and risks of participating?

Previous research has shown that the classroom component of STAMPP was associated with a reduction in children's drinking and a reduction in the harms they experienced as a result of their own (e.g. risky behaviour) or others' (e.g. fights) drinking. As with all substance use education interventions there is a small risk that some children's interest in alcohol will be piqued by participation in the trial and will initiate use at an earlier age. However, young people are subject to many other social, cultural, and family influences in their day to day life which are likely to have a greater effect on drinking initiation than participation in this research.

Where is the study run from?

105 schools will take part in the research. The principal investigator is based in Liverpool, UK, although university researchers in Oxford and Belfast are also collaborating.

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

The study will start in 2011 and last for 51 months. School recruitment is expected to have finished by May 2012. The intervention will begin in Autumn 2012 and takes place across two annually delivered blocks of lessons.

Who is funding the study?

National Institute for Health Research - Public Health Research Programme (UK)

Who is the main contact?

Prof. Harry Sumnall
h.sumnall@ljamu.ac.uk

Contact information

Type(s)

Scientific

Contact name

Prof Harry Sumnall

Contact details

Centre for Public Health
Liverpool John Moores University
Henry Cotton Building
Webster Street
Liverpool
United Kingdom
L3 2ET

-
h.sumnall@ljmu.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

10/3002/09

Study information

Scientific Title

The effectiveness of a classroom psychoeducational intervention with parental components in reducing hazardous drinking and the harms associated with alcohol use in school pupils compared with education as usual (EAU)

Acronym

STAMPP

Study objectives

Current hypothesis as of 17/02/2015:

Is a classroom psychoeducational intervention with parental components (STAMPP) [cost] effective in reducing hazardous drinking and the harms associated with alcohol use in young people compared with education as usual (EAU)?

This will be assessed by determining changes in several indicators of alcohol consumption, alcohol cognitions, and other alcohol-related behaviour.

The primary research objectives of STAMPP are:

1. To ascertain the effectiveness and cost-effectiveness of STAMPP in reducing alcohol consumption (defined as self-reported consumption of ≥ 6 units in a single episode in the previous 30 days for males and ≥ 4.5 units for females) in school pupils (school year 9/S2 in the academic year 2012/2013) at + 33 months (T3) from baseline. This will be dichotomised at never /one or more occasions.
2. To ascertain the effectiveness of STAMPP in reducing alcohol-related harms as measured by the number of self-reported harms (harms caused by own drinking) in school pupils (school year 9 /S2 in the academic year 2012/2013) at +33 months (T3) from baseline

The secondary research objectives of STAMPP are:

1. To ascertain the effectiveness and cost-effectiveness of STAMPP in reducing alcohol consumption (defined as self-reported consumption of ≥ 6 units in a single episode in the previous 30 days for males and ≥ 4.5 units for females) in school pupils (school year 9/S2 in the academic year 2012/2013) at + 24 months (T2) from baseline. This will be dichotomised at never /one or more occasions.
2. To ascertain the effectiveness of STAMPP in reducing alcohol consumption (self-reported alcohol use in lifetime, last year and previous month; number of drinks in 'typical' and last use episodes; age of alcohol initiation, unsupervised drinking) in school pupils (school year 9/S2 in the academic year 2012/2013), at +24 (T2) months and + 33 (T3) months.
3. To ascertain the effectiveness of STAMPP in reducing alcohol-related harms as measured by self-reported harms caused by own drinking at +24 months (T2), and self-reported harms caused by the drinking of others at +24 (T2) months and + 33 (T3) months, in school pupils (school year 9 /S2 in the academic year 2012/2013).

Previous hypothesis from 25/11/2013 to 17/02/2015:

Is a classroom psychoeducational intervention with parental components (STAMPP) [cost] effective in reducing hazardous drinking and the harms associated with alcohol use in young people compared with education as usual (EAU)?

This will be assessed by determining changes in several indicators of alcohol consumption, alcohol cognitions, and other alcohol related behaviour.

