

Preventing alcohol misuse in young people: an exploratory cluster randomised controlled trial of the Kids, Adults Together (KAT) programme

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**National Institute for
Health Research**

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Declared competing interests of authors: none

Published November 2015

DOI: 10.3310/phr03150

This report should be referenced as follows:

Segrott J, Rothwell H, Hewitt G, Playle R, Huang C, Murphy S, *et al.* Preventing alcohol misuse in young people: an exploratory cluster randomised controlled trial of the Kids, Adults Together (KAT) programme. *Public Health Res* 2015;**3**(15).

Public Health Research

ISSN 2050-4381 (Print)

ISSN 2050-439X (Online)

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

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This report

The research reported in this issue of the journal was funded by the PHR programme as project number 10/3002/03. The contractual start date was in May 2012. The final report began editorial review in August 2013 and was accepted for publication in July 2014. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PHR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the PHR programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the PHR programme or the Department of Health.

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Abstract

Preventing alcohol misuse in young people: an exploratory cluster randomised controlled trial of the Kids, Adults Together (KAT) programme

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Background: Involvement of parents/carers may increase the effectiveness of primary school-based alcohol-misuse prevention projects. However, few interventions have been designed for pre-adolescent children, or specifically involve parents/carers. The Kids, Adults Together (KAT) programme in primary schools aimed to reduce alcohol misuse through such an approach.

Objective: To determine the value and feasibility of conducting an effectiveness trial of KAT.

Design: Parallel-group cluster randomised exploratory trial with an embedded process evaluation. Schools were the unit of randomisation.

Setting: Primary schools ($n = 9$) in south Wales, UK.

Participants: Pupils in Year 5/6 (aged 9–11 years) and their parents/carers; school staff.

Intervention: The Kids, Adults Together programme consisted of (1) classwork addressing the effects of alcohol; (2) a family event for children and parents/carers; and (3) a 'goody bag' containing fun items, including a digital versatile disc (DVD) for families to watch together. The intervention comprised KAT plus existing alcohol-related activities and lessons. Control-group schools continued with existing alcohol-related lessons and activities.

Main outcome measures: Key outcomes related to the progression criteria for a potential future effectiveness trial. These included the acceptability, participation equity, feasibility and implementation of KAT; the recruitment and retention of research participants; and the acceptability and feasibility of research processes, including data collection methods and outcome measures.

Results: Nine schools (free school meal entitlement ranging from 1% to 37.2%) participated. Two of five intervention schools withdrew but all four control schools were retained, and these seven schools facilitated all research data collections. Programme acceptability and participation rates were high in all three intervention schools (parent/carer participation rates ranged from 45.1% to 65.7%), although implementation quality varied. At baseline, approximately 75% of eligible children ($n = 418$) provided data, of whom 257 also provided data at follow-up. Only 27 parents/carers (estimated response rate 6.5%) completed interviews. Most children were willing to complete questionnaires but measures were not appropriate for this age group. Measures of alcohol consumption produced inconsistent responses. Intermediate outcomes on family communication showed no evidence of intervention effectiveness.

Conclusions: In the three schools that received the KAT intervention, it was found to be acceptable to schools and pupils and there were good levels of participation from parents/carers from across a range of socioeconomic groups. However, two intervention schools withdrew from the trial. Findings from intermediate outcomes on family communication did not support programme theory. In addition, the study highlighted challenges in identifying suitable outcome measures for children aged 9–11 years and the feasibility of long-term follow-up via secondary schools.

Future work: It would not be appropriate to proceed to an effectiveness trial of KAT. There are doubts/uncertainties about the potential effects of KAT; suitability of measures; the large number of schools which would be required for an effectiveness trial of KAT, and the cost of this; feasibility of follow-up in secondary schools; and programme implementation and theory. There is a need to develop and validate measures for children aged 9–11 years; to test the feasibility of follow-up data collection methods in secondary schools; and to further consider sample size requirements and feasibility.

Trial registration: Current Controlled Trials ISRCTN80672127.

Funding: The exploratory trial of this project was funded by the National Institute for Health Research Public Health Research programme and the process evaluation was funded by the Economic and Social Research Council. The work was undertaken with the support of The Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement (DECIPHER), a UK Clinical Research Collaboration Public Health Research Centre of Excellence. Joint funding (MR/KO232331/1) from the British Heart Foundation, Cancer Research UK, Economic and Social Research Council, the Welsh Government and the Wellcome Trust, under the auspices of the UK Clinical Research Collaboration, is gratefully acknowledged. This project will be published in full in *Public Health Research*; Vol. 3, No. 15. See the NIHR Journals Library website for further project information.

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List of abbreviations

CSO	Chief Scientist Office	NIHR	National Institute for Health Research
DECIPHer	Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement	PAKT	Parents, Adults, Kids Together
DVD	digital versatile disc	PCCS	Parent–Child Communication Scale
FCS	Family Communication Scale	RCT	randomised controlled trial
FSM	free school meal	SD	standard deviation
HBSC	Health Behaviour in School-aged Children	SDM	social development model
ICC	intracluster correlation	SEWTU	South East Wales Trials Unit
INSET	in-service training	SFP10–14	Strengthening Families Programme 10–14
ITT	intention to treat	TPCCAS	Targeted Parent–Child Communication about Alcohol Scale
KAT	Kids, Adults Together	TV	television
MRC	Medical Research Council		

Plain English summary

Alcohol misuse has high personal, social and economic costs, and misuse by young people is of particular concern. Schools have been identified as having an important role in the delivery of alcohol misuse prevention interventions. Researchers compared primary schools which ran the Kids, Adults Together (KAT) programme with schools which did not run the programme (control group). KAT aims to prevent misuse of alcohol by encouraging children and parents to talk about alcohol before children grow up and start drinking. It comprises classroom work about the effects of drinking alcohol, a family event and an educational digital versatile disc (DVD).

The best way to find out if KAT can prevent alcohol misuse is to conduct a randomised controlled trial (RCT) lasting 2 or more years, comparing a large number of schools running KAT with an equal number of schools which continue with their normal curriculum. This study assessed whether or not a RCT would be useful and practicable. Many schools invited to take part did not reply or declined. The research, lasting 14 months, involved nine schools and investigated whether or not (1) schools could run KAT successfully; (2) the research methods which would be used in a RCT were suitable and acceptable for children, parents and schools; and (3) how likely it was that KAT would increase family communication if we measured this in a RCT.

All four control-group schools completed the study and there was positive feedback from the three schools which ran KAT, where large numbers of parents and children participated. Two schools which should have run KAT withdrew. Most children completed questionnaires for the research but some of the questions were too hard for 9- to 11-year-olds. Few parents took part in interviews and KAT did not appear to increase family communication.

It is not appropriate to conduct a RCT of KAT because (1) we need to develop better questionnaires first; (2) the programme did not appear to increase family communication; (3) KAT's impact on alcohol misuse could be small, meaning that a RCT would be very expensive; and (4) we need to test how practicable it would be for a RCT to do follow-up questionnaires with children after they had moved to secondary schools.

Scientific summary

Background

Alcohol misuse has high social, economic and personal costs, and misuse by young people is of particular concern. Schools are a key setting for the delivery of interventions to prevent alcohol misuse owing to their near-to-complete coverage of the target population and their expanding function as health promoting institutions. To date, however, most programmes have been designed for secondary schools and have not always included parents/carers, despite parental involvement being identified as a characteristic of effective programmes. Intervention earlier in the life course could capitalise on the greater social influence of parents/carers and teachers before children start drinking regularly and socialise more with peers.

The Kids, Adults Together (KAT) programme is an alcohol misuse prevention programme drawing on the social development model (SDM). The SDM proposes that young people learn social behaviour through interactions with others, resulting in the formation of attachments which, if strong, can have a lasting effect on behaviour through supporting acquisition of skills and influencing norms and values. Attachment to others who offer opportunities for and reward pro-social behaviour (e.g. parents/carers, teachers) is a protective factor against antisocial behaviour, such as underage drinking. Thus, involvement of parents/carers and children in interventions may increase the quality and frequency of parent–child interactions.

The KAT programme comprises (1) teacher-delivered classwork on the effects of alcohol consumption, and preparation for a family event; (2) the family event, involving children and parents/carers in activities addressing key health messages around alcohol; and (3) a ‘goody bag’ for families with an educational digital versatile disc (DVD) for parents/children to watch together. KAT requires approximately 5 days’ classroom time, but can be delivered over a longer period to suit the class teacher’s needs, plus approximately 1 hour for the KAT family event at the school.

Kids, Adults Together operationalises the SDM by providing opportunities for children to interact with their parents/carers through homework related to what they learn in class about the social and health effects of alcohol; attending the KAT event, where parents/carers can see and praise their children’s work; and watching the DVD together at home. Through this mechanism of strengthening pro-social family norms and communication about alcohol, KAT aims to reduce future alcohol misuse in participating children.

Programmes that aim to involve parents/carers frequently struggle to engage them. KAT schools ask parents/carers to attend just a single event held in school at a time that is convenient to them, and this is promoted as an opportunity for them to see what their children have been learning in class, not as an educational event about alcohol misuse.

Kids, Adults Together has been piloted in two schools in Wales, where it showed potential to influence knowledge and family communication processes and an ability to engage large numbers of parents/carers. In line with the Medical Research Council evaluation framework for complex interventions, it was therefore appropriate to move forward to an exploratory trial of KAT.

Objectives

The aim was to further develop and evaluate KAT in a larger number of schools in order to determine the value and feasibility of an effectiveness trial. Specific objectives were to:

1. refine the theoretical model and outcome pathways of the intervention
2. assess the feasibility and acceptability of the intervention
3. assess intervention reach and rates of participation, including equality of engagement across socioeconomic localities and groups
4. assess trial recruitment and retention rates
5. identify possible effect sizes that are likely to be detected as part of a definitive trial and an appropriate sample size
6. determine the cost and feasibility of the proposed methods for measuring primary and secondary outcomes
7. identify the costs of delivering KAT, and to pilot methods for assessing cost-effectiveness as part of a future definitive trial; and
8. determine whether or not to proceed with a definitive trial.

Thus, the study did not assess the effectiveness of KAT, but tested intervention feasibility and trial methods.

Methods

Research design

An exploratory cluster randomised controlled trial (RCT) of KAT with an embedded process evaluation was undertaken. In October 2011, English medium schools with Year 5/6 classes in Newport in south Wales were invited to participate. Eight schools which responded were stratified by free school meal entitlement and size and then randomly assigned to the intervention or control in a 1 : 1 ratio. One school in the intervention group withdrew before data collection at baseline and was replaced, but the replacement school also withdrew after baseline. In both schools, reasons for withdrawal appeared to relate to the nature of the intervention. Seven schools remained in the study.

The intervention was administered at cluster (school) level and consisted of the KAT programme in addition to any existing alcohol-related lessons/school activities. Head teachers in each intervention school selected two or three classes, including two Year 4/5 classes in two schools with mixed year-group classes. In intervention schools, all children in participating classes received KAT whether or not they provided data for the research. KAT activities were linked to the curriculum and integrated into normal classroom work and all parents/carers were invited to attend the KAT family events. All children in classes which received KAT, and their parents/carers, were eligible to take part in the trial regardless of the extent of their participation in the programme.

Training for staff was organised at intervention schools, and teachers of participating classes received a programme handbook and other resources. Teachers were encouraged to choose their own way of achieving programme aims rather than adhere strictly to activities suggested in the handbook. The four control group schools continued with their normal activities, including any school activities/classroom work on alcohol.

Participating children completed two questionnaires: one at baseline and another 4 months later. Children in intervention schools also took part in focus groups for the process evaluation. Participating parents/carers took part in telephone interviews 6 months after baseline and some parents/carers of intervention-group children also took part in interviews for the process evaluation.

Measures

Key outcomes were acceptability, participation equity and the quality of programme implementation; recruitment and retention of research participants; and the feasibility and acceptability of research processes, including methods for data collection. The study also assessed the acceptability and feasibility to children and parents/carers of providing demographic data and of answering questions measuring potential outcomes of any future effectiveness trial.

Potential primary outcome measures used at baseline and follow-up to assess their acceptability and feasibility were:

- ever had an alcoholic drink
- ever been drunk
- frequency of alcohol consumption
- frequency of being drunk; and
- frequency of smoking cigarettes.

Kids, Adults Together is hypothesised to prevent alcohol misuse through improving adult–child communication and, thus, promote the formation of attachments to parents/carers or other influential adults. Relevant literature was searched for measures used in similar studies. Questionnaires for children were adapted after piloting at baseline and again between baseline and follow-up. Measures used were:

- KIDSCREEN-52: parent relationship and home-life dimension (baseline and follow-up)
- Family Activities Scale (baseline and follow-up)
- Targeted Parent–Child Communication about Alcohol Scale (baseline only)
- Parent–Child Communication Scale (PCCS) (follow-up only)
- Family Communication Scale (follow-up only).

Secondary outcome measures for parents/carers were:

- Family Activities Scale
- PCCS
- Family Communication Scale.

The acceptability and feasibility of measuring changes in parents/carers' alcohol-related behaviour were also evaluated using two measures:

- change in alcohol-related behaviour; and
- Daily Drinking Questionnaire.

Measures of age, sex, socioeconomic status and ethnicity and (for parents/carers) employment and qualifications were utilised to assess their acceptability and comparability between control and intervention groups. For children, the Family Affluence Scale was used to measure socioeconomic status.

Process evaluation

The objectives of the process evaluation were to:

- assess quality of delivery and fidelity
- develop and refine the programme logic model
- develop and refine the programme's theory of behaviour change; and
- assess programme reach, particularly in relation to hard-to-reach families and families with a history of alcohol misuse.

Interviews with head teachers of all participating schools explored their motivation to participate in the study; parental involvement in school events; normal practice in relation to education concerning alcohol; and, in the intervention group, their views on KAT and experiences of implementation. Eighteen hours of KAT classwork were observed along with the three family events to assess whether or not the programme was delivered in accordance with the aims stated in the handbook; the engagement of pupils and parents/carers; acceptability; and integration with class timetables. All teachers involved in programme delivery were interviewed about their experiences of implementing KAT classroom work and family events and their perceptions of children's engagement. Eighteen parents/carers of children in the intervention group were interviewed about their involvement in the family event and motivation to attend. Four focus groups were held with intervention-group children to explore their views on the programme components and engagement in KAT by members of their families.

Criteria for recommending an effectiveness trial of Kids, Adults Together

Criteria were developed through discussions among the Trial Management Group to inform a decision on whether or not to proceed with a proposal to evaluate KAT in an effectiveness trial. The criteria, based on the objectives of the study listed in the protocol, related to the value, feasibility and acceptability of implementing the KAT programme and of conducting a RCT in schools.

Results

The Kids, Adults Together programme

Overall, teachers liked the way in which the programme fitted within the curriculum and they delivered the programme with skill and confidence. Pupils enjoyed working interactively to produce work for performance and display at the family events. KAT successfully engaged parents/carers at the family events organised in all three schools. Fifty per cent of families from all schools were represented by at least one adult member at family events and school staff were pleased with the high attendance rates. Parents/carers felt that the event was enjoyable and non-judgemental and that they had learned new things about alcohol in a non-stigmatising way. Parents/carers and teachers thought that it was desirable and appropriate to address the topic at primary school. Most children in the focus groups said that they had enjoyed the programme, although there was evidence that it might not be suitable for Year 4 children, some of whom found the group work and writing challenging.

Most key elements of KAT were implemented as intended in most schools. However, there were some gaps. One teacher took a negative approach to the topic of alcohol rather than communicating the more balanced 'not too much, not too soon' programme message. Only one school set KAT-related homework, and at two schools some children were given no active role in the family events. In one school, staff did not understand their role in organising and introducing activities at the family event. Some staff did not seem to be aware of the contents of the programme handbook or to have attended training sessions.

There was no evidence from either quantitative or qualitative findings that KAT had increased family communication. All confidence intervals for between-groups comparison of communication measures included the possibility of no intervention effect; in interviews, although some parents/carers and children said that they had talked more at home about alcohol, others maintained that they had always been open about discussing alcohol and that there was no change. A small number of interview data suggested that further development of programme theory might be required to understand pathways through which KAT might influence children from families with negative experiences of alcohol use.

Measures of alcohol consumption produced inconsistent responses and intermediate outcomes on family communication showed no evidence of intervention effect, suggesting that any potential long-term impacts on alcohol-related behaviours were likely to be small or non-existent. Sample size calculations based on 24.5% prevalence of 11- to 13-year-olds' past-month drinking found that 263 schools would be required for a trial with 80% power to detect a 2.5% between-groups difference.

Feasibility and acceptability of the research

The nine schools recruited varied in terms of free school meal entitlement rates (an indicator of area deprivation) (from 1% to 37.2%; eligible schools median 18.4%) and in size (from 69 to 483 pupils; eligible schools median 211 pupils), enabling a test of the feasibility of both programme implementation and research methods within different school and area contexts.

'Opt-out' consent was sought from parents/carers for children to provide research data and proved acceptable to schools and parents/carers. At baseline, 74% (intervention group) and 81% (control group) of eligible pupils completed questionnaires. These figures were 68% and 74% respectively at follow-up.

The number of missing data for the potential primary outcome measures was small, indicating that pupils of this age are comfortable answering questions about alcohol consumption. However, both questions about alcohol use produced inconsistent responses, with some children saying that they had consumed alcohol at baseline but not at follow-up.

Reliability of adapted secondary outcome measures of family communication was demonstrated using Cronbach's alpha. Missing data rates were higher than for alcohol measures, but no questions stood out as presenting particular difficulties. Scoring methods for scales are likely to have at least partly accounted for the higher missing rates. However, experience during data collections suggested that many children did not readily understand some of the questions. Missing rates at follow-up were higher than at baseline: fewer boys than girls, and fewer children in Year 5 than in Years 4 and 6, completed follow-up questionnaires.

Children appeared to find the demographic questions easy to answer and there were few missing data. Only one question was not well understood and this concerned family structure: 'which grown-ups look after you all or most of the time?'

Recruitment rates were low for parent/carer telephone interviews. Estimating that eligible pupils had one parent/caregiver, only 12% volunteered to take part, with 6.5% ($n = 27$) eventually providing data. Demographic data were summarised but no additional analyses were undertaken.

Conclusions

Our findings suggest that it would be inappropriate to undertake an effectiveness trial of KAT. While the programme has significant strengths, including its ability to engage with families and to integrate with schools' curricular activities, teachers' participation in training was patchy and the withdrawal of two schools in the intervention group raised doubts about KAT's acceptability. Findings did not support programme theory. Secondary outcome analysis suggested that KAT may either be ineffective or produce small changes on alcohol-related behaviour which would require a very large sample size to be able to detect. Measurement error may have been a factor because it is uncertain whether or not children understood all of the research questions.

This study has highlighted areas for further research which would need to be undertaken should any future effectiveness trial of KAT take place. A number of these areas may be of more general importance in prevention of alcohol misuse:

1. consideration of the role and importance of data from parents/carers and the cost-effectiveness of recruiting representative samples of parents/carers for data collection
2. identification, development and validation of suitable primary and secondary outcome measures for children aged 9–11 years
3. assessment of the feasibility and acceptability of collecting follow-up data from pupils in secondary schools

4. further consideration of the final sample size calculation, and the feasibility of recruiting the necessary number of schools and pupils
5. inclusion in the design of adequate time, agency support and financial incentives to optimise school recruitment and retention rates.

Trial registration

This trial is registered as ISRCTN80672127.

Funding

Funding for the exploratory trial of this study was provided by the Public Health Research programme of the National Institute for Health Research and funding for the process evaluation was provided by the Economic and Social Research Council. The work was undertaken with the support of The Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement (DECIPHer), a UK Clinical Research Collaboration Public Health Research Centre of Excellence. Joint funding (MR/KO232331/1) from the British Heart Foundation, Cancer Research UK, Economic and Social Research Council, the Welsh Government and the Wellcome Trust, under the auspices of the UK Clinical Research Collaboration, is gratefully acknowledged.

Chapter 1 Introduction

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This report describes an exploratory trial of Kids, Adults Together (KAT), a primary school-based, universal programme to promote prosocial family communication about alcohol, with the aim of preventing alcohol misuse in young people. This chapter summarises the literature on early preventative interventions for alcohol misuse, and describes the background and theoretical basis of KAT and the aims and objectives of the trial.

Scientific background and rationale

Public health context

Alcohol misuse has high personal, social and economic costs, and widens inequalities in health.² Harmful drinking has risen steeply in the UK during the last 20 years³ and the annual cost of alcohol misuse in the UK has been estimated at £25B, of which £1B was spent in Wales.^{4,5} Misuse of alcohol by young people has raised particular concerns about the number who initiate alcohol consumption at a young age, and the high levels of regular and harmful alcohol use.^{6,7} For example, 5% of 11-year-old boys in Wales report drinking alcohol at least once a week; the proportion increases to 35% at 15 years, by which age nearly half report having been drunk at least twice.⁸ Alcohol misuse in young people has a range of health and social impacts, including disorderly and violent behaviour, risky sexual behaviour,⁹ accidental injury, and poor school attendance and achievement.^{10,11} In the longer term, early initiation of alcohol consumption increases the risk of alcohol-related problems in later life.^{12–15} There is also evidence to suggest that alcohol misuse in young people clusters with other risk behaviours. For instance, the 2011 survey of drug use, smoking and drinking among 11- to 15-year-olds in England found strong associations between past-year drug taking and alcohol use, while people who smoked were roughly twice as likely to have consumed alcohol in the previous 7 days.¹⁶

Interventions to prevent alcohol misuse in children and young people

Schools have long been considered an important setting for delivering health behaviour interventions to young people, including those addressing alcohol misuse. In May 2013, four electronic databases [MEDLINE, Allied and Complementary Medicine (AMED), EMBASE and PsycINFO] were searched from 2010–13 to identify recent evaluations of school-based alcohol misuse programmes for children and young adolescents (see *Appendix 1*). Search terms for alcohol misuse (alcohol, alcoholic, binge drinking) were combined with a term for school based (school*) and terms for programme (interven*, prevent*, promot*, program*), with results limited to English-language publications. Evaluations identified by the search, including those that were community rather than school based, are presented in *Appendix 1* and illustrate the breadth of approaches being investigated and the scarcity of programmes focused on younger children. Rather than focusing exclusively on individual behaviour, school-based interventions provide an opportunity to draw on the socioecological health promotion framework, thereby acknowledging and exploiting the wider influences on health behaviours, such as friendship groups and organisational (school) system influences.^{17,18} Furthermore, schools have near-to-complete coverage of the target population, and so intervention reach is potentially very high, and they also have an expanding function as health-promoting institutions.^{19–21} Health-promoting schools work within a framework based on the World Health Organization's Ottawa Charter for Health Promotion²² and promote health through the whole school environment, not just through health education curricula.²³ Health-promoting schools, therefore, strive to integrate their curriculum teaching with the school's physical, social and policy environment, and the wider school community including parents.

Teaching about alcohol is a component of the personal and social education (PSE) curriculum from Key Stage 2 (8- to 11-year-olds) onwards in Wales,²⁴ and so classroom-based alcohol misuse interventions do not necessarily place additional strain on the curriculum and can help to fulfil key requirements. Since 2003, the All-Wales School Liaison Core Programme, funded by the Welsh Government,²⁵ has provided lessons on alcohol and other drugs to pupils at Key Stages 1–4, delivered by police school liaison officers. While the programme has been well received by pupils and schools^{26,27} and is currently delivered in approximately 97% of schools in Wales,²⁸ it has not been subjected to a rigorous outcome evaluation. Many studies of similar classroom-based programmes suggest that preventing alcohol misuse requires an approach which may be more complex than that used to teach subjects in which students are required to demonstrate knowledge, rather than to adopt and observe a behavioural principle.^{29–34} Such complex interventions might have multiple interacting components and target different levels of the socioecological framework.³⁵ Effective alcohol-misuse prevention programmes for young people have been found to share characteristics which generally fall into one or more of three main themes outlined below: (1) use of a clear theoretical basis in programme design; (2) interactive delivery style; and (3) community (including family and parental) involvement.^{29–34} We summarise each in turn.

Theory-based programme and design

Health-promotion research and practice have been criticised for being poorly theorised,^{36,37} but recent and influential guidance on the development and evaluation of complex health interventions has clarified the importance of identifying and developing the theory/theories upon which interventions are based.³⁵ The explication of programme theory, namely the assumptions of how and why an intervention will produce specified outcomes, is essential for meaningful programme evaluation and intervention development, and can be visually presented in a logic model.³⁸

Nation *et al.*³⁹ distinguish aetiological theory, which focuses on the causes of behaviour, from intervention theory, which focuses on how to address aetiological factors associated with the behaviour, and say that both are required to drive effective programmes. Aetiological theory around problem behaviours in adolescence has centred on risk factors and protective influences.⁴⁰ Risk factors, however, are often common to several problem behaviours, and so effective programmes addressing the aetiology of alcohol misuse will share many characteristics of interventions addressing other behaviours arising from the same risk factor(s), for example tobacco and other substance use. This is significant because interventions aimed at addressing one health behaviour may also have effects on other behaviours that share common antecedents. The development of KAT has, therefore, drawn on evidence about the prevention of antisocial behaviour in children and adolescents generally, as well as that specific to alcohol-prevention programmes.

The social influence model has been recommended as the most suitable intervention theory for school-based programmes which address risk and protective factors.⁴¹ The model posits that children can be ‘inoculated’ against social pressure to adopt undesirable behaviours such as drug and alcohol use.⁴² Social pressure can be active, for example explicit offers of drugs from peers, or passive, such as overestimating alcohol consumption among peers. The model suggests various programme mechanisms that can help children counter social pressures, for example resistance and refusal training, public pledges, critiques of tobacco and alcohol advertising, learning about real and perceived norms, and the use of peer leaders.^{42–44}

Interactive delivery style

Most of the mechanisms through which the social influence model is operationalised are highly compatible with an interactive delivery style, and programmes that employ such a style are more effective than those using more didactic, non-interactive methods.⁴³ According to the social influence model, interactive teaching and learning methods (e.g. role play) might increase programme effectiveness by providing opportunities for communication and social interaction and enhancing young people’s critical awareness of social norms and pressures around substance use.^{41,45} Effective interactive learning strategies also enhance children’s negotiation skills and let them rehearse problem-solving strategies.⁴⁵ Involvement of peer leaders can make programmes highly interactive and participatory and can increase engagement

of young people who feel more comfortable talking to peers than to teachers. Young people may also talk more openly with peers and find it more fun.⁴⁴

Community and family involvement

Engaging the wider community beyond the school strengthens the effects of school-based programmes⁴¹ and, like interactive delivery, is consistent with the social influence model. Community involvement increases young people's opportunities for communication and social interaction, including opportunities to develop positive relationships with adults, be they parents, teachers or other community members.³⁹ Where parents or other community members are actively involved in programmes, they are exposed to the same health-behaviour messages as younger participants and, if they accept those messages, can reinforce them through their own actions, behaviours and attitudes. The consistency of what children learn in school with their experiences outside school may, therefore, increase,⁴⁶ for example in the rules their parents set around drinking or the vigilance of alcohol vendors.⁴⁷

Involvement of pupils' families in school life is part of schools' core business^{48,49} and may be more important than other aspects of community engagement in alcohol misuse programmes.⁵⁰ In the UK, the National Institute for Health and Care Excellence (NICE) recommends that schools involve families in alcohol education initiatives.^{34,51} Dimensions of family functioning such as parenting operate as key protective and risk factors for later alcohol misuse by young people.^{29,31,32,52–54} The family environment plays an important role in shaping young people's attitudes and behaviour towards alcohol, including the timing of first use.^{29,55,56} Parental norms and examples may encourage children's early alcohol use through providing models of alcohol consumption⁵⁶ or easy access to alcoholic drinks. Parental rules relating to alcohol are also an important factor,⁵⁷ but the sharing of values within a trusting parent–child relationship is more effective in preventing antisocial behaviour than formal rule-setting and surveillance by parents.⁵⁸

Despite the importance of parent participation being widely noted, programmes continue to be designed with no parent component (see *Appendix 1*). Meanwhile, those that do try to involve parents, be they community or school based, have experienced significant challenges in recruiting and retaining parents. Community-based interventions commonly seek to strengthen parenting skills, for example the Chicago Parent Programme for low-income parents of 2- to 4-year-olds. This programme recruited parents through day-care centres, but only 31% of those eligible in intervention centres enrolled; the most frequent reasons for not enrolling were being unaware of the programme, being too busy or the programme conflicting with work/school schedules.⁵⁹ Retention often proves equally problematic. When Incredible Years, a parenting programme for parents of 2- to 10-year-olds, was implemented in one English city, 38% of enrolled families never attended a session, and even after efforts to improve retention this only fell to 30%.⁶⁰ School-based programmes have experienced similar problems and low levels of engagement are common.^{31,61} Even when school-based programmes have been modified to increase levels of parental involvement, poor engagement has persisted.^{62–64} In the Blueprint Programme for drug prevention in English secondary schools, for example, attendance of parents at the programme launch in phase 1 schools was only 16% of those invited and, despite revised and more intensive recruitment strategies, attendance fell to < 10% in phase 2 schools.⁶²

Factors which affect parent participation in community and school-based prevention programmes include practical barriers such as programme timing and travel arrangements;^{65,66} programme length and location;⁶⁷ parent beliefs about their child's susceptibility to problematic behaviours;⁶⁷ and sociodemographic characteristics such as educational background.^{68,69}

While reaching families at higher risk of alcohol misuse problems is important, accurate identification of such families is often challenging, and programmes targeted at families on the basis of risk may stigmatise attendance, thus affecting take-up.^{70,71} Universal programmes are less likely than targeted interventions to deter parents, and, ideally, will reach families at higher risk from alcohol misuse while avoiding stigmatisation. Because alcohol consumption is a part of everyday life in the UK, a universal programme is relevant to everyone because they either drink alcohol themselves or are exposed to

the effects of others' alcohol consumption. From near-abstinence to alcohol dependence, drinking is associated with a continuum of alcohol-related risk. A universal programme can potentially significantly reduce the overall prevalence of alcohol-related harm by shifting the distribution of risk.⁷² Patterning of take-up is a possibility, however, and care is needed to ensure that universal programmes fully cover the spectrum of risk. In terms of implementation in schools, a programme delivered to a whole class or year group is likely to cost no more than identifying and targeting a smaller group.

In addition to being consistent with the social influence model, parent participation in alcohol misuse programmes is also compatible with the social development model (SDM), a theory of antisocial behaviour upon which KAT draws.

The social development model

In terms of aetiological theory, the SDM supports the view that parental involvement should be a key principle of intervention theory. In addition to the general model, the SDM incorporates four key age periods, showing how social influences expand over time beyond the family environment to include school and peer influences and legal sanctions through the preschool period and (US) elementary, middle and high school periods.⁷³ By high school, peer norms, classroom management, school policies and legal sanctions are influential in addition to the family.

The SDM has predicted alcohol misuse in young people⁷⁴ and interventions such as the Seattle Social Development Project in the USA and Preparing for the Drug Free Years, which operationalise the model, have achieved reductions in alcohol misuse.^{75,76} The SDM proposes that young people learn social behaviour through interactions with others, resulting in the formation of attachments which, if strong, can have a lasting effect on behaviour through supporting the acquisition of skills and influencing norms and values.⁷⁷ Attachment to others who offer opportunities for and reward prosocial behaviour is a protective factor against antisocial behaviour.^{73,78,79} Thus, involvement of both parents and children in interventions may increase the quality and frequency of parent-child interactions.

Pre-adolescent children who are still highly dependent on their parents will usually have more opportunities for interacting with and forming attachments to their parents than when they enter adolescence and develop a social life outside the home. Social influences expand over time beyond the family environment to include school and peer influences and legal sanctions.⁷³ Thus, a further implication of the SDM for intervention theory is that programmes involving parents and children will be more likely to succeed if they are based in primary rather than secondary schools. Intervention earlier in the life course is also supported by evidence that programme effectiveness is enhanced by involving young people who have not yet adopted the targeted behaviour(s).^{39,53}

The SDM also explains why interactive delivery methods and other features of the social influence model have been identified as elements in more effective preventative programmes. According to the SDM, initiation of social interactions depends on people perceiving that there is an opportunity for them to get involved with someone or some activity around them. That is, they see that interactions are relevant to, and intended for, themselves, and that they are competent to take part. Prevention programmes using interactive methods will boost opportunities for prosocial interaction. Perception of opportunities for social interaction is influenced by social structural factors (socioeconomic status, age, sex and race⁷⁸), suggesting that programmes should include features which are acceptable to all social groups in the target population and which enhance participants' confidence and skills.

Strength of the evidence base

Gaps remain in the knowledge base for alcohol misuse prevention, particularly in countries outside the USA, where most programme development and evaluation has been conducted. This was borne out in a recent Cochrane Library systematic review of school-based programmes which identified 53 randomised trials, 41 of which were conducted in North America and none in the UK.⁵⁰ Promising programmes from the USA may require adaptation and further evaluation when used elsewhere,^{80,81} to ensure that both

aetiological and intervention theories are appropriate for participants with different cultural values and customs. While reviewers are clear that several programme components are needed and that components work together to increase effectiveness, the large number and variety of programmes, the relative rarity of long-term outcome evaluation (e.g. see the range of interventions and follow-up periods in *Appendix 1*) and systematic adaptation complicate efforts to understand the essence of effective prevention.⁵⁰ Lastly, most evidence relates to older age groups because relatively few interventions have been based in primary schools,^{31,82} despite the SDM indicating that programmes for younger children may be efficacious. Furthermore, most primary school programme evaluations use aggressive behaviour as a precursor to alcohol use as their primary outcome, as their follow-up of participants is not long enough to measure impact on alcohol use in adolescence.⁸²

An urgent priority in improving the evidence base is to identify and develop effective methods of engaging parents in prevention programmes. As outlined above, while the importance of family-based protective factors for alcohol misuse is widely recognised,^{29,32,52} knowledge remains limited regarding effective mechanisms for engaging parents in prevention programmes, particularly those that are school based, and differences in programme reach and acceptability between different socioeconomic groups.^{83–86}

Kids, Adults Together

Anecdotal evidence that some prevention programmes have attracted large numbers of parent participants is not well supported by detailed accounts of percentages or mechanisms of engagement. One such programme was the Parents, Adults, Kids Together (PAKT) programme in Victoria, Australia.⁸⁷ PAKT was designed as a family drug education forum prepared by children aged 10–12 years in class and presented to their parents after school. The forum was delivered in addition to existing school drug-education work. A police community safety officer from Wales visited Australia to see PAKT in action and subsequently adapted it for use in south-east Wales, specifically for prevention of alcohol misuse. An advisory group developed a teacher's pack for the classroom work and Gwent police commissioned a digital versatile disc (DVD) for distribution to participants. The adapted programme was called Kids, Adults Together Family Forum, subsequently shortened to Kids, Adults Together or KAT, and piloted in two primary schools in Gwent, with the police officer presenting the family events.

Kids, Adults Together integrates specially designed classroom activities with a family education evening and a DVD to promote prosocial communication. The programme design addresses key factors affecting parental engagement and is promoted to parents as an opportunity for them to learn about the work their children have been doing in class, rather than as an educational evening about alcohol misuse. To encourage take-up by schools and parents, KAT is of much shorter duration and intensity than other such interventions; the Strengthening Families Programme 10–14 (SFP10–14), for example, requires parents to attend seven weekly 2-hour sessions.⁸⁸ A shorter approach is supported by evidence that brief interventions can be as effective as longer interventions in older adolescents.⁸⁹

An evaluation at the development stage⁹⁰ found that KAT had important features previously identified in more effective interventions. Interactive delivery methods are used throughout, and it is based in primary schools, where most children have not yet become regular drinkers. The early timing of programme delivery and the programme content were acceptable to parents, children and school staff. *Figure 1* illustrates how KAT incorporates three crucial aspects of the causal pathways to prosocial behaviour contained within the SDM: (1) the creation of opportunities for prosocial interaction between and within families; (2) the strengthening of the necessary skills which parents and young people need to communicate about alcohol-related issues; and (3) the encouraging of parents to reward and reinforce prosocial behaviour and attitudes in relation to alcohol.⁹¹ Crucially, the programme succeeded in involving 40–50 adult family members in the family events at both schools.

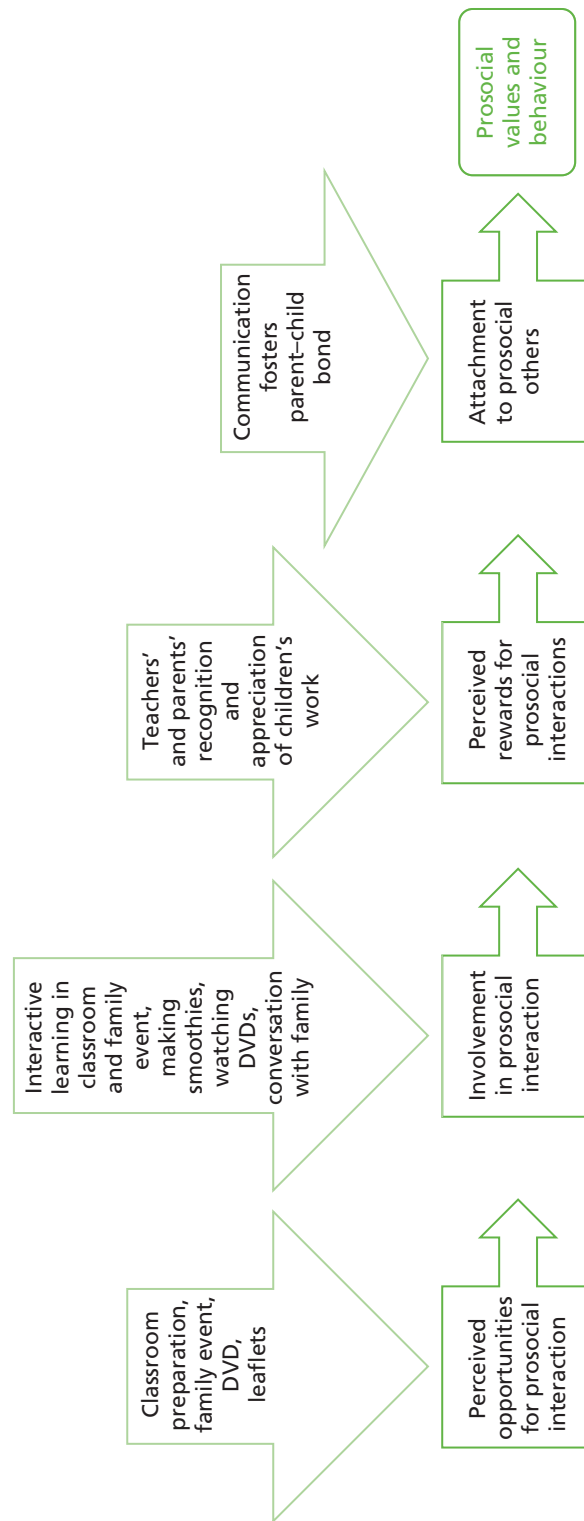


FIGURE 1 How KAT maps on to the SDM. Reproduced with permission from Segrott *et al.*¹

Aims and objectives

Findings from the evaluation at the development stage were promising,⁹⁰ but questions remained about the acceptability and feasibility of KAT across a larger number of schools; its reach across social groups; and its effectiveness in preventing alcohol misuse. In line with the Medical Research Council (MRC) evaluation framework for complex interventions,³⁵ it was, therefore, appropriate to move forward to an exploratory trial, the aim of which was to further develop and evaluate KAT in a larger number of schools in order to determine the value and feasibility of conducting a definitive effectiveness trial.

Specific objectives are listed below and pertained to the level of the individual participant, the family, the cluster or all three:

1. to refine the theoretical model and outcome pathways of the intervention (all)
2. to assess the feasibility and acceptability of the intervention (all)
3. to establish intervention participation rates and reach, including equality of engagement across socioeconomic groups and localities (all)
4. to assess trial recruitment and retention rates (individual and school)
5. to identify potential effect sizes that are likely to be detected as part of a definitive trial and an appropriate sample size (individual and school)
6. to determine the feasibility and cost of the proposed methods for measurement of the primary and secondary outcomes (individual and school)
7. to identify the costs of delivering KAT, and to pilot methods for assessing cost-effectiveness as part of a future definitive trial (school); and
8. to determine whether or not to proceed with a definitive trial (individual and school).

This exploratory trial was, therefore, not assessing the effectiveness of KAT, but testing the feasibility of the intervention and the trial methods. The logic model for the exploratory trial is shown in *Table 1*.

The objectives are those of a Phase II trial described in the MRC framework for evaluation of complex interventions⁹² as:

- acceptability and feasibility, including optimising the intervention and study design
- defining the control: in this study, examining the acceptability of 'usual practice' in control-group schools
- designing the main trial: in this study, noting the relevance of findings to the design of any future effectiveness trial and estimating sample size
- outcomes: piloting measures which could be used in the main trial.

The study presented an opportunity to scrutinise two pertinent methodological issues:

- family communication measures appropriate for 9- to 11-year-olds; and
- criteria for progressing to an effectiveness trial.

Measures of both general family communication and family communication about alcohol were required for the study. While validated measures for both exist,⁹³⁻¹⁰² they have been developed with adolescents (usually 12 years and/or older) and their acceptability and validity for younger children and their parents is unclear. The lack of communication measures likely reflects the fact that programmes targeting the late primary school years are less common. An opportunity, therefore, arose in KAT to use some of the measures developed for older children in 9- to 11-year-olds, to evaluate their acceptability and, if appropriate, to suggest adaptations.

TABLE 1 Logic model of KAT exploratory trial

Outputs		Study outcomes		Medium term	Long term
Inputs	Actions	Participants	Short term	Medium term	Long term
<ul style="list-style-type: none"> ● Research staff and funding ● Education consultant ● KAT programme materials ● KAT logic model <p>... will enable us to ...</p>	<ul style="list-style-type: none"> ● Recruit and randomise schools ● Recruit parents and children ● Develop and pilot research tools ● Visit schools ● Write letters and information sheets for participants ● Observe KAT delivery ● Interview parents and school staff ● Conduct baseline and follow-up questionnaire surveys ● Hold focus groups with pupils ● Monitor costs ● Analyse data <p>... with ...</p>	<ul style="list-style-type: none"> ● Four control schools ● Four intervention schools ● Pupils and parents from each school <p>... in order to achieve ...</p>	<ul style="list-style-type: none"> ● Effective relationships with schools ● KAT classwork ● KAT fun evenings <p>... which will enable us to ...</p>	<p>1. Estimate:</p> <ul style="list-style-type: none"> i. for KAT programme: <ul style="list-style-type: none"> – quality of programme delivery – reach, including equality of engagement across socioeconomic groups and localities – acceptability ii. for study: <ul style="list-style-type: none"> – participant recruitment and retention rates (cluster and individual) – feasibility and acceptability to participants of measuring (1) age of alcohol consumption initiation (pupils); (2) past month alcohol consumption frequency (pupils); (3) past-month drunkenness (pupils); (4) prosocial communication in families (pupils and parents); (5) parental drinking behaviours (parents); and (6) socioeconomic status and educational background (pupils and parents) – potential effect sizes that are likely to be detected as part of an effectiveness trial and an appropriate sample size – feasibility and cost of the proposed methods for measurement of the primary and secondary outcomes 	<p>1. For KAT programme:</p> <ul style="list-style-type: none"> i. refine KAT logic model ii. identify optimal delivery structures and systems for the KAT programme <p>2. For study:</p> <ul style="list-style-type: none"> i. determine whether or not to proceed with designing an effectiveness trial
				<p>2. Pilot methods for assessing cost-effectiveness as part of a future effectiveness trial</p> <p>... and use these findings to ...</p>	

The MRC guidance on developing and evaluating complex interventions recommends a systematic and phased approach which moves through literature review and theory development to pilot studies, exploratory trials and finally definitive (effectiveness) evaluations.³⁵ While the guidance is a welcome acknowledgement of the role and importance of exploratory trials, it neither provides comprehensive advice on how to conduct such trials nor describes the hallmarks of a 'good' exploratory trial. Detailed reports of exploratory trials of complex interventions in public health are beginning to emerge and these provide valuable insights,¹⁰³⁻¹⁰⁵ but detailed guidance on the design, analysis and reporting of exploratory trials remains absent.

