Preventing alcohol misuse in young people: An exploratory trial of the Kids, Adults Together (KAT) Programme

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1 Trial summary

The proposed study will develop and evaluate a school-based intervention – Kids, Adults Together (KAT) - which draws on the Social Development Model and seeks to prevent alcohol misuse by strengthening pro-social communication in families. The key aim of the proposed study is to determine the value and feasibility of conducting an effectiveness trial of the Kids, Adults Together Programme. The study will (i) refine the theoretical model and outcome pathways of the intervention; (ii) assess the feasibility and acceptability of the intervention; (iii) establish intervention participation rates and reach, including equality of engagement across socio-economic groups and localities; (iv) assess trial recruitment and retention rates; (v) identify potential effect sizes that are likely to be detected as part of an effectiveness trial and an appropriate sample size; (vi) identify appropriate outcome measures and data collection methods for an effectiveness trial; and (vii) pilot methods for assessing cost effectiveness in any effectiveness trial. The study will provide a comprehensive description of the structures and resources required for successful implementation of the intervention in an effectiveness trial, and establish policy and practice partnerships to facilitate this. Full resources for a process evaluation of the programme have already been secured through an ESRC studentship, which will be fully integrated into the exploratory trial.

The key test of KAT's effectiveness which will be measured by a future effectiveness trial would be long term impact (2 years) on alcohol related behaviours, particularly age of initiation, and frequency of harmful drinking. Pro-social communication and bonding would be the planned secondary outcomes as part of an effectiveness trial, measured at 6 months. To collect 2-year follow-up data from pupils or parents in an exploratory trial of this nature would lead to unnecessary expense and delay. Thus, the exploratory trial will assess the potential effect sizes in relation to short term changes in pro-social communication, which form a key protective process in the causal mechanisms forming the theoretical basis for KAT. It will also test the feasibility and acceptability of collecting data from primary school pupils on drinking behaviours so that potential response rates can be determined, optimal data collection approaches identified for an effectiveness trial, and the costs of these data collection methods assessed. Data from other sources (including a trial of the Strengthening Families Programme) will be used to estimate prevalence and intra-cluster correlation of alcohol outcomes at 2 years.

2 Introduction

2.1 Background

Misuse of alcohol by young people has been identified as a major public health issue in the UK [1, 2]. Attention has focused both on the number of children who initiate alcohol consumption at a young age, and high levels of regular and harmful alcohol use. For instance, English data from the Health Behaviours in school-aged Children (HBSC) survey indicates that 17% of girls and 20% of boys aged 13 drink weekly. The proportion of 15 year olds reporting having first been drunk before the age of 13 in Wales was 21% (girls) and 25% (boys). In terms of 13 year olds who had been drunk at least twice, Wales had the highest levels among all countries included in the survey (26/27%) [3]. The 2007 ESPAD study of 15 and 16 year olds found that 70% of UK respondents had used alcohol within the last 30 days and 30% had been drunk [4]. Alcohol misuse in young people has a range of health and social impacts, including disorderly and violent behaviour, risky sexual behaviour [5], accidental injury, and poor school attendance and achievement [6, 7]. Long-term consequences of early alcohol consumption initiation have also been identified, including increased risk of alcohol-related problems in later life [8-11].

Schools have been identified as an important setting for delivering interventions designed to prevent young people from misusing alcohol, both because of their expanding function as a health promoting institution, and their reach in relation to the target population [12, 13].

However, there is little evidence in the UK that school programmes are effective in changing behaviour when they rely solely upon classroom-based learning [14]. Previous research has identified characteristics of school-based programmes which may increase their effectiveness, though this is generally an under-researched area. These include a focus on harm reduction rather than abstinence; interactive activities and delivery; targeting children at primary school, when they are less likely to have experimented with alcohol or other substances; and involving parents as well as children [15-19].

Engagement of parents in prevention programmes has been identified as important because dimensions of family functioning such as parenting operate as key protective and risk factors for later alcohol misuse by young people [16, 20, 21]. The family environment plays an important role in shaping young people's attitudes and behaviour towards alcohol, including the timing of young people's first alcohol use [22]. Parental norms and examples may encourage children's early alcohol use through providing models of alcohol consumption [23] or easy access to alcoholic drinks. Parental rules relating to alcohol are an important factor, but broader forms of parental monitoring, and the quality of relationships within families also figure as important protective factors.

Whilst there is clear evidence of the importance of family-based protective factors for alcohol misuse and the need to engage parents in prevention interventions, current knowledge about the best mechanisms for engaging parents in school-based interventions, and differences in reach and acceptability between different socio-economic groups, is limited. Many interventions have experienced significant challenges in recruiting parents, with typically low levels of engagement [11, 16, 24-26], even when programmes have been modified with the aim of increasing levels of parental involvement. Factors which affect participation in prevention programmes include practical barriers such as programme timing and travel arrangements [27, 28], programme length and location [29], parents' beliefs about the susceptibility of their children to problematic behaviours [29], and sociodemographic characteristics such as educational background [30, 31]. Whilst 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 [32, 33].

A theoretical model of risk and protective factors which has formed the basis for a number of effective interventions is the Social Development Model (SDM). The model provides an explanatory framework for the development of anti-social behaviour (including alcohol misuse) in young people. It hypothesises that social behaviour is learned through interactions with others (including parents), resulting in the formation of an attachment which, if strong, can have a lasting effect on behaviour through supporting acquisition of skills and influencing norms and values [34]. Attachment to others who offer opportunities for and reward pro-social behaviour is seen as a protective factor against antisocial behaviour [35-37]. The Social Development Model has been shown to predict alcohol misuse in young people [38], and interventions such as the Seattle Social Development Project in the United States and Preparing for Drug Free Years, which operationalise the model, have achieved reductions in alcohol misuse by young people [39, 40].