The primary research objective of STAMPP is:

1. To determine the effectiveness and cost-effectiveness of STAMPP in reducing alcohol consumption (frequency of consuming >5 drinks in a single episode in the previous 30 days) in second form pupils (aged at least 13 on the 01/09/2012) at + 18 months after intervention.

The secondary research objectives of STAMPP are:

1. To ascertain the effectiveness and cost-effectiveness of STAMPP in reducing alcohol consumption (frequency of consuming >5 drinks in a single episode in the previous 30 days) in second form pupils (aged at least 13 on 01/09/2012) at + 6 months after intervention.
2. To ascertain the effectiveness of STAMPP in reducing alcohol consumption (self-reported alcohol use in lifetime, last year and previous month; number of drinks in typical and last use episodes; age of alcohol initiation, unsupervised drinking) in second form pupils (aged at least 13 on 01/09/2012) at + 6 months and + 18 months after intervention.
3. To ascertain the effectiveness of STAMPP in reducing alcohol-related harms as measured by health service utilisation and self-reported harms (harms caused by own drinking and that of others) in second form pupils (aged at least 13 on 01/09/012) at + 6 months and + 18 months after intervention.

Original hypothesis:

Is a classroom psychoeducational intervention with parental components (STAMPP) [cost] effective in reducing hazardous drinking and the harms associated with alcohol use in young people compared with education as usual (EAU)?

This will be assessed by determining changes in several indicators of alcohol consumption, alcohol cognitions, and other alcohol related behaviour.

The main objectives of the research are to determine the following in year 10 pupils immediately post intervention, + 6 months and + 18 months after intervention:

1. The (cost) effectiveness of STAMPP in reducing alcohol consumption:

1.1. Self reported alcohol use in lifetime

1.2. Last year and previous month

1.3. Number of drinks in 'typical' and last use episodes

1.4. Frequency of consuming >5 drinks in a single episode in the previous 30 days

1.5. Age of alcohol initiation

2. The effectiveness of STAMPP in reducing alcohol related harms as measured by health service utilisation and self reported harms (harms caused by own drinking and that of others)

3. Which components of STAMPP make it effective in reducing alcohol related harm

4. What are the behavioural and cognitive mediators of change (individual and family factors) that lead to the effectiveness of STAMPP

Ethics approval required

Old ethics approval format

Ethics approval(s)

Liverpool John Moores University Ethics Board, November 2011

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Alcohol drinking and experiences of harms associated with own and others' use of alcohol

Interventions

Current interventions as of 25/11/2013:

STAMPP is a UK adaptation of the Australian developed Schools Alcohol Harm Reduction Programme (SHAHRP) with the inclusion of a parental component that is delivered (staggered introduction) in Phase 2 of the classroom intervention.

Phase 1 is delivered when pupils are in the second year of post primary schooling, coinciding with the onset of alcohol use for many children, and phase 2 one year later, when alcohol use becomes more established.

Phase 1 consists of six sessions (with 16 activities) and phase 2 consists of four sessions (with 10 activities). Each lesson uses skills-based activities and individual and small group discussions to emphasise the identification of alcohol-related harm and the development of harm reduction strategies. Interactive involvement is a key feature of the sessions.

Based on previous work it is hypothesised that changes in alcohol outcomes associated with the classroom curriculum are mediated by changes in self efficacy, self regulation, and time perspective and orientation, whereby the skills developed in the sessions enable children to make more accurate decisions on the likely immediate short- and long-term consequences of different types of alcohol use, and to develop (and adhere to) personal and group strategies to reduce harm experienced by the recipients' own and others' alcohol use. These changes will be reinforced and supported by changes in family-based skills.

The parental component is a brief intervention comprising a short standardised presentation delivered by a trained facilitator at school parent evenings. The presentation includes information on alcohol prevalence in young people, corrects parents' (under)estimates of youth drinking, and highlights the importance of setting strict family rules around alcohol. The presentation is followed by a brief discussion on family rules, and followed up by a leaflet providing a summary of the key information from the evening.