One crucial area yet to be addressed in the literature is the decision that arises at the end of an exploratory trial on whether or not to recommend proceeding to a full effectiveness trial. This is a core purpose of exploratory trials, yet there are no precedents in the literature to guide the development of criteria upon which to make an objective decision. There were three key areas to consider in relation to KAT. First, whether or not structures and capacity were in place in schools and among the practitioners (police) who would support schools (through training and compering the family events) to implement the programme on a wide scale. Second, whether or not a randomised controlled trial (RCT) design using the piloted measures of family communication and pupil alcohol consumption would be an appropriate and acceptable method to evaluate KAT in an effectiveness trial. Finally, whether or not the intervention appeared to work as planned in schools (in a range of socioeconomic settings) (and in line with its logic model), and the extent to which it was acceptable to school staff, pupils and parents/carers. Criteria had to be developed to ensure that an objective and transparent decision was made at the end of this study. Reporting this process addresses an important gap in the literature and will possibly be of value to others conducting exploratory trials of complex interventions. *Chapter 2* includes a description of how the criteria were developed and assessed (see *Health economics*).

Study design

An exploratory cluster RCT was used to evaluate KAT. A RCT is the most robust design available to obtain an unbiased estimate of a potential effect size, even with a complex intervention in a 'real-world' setting such as schools.¹⁰⁶ As an intervention delivered in the classroom, randomisation at the level of the individual child was not appropriate, and so schools were chosen as the unit of randomisation.

Because it was originally anticipated that programme delivery as part of the trial would need to take place before the outcome of a funding decision on our grant application, we did not request funding to cover recruitment of schools, parents and pupils, or baseline data collection. Recruitment and baseline data collection, therefore, took place before the start of the funded study. While the main trial was funded by the National Institute for Health Research (NIHR), a nested process evaluation was conducted by a PhD student from the Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement (DECIPHer). The process evaluation assessed implementation processes, fidelity and acceptability to families and schools. Qualitative methods, described in *Chapter 2*, were used to capture the experiences and perspectives of those delivering and receiving the intervention. A summary of key findings from an interim analysis is presented in *Chapter 3*.

Public and stakeholder involvement

The involvement of children, and stakeholders from the police, education, public health and national government has been integral to both KAT and this exploratory trial. Their involvement has included the development and piloting of KAT and development of the pupil questionnaires. Public and stakeholder involvement is fully described in *Chapter 2*.

Chapter 2 Methods

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Research design

The study is a parallel-group cluster exploratory trial, with an embedded process evaluation. Schools were the unit of randomisation and were randomly assigned to intervention and control in a 1 : 1 ratio. *Figure 2* provides a summary of the study.

The funded study lasted 14 months. Each child in the study was asked to complete two questionnaires: one at baseline and another approximately 4 months past baseline. Programme delivery in intervention schools took place immediately after baseline data collection. Children in intervention schools were also invited to take part in focus groups following the family events. Parents/carers who took part in the study participated in one telephone interview approximately 6 months post baseline, and parents of children in intervention-group schools also participated in interviews as part of the study's process evaluation.

Ethical approval was given by the Cardiff School of Social Sciences Research Ethics Committee (SREC reference SREC/697). Amendments to the protocol were approved by the Trial Management Group; recorded; and communicated to the NIHR programme manager and the chair of the Research Ethics Committee. Because of delays in school recruitment, the interval between baseline and follow-up pupil questionnaires was changed from 6 months (stated in the original protocol) to 4 months, so that follow-up data collection could be carried out before the end of the summer term, when Year 6 pupils would be leaving their primary schools. Although this change was made for pragmatic reasons, it did not present a barrier to assessing the feasibility of measuring outcomes, which was a central aim of the evaluation. *Process evaluation* gives a detailed account of process evaluation methods.

The intervention

Kids, Adults Together has three main components: (1) classroom work (delivered by teachers) on the effects of alcohol consumption, and preparation for a family event; (2) the family event, delivered in school, and involving children and parents in activities addressing key health messages around alcohol; and (3) a 'goody bag' to take home, containing fun items, educational leaflets and an educational DVD for families to watch together.

Development

The first pilot study⁹⁰ theorised the function of each KAT component using Valente's framework of exposure, knowledge and attitudes, and practice.¹⁰⁷ There was evidence that each component had set off family communication which could mediate later drinking behaviour through parental regulatory practices (*Figure 3*). Viewing the DVD at home (and, as originally intended, on national television) had the potential to sustain, over a longer period, the immediate impacts of a short intervention. All of the components were thought to be necessary because of their cumulative effect: the classroom preparation led into the family event; the goody bags with the KAT badging and contents were physical reminders of the programme in children's homes; and the DVD was particularly important for impact in the longer term.

The first pilot study also established the importance of the classwork component in attracting parents to the family events. Children's eagerness to show parents their work and parents' status at the family events as proud supporters of their children were powerful factors in securing parental participation in the programme and were likely to be constant across different school contexts.

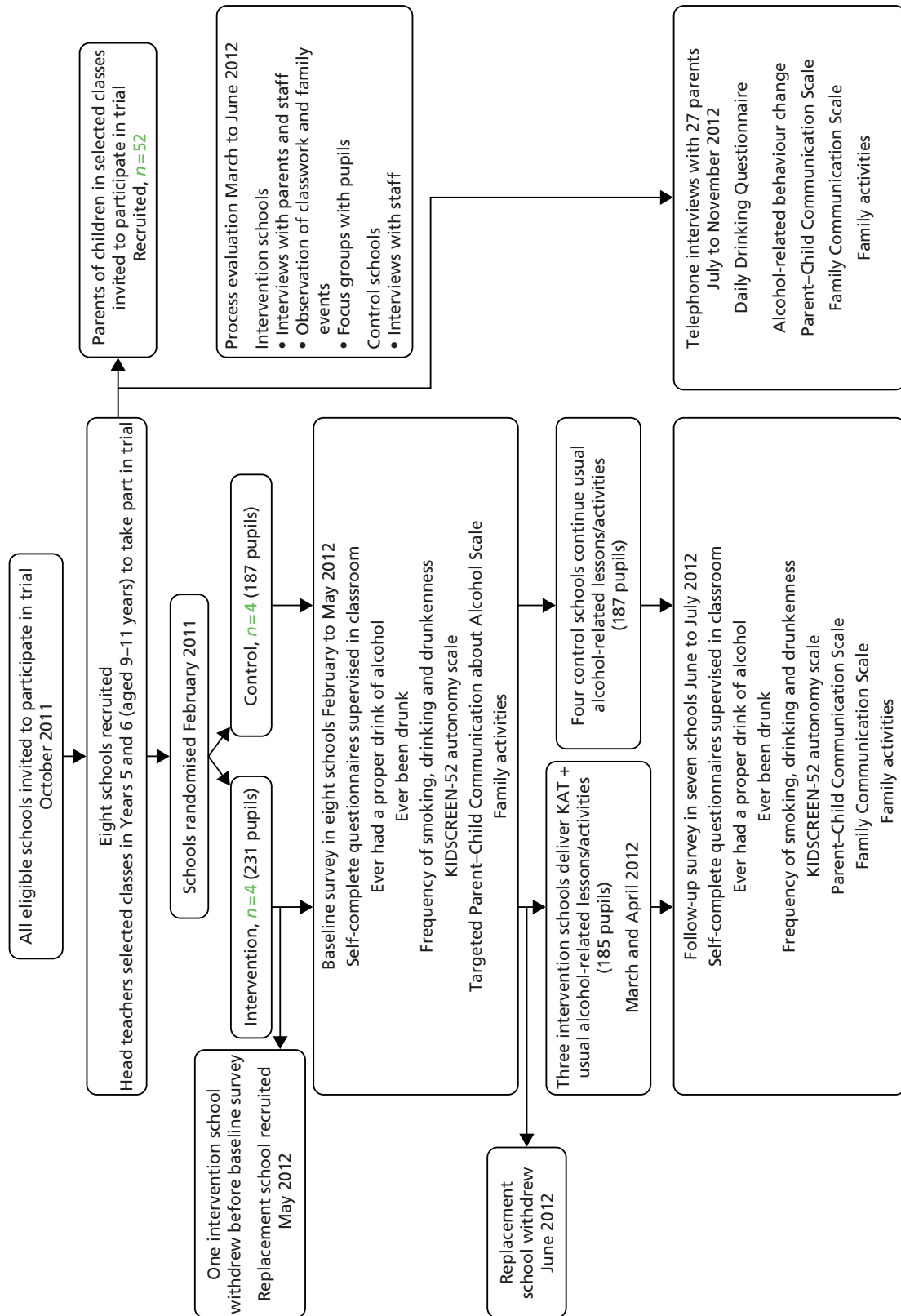


FIGURE 2 Research design.

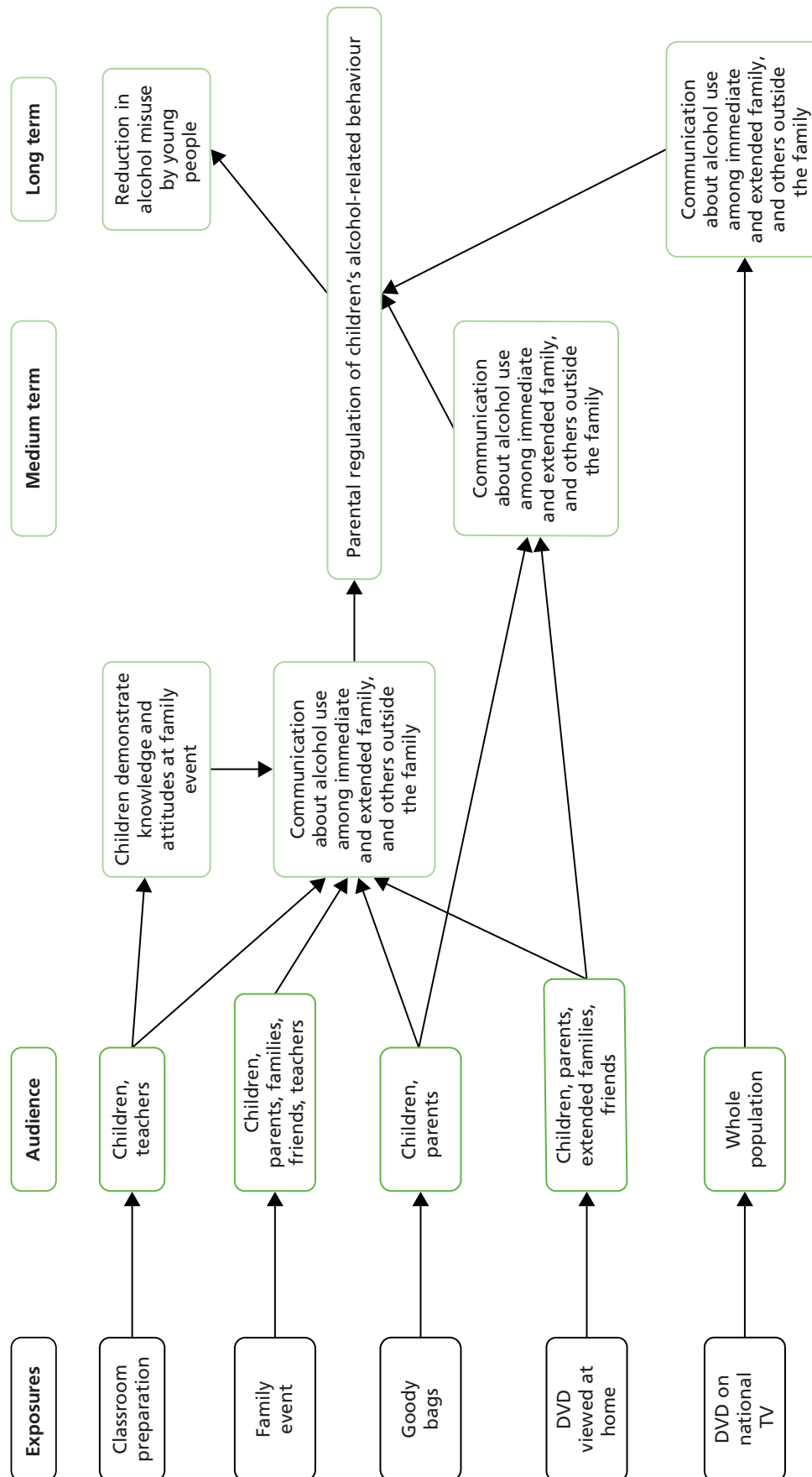


FIGURE 3 How KAT is expected to achieve its long-term aim. TV, television.

A further pilot study in 2011 focused on refining the materials provided to schools. An independent health education consultant employed by the research team modified the teachers' handbook which had been developed for the earlier pilot study, clarifying the aims, learning outcomes and links to the curriculum for each lesson/activity and providing supporting information such as a timetable for the family event and a list of suggested questions for a quiz. As part of this work, the programme was implemented in two schools outside the trial area (one school which had previously implemented the programme, and one with no prior involvement) and feedback from staff, pupils and parents drawn upon. The number of suggestions for classroom activities in the teachers' handbook was reduced and teachers were encouraged to choose their own way of achieving programme aims. That is, they had freedom (within limits) to alter the form of the activities, as long these still performed the same function.¹⁰⁸ The handbook included contact details of alcohol support services, and schools were encouraged to request one of them to attend the family event to facilitate contact between agencies and families needing support.

Implementation

The intervention was administered at cluster level (schools) and consisted of the KAT programme in addition to any existing alcohol-related lessons/school activities.

Kids, Adults Together requires approximately 1 week's total classroom contact time (or around 20 hours). Classroom preparation for children was planned to take place over at least 1 week, with flexibility for schools to take longer according to, for example, the timing of the family event and the needs of the class. The KAT family event lasts about 1 hour and the contents of the 'goody bag' may be used by children and their families over an indefinite period.

Following baseline data collection in all schools, the health education consultant asked to visit all intervention schools to train teachers whose classes would be involved and to provide information about the programme to any other relevant members of staff. Staff training covered the key points in the KAT handbook and staff were also given a Microsoft PowerPoint (Microsoft Corporation, Redmond, WA, USA) presentation for use at the family event; appropriate information from websites, downloaded and photocopied; and Tacade's *Keys to Alcohol for Children Aged 7 to 11 Years Old* resource.¹⁰⁹ Teachers were asked to ensure that support would be available for children who might be distressed by the topic (although this should usually have been in place to back up the usual alcohol-related curriculum content).

Evidence gathered during the pilot¹¹⁰ suggested that school staff would modify KAT in order to achieve programme aims and objectives in ways they thought would be more appropriate in the context of their own schools. The process evaluation included observation of classroom work so that analysis of any such adaptations could inform future programme development and evaluation.

The four schools randomised to the control group did not receive KAT, but continued with their usual activities, including any classroom work/school activities on alcohol. Process evaluation interviews with staff in control schools identified normal practice in relation to both substance education and structures for involving parents in school life.

Recruitment of schools

All English-medium primary schools ($n = 39$) in Newport County with Year 5/6 classes were invited to participate in the trial. Letters were sent to all 39 schools, inviting them to participate in the research, and telephone calls were then made to each school until eight schools had agreed to participate. The letter (see *Appendix 2*) sent to schools was drafted with input from the education consultant and the Healthy Schools Team in Newport. A member of staff from the Healthy Schools Team also accompanied the research team at some of the initial meetings with interested schools.

Recruitment of pupils

In each school, a member of the research team visited the classes which it had been agreed would participate in the trial. The researcher explained the study to the pupils, described the proposal to involve them in the study and answered any questions they had. All pupils in the class were provided with age-appropriate participant information sheets (see *Appendix 3*). Teachers were asked to ensure that pupils who were absent on the day of the visit received a copy of the participant information sheet.

Recruitment of parents/carers

Owing to data protection regulations, it was not possible for the research team to access names or any contact details of parents/carers of pupils who had been invited to participate in the trial. We therefore prepared a letter (which began 'Dear parent/carer') which we asked schools to send by Royal Mail to all parents/carers of pupils in those classes which were participating in the trial (see *Appendix 4*). This letter was accompanied by a participant information sheet (see *Appendix 4*). The letter asked parents/carers to return a reply slip to the research team if they were interested in participating in the research.

A follow-up letter to parents/carers was sent home via 'pupil post' (i.e. pupils were asked to take the letter home and show it to their parent/carer) approximately 1 week after the initial letter.

Parents who returned reply slips indicating that they would like to take part in the research telephone interviews were contacted by a member of the research team to check contact details and ascertain the best time to conduct a telephone interview.

Consent

Consent from head teachers for school participation was obtained before randomisation, and consent from children and parents as individual participants was sought after randomisation, with allocation revealed to both cluster and individual participants. Each head teacher signed a formal commitment form (see *Appendix 5*) for their school to take part in the study. The commitment form described the roles and responsibilities of the school and the research team, respectively, during the research period at the school.

The study tested the feasibility and acceptability to schools of using 'opt-out' parental consent to develop recruitment and data collection systems which would maximise response rates and minimise selection bias.^{111,112} The use of 'opt-out' consent methods is more effective than 'opt-in', which often results in sample sizes which are too small to power a RCT.¹¹²⁻¹¹⁴ Approval for the use of 'opt-out' consent was obtained from the ethics committee which had reviewed our study. At each school, we explained our preference to use 'opt-out' parental consent, but head teachers were able to stipulate that 'opt-in' consent should be used, and schools could participate in the study regardless of their preferences concerning parental consent. None of the schools raised any objections to us using 'opt-out' consent procedures, and this method was, therefore, used in all participating schools.

Approximately 1 week after the second letter was sent to parents, a member of the research team visited the class and asked those pupils who were willing to participate to complete a written questionnaire. An assent form for completion by pupils was attached to the front of each questionnaire.

Each potential parent participant was sent an information sheet, a booklet to assist them during telephone interviews and a consent form (see *Appendix 6*). They were requested to complete the consent form and return it in a prepaid envelope to the research team.

Individual teachers were asked to give informed consent to take part in the research. School and individual participants could withdraw at any time, without giving a reason, by informing the principal investigator or study manager that they did not wish to continue.

Inclusion/exclusion criteria

Primary schools which included Years 5 and 6 and taught through the medium of English were eligible to take part in the research. Welsh-medium schools and those with infant classes only were excluded. In each participating school, all children in Year 5 and Year 6 classes were eligible. Head teachers were encouraged to involve as many classes as possible, but were allowed to select which classes should take part, because we were interested in understanding how schools' preferences would shape the likely cluster sizes as part of a future effectiveness trial. *Table 2* gives details of numbers of classes taking part in intervention and control schools. A number of the schools had mixed year-group classes, and we allowed those with Year 4/5 classes to participate in the trial.

Where parents/carers or children refused consent for children's participation, these children did not participate in the trial. Children who were absent at both baseline and follow-up data collections and parents who were unable to communicate in English or who did not return their contact details did not participate in the trial. In intervention schools, all children in participating classes received KAT whether

TABLE 2 Classes selected by head teachers to take part in the KAT study: trial arm, year group, reason for selection (where known) and proportion of total number of eligible classes taking part

School	Trial arm	Classes selected, <i>n</i>				Total classes selected, <i>n</i>	Total classes eligible, <i>n</i>	Eligible classes taking part, %	Reason for selection
		Year 4/5	Year 5/6	Year 5	Year 6				
3	I	1	1	0	0	2	2	100	All eligible classes involved
4	I	0	0	0	2	2	5	40	All Year 6 involved; Year 5 not selected because of impending inspection and demands on staff time
6	I	1	0	1	1	3	3	100	All eligible classes involved
8	I	0	0	2	0	2	4	50	All Year 5 involved; Year 6 not selected (reasons unknown)
Total (%) in intervention group		2	1	3	3	9	14	64	
1	C	0	0	2	0	2	4	50	All Year 5 involved; Year 6 not participating as have already done SM work this year, and also practical considerations
2	C	0	1	0	0	1	1	100	All eligible classes involved
5	C	0	3	0	0	3	3	100	All eligible classes involved
7	C	0	0	1	0	1	2	50	Year 6 not included – reasons unknown
Total (%) in control group		0	4	3	0	7	10	70	
Total (%) in both trial arms		2	5	6	3	16	24	67	

C, control; I, intervention; SM, substance misuse.

or not they participated in the trial. KAT programme activities were integrated into their normal classroom work and their parents/carers were invited to attend the KAT family events. Head teachers in all participating schools, and parents and teachers of children in the relevant classes at intervention schools, were invited to take part in process evaluation interviews. Children in intervention schools also took part in focus groups.

Confidentiality

The chief investigator and the research team protected the confidentiality of participants in accordance with the Data Protection Act 1998.¹¹⁵

All focus-group participants were asked to treat the discussion as strictly confidential. In reporting the results of the process evaluation, care has been taken to use quotations which do not reveal the identity of respondents. Individual teachers at participating schools were assured that if they decided not to participate, their decision would be handled confidentially.

All data collected as part of the trial were treated as confidential and accessed only by members of the trial team; anonymised data have been used wherever possible. However, all participants were informed that if they disclosed information about neglect, abuse, serious suicidal thoughts or self-harm, we would pass this information on to an appropriate agency: their assent for this was sought prior to data collection. The study adhered to the Cardiff University policy on safeguarding children and vulnerable adults and to schools' own child protection policies. In each school, we also asked for guidance on which member of staff we could speak with if any children became upset during questionnaire completion or focus groups, and what procedures we should follow.

Measures

Key outcomes were the quality of programme implementation; recruitment and retention of research participants; and the acceptability and feasibility of research processes, including data collection methods. The study also assessed the feasibility and acceptability to children of providing demographic data and of answering questions measuring potential primary and secondary outcomes of any future effectiveness trial.

Table 3 lists outcome measures used with parents and children, and their function within the exploratory trial.

Questionnaire piloting

The MRC guidance on complex interventions encourages researchers to include user involvement in key phases of intervention development and evaluation, so as to maximise the relevance of research and the opportunities to implement findings.¹¹⁶ Further still, the involvement of the public in research has been advocated to ensure that research is relevant, reliable and understandable.^{117,118} Although the previous documents recommend involvement, they do not advise how to conduct public involvement and what issues should be covered.

As part of the trial, it was deemed most important to capture children's views on the questionnaires, particularly as some of the measures had been taken from studies of older young people (≥ 11 years old) (e.g. an ongoing trial of the SFP10–14).

TABLE 3 Potential primary and secondary outcome measures used with child and parent participants

Measure (potential primary outcomes in bold)	Children		Parents	Rationale	
	Baseline	Follow-up		Assess feasibility and acceptability	Assess potential effect sizes
Ever had a proper drink	✓	✓		✓	
Ever drunk	✓	✓		✓	
Drinking frequency	✓	✓		✓	
Drunkenness frequency	✓	✓		✓	
Smoking frequency	✓	✓		✓	
KIDSCREEN-52: parent relationship and home-life dimension	✓	✓		✓	✓
Targeted Parent–Child Communication about Alcohol Scale	✓			✓	
Family Activities Scale	✓	✓	✓	✓	✓
Parent–Child Communication Scale		✓	✓	✓	✓
Family Communication Scale		✓	✓	✓	✓
Change in alcohol-related behaviour			✓	✓	
Daily Drinking Questionnaire			✓	✓	

Source: reproduced with permission from Segrott *et al.*¹

Prior to baseline data collection, the pupil questionnaire was piloted in a school not involved in the study. A group of pupils from Year 6 (five boys and four girls) were asked to read through the questionnaire and to use a highlighter pen to indicate any questions, response categories or other text which was unclear or difficult to understand, and to mark with an 'X' any question that they thought people in their class might feel uncomfortable or unhappy about answering. The pupils were then asked to discuss their thoughts about the questionnaire.

In general, the pupils felt that the questionnaire content was acceptable and accessible. In response to pupils' comments about the sensitivity of questions concerning family structure and ethnicity, we made a number of changes to the baseline questionnaire. For example, in relation to questions on who participants lived with, we changed the closed questions with tick-box responses to an open question and invited participants to describe, using free text, who they lived with all or most of the time.

Children's follow-up questionnaires were piloted with 36 children in Year 5 at a school outside the study area. The children were divided into small groups, each of which commented on a different part of the questionnaire. Children were asked about the meaning of questions and answers, and the acceptability and difficulty of the questions. Any questions children did not understand were explained by the researchers, and children were further asked to give examples of how we should word the questions. In this second round of piloting, we specifically asked the pupils to explain to us what they thought individual questions meant so that we could ascertain that participants were likely to derive the correct meaning from them. Amendments were made to the questionnaire; for example, the majority of children did not understand the term 'peer pressure', so this was changed to 'pressure to use alcohol from other children who are about my age'.

The pilot was conducted during the school day, with each group spending about half an hour away from their class. Parents at the same school were invited to pilot the questions for telephone interviews but there were no volunteers.

Feedback to schools

Schools were offered a presentation on the KAT study at the end of the summer term in 2013. Two schools, both from the intervention group, accepted the offer. Presentation topics included information about research generally, the number of schools, children and parents who had taken part and some of the key findings. Parents were invited to both presentations but only two (both in the second school) attended.

Feasibility and acceptability of primary outcomes

The primary outcome for any future effectiveness trial was likely to be drinking initiation (at age 11–13 years). The age at which young people start drinking alcohol is strongly associated with later alcohol-related harm, and greater harm is related to earlier initiation.¹¹⁹ An intervention which delayed drinking initiation, therefore, could reduce the prevalence of alcohol-related health and social problems in the long term. At the exploratory stage described here, the aim of asking children about alcohol consumption was to understand its acceptability and feasibility for this age group. Drinking initiation was assessed by adapting a question from the Survey of Smoking, Drinking and Drug Use Among Young People in England in 2008.¹²⁰

Measures of two other key alcohol initiation behaviours, namely alcohol consumption frequency and drunkenness frequency, were also used. The relevant questions from the 2009 Health Behaviour in School-aged Children (HBSC) survey were used as measures in this study.¹²¹ The original item incorporates three questions measuring frequency of smoking cigarettes, drinking and drunkenness over the previous 30 days. The item on smoking was retained, in case any effectiveness trial might examine the intervention's impact on more than one risk behaviour.

These three measures were adapted from an earlier HBSC survey and the European School Survey Project on Alcohol and other Drugs (ESPAD) for the HBSC 2009 survey. The alcohol items had previously been used in the HBSC 2005–6 optional package. The alcohol questions have good consistency with other HBSC measures of alcohol use but the smoking question has not been validated. The wording of the questions was:

On how many occasions (if any) have you done the following things in the last 30 days?

- smoked cigarettes
- drunk alcohol
- been drunk.

(Never/1–2 times/3–5 times/6–9 times/10–12 times/20–39 times/40 or more.)

During baseline data collections, many children did not understand the term 'occasions'; the concept of '30 days' was troublesome for many; and those with low literacy had difficulty in linking the items in the list to the core question. Therefore, at follow-up the wording and response categories were adapted and a separate question was asked for each behaviour:

On how many days (if any) have you drunk alcohol in the last month?

On how many days (if any) have you been drunk in the last month?

On how many days (if any) have you smoked cigarettes in the last month?

(Never/1–2/3–5/6–9/10–12/13–19/20–29/every day.)

We also asked pupils a single question about whether or not they had ever been drunk, and adapted this question from the HBSC international survey of 11- to 15-year-old schoolchildren.¹²¹ The original question (p. 282) asked, 'Have you ever had so much alcohol that you were really drunk?' (no, never/yes, once/yes, 2–3 times/yes, 4–10 times/yes, more than 10 times). It has been used in six HBSC surveys and found to be correlated with other measures of alcohol consumption. In this study, because the prevalence of drunkenness is generally low among 9- to 11-year-olds, it was not considered useful to distinguish between different frequencies of drunkenness; and as the term 'really drunk' may not be commonly used by children in this age group, they were thought likely to question the term 'really'. Therefore, the question and response categories were simplified to read:

Have you ever had so much alcohol that you were drunk? (Yes/no)

Data on past-month frequency of drinking and frequency of drunkenness from 11- to 13-year-old pupils in the 2009 HBSC study in Wales were used to estimate prevalence of drinking in this age group as a basis for estimation of the sample size required for a potential future effectiveness trial. Data on rates of drinking among 11- to 13-year-olds from an ongoing trial of the SFP10–14 were also examined.

Feasibility and acceptability of secondary outcomes for a future effectiveness trial

We have proposed that the SDM⁷³ can explain how KAT is expected to prevent alcohol misuse through improving adult–child communication and, thus, promote the formation of attachments to parents or other influential adults. Adult–child communication appears to be an important secondary outcome and appropriate measures would be needed to test programme theory. Measures of opportunities for communication and the quality and quantity of interaction were therefore used in this study.

The SDM postulates that perception of opportunities for communication is a preliminary to communication taking place. The KIDSCREEN-52 subscale on parent relations and home life was used as a measure of children's perceptions of such opportunities at home. The Family Activities Scale and questions about the degree of involvement in KAT classwork and attendance at the family event were used to measure involvement in prosocial activity, assuming these also to be measures of the minimum number of participants who perceived such activities as opportunities which were relevant to them. We accept that there may have been some people who perceived KAT as a social opportunity but were prevented by other commitments from taking part.

Measures of family communication and of parent–child communication specifically about alcohol which could assess the quantity and quality of interaction taking place were also used. No measure of attachment was used because KAT is not aimed directly at increasing parent–child attachment but focused on earlier stages of the model. We speculate that in any future effectiveness trial, changes in scores for measures used at baseline (opportunities for, quality and quantity of communication in families) might be regarded as indicators of increased or decreased potential for attachment to a parent/caregiver. However, a more direct measure of attachment might be desirable for use in any effectiveness trial in which measures would be used to test the theoretical pathways hypothesised in the model. *Figure 4* illustrates the relationship of the measures to the KAT logic model and the SDM.

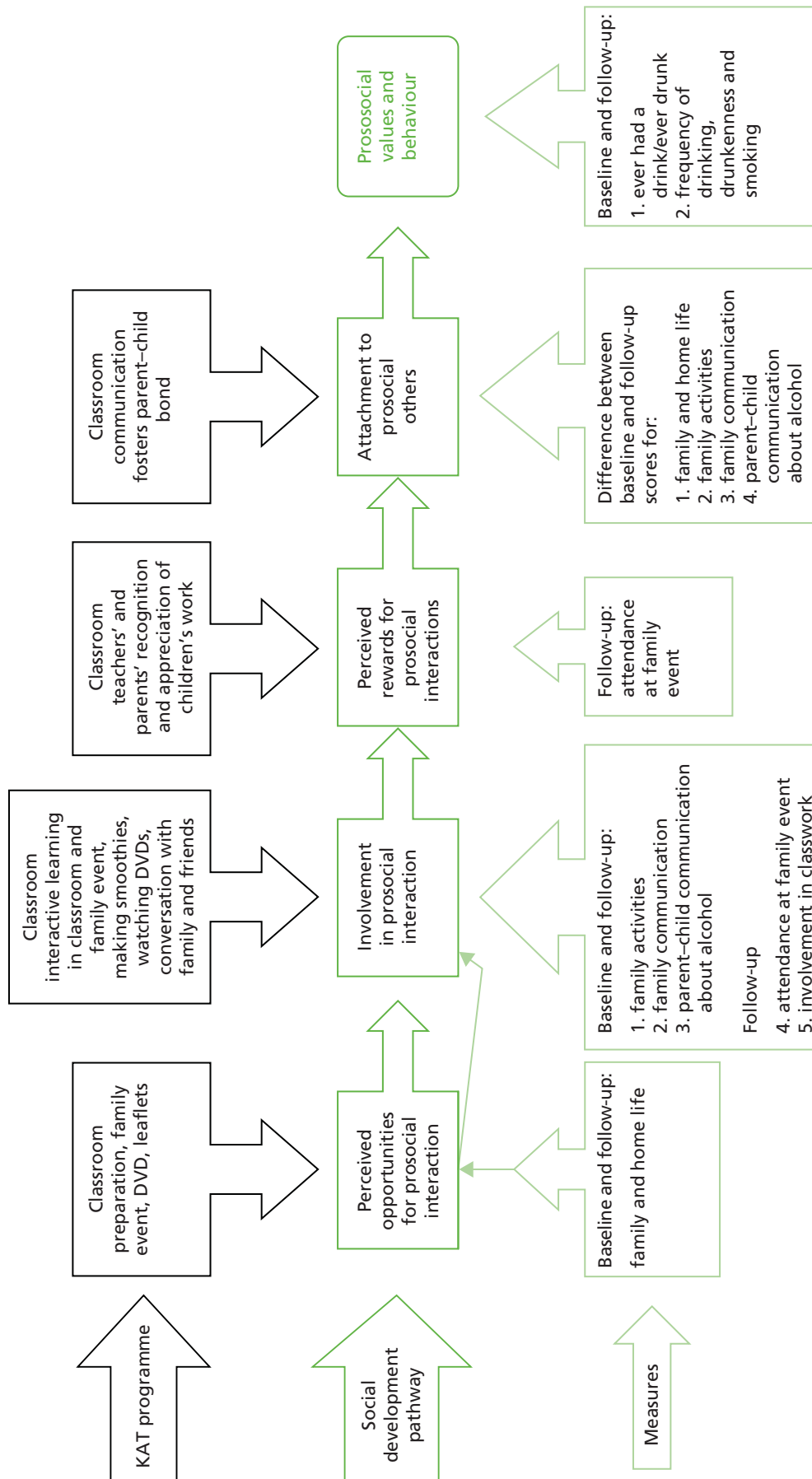


FIGURE 4 Kids, Adults Together programme activities and measures and their relationship to the SDM.

The main aim of this trial is to assess the feasibility of the communication measures, and they were expected to provide some indication of short-term differences between the groups which might be detected at follow-up in an effectiveness trial, probably falling short of statistical significance. We describe each of the measures below.

The Family Activity Scale formed part of the HBSC international survey of 11- to 15-year-old schoolchildren.¹²¹ There are eight items in the scale, which was used in baseline and follow-up questionnaires for children and parents. Participants are asked 'How often do you and your family usually do each of the following things?' followed by the list of potential activities, for example watching television (TV) or a video together (every day/most days/about once a week/less often/never).

The context for family communication was assessed with the **KIDSCREEN-52**¹²² Parent Relation and Home Life dimension, which measures the quality of children's home life, including parent/child interaction. KIDSCREEN-52 is a generic measure of children's health-related quality of life across 10 dimensions, each of which has been independently validated with European children aged 8–18 years and their parents. The parent and home life subscale includes items on the home atmosphere and the child's feelings towards parents/carers, each scored on a five-point scale (never/not very often/quite often/very often/always). In this study, question wording was adapted to facilitate responses from children who lived with adults other than parents, so, for example, 'Have your parent(s) understood you?' became 'Has at least one of the grown-ups at home understood you?'

The **Targeted Parent–Child Communication about Alcohol Scale (TPCCAS)**¹²³ measures general openness, frequency and, specifically, alcohol-related content of parent–child communication. Development of the measure was based on evidence that parent–child communication which was more protective against substance misuse not only involved open and frequent general communication but also specifically addressed the topic of substance misuse. As with the KIDSCREEN-52 measure, the wording was adapted by us to facilitate responses from children who lived with adults other than parents by substituting 'the grown-ups at home' for 'parents'. The scale was validated with US children aged 11–13 years, and, to facilitate responses from the younger children in this study, a separate question was asked for each item instead of presenting the scale as one question followed by a list. In addition, children were asked whether they agreed or disagreed with each statement instead of being asked to indicate the extent of agreement on a five-point scale, for example 'At least one of the grown-ups at home has warned me about the dangers of drinking alcohol' (agree/disagree); 'At least one of the grown-ups at home has talked to me about how to handle offers of alcoholic drinks' (agree/disagree), etc. Nevertheless, the questions presented difficulties for a substantial number of children at baseline and the scale was not used at follow-up.

The **Parent–Child Communication Scale (PCCS)**,¹⁰¹ which was used at follow-up in place of the TPCCAS, has been developed for use with parents and children to assess the nature of alcohol-related content in parent–child communication during the previous 6 months. Ten items are parallel in both questionnaires but the parent version has an eleventh question asking whether or not parents check the child's room or clothes for evidence of alcohol use, and measures frequency of communication. The scale was used in telephone interviews with 537 parent–adolescent pairs in a US longitudinal study across 48 states. Adolescents in the sample were aged from 12 to 15 years. This was not the first choice for the KAT study because of the three types of communication identified by the US researchers – relating to rules, consequences and media examples – rule-related communication appeared to be associated with a small increase in adolescent alcohol misuse and there was no evidence that the other types of communication were predictive of later alcohol-related behaviour. However, Ennett *et al.*¹⁰¹ point out that the timing of communication in relation to adolescent drinking initiation is likely to be an important influence on the impact of parent–child communication, and this factor was not accounted for in their study. More generally, imposition of rules by parents in the absence of reciprocity in the parent–child relationship has been found to be ineffective in preventing children's antisocial behaviour.⁵⁸ Thus, the scale was judged likely to be satisfactory when used with younger children, of whom a larger proportion would not have

initiated alcohol use, and when combined with measures of the home context and more general qualities of communication, as in this study.

With parents participating in the KAT study, the scale was used in an unmodified form. In the children's questionnaire, the wording of six items was revised in line with guidance from children who piloted the questionnaire; in addition, the format was changed from a single question followed by a list to a series of discrete statements. References to parents were removed as for other questionnaire scales and the 6-month recall period was not specified. For example, the questions in the original scale were:

During the last 6 months, how many of the (n) other people living in your house

... encouraged you not to use alcohol?

... talked to you about how they would discipline you if you used alcohol?

These became:

At least one of the grown-ups at home has said I should not use alcohol (true/not true).

At least one of the grown-ups at home has talked to me about what they would do if they found out that I had used alcohol (true/not true).

Response categories 'true/not true' were preferred to 'agree/disagree' following advice from a teacher present at a baseline data collection who said that some children might feel reluctant to 'disagree' because the word held strong oppositional connotations for them.

The **Family Communication Scale (FCS)**⁹⁵ evaluates respondents' satisfaction with communication processes between family members. It was included in parent and pupil follow-up questionnaires to supplement the PCCS (see above), which covered only the alcohol-related content of communication. It is uncertain whether KAT would work through alcohol-specific or more general communication, and so measures of both were piloted.

The FCS was developed from the Parent-Adolescent Communication Scale¹²⁴ which has previously been used to assess the role of parent-child communication in the pathways to adolescent drinking.⁹⁷ The FCS is briefer (10 items) and includes only the more predictive of the two subscales included in the earlier measure. It has been validated for use with both adolescents and their parents. In the parent interviews, the scale was used unchanged, for example 'Family members are satisfied with how they communicate with each other' (strongly disagree/generally disagree/undecided/generally agree/strongly agree). Scores are summed. Very high scores indicate that 'family members feel very positive about the quality and quantity of their family communication' and very low scores indicate that they 'have many concerns about the quality of their family communication'.

Children who piloted the follow-up questionnaire suggested some changes to the wording to facilitate responses from 9- to 11-year-olds. 'Family members' in the original was changed to 'the people in my family' throughout, and the vocabulary was simplified; for example, 'When angry, family members seldom say negative things about each other' became 'Even when they are angry, the people in my family hardly ever say nasty things about each other'. Following guidance from the children who piloted it, responses in the children's questionnaire were changed from the original five-point scale to 'true/not true' except for two items, for which the option 'sometimes true' was added.

Effect sizes detected in previous studies

We undertook a search for previous studies which had used these selected outcome measures, to identify what size of effect had been detected in evaluations of interventions comparable with KAT. We present the results of this search in *Chapter 3* [see *Effect sizes detected in previous studies (secondary outcomes)*].

Feasibility and acceptability of measuring changes in alcohol-related behaviour (parent telephone interviews)

Because evidence from our previous research on KAT¹¹⁰ suggested that adults might change their behaviour after participating in KAT, the following two questions were included to assess their feasibility and acceptability:

Thinking now about the last six months, has there been any change in your drinking habits (yes/no/don't know/rather not say)?

How have your drinking habits changed (drink more than I used to/drink less than I used to/drink a different kind of alcohol/drink in a different place/take measures to ensure drinking does not cause harm)?

We also used the Daily Drinking Questionnaire in our telephone interviews with parents/carers. This measure asks for details of a typical week, rather than exact quantities for the last 7 days, to ensure that it reflects habitual drinking. Although it has been developed for, and used mainly with, student populations^{125,126} we decided to assess its acceptability to parents because of its proven ability to detect post-intervention changes.

Demographic information

Measures of sex, age, ethnicity, socioeconomic status and (for parents) qualifications and employment were used to assess their acceptability to participants and comparability between intervention and control groups. For children, the Family Affluence Scale^{127,128} was used as a measure of socioeconomic status.

Holstein *et al.*¹²⁹ point out that the Family Affluence Scale measures family consumption rather than occupation, education and income, which are usually considered to constitute a more accurate measure of socioeconomic status. However, the scale has been developed for use in HBSC surveys because younger children had difficulty in answering questions about parents' occupations and because it measures more than one dimension of socioeconomic status. It was considered the best available measure for use with the children in our sample, some of whom are younger than the youngest taking part in the HBSC surveys and so may be considered even less likely to provide accurate data on parental occupation. The scale's validity and the suitability of the items are subject to continual review, and in our study the scoring used in the 2009–10 survey was used.¹²¹ The scale is composed of four items:

- Does your family own a car, van or truck?
 - [no (0); yes, one (1); yes, two or more (2)]
- Do you have your own bedroom for yourself?
 - [no (0); yes (1)]

- During the past 12 months, how many times did you travel away on holiday with your family?
 - [not at all (0); once (1); twice (2); more than twice (3)]
- How many computers does your family own?
 - [none (0); one (1); two (2); more than two (3)]

Participation in Kids, Adults Together

To assess reach, parents and children in the intervention group were asked about their own and other family members' participation in KAT. The process evaluation also examined this issue in order to provide information about parents' and children's motivation to participate and their response to the programme.

Scale scores

Methods for calculating scores for the following scales are described in *Appendix 7*:

- Family Activity Scale
- Quality of parent relations and home life KIDSCREEN-52 subscale
- PCCS
- TPCCAS
- FCS
- Family Affluence Scale.

Data collection

In addition to piloting the acceptability and feasibility of measures, the study aimed to identify optimal data collection methods and to assess their costs.

At baseline and 4-month follow-up, measures were collected through self-completion questionnaires by children who were present on the day of data collection in all classes participating in KAT, subject to their own assent and parents not refusing permission. Questionnaires were completed in classroom time, supervised by members of the research team. Researchers and school staff assisted children who had difficulties in reading or writing English. Some children who were absent at baseline completed follow-up questionnaires.

The original study protocol stated that the follow-up data collections in schools would be conducted at 6 months after baseline. However, delays in the early stages of the project meant that the interval between baseline and follow-up data collection was reduced to ensure that the latter took place before the school summer holidays, and before Year 6 pupils left their primary school. This change would be significant in a trial which aimed to measure effects. However, in the current exploratory phase it has not been a barrier to achieving the aims of establishing recruitment and retention rates (for intermediate outcomes), and has resulted in some learning about time scales to be considered in the design of any future effectiveness study.

Contact details of parents who volunteered to participate in the research were forwarded to trained telephone interviewers at Cardiff University, who conducted the interviews approximately 6 months post baseline. Personal interviews would not be a practical method to collect data from larger numbers of parents who would participate in any future effectiveness trial, and so the feasibility and acceptability of

telephone interviews were assessed by staff at the Participant Resource Centre (PRC) at Cardiff University. Calls were recorded (with the knowledge of interviewees) and responses were recorded on paper schedules during the interviews. Parents who completed interviews were given £15 gift vouchers.

Following baseline data collection, each participant was allocated a numerical identifier stored in an index list of study participant numbers and names held separately from the project data. At follow-up data collection, we gave each pupil a questionnaire which had their unique participant ID pre-printed on it. Pupils who had not completed baseline questionnaires (because either they had been absent from school/class or they did not want to complete the questionnaire) but wished to complete follow-up questionnaires were allowed to do so. All files were stored in secure password-protected folders with restricted access. Data from completed questionnaires and interviews were encrypted at the point of entry and stored in anonymised form, using participant identification numbers. PASW 18 (SPSS Inc., Chicago, IL, USA) software was used to store pupil questionnaire data, and parent data were stored in Excel (Microsoft Excel, Microsoft Corporation, Redmond, WA, USA). Ten per cent of questionnaires were selected at random from the electronic files and checked against the original paper questionnaires. The error rate was < 0.4% and the files were passed to the trial statistician for analysis.

During the study, we followed the Cardiff University Child Protection Guidelines.¹³⁰ As our data collection included issues relating to young people's alcohol consumption, and family relationships, it was important for us to be prepared for responses that indicated that a child (or other person) was at risk of harm or abuse. In such cases, as data were collected in schools, Cardiff University policy dictated that any child protection concerns should be communicated to the head teacher of the school in question. A number of questionnaire responses (as can be seen in *Chapter 3*) indicated that child participants had consumed alcohol or been drunk – either in the last 30 days or in their lifetime. This presented us with a challenge in terms of how to respond to such information. It was important that we preserved confidentiality wherever possible, but also shared any information that might indicate risk of harm with schools. In the case of alcohol use, it was not appropriate or ethical to simply report all cases of children's alcohol consumption to school staff. The law permits parents to provide alcohol to children aged ≥ 5 years within the family home, and so the consumption of alcohol by a child aged 9–11 years (as in this study) does not necessarily indicate illegality or parental irresponsibility. The measuring of alcohol consumption also raises challenges, in that, for instance, a child reporting having had a drink of alcohol could be referring to a whole drink or just a sip. The notion of drunkenness is subjective, and we, as adult researchers, and participants, being children, might have had very different understandings of the term. There was also clear evidence in our data (see *Chapter 3*) of inconsistent responses by pupils to alcohol-related questions. For instance, some participants reported drinking in the last month but also reported that they had never had an alcohol drink, and their responses also contradicted each other across data collection points. The ability to assess these reports was also made more difficult due to the fact that, unlike face-to-face interviews (where participants provide a response to the researcher), our questionnaire data were via written reports from pupils which were entered into the project database some time later. In many cases, children had moved schools, transferring to secondary schools at age 11 years.

Our approach to this issue was that reports of frequent drunkenness during the last month would constitute concern regarding the potential for an individual to experience harm, and would be shared. During data entry, significant concerns were raised regarding the responses of one child who answered 'yes' at both baseline and follow-up to the question 'Have you ever had so much alcohol that you were drunk?' Although this child answered 'yes' at baseline and 'no' at follow-up to the question 'Have you ever had a proper alcoholic drink – a whole drink, not just a sip?', they also reported in both questionnaires having drunk alcohol during the previous 30 days: on 3–5 occasions (baseline) and 6–9 days (follow-up). We complied with Cardiff University's Child Protection Guidelines¹³⁰ by following the policy of the relevant school and informing the teacher responsible for child protection.

Sample size

As this was an exploratory cluster randomised trial, no formal sample size calculation was carried out. However, in order to collect enough data to validate the outcome measures being tested and to calculate intracluster correlation coefficients (ICCs), eight schools were anticipated to equate to approximately 640 families, which with an estimated consent rate of 50% at baseline would achieve a sample of 320 families: 160 per group. No interim analyses or stopping guidelines were implemented.

Randomisation

The schools were stratified by size and free school meal (FSM) entitlement and these variables were used to balance the randomisation. The method of optimal allocation was used to determine the randomisation sequence. Here, a balance algorithm was used to provide a predefined sequence, and all schools were randomised jointly.^{131,132} The method was implemented in R statistical software (The R Foundation for Statistical Computing, Vienna, Austria) in the South East Wales Trials Unit (SEWTU) and the allocation was concealed until after recruitment and the start of the intervention. An independent statistician within SEWTU assigned schools to the intervention arm. During recruitment of schools in the autumn term of 2011, a pragmatic decision was made to randomise in advance of baseline data collection so that schools allocated to the intervention group would have time to plan for programme delivery in the spring term of 2012. As explained earlier (see *Chapter 1, Study design*), recruitment and baseline data collection took place before the start of the funded study and there was no capacity to finalise children's baseline measures until early 2012, by which time all schools in the study would have embarked upon their scheduled activities for the spring term.

Individual participants within schools were included according to complete class lists for Year 5 and 6 irrespective of attendance at KAT events and completion of group work. Pupils who were at school on the day of data collection were included in the study. Return visits to collect missing pupil data were not conducted owing to lack of capacity.

Statistical methods

In the context of an exploratory study, the main purpose of the statistical analysis was to assess the feasibility and acceptability of the measures used. Thus, an essential function of the analysis was to look for any pattern in the missing responses which might indicate respondents' unwillingness or inability to answer certain questions. Some of the measures of potential secondary outcomes which were tested in this study had previously been used with different populations (e.g. older children than the KAT sample, data collected in countries other than the UK), and in some cases we used subscales which belonged to larger measures. It was, therefore, important to assess the reliability of the scales, including those which it was necessary to adapt. For some of the scales, the scoring methods previously used also needed to be adapted.

Assessment of the reliability of questionnaire measures

Assessment of reliability was carried out using Cronbach's alpha for internal consistency and factor analysis for unidimensionality. Summed scores were created for each outcome scale. With previously validated scales, the outcome was used as directed in the manuals or scale references – either categorical (using validated cut-offs) or used as a continuous score. Where no guidance was given, the continuous data were used in the primary analysis and, if necessary, the categorical outcome was examined as a secondary analysis.

Analysis of future primary outcomes

All analyses were on an intention-to-treat (ITT) basis using all randomised participants in the groups to which they were randomised, regardless of the intervention received. However, missing data were not imputed, and so all analyses were carried out on complete cases. The primary outcomes were alcohol consumption and levels of harmful drinking and drunkenness at follow-up. Alcohol outcomes were analysed using two-level generalised logistic models. Responses from pupils were nested within schools fitted using models adjusting for baseline data where appropriate. The distribution of frequency of drinking and drunkenness in the last month was examined and it was determined that these ordinal categorical data were most appropriately collapsed into binary outcomes due to sparse data in higher categories. Covariates included in the models were those that were used to balance the randomisation (school size and FSM entitlement). While we acknowledge that a household-level cluster is present (siblings within a school), the number of these per school was very small and was not incorporated. As well as any differences between trial arms, estimates of ICCs at school level were reported.

Analysis of future secondary outcomes

Questionnaire outcome score data from pupils were analysed using two-level generalised linear models, with responses from pupils nested within schools fitted using models adjusting for baseline data. Covariates included in the model include those that were balanced on at randomisation (school size and FSM entitlement). As well as any differences between trial arms, estimates of ICCs and an indication of effect sizes are reported.

Outcome measures from parents were also collected but only a small number of parents returned data and, therefore, only descriptive analyses of these are provided.

No formal subgroup analyses were carried out; however, as there were differences in the ratio of Year 5 and 6 pupils between arms, the effects of age were investigated further, as it was important to identify any patterns in the data relating to these groups which might be present in a future effectiveness trial.

Process evaluation

Schools and families are complex systems within which KAT aims to achieve change. A process evaluation is vital to understand how these systems may influence intervention delivery in ways which support or obstruct the intended change. A process evaluation was conducted throughout the implementation of KAT with the following objectives:

- to assess quality of delivery and fidelity
- to develop and refine the programme logic model
- to develop and refine the programme's theory of behaviour change
- to assess programme reach, particularly in relation to hard-to-reach and high-risk families.

Methods

This study used classroom observations, semistructured interviews and focus groups to develop the theoretical framework and explore implementation fidelity and acceptability of KAT. Semistructured schedules allowed the researcher to probe and explore key themes and issues while allowing participants to discuss issues, experiences and opinions about KAT that had not been anticipated by the interviewer. Observation, and interview and focus-group schedules are included in *Appendix 8*.

Observation

Non-participant observations were conducted during the KAT classroom delivery and fun evenings in order to gain a deeper insight into implementation fidelity and an understanding of contextual influences on implementation. Observation as a qualitative approach is useful to observe a phenomenon in its natural state.¹³³ Observers typically take extensive field notes which can be coded and analysed. In non-participant

observation, the researcher endeavours to be as unobtrusive as possible because increased participant awareness of the researcher's presence may affect participants' behaviour (i.e. produce a Hawthorne effect). Observational data tend to be more valid and reliable than self-report data as they provide better understanding of the phenomenon and context under study.¹³⁴ However, combining observation with other data collection methods, such as interviews, will further strengthen the validity of the methods used¹³⁵ and observational data can develop questions or emergent themes to be addressed by other methods and subsequent analyses. Moreover, observers may not always be present when program delivery takes place, and so it is important that information on implementation is also obtained through other methods. An example of a completed observation schedule is included in *Appendix 8*.

Classroom preparations for the KAT fun evening and the fun evening itself were observed in order to gain insight into the delivery of KAT and pupil and parent engagement in the programme. A total of 11 hours of observation took place in school 1 (over eight observations), 7 hours in school 2 (over four observations) and 6 hours in school 3 (over three observations). Notes were taken during observations and written up as soon as possible. The observations were used to inform interview questions and analysis. *Table 4* shows the number of hours of observation and the estimated proportion of classwork observed in each intervention school.

Focus groups

The views and experiences of the pupils were captured through focus groups. Focus-group research involves organised discussion with a selected group of individuals to gain information about their views and experiences of a topic.¹³⁶ It was decided that a focus group would be a more suitable approach to use with children than individual interviews because children may be more comfortable expressing their attitudes, feelings and beliefs towards KAT in a peer-group setting than directly to an adult. This may be particularly pertinent in a school context where there may be considerable power imbalance in adult-child relationships. Reducing power dynamics may discourage children from providing responses they think the interviewer wants to hear.¹³⁷ Furthermore, in focus groups children may feel less pressure to answer questions they may not feel comfortable with or know the answers to, reducing the chance of false answers being given.¹³⁸

Focus groups with children were held in three schools. They were held by researchers away from the children's classrooms so that teachers could not overhear the discussion. Pupils were asked about their experiences of participating in the KAT activities and about whether or not they had talked about KAT with family members or friends. Focus groups with children who received KAT took place in three schools (two focus groups with four children in each group at school 2, and one focus group with six children each at school 1 and school 3). A total of 17 parents took part in interviews: seven at school 1 (three of whom were fathers), four at school 2 and six at school 3. Lengths of interviews with parents ranged from 10 minutes to 30 minutes.

TABLE 4 Hours of KAT classwork observed in each intervention school

School	Classwork (estimated ^a total duration in hours)	Duration of observation (hours : minutes)	Percentage of classwork observed
3	40	3 : 30	8.7
4	40	8 : 25	21.0
6	60	3 : 55	6.5
8	Not completed	2 : 25	Not known

a Based on 20 hours of KAT work per class.

Interviews

One-to-one interviews with parents, programme deliverers and head teachers were chosen as the most effective methods for obtaining detailed information about individual participants' thoughts and experiences of KAT. The privacy of an individual interview was felt to encourage frank responses from both junior and senior members of school staff¹³⁹ and from parents who might be affected by sensitive family issues. The aim was for all interviews and focus groups to take place within a week of the KAT fun evening so that the programme would be fresh in the interviewees' minds. Telephone and face-to-face interviews were used and have yielded similar qualitative results.¹⁴⁰

Teachers were asked about their experiences of delivering KAT, school contextual influences, acceptability and implementation. Teachers and head teachers could choose to have their interview at their workplace or somewhere more convenient to them. Three head teachers participated in interviews lasting between 10 and 15 minutes, with interviews with the heads at school 4 and school 3 taking place over the telephone. All teachers who delivered KAT took part in face-to-face interviews in school, each averaging around 20–30 minutes. This totalled nine teacher interviews (two at school 4 where one was also the head teacher, two at school 3, four at school 6 and one at school 8).

Interviews with parents explored family communication and their experiences of the fun evening. Parents were given a choice of interview location or telephone interview in order to suit their convenience and encourage participation.

Validity

Maxwell¹⁴¹ describes validity in relation to qualitative research as 'the correctness or credibility of a description, conclusion, explanation, interpretation, or other sort of account' (p. 87). The validity of qualitative research in the present study was maintained by following the recommendations of Ratcliff.¹⁴² First, a reflective journal of personal notes was kept in order to capture and recognise data that diverged from initial expectations. This journal included initial assumptions, and identification of potential bias was noted. Second, different sources of data – observation notes, interviews and focus groups – were triangulated and their degree of convergence was estimated. Third, extensive quotations from interview transcripts and observation notes were used in order to create 'think descriptions' of themes from the data and to represent participants' voices. Fourth, emerging findings from the process evaluation were regularly compared with the findings of other comparative studies, both empirical work on alcohol misuse prevention interventions and the broader theoretical literature. Finally, independent checks were made, with transcriptions and emerging themes shared with supervisors in order for discussion of key themes and interpretation to take place.

Although *Table 4* shows small proportions of observed class work, it should be noted that on many occasions, two or more classes were delivering KAT at the same time and, consequently, the 'observable hours' total is likely to have been considerably smaller than the estimated total number of hours of classwork delivered. Despite many requests, teachers at school 4 did not always inform the researcher of when the work was going to be carried out, and so in those instances the researcher arrived at the classroom only to find that children had already completed their work on KAT for that day. Two periods of observation were carried out at each of the other three schools. *Table 5* provides a summary of the interviews with parents and teachers, focus groups and classroom observation conducted in intervention schools as part of the process evaluation. In addition, interviews with the head teachers of schools 3 and 6 and observation of family events at schools 3, 4 and 6 were carried out.

Qualitative data were coded using Atlas.ti (ATLAS.ti Scientific Software Development GmbH, Berlin, Germany). The process evaluation was funded separately from the main trial, and its reporting timeline is behind that of the main evaluation. In this report, we have, therefore, provided an interim analysis of the findings from the process evaluation, concentrating on the extent to which key programme-related progression criteria have been met.

TABLE 5 Summary of process evaluation data collected in KAT intervention schools

Data collection method	School											
	4	3			6			8				
Class	Year 6 (class 1)	Year 6 (class 2)	Year 4/5	Year 6	Not known	Year 4/5	Year 5	Year 6	Not known	Year 5 (class 1)	Year 5 (class 2)	
Parent interviews	1		6	1 (two children)	1	3	2	1	2	1	0	0
Teacher interviews (acting head)	1	1	0	1	0	0	1	1	1 (joint with teacher and deputy head)	0	1	0
Focus groups	1 (seven pupils)		0	1 (four pupils)	1 (four pupils)	0	1 (six pupils)			0		0
Class observation records	4	2	0	1	0	1	1	1	1	0	1	1

Health economics

To enable a cost-effectiveness study to be conducted as part of a potential definitive trial, we mapped key cost and consequence domains, and tested the feasibility of data collection as part of a definitive trial. We sought to identify all inputs, including staff time, materials, equipment and facilities, that were used during the delivery of KAT. This included all relevant inputs and contributions by young people, parents, schools and other agencies to all aspects of the intervention and its processes and procedures. The extent to which these inputs could be translated into financial costs was examined. The primary and secondary outcomes were considered for their suitability as measures of output and outcomes for an economic evaluation, and to inform the nature of the evaluation to be conducted.

Criteria for recommending an effectiveness trial of Kids, Adults Together

Between February and April 2013, a set of criteria were developed through discussions among the Trial Management Group in order to assess and inform a decision on whether or not to proceed with a proposal to evaluate KAT in an effectiveness trial. *Tables 6 and 7* show the criteria developed relating to the value, feasibility and acceptability of implementing the KAT programme; and of conducting a RCT in schools; and their relationship to the study objectives outlined above (see *Chapter 1, Aims and objectives*) and set out in the study protocol.

We structure our discussion chapter around these criteria, and assess the evidence for each of them individually before providing an overall assessment of the evidence.

Involvement of practice and policy stakeholders

A crucial aspect of any further evaluation is the availability of systems for the wider-scale programme implementation required for an effectiveness study. A stakeholder group was convened in February 2013 which included relevant individuals and representatives of key policy, health and education agencies. Membership comprised:

- Head of Substance Misuse Policy and Finance, Welsh Government
- Representative of Pupil Wellbeing Branch, Department for Education and Skills, Welsh Government
- Consultant in Public Health, Public Health Wales
- Retired head teacher of a school which piloted KAT
- Chief Superintendent, Gwent Police (chairperson, Gwent Substance Misuse Area Planning Board)
- Welsh Network of Healthy School Schemes Programme Manager
- Health education consultant responsible for KAT development and training
- National Co-ordinator, All-Wales Schools Liaison Core Programme.

Members of the group advised on the likely value of the programme to schools in Wales and the feasibility of implementation and funding on a wider scale. The principal investigator held separate discussions with the Chief Superintendent of Gwent Police to ascertain ownership rights to the programme and the extent to which Gwent Police wished to be involved in further implementation and evaluation.

TABLE 6 Criteria relating to programme content and implementation

Criteria	Basis for assessment	Secondary objectives stated in study protocol
1. KAT can be implemented successfully in primary schools	Process evaluation findings indicate that at least two of the intervention schools delivered key elements of KAT classroom work and family events in line with the teachers' handbook; AND it is reasonable to expect that any significant problems identified can be overcome	Assess the feasibility of the intervention (objective 2)
2. KAT is acceptable to children in the target age group (9–11 years)	Process evaluation findings from intervention schools suggest that KAT was acceptable to the majority of pupil participants in each school	Assess the acceptability of the intervention (objective 2)
3. KAT is acceptable to parents of children aged 9–11 years	Process evaluation findings from intervention schools suggest that KAT was acceptable to the majority of parent participants in each school	
4. KAT is acceptable to school staff involved in implementation (head teachers, teachers of Year 5 and 6 classes, and support staff)	Process evaluation findings indicate that a majority of school staff in each school support the concept of primary school education about alcohol; feel competent to deliver KAT; and think that KAT has potential benefits for families and school; AND that it is reasonable to expect that any significant problems identified can be overcome	
5. KAT attracts high rates of participation from children aged 9–11 years	Process evaluation findings and pupil questionnaires from intervention schools suggest that all pupils in participating classes take part in classroom work (if present in school) and few if any objections from parents are received; AND that a minimum 50% of pupils attend KAT events	Establish intervention participation rates (objective 3)
6. KAT attracts high rates of participation from parents of children aged 9–11 years	Pupil questionnaire data (intervention group) and process evaluation findings suggest that parents/caregivers or other adults from families of a minimum 25% of pupils attended KAT events	
7. KAT can be implemented in schools serving a range of socioeconomic groups and localities	Details of FSM entitlement and school demographics (from Estyn school inspection reports) show that, of schools which implemented KAT, some were above and some below median FSM for the county	Establish intervention reach, including equality of engagement across socioeconomic groups and localities (objective 3)
8. KAT can engage parents and children from a range of socioeconomic groups and localities	Ethnicity and Family Affluence Scale data from pupil questionnaires; deductions about families from FSM rates and demographics of school area; and process evaluation interviews with school staff demonstrate inclusion of families from a range of social groups and localities that reflects the local population	
9. KAT delivery costs can be recorded in a way which facilitates assessment of cost-effectiveness	Systems developed in current project can be used to monitor costs of larger-scale implementation	Identify the costs of delivering KAT and pilot methods for assessing cost-effectiveness as part of a future effectiveness trial (objective 7)
10. Sufficient support exists in terms of policy and resources at school, LEA and national levels, to allow successful delivery of KAT on a large scale	Stakeholder group judge that structures and resources for further implementation can be put in place	Identify optimal delivery structures and systems for the KAT programme post trial (objective 2)

LEA, local education authority.

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TABLE 7 Criteria relating to value and feasibility of an effectiveness trial of KAT

Criteria	Basis for assessment	Secondary objectives stated in study protocol 2
11. KAT is consistent with a theoretical basis which suggests that short-term impacts on parent-child communication may shape longer-term alcohol-related behaviours	Process evaluation findings and comparison of intervention and control group scores for intermediate outcomes (communication measures) indicate that participation in KAT is associated with an increase in parent-child communication	Refine the theoretical model of the intervention (objective 1)
12. It is feasible to conduct a trial of KAT in schools serving a range of socioeconomic groups and localities	Details of FSM entitlement and school demographics (from Estyn school inspection reports) show that schools within each trial arm varied in terms of social, demographic and geographic characteristics and that at least two were in areas above the county median for deprivation	Assess trial recruitment and retention rates (objective 4)
13. The sample required to demonstrate a significant effect of KAT is achievable	Recruitment records indicate that we were able to recruit eight schools as per protocol; project records demonstrate that schools in both trial arms are retained in the study; questionnaire returns indicate that at least 80% of pupils in a majority of eligible classes provide data at each time point	Assess trial recruitment and retention rates (objective 4) Identify potential effect sizes that are likely to be detected as part of an effectiveness trial and an appropriate sample size (objective 5)
14. Methods for measurement of primary and secondary outcomes are feasible and the cost of measurement can be estimated	Measures were understood by, and acceptable to, more than 75% of Year 5 and 6 pupils in each school	Determine the feasibility and cost of the proposed methods for measurement of the primary and secondary outcomes (objective 6)
15. Promising effect sizes are achieved for key outcomes	After adjusting for baseline differences, comparison of intervention and control group pupil scores at follow-up shows that intervention group average scores are higher than control for at least one of the following measures: KIDSCREEN-52 autonomy dimension PCCS FCS Family Activities Scale AND that intervention group average scores are not lower than control group average scores for any of the other scales	

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Chapter 3 Findings

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Data analysis was similar to that which would be carried out in an effectiveness trial, but the objectives and interpretation which flow from this analysis are different. For example, important functions of the statistical analysis of primary and secondary outcome measures were to identify and interpret patterns of missing data and to estimate the sample size for an effectiveness trial. Recruitment rates, and aspects of data collection, which would ordinarily form part of the methods section in an effectiveness trial, are key findings in this exploratory trial because they help to determine the feasibility of the research design and procedures. The process evaluation was intended to examine feasibility of implementing KAT in different schools and whether or not the programme could be further developed in ways which would facilitate implementation and acceptability. Learning points for a future effectiveness trial are examined in *Chapter 4*.

Chapter overview

This chapter begins by describing the implementation and fidelity, acceptability, participation rates and perceived impacts on communication of KAT class work and family event components. For the trial, we describe recruitment and retention rates, feasibility of potential primary and secondary outcome measures, and estimation of the sample size required for any future effectiveness trial. The chapter finishes with a summary of financial costs of implementing and evaluating KAT.

Programme implementation and fidelity

Of the five schools allocated to the intervention group, one withdrew from the study before baseline data collection (school A) and another (school 8) withdrew after baseline data collection, shortly after beginning the KAT classwork. The following findings are based on data collected from the three schools (schools 3, 4 and 6) which completed programme delivery and follow-up data collections, with some additional information from school 8 on acceptability.

Training and roles and responsibilities

Training was offered to staff in intervention schools but some teachers in school 6 did not attend training sessions, mostly due to pressure of other work or because it was impossible for the school to bring together all relevant staff at one time. Consequently, the Year 6 teacher and Year 5 deputy head did not appear to be familiar with the contents of the handbook or to be aware of other information they would have received through training. In addition, although school staff arranged the date and venue for the family event and contacted parents, they did not get the hall ready or take charge of the activities. Teachers in the other two schools were on the whole satisfied that the KAT handbook provided 'a good basis to work from' (Year 6 teacher, head, school 4), but it was apparent that the success of the intervention was dependent on senior manager buy-in and support.

Classwork component

The programme handbook identified five key elements which teachers were asked to deliver as part of the classroom work:

- establish pupil knowledge
- emphasise healthy use of alcohol (not negatives)
- develop responsible attitudes to alcohol use
- improve communication skills – group/pair work

- produce work for the family event including:
 - posters to advertise event
 - personal invitations
 - take work home to finish.

Classroom observation suggested that the majority of these elements were implemented with high fidelity in all three schools. Observation and interviews showed teachers followed the handbook closely, including the suggestions for assessing children's knowledge. Interviews with teachers and focus groups with pupils demonstrated a good understanding of the 'not too much, not too soon' healthy approach to alcohol, with teachers highlighting that in order for children to develop enough confidence to raise the topic at home, it was important for them to realise that alcohol was not 'all bad' and that parents who drank alcohol were not doing wrong. However, it was recognised by some teachers and parents that in families where there was significant alcohol misuse, the balanced message might not reflect children's experiences. In these cases, it was thought that children would benefit from more intensive support outside the family. If such children do talk to school staff or other adults, then KAT could maintain its reach to high-risk families, with children forming an attachment to a teacher or other supportive adult.

Group/pair work had high levels of fidelity and was something that pupils responded positively to, with clear examples of how interactive teaching and learning could be used to good effect in encouraging responsible attitudes to alcohol use, for example the 'drinkers and thinkers' role play rehearsal at school 4:

The drinkers were calling the thinkers 'un-cool', 'boring', 'chicken' etc., for not drinking. The thinkers were saying things like, 'they had an exam tomorrow, they didn't want smelly breath', 'didn't want to get into trouble with police', or 'be ill'. The drinkers were being sick and falling over.

Observation 4, class 1

Group work was also thought to play a significant role in helping children to talk about alcohol at home because they had 'almost practised saying it' (Year 4/5 teacher, school 3).

Finally, while all classes prepared work for display or performance at the family event, including posters (though it is not clear that these were used to advertise the event), personal invitations were produced at only one school and there was no evidence from any school that children, parents or teachers thought that they were particularly important. Homework activities also had poor implementation, with school policies or existing practices resulting in low fidelity.

Kids, Adults Together family events

Key elements of KAT family events were identified from the manual as:

- a presentation by pupils
- a non-judgemental approach
- an emphasis on healthy use of alcohol, not negatives
- an aim for all pupils to take part in the event.

The handbook suggested how the event could be organised, with details of a suggested format and instructions on how to run two activities aimed at encouraging communication about alcohol: a quiz/treasure hunt and an activity called 'Agree or Disagree'. This information, together with answers to the quiz, was repeated in a PowerPoint presentation which accompanied the handbook. The three intervention school events included both activities suggested in the handbook, alongside presentations by the children. *Table 8* lists the presentations children made at each school.

TABLE 8 Presentations by children at three KAT intervention schools

School	Presentation
School 3	Role play
	Mock TV game show
School 4	Role play
	Talk by children about KAT classwork
	Animation including poems written and read out by children
School 6	Role play
	Rap
	PowerPoint presentation

Observation at all three schools found that they achieved a non-judgemental approach, and, overall, parents who participated in research interviews agreed with this. Interviews with teachers also suggest that they tried to ensure that the approach was 'light-hearted' and humorous. There was evidence from all three schools that the family events promoted a healthy approach to alcohol use, with only a minority of parents indicating that their children were more focused on the dangers of alcohol than healthy use. There was less success in involving all children in the event, with two of the schools not appearing to have followed the guidance in the handbook.

Acceptability of the Kids, Adults Together intervention

Parents/carers

Initially, there were a very small number of objections to KAT from parents/carers (schools 3 and 4) and these were withdrawn after discussions with school staff. In all three schools, parents/carers were positive about the topic of alcohol being addressed at primary school, with parents generally seeing it as the 'perfect age I think, 10. I wish I had it when I was in school' (parent interview 6).

All parents interviewed across all schools said they had enjoyed the family event, and this was confirmed by children's focus groups who reported positive feedback from their family and observations. Teachers at all three schools also reported having received positive feedback from parents about the event, directly and/or through the children.

In the school which withdrew from the study after baseline (school 8), it is not clear how big a part KAT's acceptability to predominantly Muslim parents played in the circumstances leading to the school's withdrawal. The teacher of one class made it clear that he did not think KAT would benefit either the school or the children in his class and had expressed concern from the outset about delivering KAT to children from mostly Muslim families. Because the school decided to withdraw completely from the study, we were not able to conduct interviews with parents/carers in this school in order to ascertain to what extent the programme was acceptable to them.

Children

Observation suggested that the vast majority of pupils enjoyed KAT and were fully engaged in it. There was no evidence that large numbers of children had been bored or alienated by the project. This was supported by focus groups, with the participants stating that they had enjoyed the classwork and the family events; parents and teachers at all three schools also reported that the children had enjoyed KAT.

A few small issues were noted which slightly impaired the overall acceptability of the programme for children. Although KAT is intended for children in Years 5 and 6, Year 4 children were involved because they were in mixed classes, and they found the group work and writing tasks challenging. Observation records of the family event at school 6 where the school staff took no responsibility for organising or introducing activities showed some levels of boredom and restlessness among pupils. However, three parents from school 6 said that their own children had enjoyed the events, and general feedback from teachers and children was positive.

School staff

The vast majority of teachers thought that the intervention was age-appropriate, the 'perfect age' to deal with this topic. Teachers were also pleased with the way KAT fitted into the curriculum and there was no evidence that teachers lacked the confidence or skills to deliver the classroom work. The Year 6 teacher at school 3 said that children had disclosed sensitive issues in class and it was not a problem for her: 'At this age they need to be talking about stuff like that'. Staff in all schools liked the way KAT facilitated parent-school contact (although there was some disquiet among teachers at the level of organisation at school 6), with some head teachers keen to use the same format for other topics.

Rates of intervention participation

Follow-up questionnaires completed by pupils in intervention schools included questions on whether or not pupils had done the KAT classroom work (all, part or none), whether or not they had attended the KAT family event, if any adult member of their family had attended and how many adult members from their family attended. The findings in the following sections are based on data from the recruited sample of pupils. Whole school classes undertook the KAT classroom work and were invited to the KAT family event. Participation rates, and their social patterning, may have differed for the classes as a whole.

Classwork

Table 9 shows that the majority (70.9%) of pupils who completed follow-up questionnaires reported covering KAT classroom work in full, and most of the remaining pupils (22.8%) had done part of it. These patterns held true across all three intervention schools which completed KAT, although there was significant variation in the proportion of pupils who completed KAT in full or in part. A greater proportion of pupils in school 4 had completed all the work (86%) than in schools 3 and 6 (64.7% and 63%, respectively).

Family event

Table 10 shows the participation rates at the family event reported by pupils. An average of 59% of pupils reported attending the family events and 50% with their parents/carers. For the individual schools, the proportions of pupils whose families were represented by at least one adult member were 45.1%, 46.6% and 65.7%. For attendance by pupils themselves, the figures were 47.1%, 58.9% and 79.4%.

TABLE 9 Kids, Adults Together classwork participation in three intervention schools

School	Did you do the KAT work in school? [n (%)]			
	All	None	Part	Not answered
3 (34 pupils)	22 (64.7)	1 (2.9)	10 (29.4)	1 (2.9)
4 (51 pupils)	44 (86.3)	0	7 (13.7)	0
6 (73 pupils)	46 (63.0)	6 (8.2)	19 (26.0)	2 (2.7)
Total (158 pupils)	112 (70.9)	7 (4.4)	36 (22.8)	3 (1.9)

TABLE 10 Participation in KAT events at three intervention schools: families and children

School	Did any of your family go to the KAT event? [n (%)]			Total family members attending, N	Did you go to the KAT event? [n (%)]		
	Yes	No	Not answered		Yes	No	Not answered
3 (34 pupils)	22 (65.7)	12 (34.3)	0	47	27 (79.4)	6 (7.6)	1 (2.9)
4 (51 pupils)	23 (45.1)	28 (54.9)	0	36	24 (47.1)	26 (51.0)	1 (2.0)
6 (73 pupils)	34 (46.6)	39 (53.4)	0	51	43 (58.9)	28 (38.4)	2 (2.7)
Total (158 pupils)	79 (50)	79 (50)	0	134	94 (59.5)	60 (38.0)	4 (2.5)

Reach across socioeconomic groups and localities

Table 11 provides the KAT attendance rates categorised by Family Affluence Scale score (low, medium and high). When Family Affluence Scale scores are taken into account, pupils with high scores were more likely to have an adult member of their family present at the family event than pupils who had low/medium scores (56.6% vs. 41.4%). However, there was no such pattern in relation to whether or not pupils themselves attended (59% vs. 60.3%).

Table 12 displays rates of participation in the family event for pupils and parents/carers for each school, and includes the FSM rate for each school. It shows clearly that the school with the highest FSM score (37.3%) also had the highest proportion of families represented by at least one adult (65.7%). The school with the lowest FSM had the lowest proportion of families represented, and the school with the middle-ranking representation rates also had the middle-ranking FSM score.

At schools 3 and 4, staff reported that attendance by parents was higher than usual, with one teacher (school 3) 'shocked' when he or she saw the queue waiting to get in. At school 6, parental attendance was 'on a par' with the turnout for class assemblies. This appeared to be a positive assessment because the Year 5 deputy head said that the school had been making a special effort to get parents involved with their children in events at the school and that attendance at the KAT event had followed the recent trend.

Analysis of the process evaluation data suggested that there were three key reasons why parents/carers attended the family events: to support their children, to support the school and to satisfy children who put pressure on them to go. Also mentioned frequently by parents and children was that parents wanted to see their children's work; and some had a general rule of always attending school events (school 4, parent 5, 6 and 7; school 6, parent 3). At school 3, the free tea and coffee may also have been influential (Year 4 focus group, Year 6 teacher, school 3).

TABLE 11 Attendance at KAT family events by Family Affluence Scale score

Family Affluence Scale score	Did any of your family go to the KAT event? [n (%)]			Total family members attending, N	Did you go to the KAT event? [n (%)]		
	Yes	No	Not answered		Yes	No	Not answered
Low/medium (58 pupils)	24 (41.4)	34 (58.6)	0	43	35 (60.3)	20 (34.5)	3 (5.2)
High (83 pupils)	47 (56.6)	36 (43.4)	0	76	49 (59)	33 (39.8)	1 (1.2)
Unknown (17 pupils)	8 (47.1)	9 (52.9)	0	15	10 (58.8)	7 (41.2)	0 (0)
Total (158 pupils)	79 (50)	79 (50)	0	134	94 (59.5)	60 (38.0)	4 (2.5)

TABLE 12 Attendance at KAT family events by school and FSM entitlement rates

School	School FSM, %	Did any of your family go to the KAT event? [n (%)]			Total family members attending, N	Did you go to the KAT event? [n (%)]		
		Yes	No	Not answered		Yes	No	Not answered
3 (34 pupils)	37.2	22 (65.7)	12 (34.3)	0	47	27 (79.4)	6 (17.6)	1 (2.9)
4 (51 pupils)	2.3	23 (45.1)	28 (54.9)	0	36	24 (47.1)	26 (51.0)	1 (2.0)
6 (73 pupils)	27.9	34 (46.6)	39 (53.4)	0	51	43 (58.9)	28 (38.4)	2 (2.7)
Total (158 pupils)		79 (50)	79 (50)	0	134	94 (59.5)	60 (38.0)	4 (2.5)

Children whose parents do not attend the family event

Organising the event for family groups could be difficult for children whose parents do not attend. It was possible to count the number of children who had gone to the family event unaccompanied by members of their family using two questions from the children's follow-up questionnaire: 'Did you go to the KAT fun event at your school?' and 'Did any of your family go to the KAT fun event at your school?'. *Table 13* shows that out of 94 children who said they had attended, 18 (19%) had gone without a member of the family.

Schools 3 and 6 held their family events immediately following on from the school day, which might have led to more children staying on for the event without an adult. School 4 had started their event later so that children would have returned home after school and come back to school later in the evening. Responses for each school from the 18 unaccompanied children are shown in *Table 14*.

Although proportions of unaccompanied children are slightly higher in the schools which ran the events straight after the school day, there is not much difference between the three schools. It should also be noted that children may have attended the events without having completed questionnaires, and so total rates of attendance by unaccompanied children could be higher or lower than described above.

TABLE 13 Numbers of children who attended KAT family events unaccompanied by a family member

Did you go to the KAT fun event at your school?	Did any of your family go to the KAT fun event at your school?		
	No	Yes	Total
No	58	2	60
Yes	18	76	94
Not answered	3	1	4
Total	79	79	158

TABLE 14 For each intervention school, numbers and percentages of children who attended the KAT family event unaccompanied by a family member

Did you go to the KAT fun event at your school?	Did any of your family go to the KAT fun event at your school?			
	No			
	School 3	School 4	School 6	Total
Yes	5 (18%)	4 (17%)	9 (21%)	18 (19%)
Total children attending	27	24	43	94

Programme theory

Although this study is not designed to estimate the effect of KAT, it provides an opportunity to assess whether or not KAT has the potential to encourage more communication among family members – which is thought to be a precursor of the eventual intended reduction in alcohol misuse. Participants in the study's process evaluation were, therefore, asked about the specific effects of classwork and the family event on communication about alcohol.

Classwork

In each school, both parents and children reported that children told their parents about what they were doing in class. Topics included the kinds of work they were doing (posters, etc.); the physical effects of alcohol; dangers of alcohol; safe drinking; parental alcohol use; the nature of the KAT project; reasons why people drink; and units of alcohol. There were a few reports that children had not talked about it (focus-group participants A and C, school 4; parent 5, school 4; parent 1, school 6) and two children withheld information so that their parents would have a surprise at the family event (focus-group participant school 3, parent 6, school 6).

Homework

The KAT programme manual encourages teachers to ensure that there are opportunities for pupils to take some of the classroom work home to finish, 'to generate interest amongst family members'. No homework was set in school 6, but at school 4 and school 3 two teachers set homework with the specific aim of stimulating conversation between parents and children (second Year 6 teacher, school 4; Year 6 teacher, school 3). In both schools, there were more reports that parents helped with homework than not. Topics covered included support groups (parent 1, school 4), physical harm (parent 2 Year 4, school 3) and consequences of misuse (parent 3, school 4). This teacher thought that girls were more willing than boys to take work home and talk to their parents.

Family event

Parents at school 4 and school 3 enjoyed talking to other parents at the events (parent 5 and parent 7, school 4; parent 1, school 3). Most parents maintained that they were 'quite open' about alcohol, that they talked about it at home anyway, and that attending the family event had not made any difference to that. However, some went on to say things which suggested that there had actually been at least small changes: one said that their child would 'chip in' more when alcohol was discussed (parent 1, school 4); another parent had been shocked at some of the information and had become more aware of the implications of her own drinking behaviour (parent 7, school 4). Parent 4 (school 4) seemed to reflect that the KAT project as a whole had led to more conversation, and parent 5 (school 4) said that while there possibly had been more conversation after the family event, this was just repeating what had been said at home before.

A significant number of children at each school said that they had discussed alcohol with their families after the event, though it was not clear (except for boy D, Year 6, school 3) whether or not families had discussed it more than usual. At all schools, some parents and children had told other members of their family and friends about the KAT activities and what they had learnt. Teachers at all of the intervention schools said that KAT provided an *opening* for discussions, or more serious discussions, about alcohol, and drew on evidence of children having conversations not only with their parents but also with friends, classmates, siblings and other relatives, and suggested that during the project, other children became informed and informative participants in a wide-ranging dialogue about alcohol.

Trial recruitment and retention

One of the study objectives was to assess trial recruitment and retention rates (to help determine if an effectiveness trial would be feasible) and key design parameters. This section describes numbers of schools, children and parents recruited and retained in the research trial (i.e. those individuals who provided

questionnaire data), and the issues arising during recruitment and data collection processes. The latter are dealt with here because in an exploratory context they constitute findings about the feasibility of conducting the evaluation rather than a simple account of methods.

Schools

All 39 eligible schools were contacted by letter, and invited to participate in the study, and telephone calls were made to all schools until sufficient schools were recruited. Meetings were held with nine schools which expressed an interest in the study. One head teacher was willing for the school to participate but only if it was not in the intervention group because there was no capacity within the school timetable to deliver KAT. The school was not, therefore, eligible to participate in the trial. However, they offered to assist with the piloting of the study questionnaires. The other eight schools with whom the principal investigator had meetings all went on to participate in the trial (a participation rate of 20.5%). Of the 31 eligible schools which did not participate at this point, 19 did not respond to letters or telephone calls, six indicated to the research team that they were not interested, four were too busy and two schools declined because they were already delivering projects similar to KAT.

Table 15 shows the number of pupils and percentages entitled to FSM in each of the recruited schools, alongside the average, median and range for all 39 eligible schools. It can be seen that the FSM rates in the recruited schools ranged from 1% to 37.2%. Six schools were above the county median, and three below.

Figure 5 summarises the recruitment process. One intervention school (school A) withdrew from the study before baseline data collection. The school's main reason for withdrawing from the study was parents' concern about the research topic, and appeared to be linked to the fact that, due to an administrative error, main information letters and reminder letters were switched in order. However, given the fact that the reminder letter explained how parents could access the original letter if for some reason they had not received a copy (and a link to the information online was also provided), there may also have been other reasons. We were not able to obtain more detailed information from the school, though we requested this on several occasions.