The control group participants will receive questionnaires only and will continue with the normal curriculum within their school. Exposure to drug, alcohol and other health education delivered as part of the curriculum will be monitored in all schools.

Previous interventions:

STAMPP is a UK adaptation of the Australian developed Schools Alcohol Harm Reduction Programme (SHAHRP) with the inclusion of a parental component (Talking About Tough Issues (TATI)) that is delivered (staggered introduction) from the beginning of Phase 1 of the classroom intervention.

Phase 1 is delivered when pupils are in year 10 (age 13-14), coinciding with the onset of alcohol use for many children, and phase 2 in year 11 (age 14-15), when alcohol use becomes more established. Phase 1 consists of six sessions (with 16 activities) and phase 2 consists of four sessions (with 10 activities). Each lesson uses skills-based activities and individual and small group discussions to emphasise the identification of alcohol-related harm and the development of harm reduction strategies. Interactive involvement is a key feature of the sessions.

Based on previous work it is hypothesised that changes in alcohol outcomes associated with the classroom curriculum are mediated by changes in self efficacy, self regulation, and time perspective and orientation, whereby the skills developed in the sessions enable children to

make more accurate decisions on the likely immediate short and long term consequences of different types of alcohol use, and to develop (and adhere to) personal and group strategies to reduce harm experienced by the recipients' own and others' alcohol use. These changes will be reinforced and supported by changes in family based skills.

The parental component to be tested will be an adapted form of the Talking to Children about Tough Issues (TATI), a locally developed (Northern Ireland), evidence based (social interaction /development models of parenting) programme that takes place over three two hour long sessions and is targetted at parents/carers of intervention children. Through a series of supported activities, parents/carers are encouraged to develop general strategies for reducing conflict, to pursue reflective listening, and to help establish authoritative family rules on behaviours such as alcohol use.

The control group participants will receive questionnaires only and will continue with the normal curriculum within their school. Exposure to drug, alcohol, and other health education delivered as part of the curriculum will be monitored in all schools.

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measures as of 17/02/2015:

1. Alcohol consumption (defined as self-reported consumption of ≥ 6 units in a single episode in the previous 30 days for males and ≥ 4.5 units for females) in school pupils (school year 9/S2 in the academic year 2012/2013) at + 33 months (T3) from baseline. This will be dichotomised at never/one or more occasions.
2. Alcohol-related harms as measured by the number of self-reported harms (harms caused by own drinking) in school pupils (school year 9/S2 in the academic year 2012/2013) at +33 months (T3) from baseline

Previous primary outcome measures from 25/11/2013 to 17/02/2015:

To ascertain the effectiveness and cost-effectiveness of STAMPP in reducing alcohol consumption (frequency of consuming >5 drinks in a single episode in the previous 30 days) in second form pupils (aged at least 13 on 01/09/2012) at + 18 months after the intervention

Original primary outcome measures:

1. Period prevalence of alcohol use - self-reported alcohol use in lifetime, last year and previous month
2. Amount and frequency of episodic alcohol use - number of drinks in 'typical' and last use episode, frequency of consuming >5 drinks in a single episode in the previous 30 days
3. The age of alcohol initiation - age at which a whole drink of alcohol was first consumed, not just a sip or a shared drink

Secondary outcome measures

Current secondary outcome measures as of 17/02/2015:

1. Alcohol consumption (defined as self-reported consumption of ≥ 6 units in a single episode in the previous 30 days for males and ≥ 4.5 units for females) in school pupils (school year 9/S2 in the academic year 2012/2013) at + 24 months (T2) from baseline. This will be dichotomised at never/one or more occasions.
2. Alcohol consumption (self-reported alcohol use in lifetime, last year and previous month; number of drinks in 'typical' and last use episodes; age of alcohol initiation, unsupervised

drinking) in school pupils (school year 9/S2 in the academic year 2012/2013), at +24 (T2) months and + 33 (T3) months.