TABLE 15 Pupil numbers and percentages entitled to FSM: KAT sample and all eligible schools

Schools	Pupils, <i>n</i>	FSM entitlement, %
KAT intervention schools		
3	188	37.2
4	264	2.3
6	312	27.9
8 (withdrew)	384	21.6
A (withdrew)	205	1
KAT control schools		
1	483	11.4
2	69	31.9
5	196	23.5
7	188	25.5
All eligible schools (<i>N</i> = 39)		
Average	283	21.8
Median	211	18.4
Range	69–653	1–48.3

Source: adapted with permission from Segrott *et al.*¹

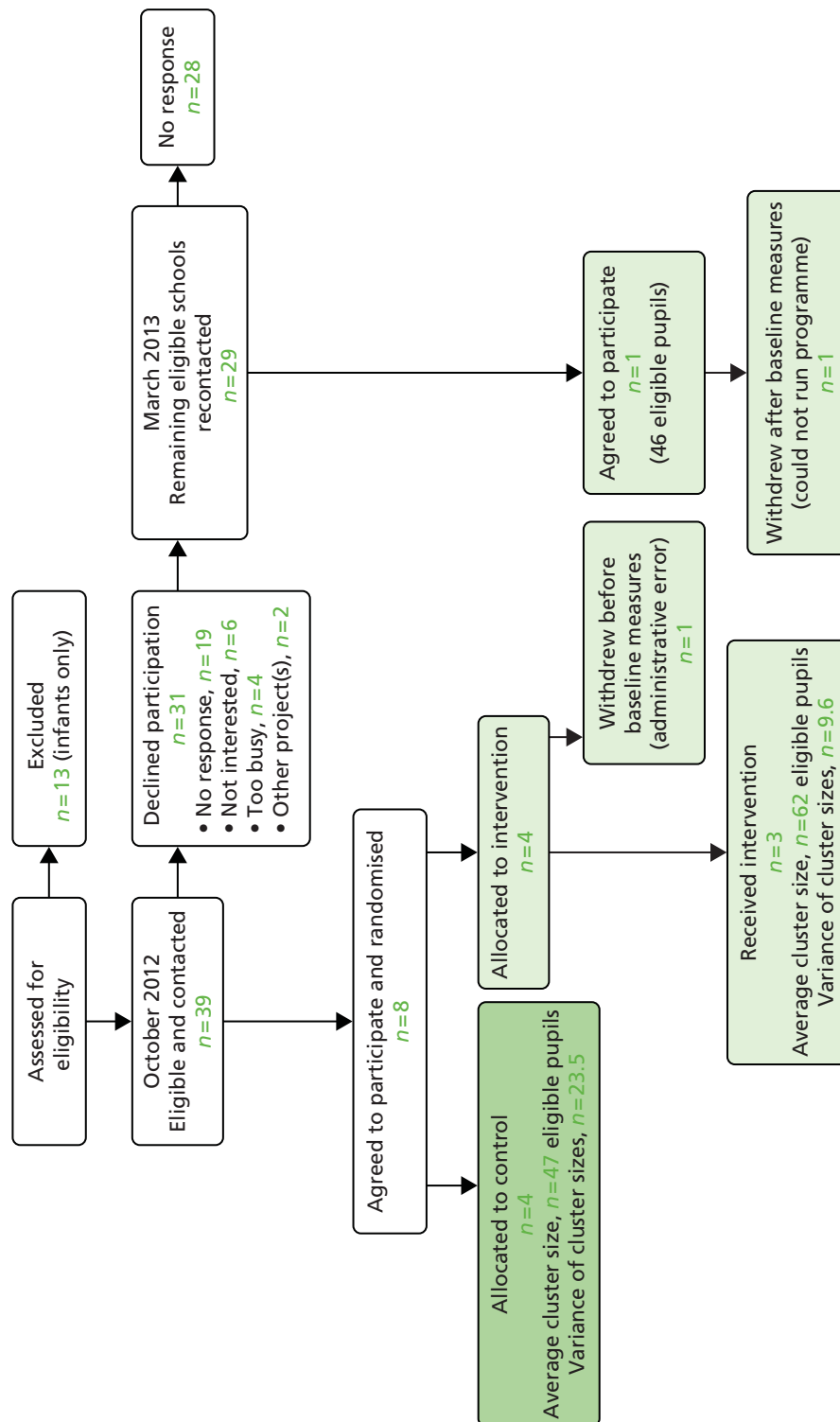


FIGURE 5 Recruitment of schools. White, recruitment activities; pale green, intervention group; dark green, control group.

Following the withdrawal of this school, we wrote again in March 2012 to all eligible schools which were not already participating in the trial ($n = 29$) inviting them again to participate in the trial as an intervention school, but indicating that to take part they would need to be able to deliver the programme in the summer term of 2012. One school responded to this letter and agreed to participate in the trial. This school withdrew from the trial after baseline data collection had taken place, and shortly after programme delivery had commenced. Although the required timing and workload associated with the programme had been clearly explained to the school before they agreed to participate (see *Appendix 9*), their main reason for withdrawing from the study concerned these issues, and was mostly related to programme implementation and the need for multiple members of the study and programme support team to contact the school. However, it would appear that other issues, including one of the teacher's concerns about the appropriateness of KAT for Muslim families, also played a part.

In total, therefore, we recruited nine schools from the 39 eligible (participation rate of 23.5%). We retained all four control group schools for the life of the trial, and three of the intervention schools, with two withdrawing as described above.

Pupils

Determining research trial participation rates

We originally aimed to recruit 50% of eligible children into the research trial order to achieve the sample size target (though this was based on using 'opt-in' parental consent for children's participation, whereas we eventually used 'opt-out' parental consent). *Table 16* shows the proportion of eligible pupils (at baseline) who provided questionnaire data. At baseline, this was 74% (intervention group) and 81% (control group). At follow-up, these figures were 68% and 74% respectively.

Table 16 also shows response rates using two other denominators. First, the proportion of children present in class on the day when questionnaires were completed, which in every case was higher than the proportion of eligible children (which included those absent from school). Second, for the intervention group schools, we provide the response rate at follow-up based only on the three schools which were still in the study (we could not collect any follow-up data in the school which withdrew). Using this calculation, the proportion of children eligible at baseline who went on to complete follow-up questionnaires was 85% (compared with 68% when the school which withdrew is included in this figure).

TABLE 16 Summary of numbers and percentages of children completing KAT questionnaires, using different denominators

Time point	Intervention				Control		
	<i>n</i>	% eligible, four schools	% eligible, three schools	% present	<i>n</i>	% eligible, four schools	% present
Baseline	172	74	N/A	78	152	81	88
Follow-up	158	68	85	92	138	74	77

N/A, not applicable.

All eight schools at which data collections were conducted were asked to confirm numbers of pupils on the registers of classes involved, in order to ensure that participant information sheets were distributed to all parents/carers and pupils, and to allow preparation of sufficient copies of the questionnaire. We also asked schools for information on numbers of parental refusals (to ensure that no data were collected from the relevant pupils), and pupils present on the day we visited. Some of the information supplied by the schools appeared to be inaccurate; for example, the number of questionnaires completed was greater than the number of pupils that schools said were on the register. Where discrepancies were identified, we contacted schools to check the information.

Figure 6 displays the participation rates in the intervention and control groups, and reasons for non-completion of questionnaires. Absence from school or the classroom were the most likely reasons for non-completion, and rates of parental refusal for participation were very low. In one intervention school, a large number of children came from families who did not speak English as a first language, and were from Muslim families. When we visited the school to collect baseline data, some of the children were unsure whether or not their parents were happy for them to take part (though their parents had not contacted the school to refuse permission). To make absolutely sure that we did not collect any data from pupils whose parents were not happy for them to participate, we advised 15 children at this school not to complete a questionnaire. There were no other possible/definite parental refusals in the intervention schools, and only two in the control group schools, indicating that the vast majority of parents were happy for their child(ren) to participate in the trial and intervention.

The pupils shown in as 'Absent from classroom' are those we cannot reasonably account for. This is the difference between the total number reportedly on the register, and the sum of those who completed questionnaires; absentees from school; and those who did not assent or whose parents withheld consent. In the intervention group, this number was 21 pupils (from 231 who were eligible), while in the control group 19 pupils (from 187 eligible) fell into this category. *Figure 7* shows questionnaire completion rates as a percentage of those present in school on the day of data collection. Participation rates for the intervention group were 78% (baseline) and 92% (follow-up). For the control group, the figures were 88% and 77% respectively. The intervention school which withdrew after baseline (school 8) included a large number of pupils from ethnic minority groups, many belonging to Muslim families, and recent immigrants who did not speak or understand English very well. Letters and information sheets for parents and children were translated but because of the late recruitment of the school and the short time remaining for programme delivery, we did not adapt the information-giving process as completely as we would have liked, and school staff were unable to accept our proposals for providing extra information and explanations for participants. Consequently, when we spoke to the children at the data collection visit, we said that those who were at all uncertain about their parents' wishes should not take part, although their parents had not actually contacted the school to refuse consent. This partly accounts for the lower numbers participating in this school and the impact on the overall recruitment rate.

Figure 7 shows that 21 pupils in the intervention group are recorded as 'Absent from classroom' at baseline. If all of these had provided data on return visits, the percentage of those present who completed questionnaires at baseline would have been a little higher than the response rate of 92% at follow-up. In the control group, returning to recruit the 19 (baseline) and 25 (follow-up) pupils recorded as possibly absent from the classroom could also have increased response rates.

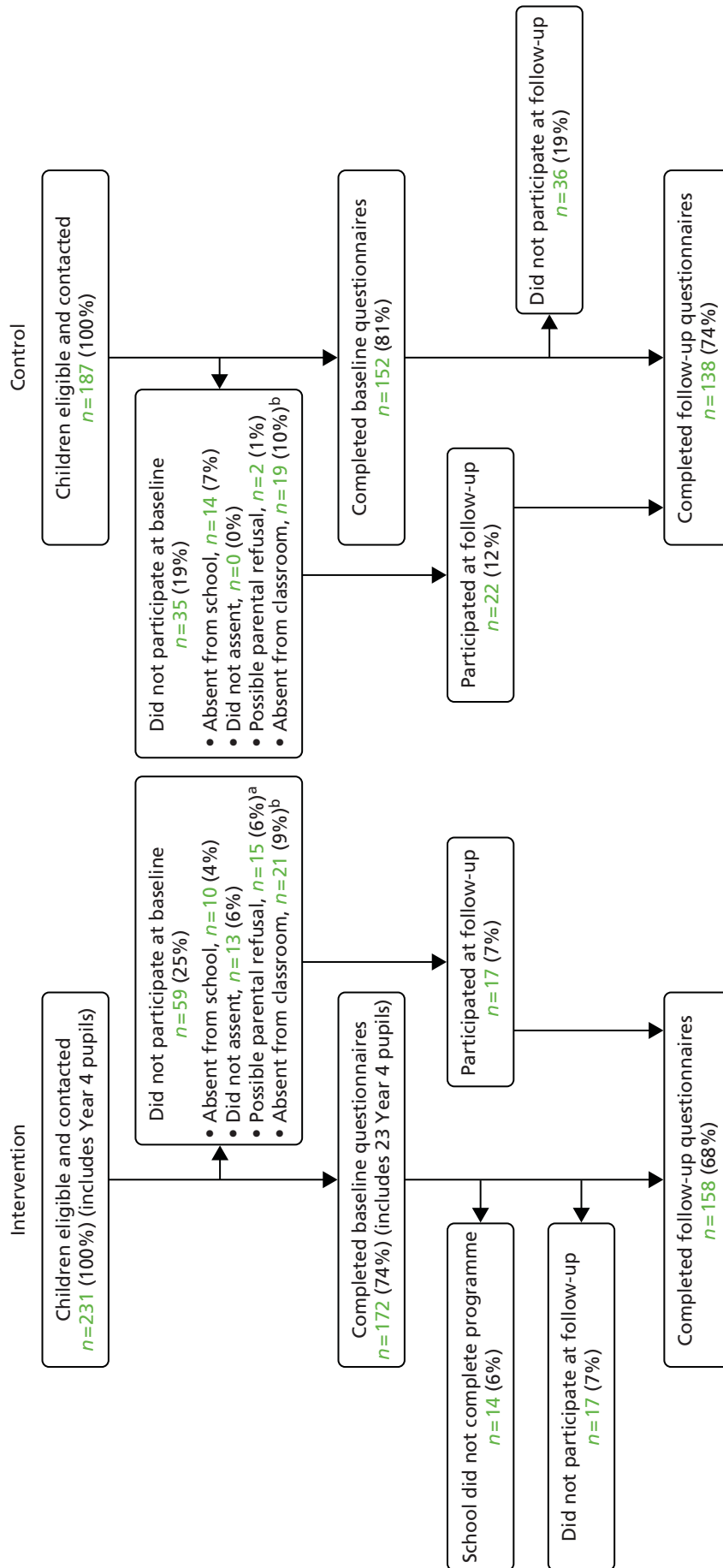


FIGURE 6 Kids, Adults Together participation rates: percentage of children eligible at baseline who completed questionnaires. a, All of these pupils were from one school where many pupils and their families did not speak English as a first language, and many came from Muslim homes. When we spoke to the children at the baseline visit, some were uncertain whether or not their parents would be happy for them to take part, and so we advised that these children should not complete questionnaires; b, uncertainty over the exact number. Reproduced with permission from Segrott et al.¹

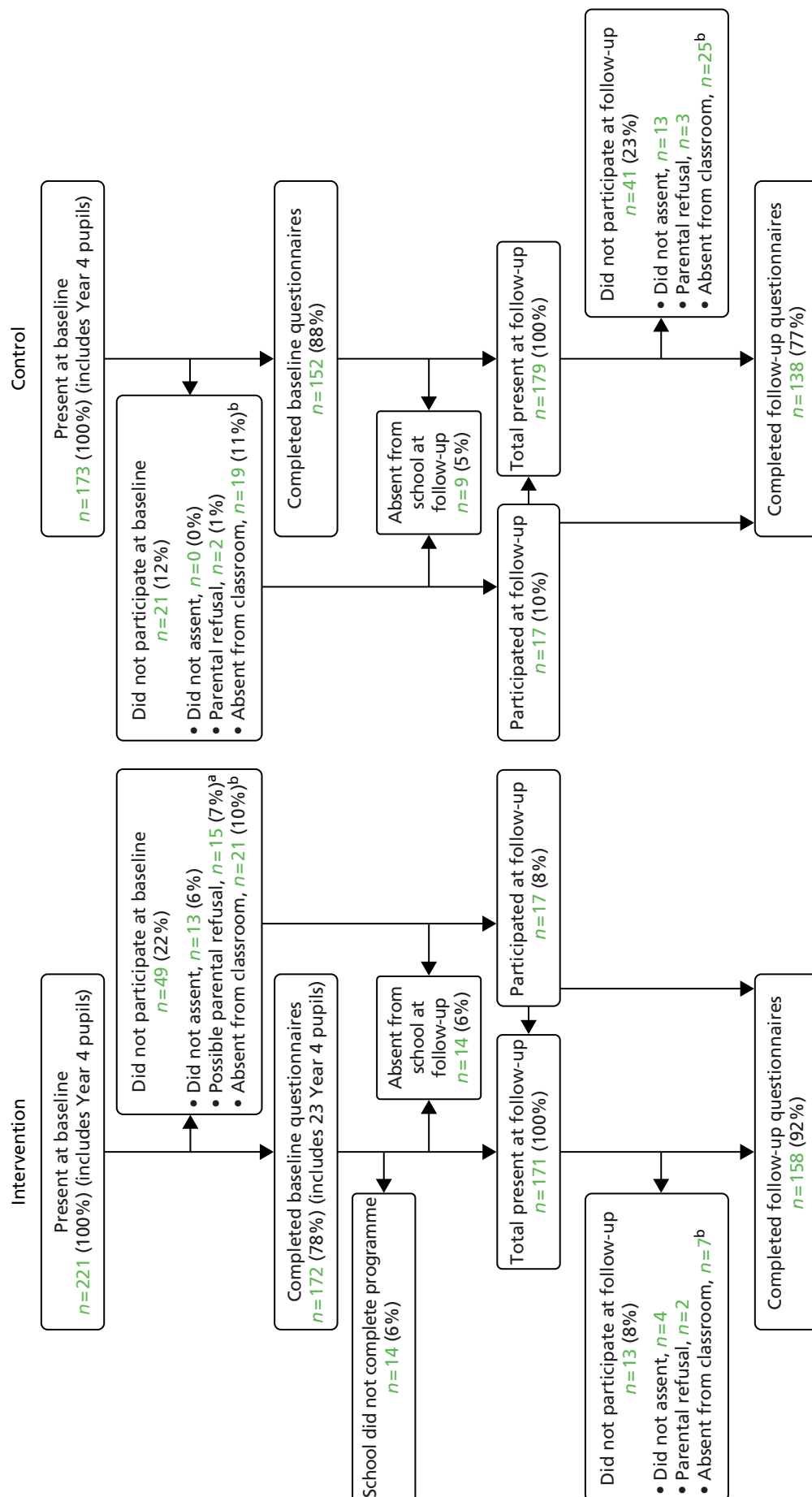


FIGURE 7 Kids, Adults Together participation rates: percentage of children present at baseline and follow-up who completed questionnaires. a, All of these pupils were from one school where many pupils and their families did not speak English as a first language, and many came from Muslim homes. When we spoke to the children at the baseline visit, some were uncertain whether or not their parents would be happy for them to take part, and so we advised that these children should not complete questionnaires; b, uncertainty over the exact number.

Figure 8 gives details of participation for only the three intervention schools which completed the programme, showing that 85% (baseline) and 85% (follow-up) completed questionnaires. In an effectiveness trial using an ITT analysis, the participants in school 8 would have been followed up.

Table 17 shows the proportion of pupil participants with low, medium and high Family Affluence Scale scores in each school, and also shows each school's FSM rate. Participants with high Family Affluence Scale scores formed the majority of participants in each school. It is not possible to determine to what extent the distribution of Family Affluence Scale scores among the recruited sample reflects the total eligible population of classes.

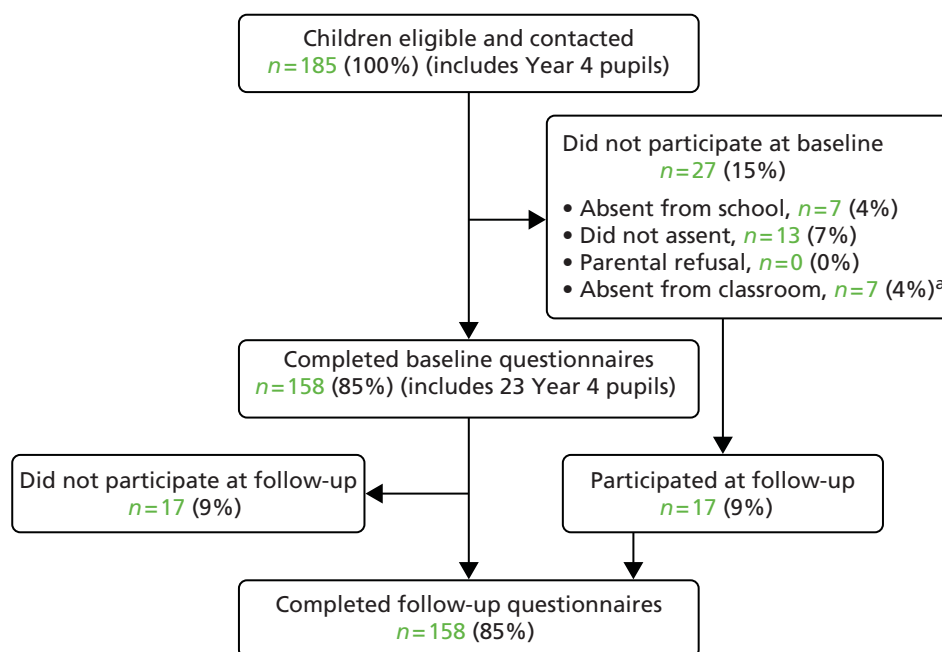


FIGURE 8 Kids, Adults Together participation rates: percentage of children eligible at baseline in intervention schools who completed questionnaires, excluding the school which withdrew after baseline. a, Uncertainty over the exact number.

TABLE 17 Numbers and percentages of children who provided data for Family Affluence Scale, in each intervention school

School	Family Affluence Scale				Total
	Low	Medium	High	Missing	
3 (FSM = 37.2%), n (%)	8 (18.6)	9 (20.9)	16 (37.2)	10 (23.3)	43 (100)
4 (FSM = 2.3%), n (%)	0 (0)	12 (21.1)	43 (75.4)	2 (3.5)	57 (100)
6 (FSM = 27.9%), n (%)	5 (6.3)	31 (38.8)	38 (47.5)	6 (7.5)	80 (100)
8 (FSM = 21.6%), n (%)	0 (0)	6 (42.9)	7 (50.0)	1 (7.1)	14 (100)
Total, N (%)	13 (6.7)	58 (29.9)	104 (53.6)	19 (9.8)	194 (100)

Source: adapted with permission from Segrott *et al.*¹

Retention of children

Three hundred and twenty-four pupils completed the baseline questionnaire (152 control and 172 intervention), while 296 pupils completed the follow-up questionnaire (138 control and 158 intervention). An additional 39 pupils (22 control and 17 intervention) who did not complete baseline questionnaires completed follow-up questionnaires. The study retention rate in the control arm is, therefore, $(138 - 22)/152$ or 76.3% and that in the intervention arm is $(158 - 17)/172$ or 82.0%, an overall retention rate of 79.9%. *Figure 9* displays these figures in the form of a flow chart.

Demographic characteristics of children allocated to intervention and control groups

Of the 363 pupils (324 participating from baseline, 39 at follow-up only), 358 provided their demographic information. These figures were 169 in the control arm and 189 in the intervention arm.

The balance of the trial arms with regard to the demographic variables collected is given in *Table 18*. Sex, year of birth, nationality and family affluence were well balanced. However, there were more Year 5 pupils in the control group than in the intervention group, and slightly more Caucasian pupils in the intervention group. Pupils in the intervention group were generally older, with almost twice as many in Year 6 (10–11 years) than in the control group. Older children might be more competent to understand and complete questionnaires, and so this was examined in the analysis.

It can be seen from *Table 19* that more boys than girls had missing follow-up data (58.2% and 40.3%, respectively). Year 5 pupils, and those born in 2001, were also more likely to have missing follow-up data. There appeared to be little variation in rates of missing data at follow-up by country of birth or Family Affluence Scale.

Parents/carers

When schools were recruited (October 2011 to February 2012 and April 2012), we invited all parents/carers of children in participating classes to take part in telephone interviews (to collect outcome measure data at 6-month follow-up), and 52 volunteered. Interviews commenced in July 2012, and in an attempt to increase the number of participants, each participant was asked at the end of the interview if any other adult in the household would like to take part. One additional participant was recruited using this method. All interviews were completed by the end of September 2012 but interviewers continued their attempts to contact the remaining volunteers until the end of November 2012. Using an estimate that each eligible pupil would have only one parent/caregiver, the number of eligible parents was 418, of whom 12% volunteered to take part.

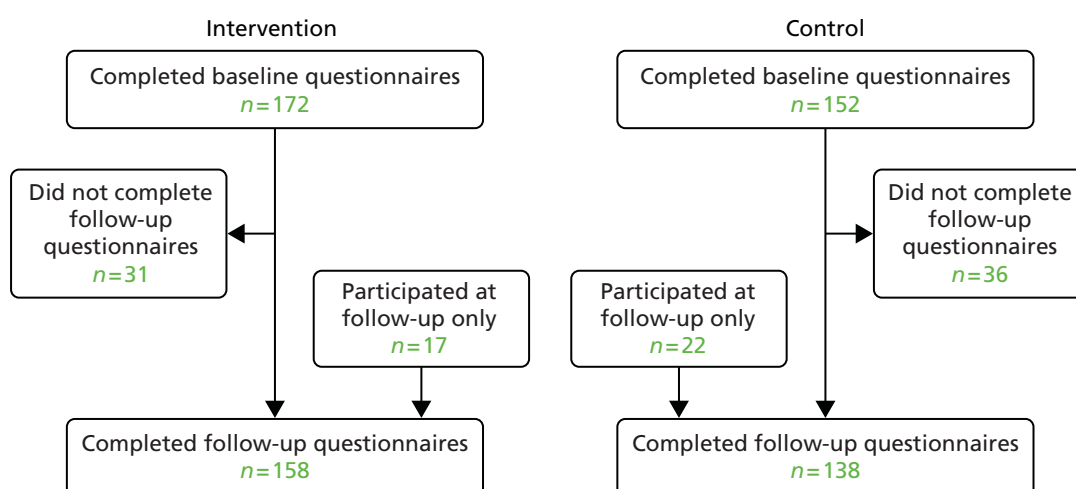


FIGURE 9 Pupil flow chart.

TABLE 18 Demographic balance of the groups

Characteristics	Pupils (<i>N</i> = 358)		
	Control, <i>n</i> (%)	Intervention, <i>n</i> (%)	Overall, <i>n</i> (%)
Sex			
Boy	81 (47.9)	90 (47.6)	171 (47.8)
Girl	87 (51.5)	99 (52.4)	186 (51.9)
Missing	1 (0.6)	0 (0.0)	1 (0.3)
Year of birth			
2000	17 (10.1)	34 (18.0)	51 (14.2)
2001	76 (45.0)	87 (46.0)	163 (45.5)
2002	76 (45.0)	55 (29.1)	131 (36.6)
2003	0 (0.0)	10 (5.3)	10 (2.8)
Missing	0 (0.0)	3 (1.6)	3 (0.8)
Year group			
Year 4	1 (0.6)	27 (14.3)	28 (7.8)
Year 5	119 (70.4)	60 (31.7)	179 (50.0)
Year 6	48 (28.4)	100 (52.9)	148 (41.3)
Missing	1 (0.6)	2 (1.1)	3 (0.8)
UK-born			
Yes	158 (93.5)	176 (93.1)	334 (93.3)
No	10 (5.9)	12 (6.3)	22 (6.1)
Missing	1 (0.6)	1 (0.6)	2 (0.6)
Ethnicity			
White	129 (76.3)	162 (85.7)	291 (81.3)
Black or black British	5 (3.0)	3 (1.6)	8 (2.2)
Mixed race	9 (5.3)	6 (3.2)	15 (4.2)
Chinese	0 (0.0)	1 (0.5)	1 (0.3)
Asian or Asian British	15 (8.9)	11 (5.8)	26 (7.3)
Other	5 (3.0)	4 (2.1)	9 (2.5)
Missing	6 (3.6)	2 (1.1)	8 (2.2)
Family Affluence Scale score			
Low	11 (6.5)	12 (6.3)	23 (6.4)
Medium	59 (34.9)	59 (31.2)	118 (33.0)
High	85 (50.3)	104 (55.0)	189 (52.8)
Missing	14 (8.3)	14 (7.4)	28 (7.8)
Language			
English	152 (89.9)	173 (91.5)	325 (90.8)
Not English	15 (8.9)	16 (8.5)	31 (8.7)
Missing	2 (1.2)	0 (0.0)	2 (0.6)

TABLE 19 Demographic balance of the group of pupils who completed baseline and follow-up data, compared with those who only completed baseline

Characteristics	Pupils (N = 324)	
	Baseline and follow-up (n = 257)	Baseline only (n = 67)
	n (%)	n (%)
Sex		
Boy	117 (45.5)	37 (58.2)
Girl	140 (54.5)	29 (40.3)
Missing	0 (0.0)	1 (1.5)
Year of birth		
2000	40 (15.6)	7 (10.4)
2001	112 (43.6)	34 (50.7)
2002	96 (37.4)	24 (35.8)
2003	7 (2.7)	2 (3.0)
Missing	2 (0.8)	0 (0.0)
Year group		
Year 4	21 (8.2)	5 (7.5)
Year 5	123 (47.9)	40 (59.7)
Year 6	110 (42.8)	22 (32.8)
Missing	3 (1.2)	0 (0.0)
UK-born		
Yes	241 (93.8)	63 (94.0)
No	14 (5.4)	4 (6.0)
Missing	2 (0.8)	0 (0.0)
Ethnicity		
White	211 (82.1)	50 (74.6)
Black or black British	5 (1.9)	2 (3.0)
Mixed race	11 (4.3)	3 (4.5)
Chinese	1 (0.4)	0 (0.0)
Asian or Asian British	15 (5.8)	10 (14.9)
Other	7 (2.7)	2 (3.0)
Missing	7 (2.7)	0 (0.0)
Family Affluence Scale score		
Low	17 (6.6)	5 (7.5)
Medium	86 (33.5)	23 (34.3)
High	134 (52.1)	33 (49.3)
Missing	20 (7.8)	6 (9.0)

Figure 10 shows that numbers of parents from intervention schools who expressed interest in the research were much larger than in control schools. However, the larger drop-out rate from the intervention arm meant that approximately equal proportions of parents from each group provided data. Demographic data supplied by the 41 respondents were examined in case they were all alike in one or more respects but this was not the case (see Appendix 10). As the data set was so small, no further analyses were conducted.

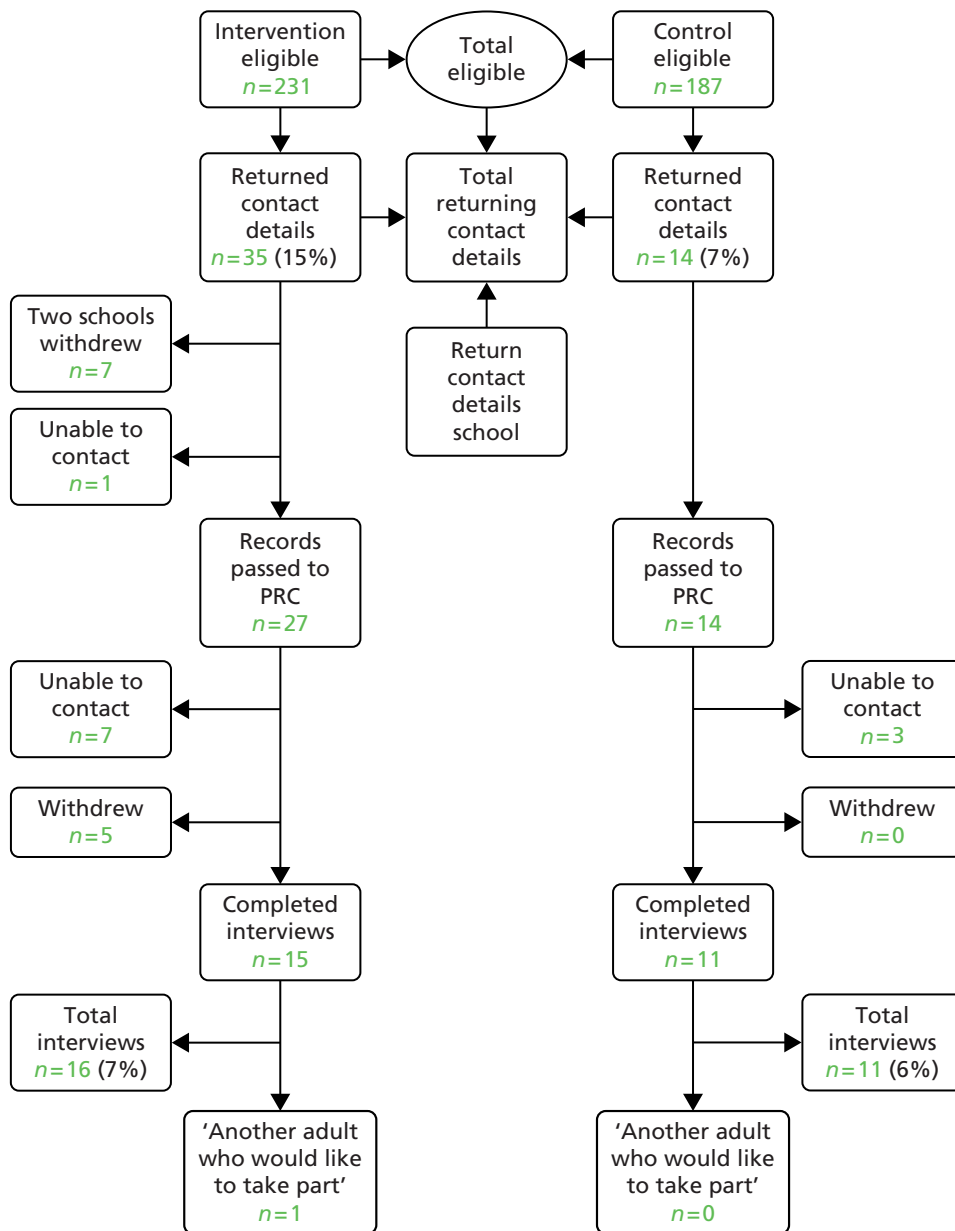


FIGURE 10 Parent recruitment for telephone interviews.

Numbers analysed (pupil data)

All analyses are ITT in the groups to which they were randomised using complete data for baseline and follow-up. In intervention schools, all trial participants' data were included in the analyses, regardless of the extent of their engagement with the KAT programme. Numbers for each analysis are given in all results tables. *p*-values in the tables are indicative only and should not be interpreted as a definitive result. Confidence intervals are more useful to interpret the data at this stage.

Feasibility of primary outcome measures

Summary data for the alcohol questions in the baseline and follow-up questionnaires are given in *Table 20*. Data are given for all 324 pupils at baseline, irrespective of whether or not they were followed up, as well as data for all pupils at follow-up irrespective of baseline assessment.

Table 20 shows that rates of missing data for all of the questions were low, ranging from 0.7% to 3.4%. Reported rates of ever having consumed alcohol were 13.9% at baseline and 16.2% at follow-up. Rates of ever-drunkenness were 2.8% and 3.4%. It can be seen that at both baseline and follow-up there are some inconsistencies in the data. For example, at baseline 45 participants said that they had had a drink at some point in their lives, but 61 indicated that they had consumed alcohol at some point during the last month. The question about smoking was included to assess its feasibility in case an effectiveness trial should examine the effect of KAT on multiple risk behaviours, but responses were not analysed. The findings reported below focus on the alcohol-related questions.

The categories used for drinking frequency were changed between baseline and follow-up. For this reason, as well as the sparse data in the drinking categories, the data were recoded into binary responses of never/once or more, for further analysis, and this is shown in *Table 21*. The majority of pupils reported not having either consumed alcohol or been drunk in the last 30 days at both data collection points (e.g. 77.8% and 93.8% at baseline).

TABLE 20 Summary of alcohol consumption and smoking

Question	Response, <i>n</i> (%)
Baseline (324 pupils)	
Ever had an alcoholic drink?	
Yes	45 (13.9)
No	268 (82.7)
Missing	11 (3.4)
Ever been drunk?	
Yes	9 (2.8)
No	308 (95.1)
Missing	7 (2.2)
Drinking frequency in the last 30 days	
Never	252 (77.8)
1–2 times	46 (14.2)
3–5 times	13 (4.0)
6–9 times	2 (0.6)
Missing	11 (3.4)

continued

TABLE 20 Summary of alcohol consumption and smoking (continued)

Question	Response, n (%)
Drunk frequency in the last 30 days	
Never	304 (93.8)
1–2 times	8 (2.5)
3–5 times	1 (0.3)
Missing	11 (3.4)
Smoking frequency in the last 30 days	
Never	312 (96.3)
3–5 times	3 (0.9)
6–9 times	1 (0.3)
Missing	8 (2.6)
Follow-up (296 pupils)	
Ever had an alcoholic drink?	
Yes	48 (16.2)
No	246 (83.1)
Missing	2 (0.7)
Ever been drunk?	
Yes	10 (3.4)
No	279 (94.3)
Missing	7 (2.4)
Drinking frequency in the last 30 days	
Never	255 (86.1)
1–2 days	27 (9.1)
3–5 days	6 (2.0)
6–9 days	2 (0.7)
20–29 days	2 (0.7)
Missing	4 (1.4)
Drunk frequency in the last 30 days	
Never	289 (97.6)
1–2 days	3 (1.0)
10–12 days	1 (0.3)
Missing	3 (1.0)
Smoking frequency in the last 30 days	
Never	292 (98.6)
1–2 days	1 (0.3)
Missing	3 (1.0)

Source: reproduced with permission from Segrott *et al.*¹

TABLE 21 Summary of alcohol consumption and smoking recoded into binary categories

Question	Baseline (324 pupils), n (%)	Follow-up (296 pupils), n (%)
Drinking frequency in the last 30 days		
Never	252 (77.8)	255 (86.1)
Once or more	61 (18.8)	37 (12.5)
Missing	11 (3.4)	4 (1.4)
Drunk frequency in the last 30 days		
Never	304 (93.8)	289 (97.6)
Once or more	9 (2.8)	4 (1.4)
Missing	11 (3.4)	3 (1.0)
Smoking frequency in the last 30 days		
Never	312 (96.3)	292 (98.6)
Once or more	4 (1.2)	1 (0.3)
Missing	8 (2.5)	3 (1.0)

Prevalence and odds ratios in the following tables are given for only those pupils who provided both baseline and follow-up outcomes as baseline drinking was used as a covariate. *Table 22* gives the proportion of pupil responses for each of the drinking variables alongside the intervention effects. School size and FSM entitlement have been included as school-level covariates in the model as they were used to balance the randomisation, but were not statistically significant. The ICC values for each outcome demonstrate that up to 11% of the variation in outcomes is due to clustering by school and that the majority of the variation is at the pupil level. Baseline levels of alcohol consumption were also included in each model as pupil-level covariates to provide baseline adjusted odds ratios for the intervention effects. The zero ICC value (drunk, last 30 days) may be due to sparse data leading to an inability to estimate ICCs for these outcomes, rather than an indication of no school-level variation.

Overall, the levels of alcohol consumption at baseline in both groups are low, especially for those reporting drinking enough alcohol to be drunk. For the 'ever had an alcoholic drink' question, in the control group at baseline 14 of the 117 (12%) pupils said yes, which reduces to 9 out of 117 (7.7%) at follow-up. In the intervention group, the proportion reporting 'ever had a drink' was higher than in the control group at baseline (18%) and increased to 23.8% at follow-up. The intervention effects are given as odds ratios

TABLE 22 Intervention effect on primary alcohol consumption outcomes

Question	Control			Intervention			Intervention effect adjusted for baseline consumption level, FSM and school size		
	N	Baseline, n (%)	Follow-up, n (%)	N	Baseline, n (%)	Follow-up, n (%)	ICC	Odds ratio and 95% CI	p-value
Ever had an alcoholic drink?	117	14 (12.0)	9 (7.7)	130	24 (18.5)	31 (23.8)	0.112	5.3 (1.2 to 23.9)	0.030
Ever been drunk?	114	1 (0.9)	0 (0.0)	131	7 (5.3)	8 (6.1)	0.000	1.7 (0.5 to 6.8)	0.423
Had drink in the last 30 days?	115	15 (13.0)	14 (12.2)	131	34 (26.0)	19 (14.5)	0.077	0.7 (0.2 to 2.5)	0.558
Been drunk in the last 30 days?	117	3 (2.6)	0 (0.0)	129	6 (4.7)	4 (3.1)	0.000	1.5 (0.4 to 5.8)	0.564

corrected for baseline drinking, FSM and school size. They can be interpreted as intervention group pupils being 5.3 times more likely to have ever had a drink at follow-up and 1.7 times more likely to have ever been drunk than those in the control group. Baseline rates of past-month drinking were higher in the intervention group [34 (26%)] than in the control group [15 (13%)]. At follow-up, the rates were 19 (14.5%) for the intervention group, and 14 (12.2%) for the control group.

Again, it can be seen that there are inconsistencies in pupils' responses. For instance, at follow-up more children in the control group said that they had consumed alcohol in the last 30 days than reported ever having consumed alcohol. Another example is that the same type of discrepancy was also present for the intervention group at baseline.

To investigate the issue of changing responses, a cross-tabulation of baseline versus follow-up response was performed. *Table 23* shows that for 'ever had a drink', eight pupils in the control group gave their answer as 'yes' at baseline and 'no' at follow-up. This also occurred in the intervention group, where six pupils answered 'yes' at baseline and 'no' at follow-up. For the question 'have you ever been drunk?' the data are extremely sparse, with only one pupil in the control group reporting that they had been drunk; moreover, this pupil answered 'no' at follow-up. There were seven pupils in the intervention group who answered 'yes' at baseline, two of whom answered 'no' at follow-up.

Because there was a small imbalance in age between the trial arms, the influence of the difference in age between the trial arms on the main outcomes was examined. Of the 358 pupils who provided their demographic variables, three failed to give their year group. Among the other 355 pupils, 28 were in Year 4, 179 in Year 5 and 148 in Year 6. *Table 24* gives the data for year group and alcohol consumption. It can be seen that it is difficult to discern a clear pattern in the data.

TABLE 23 Cross-tabulation of baseline and follow-up responses for the primary drinking outcomes

Response		Question							
		Ever had an alcoholic drink?, <i>n</i>		Ever been drunk?, <i>n</i>		Frequency of drinking in last month/last 30 days?, <i>n</i>		Frequency of drunkenness in last month/last 30 days?, <i>n</i>	
Baseline	Follow-up	C	I	C	I	C	I	C	I
Never	Never	100	93	113	121	94	93	114	122
Never	Yes	3	13	1	3	6	4	0	1
Yes	Yes	6	18	0	5	8	15	0	3
Yes	Never	8	6	1	2	7	19	3	3

C, control; I, intervention.

TABLE 24 Responses to alcohol consumption questions, by year group

Question	Year 4		Year 5		Year 6	
	Baseline, n (%)	Follow-up, n (%)	Baseline, n (%)	Follow-up, n (%)	Baseline, n (%)	Follow-up, n (%)
Ever had an alcoholic drink?						
Yes	3 (10.7)	5 (17.9)	23 (12.8)	19 (10.6)	17 (11.5)	23 (15.5)
No	19 (67.9)	18 (64.3)	136 (76.0)	117 (65.4)	112 (75.7)	104 (70.3)
Missing	6 (23.4)	5 (17.9)	20 (11.2)	43 (24.0)	19 (12.8)	21 (14.2)
Ever been drunk?						
Yes	1 (3.6)	2 (7.1)	3 (1.7)	3 (1.7)	5 (3.4)	5 (3.4)
No	23 (82.1)	20 (71.4)	156 (87.2)	131 (73.2)	126 (85.1)	121 (81.8)
Missing	4 (14.3)	6 (21.4)	20 (11.2)	45 (25.1)	17 (11.5)	22 (14.9)
Drink frequency in last 30 days						
Ever	8 (28.6)	5 (17.9)	26 (14.5)	18 (10.1)	25 (16.9)	14 (9.5)
Never	16 (57.1)	17 (60.7)	131 (73.2)	120 (67.0)	104 (70.3)	111 (75.0)
Missing	4 (14.3)	6 (21.4)	22 (12.3)	41 (22.9)	19 (12.8)	23 (15.5)
Drunk frequency in last 30 days						
Ever	1 (3.6)	0 (0.0)	4 (2.2)	1 (0.6)	4 (2.7)	3 (2.0)
Never	23 (82.1)	22 (78.6)	153 (85.5)	136 (76.0)	125 (84.5)	123 (83.1)
Missing	4 (14.3)	6 (21.4)	22 (12.3)	42 (23.5)	19 (12.8)	22 (14.9)

To investigate any effect of school year group on the results shown in *Table 22*, school year group was included as a covariate in the model. Results are shown in *Table 25*.

Table 25 shows that adding the year group to the models for drinking outcomes does not have a statistically significant impact. However, the significant difference in 'ever had an alcoholic drink' between the trial arms in *Table 22* is no longer significant, indicating that some of the difference observed between the trial arms has been explained by a difference in ages between the intervention and control groups. *Tables 22* and *25* also indicate that the intervention group participants are less likely than those in the control group to report drinking alcohol in the last 30 days. Again, this highlights the mixed, and sometimes contradictory, patterns in the data.

Of the 358 pupils who provided their demographic variables, eight failed to provide information on their ethnic group. Among the 350 pupils who did, 291 were white and 59 were from another ethnic group.

Table 26 shows the responses and missing data rates for the alcohol-related questions for those participants who described themselves as white, compared with all other participants. We used this classification mainly because the numbers for individual ethnic groups were very small. There does not appear to be a clear difference between these two groups at baseline in terms of rates of missing data. At follow-up, the rates of missing data appear to be higher among non-white participants.

TABLE 25 Intervention effect on primary alcohol consumption outcomes, adjusted for school year group (Years 4 and 5 vs. Year 6)

Question	Control		Intervention		Intervention effect		Year 4 and 5 effect	
	N	Baseline, n (%)	N	Baseline, n (%)	ICC	Effect and 95% CI	Effect and 95% CI	p-value
Ever had an alcoholic drink?	117	14 (12.0)	130	24 (18.5)	0.122	3.3 (0.9 to 25.0)	2.0 (0.6 to 5.0)	0.264
Ever been drunk?	114	1 (0.9)	131	7 (5.3)	0.000	1.7 (0.4 to 10.0)	0.9 (0.2 to 5.0)	0.915
Drink frequency in last 30 days	115	15 (13.0)	131	34 (26.0)	0.077	0.9 (0.4 to 2.5)	0.7 (0.2 to 2.0)	0.440
Drunk frequency in last 30 days	117	14 (12.0)	130	24 (18.5)	0.122	3.3 (0.9 to 25.0)	2.0 (0.6 to 5.0)	0.264

CI, confidence interval.

TABLE 26 Responses and missing data rates for white and non-white participants

Question	White		Others	
	Baseline, <i>n</i> (%)	Follow-up, <i>n</i> (%)	Baseline, <i>n</i> (%)	Follow-up, <i>n</i> (%)
Ever had an alcoholic drink?				
Yes	42 (14.4)	43 (14.8)	3 (5.1)	3 (5.1)
No	210 (72.2)	195 (67.0)	52 (88.1)	40 (67.8)
Missing	39 (13.4)	53 (18.2)	4 (6.8)	16 (27.1)
Ever been drunk?				
Yes	8 (2.7)	8 (2.7)	1 (1.7)	1 (1.7)
No	247 (84.9)	228 (78.4)	55 (93.2)	40 (67.8)
Missing	36 (12.4)	55 (18.9)	3 (5.1)	18 (30.5)
Drink frequency (past month)				
Ever	53 (18.2)	31 (10.7)	8 (13.6)	6 (10.2)
Never	202 (69.4)	207 (71.1)	45 (76.3)	37 (62.7)
Missing	36 (12.4)	53 (18.2)	6 (10.2)	16 (27.1)
Drunk frequency (past month)				
Ever	8 (2.7)	3 (1.0)	1 (1.7)	1 (1.7)
Never	247 (84.9)	235 (80.8)	51 (86.4)	42 (71.2)
Missing	36 (12.4)	53 (18.2)	7 (11.9)	16 (27.1)

Feasibility of secondary outcomes

Secondary outcomes validation

There were five secondary outcomes in the pupils' questionnaire: the Family Activity Scale, KIDSCREEN-52, TCPPAS, PCCS, and the FCS. All outcomes were modified and/or adapted for KAT, and therefore needed validation. For the outcomes measured at baseline and follow-up (Family Activity Scale, KIDSCREEN-52, TCPPAS), validation was carried out using baseline data, while the outcomes used only at follow-up (PCCS and FCS) were validated using the follow-up data set.

Table 27 shows that the reliability of the secondary outcomes was demonstrated using Cronbach's alpha values. All were greater than 0.7, indicating high internal consistency of items. Factor analysis confirmed that each scale consisted of one factor, indicating that using a summed score for each is a valid interpretation of the data. Summed responses were investigated for normality and demonstrated negative

TABLE 27 Secondary outcomes validation

Secondary outcome	Cronbach's alpha
Family Activity Scale	$\alpha = 0.807$
KIDSCREEN-52	$\alpha = 0.752$
TCPPA	$\alpha = 0.775$
PCCS	$\alpha = 0.758$
FCS	$\alpha = 0.731$

skew. Positively skewed data can be log-transformed so that they become normally distributed before analysis. However, negatively skewed data are difficult to normalise using transformation. We have, therefore, left the data untransformed, as analysis of variance (ANOVA) and analysis of covariance (ANCOVA) are relatively robust to non-normality and the extension to two-level linear models should not invalidate the interpretation of the likely intervention effects. However, caution should be exercised when examining these data and reanalysing these scales as categorical outcomes rather than continuous scores may be preferable for investigating these data in a larger definitive trial.

Two-level generalised linear modelling

Secondary outcome scores were analysed using two-level generalised linear models, with responses from pupils nested within schools using models adjusting for baseline data (if available). Covariates included in the model were school size and FSM entitlement. As TCPPA was captured only in baseline questionnaires and was replaced by the PCCS in the follow-up questionnaire, we did not conduct two-level modelling for TCPPA. Models for secondary outcomes were adjusted for school size and FSM. Neither covariate was statistically significant but they remained in the final model due to their use as balancing variables in the randomisation.

Rates of missing data

Of the 358 pupils who provided their demographic variables, three failed to provide their year group. Among the other 355 pupils, 28 were in Year 4, 179 in Year 5, and 148 in Year 6. *Table 28* shows how many pupils in each year provided data for secondary outcome measures.

Excluding the FCS, rates of missing data ranged from 14.1% to 23.5%. Rates of missing data were, thus, higher for the secondary outcomes than for the alcohol-related questions discussed above. For the measures used at both baseline and follow-up (the Family Activity Scale and KIDSCREEN-52 subscale), rates of missing data were higher at follow-up than at baseline, except for KIDSCREEN-52 in Year 6,

TABLE 28 Numbers and percentages of pupils who provided data for secondary outcome measures, by school year group

Outcome measure	Year 4		Year 5		Year 6	
	Baseline, n (%)	Follow-up, n (%)	Baseline, n (%)	Follow-up, n (%)	Baseline, n (%)	Follow-up, n (%)
Family Activity Scale						
Calculated	26 (92.9)	22 (78.6)	158 (88.3)	137 (76.5)	129 (87.2)	124 (83.9)
Missing	2 (7.1)	6 (21.4)	21 (11.7)	42 (23.5)	19 (12.8)	24 (16.1)
KIDSCREEN-52						
Calculated	26 (92.9)	23 (82.1)	162 (90.5)	137 (76.5)	126 (85.1)	127 (85.8)
Missing	2 (7.1)	5 (17.9)	17 (9.5)	42 (23.5)	22 (14.9)	21 (14.2)
PCCS						
Calculated	N/A	22 (78.6)	N/A	134 (74.9)	N/A	125 (84.5)
Missing	N/A	6 (21.4)	N/A	45 (15.1)	N/A	23 (15.5)
FCS						
Calculated	N/A	16 (57.1)	N/A	104 (58.1)	N/A	108 (73)
Missing	N/A	12 (42.9)	N/A	75 (41.9)	N/A	40 (17)

N/A, not applicable.

where there was a small decrease in the rate from 14.9% at baseline to 14.2% at follow-up. For the FCS, there was a much lower rate of missing data in Year 6, 17%, compared with 41.9% in Year 5 and 42.9% in Year 4. One factor contributing to the highest rates of missing data found for the FCS (42.9% for Year 4) is that on 28 questionnaires, one item was accidentally omitted from the scale; otherwise, there was no discernible pattern to the unanswered items. Another possible reason is that the FCS was counted as missing if any one item out of 10 was not answered because the score for this measure is summed from the individual responses. However, we cannot rule out the possibility that the questions may have been unsuitable for children in all year groups. For the other scales, comparisons of rates across year groups do not support an age-related explanation for any differences, and the very small numbers of Year 4 pupils limit the scope for interpretation.

Table 29 shows the scores for the secondary outcomes. At follow-up, the average scores on the Family Activity Scale and PCCS were marginally higher for the intervention group. There was no difference between the average scores for the two groups on KIDSCREEN-52. The average score for the control group was marginally higher for the control group on the FCS. None of these effects reaches levels of conventional statistical significance and confidence intervals are wide. Of the four measures, two (the FCS and the PCCS) were used only at follow-up, while the other two were used at both baseline and follow-up.

Effect sizes detected in previous studies (secondary outcomes)

We identified previous studies which have used our selected secondary outcome measures, to identify what size of effect had been detected in evaluations of interventions comparable with KAT. However, this search yielded only limited information. For the FCS, we could find no trials which had used this measure, and the studies which had used it had done so with older children than KAT participants, and only at one time point. All of these studies were in countries other than the UK. Typical scores on the FCS appeared to be relatively high (around 35–45 out of a possible total score of 50). In our study, we replaced the five-point Likert scale with yes/no responses (to aid question comprehension), meaning that the total possible score was 10. Scores were 9.11 (intervention) and 8.81 (control). It is, therefore, not possible to make direct comparisons between our data and previous studies using the FCS. However, our scores appear to fit within the broad range of scores reported by previous studies.^{143–145}

TABLE 29 Summary of two-level modelling on secondary outcome scales

Outcome measure	Control			Intervention			Intervention effect	
	<i>n</i>	Baseline, mean (SD)	Follow-up, mean (SD)	<i>n</i>	Baseline, mean (SD)	Follow-up, mean (SD)	Coefficient and 95% CI	<i>p</i> -value
Family Activity Scale	118	2.6 (0.8)	2.55 (0.77)	132	2.6 (0.8)	2.7 (0.7)	0.1 (–0.1 to 0.3)	<i>0.182</i>
KIDSCREEN-52	118	81.9 (18.2)	82.5 (17.6)	134	82.0 (15.7)	81.7 (17.6)	0.0 (–6.0 to 6.1)	0.993
PCCS	136	Not measured	1.3 (0.3)	153	Not measured	1.4 (0.3)	0.1 (–0.1 to 0.3)	<i>0.314</i>
FCS	117	Not measured	9.1 (1.4)	118	Not measured	8.8 (1.8)	–0.2 (–1.1 to 0.6)	<i>0.610</i>

CI, confidence interval.

Italics in *p*-value column indicate that as an exploratory trial, the main focus should be on the CIs.

Source: reproduced with permission from Segrott *et al.*¹

Previous studies which have used KIDSCREEN (or only its parent relation and home life dimension as we did) have found relatively small changes in these scores; however, the studies identified were all observational,^{146–148} with the exception of Karasimopoulou *et al.*¹⁴⁹ They used KIDSCREEN-52 with 10- to 12-year-olds in Greece as part of an evaluation of a health education/social skills programme (possible scores ranged from 6 to 30). The experimental group had a mean [\pm standard deviation (SD)] parent relation/home life score of 23.81 (\pm 6.46) before the intervention and 25.54 at follow-up (\pm 4.09). The control group's baseline score was 24.66 (\pm 4.20) and 24.3 (\pm 4.45) at follow-up. As with the FCS above, it is difficult to make direct comparisons with our study because we used a score of 0 (rather than 1) for the 'not at all' response on the Likert scale and linearly transformed scores to a 0–100-point scale. The control group in KAT had a baseline score of 81.87 (\pm 18.23) and a follow-up score of 82.47 (\pm 17.56). The respective figures for the intervention group were 81.98 (\pm 15.66) and 81.74 (\pm 17.56).

For the Family Activity Scale, we were unable to identify any previous RCTs or longitudinal studies which had used the scale. In our study, we created a single mean score based on all eight items in the scale (follow-up scores were 2.55 (intervention) (SD 0.77) and 2.70 (control) (SD 0.70). These appear to be broadly comparable with scores reported in previous studies, though they are mainly for the individual questions within the measure (in all cases, 1 = never and 5 = every day). For instance, Garmiene's study⁵⁵ of children aged 10 in Lithuania found mean scores which ranged from 2.62 for playing sports (\pm 1.24) to 4.57 for watching TV together (\pm 1.16).

For the PCCS, we were unable to identify any studies which reported baseline and follow-up scores from RCTs, and there were no studies of any design which had used the measure in the UK, or with the same age group as in the current study. It is, therefore, very difficult to assess what magnitude of effect a programme such as KAT might potentially have on alcohol-related parent–child communication using this scale. In Mares *et al.*'s study,⁹⁹ baseline means (11- to 12-year-olds) for communication frequency were 2.09 (\pm 0.85) (intervention) and 2.19 (\pm 0.91) (controls), while in Van der Vorst *et al.*'s study¹⁵⁰ of 13- to 16-year-olds, the mean report for younger siblings was 1.75 (\pm 0.67). In our study, the follow-up means were 1.25 (SD 0.26) (intervention) and 1.38 (SD 1.79) (control).

Estimation of sample size needed for an effectiveness trial of Kids, Adults Together

Determining the primary outcome for an effectiveness trial

Our data suggest some problems with the reliability of pupils' recall of lifetime drinking. These may have related to the young age of the children, or heightened awareness of alcohol issues as a result of questionnaire completion/intervention receipt, though we do not have evidence to confirm or refute this. If follow-up took place at 2 years past baseline in a future trial, the participants would be 2 years older than they were in this study. Age-related issues around comprehension might, therefore, be less of a problem. However, basing the primary outcome on whether or not participants have had a drink in the last 30 days would provide a good indicator of recent drinking behaviour, and may avoid the problems described above concerning recall over a child's entire life. Our sample size calculations for an effectiveness trial are, therefore, based on detecting differences in past-month drinking (as a binary outcome) between intervention and control. However, should any future trial be planned it would also aim to measure other aspects of alcohol behaviour (lifetime drinking, and aspects of drunkenness) as key secondary outcomes.

Rates of drinking behaviours in the Health Behaviour in School-aged Children survey and randomised controlled trial of the Strengthening Families Programme 10–14

To estimate the prevalence of past-month drinking rates, we examined the 2009 HBSC survey, which collected data on this outcome. We also examined baseline data from an ongoing trial of another alcohol misuse prevention programme (SFP10–14). That trial does not collect data on past-month drinking at baseline, but we were able to use the other alcohol-related data to provide some additional context on drinking behaviours among 11- to 13-year-olds (the age which participants would be at main follow-up in an effectiveness trial of KAT). The SFP10–14 trial is using past-month drinking as one of its twin primary outcomes, and these data will be available in 2014 (and, therefore, could aid further work on developing a sample size for any future effectiveness trial of KAT).⁸

Table 30 shows data from the HBSC for participants born in 1997, 1998 and 1999 (i.e. 11- to 13-year-olds at the time of data collection) relating to the number of times that they consumed alcohol during the last 30 days.

The data in Table 30 show an overall prevalence rate for past-month drinking of 24.5% ($773/3151 = 24.5\%$), and the majority of those who have consumed alcohol have done so on only a few occasions.

Table 31 shows data from the baseline questionnaire used in the SFP10–14 trial. It indicates that for the 13-year-olds in the sample, around 21% drink alcohol monthly or more frequently. This is slightly lower than, but broadly comparable to, the HBSC data.

Table 32 below displays data for the question on whether or not participants in the SFP10–14 trial had ever had a drink of alcohol. At age 11, only 15.2% of participants report ever having had a drink of alcohol, but this increases to 52% by age 13.

TABLE 30 Frequency of drinking in the last 30 days (HBSC)

Birth year	Frequency, <i>n</i> (%)							Total, <i>N</i> (%)
	Never	1–2 times	3–5 times	6–9 times	10–19 times	20–39 times	40 times or more	
1997	1412 (73.31)	356 (18.48)	83 (4.31)	34 (1.7)	20 (1.04)	9 (0.47)	12 (0.62)	1926 (100)
1998	962 (78.98)	182 (14.94)	43 (3.53)	12 (0.99)	7 (0.57)	5 (0.41)	7 (0.57)	1218 (100)
1999	4 (57.14)	1 (14.29)	1 (14.29)	1 (14.29)	0	0	0	7 (100)

TABLE 31 Frequency of drinking (SFP10–14 trial baseline data)

Age in years	How often do you usually have an alcoholic drink?					Total
	Two or three times a week	About once a week	About once a month	Only a few times a year	I never drink alcohol now	
9						
<i>n</i> (% total in age group)	0	0	1 (25.0)	2 (50.0)	1 (25.0)	4 (100)
% all answers in this category	0	0	2.8	1.1	2.2	1.4
10						
<i>n</i> (% total in age group)	0	0	1 (4.5)	15 (68.2)	6 (27.3)	22 (100)
% all answers in this category	0	0	2.8	8.2	13.0	7.8
11						
<i>n</i> (% total in age group)	0	0	2 (5.7)	22 (62.9)	11 (31.4)	35 (100)
% all answers in this category	0	0	5.6	12.1	23.9	12.4
12						
<i>n</i> (% total in age group)	0	0	4 (7.8)	41 (80.4)	6 (11.8)	51 (100)
% all answers in this category	0	0	11.1	22.5	13.0	18.0
13						
<i>n</i> (% total in age group)	1 (1.1)	6 (6.6)	12 (13.2)	57 (62.6)	15 (16.5)	91 (100)
% all answers in this category	25.0	40.0	33.3	31.3	32.5	32.2
14						
<i>n</i> (% total in age group)	3 (3.8)	9 (11.2)	15 (20.0)	45 (56.2)	7 (8.8)	80 (100)
% all answers in this category	75.0	60.0	44.4	24.7	15.2	28.3
Total						
<i>N</i> (%)	4 (1.4)	15 (5.3)	36 (12.7)	182 (64.3)	46 (16.3)	283 (100)
% answers in each category	100	100	100	100	100	100

TABLE 32 Rates of 'ever drinking' at baseline in the SFP10–14 trial

Age in years	Have you ever had a proper alcoholic drink – a whole drink, not just a sip?		
	Yes	No	Total
9			
<i>n</i> (% in age group)	4 (18.2)	18 (81.8)	22 (100)
% answers from children this age	1.4	2.8	2.4
10			
<i>n</i> (% in age group)	23 (11.0)	187 (89)	210 (100)
% answers from children this age	8.0	29.3	22.7
11			
<i>n</i> (% in age group)	35 (15.2)	196 (84.8)	231 (100)
% answers from children this age	12.2	30.7	25.0
12			
<i>n</i> (% in age group)	51 (30.2)	118 (69.8)	169 (100)
% answers from children this age	17.8	18.5	18.3
13			
<i>n</i> (% in age group)	92 (52.0)	85 (48.0)	177 (100)
% answers from children this age	32.2	13.3	19.1
14			
<i>n</i> (% in age group)	81 (69.8)	35 (30.2)	116 (100)
% answers from children this age	28.3	5.5	12.5
Total			
<i>N</i> (%)	286 (30.9)	639 (69.1)	925 (100)
% answers	100	100	100

Sample size calculation

Our sample size calculations use the prevalence rate of 24.5% for past-month drinking, derived from the HBSC data above. *Tables 33* and *34* present sample size calculations based on KAT reducing past-month drinking by 2.5%, 5% and 7.5% respectively, using the ICC of 0.021 from the HBSC data for 11- to 13-year-olds' drinking in the last 30 days. We are not able to specify with precision what effect KAT would achieve, and have therefore included a range of sample size calculations (based on 2.5%, 5% and 7.5% reductions in past-month drinking). However, the brief duration of the KAT intervention and the evidence

TABLE 33 Two-group, two-tailed chi-squared test of equal proportions (80% power, not continuity corrected)

Difference to detect	Control group proportion	Intervention group proportion	Significance	Power	OR	<i>n</i> per group	Total, <i>N</i>
2.5%	24.5%	22%	5%	80%	0.869	4481	8962
5%	24.5%	19.5%	5%	80%	0.746	1077	2154
7.5%	24.5%	17%	5%	80%	0.631	458	916

OR, odds ratio.

TABLE 34 Inflating for clustering (80% power)

Difference to detect	ICC	Average cluster size	DE	CV	DE (adjusted for CV)	Drop out/absent	Total sample size	Number of schools required	Pupils per school to recruit
2.5%	0.021	30	1.61	0.487	1.76	20%	9849	263	38
5%	0.021	30	1.61	0.487	1.76	20%	4734	127	38
7.5%	0.021	30	1.61	0.487	1.76	20%	2013	54	38

CV, coefficient of variation of cluster size; DE, design effect.
Where $DE = 1 + (m - 1)ICC$, $DE(\text{adjusted for CV}) = 1 + [m(1 + CV^2)]ICC$ if $CV > 0.23$.

from this study, including the lack of evidence of effect on hypothesised mediators, suggest that any effect would be small, and a 2.5% reduction may be the most appropriate of the three we present below.

The total sample size estimated from *Table 33* must then be inflated for clustering. It should also be inflated for varying cluster size and pupil drop out.

Table 34 shows that for an effectiveness trial designed to detect a 2.5% difference between the two trial arms, the necessary sample size would be 9849 participants, and 263 schools. To detect a difference of 5% and 7.5% would require 127 and 54 schools, respectively.

The estimated sample sizes with 90% power for the same range of differences in drinking prevalence are given in *Tables 35* and *36*.

The total sample size estimated from *Table 35* must then be inflated for clustering (see *Table 36*). It should also be inflated for varying cluster size and pupil drop-out.

TABLE 35 Two-group, two-tailed chi-squared test of equal proportions (90% power, not continuity corrected)

Difference to detect	Control group proportion	Intervention group proportion	Significance	Power	OR	n per group	Total, N
2.5%	24.5%	22%	5%	90%	0.869	5998	11,996
5%	24.5%	19.5%	5%	90%	0.746	1441	2154
7.5%	24.5%	17%	5%	90%	0.631	613	916

OR, odds ratio.

TABLE 36 Inflating for clustering (90% power)

Difference to detect	ICC	Average cluster size	DE	CV	DE (adjusted for CV)	Drop out/absent	Total sample size	Number of schools required	Pupils per school to recruit
2.5%	0.021	30	1.61	0.487	1.76	20%	13,183	351	38
5%	0.021	30	1.61	0.487	1.76	20%	6335	169	38
7.5%	0.021	30	1.61	0.487	1.76	20%	2695	72	38

CV, coefficient of variation of cluster size; DE, design effect.
Where $DE = 1 + (m - 1)ICC$, $DE(\text{adjusted for CV}) = 1 + [m(1 + CV^2)]ICC$ if $CV > 0.23$.

Table 36 indicates that based on 90% power, a total of 351 schools would be needed to detect a 2.5% reduction in drinking in the intervention group. For 5%, the figure would 169 schools, and for 7.5% a total of 72 schools would need to be recruited.

Table 37 shows the total number of eligible schools (English-medium primaries) in each of the 22 local authorities in Wales, and the number of schools which could be recruited from each of these areas if 23% agreed to participate an effectiveness trial (the same proportion as in the current study). Using these calculations, it can be seen that if all eligible schools across Wales were invited to participate in the trial using the methods employed in the current study, 198 schools could be recruited, assuming that 23% agreed to participate. Presuming that a future effectiveness trial would use 80% power and would seek to detect a reduction of 2.5% in past-month drinking, this figure falls well short of the 263 schools which would be needed.

TABLE 37 Number of schools in Wales eligible to participate in an effectiveness trial, and potential numbers of recruited schools

Name of local authority area	Number of eligible schools ^a	Number of schools recruited if 23% agreed to take part
Isle of Anglesey	2	0
Gwynedd	1	0
Conwy	36	8
Denbighshire	29	7
Flintshire	62	14
Wrexham	51	12
Powys	75	17
Ceredigion	7	2
Pembrokeshire	45	10
Cardiganshire	39	9
Swansea	68	16
Neath Port Talbot	6	1
Bridgend	43	10
Vale of Glamorgan	39	9
Rhondda Cynon Taf	85	20
Merthyr Tydfil	20	5
Caerphilly	57	13
Blaenau Gwent	24	6
Torfaen	25	6
Monmouthshire	29	7
Newport	39	8
Cardiff	81	19
Totals	863	198

^a Eligible schools are English-medium schools, and those 'dual-stream' schools which use both English and Welsh as their main school language. Because no Welsh-language version of the programme materials exist, we have presumed that Welsh-medium schools would not be eligible to participate in the effectiveness trial. However, if the programme was found to be effective, a Welsh-language version would need to be produced. The other key inclusion criterion is that primary schools have to have pupils in the 9–11 years age range; therefore, infant schools are excluded.

Exploratory work to facilitate an economic evaluation

Key cost domains

To enable an economic evaluation to be conducted as part of any future effectiveness trial, we sought to map, in as much detail as possible, the key cost domains.

The costs associated with running KAT can be mapped on to three levels, namely families, schools, and external organisations. We deal with each in turn. For families, the main costs incurred relate to the opportunity cost of attending the family event and the expenses incurred through travelling to and from school. Some parents/carers might also incur childcare costs for young siblings of children involved in KAT, though the family events are open to all family members.

Schools' costs fall into three clear categories. First, there is the cost of staff time devoted to the programme. This comprises teaching staff, teaching assistants, and non-teaching staff such as caretakers. Second, there is a cost attached to the production of materials for the family event. These are mainly paper and stationery – there is no requirement for schools to buy equipment as part of their classroom preparation. Third, by delivering KAT, schools incur an opportunity cost – i.e. the time spent on the programme by staff and pupils could have been utilised for other curricular or non-curricular activities.

During this exploratory trial we were also able to map out which external organisations were involved in programme delivery, the nature and extent of their input, and how this might evolve as part of the systems and structures established for any future effectiveness trial. In the current study, the following agencies supported the implementation of KAT:

- A Healthy Schools Scheme officer, who assisted with recruitment of schools, and also attended some of the training events for school staff and the family events.
- An educational consultant who provided training and support for school staff and also assisted with the running of the family events. The cost of her employment was covered by a grant from the Welsh Government.
- A local drugs agency which provided an information stand at all of the KAT events.
- A local secondary school which loaned its 'smoothie bike' free of charge for use at the family event in all of the intervention schools.

A number of non-staff costs were also covered by external agencies (principally, by a grant from the Welsh Government). These were the updating and printing of the programme manual and the purchase of additional educational resources; the cost of providing refreshments at all three schools which ran family events; the purchase of additional display boards (which were used in multiple schools); and the cost of van hire to transport the 'smoothie bike' between schools. The 'goody bags' and their contents (including the DVD) had already been produced and paid for by Gwent Police before the start of the trial as part of the earlier phase of programme delivery; Gwent Police made these items freely available.

Questionnaires completed by pupils in this study included questions on whether or not they completed the KAT classroom work, and rates of attendance at the family event (for pupils, families, and the number of adults present from each family). This information on programme reach could be used alongside data on programme costs to ascertain the cost per participant/family.

Translating inputs into financial costs

Based on our experience in this exploratory trial, we believe that it should be possible to translate all of the key inputs into financial costs which could then be used as part of an economic evaluation. A section of the programme handbook could be used to ask staff to record (in a pro forma in the book) how many hours they spend on KAT (pupil contact time and other preparation time). It should be possible for a process evaluation within any future effectiveness trial to record total pupil contact time in a subsample of the intervention schools, so that teacher self-reports and researcher observations can be compared.

Although we did not ask schools to calculate the cost of teacher input into the programme, we believe that it would be feasible to ask head teachers either to provide this information or to share sufficient information for us calculate an hourly cost.

In this exploratory trial, the cost of refreshments, transportation of the 'smoothie bike', and other non-staff costs were paid directly by the research team from a centrally held programme grant. In any future effectiveness trial, we would expect schools to organise and pay for refreshments at their family event, and to submit invoices for these and other costs (such as those associated with the use of 'smoothie bikes') to a central programme co-ordinator. These data could, therefore, be used to provide accurate information on the non-staff costs which schools need to recoup.

Process evaluation observation of classroom preparation activities allowed us to generate an overall impression of the amount of consumable materials (e.g. paper, pens and posters) that schools used. Given the difficulty of producing exact costs for these materials, the most efficient way of estimating the costs would be to ask each school to provide an estimate of all of the non-staff expenditure items they provide. This information could be requested at the same time as schools submit invoices for reimbursement of costs paid by a central programme grant. It was feasible to separate research-related and programme delivery-related costs in this exploratory trial. A health economic evaluation as part of any effectiveness trial would also need to ensure that all costs could be allocated to the research process or the delivery of the KAT programme.

Suitability of primary and secondary outcomes for an economic evaluation

In a future effectiveness trial it should be possible to analyse primary outcomes (relating to alcohol consumption) and secondary/tertiary outcomes (relating to family communication) alongside data on costs relating to programme delivery. We would be likely to adopt a similar approach to that currently being used in an ongoing trial of the SFP10–14, in which a cost–consequences analysis is being used. However, given the problems experienced with recruitment of parents into the current trial, it is unlikely that we would be able to access data from parents on service utilisation, which is a component of the data collection from parents in the SFP10–14 trial. Traumatic, rather than medical, problems are common consequences of adolescent alcohol misuse, and so estimating service use would focus on accident and emergency admissions 2 years post intervention (or after other specified follow-up intervals).

Feasibility of the data collection instruments

Our experience in this exploratory trial suggests that it is feasible to collect comprehensive and reliable data concerning programme delivery costs, and intervention reach and engagement. Low rates of missing data for the questionnaire items in this study which would form the primary and secondary outcomes in any future effectiveness trial suggest that it would be feasible to link these data with programme cost data. However, it is unlikely that we could collect service utilisation data from large numbers of parents using the methods employed in this exploratory trial, given the low recruitment rates encountered.

Chapter 4 Discussion

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Introduction

In this chapter, we discuss our key findings. We begin by outlining the study's main limitations. The chapter then discusses the study's findings, structured around our progression criteria – starting with those relating to programme implementation, followed by the criteria concerned with a future effectiveness trial of KAT. For each criterion we provide a summary of the evidence generated by the study, and also map this onto the study's objectives. This is followed by an overall assessment of our programme- and trial-related progression criteria. We then situate our findings in relation to the existing literature on school-based alcohol misuse prevention programmes.

Study limitations

In this exploratory trial we assessed the feasibility and acceptability of an effectiveness trial of KAT, and also aimed to identify systems and structures which would be required for such an effectiveness trial. The study was therefore designed to generate learning that could inform the decision about whether or not to proceed with an effectiveness trial, and optimising its design and implementation. For instance, we tested strategies for recruiting parents/carers into the trial, and the low rates of involvement are an important finding concerning the feasibility of these strategies, rather than a weakness in the design or implementation of the research. However, the current study does have a number of limitations. Although these have generated important learning, which would be incorporated into any future research we conduct on KAT, they should also be borne in mind when interpreting the results presented in this report.

Systems for identifying eligible pupils

Although we asked schools for accurate and up-to-date information on numbers of pupils eligible to participate in the trial, and the number present in school on the days when data collection took place, we could have developed better systems for capturing and managing this information. To some extent, this weakness in our systems happened because recruitment and baseline data collection took place before the funded trial, and when there were no dedicated resources. However, we could have developed more accurate and comprehensive systems for determining total numbers of eligible pupils, how many pupils were present in school, and present in class, during data collections. More attention should have been given to this aspect of recruitment and data collection during initial discussions with schools, and accurate class lists should have been obtained at the earliest point possible.

Withdrawal of two schools from the study

During the trial we lost two intervention group schools, which decided to withdraw. The first of these did so because parents raised objections after main information and follow-up letters were mixed up in error. It is difficult to identify to what extent the parents' objections were based on the nature of the study, or the switching of the letters, but this experience underlines the critical importance of systems to ensure that nothing is done by the research team which might unnecessarily cause concern to parents.

The second school withdrew on the basis of two main issues: the timing of, and the workload generated by, the KAT programme, and the burden created by contact from multiple members of the research team. In this case it is harder to identify ways in which we could have managed the process better, given that we spelled out very clearly on multiple occasions the timing and workload which participation in the trial would involve. In this second school, at least one member of staff appeared to have concerns about

the applicability and acceptability of the KAT programme to Muslim families, though the school did not present this as a reason for their withdrawal. We knew that implementation of the programme and research in a school with large numbers of ethnic minority families, including a number in which adults did not speak English, was likely to be challenging. However, we discussed these issues in depth with the school, who felt they would not be problematic, and, because the school met our inclusion criteria and a key aim of the study was to assess the feasibility of the trial in different school contexts, we felt it was right to include them in our study. However, there may have been ways in which we could have reduced the perceived burden of multiple contacts from the research team.

Our data on the acceptability and feasibility of KAT to schools, parents/carers and pupils need to be viewed in the context of the withdrawal of these two schools. In particular, there are two specific limitations which should be noted. First, we are not entirely clear on the precise reasons why the two schools which withdrew did so, and the extent to which their withdrawals related to (1) the general acceptability of the research/KAT; (2) the manner in which we carried out the research; and (3) characteristics of the school, and the population of parents/carers which it served. Second, it must be acknowledged that for key aspects of programme implementation, we have data from only the three schools which remained in the study. It is possible that the balance or content of the themes present in the data might have been different had these two schools remained in the study, or if we had been able to collect more data subsequent to their withdrawal from the study.

Feasibility of collecting follow-up data in secondary schools

In our application for funding we did not plan to conduct long-term follow-up of pupils (as would happen in a future effectiveness trial), as this would be unfeasibly costly for an exploratory trial, and would delay any decision on the future of the programme beyond that which was likely to be acceptable to policy and practice partners. Our focus in this trial was on the overall acceptability of the KAT programme to schools, parents and pupils, and participation in a randomised trial, and the feasibility of implementing KAT as part of such a trial.

During recruitment of primary schools we decided to test the acceptability of using 'opt-out' parental consent for pupils' involvement in the research component of the trial. We did this so that we would know whether or not such an approach would be feasible in a future effectiveness trial. All schools (including those which later withdrew from the study) were happy for us to use this method. However, the use of 'opt-out' parental consent at recruitment does have important implications for our ability to follow up children 2 years later, and after they have moved to secondary schools. In another ongoing trial, we have been able to successfully engage secondary schools in allowing the research team to conduct follow-up interviews in school with young people who were recruited either in the community or via primary schools. However, in that trial we have explicit written consent from parents (collected at baseline) for all aspects of the data collection involving their child(ren), including follow-up interviews.

Secondary schools may be less likely to provide assistance to us if we do not have written consent from parents. Therefore, although we have relatively strong data on rates of recruitment for primary schools and pupils at baseline, there is still significant uncertainty about the extent to which we could achieve adequately high response rates at long-term follow-up via secondary schools. In retrospect, we should have included some exploratory work with secondary schools to assess the acceptability to them of collecting follow-up data from pupils, and what requirements they were likely to have.

Assessment of cost-effectiveness

This study has provided a description of key cost and outcomes domains, and the feasibility of monitoring them on a wider scale. Based on our experience in this exploratory trial, we believe that it should be possible to identify all key costs and to translate programme inputs into financial costs which could then be used as part of an economic evaluation in any future effectiveness trial. Low rates of missing data in pupil questionnaires mean that in any future effectiveness trial it should be possible to use primary and secondary outcomes alongside programme cost data. Given the low rates of parental recruitment into the

trial, it would probably not be possible to collect service utilisation data from parents/carers, though it could be feasible to access data for young people on alcohol-related harms (e.g. A&E attendance). We recognise that our exploratory work for a future cost-effectiveness evaluation has some limitations, and that a more detailed economic evaluation setting programme costs against potential future savings would have provided a better basis for decisions about investment in any future RCT.

Key findings: programme implementation

Implementation feasibility

Three schools completed programme delivery. One intervention school withdrew without delivering any part of the intervention, and one withdrew from the study after starting programme delivery, but had only done a small part of the classroom component (and had not held a family event). The three schools which completed programme delivery appeared to deliver most or all of the main components, and to retain the main underlying messages of KAT. In at least one class, there was a tendency for the negative aspects of alcohol to dominate rather than a more balanced set of messages on the healthy use of alcohol ('not too soon, not too much'). Schools appeared to be generally happy with the KAT programme manual and the training provided by the health education consultant. However, some teachers had not read the programme manual, or were not aware of key guidance/instructions in it, and a number of teachers suggested that the manual could provide more detailed guidance. Of the three schools which completed programme delivery, only one asked pupils to write invitations to the family evening for their parents/carers. In one of the schools, the teaching staff appeared to believe that the health education consultant and research team would lead the KAT family event. This highlights the importance of ensuring that senior managers and other staff in schools take ownership and support the implementation of the programme (Table 38).

TABLE 38 Summary of assessment evidence for progression criterion 1

Progression criterion 1	Basis for assessment	Summary of assessment evidence
KAT can be implemented successfully in primary schools Addresses study objective 2: ^a <i>Assess the feasibility of the intervention</i>	Process evaluation findings indicate that at least two of the intervention schools delivered key elements of KAT classroom work and family events in line with the teachers' handbook; AND it is reasonable to expect that any significant problems identified can be overcome	Three of the five intervention group schools delivered most or all of the main components of KAT. One intervention school withdrew before delivering any part of the programme. A second intervention school withdrew shortly after programme delivery had commenced There are ways in which the challenges encountered in the three schools which completed KAT could be addressed, particularly through optimising staff training, and ensuring that the roles and responsibilities are clear from the outset

a All criteria map on to study objective 8 (to determine whether or not to proceed with a definitive trial). To avoid unnecessary repetition, we have not therefore included objective 8 in the description of each criterion in the boxes/tables in this chapter.

Intervention acceptability

The three schools which completed delivery of the KAT programme were happy with its content and structure, and were willing to deliver all of the main components. In these schools, very few parents objected to the study or intervention, or refused permission for their children to take part because they objected to the alcohol-related content. Most pupils enjoyed undertaking the KAT programme and few, if any, issues were raised about the content (Table 39). Process evaluation data support the idea that most parents who attended the KAT fun evening or who discussed the programme with their children found it acceptable (Table 40). In the first school which withdrew from the study, parents did raise concerns about the topic of the research/KAT programme to the school. It is difficult to ascertain whether this was mainly because the information and follow-up letters sent to parents/carers had been switched in order; as a result of particular aspects of the school population; a combination of these reasons; or due to another set of factors of which we were unaware. One of the reasons given by the second school which withdrew from the study was the time commitment needed by the programme and the timing of intervention delivery. However, one of the class teachers tasked with delivering the programme had concerns about its acceptability to the large number of Muslim parents in the school. Although process evaluation data indicated that some parents had asked questions about the KAT programme, we were not able to determine whether or not there were widespread concerns among parents at the school about either the research or the KAT intervention (Table 41).

Although we were not able to interview parents in school 8 (which withdrew after baseline data collection), the interview with one of the class teachers involved indicated that they had concerns about the relevance and acceptability of KAT to Muslim families. This was mainly related to the fact that because these families did not drink, an intervention which examined healthy behaviours and positive family communication in the home concerning alcohol would not be relevant. However, the programme does not assume that all families will drink alcohol, or that its content will be applicable only to those who do. The programme recognises that children will be exposed to alcohol-related behaviours, advertising and media portrayals, all of which take place outside the home setting. The programme aims to promote positive communication within families about alcohol, but the exact content of this communication is not intended, necessarily, to be based on family drinking. If KAT was to be run in schools with similar populations it would be important to fully address these issues.

TABLE 39 Summary of assessment evidence for progression criterion 2

Progression criterion 2	Basis for assessment	Summary of assessment evidence
KAT is acceptable to children in the target age group (9–11 years) Addresses study objective 2: <i>Assess the feasibility of the intervention</i>	Process evaluation findings from intervention schools suggest that KAT was acceptable to the majority of pupil participants in each school	Process evaluation findings indicated that children enjoyed doing the KAT classroom work and taking part in the family event. Few, if any, concerns were raised about the programme content

TABLE 40 Summary of assessment evidence for progression criterion 3

Progression criterion 3	Basis for assessment	Summary of assessment evidence
KAT is acceptable to parents of children aged 9–11 years Addresses study objective 2: <i>Assess the feasibility of the intervention</i>	Process evaluation findings from intervention schools suggest that KAT was acceptable to the majority of parent participants in each school	All parents who participated in process evaluation research interviews identified high levels of acceptability. This was supported by data from researcher observations at the family events School A reported that parents had raised concerns about the topics covered in the research study/KAT programme

TABLE 41 Summary of assessment evidence for progression criterion 4

Progression criterion 4	Basis for assessment	Summary of assessment evidence
<p>KAT is acceptable to school staff involved in implementation (head teachers, teachers of Year 5 and 6 classes, and support staff)</p> <p>Addresses study objective 2: <i>Assess the feasibility of the intervention</i></p>	<p>Process evaluation findings indicate that a majority of school staff in each school support the concept of primary school education about alcohol; feel competent to deliver KAT; and think that KAT has potential benefits for families and school; AND that it is reasonable to expect that any significant problems identified can be overcome</p>	<p>The majority of school staff supported the concept of KAT, were able to deliver its core components, and identified potential benefits for their school and families. Some of the challenges which arose during implementation related to training systems, and clarifying roles and responsibilities, and could be addressed in future implementation of the programme</p> <p>Parents at one school raised concerns about the topic being covered by the research study/KAT programme and the school withdrew from the study. A second intervention school also withdrew from the study. Dissatisfaction with the timing of and workload created by delivering the programme were some of the reasons given by this school</p>

Programme reach

The KAT programme demonstrated high levels of reach among both pupils and parents (*Tables 42 and 43*). In the three intervention schools which delivered KAT, 70.9% of pupils reported doing all of the KAT work in school, and a further 22.8% said that they had done part of it; 59.5% of pupils reported having attended the KAT fun evening at their school. For the three intervention schools as a whole, an average of 50% of children reported that at least one adult member of their family had attended the family event. While in two of the schools the figures were just below 50%, in the third school 65.7% of those families invited were represented by at least one adult. The ability of KAT to engage half of all the families invited to participate in the intervention is a significant achievement. When the three schools are ranked in order of the proportion of the families that attended, there is a positive association with FSM levels (*Table 44*). In the intervention group as a whole, pupils with higher Family Affluence Scale scores were more likely to have a parent who attended, suggesting that there is social patterning of family attendance at the school level. However, when rates of *pupil* attendance at the family event are examined, the proportions of pupils reporting low/medium and high Family Affluence Scale scores who attended the family event were almost identical (*Table 45*). A significant minority of pupils reported attending the KAT family event without a member of their family. It may be that these children remained in school (particularly where the fun evening was directly after the end of the school day) and were supervised by school staff, or that they came with other children's parents. It is also possible that some children provided incorrect responses to the questions on attendance. Although the process evaluation researcher observed the family events, it was not possible to accurately identify the total number of pupils from the specific classes involved in the programme,

TABLE 42 Summary of assessment evidence for progression criterion 5

Progression criterion 5	Basis for assessment	Summary of assessment evidence
<p>KAT attracts high rates of participation from children aged 9–11 years</p> <p>Addresses study objective 3: <i>Establish intervention participation rates</i></p>	<p>Process evaluation findings and pupil questionnaires from intervention schools suggest that all pupils in participating classes take part in classroom work (if present in school) and few if any objections from parents are received; AND that a minimum 50% of pupils attend KAT events</p>	<p>Questionnaire responses indicated that the majority of pupils had done either all or part of the KAT classroom work. An average of 59% of pupils reported attending the KAT family events</p>

TABLE 43 Summary of assessment evidence for progression criterion 6

Progression criterion 6	Basis for assessment	Summary of assessment evidence
KAT attracts high rates of participation from parents of children aged 9–11 years Addresses study objective 3: <i>Establish intervention participation rates</i>	Pupil questionnaire data (intervention group) and process evaluation findings suggest that parents/caregivers or other adults from families of a minimum 25% of pupils attended KAT events	Pupils reported that on average, 50% of those families invited to the family events were represented by at least one adult. In the three schools which delivered family events the rates were 45.1%, 46.6% and 65.7%

TABLE 44 Summary of assessment evidence for progression criterion 7

Progression criterion 7	Basis for assessment	Summary of assessment evidence
KAT can be implemented in schools serving a range of socioeconomic groups and localities Addresses study objective 3: <i>Establish intervention participation rates</i>	Details of FSM entitlement and school demographics (from Estyn school inspection reports) show that of schools which implemented KAT, some were above and some below median FSM for the county	Rates of FSM entitlement for the three schools which completed programme delivery were 37.2%, 2.3%, and 27.9% (county median = 18.4%). The two schools which withdrew from the study had rates of 1% (first school) and 21.6% (second school)

TABLE 45 Summary of assessment evidence for progression criterion 8

Progression criterion 8	Basis for assessment	Summary of assessment evidence
KAT can engage parents and children from a range of socioeconomic groups and localities Addresses study objective 3: <i>Establish intervention participation rates</i>	Ethnicity and Family Affluence Scale data from pupil questionnaires; deductions about families from FSM rates and demographics of school area; and process evaluation interviews with school staff demonstrate inclusion of families from a range of social groups and localities that reflects the local population	KAT was delivered in schools with a range of FSM scores, and rates of parental engagement with the programme were particularly high in the school which had the highest FSM score. The programme engaged with pupils with both low/medium and high Family Affluence Scale scores. Rates of attendance for parents/carers were higher for those whose children had higher Family Affluence Scale scores

and the precise number of families which were represented. In summary, KAT was able to engage with families from a range of socioeconomic backgrounds, and there is evidence to suggest that the programme could operate in a variety of school contexts.