3. Alcohol-related harms as measured by self-reported harms caused by own drinking at +24 months (T2), and self-reported harms caused by the drinking of others at +24 (T2) months and + 33 (T3) months, in school pupils (school year 9/S2 in the academic year 2012/2013).

Current secondary outcome measures from 25/11/2013 to 17/02/2015:

1. To ascertain the effectiveness and cost-effectiveness of STAMPP in reducing alcohol consumption (frequency of consuming >5 drinks in a single episode in the previous 30 days) in second form pupils (aged at least 13 on 01/09/2012) at + 6 months after the intervention.
2. To ascertain the effectiveness of STAMPP in reducing alcohol consumption (self-reported alcohol use in lifetime, last year and previous month; number of drinks in 'typical' and last use episodes; age of alcohol initiation, unsupervised drinking) in second form pupils (aged at least 13 on 01/09/2012) at + 6 months and + 18 months after the intervention.
3. To ascertain the effectiveness of STAMPP in reducing alcohol-related harms as measured by health service utilisation and self-reported harms (harms caused by own drinking and that of others) in second form pupils (aged at least 13 on 01/09/2012) at + 6 months and + 18 months after the intervention.

Original secondary outcome measures:

1. Alcohol knowledge and attitudes
2. Harm cause by own and others' alcohol use
3. Un/supervised alcohol use - prevalence of drinking with peers with or without the supervision of parents/guardians

Overall study start date

01/11/2011

Completion date

31/03/2016

Eligibility

Key inclusion criteria

Current inclusion criteria as of 17/02/2015:

Male and female school pupils (school year 9/S2 in the academic year 2012/2013) and their parents/carers, attending post primary secondary schools in Northern Ireland and Glasgow /Inverclyde Local Authorities.

Previous inclusion criteria from 25/11/2013 to 17/02/2015:

Male and female school children (second year post primary; aged 13/14) and their parents /carers, attending post-primary secondary schools in Northern Ireland and Glasgow/Inverclyde Local Authorities.

Original inclusion criteria:

Male and female school children (Year 10; aged 13/14) and their parents/carers, attending post-primary secondary schools in Northern Ireland and Glasgow.

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

10,000 pupils in 105 schools

Key exclusion criteria

1. Pupils not in the specified school year and ages
2. Pupils in non mainstream and vocational education (e.g. pupil referral units, further education colleges)
3. Pupils with special educational needs are excluded as the intervention materials have not been developed for use with this population

Date of first enrolment

01/11/2011

Date of final enrolment

01/01/2012

Locations**Countries of recruitment**

England

Northern Ireland

United Kingdom

Study participating centre

Liverpool John Moores University

Liverpool

United Kingdom

L3 2ET

Study participating centre

Oxford Brookes University

Gipsy Lane

Headington

Oxford

United Kingdom

OX3 0BP

Study participating centre
University of Liverpool
Liverpool
United Kingdom
L69 3BX

Study participating centre
Queen's University Belfast
University Road
Belfast
United Kingdom
BT7 1NN

Study participating centre
Northern Ireland Clinical Trials Unit
1st Floor Elliott Dynes Building
The Royal Hospitals
Grosvenor Road
Belfast
United Kingdom
BT12 6BA

Sponsor information

Organisation
Liverpool John Moores University (UK)

Sponsor details
Research Support Office
Kingsway House
Hatton Garden
Liverpool
England
United Kingdom
L3 2AJ

Sponsor type
University/education

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

ROR

Funder(s)

Funder type

Government

Funder Name

Public Health Research Programme

Alternative Name(s)

NIHR Public Health Research Programme, PHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2017	18/04/2017	Yes	No
Results article	results	09/03/2018	13/03/2018	Yes	No
Results article	results	01/08/2019	16/01/2019	Yes	No