There was some evidence from the study's process evaluation that the 'balanced approach' advocated by KAT did not necessarily fit well with the experiences of families who had experienced alcohol-related problems. Although the training given to teachers as part of the KAT implementation dealt with this issue, the findings from the process evaluation may need to be further explored if KAT is implemented in the future. Although much of KAT's content maps closely onto the school curriculum, some children may need additional support during the programme. Family communication processes are central to the programme's intended mechanism of action. Children's experiences of the programme may be negative if their parents/carers are not willing to engage in the intended prosocial communication, or do so in ways which are at odds with the core values of the programme.

Data from the study's process evaluation – particularly from focus groups with pupils – highlighted that children were more likely to want to attend the family evening if their parents accompanied them. Ensuring that as many parents/carers as possible attend the family event would appear to be very important in ensuring that both pupils and parents receive the majority of the intervention, and that key intended family communication processes are set in motion. Were we recommending a future trial, we would need to maximise rates of participation by parents/carers, rather than aim for figures comparable with those achieved in this exploratory trial. As discussed above, a small but significant minority of pupils attended the KAT family event unaccompanied by members of their own families. It is not clear whether these pupils were with other participants' families (and, therefore, may have directly experienced some of the key communication processes intended to occur) or if they sat by themselves or with friends.

Assessing whether or not policy and practice support exists for future implementation of Kids, Adults Together, and identifying optimal delivery systems

An important component of our work has been to identify whether or not there is support among key policy and practice organisations for future implementation of KAT. We also aimed to identify what might be the most effective systems and structures to develop KAT. We were able to engage key organisations to become members of a stakeholders group, whose advice we initially sought on the value and appropriateness of our draft progression criteria. The group supported the criteria which we had developed, subject to some minor modifications. We then shared our key findings with this group to identify whether or not they had value and importance for them, and if the constituent members would support further development of KAT.

Our discussions identified that all organisations were supportive of further development of the KAT programme. Some of the key reasons for their support included the fact that KAT had succeeded in engaging large numbers of parents; the way in which the programme had relevance and might contribute to other existing initiatives (e.g. the Healthy Schools Scheme, schools' work on applying for Investors in Families Awards, the All-Wales School Liaison Core Programme); and the importance of alcohol misuse prevention.

We were unable to identify an organisation with the resources to fund and lead the next phase of development of KAT, although the national Healthy Schools Scheme in Wales was willing to assist with the training of teachers to deliver KAT. Gwent Police – who originally developed the KAT programme – were also willing for the next phase of programme implementation to be wholly within a RCT. However, without dedicated funding, no effectiveness trial of KAT could be contemplated (*Table 46*).

TABLE 46 Summary of assessment evidence for progression criterion 1

Progression criterion 1	Basis for assessment	Summary of assessment evidence
Sufficient support exists in terms of policy and resources at school, LEA and national levels, to allow successful delivery of KAT on a large scale	Stakeholder group judge that structures and resources for further implementation can be put in place	The stakeholder group supports further development of the KAT programme. The national Healthy Schools Team in Wales has agreed in principle to assist with training school teachers to deliver KAT, as part of an effectiveness trial. However, no organisation is presently able to fund the remaining intervention costs or to lead programme delivery as part of an effectiveness trial

LEA, local education authority.

Trial recruitment and retention

Schools

This study tested the feasibility of recruiting schools for a future effectiveness trial and assessed the acceptability of randomisation to schools. From a total of 39 eligible schools, nine were recruited into the study (23%), though the recruitment process took longer than initially anticipated because of delays in identifying the final school needed prior to randomisation. We purposefully selected recruitment strategies which could be scaled up as part of a future effectiveness trial, and tested their feasibility. We wrote to all schools in the study county inviting them to take part, and then made follow-up calls to all schools, until sufficient schools had been recruited. Therefore, we can be reasonably confident that the schools recruited into this exploratory trial might be broadly comparable with those likely to participate in a future effectiveness trial, and that the recruitment rates achieved in the current study could be achieved across multiple counties.

School recruitment could probably have been improved by inviting schools to participate during the academic year preceding a trial when it would have been easier for schools to include KAT in planning. However, evidence from two UK reports suggests that school staff generally may feel that their core function of delivering high-quality education to pupils may be compromised because they are overwhelmed with new initiatives.^{151,152} Thus, it may not be realistic to expect better timing to result in a big increase in schools willing to participate in any further evaluation. McCrone *et al.*¹⁵¹ note that involving staff is important to bringing about and maintaining change, suggesting a possible explanation for school 8's withdrawal from the study.

Although KAT required input and commitment from head teachers, it also depended on the engagement of individual members of teaching staff, who were asked to deliver the intervention and facilitate data collection. Our findings, and those of our previous evaluation of KAT's implementation,⁹⁰ suggest that the quality and completeness of delivery of the intervention does depend to a large extent on the commitment and enthusiasm of individual teaching staff. A key issue here is perhaps the need to ensure that programmes such as KAT, which have a primary focus on health and well-being, can demonstrate how they might address educational outcomes for pupils, and thus help teachers to deliver their core role as educators. If such teachers can see the direct relevance and value of KAT, and its suitability for the pupils and families they work with, they may be more likely to fully engage with it. Individualised on-site coaching involving demonstrations, which show how interventions can be delivered in the 'real world' of the classroom, may be more effective ways of gaining teachers' understanding of and commitment to an intervention than simply providing initial training alongside a handbook and support on request.¹⁵³ In this study, we sometimes found it very difficult to involve class teachers in initial meetings to discuss participation in KAT, and subsequent training and briefing sessions. Had we been able to achieve their involvement across all schools at initial programme set-up meetings, it might have been possible to identify and deal more effectively with some of the challenges which arose, in relation to both delivery of the intervention (e.g. the failure to include child invitations to parents in some schools), and teachers' concerns about the appropriateness of the programme for families from ethnic minority backgrounds.

We recruited schools with a range of FSM entitlement rates, suggesting that, were we recommending a future trial, it would be possible to reach schools with families from a range of different socioeconomic backgrounds. In Newport, FSM rates range from 1% to 48.3% (median 18.4). FSM rates of the schools which participated in the trial were 1%, 2.3%, 21.6%, 27.9% and 37.2% (intervention), and 11.4%, 23.5%, 23.5% and 31.9% (control schools). The support of the local Healthy Schools Team (one of whose officers accompanied the research team on visits to schools to seek formal agreement to take part in the study) appeared to help communicate the value and importance of the study (*Table 47*).

From a small sample of nine schools, it is difficult to ascertain to what extent the recruitment and withdrawal rates in this trial might be replicated in a much larger effectiveness trial. For a larger effectiveness study, greater resources would be needed to recruit schools and develop better systems from

TABLE 47 Summary of assessment evidence for progression criterion 12

Progression criterion 12	Basis for assessment	Summary of assessment evidence
It is feasible to conduct a trial of KAT in schools serving a range of socioeconomic groups and localities Addresses study objective 4: <i>Assess trial recruitment and retention rates</i>	Details of FSM entitlement and school demographics (from Estyn school inspection reports) show that schools within each trial arm varied in terms of social, demographic and geographic characteristics and that at least two were in areas above the county median for deprivation	Schools varied in terms of key demographic factors. Nine schools were recruited. Six had FSM scores above the county median, and three below

the start, including contacting schools well in advance of the planned programme delivery period (thus minimising barriers to engagement in the trial). Because follow-up data would be collected from pupils in secondary schools, the loss of primary schools after baseline data collection (as happened in one of the cases in this study) would not have a major impact on the ability to collect follow-up data.

Although some of the schools which participated in the study expressed a clear preference to receive the KAT programme, randomisation was acceptable to all schools, and all those in the control group remained in the study and facilitated all data collection. Were we recommending a future trial, we would plan to collect baseline data before randomisation of schools took place, so it is unlikely that randomisation allocation would create significant risks to the viability of the trial. However, as noted above, the main follow-up data collections would take place in secondary schools, and not in the primary schools in which pupils were initially recruited. We did not include this aspect of data collection in our exploratory trial. If an effectiveness trial were to be considered in future, it would be important to undertake further work to assess the feasibility and acceptability of collecting follow-up data in secondary schools which had not been involved in the study from the start. In the trial itself, it would be important to engage with these secondary schools early in the research process, probably at the same time as the initial recruitment of feeder primary schools in which the study was taking place. As part of a current RCT of the SFP10–14, we have successfully engaged with secondary schools (most of whom have not had any role hitherto in the trial or the programme being evaluated) in order to conduct questionnaire completion with pupils in school. In these schools, we have written to the parents of the pupils concerned to inform them that we would like to conduct follow-up interviews with their child in school, and have given them the option to refuse permission. This system has been acceptable to most schools and enabled a significant number of interviews to be conducted in school, with very few parents refusing permission. Similar methods could be adopted for other school-based trials and also draw upon the network of contacts developed as a result. For instance, in our trial of SFP10–14, we have engaged the services of a retired head teacher, who has helped to negotiate entry into a large number of secondary schools. However, in the SFP10–14 study, 'opt-in' parental consent is being collected at baseline. Were we recommending a future trial of KAT, we would need to be clear right from the start about how many schools would be willing to allow follow-up interviews to take place with children without this 'opt-in' consent in place. Because pupils in KAT are recruited exclusively through the schools we would also be likely to need to interview more pupils per school at follow-up than is the case for the SFP10–14 study.

Pupil recruitment

Of those pupils eligible to participate in the study at baseline, response rates were 74% for the intervention group and 81% for the control group. Follow-up rates were 68% for the intervention group and 74% for the control group. If the school which completed baseline data collection but then withdrew from the study is removed (and from whose pupils no follow-up data could be collected) from the completion rates at follow-up, the figure for the intervention group rises from 68% to 85%. The main reason for non-completion of the questionnaires was absence from school or the classroom. In the control group, no eligible participants refused to complete questionnaires at baseline, and in the intervention group only 13 did so.

For both baseline and follow-up data collection, we paid a single visit to each school to collect data. At baseline, there were a total of 24 pupils absent from school on the day of data collection, and a further 40 who may have been present in school but not present in the classroom during data collection. Of those present in the classroom at baseline, 78% (intervention) and 88% (control) completed questionnaires – higher than the completion rates if the denominator used is those eligible. At follow-up, completion rates as a proportion of those present were 92% (intervention) and 77% (control). Had we made a second visit to each school to collect questionnaire data from pupils who were previously absent from school/their classroom, our recruitment and retention rates could have been increased. It should also be possible to optimise provision of support for pupils with low literacy levels, and we were able to achieve this to some extent when we conducted follow-up data collection. Literacy levels, rather than the questionnaire content, appeared to be the main reason for pupils refusing to complete questionnaires at baseline in at least one of the schools, based on feedback from teaching staff. A total of 39 pupils who did not complete questionnaires at baseline went on to complete follow-up questionnaires. Although we cannot be certain of the reasons for this, we feel it may be due in part to the provision of more members of research staff at follow-up data collection, and asking schools in advance how many pupils were likely to need assistance with reading questions. One suggestion made in one of the stakeholder group meetings (attended by key practice and policy collaborators) is that the use of online computer-based questionnaires could be considered. Internet-based activities and use of laptops is increasingly common in primary schools, though these might not be available in all schools. An internet-based questionnaire might be able to incorporate support for pupils with low literacy or offer questionnaires in languages other than English, and could also provide a means for pupils who were absent during data collection visits to complete the questionnaire at a later time point.

Our response rates also show some patterning according to sex and year group. More boys, and pupils in Year 5, completed questionnaires at baseline only. This may relate to differences in the proportion of girls and boys reaching expected literacy levels,¹⁵⁴ but we cannot be certain as to the exact reasons. Were we recommending a future trial, it might be useful to consider in more detail whether there are aspects of data collection which are less appealing or more off-putting to boys, and how these could be modified. There were also sex differences in completion rates for our secondary outcomes (see *Feasibility and acceptability of secondary outcomes*).

Although rates of recruitment of pupils are important, the use of a cluster RCT design means that they need to be considered alongside rates of school recruitment (which is the unit of randomisation). Were we recommending an effectiveness trial, rates of school recruitment and retention would be very important in achieving the necessary statistical power.

Parents/carers

The number of eligible parents/carers who agreed to complete questionnaires was very low. Only 6.5% of eligible parents/carers participated in the questionnaire aspect of the study, and this is based on an assumption that there was only one adult in each household, so the true figure may be even lower. There are a number of factors which may explain this low rate. First, owing to data protection regulations, the research team was not able to access the names and contact details of eligible parents/carers from schools. We were only able to send a standard letter (which began 'Dear parent/carer') to parents via schools, and there was no way of identifying recipients who had not expressed an interest in participating in the research. Second, in this letter we asked parents to contact the school if they did not wish their child(ren) to participate in the study. If they were content for their child to participate, they did not need to make contact with school. In the same letter, parents were asked to complete a reply slip and return it to the research team if they themselves wished to take part in the study. It is possible that having two different consenting methods for children and parents in the same letter created confusion, or that, having established that no action was required of them in relation to their child's participation, parents/carers were less inclined to respond to the remaining information. The method of providing parents with the option to withdraw their child from the study, rather than asking them to give explicit consent for their participation, is likely to have increased the rates of pupil involvement, and we chose this strategy

deliberately as in an effectiveness trial primary outcome data would be collected from children. However, the relatively high rates of pupil questionnaire completion may have been at the expense of parental involvement. Third, in this exploratory trial we sought to use the best recruitment strategies which would be feasible and affordable if scaled up as part of a large effectiveness trial. With investment of more resources we could potentially have increased the rate of parental involvement in questionnaire completion (e.g. through holding information events, and spending more time in school, and placing less emphasis on letters). However, these procedures would be hard to sustain if an effectiveness trial involved a large number of schools. We were also concerned that a significant package of parental engagement work by the study team in schools could influence parental engagement in the KAT programme and school work, making it hard to disentangle programme processes from the research recruitment strategies. It is unlikely that we would be able to resolve all of these key challenges, and we return to this issue in our conclusion to suggest ways in which parents could be involved in effectiveness research.

Ethical issues raised by the study

A study such as this one, which involved collecting data from children on alcohol consumption and aspects of family communication in relation to alcohol, has the potential to encounter ethical challenges in relation to determining whether or not certain disclosures might amount to evidence of an individual being at risk of harm or abuse. We followed the Cardiff University policies and guidelines on child protection, part of which stipulated that because data collection had taken place in an external organisation, any child protection concerns should be shared with that institution (schools, in our case). One particular challenge we faced was to decide what frequency or type of alcohol consumption by young people might be considered an indication of a child being at risk of harm. The law permits parents to provide alcohol to children from the age of 5 years, and it was difficult to know whether some reports of drinking were based on whole drinks or on sips, and if children's understanding of drunkenness corresponded with our own as adult researchers. The interval between data collection and data entry, the difficulties which some pupils experienced in understanding the questionnaires, the inconsistent responses within the data and the lack of personal contact with the child all added to the difficulties we faced.

Our approach as a Trial Management Group was to consider frequent drunkenness among child participants to be a possible indicator of harm, and in such cases our concerns would have to be shared with schools. One pupil's questionnaire responses raised concerns which led to our contacting the school's teacher who had responsibility for child protection. The recent Unicef guidance on researchers' ethical responsibilities¹⁵⁵ emphasises that guidelines can never be comprehensive enough to cover all possible contexts and individuals; this means that critical reflection on practice is always necessary. We sought to maintain the confidentiality of participants' identities wherever possible, while ensuring that we followed good practice in relation to child protection procedures.

Sample size calculation

Basing the primary outcome on whether or not participants have had a drink in the last 30 days might provide a good indicator of recent drinking behaviour. Current practice in the field of alcohol misuse prevention intervention evaluation appears to vary widely, with studies using measures of current alcohol consumption frequency, past-week, past-month, past-year and lifetime drinking.¹⁵⁶ Our sample size calculations for an effectiveness trial are, therefore, based on detecting differences in past-month drinking (as a binary outcome) between intervention and control.

Based on data from the HBSC survey (using the ICC of 0.021 found in that survey for past-month drinking, and with 90% power), an effectiveness trial would require at least 351 schools, and 38 pupils per school, to be able to detect a 2.5% reduction in drinking rates in the intervention group. With 80% power to detect a 2.5% difference between groups, the total sample size would be 263 schools. If we were to invite

all eligible schools across Wales ($n = 863$) to participate in the trial, and 23% participated (this is the same proportion as we achieved in the current study), then we would be able to recruit 198 schools. This would be challenging and costly to achieve, and would still fall well short of the 263 schools needed for a trial with 80% power. Retention of a large number of schools over a wide geographical area would also be a significant undertaking. The sample size calculations are our best current estimates, rather than final numbers, but it seems reasonable to expect that any intervention effects on alcohol-related behaviours are likely to be small (based on our findings in this trial which demonstrated no evidence of effects or a trend towards them on intermediate outcomes which hypothesised to prevent alcohol consumption) (Table 48).

Acceptability to schools of pupil recruitment methods

As part of the initial contact with interested schools, we tested the acceptability of methods for recruiting pupils into the study, and in particular our preference to offer parents/carers the opportunity to refuse permission for their children to participate in the study rather than asking them to provide written consent for their children's participation (though in each school we included pupils in the study only if they were happy to participate and provided written assent). All nine schools which participated in the trial were happy to use this method, and it appeared to have a good fit with the approach they normally used when parents were consulted on activities which pupils would be involved with in school. The uniform acceptability of this approach is important, because it suggests that, if we were recommending an effectiveness trial, we would be able to at least replicate the pupils' response rates at baseline achieved in this study. The method which we used for parental consent thus helped to maximise rates of pupil involvement in the study, and to avoid potential response bias which might occur using parental opt-in.¹¹² However, before undertaking any further study, we would have needed to investigate the extent to which pupils could be followed up in secondary schools, particularly in the absence of written consent from parents/carers.

TABLE 48 Summary of assessment evidence for progression criterion 13

Progression criterion 13	Basis for assessment	Summary of assessment evidence
<p>The sample required to demonstrate a significant effect of KAT is achievable</p> <p>Addresses study objective 5: <i>Identify potential effect size and appropriate sample size</i></p>	<p>Recruitment records indicate that we were able to recruit eight schools as per protocol; project records demonstrate that schools in both trial arms are retained in the study; questionnaire returns indicate that at least 80% of pupils in a majority of eligible classes provide data at each time point</p>	<p>Nine schools were recruited (23% of those eligible), two of which (both intervention arm) withdrew from the study, one of which did so after baseline data collection</p> <p>Overall questionnaire completion rates at follow-up rates were 71% of those eligible at baseline. If the school which withdrew from the trial after baseline data collection is removed from the denominator the figure is 79.5%</p> <p>Our best estimate for the sample size needed to detect a 2.5% reduction in past-month drinking at 2-year follow-up is 351 schools (90% power) or 263 schools (80% power). To recruit this number of schools would be challenging and require significant resources</p>

Acceptability and feasibility of chosen measures

Alcohol-related questions

Were we recommending an effectiveness trial, the primary outcome would be based on alcohol consumption. Thus, in this exploratory trial, we were concerned with assessing the acceptability and feasibility of collecting these data from primary school age children. Low rates of missing data (maximum 3.4%) suggest that most pupils felt comfortable with answering questions on alcohol consumption and understood their meaning. Rates of missing data were slightly lower at follow-up than at baseline.

There was, however, some evidence of misclassification, with pupils providing inconsistent answers. The main example of this was that a number of pupils answered 'yes' to having 'ever had a drink' at baseline, but answered 'no' to the same question at follow-up. It may be that children in this age group find it difficult to accurately remember such events over their entire life, especially if they do not have strong salience for the individual concerned,¹⁵⁷ or that the measures are unreliable in other ways. Another possibility is that the baseline/follow-up questionnaires, the KAT intervention, or a combination of the two caused pupils to change their perception of their past drinking behaviours, or created a desire to provide socially acceptable answers. There were discrepancies between rates of 'ever drinking' and 'past-month' drinking at individual data collection points (i.e. there were more reports of 'past-month' drinking than 'ever drinking'). The wording of the questions on past-month drinking was modified at follow-up based on feedback from pupils at baseline that the original phrasing was confusing, but this did not appear to improve the reliability of the data.

Our findings suggest that in effectiveness studies with children of a similar age, it may be preferable to measure past-month drinking rather than lifetime drinking as a primary outcome, and to use 'ever use' as a marker of reliability. Past-month drinking should provide a relatively accurate picture of whether or not children have started to drink regularly. Were we recommending an effectiveness trial of KAT, additional secondary outcomes related to drinking (e.g. age of first drink, ever drink, drunkenness) would have formed important aspects of the overall design and analysis as well as the choice of a primary outcome (on which to base sample sizes and other statistical calculations).

In this study, data on alcohol-related behaviours were collected from young people at a point when most of them had yet to start drinking. Thus, for some of our data points (particularly past-month and lifetime drunkenness), prevalence rates are very low. Were we recommending an effectiveness trial, these data would have been collected after an interval of several years (at age 11–13 years for most participants). Because the children would be older, issues of questionnaire comprehension might be less apparent; it is also likely that rates of drinking and drunkenness would be higher (given the normal increase in drinking behaviours as children grow older), meaning that any issues with sparse data present in this trial would not be present. Clearly, age adjustment would be important and assessment of drinking trajectories between intervention and control group might be required.

In this exploratory trial, we did not aim to assess the effectiveness of KAT on alcohol-related behaviours, and there were a number of methodological and theoretical reasons for this. First, the focus of the trial was to examine the feasibility of an effectiveness trial of KAT, rather than to conduct a 'mini trial' of the intervention's effectiveness. Second, especially given its delivery to children of primary school age in order to prevent early alcohol consumption, and among whom rates of drinking are very low, any impacts of KAT on alcohol behaviours would need to be measured several years later once the natural prevalence of such behaviours had increased. Third, the logic model for KAT clearly hypothesises that prevention of alcohol misuse is mediated via the strengthening of family communication and attachment, and, thus, any short-term assessment of the programme should focus on these intermediate outcomes. In this trial, we collected alcohol-related data mainly to assess potential completion rates, reliability, and the acceptability of the individual questions to participants. The trial was not, therefore, designed or statistically powered to detect differences in alcohol-related behaviours between trial arms. Given these caveats, it is not possible to use the data presented in *Chapter 3* to draw conclusions as to the effectiveness of KAT in preventing

alcohol misuse. Our data on rates of drinking and drunkenness at follow-up are mixed, and there is evidence of inconsistent reporting by pupils. However, taking into consideration the above caveats, some of our results suggest that KAT may have potentially harmful effects (particularly whether or not pupils report ever having had a drink of alcohol). There may be a number of reasons for these results, including actual harmful effects of the intervention, the imbalance in the trial arms at baseline in terms of age, etc., or the reliability of the measures used for this age group. It is also possible that the intervention content may have influenced how children answered questions at follow-up, though we do not know if this is the case.

Existing research provides numerous examples of alcohol, drug and other prevention interventions which have produced iatrogenic effects (including increasing substance use), even when carefully designed and well implemented.^{158,159} It is important to understand whether such effects arise from a particular intervention component (or negative effects for a particular subgroup), an overall failure of intervention theory, or inadequate implementation which undermines the intervention's theoretical basis.¹⁵⁹

Feasibility and acceptability of secondary outcomes

We faced considerable difficulties in identifying suitable and validated measures of family communication which were designed for children aged 9–11 years, and this was particularly the case for measures of family communication in relation to alcohol. These difficulties have significance beyond our particular study, as many other researchers may potentially need to measure outcomes similar to ours among primary school-aged children. Given the emphasis on delivering family-based prevention interventions to children before they start drinking, and while parents are still a primary point of attachment (i.e. prior to the teenage years),^{31,53,73} we were surprised at the paucity of validated measures in this area for primary school-aged children.

From the very small number of candidate measures that we identified, most were aimed at older age groups of children (and outside the UK), and were not always easily understood by participants in our study. Another weakness of many of the measures we considered using was that they assumed that children lived with either one or two parents at home, and were difficult to answer for some pupils who spent time with different non-cohabiting parents, or lived with other adult figures. While the measures we eventually used had strong internal consistency, it was not always possible to determine how the measures had originally been validated by their authors. In most cases, the measures had been used in cross-sectional or longitudinal studies, and there were few examples of their use in trials, and, thus, of what kinds of effect sizes might be expected from interventions similar to KAT.

The measures used were validated on our data set and showed good levels of internal reliability. Factor analysis showed that single summed scores were an appropriate way to summarise the data. However, the distributions of the scores indicated that linear modelling may not be the most appropriate method of analysis for these scores if used in an effectiveness trial, and that categorising the scores and using ordinal or logistic methods would be more appropriate.

Rates of missing data for secondary outcomes were higher than for the alcohol-related questions. For the Family Activity Scale, KIDSCREEN-52 and the PCCS, the completion rates all lay between approximately 75% and 90%. The FCS had higher rates of missing data than the other secondary outcome measures, particularly for Year 4 and 5 participants, but this is probably due to the way in which missing data were categorised, rather than because there were more questions unanswered. For all of these measures, missing data rates were higher for boys than for girls. Missing data rates appeared to be higher at follow-up than at baseline in Years 4 and 5, though there was no clear pattern for Year 6 pupils. The reasons for non-completion of the measures (or individual questions within them) could relate to their acceptability, the phrasing of the questions not being clear, or the fact that participants found them hard to answer. Analysis of the patterning of missing data suggested that 'missingness' was broadly equal across individual questions within the measures, rather than due to a small number of questions consistently being left unanswered (*Table 49*).

TABLE 49 Summary of assessment evidence for progression criterion 14

Progression criterion 14	Basis for assessment	Summary of assessment evidence
<p>Methods for measurement of primary and secondary outcomes are feasible and the cost of measurement can be estimated</p> <p>Addresses study objective 6: <i>Determine feasibility and cost of measuring primary and secondary outcomes</i></p>	<p>Measures were understood by and acceptable to > 75% of Year 5 and 6 pupils in each school</p>	<p>Rates of missing data were very low for the alcohol-related questions (maximum 3.4%). However, there was evidence that reports of alcohol consumption were unreliable, especially in relation to lifetime drinking</p> <p>Rates of missing data for secondary outcomes on family communication lay between 10% and 25%. We were not able to identify measures that had been developed for the age group included in this study, and those that we used required adaptation. The secondary outcome measures used in this exploratory trial would have required further testing and adaptation, or replacement with more suitable measures, had we been recommending an effectiveness trial</p> <p>We were able to determine the number of staff which would be needed to collect questionnaire data as part of an effectiveness trial, and the cost of employing them</p>

Identifying potential effect sizes

In this exploratory trial, our main aim in collecting data on alcohol-related behaviours was to assess the acceptability and feasibility of doing so in a future effectiveness trial, and we used data from 11- to 13-year-olds in the HBSC data set to calculate the sample size which would be needed for a 2-year follow-up.

As an exploratory trial, this study did not aim to measure the effectiveness of the KAT programme on predicted short-term outcomes. It is important to note that the trial was not powered to detect differences between the two groups, nor was it designed to ensure that intervention and control groups were equivalent in relation to key dimensions at baseline. In an exploratory trial such as this one, effect sizes provide only a broad estimation of what *might* be expected in an effectiveness trial in relation to intermediate outcomes on family communication. Analysis of these secondary outcomes indicated no evidence of any intervention effect (*Tables 50 and 51*). There are a number of possible explanations for these results. One is that KAT simply does not work, and that the results accurately reflect a lack of intervention effect. A second possibility is that KAT does, or may, have small short-term effects, but that our study has not detected them. This could be due to the imbalance of the intervention groups in important respects, the fact that the study was not large enough and not powered to detect effects, the unreliability of the measures used, or a combination of these factors. As noted above, we faced considerable difficulty in identifying suitable measures of family communication, and, even after adaptation by us, they were not always easily understood by participants, which may have influenced how they were completed. A third possibility is that our logic model for the programme (and, therefore, the dimensions we chose to measure) is incorrect or incomplete, and KAT operates through processes which we did not assess.

There were very few examples of previous studies which had used our secondary outcome measures. None were directly comparable to the current study, as they had used the measures with older age groups, in countries other than the UK, and had not used the measures to compare trial arm outcomes in RCTs. However, the average scores in our study sat within the range of scores previously recorded for these measures (see *Table 50*).

TABLE 50 Summary of assessment evidence for progression criterion 15

Progression criterion 15	Basis for assessment	Summary of assessment evidence
Promising effect sizes are achieved for key outcomes	After adjusting for baseline differences, comparison of intervention and control group pupil scores at follow-up shows that intervention group average scores are higher than control for at least one of the following measures:	There were no significant difference between intervention and control groups for any of the secondary outcomes, and no evidence of promising effect sizes
Addresses study objective 2: <i>Assess the feasibility of the intervention</i>		
Addresses study objective 5: <i>Identify potential effect size and appropriate sample size</i>	KIDSCREEN-52 autonomy dimension	It was not possible to identify previous RCTs which had used any of these outcome measures to evaluate comparable interventions, and with comparable study populations (country, age group, etc.)
	PCCS	
	FCS	
	Family Activities Scale	
	AND that intervention group average scores are not lower than control group average scores for any of the other scales	

TABLE 51 Summary of assessment evidence for progression criterion 11

Progression criterion 11	Basis for assessment	Summary of assessment evidence
KAT is consistent with a theoretical basis which suggests that short-term impacts on parent–child communication may shape longer-term alcohol-related behaviours	Process evaluation findings and comparison of intervention and control group scores for intermediate outcomes (communication measures) indicate that participation in KAT is associated with an increase in parent–child communication	There was some evidence from the process evaluation findings that KAT promoted parent–child communication
Addresses study objective 1: <i>Refine the intervention’s theoretical model</i>		There was no evidence from the scores for intermediate outcomes to indicate any increase in parent–child communication

Assessment of Kids, Adults Together delivery costs

In this trial, we were able to identify key cost domains relating to the delivery of KAT and to capture the financial costs of most of these domains. Had we been recommending an effectiveness trial, it should have been possible to measure the cost of programme delivery, including those costs (such as staff time) incurred by schools. However, our inability to recruit parents/carers into this exploratory trial means that it would have been difficult to capture data on variations in service utilisation between trial arms. This would be a significant barrier to conducting a cost-consequence analysis (*Table 52*).

TABLE 52 Summary of assessment evidence for progression criterion 9

Progression criterion 9	Basis for assessment	Summary of assessment evidence
KAT delivery costs can be recorded in a way which facilitates assessment of cost-effectiveness	Systems developed in current project can be used to monitor costs of larger-scale implementation	It was possible to identify key cost domains for KAT programme delivery, and systems developed in this study could be used in a larger effectiveness trial to monitor implementation costs. Low rates of parental recruitment into the current study mean that it is unlikely that an effectiveness trial could capture data on variations in service utilisation
Addresses study objective 7: <i>Identify programme costs and pilot methods for measuring them</i>		

Criteria for progression to effectiveness trial

Tables 53 and 54 display all of the progression criteria, the basis for their assessment (and what outcome would be needed to proceed to an effectiveness trial), and a summary of the evidence relating to them. They also map each criterion onto the study's objectives.

TABLE 53 Assessment of criteria relating to programme content and implementation

Progression criterion	Basis for assessment	Summary of assessment evidence
<p>Progression criterion 1</p> <p>KAT can be implemented successfully in primary schools</p> <p>Addresses study objective 2:^a <i>Assess the feasibility of the intervention</i></p>	<p>Process evaluation findings indicate that at least two of the intervention schools delivered key elements of KAT classroom work and family events in line with the teachers' pack; AND it is reasonable to expect that any significant problems identified can be overcome</p>	<p>Three of the five intervention group schools delivered most or all of the main components of KAT. One intervention school withdrew before delivering any part of the programme. A second intervention school withdrew shortly after programme delivery had commenced. There are ways in which the challenges encountered in the three schools which completed KAT could be addressed, particularly through optimising staff training, and ensuring that the roles and responsibilities are clear from the outset</p>
<p>Progression criterion 2</p> <p>KAT is acceptable to children in the target age group (9–11 years)</p> <p>Addresses study objective 2: <i>Assess the feasibility of the intervention</i></p>	<p>Process evaluation findings from intervention schools suggest that KAT was acceptable to the majority of pupil participants in each school</p>	<p>Process evaluation findings indicated that children enjoyed doing the KAT classroom work and taking part in the family event. Few, if any, concerns were raised about the programme content</p>
<p>Progression criterion 3</p> <p>KAT is acceptable to parents of children aged 9–11 years</p> <p>Addresses study objective 2: <i>Assess the feasibility of the intervention</i></p>	<p>Process evaluation findings from intervention schools suggest that KAT was acceptable to the majority of parent participants in each school</p>	<p>All parents who participated in process evaluation research interviews identified high levels of acceptability. This was supported by data from researcher observations at the family events</p> <p>School A reported that parents had raised concerns about the topics covered in the research study/KAT programme</p>
<p>Progression criterion 4</p> <p>KAT is acceptable to school staff involved in implementation (head teachers, teachers of Year 5 and 6 classes, and support staff)</p> <p>Addresses study objective 2: <i>Assess the feasibility of the intervention</i></p>	<p>Process evaluation findings indicate that a majority of school staff in each school support the concept of primary school education about alcohol; feel competent to deliver KAT; and think that KAT has potential benefits for families and school; AND that it is reasonable to expect that any significant problems identified can be overcome</p>	<p>The majority of school staff supported the concept of KAT, were able to deliver its core components, and identified potential benefits for their school and families. Some of the challenges which arose during implementation related to training systems, and clarifying roles and responsibilities, and could be addressed in future implementation of the programme</p> <p>Parents at one school raised concerns about the topic being covered by the research study/KAT programme and the school withdrew from the study. A second intervention school also withdrew from the study. Dissatisfaction with the timing of, and workload created by, delivering the programme were some of the reasons given by this school</p>

continued

TABLE 53 Assessment of criteria relating to programme content and implementation (*continued*)

Progression criterion	Basis for assessment	Summary of assessment evidence
<p>Progression criterion 5</p> <p>KAT attracts high rates of participation from children aged 9–11 years</p> <p>Addresses study objective 3: <i>Establish intervention participation rates</i></p>	<p>Process evaluation findings and pupil questionnaires from intervention schools suggest that all pupils in participating classes take part in classroom work (if present in school) and few, if any, objections from parents are received; AND that a minimum 50% of pupils attend KAT events</p>	<p>Questionnaire responses indicated that the majority of pupils had done either all or part of the KAT classroom work. An average of 59% of pupils reported attending the KAT family events</p>
<p>Progression criterion 6</p> <p>KAT attracts high rates of participation from parents of children aged 9–11 years</p> <p>Addresses study objective 3: <i>Establish intervention participation rates</i></p>	<p>Pupil questionnaire data (intervention group) and process evaluation findings suggest that parents/caregivers or other adults from families of a minimum 25% of pupils attended KAT events</p>	<p>Pupils reported that an average of 50% of those families invited to the family events were represented by at least one adult. In the three schools which delivered family events, the rates were 45.1%, 46.6% and 65.7%</p>
<p>Progression criterion 7</p> <p>KAT can be implemented in schools serving a range of socioeconomic groups and localities</p> <p>Addresses study objective 3: <i>Establish intervention participation rates</i></p>	<p>Details of FSM entitlement and school demographics (from Estyn school inspection reports) show that of schools which implemented KAT, some were above and some below median FSM for the county</p>	<p>Rates of FSM entitlement for the three schools which completed programme delivery were 37.2%, 2.3%, and 27.9% (county median = 18.4%). The two schools which withdrew from the study had rates of 1% (first school) and 21.6% (second school)</p>
<p>Progression criterion 8</p> <p>KAT can engage parents and children from a range of socioeconomic groups and localities</p> <p>Addresses study objective 3: <i>Establish intervention participation rates</i></p>	<p>Ethnicity and Family Affluence Scale data from pupil questionnaires; deductions about families from FSM rates and demographics of school area; and process evaluation interviews with school staff demonstrate inclusion of families from a range of social groups and localities that reflects the local population</p>	<p>KAT was delivered in schools with a range of FSM scores, and rates of parental engagement with the programme were particularly high in the school which had the highest FSM score. The programme engaged with pupils with both low/medium and high Family Affluence Scale scores. Rates of attendance for parents/carers were higher for those whose children had higher Family Affluence Scale scores</p>
<p>Progression criterion 9</p> <p>KAT delivery costs can be recorded in a way which facilitates assessment of cost-effectiveness</p> <p>Addresses study objective 7: <i>Identify programme costs and pilot methods for measuring them</i></p>	<p>Systems developed in current project can be used to monitor costs of larger-scale implementation</p>	<p>It was possible to identify key cost domains for KAT programme delivery, and systems developed in this study could be used in a larger effectiveness trial to monitor implementation costs</p> <p>Low rates of parental recruitment into the current study mean it is unlikely that an effectiveness trial could capture data on variations in service utilisation</p>
<p>Progression criterion 10</p> <p>Sufficient support exists in terms of policy and resources at school, LEA and national levels, to allow successful delivery of KAT on a large scale</p> <p>Addresses study objective 2: <i>Assess the feasibility of the intervention</i></p>	<p>Stakeholder group judge that structures and resources for further implementation can be put in place</p>	<p>The stakeholder group supported further development of the KAT programme. The national Healthy Schools Team in Wales agreed in principle to assist with training school teachers to deliver KAT, as part of an effectiveness trial. However, no organisation was able to fund the remaining intervention costs or to lead programme delivery as part of an effectiveness trial</p>

LEA, local education authority.

TABLE 54 Assessment of criteria relating to value and feasibility of an effectiveness trial of KAT

Progression criterion	Basis for assessment	Summary of assessment evidence
<p>Progression criterion 11</p> <p>KAT is consistent with a theoretical basis which suggests that short-term impacts on parent-child communication may shape longer-term alcohol-related behaviours</p> <p>Addresses study objective 1: <i>Refine the intervention's theoretical model</i></p>	<p>Process evaluation findings and comparison of intervention and control group scores for intermediate outcomes (communication measures) indicate that participation in KAT is associated with an increase in parent-child communication</p>	<p>There was some evidence from the process evaluation findings that KAT promoted parent-child communication</p> <p>There was no evidence from the scores for intermediate outcomes to indicate any difference in parent-child communication between intervention and control schools</p>
<p>Progression criterion 12</p> <p>It is feasible to conduct a trial of KAT in schools serving a range of socioeconomic groups and localities</p> <p>Addresses study objective 4: <i>Assess trial recruitment and retention rates</i></p>	<p>Details of FSM entitlement and school demographics (from Estyn school inspection reports) show that schools within each trial arm varied in terms of social, demographic and geographic characteristics and that at least two were in areas above the county median for deprivation</p>	<p>Schools varied in terms of key demographic factors. Nine schools were recruited. Six had FSM scores above the county median, and three below</p>
<p>Progression criterion 13</p> <p>The sample required to demonstrate a significant effect of KAT is achievable</p> <p>Addresses study objective 5: <i>Identify potential effect size and appropriate sample size</i></p>	<p>Recruitment records indicate that we were able to recruit eight schools as per protocol; project records demonstrate that schools in both trial arms are retained in the study; questionnaire returns indicate that at least 80% of pupils in a majority of eligible classes provide data at each time point</p>	<p>Nine schools were recruited (23% of those eligible), two of which (both intervention arm) withdrew from the study, one of which did so after baseline data collection</p> <p>Overall questionnaire completion rates at follow-up were 71% of those eligible at baseline. If the school which withdrew from the trial after baseline data collection is removed from the denominator the figure is 79.5%</p> <p>Our best estimate for the sample size needed to detect a 2.5% reduction in past month drinking at 2-year follow-up is 351 schools (90% power) or 263 schools (80% power). To recruit this number of schools would be challenging and require significant resources</p>
<p>Progression criterion 14</p> <p>Methods for measurement of primary and secondary outcomes are feasible and the cost of measurement can be estimated</p> <p>Addresses study objective 6: <i>Determine feasibility and cost of measuring primary and secondary outcomes</i></p>	<p>Measures were understood by, and acceptable to, more than 75% of Year 5 and 6 pupils in each school</p>	<p>Rates of missing data were very low for the alcohol-related questions (maximum 3.4%). However, there was evidence that reports of alcohol consumption were unreliable, especially in relation to lifetime drinking</p> <p>Completion rates for secondary outcomes lay between 75% and 90%. We were not able to identify measures that had been developed for the age group included in this study, and those that we used required adaptation. The secondary outcome measures adapted for use in this exploratory trial were not well suited to children aged 9-11 years</p> <p>We were able to determine the number of staff which would be needed to collect questionnaire data as part of an effectiveness trial, and the cost of employing them</p>

continued

TABLE 54 Assessment of criteria relating to value and feasibility of an effectiveness trial of KAT (*continued*)

Progression criterion	Basis for assessment	Summary of assessment evidence
Progression criterion 15		
Promising effect sizes are achieved for key outcomes	After adjusting for baseline differences, comparison of intervention and control group pupil scores at follow-up shows that intervention group average scores are higher than control for at least one of the following measures:	There were no significant difference between intervention and control groups for any of the secondary outcomes, and no evidence of promising effect sizes
Addresses study objective 2: <i>Assess the feasibility of the intervention</i>	KIDSCREEN-52 autonomy dimension	It was not possible to identify previous RCTs which had used any of these outcome measures to evaluate comparable interventions, and with comparable study populations (country, age group, etc.)
Addresses study objective 5: <i>Identify potential effect size and appropriate sample size</i>	PCCS	
	FCS	
	Family Activities Scale	
	AND that intervention group average scores are not lower than control group average scores for any of the other scales	

The summary of the criteria and their assessment above indicates that some of them have been met, at least in part. KAT was successfully implemented in three schools, and achieved high rates of engagement and acceptability in relation to both pupils and parents. Although pupils with higher Family Affluence Scale scores were more likely to have been accompanied to their family event by an adult member of their family, the overall rates of family engagement were highest in the school with the highest FSM score. The programme was implemented in schools with very different socioeconomic catchment areas. Against these findings must be balanced the fact that two schools withdrew from the study, and this may have been due in part to the feasibility and acceptability of the intervention. While key policy and practice partners are supportive of the future development of KAT, no agency was able to fund the cost of delivering it in the number of schools, which would have been needed in an effectiveness trial.

Table 54 shows that, in relation to the trial-related criteria, there is considerable uncertainty about the extent to which these have or have not been met. The process evaluation findings suggest that some of the KAT programme's key processes appeared to be operating as intended in relation to family communication. The trial succeeded in engaging schools which served a range of groups and socioeconomic localities, and overall, it was feasible to collect key outcome data from pupils (though not from parents), although two schools withdrew from the study. Either a number of the criteria have not been met, or there is not sufficient evidence to fully assess this. There was no evidence of any effect for the intermediate outcomes relating to family communication, although we cannot be certain that this indicates the absence of an effect. Rates of missing data were very low for the alcohol-related questions, but there are clear indications of unreliability in pupils' reports, and we had difficulty in identifying suitable measures of family communication for children aged 9–11 years. Although our sample size calculation is not final, it suggests that a large number of schools would be required for an effectiveness trial, which raises issues of both feasibility and affordability.

A strength of the current study is that it developed a clear set of progression criteria based on the study aims and objectives, and these were shared with key policy/practice stakeholders whose input was sought on their value and appropriateness. We identified very few examples of guidance in the literature on how to design and conduct exploratory trials, and were unable to locate detailed guidance from previous studies on how researchers should identify, specify and assess progression criteria. We also identified considerable variation in the designs, aims and terminology employed by exploratory trials. We hope that the process we followed in this study to identify and evaluate our progression criteria might form a useful resource for future studies seeking to assess the feasibility of conducting a RCT of complex interventions.

Comparison with the existing literature

School-based alcohol misuse prevention programmes

Our review of recent studies identified that, while schools are generally acknowledged to be an important setting for the delivery of alcohol misuse prevention interventions and activities, there are a number of significant gaps in the literature. The majority of research on school-based alcohol misuse prevention interventions has been conducted in the USA, and the evidence base for UK programmes is, therefore, limited.⁵⁰ There is relatively little research on prevention interventions for primary school-age children,^{31,82} despite the recognition that this age group is the most appropriate development point for family-based programmes.³¹ Long-term follow-up of participants is relatively rare. Although the involvement of parents and other community members has been shown to enhance intervention effectiveness, many school-based alcohol misuse prevention do not include them.

Our exploratory trial of KAT, therefore, makes an original contribution to the evidence base in these areas. KAT demonstrates features which have been shown to characterise effective prevention interventions: a theory-based design, interactive delivery styles and community involvement.^{29–34} We deal with each of these in turn.

The importance of a strong theoretical design

Kids, Adults Together addresses key risk and protective factors for young people's use of alcohol, particularly family relationships and communication.^{29,31,32,52–54} The programme's intended change processes are well explained by the SDM, which emphasises the critical role played by children's attachment to prosocial adults in preventing later risk behaviours, and the important roles played by opportunities for prosocial interaction, the perceived availability of these opportunities, reinforcement of prosocial behaviour, and skill development in forming prosocial attachment.⁷³ The goals and activities within the KAT programme map very clearly onto this theoretical framework. For instance, the family evening provides clearly articulated opportunities for prosocial interaction (through encouraging children and parents to work together on quizzes), reinforcement of the achievements of children (through parental interest in pupils' displays of work, and applause for pupils' presentations), while the classroom component seeks to build children's knowledge about the key health aspects of alcohol and develop their skills in discussing these issues with others.

Our findings suggest that within this overarching theoretical framework there are a number of key processes which may help KAT to achieve acceptability and engagement. For instance, findings from the process evaluation suggest that the mechanisms used by teachers to present a balanced view of alcohol, rather than focus solely on its negative health effects, were designed to allay concerns children might have about the appropriateness of moderate alcohol consumption by parents, and to ensure that communication between children and parents on the topics raised by KAT was not inhibited. Similarly, the attendance by parents at the KAT evening was mainly motivated by a desire to support their children, and children's expressed desire that their parents should attend.

Interactive delivery

Interactive activities form an important aspect of all KAT components (classroom work, family event and the programme DVD). Teachers appeared to be comfortable with the interactive nature of the KAT classroom work, and there was evidence that interactive teaching methods were used consistently across the three intervention schools which completed intervention delivery. Pupils enjoyed the group-based work that they did as part of the KAT classroom work.

Rates of parental engagement in the programme

Involvement of parents/carers in school-based prevention programmes is important, as it can strengthen effectiveness through creating opportunities for prosocial interactions within families. Family and community engagement, more generally, is an important aim for many schools. However, previous studies have highlighted the challenges of engaging parents/carers in school-based prevention programmes.

Rates of engagement are typically low, even when programmes have been modified to promote involvement.⁶²⁻⁶⁴ There are also significant gaps in the literature, with relatively little written about why some strategies to engage parents/carers appear to work, while others do not.¹¹⁰

The high rate of parental engagement in the KAT programme is, therefore, one of its key strengths, and create important opportunities for prosocial communication in families to take place. The rates of engagement compare favourably with those of other school-based programmes and appear to be achieved consistently across a range of school contexts. An important strength of the current study (and our previous research on KAT) is that we have been able to identify some of the key engagement processes and the ways in which they may be operating. In this way, it should be possible to identify aspects of programme implementation which contribute to these processes, and which need to be emphasised in future training activities and manuals. Two key processes were identified in our process evaluation. First, pupils were keen to go to the family event with their parents, and this may have encouraged family members to attend. Second, the family event was largely promoted and framed around parents/carers coming to school to see their children's work and to support their children. The importance of this is that the event was not primarily marketed or understood as being about alcohol education. It may be that the opportunity to see the work that their children have done in school is a stronger draw for parents/carers than a more generic focus on a particular health issue or message, which has less of a personal connection. These insights should be generalisable to other similar interventions which seek to engage parents/carers in school-based health education activities.

Chapter 5 Conclusion

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Recommendations for future research

Our findings suggest that it would not be appropriate to undertake an effectiveness trial of KAT at this point. They have raised doubts or uncertainties about the potential effects of KAT; suitability of measures; feasibility of follow-up in secondary schools; and programme implementation and theory. While the KAT programme has a number of strengths, including its ability to engage with significant numbers of families and the way in which it can integrate with schools' curricular activities, important trial-related progression criteria have not been met. Intermediate outcomes on family communication showed no evidence of intervention effectiveness, and it is also possible that KAT had negative impacts on certain aspects of family communication or alcohol-related behaviours. In essence, our findings indicate that KAT is likely either to be ineffective or to produce small changes in family communication which would require a very large sample size to be able to detect, and based on this it is likely that its effects on alcohol-related behaviour are also potentially small. Such a large trial could not be justified given the concerns identified regarding measurement of outcomes and the unknown feasibility of following up pupils after their transition to secondary school.¹⁶⁰

In this concluding chapter, we identify key issues for study design and implementation which may have broader methodological relevance for others conducting school-based trials. Finally, we outline a number of points for consideration in relation to the delivery of the KAT programme.

Issues requiring further research

Although we do not propose to proceed to an effectiveness trial at this point, we have identified a number of issues which would require additional research should any such trial take place in the future. Some of the methodological issues identified here also have broader relevance for researchers undertaking studies on family communication with primary school-age children.

1. For both primary and secondary outcomes, further work would be needed to identify valid, reliable, sensitive and precise measures suitable for children aged 9–11 years. This could involve additional searches of the literature for suitable measures, qualitative work and piloting of measures with children in the target age group, and validation of the measures.
 - i. The study has highlighted the challenges of asking primary school-age children to answer questions about alcohol consumption. Alcohol-related questions may require adaptation of wording or presentation in order to avoid the inconsistencies identified in this study.
 - ii. The measures of family communication would need to be reviewed carefully. Ideally, measures designed for, and validated with, children aged 9–11 years should be used to assess intermediate outcomes. Alternatively, existing measures might need to be adapted and validated.
 - iii. Methods are required for collecting information on family structure which would be acceptable to children in this age group, and which would yield useful responses.
2. The feasibility and acceptability of collecting follow-up data from pupils in secondary schools, and the response rates which would be achieved, should be assessed. Schools should be asked if they would require evidence of written consent from parents, which would have implications for the use of 'opt-out' parental consent at baseline.

Given the low costs of implementation, and its high levels of reach, KAT may be a worthwhile and cost-effective programme, but the size of effect is likely to be so small that a very large sample would be needed to estimate a statistically significant effect, and any trial would, therefore, be prohibitively expensive. In addition, issues concerning accurate measurement of primary and secondary outcomes described in this study would need to be resolved.

Issues which may have general relevance for school-based trials

1. Although rates of parent/carer involvement in the KAT programme were very high, we were not able to engage large numbers in the research element of the trial, and questionnaire completion rates were very low. Based on these findings, it would not be feasible to collect data on secondary outcome and service utilisation from parents in an effectiveness trial using the methods employed in this exploratory trial. Given that data for primary outcomes would be collected from children only, and that secondary outcomes would also be measured in children's questionnaires, one option would be to remove all parent-based data collection from the trial. Another option would be to invest significant resources into increasing parent questionnaire completion rates, for example by offering a range of alternative response modes. However, the cost of this would probably be prohibitive and, for studies such as KAT that try to promote parental engagement, could have the effect of mimicking some of the intermediate processes, which would be problematic. It would also be very important not to alter parent recruitment methods in ways which could reduce the number of children who take part in the study. A study's process evaluation could be designed in such a way that sufficient interviews with parents were included to explore potential intervention pathways. These data collection strategies would not provide an estimate of differences between the trial arms in relation to parent-derived outcomes, but they would allow greater understanding of potential mechanisms of action and provide information about the characteristics of parents who engaged with the programme.
2. In designing school-based trials, our findings suggest that it would be essential to build in sufficient time to recruit schools, and to approach them early in the life of the trial, so that intervention group schools had sufficient time to plan for programme delivery. However, while contacting schools well in advance may reduce the likelihood of schools refusing to take part because of time constraints or other projects, it could increase the risk of post-agreement/randomisation drop-out.
3. School recruitment was aided by having the support of a Healthy Schools Team practitioner. Recruitment and retention in school-based trials is likely to be increased by identification of influential figures such as healthy schools practitioners who can encourage schools to participate and remain in a study.
4. Offering incentives to schools to compensate them for the staff time and general inconvenience/disruption caused by trial participation (and staging these throughout a school's involvement in the research process) may help to increase recruitment and retention rates.

Development and future implementation of the Kids, Adults Together programme: points for consideration

Our findings have indicated that KAT is unlikely to achieve large effect sizes in relation to alcohol-related behaviours, and that it would be unfeasible and poor value to conduct a RCT of the programme, given the large number of schools which would need to be recruited. However, the study has also shown that KAT has valuable assets: in terms of the RE-AIM framework¹⁶⁰ it has good reach; challenges in implementation are surmountable; through the stakeholder group we identified a route for adoption and maintenance; and it would be easy to integrate with existing programmes. It is inexpensive to implement and could be cost-effective with a small effect, despite the fact that it is not cost-effective to conduct a trial to detect this effect. Even if the programme is not taken forward in its current form, there are a number of its constituent mechanisms which could be employed in other school-based prevention programmes and activities, particularly those relating to family engagement.

In general, the programme appears to have been delivered as intended in those schools which completed delivery, with the key components implemented, and the core messages conveyed with fidelity. However, there are a number of aspects of the programme manual and its implementation with teachers which could be further enhanced:

1. Although in each school we attempted to run an in-service training (INSET) session for the staff who would be delivering the intervention (and other school staff, where possible), some school staff either had not read all of the programme manual content, or had missed key guidance on how to deliver the intervention which it contained.
2. In at least one of the intervention schools, school staff expected the research team to organise and lead the family fun event, even though we had sought to clearly map out roles and responsibilities at the start of our discussions with school staff.
3. The KAT manual appeared, in general, to provide teachers with a relatively clear guide as to how to deliver the intervention. Some teachers felt that more information and guidance was needed in the manual, but not all staff shared this view.
4. KAT is designed to be relevant to families regardless of whether or not they drink; it promotes prosocial communication about alcohol, but it does not assume that this will always be based on rules and norms relating to drinking at home. However, in at least one school a teacher felt that the programme did not have relevance to Muslim families because they did not drink at home. The programme manual and the INSET training could have given greater guidance in this respect.
5. More generally, the trial has highlighted the challenges of delivering and evaluating an alcohol misuse prevention intervention such as KAT in schools with large numbers of families from ethnic minority backgrounds, in relation to both cultural acceptability and the availability of project materials in multiple languages.
6. The KAT programme achieved high rates of parental involvement. Our findings suggest that the involvement of parents in the intervention is very important because (1) children may be more likely to want to prepare for and attend the family event if they know that their family members will be present; and (2) some of the intended family communication processes may not take place if children attend the family events without their family.

Acknowledgements

Kids, Adults Together study participants

We are grateful to the staff and children, and parents/carers of children, in all schools who took part in the study.

Other assistance

The project benefited from funding provided for implementation of KAT by the Welsh Government and from the expertise of Mrs Ana Koleva-Thompson and Ms Maggie Gregory and their team at the Participant Resource Centre, Cochrane Institute of Primary Care and Public Health.

Thanks to Dr Rebecca Cannings-John, Senior Statistician, South-East Wales Trials Unit, who provided statistical expertise to the project during the absence on leave of the Trial Statistician; Dr Sara Jones (DECIPHer Centre Manager) for assistance with project budget management and accounting; Mrs Cheryl Briscoe (DECIPHer Centre Support Officer) for administrative support and assistance with data collection and input; Mrs Julie Hayward and Miss Elen Jones (fieldworkers, DECIPHer) for assistance with data collections.

Contribution of authors

Dr Jeremy Segrott (Research Fellow in Public Health, DECIPHer) was the lead applicant and chief investigator for the KAT trial. Substantial contributions were made to the overall design of the study; management and conduct of data collections; process evaluation supervision; the statistical analysis plan; and the writing of the background, methods, results and discussion sections of the report.

Mrs Heather Rothwell (Research Associate, DECIPHer) was the study manager; analysed the process evaluation data; and contributed to the conduct of data collections, the statistical analysis plan and the writing of the background, methods, results and discussion sections of the report.

Dr Gillian Hewitt (Research Associate, DECIPHer) updated the literature search and contributed to the writing of the background section of the report.

Dr Rebecca Playle (Senior Statistician, South East Wales Trials Unit) was a co-applicant and lead trial statistician; contributed to the study design; designed and carried out the randomisation; led the writing of the statistical analysis plan; supervised the statistical analysis of the trial data; and contributed to the methods, results and interpretation of the study and report.

Dr Chao Huang [Research Associate (Statistician), South East Wales Trials Unit] undertook the analysis of trial data.

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Professor Ceri Phillips (co-applicant, Swansea Centre for Health Economics): Professor Phillips acted as an advisor to the project and provided guidance on key elements of a health economics evaluation which would need to be included an effectiveness trial, which data collection procedures it would be helpful to pilot at exploratory trial stage, and key cost information which needed to be collected.

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Publication

Segrott J, Rothwell H, Pignatelli I, Playle R, Hewitt G, Huang C, *et al.* Exploratory trial of a school-based alcohol prevention intervention. *Health Educ* 2015; in press.

Data sharing statement

Requests to access available data should be made to the corresponding author.

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Appendix 1 Recently published trials and evaluations of programmes to address alcohol misuse in young people

Programme name and reference	Age group	Setting, location and focus	Intervention and parental involvement	Theoretical basis	Alcohol or communication outcomes
Örebro Prevention Programme; Bodin and Strandberg, 2011 ¹⁶¹	13–16 years	School based; Sweden; alcohol only	Six 20-minute presentations during termly teacher-parent meetings. No additional incentives described. Parents encouraged to make written agreements on how to prevent their child drinking. No child component. Parent response rates to evaluation 75%, 70%, 67.6% over 3 years	Not specified	Drunkness frequency by self-report. No effect at 2-year follow-up
Strong African American Families Programme; Brody <i>et al.</i> 2010 ¹⁶²	11 years	Community based; Georgia, USA; alcohol only	Family-centred programme. Seven consecutive weekly meetings with separate parent and child skill-building curricula and a family curriculum. Sixty-four per cent of families invited to participate did so and 85% of recruited families completed the trial (5.4 years). Recruitment was undertaken by AA community members, not researchers, and AA community members and AA students did the home visits for data collection. Families were paid US\$100 at each data collection point	Informed by other family-centred programmes and based on a developmental model of processes through which programme participation might protect rural AA youths from the initiation and escalation of alcohol use	Self-report of ever drinking alcoholic drinks and frequency of consumption in the last month At 65-month follow-up, youths in intervention arm drank 0.68 times in the previous month and youths in control arm drank 1.41 times
Unplugged (EU-Dap), ⁶⁴ Caria <i>et al.</i> 2011 ⁶³ and Faggiano <i>et al.</i> 2010 ⁶³	12–14 years	School based; Austria, Belgium, Germany, Greece, Italy, Spain, Sweden; alcohol, tobacco and drugs	Interactive curriculum with knowledge, life skills and normative education components. Delivered in the classroom across 12 weekly lessons. Parents were involved in one of three formats of the programme (5). Three evening workshops 2–3 hours long on parenting skills, substance misuse information and skills to enhance parents' confidence. Personal invitation signed by study co-ordinator/college principal sent to parents of all students involved. No incentives described. Maximum 28% students' parents attended any one workshop (average 12 per workshop) (6). Student data were pooled across three intervention groups for analysis	Social influence model	Frequency of alcohol consumption, drunkness and problem behaviours due to alcohol After 18 months, programme did not modify the risk of being a current or frequent drinker, and a lower prevalence of problem behaviours was seen in only some children, e.g. those who were not drinking at baseline and girls ≤ 12 years. Frequency of drunkness episodes significantly reduced in intervention arm

Programme name and reference	Age group	Setting, location and focus	Intervention and parental involvement	Theoretical basis	Alcohol or communication outcomes
Adventure; Conrad <i>et al.</i> 2013 ¹⁶⁴	13–14 years	School based; London, UK; alcohol and other substances	No parent involvement. Two 90-minute group sessions for each of four high-risk groups of students (sessions differ according to risk group). Sessions focused on personality traits, not problem behaviours so alcohol was a minor focus. Used workbooks and goal setting. High-risk students identified from baseline survey	Personality is a risk factor for alcohol use. Selective preventions targeting specific risk profiles provide coping skills before the onset of drinking behaviours	Alcohol use in last 6 months, binge drinking in last 6 months and severity of alcohol problems in last 6 months After 24 months, risk intervention students drank less and their growth in quantity drunk and binge drinking frequency was lower. Positive herd effects in low-risk students (who attended intervention schools but did not receive the intervention) were observed
CHOICE; D'Amico <i>et al.</i> 2012 ¹⁶⁵	11–14 years	Middle-school based, but after school; California, USA; alcohol and other drugs	No parent involvement. Voluntary programme; students met once a week after school; 5 x 30-minute sessions that rotate over 12 months; used motivational interviewing to present the curriculum	Social Learning Theory, Decision-making Theory and Self Efficacy Theory	Lifetime and past-month frequency of alcohol use and intention to drink in the next 6 months. Effect seen on lifetime alcohol use only OR = 0.7
Eddy <i>et al.</i> 2012 ¹⁶⁶ <i>Note: before-and-after design, not a trial; repeat cross-sectional surveys</i>	12–17 years	School, family and community based; Wisconsin, USA; alcohol only	Two family-strengthening programmes were selected for use – Guiding Good Choices (parents with 9- to 14-year-olds) and Staying Connected With Your Teen (parents with 12- to 17-year-olds); both teach parenting strategies for setting and enforcing standards and strengthening family bonds. Rates of participation not provided. No incentives to participate described. All Stars implemented in schools and community settings for sixth to eighth graders (no parent involvement)	Used the Strategic Prevention Framework, a tool for communities seeking to use evidence-based programmes	Self-report age of first alcohol use, past-month alcohol use, ease of obtaining alcohol, binge drinking and perceived parental disapproval of alcohol use. Over 8 years, first use increased from 12.3 to 13.1 years and monthly alcohol use dropped by 8.6%
Evers <i>et al.</i> 2012 ¹⁶⁷	10–14 years	School based; USA; alcohol, tobacco and other drugs	No parent involvement other than some substance information by post. Pupils did an individualised, interactive computer/internet intervention with three sessions over 3 months	Transtheoretical model of behaviour change	Self-report of lifetime and past-month alcohol use and past-month binge drinking. All substances combined in results. Significant impact at 3 months disappeared by 14 months

Programme name and reference	Age group	Setting, location and focus	Intervention and parental involvement	Theoretical basis	Alcohol or communication outcomes
Fang <i>et al.</i> 2010 ¹⁶⁸	10–14 years	Home based; USA; alcohol and other drugs	Nine internet-based sessions which Asian American mothers and daughters did together interactively. Recruitment via a 'noticeboard' website and mailings to Asian community services agencies. Eighty-two per cent of those coming forward were eligible and, of those, 64% were entered into the trial. Ninety-six per cent of participants completed the trial. Gift vouchers worth US\$20 and US\$25 were given at the two data collection points	Family interaction theory	Self-report of alcohol use in last month and intention to use in future; questionnaire items on mother–daughter closeness and communication (lowa Family Interaction Rating Scale), maternal monitoring and rules At 3 months effect seen on alcohol use, closeness, communication, monitoring and rules
Unplugged; Gabrielik <i>et al.</i> 2012 ¹⁶⁹	11–13 years	School based; the Czech Republic; alcohol, tobacco, inhalants and other drugs	No parental involvement. Twelve 45-minute sessions delivered by teachers over a school year; each pupil has their own workbook; interactivity unclear	Comprehensive social influence model	Self-report frequency of drunkenness in past month. No effect
Hodder <i>et al.</i> 2011 ¹⁷⁰ <i>Note: before-and-after design, not a trial</i>	12–16 years	School based; New South Wales, Australia; alcohol, tobacco and marijuana	Interventions tailored to each school and had elements addressing all Health Promoting School areas; including initiatives to increase parent engagement with school. Parents were involved in intervention planning workshops. No information on number of parents involved or incentives provided	Resilience theory	Alcohol use in past 3 months, binge drinking in last month, resilience (empathy, help seeking, self-esteem, communication and cooperation, self-awareness, goals and aspirations) and protection (family connection, prosocial peers, autonomy experience, community connection, school connection, prosocial group)
Koning <i>et al.</i> 2011 ¹⁷¹	11–13 years old	School based; the Netherlands; alcohol only	Parent intervention to encourage restrictive rule setting delivered at a parents' meeting at the start of the school year with a 20-minute presentation, consensus building around alcohol rules and a leaflet (no additional incentives described); pupil intervention to increase self-control and attitude towards alcohol delivered through four digital lessons (four-arm trial). Parent response rates to the evaluation were 86.1% at the first follow-up and 72.6% at the second	Theory of planned behaviour and Social Cognitive Theory	Resilience and protection went up and percentage of students reporting drinking behaviours decreased Self-report onset of weekly drinking in non-drinkers at baseline At 34 months, fewer students had started to drink or drink heavily on a weekly basis in combined intervention group. No effects in pupil/parent-only arms

Programme name and reference	Age group	Setting, location and focus	Intervention and parental involvement	Theoretical basis	Alcohol or communication outcomes
Project Alert; Kovach Clark <i>et al.</i> 2010 ¹⁷²	11–13 years	School based; USA; alcohol, tobacco and marijuana	No parent involvement. Eleven core lessons in 6th grade and three booster lessons in 7th grade delivered by teachers	Integrates several models of health promotion and behaviour change, including the health belief model and the self-efficacy theory of behaviour change	Self-report of intention to use alcohol in next 6 months, beliefs about alcohol use consequences, normative beliefs, and resistance self-efficacy No effects after 1 year
Media Detective; Kupersmidt <i>et al.</i> 2010 ¹⁷³	7–13 years	School based; North Carolina, USA; alcohol and tobacco	No parent involvement. Ten 45-minute lessons culminating in pupils creating a 'counter-advert'	Based on the MIP model designed to increase children's critical thinking around media messages; MIP draws on social cognitive theory, dual process theories of attitude change and the theory of reasoned action	Self-report of intention to use alcohol after 2 weeks. Results not presented separately from tobacco
Media Ready; Kupersmidt <i>et al.</i> 2012 ¹⁷⁴	11–14 years	School based; North Carolina, USA; alcohol and tobacco	No parental involvement. Ten 45-minute lessons culminating in pupils creating a 'counter-advert'	Based on the MIP model, as above	Self-report of intention to use alcohol in the next year and before age 21 years after 2 weeks. Impact seen on boys only
In control: no alcohol! Mares <i>et al.</i> 2012 ⁹⁹	10–13 years	Home based; South Holland, the Netherlands; alcohol only	Focus on alcohol-specific communication, rules (drinking contracts) and monitoring; intervention was five monthly magazines sent to the home with activities for the child and mother to do together, also a website with more information and more games. Two hundred and eighteen out of 892 (24%) mothers returned consent forms and 213 entered the trial. One hundred and ninety (89%) completed the trial. No incentives reported	Based on socialisation and communication theories, namely that parent-child communication is a powerful tool in the socialisation of young adolescents so programme aimed to improve conversation quality; derived from social cognitive theory	Alcohol-specific communication (frequency and quality), alcohol specific rules, non-drinking contract after 5 months (immediately post intervention). Effect seen on frequency of communication, especially in mothers with alcohol problems. Quality of communication only improved in mothers who drank more than average

Programme name and reference	Age group	Setting, location and focus	Intervention and parental involvement	Theoretical basis	Alcohol or communication outcomes
Drug Education in Victorian Schools; Midford <i>et al.</i> 2012 ⁴⁵	13–15 years	School based; Victoria, Australia; alcohol and other drugs	No parental involvement. 12 year 8 and 10 year 9 interactive lesson plans which addressed issues around alcohol, tobacco, marijuana and other drugs	Drew on earlier research and development projects on drug education in Australia. Incorporated elements of effective practice from the literature	Alcohol and other drug use knowledge, attitudes and harms; annual consumption of alcohol, drinking to get drunk, drinking more than planned, drinking in a manner that risks acute harm, communication with parents about alcohol
Morgenstern <i>et al.</i> 2009 ⁷⁵	12–15 years	School based; Schleswig-Holstein, Germany; alcohol only	Four interactive classroom teaching units, a booklet for students and a booklet for parents. Parents therefore not actively recruited to programme and not involved in evaluation	Based on addressing social influences and enhancing motivation to avoid substance use	At 20 months, improvements in knowledge, communication with parents, annual consumption, drinking to get drunk and alcohol harms Alcohol use and alcohol knowledge, attitudes and intentions
Climate Schools Alcohol and Cannabis Course; Newton <i>et al.</i> 2010 ⁷⁶	13 years	School based; Sydney, Australia; alcohol and marijuana	No parental involvement. Internet-based intervention with 12 x 40-minute lessons over 6 months; 20 minutes on the computer completed individually and then 20 minutes of teacher-led interactive activity	Consistent with the harm reduction approach and based on the social influence approach, derived from social learning theory	At 12 months, impact on knowledge, but not attitudes nor intentions. Only positive change in alcohol use was for lifetime binge drinking (OR 0.74) Alcohol knowledge and expectancies, weekly alcohol consumption, frequency of drinking to excess and alcohol-related harms
Especially for Daughters; O'Donnell <i>et al.</i> 2010 ⁷⁷	11–13 years	Home based; New York City, NY, USA; alcohol and sex initiation	Four audio CDs posted to homes every 6 weeks, each containing a drama for parent to listen to. No child component. Recruitment of parents through pupil post. Six hundred and six families expressed an interest, of whom 75% were eligible for the trial. Sixty per cent of eligible families consented. Parents given a portable CD player as an incentive after baseline data collection. Project staff telephoned all parents at least once during the study	Grounded in multiple theories: social development model, theory of planned behaviour, behavioural learning theory, sex theories; parents asked about alcohol-related communication in the evaluation	At 12 months, impact seen on alcohol knowledge, weekly consumption and drinking to excess Alcohol use At 3 months, impact seen on reported alcohol use (OR 0.38)

Programme name and reference	Age group	Setting, location and focus	Intervention and parental involvement	Theoretical basis	Alcohol or communication outcomes
Strong and Clear; Pettersson <i>et al.</i> 2011 ¹⁷⁸ <i>Note: not a randomised control group</i>	13–16 years	Home based with some meetings held in school; Värmland County, Sweden; alcohol focus	Four types of group and self-administered activities – parent meetings, family dialogues, friend meetings, family meetings (13 activities in all); children involved in some of the activities. Parent response rates to evaluation questionnaires were 69%, 54% and 46% at baseline and two follow-ups. No incentives mentioned	Not well described	Alcohol consumption Suggestion that intervention delayed alcohol debut, but no difference between groups by 27 months. Less drunkenness in intervention group
Rowland <i>et al.</i> 2013 ⁴⁷	12 years	School and community based; Australia; alcohol only	Community mobilisation to reduce sale of alcohol to minors and social marketing interventions delivered through schools but targeting parents too, e.g. mail-outs and parents nights. Parents not directly involved in the evaluation	Based on the Communities that Care approach and grounded in social ecological theory. Also integrated behavioural model, a more developed version of the theory of planned behaviour and the theory of reasoned action	Alcohol use Trial ongoing
Schinke <i>et al.</i> 2010 ¹⁷⁹	9–11 years	Community agency and home based; New York City, NY, USA; alcohol only	Two intervention arms, one with parent involvement on top of computer-based, 10 x 45-minute CD-ROM session intervention for children (interactive exercises, puzzles and games); parent involvement via parallel, reinforcing supplemental materials (printed and video, then CD-ROM and iPod recordings) and a workshop. Both parent and child interventions had booster elements. Parent adherence rates ranged from 50% workshop attendance to 78% digital audio recording. No evaluation data collected from parents	Informed by social learning theory	Alcohol consumption in past 30 days, binge drinking, intentions to drink and alcohol refusal skills At 7 years, interventions had positive impact on the alcohol measures, but there was no additional benefit of the parent component
IPSY life skills programme; Spaeth <i>et al.</i> 2010 ¹⁸⁰	10–13 years	School based; Thuringia State, Germany; alcohol and tobacco	No parent involvement: teachers deliver 15 interactive classroom sessions in 5th grade with seven booster lessons in 6th and 7th grades	Based on the model for life skills education, developmental psychological models and empirical findings	Alcohol use At 2 years, the intervention decreased the likelihood of drinking and the quantity drunk at each drinking occasion

Programme name and reference	Age group	Setting, location and focus	Intervention and parental involvement	Theoretical basis	Alcohol or communication outcomes
Prospier; Spoth <i>et al.</i> 2013 ¹⁸¹	11–13 years	Family-focused and school-based interventions; Iowa and Pennsylvania, USA; alcohol, tobacco and drugs	School–community–university partnership; communities (including parent representatives) chose their own evidence based interventions and these included SFP10-14, Life Skills Training, Project Alert and All Stars; SFP10-14 involved parents, the other three are delivered in the classroom. Parents not involved in evaluation and participation in intervention not reported. Parent incentives not mentioned	Interventions were theory and evidence based	Past-month and frequency of drunkenness and drink driving After 6.5 years effects observed for drunkenness but not drink driving. Impact for both was greater in higher-risk students

AA, African American; CD, compact disc; CD-ROM, compact disc read-only memory; MIP, message interpretation processing; OR, odds ratio.

Appendix 2 Letter to all eligible schools

Invitation to participate in research project on the Kids, Adults Together Programme

Dear

I am writing to invite [name of school] to participate in a major new research project which is evaluating the Kids, Adult Together Programme (KAT).

KAT is a universal alcohol misuse prevention programme for pupils in Years 5/6 and their families. It aims to increase **pupils' awareness of the key health and social issues around alcohol, and to promote positive communication between pupils and their parents**. KAT has been designed to help schools deliver key elements of the **PSE curriculum**, and other subject areas, such as Maths, Science and English. It can support schools to address their goals in relation to:

- Welsh Government guidance on substance misuse education;
- The Welsh Network of Healthy School Schemes National Quality Award;
- Programmes such as Investors in Families that value and support the role of parents; and
- achieving outcomes and objectives of Newport's Community Safety, Health, Social Care and Well-being, and Children and Young People's Partnership Strategy.

KAT comprises **two main components**:

- a series of interactive **classroom activities** (delivered by class teachers) guided by a teachers' pack and resources. A twilight inset session for teaching staff involved in KAT is offered before the programme starts; and
- the classroom work culminates in a **family fun evening** to which parents (and other family members) are invited. This includes opportunities for pupils to share their work and learning with parents, and activities for families to work on together (such as quizzes, treasure hunts, etc).

KAT has now been piloted in three schools, has been well evaluated, and has succeeded in engaging large numbers of parents who have attended family fun evenings. Cardiff University has recently been awarded funding to undertake a larger evaluation of KAT which will determine whether or not to further develop and evaluate KAT. We are working with a number of agencies on the project, including Gwent Police, and Matthew Green from Newport Healthy Schools Scheme.

This study will take place in the city of Newport. All English medium primary schools have been invited to express an interest in participation, and from

those which respond we will select eight schools. Four of these schools will deliver the KAT programme in January 2012 (intervention group), and the other four schools will form a comparison (or control) group and not receive the programme during the 2011-2012, though if funds are available they will be able to receive it during 2012-2013.

Schools which participate in the research will be asked to:

- assist the research team in **promoting the study to pupils and parents**, in order to obtain consent for their participation in the research;
- allow the research team to distribute **questionnaire surveys to pupils** to complete in class time on two occasions and invite some pupils to take part in a discussion group on their involvement in KAT;
- **be willing to be allocated to either the intervention or control group;**
- **if allocated to the intervention group to deliver the KAT programme in January 2012.** KAT classroom activities amount to about 5 days teaching, but can be spread over a number of weeks; and
- **Organise and facilitate the family fun evening** (with support from the research team) if allocated to the intervention group.

If you would be interested in participating in the study, please could you contact me (by phone, email or letter) as soon as possible? I can arrange to visit your school and provide you with more information about the research study and the KAT programme.

I look forward to hearing from you.

Yours Sincerely

Dr Jeremy Segrott

Appendix 3 Participant information for pupils



EVALUATION OF THE KIDS, ADULTS TOGETHER (KAT) PROGRAMME

INFORMATION FOR PUPILS



What is KAT?

Your school is one of four schools chosen to test the KAT programme. KAT tries to get parents and children to think more about the way people talk about alcohol and when people might want to drink alcoholic drinks. This might help

young people to be more sensible about drinking alcohol when they are growing up. You will learn about this in school with the rest of your class and then you and your parents will be invited to a fun evening at the school.

What is the research about?

We are researchers based at Cardiff University. Our research is looking at what happens in schools as part of the KAT programme, and if KAT is a good programme.

What do I have to do?

As part of this research we would like to ask you to answer two questionnaires for us. The questionnaires have questions about what things are like in your family, and also some questions about alcohol. We may also ask you if you would like to take part in a focus group discussion when you can tell us what you thought of the KAT programme. You can decide if you want to take part in the research or not.

We would also like to watch classes where you are learning about KAT, and the KAT fun evening. Your school has posted a letter to your parents to tell them what the research is about. We would like you to do just what you would normally do in class or at the fun evening and we will try not to get in the way. You will be asked at the beginning of the class or the fun evening if it is all right for us to be there. You will not get into trouble if you say you do not want us there.

What will you do with the information you collect?

We will come back to your school to tell you what we found (if your Head teacher gives permission). We will also make presentations to everyone else who takes part, to international

conferences and to other groups of people who are interested. We will also write papers for academic journals.

We will not use the names of individual pupils or schools so no-one who hears about the evaluation will know who has taken part. Written notes and voice recordings will be locked up in offices at Cardiff University. **We won't tell your parents, teachers and friends about anything we hear you say or see you do. However we would have to tell someone else if we found out about something that might put someone in danger**

What if I've got some questions?

If you see us at your school, please come and talk to us.

Jeremy Segrott

Anna Flicker

[Photographs included in original]

Or you can contact Jeremy Segrott at Cardiff University (email: SegrottJ@cardiff.ac.uk, telephone: 029 20875360).

Kids, Adults Together (KAT): programme evaluation*(2 copies to be completed – 1 for participant, 1 for researcher)*

Please read each of the sentences below and tick the box if you understand.

If you do not understand anything, please ask one of the researchers.

Please tick

I have read the information sheet about the research project

I have asked all the questions I want about the research project

The researchers have answered my questions in a way I understand

I understand what the research is about

I understand that it's OK to stop taking part at any time before the end of the study

I am happy to fill in questionnaires for the research project

Are you happy for a researcher to watch the work your class does as part of KAT? Yes

No

Are you happy to take part in a group discussion about KAT Yes

No

I understand that if I take part in a discussion group it will be recorded and written up

I am happy for the researchers to use parts of what I say in the discussion group as long
as my name is not mentioned

Now please tick **ONE** of the boxes below.

I DO want to take part in the research on KAT

I DO NOT want to take part in the research on KAT

My name

School.....

Date

My Signature.....

Researcher's name.....

Date.....

Researcher's signature

2 copies: 1 for participant, 1 for research file

Appendix 4 Documents sent to parents in intervention schools

Information for parents - intervention schools

Background to the study

Your child's class is taking part in a programme called the Kids, Adults Together programme (KAT). The programme aims to encourage young people to develop a responsible attitude to drinking alcohol by making families more aware of ways in which people use and talk about alcohol.

The KAT programme is run in partnership with Gwent Police. Cardiff Institute of Society and Health is undertaking an evaluation of the KAT programme. The evaluation will assist in planning the expansion of the programme into other areas of Wales and improve understanding of how young people learn about and use alcohol.

The evaluation will employ a randomised controlled trial design and will be conducted across 8 schools. This means that schools will be randomly allocated to either '*intervention*' or '*control*' status. Schools allocated to the intervention status will run the KAT programme. Schools allocated to the control group will not receive the KAT programme and will just carry on as normal. **Your school was chosen to be in the intervention group.**

How the evaluation will be carried out

- A telephone interview with parents
- Two questionnaires for pupils (completed during school time)
- Researchers' attendance at classroom preparation and fun evenings in schools;
- Focus groups with children to explore their views about KAT
- Interviews with parents to explore their views about KAT
- Interviews with staff involved in organising and delivering the programme;
- Interviews with head teachers and teachers

What you are being asked to do

You are asked to read through the enclosed information leaflet with your child to see if you are both willing to take part in the research, and whether you are happy for us to attend the classroom preparation and the fun evening for KAT.

For parents, taking part in the research will mainly involve a telephone interview (in about six months time). The interviews are about family life, and there are also some questions about alcohol. We may also invite you to take part in a face-to-face interview to ask you what you thought of the KAT programme.

For your child, taking part in the research will involve completing two questionnaires, which include questions about family life, and also about young people's attitudes and behaviour in relation to alcohol. We may also invite your son/daughter to take part in a focus group discussion about what they thought of the KAT programme.

As a way of saying thank you, all families which participate in the research will receive a £15 gift voucher.

If you are interested in taking part in the research as a parent or would like to find out more, please could you complete the attached form, and return it in the FREEPOST envelope provided. Alternatively you can email us (segrottj@cardiff.ac.uk) or call us (029 2087 5360).

If you do not wish your child to take part in the research please contact the school by the date included in the letter sent to you, informing them of this. If you are happy for your child to take part in the research you do not need to do anything.

Ethical approval

The evaluation has been approved by Cardiff School of Social Sciences Research Ethics Committee.

Confidentiality

Your answers to the questionnaire will not be seen by anyone outside the evaluation team and will be anonymous. Some answers may be quoted in presentations and written reports but

any details which could lead to the identification of individuals or schools would not be included. Returned questionnaires will be kept in a locked cabinet and only the evaluation team will have access. Data from questionnaires will also be stored electronically in a folder to which only the evaluation team will have access through password-protected personal computers. Questionnaires will be kept for five years after the end of the project, and will then be destroyed (in accordance with the Data Protection Act 1998).

Every effort will be made to ensure that the identity of individuals and schools taking part is not revealed. However, the researchers are obliged to disclose information about circumstances which may result in harm to someone.

Results

Data from this study will be used to write a report in academic papers. Findings will be presented at an event for participants, practitioners and policy makers and to children at the schools taking part (provided this is authorised by their Head teachers). Presentations will also be made at international conferences and to other interested groups.

Further information

If you have any questions or would like to offer comments or suggestions, please get in touch: Jeremy Segrott, Cardiff Institute of Society and Health, Cardiff University, 1-3 Museum Place, Cardiff CF10 3BD. Telephone: 02920 875360. Email: SegrottJ@Cardiff.ac.uk

Evaluation of the Kids, Adults Together

Contact details form

Name: _____

Address:

Landline: _____

Mobile number: _____

Email: _____



Director Cyfarwyddwr Professor Yr Athro Laurence Moore

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Cardiff University

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Cymdeithasol
Prifysgol Caerdydd
1-3 Plas yr Amgueddfa
Caerdydd CF10 3BD
Cymru, Y Deyrnas Gyfunol*



Research project on the Kids, Adults Together (KAT) Programme

Dear Parent/Carer,

Earlier this week we sent you a letter about a research project which your child's school is taking part in.

This is just a quick reminder that we would like to invite you and your child to take part in the research, which mainly involves completing questionnaires.

If you did not receive the information, or you would like another copy, please contact me by phone, email or letter, and I will be very happy to send it to you. Alternatively, this information is available at the following website - <http://bit.ly/wvBjGi>. The pages have a password which is Newport.

If you are interested in taking part in the research as a parent or would like to find out more, please could you complete the attached form, and return it in the FREEPOST envelope provided. Alternatively you can email me (segrottj@cardiff.ac.uk) or call us (029 2087 5360).

If you do not wish your child to take part in the research please contact the school by [INSERT DATE] informing them of this. If you are happy for your child to take part in the research you do not need to contact the school.

With many thanks

Yours Faithfully

Dr Jeremy Segrott
Principal Investigator



Evaluation of the Kids, Adults Together programme (KAT)

I am / We are interested in taking part in the KAT evaluation study

Name: _____

Name: _____

Home address:

Landline: _____

Mobile number: _____

Email: _____

Your child(ren):

Child(ren)'s school: _____

Name: _____ Class: _____

Name: _____ Class: _____

Appendix 5 Commitment form for head teachers

Evaluation of the Kids, Adults Together programme (KAT)

Information for head teachers

Cardiff Institute of Society and Health is undertaking an evaluation of the KAT programme to obtain evidence about the potential impacts of the programme, how it is implemented and the views of those involved. The evaluation will assist in planning the expansion of the programme into other areas of Wales and improve understanding of how young people learn about and use alcohol. We would like to invite your school to participate in the evaluation. The evaluation will employ a randomised controlled trial design and will be conducted across 8 schools.

During the current academic year only schools which agree to participate in the evaluation have a possible chance of receiving the KAT programme. Schools will be randomly allocated to either '*intervention*' or '*control*' status. Schools allocated to the intervention status will run the KAT programme. Schools allocated to the control group will not receive the KAT programme and will just carry on as normal. Control status schools play a crucial role in this study as they allow us to compare changes in their pupils with those in pupils who have been involved in the KAT programme.

It is important to remember that allocation to these groups is random. There is a 50% chance of your school being in the intervention group. If your school is selected to be part of the intervention group you will receive details from the programme delivery team about the KAT programme and how it will work in your school.

As part of the evaluation your school would be asked to:

- Address and post documents in stamped envelopes supplied by CISHE to parents of all pupils in Year 5/6 to inform parents about the research and to seek their participation and consent for their children's involvement. A second reminder letter may need to be sent to some parents.
- Allow us to ask Year 5/6 pupils to complete a written questionnaire during school time on two occasions – when the study first starts, and then 6 months

later. The questionnaires are mainly about how families get on together, and also ask pupils about attitudes and behaviours in relation to alcohol

- Allow us to invite relevant teaching staff to take part in an interview

And if your school is in the intervention group:

- (Following the fun evening) Address and post questionnaires in stamped envelopes to parents of all pupils in Year 5/6 who have not previously returned contact details to the research team.
- To provide space within the school for us to conduct a focus group and to allow 6-8 children to take time out of lessons to participate in each focus group.
- Allow one of our researchers to sit in on classroom preparation for the KAT fun evenings
- Allow one of our researchers to attend fun evenings

All planning and implementation of the evaluation will be undertaken by University staff/students, who have undergone a CRB check. It is not envisaged that the evaluation will impact on current teaching commitments in any significant way.

Parents will be informed before the study is carried out that their children's school is to take part in the research. Pupils will receive verbal and written information about the study and will be informed that participation is voluntary, before being asked to give formal consent. Pupil questionnaires will take about 15 minutes to complete. Researchers have enhanced clearance from the Criminal Records Bureau. Parents will be asked to inform the school if they do not wish their children to complete questionnaires or if they do not wish the research team to observe the classroom work and/or KAT fun evening which their child is involved with.

Note-taking will be used as a method of recording data during attendance at classroom preparation and fun evenings. No-one outside the project team will have access to these notes. Any personal statements made by participants during the evaluation will not be divulged. Your school, and individuals in the school, will remain anonymous. All comments quoted in any reports or papers that are produced as a result of the evaluation will be anonymised. Focus-group discussions will be

recorded and transcribed with the permission of those taking part. Audio and written records will be stored and disposed of in accordance with the requirements of the Data Protection Act 1998.

Should any information be revealed about circumstances which may result in harm to someone, the evaluation team have a duty to report this to the appropriate authorities and in this special case the researchers will not be bound to preserve confidentiality.

Data will be used to write a project report and academic papers. Findings will be presented at an event for participants, practitioners and policy makers and to children at the schools taking part (provided this is authorised by their Head teachers). Presentations will also be made at international conferences and to other interested groups.



Director *Cyfarwyddwr* Professor *Yr Athro* Laurence Moore

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Ysgol y Gwyddorau Cymdeithasol
Prifysgol Caerdydd
1-3 Plas yr Amgueddfa
Caerdydd CF10 3BD
Cymru, Y Deyrnas Gyfunol



Date

Dear

Evaluation of the Kids, Adults Together programme (KAT)

Thank you very much for agreeing to participate in the KAT evaluation. We very much appreciate your school's involvement and the time you have spent discussing details of the work we plan to do. I am writing to confirm these arrangements.

Brief information about the research is provided overleaf, along with details of the work involving your school. I would be grateful if you could sign one copy of this statement and return it to me as soon as possible. Please retain the other copy for your own records.

Thank you again for your interest in this important study. We look forward to working with you and your staff, and to visiting your school.

If you have any questions regarding this letter, do not hesitate to contact Jeremy Segrott by telephone on 02920 875360 or email: at SegrottJ@cardiff.ac.uk

Yours sincerely,

Jeremy Segrott
Principal Investigator

School commitment

I have read and understood the documents received from CISHE and I wish formally to commit our school to taking part in the KAT evaluation.

I understand that individual members of staff have the right to refuse to participate in the study and in these circumstances the evaluation team will make alternative arrangements to collect the necessary data.

I am happy with the procedure which asks parents to inform the school if they do not want their child(ren) to complete questionnaires or if they do not want the researchers to attend the classroom preparation or fun evening for KATFF.

The following arrangements have been agreed:

- The school will address and post documents in stamped envelopes supplied by CISHE to parents of all pupils in Year 5/6 to inform parents about the research and to seek their participation and consent for their children's involvement. A second reminder letter may need to be sent to some parents.
- The research team is permitted to ask Year 5/6 pupils to complete a written questionnaire during school time on two occasions – when the study first starts, and then 4 months later
- The school will address and post questionnaires in stamped envelopes supplied by CISHE to parents of all pupils in Year 5/6 who have not previously returned their contact details to the research team.
- The school will provide space for Anna Flicker and a co-facilitator to conduct a focus group during the school day. Six to eight pupils whose parents have given them permission will be allowed to take time off from lessons to take part in each group.
- Anna Flicker is permitted to attend classroom preparation for the fun evening and to take notes, provided the teachers, pupils and pupils' parents do not object.
- Anna Flicker is permitted to attend the fun evening and to take notes, provided the facilitator, pupils and pupils' parents do not object.
- The school will inform Anna Flicker in advance of the dates and times of classroom preparation and fun evenings.

(greyed area is only for inclusion in leaflets for schools in the intervention group)

INFORMATION AND CONSENT

School responsibilities

The school will be responsible for ensuring that parents receive letters, information sheets, questionnaires and consent forms regarding the evaluation. To comply with the requirements of the Data Protection Act 1998, the school will mail pre-printed letters, information sheets, questionnaires and consent forms on behalf of the evaluation team to the homes of pupils taking part in the research.

CISHE responsibilities

CISHE will provide pre-printed letters, information sheets, questionnaires, envelopes and stamps for the school to post to the homes of pupils taking part in the KAT programme.

CISHE will be responsible for ensuring that teachers and pupils involved in classroom preparation and facilitators and families at fun evenings have understood information about the study and do not object to the researcher's attendance during these events.

CISHE will be responsible for administering questionnaires to Year 5/6 pupils, and will ensure that only those pupils have given consent (and whose parents) have given consent are asked to complete a questionnaire.

CISHE will be responsible for checking that parents of pupils attending focus groups have given consent for them to take part and for obtaining informed assent from the pupils, after ensuring that they have understood information about the study and are aware of their right to refuse to participate.

Signed: (Head teacher)

Name:

School name

Date:

Appendix 6 Documents sent to potential parent interviewees

Kids, Adults Together (KAT): programme evaluation

INFORMATION FOR PARENTS

Background to the study

Your child's class is taking part in an evaluation of a programme called the Kids, Adults Together programme (KAT). The programme aims to encourage young people to develop a responsible attitude to drinking alcohol by making families more aware of ways in which people use and talk about alcohol.

The KAT programme is run in partnership with Gwent Police. The DECIPHER research centre at Cardiff University is undertaking an evaluation of the KAT programme. The evaluation will assist in planning the expansion of the programme into other areas of Wales and improve understanding of how young people learn about and use alcohol.

The evaluation employs a randomised controlled trial design and is conducted across 8 schools. This means that schools have been randomly allocated to either 'intervention' or 'control' status. Schools allocated to the intervention status run the KAT programme. Schools allocated to the control group do not receive the KAT programme and just carry on as normal.

How the evaluation is being carried out

- A telephone interview with parents
- Two questionnaires for pupils (completed during school time)
- Researchers' attendance at schools
- Focus groups with children
- Interviews with parents
- Interviews with school staff

What you are being asked to do

For parents, taking part in the research will mainly involve a telephone interview. The interview is about family life, and there are also some questions about alcohol. You can decide at the time whether you want to take part in an interview.

For your child, taking part in the research would involve completing two questionnaires, which include questions about family life, and also about young people's attitudes and behaviour in relation to alcohol. We may also invite your son/daughter to take part in a focus group discussion.

As a way of saying thank you, all families which participate in the research will receive a £15 gift voucher.

Ethical approval

The evaluation has been approved by Cardiff School of Social Sciences Research Ethics Committee.

Confidentiality

Your answers to the questionnaire will not be seen by anyone outside the evaluation team and will be anonymous. Some answers may be quoted in presentations and written reports but any details which could lead to the identification of individuals or schools would not be included. Completed questionnaires will be kept in a locked cabinet and only the evaluation team will have access. Data from questionnaires will also be stored electronically in a folder to which only the evaluation team will have access through password-protected personal computers. Questionnaires will be kept for five years after the end of the project, and will then be destroyed (in accordance with the Data Protection Act 1998).

Every effort will be made to ensure that the identity of individuals and schools taking part is not revealed. However, the researchers are obliged to disclose information about circumstances which may result in harm to someone.

Results

Data from this study will be used to write a report in academic papers. Findings will be presented at an event for participants, practitioners and policy makers and to children at the schools taking part (provided this is authorised by their Head teachers). Presentations will also be made at international conferences and to other interested groups.

Further information

If you have any questions or would like to offer comments or suggestions, please get in touch:

Heather Rothwell (study manager)

DECIPHer

Cardiff School of Social Sciences

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Cardiff CF10 3BD
Telephone: 02920 870296
Fax: 02920 879054
rothwellh@cardiff.ac.uk

KIDS ADULTS TOGETHER (KAT) EVALUATION STUDY

Interview guide for parents



DECIPHER
Development and Evaluation of Complex
Interventions for Public Health Improvement
A UKCRC Public Health Research Centre of Excellence





**FOR YOUR INTEREST IN OUR
RESEARCH INTO
THE KIDS, ADULTS TOGETHER
PROGRAMME (KAT)**

**PLEASE READ THROUGH THE INFORMATION SHEET
AND RETURN THE CONSENT FORM IF YOU ARE HAPPY
TO TAKE PART. YOU CAN CONTACT US IF YOU HAVE
ANY QUESTIONS OR CONCERNS.**

**SOMEONE WILL PHONE TO ASK YOU SOME QUESTIONS
ABOUT YOURSELF AND YOUR FAMILY.**

**PLEASE KEEP THIS BOOKLET SOMEWHERE SAFE UNTIL
THEY PHONE.**

**THIS BOOKLET WILL MAKE IT EASIER FOR YOU TO
ANSWER THE QUESTIONS.**

**PLEASE ASK THE TELEPHONE INTERVIEWER IF YOU
DON'T UNDERSTAND ANY OF THE QUESTIONS.**



**WE ENCLOSE SPARE COPIES OF THIS BOOKLET, THE
INFORMATION SHEET AND CONSENT FORM IN CASE
THERE IS ANOTHER ADULT IN YOUR HOUSEHOLD WHO
WOULD LIKE TO BE INTERVIEWED.**



FAMILY LIFE

1.1.1 WHO DO YOU LIVE WITH?

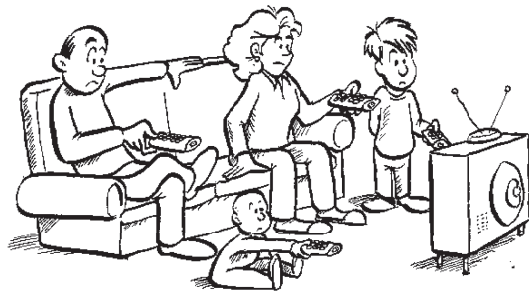
- **SPOUSE**
- **COHABITEE**
- **SON-IN-LAW/DAUGHTER-IN-LAW**
- **PARENT/GUARDIAN**
- **STEP-PARENT**
- **FOSTER PARENT**
- **PARENT-IN-LAW**
- **GRANDPARENT**
- **CIVIL PARTNER**
- **SON/DAUGHTER (INCLUDING ADOPTED)**
- **STEPSON/STEPDAUGHTER**
- **FOSTER CHILD**
- **BROTHER/SISTER (INCLUDING ADOPTED)**
- **STEP-BROTHER/STEP-SISTER**
- **FOSTER BROTHER/FOSTER SISTER**
- **BROTHER-IN-LAW/SISTER-IN-LAW**
- **GRANDCHILD**
- **OTHER RELATIVE**
- **OTHER NON-RELATIVE**

FAMILY LIFE



1.2.1 HOW OFTEN DO YOU AND YOUR FAMILY GET TOGETHER?

- EVERY DAY
- MOST DAYS
- ABOUT ONCE A WEEK
- LESS OFTEN
- NEVER





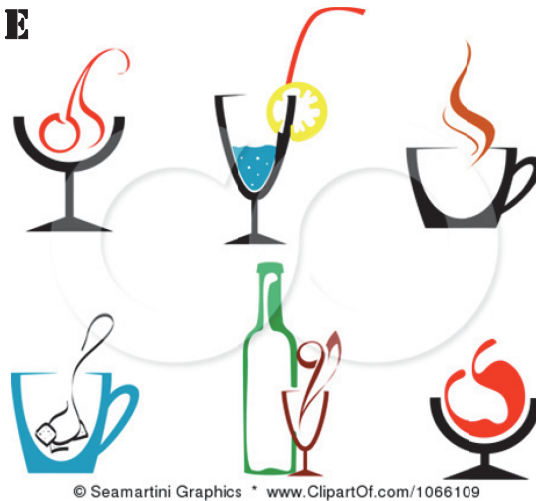
FAMILY LIFE

1.3.1 WHAT'S COMMUNICATION LIKE IN YOUR FAMILY?

- **STRONGLY DISAGREE**
- **GENERALLY DISAGREE**
- **UNDECIDED**
- **GENERALLY AGREE**
- **STRONGLY AGREE**



ALCOHOL USE



2.1.1 HOW OFTEN HAVE YOU TALKED TO YOUR CHILD(REN) ABOUT ALCOHOL?

- **NOT AT ALL**
- **ONCE**
- **TWICE**
- **3 TIMES OR MORE**
- **DON'T KNOW**





ALCOHOL USE

(2.2.2)



1 UNIT

HALF A PINT OF NORMAL STRENGTH BEER, LAGER OR CIDER (4% ABV)

ONE SINGLE (25ML) MEASURE OF SPIRITS (40% ABV)

1.5 UNITS

A 330ML BOTTLE OF NORMAL STRENGTH (4% ABV)

BEER, LAGER OR CIDER

A SMALL (125ML) GLASS OF WINE

A 35 (ML) MEASURE OF SPIRITS (40%ABV)

A 330ML BOTTLE OF ALCOPOP



2 UNITS

A PINT OF NORMAL STRENGTH (4% ABV) BEER, LAGER OR CIDER

A STANDARD (175ML) GLASS OF WINE

A DOUBLE MEASURE OF SPIRITS (40% ABV)



3 UNITS

A PINT OF PREMIUM STRENGTH (5% ABV) BEER / LAGER / CIDER

A LARGE (250ML) GLASS OF WINE



10 UNITS

A 750ML BOTTLE OF WINE

ALCOHOL USE



2.2.4 HOW OFTEN HAVE YOU HAD A DRINK CONTAINING ALCOHOL?

- **MONTHLY OR LESS**
- **2-4 TIMES A MONTH**
- **2-3 TIMES A WEEK**
- **4 OR MORE TIMES A WEEK**

2.2.5 HOW MANY UNITS OF ALCOHOL DID YOU HAVE?

- **1 TO 2**
- **3 OR 4**
- **5 OR 6**
- **7 TO 9**
- **10 OR MORE**



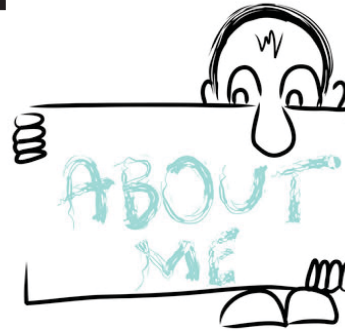


ALCOHOL USE

2.2.5 HOW OFTEN DID YOU HAVE A LOT TO DRINK ON ONE OCCASION?

- **NEVER**
- **LESS THAN MONTHLY**
- **MONTHLY**

PERSONAL INFORMATION



3.2.1 WHAT IS THE HIGHEST LEVEL OF QUALIFICATIONS YOU HAVE RECEIVED?

- **NO FORMAL QUALIFICATIONS**
- **GCSE GRADE D-G/CSE GRADE 2-5 OR STANDARD GRADE LEVEL 4-6**
- **LEVEL OR GCSE EQUIVALENT (GRADE A-C) OR O GRADE/CSE EQUIVALENT**
- **A-LEVELS OR HIGHERS**
- **ONC/NATIONAL LEVEL BTEC**
- **HIGHER EDUCATIONAL QUALIFICATION BELOW DEGREE LEVEL**
- **DEGREE LEVEL QUALIFICATION (OR EQUIVALENT)**
- **POSTGRADUATE DEGREE (E.G. POSTGRADUATE DIPLOMA, MASTERS, PHD)**
- **OTHER QUALIFICATIONS, INCLUDING FOREIGN QUALIFICATIONS**
- **DON'T KNOW**



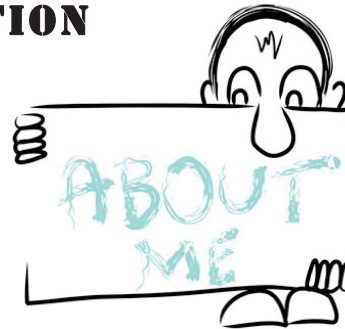


PERSONAL INFORMATION

3.3.1 WHAT'S YOUR RELATIONSHIP STATUS?

- **SINGLE, THAT IS, NEVER MARRIED AND NOT IN A RELATIONSHIP?**
- **SINGLE, THAT IS, NEVER MARRIED BUT IN A RELATIONSHIP?**
- **MARRIED AND LIVING WITH YOUR HUSBAND/WIFE?**
- **A CIVIL PARTNER IN A LEGALLY-RECOGNISED CIVIL PARTNERSHIP?**
- **MARRIED AND SEPARATED FROM YOUR HUSBAND/WIFE?**
- **DIVORCED?**
- **OR WIDOWED?**

PERSONAL INFORMATION



3.4.1 TO WHICH ETHNIC GROUP DO YOU CONSIDER YOU BELONG?

- **WHITE BRITISH**
- **WHITE IRISH**
- **ANY OTHER WHITE BACKGROUND**
- **WHITE AND BLACK CARIBBEAN**
- **WHITE AND BLACK AFRICAN**
- **WHITE AND ASIAN**
- **ANY OTHER MIXED BACKGROUND**
- **INDIAN**
- **PAKISTANI**
- **BANGLADESHI**
- **ANY OTHER ASIAN BACKGROUND**
- **CARIBBEAN**
- **AFRICAN**
- **ANY OTHER BLACK BACKGROUND**
- **CHINESE**
- **ANY OTHER ETHNIC GROUP**





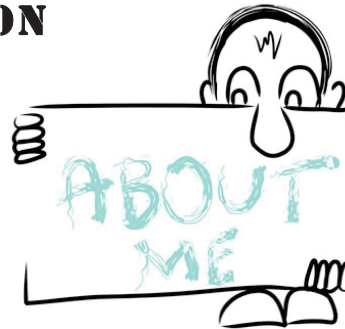
PERSONAL INFORMATION

3.5.1 ARE YOU . . .

- **IN FULL-TIME PAID WORK, AS AN EMPLOYEE OR SELF EMPLOYED**
- **IN PART-TIME PAID WORK, AS AN EMPLOYEE OR SELF EMPLOYED**
- **UNEMPLOYED AND SEEKING WORK**
- **OUT OF THE LABOUR FORCE – NOT SEEKING WORK**
- **IN FULL-TIME EDUCATION AND TRAINING**
- **IN PART-TIME EDUCATION AND TRAINING**



PERSONAL INFORMATION



3.6.4 (D) WHAT DO YOU DO?

- **MODERN PROFESSIONAL OCCUPATION**
SUCH AS: TEACHER – NURSE – PHYSIOTHERAPIST – SOCIAL WORKER – WELFARE OFFICER – ARTIST – MUSICIAN – POLICE OFFICER (SERGEANT OR ABOVE) – SOFTWARE DESIGNER

- **CLERICAL AND INTERMEDIATE OCCUPATION**
SUCH AS: SECRETARY – PERSONAL ASSISTANT – CLERICAL WORKER – OFFICE CLERK – CALL CENTRE AGENT – NURSING AUXILIARY – NURSERY NURSE

- **SENIOR MANAGER OR ADMINISTRATOR**
(USUALLY RESPONSIBLE FOR PLANNING, ORGANISING AND CO-ORDINATING WORK AND FOR FINANCE) SUCH AS: FINANCE MANAGER – CHIEF EXECUTIVE

- **TECHNICAL AND CRAFT OCCUPATION**
SUCH AS: MOTOR MECHANIC – FITTER – INSPECTOR – PLUMBER – PRINTER – TOOL MAKER – ELECTRICIAN – GARDENER – TRAIN DRIVER



- **SEMI-ROUTINE MANUAL AND SERVICE OCCUPATION**
SUCH AS: POSTAL WORKER – MACHINE OPERATIVE – SECURITY GUARD – CARETAKER – FARM WORKER – CATERING ASSISTANT – RECEPTIONIST – SALES ASSISTANT

- **ROUTINE MANUAL AND SERVICE OCCUPATION**
SUCH AS: HGV DRIVER – VAN DRIVER – CLEANER – PORTER – PACKER – SEWING MACHINIST – MESSENGER – LABOURER – WAITER / WAITRESS – BAR STAFF

- **MIDDLE OR JUNIOR MANAGER**
SUCH AS: OFFICE MANAGER – RETAIL MANAGER – BANK MANAGER – RESTAURANT MANAGER – WAREHOUSE MANAGER – PUBLICAN

- **TRADITIONAL PROFESSIONAL OCCUPATION**
SUCH AS: ACCOUNTANT – SOLICITOR – MEDICAL PRACTITIONER – SCIENTIST – CIVIL / MECHANICAL ENGINEER



THANK YOU

**YOUR FAMILY WILL RECEIVE A £15 GIFT VOUCHER AS A TOKEN
OF OUR APPRECIATION.**



Evaluation of the Kids, Adults Together Programme

PARENT / CARER CONSENT FORM

One consent form to be completed by each adult

Please initial box

1. I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily
2. I understand that my participation is voluntary and that I am free to withdraw at any time prior to the end of the study, without giving any reason, without my access to services being affected
3. I agree to take part in the above study
4. I agree to provide questionnaire data for above study as part of a telephone interview

Name of Participant Date Signature

Researcher Date Signature

2 copies: 1 for participant, 1 for research file



Appendix 7 Calculation of scores for scales used in questionnaires for Kids, Adults Together research participants

Family Activity Scale: from Health Behaviour in School-aged Children international survey of 11- to 15-year-old schoolchildren¹²¹

The scale was included as an optional package in the 2001–2 HBSC survey but we were unable to obtain information on validity, how to create a single summary score for the scale or how deal with missing data for this scale. Therefore, we used only those questionnaire responses where more than half of the items on the scale are filled in. An average score was calculated from the remaining items if validation indicates a single scale. If validation indicated more than one scale, then average scores were calculated for the subscales. Coding was reversed so that higher scores were interpreted as increased family activities.

Quality of parent relations and home life: KIDSCREEN-52 subscale

The scores for this dimension were calculated as the mean of the ratings for the six items. However, no score was computed if there was no response on two or more items. The score was transformed linearly to a 0–100-point scale, with 100 indicating the best quality of life and 0 the worst. The percentages of missing values, mean scores with standard deviation, range of scores and Cronbach's alpha were calculated. High scores indicate that children feel secure, supported and loved, well understood and well cared-for, and that they feel that parents are available and fair; lower scores indicate the absence of some or all of these qualities in their parents and home.

Targeted Parent–Child Communication about Alcohol Scale

No information about how to score the scale or how to handle missing data was found and it was, therefore, handled in the same way as the Family Activity Scale.

Parent–Child Communication Scale

Validation was carried out on this scale to confirm the three factors previously identified, and summary scores for these factors were calculated as average scores over valid responses. Any questionnaires with missing responses for any single item on this scale were excluded from the validation but included in the score calculation using the valid responses.

Family Communication Scale

Parents:

1. Add all items of the FCS.
2. The sum of these items is the total score.
3. The range of scores is from 10 to 50.

As the score for this scale is summed, rather than averaged over the items, any questionnaires with missing items on this scale had the score set as missing.

Family communication: interpretation of scores (parents)

Level	Family communication	Score ranges
Very high	Family members feel very positive about the quality and quantity of their family communication	44–50
High	Family members feel good about their family communication and have few concerns	40–43
Moderate	Family members feel generally good about their family communication, but have some concerns	36–39
Low	Family members have several concerns about the quality of their family communication	30–35
Very low	Family members have many concerns about the quality of their family communication	10–29

Pupils:

1. Add all items of the FCS.
2. The sum of these items is the total score.
3. The range of scores is 0–10.

The scoring in the pupils' questionnaire has been changed from 1–5 to 0–1, which means that total score range is reduced to 0–10. As the score for this scale is summed, rather than averaged over the items, any questionnaires with missing items on this scale will have the score set as missing. Any responses coded 2 to question 8 will be recorded as 1 (true). Score ranges have been adjusted to a 0–10 scale for interpretation.

Family communication: interpretation of scores (pupils)

Level	Family communication	Score ranges
Very high	Family members feel very positive about the quality and quantity of their family communication	9–10
High	Family members feel good about their family communication and have few concerns	8
Moderate	Family members feel generally good about their family communication, but have some concerns	7
Low	Family members have several concerns about the quality of their family communication	6
Very low	Family members have many concerns about the quality of their family communication	0–5

In the follow-up questionnaires for pupils who did not complete baseline questionnaires, only nine questions are included (question 6, 'The people in my family discuss their ideas and beliefs with each other', was left out). For these questionnaires, the answers to question 6 were treated as missing data.

Family Affluence Scale

A composite Family Affluence Scale score was calculated (summed) for each child based on his or her responses to these four items. For analysis, we used a three-point ordinal scale, where Family Affluence Scale low (score = 0–2) indicates low affluence, Family Affluence Scale medium (score = 3–5) indicates middle affluence, and Family Affluence Scale high (score = 6–9) indicates high affluence. The Family Affluence Scale score was used as a covariate in the models of alcohol consumption and also for descriptive analysis across socioeconomic status levels. As summary scores for this scale are simply summed, any missing responses to any single items were set to missing for the scale composite summary score.

Appendix 8 Process evaluation tools

Example Observation schedule classroom work (drawing on Spradley¹⁸²)

School 4 2nd yr6 class

Date: 12/03/12

Duration of observation: 1.00 – 2.00

<p>ACTORS</p> <p>No. of pupils – 27</p> <p>No. of male pupils – 12</p> <p>No. of female pupils – 15</p> <p>Year groups – year 6 class 2</p> <p>No. of staff present – 1</p> <p>Were programme deliverers male or female? - Female</p> <p>Any significant characteristics of the people?</p> <p>She was a supply teacher</p>	
<p>SPACE, OBJECTS AND SETTINGS</p> <p>What is the ambience of the room?</p> <p>Physical condition of classroom</p> <ul style="list-style-type: none"> - Rundown or modern? - lighting and temperature? - distractions and acoustics? - available space? 	<p>The yr 6 class was fairly small and dark. It was in an old building. The computer room was very small with little room to move around. They were just enough computers for the class as there were two pupils per computer. It wasn't a very light room as there was only a small window. Children had small stools to sit on.</p>

<p>Resources and equipment?</p> <p>Does layout facilitate interactive learning? (draw)</p>	
<p>ACTIVITIES AND INTERACTIONS</p> <p>Things to consider:</p> <p>What subjects were the activities integrated with?</p> <p>Was any homework taken home?</p> <p>Barriers or facilitators to delivering the activities (i.e. environment, knowledge, infrastructure, time)?</p> <p>QUALITY OF DELIVERY</p> <p>Teacher's overall effectiveness</p> <ul style="list-style-type: none"> - demeanour? - time keeping? <p>Adherence to programme manual</p> <ul style="list-style-type: none"> - Teacher's understanding of the aims of the programme? <p>Use of interactive methods</p>	<p>Activities in the morning mostly involved class discussion and brainstorming in groups. This was mostly integrated with literacy and maths. The afternoon session involved computer skills and art and design work on the computer.</p> <p>The teacher seemed to complete all the tasks as she intended as the children were quick learners and understood their tasks easily. She had a warming teaching style but also managed to maintain control of the class.</p> <p>During this first class the teacher seemed to adhere to the suggestions in the programme manual, which first steps were to establish pupil's knowledge of alcohol. She followed the manual's suggestion to use brainstorming group activities. <i>The details of the lesson are not available as, despite my best efforts, I was not informed about the morning session.</i> In the afternoon she did fact files and other activities to be shown in the fun-evening, as suggested in the manual.</p> <p>I was invited to observe their computer work but not the morning session where the majority of the group work and class discussion took place so there is a lack of insight to answer these questions. The pupils were very well behaved and attentive and worked well in their pairs.</p>

<p>activities?</p> <ul style="list-style-type: none"> - Group work? - Class discussion? - Communication <p>skills?</p> <p>PUPIL ENGAGEMENT</p> <p>Pupil engagement</p> <ul style="list-style-type: none"> - Attentive? - Enjoying? <p>Were the pupils interacting in the session?</p> <p>Were they actively participating in the session?</p> <p>Did the activities appear to develop communication skills amongst pupils?</p> <p>Did boys and girls level of engagement differ?</p> <p>Participation? Behaviour?</p> <p>How do the children appear to comprehend the complex message of alcohol use?</p>	
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First observation at School 4 (second yr. 6) - 12/03/12

1.00

This year 6 class is in a different room to the previous year 6 class at School 4. A supply teacher will be delivering KAT to this class. The teacher was a middle-aged female. She seemed friendly towards me when I entered the class. The class was fairly small and dark. It was in an old building. The seats were arranged to seat 6 or 7 per table.

The teacher asked the children to sit on the floor in front of her so she could explain the task. She told the children that they would be working in the IT room today. They would be using a special computer programme (Wordie.net) that brings out the key words in a text. They were to look up articles about alcohol and put them into this programme. This would then bring up the key words in an artistic format, where the words were provided in a bundle at different angles and in different fonts. She said this would highlight the key issues often brought up in discussions about alcohol. She told them they could add their own colours and fonts and print it out for display at the fun-evening. They seemed excited about this. She asked them to do the work 'sensibly' as they were going to show it to their parents at the fun-evening. She said the next task would be to use internet sites about alcohol to create a fact file about alcohol issues in either word or power point. Again she told them to make this colourful and tidy as it may be displayed at the fun-evening.

1.10

The children were taken over to the computer room, which was in another building. The room was pretty small and lacked any open space. The children worked in pairs for the tasks. They were very excited and talking quite loud. The teacher told them to use their 'working voice' and they began to speak quieter amongst their pairs.

1.30

While the children were getting on with their tasks I asked the teacher what she had planned for KAT this week. She said that she planned to work intensively on it this week and that they had done three sessions on it this morning. *I had phoned up the school last week and this morning to ask when they would be delivering KAT and each time I was told 1.00 until 2.00*

today by the secretary who had asked the teacher. I was a little disappointed that they had done so much this morning without providing me with the opportunity to observe. She told me that the class had started off this morning with a general overview of alcohol spending about 10 minutes in class discussion to assess what they already knew. The children then worked in groups to brainstorm ideas about alcohol and its effects on the body. The teacher then said that she had brought a bag of empty bottles into the class and asked children to arrange bottles into alcoholic and non-alcoholic order and in alcoholic strength. She said after break they had maths and after they had done some set maths work on the interactive whiteboards she incorporated some alcohol topics into maths tasks. She asked children to rate their favourite soft drinks and to rate alcoholic drinks in order of strength. They then had to work out the percentages of votes and make graphs of the results.

1.20

The teacher was constantly going around the room checking everyone was getting on with their work and providing assistance when necessary. Most children had finished their ‘wordies’ and were starting to work on their fact files. Most children choose to do this in power point so they could use more colours and fonts.

1.50

The children worked on this until 1.50 when they had break. The teacher said they will not be continuing with KAT after lunch as they had games. She said that they will be working on alcohol and the body tomorrow from 11.00 so we agreed that I would come and observe that.

Observation schedule – fun-evening

School:

Date:

Duration of observation:

<p>ACTORS</p> <p>Number of people present –</p> <p>No. of pupils –</p> <p> No. of male pupils –</p> <p> No. of female pupils</p> <p>No. of parents/family members –</p> <p> No. of males –</p> <p> No. females –</p> <p>Staff present -</p> <p>Programme deliverers?</p> <p>Any significant characteristics of the people?</p>	
<p>SPACE, OBJECTS AND SETTINGS</p> <p>What is the ambience of the room?</p> <p>Physical condition of classroom</p> <ul style="list-style-type: none"> - Rundown or modern? - lighting and temperature? - distractions and 	

<p>acoustics?</p> <ul style="list-style-type: none"> - available space? <p>Resources and equipment?</p> <p>Does layout facilitate interactive activities/opportunities? (draw)</p>	
<p>ACTIVITIES AND INTERACTIONS</p> <p>Things to consider:</p> <p><i>Quality of delivery</i></p> <p>Teacher's overall effectiveness</p> <ul style="list-style-type: none"> - Demeanour? - Time keeping? - Effort to involve families? <p><i>Adherence to programme aims</i></p> <p>Is the evening delivered in a non-lecturing way?</p> <ul style="list-style-type: none"> - Non-judgemental? <p>Use of interactive methods and activities?</p> <p>Activities to encourage families to work together?</p>	

<ul style="list-style-type: none"> - Opportunities for family discussion? - Developing family communication skills? - Awareness of family values <p>Do all children have an active role within the fun-evening?</p> <ul style="list-style-type: none"> - Was there something for each child to present to their parents at the evening? (e.g. presentations) - Was there opportunity for children to show parents their work on display/knowledge acquired? (e.g. posters, quizzes) <p>Were families given a goody bag? Were they encouraged to watch the DVD? And read the information leaflets?</p> <p>Barriers or facilitators to delivering the activities (i.e. environment, knowledge, infrastructure, time, resources)?</p> <ul style="list-style-type: none"> - What subjects were the activities integrated with? <p>PUPIL AND PARENT</p>	
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<p>ENGAGEMENT</p> <ul style="list-style-type: none"> - Attentive? - Enjoying? - Bored? - Anxious? - Are all families involved? <p>Are the families clear about the activities they have to do?</p> <p>Were they actively participating in the fun-evening?</p> <ul style="list-style-type: none"> - Interacting with each other? - Communicating about alcohol issues brought up in the activities? <p>How do the children appear to comprehend the complex message of alcohol use?</p> <p>How do parents appear to react to this?</p> <p>Did boys and girls/mothers and fathers level of engagement differ?</p> <p>Participation? Behaviour?</p>	
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Interview with head teacher

How did you decide to become involved in KAT?

What do you think is the main purpose of KAT?

What were your experiences of having the KAT programme delivered in your school?

Have you read the programme manual?

What did you think of it?

Is there anything you'd like to change about the programme manual?

Is there anything you think should stay the same?

What approach did you take to running KAT at your school?

- external facilitators

How did you integrate KAT into the school curriculum?

What did you think of the fun-evening?

- What did you think of the fun-evening activities?

How did you think the children responded to KAT?

How do you think the parents responded to the evening?

What were the facilitators which helped the running of KAT at your school?

Were there any difficulties/barriers to running KAT at your school?

How would you say KAT has compared with other health-based interventions you have run at your school?

Would you want to become involved in KAT again in the future?

What would you do differently if you could do it again?

What do you think about children being taught about alcohol misuse in school?

- How useful do you think KAT is as an alcohol misuse prevention programme for young people?
- Did you think the school was a suitable setting for KAT?
- Do you think that that KAT was a suitable programme for year 5 & 6 primary school children?
- Do you think this programme should be run in other schools?

What was the most important issue discussed?

Is there anything else that we haven't talked about that you think is important?

Interview with classroom teacher – main trial

How did you decide to become involved in KAT?

What do you think is the main purpose of KAT?

What do you think about children being taught about alcohol misuse in school? Yr5/6 age group?

EXPERIENCES OF DELIVERY – IMPLEMENTATION AND ADHERENCE

What were your experiences of delivering the classroom component of KAT?

- Confidence? Understanding for programme aims?

To what extent did you use the manual?

How useful do you think it is as a guide? (I.e. For explaining the programme aims? activity suggestions? curriculum link suggestions? resources?)

Were there any activities in the manual that you found harder/easier to stick to than others? And why?

What were the main reasons for doing activities other than those suggested in the manual?

Did you integrate KAT into the school curriculum? How? (i.e. what subjects? times?)

Were there any barriers/facilitators to integrating KAT? (i.e. time of year?)

How did you feel about having an education consultant to provide training and support for delivering KAT? How sufficient was this training?

If homework given –what was the reason for given homework or classroom work to the children to take home? How important was it for you to give them homework and why?

INTERACTIVE ACTIVITIES

Can you tell me a bit about the group activities you gave your class?

- How did you encourage class/group discussion?

- Did you adapt them from the programme manual? If so, how? Why?
- What were the underlying aims of these activities?
- What did you think the children learnt from the activities? (i.e. about alcohol? Communication skills?)

How much time did you spend preparing for the class activities?

Did you have enough time to complete the activities with your class? Enough resources? If not, why?

CHILDREN'S ENGAGEMENT – less focus here

How did you think the children responded to the activities they were given in class?

What did you think about the suitability of the activities for your class?

- Their ability level?
- Behaviour?

Did the activities appear to develop communication skills amongst pupils?

Did boys and girls level of engagement differ? Participation? Behaviour?

FUN-EVENING

EXPERIENCES OF DELIVERY – IMPLEMENTATION AND ADHERENCE

What did you think of the fun-evening?

Did it go as expected?

What did you think of the programme manual's suggestions for the fun-evening?

- To be interactive/non-lecturing?
- To encourage families to work together?
- Pupil presentations?
- The quiz/treasure hunt?
- Agree or disagree activity?
- Smoothe bike?

Reasons for adhering or not adhering to suggestions?

What would you change, do differently? Keep same?

What activities do you think encouraged the most conversation amongst families?

PARTICIPANT ENGAGEMENT

How did you think the children responded to the evening?

- The activities?
- showing their class work?
- smoothies bike?
- What did you think the children learnt from the evening?

How do you think the parents responded to the evening?

- What do you think they thought of the activities?
- Seeing what the children had been doing in class?
- Their children's knowledge of alcohol issues?
- The smoothies bike?

What did you think the parents learnt from the evening?

How has KAT compared with other interventions you have run at your school which try to engage parents?

ACCEPTABILITY (don't spend too much time on this)

What do you think about children being taught about alcohol misuse in school?

How useful do you think KAT is as an alcohol misuse prevention programme for young people?

Did you think the school was a suitable setting for KAT?

- Do you think that KAT was a suitable programme for year 5 & 6 primary school children?
- Do you think this programme should be run in other schools?

FINAL QUESTIONS

Would you want to deliver the classroom component of KAT again in the future?

What would you do differently if you could do it again?

What has been the most important issue that we have talked about?

Is there anything else that we haven't talked about?

Appendix 9 Letter to schools, March 2012

Director Cyfarwyddwr Professor Yr Athro Laurence Moore



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23rd March 2012

Invitation to participate in research project on the Kids, Adults Together Programme

Dear

I am writing to invite «School_Name» to participate in a major new research project which is evaluating the Kids, Adult Together Programme (KAT).

KAT is a universal alcohol misuse prevention programme for pupils in Years 5/6 and their families. It aims to increase **pupils' awareness of the key health and social issues around alcohol, and to promote positive communication between pupils and their parents**. KAT has been designed to help schools deliver key elements of the **PSE curriculum**, and other subject areas, such as Maths, Science and English. It can support schools to address their goals in relation to:

- Welsh Government guidance on substance misuse education;

- The Welsh Network of Healthy School Schemes National Quality Award;
- Programmes such as Investors in Families that value and support the role of parents; and
- achieving outcomes and objectives of Newport's Community Safety, Health, Social Care and Well-being, and Children and Young People's Partnership Strategy.

KAT comprises **two main components**:

- a series of interactive **classroom activities** (delivered by class teachers) guided by a teachers' pack and resources. A twilight inset session for teaching staff involved in KAT is offered before the programme starts; and
- the classroom work culminates in a **family fun evening** to which parents (and other family members) are invited. This includes opportunities for pupils to share their work and learning with parents, and activities for families to work on together (such as quizzes, treasure hunts, etc).

KAT has now been piloted in three schools, has been well evaluated, and has succeeded in engaging large numbers of parents who have attended family fun evenings. Cardiff University has recently been awarded funding to undertake a larger evaluation of KAT which will determine whether or not to further develop and evaluate KAT. We are working with a number of agencies on the project, including Gwent Police, and Matthew Green from Newport Healthy Schools Scheme.

This study is taking place in the city of Newport. Seven schools are currently participating in the study, and **we are now looking for an eighth school to participate in the research**, and deliver the KAT programme in the summer term.

Schools which participate in the research will be asked to:

- assist the research team in **promoting the study to pupils and parents**;
- allow the research team to distribute **questionnaire surveys to pupils** to complete in class time on two occasions and invite some pupils to take part in a discussion group on their involvement in KAT;
- **deliver the KAT programme during the summer term to Year 5 pupils**. KAT classroom activities amount to about 5 days teaching, but can be spread over a number of weeks; and
- **Organise and facilitate the family fun evening** (with support from the research team).

If you would be interested in participating in the study, please could you contact me (by phone, email or letter) as soon as possible? I can arrange to visit your school

and provide you with more information about the research study and the KAT programme.

I look forward to hearing from you.

Yours Sincerely

Dr Jeremy Segrott

Appendix 10 Demographic data from parents (N = 27) who completed the telephone questionnaire

Characteristics	Control		Intervention		Overall	
	n	Mean (SD) or %	n	Mean (SD) or %	n	Mean (SD) or %
Sex						
Male	1	9.1%	3	18.8%	4	14.8%
Female	10	90.9%	13	81.3%	23	85.2%
Missing	0	0.0%	0	0.0%	0	0.0%
Year of birth	10	38.6 (5.8)	16	44.3 (7.6)	26	42.1 (7.4)
Place of birth						
Abergavenny	0		1		1	
Bristol	1		0		1	
Caerphilly	1		0		1	
Cardiff	0		1		1	
Essex	0		3		2	
Margate, Kent	0		1		1	
Newport	7		5		12	
North Wales	0		1		1	
Pentaeg	1		0		1	
Pontypool	0		1		1	
Reading	1		1		1	
Somalia	1		0		1	
West Africa	0		1		1	
Missing	0		1		1	
Education						
A-level	1		0		1	
Degree level	1		3		4	
GCSE	1		3		4	
Higher education	1		1		2	
No formal qualification	0		1		1	
O-level	3		6		9	
ONC	3		1		4	
Postgraduate degree	1		1		2	

Characteristics	Control		Intervention		Overall	
	<i>n</i>	Mean (SD) or %	<i>n</i>	Mean (SD) or %	<i>n</i>	Mean (SD) or %
Marriage status						
Civil partnership	0		2		0	
Divorced	2		2		4	
Married and living with husband/wife	6		10		16	
Single, never married, in relationship	1		0		1	
Single, never married, not in relationship	2		2		4	
Ethnicity						
African	0		1		1	
White and black African	1		0		1	
White British	10		15		25	
Employment						
In full-time education	2		0		2	
In full-time paid work	4		3		7	
In part-time paid work	4		6		10	
Out of labour force	0		2		2	
Unemployed	1		3		4	
Missing	0		2		2	

A-level, Advanced level; GCSE, General Certificate of Secondary Education; O-level, Ordinary level; ONC, Ordinary National Certificate.

A decorative graphic consisting of numerous thin, parallel green lines that curve from the left side of the page towards the right, creating a sense of movement and depth.

**EME
HS&DR
HTA
PGfAR
PHR**

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This report presents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health

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