2.2 Rationale for current study/trial

The trial will address two key research areas which have been identified as requiring further investigation – the characteristics of effective school-based prevention interventions, and the structures and processes required to engage parents in such interventions. The KAT programme aims to prevent alcohol misuse by young people through integrating specially designed classroom activities with a family education evening and a DVD to promote pro-social communication. Existing evaluations of the Social Development Model [39, 40] have mainly been conducted in the United States, and this study will make an important contribution to existing knowledge about the transferability of the model to a UK context.

KAT 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 a generic programme about alcohol misuse). Universal delivery is designed to reach families at higher risk of alcohol misuse, whilst avoiding problems around stigmatisation. KAT is of much shorter duration and intensity than other interventions which have used the Social Development Model and this may also impact on take-up rates by schools and parents. The programme incorporates three crucial aspects of the causal pathways to pro-social behaviour contained within the Social Development Model – the creation of opportunities for pro-social interaction between and within families (during the family education evening, and in ongoing discussions afterwards which the DVD is designed to facilitate); strengthening the necessary skills which parents and young people need to communicate about alcohol-related issues; and encouraging parents to reward and reinforce pro-social behaviour and attitudes in relation to alcohol [41].

A recently completed formative evaluation of KAT demonstrated high levels of programme reach and acceptability, and impacts on pro-social communication in families [42]. Based on these promising findings the programme will be developed and implemented in a second group of schools during 2011/12. This presents an important opportunity to conduct an exploratory trial which can inform future development of the programme, and assess the value of and identify key design parameters for a potential large-scale cluster randomised trial of KAT. Appendix 1 shows the logic model for the study; methods and outcomes are described in detail below.

3 Study/trial objectives

3.1 Primary objective

To determine the value and feasibility of conducting an effectiveness trial of the Kids, Adults Together Programme.

3.2 Secondary objectives

- refine the theoretical model of the intervention;
- assess the feasibility and acceptability of the intervention;
- identify optimal delivery structures and systems for the KAT programme post-trial;
- establish intervention participation rates and reach, including equality of engagement across socio-economic groups and localities;
- assess trial recruitment and retention rates;
- identify potential effect sizes that are likely to be detected as part of an effectiveness trial and an appropriate sample size;
- determine the feasibility and cost of the proposed methods for measurement of the primary and secondary outcomes; and
- identify the costs of delivering KAT, and pilot methods for assessing cost effectiveness as part of a future effectiveness trial.

4 Study/trial design

The proposed project is an exploratory trial, with schools as the unit of randomisation, with an embedded process evaluation. Eight schools will participate in the trial. Four schools will be randomised to receive the KAT programme, in addition to any existing alcohol-related lessons/school activities. Four schools will be randomised to the control group, and will not receive KAT, but will continue with any existing alcohol-related lessons/school activities.

The total sample size of 8 schools is anticipated to equate to approximately 640 families, which with an estimated consent rate of 50% at baseline will achieve a sample of 320 families; 160 per group.

As this is an exploratory trial, it is not powered to detect statistically significant intervention effects, unless these estimated effects are extremely large. The purpose of this study is to assess the feasibility and acceptability of the intervention and of trial methods, and to provide estimates of key parameters such as potential effect sizes, recruitment and retention rates of the trial and participation rates of the programme, so that the value and optimal design of a full-scale trial can be determined.

The study duration is 14 months. Each pupil who participates will be in the study for approximately 4 months and will be asked to complete two questionnaires – one at baseline and another 4 months later. Parents/carers who take part in the study will participate in one telephone interview approximately 4 months post intervention, and some may also participate in an interview as part of the study's process evaluation.

4.1 Intervention period

The KAT classroom preparation for children will take place over at least one week and may take longer according to e.g. the timing of the education evening and the needs of the class. The KAT fun event for families lasts about one hour and children are given a "goody bag" containing a DVD and other materials which may be used by them and their families over an indefinite period.

4.2 Study outcomes

In this exploratory study, key outcomes are the quality of programme implementation; and recruitment and retention of research participants. The current study will also pilot the feasibility and acceptability to participants of providing demographic data and answering questions measuring proposed primary and secondary outcomes of any future effectiveness trial.

In a potential effectiveness trial the primary outcome would be young people's age of first drinking alcohol (2 years past baseline). At this stage we will pilot the feasibility and acceptability of collecting these data from pupils at 4 month follow-up, along with other key measures of alcohol use, such as consumption frequency and levels of harmful drinking and drunkenness. An existing trial (of the Strengthening Families Programme) is collecting data on drinking behaviour from 11-15 year olds (at 24 month follow-up), which will inform the appropriateness of outcome measures as part of an effectiveness trial of KAT, and will also be used to identify rates and prevalence of key drinking behaviours in KAT's target population, and the potential effect sizes which KAT may be expected to produce. Use will also be made of the Health Behaviour in School Aged Children (HBSC) survey data for Wales [3], which will allow estimation of alcohol outcomes and their intra-cluster correlation at school level.

The secondary outcome of a future effectiveness trial would be 6-month impacts of KAT on pro-social communication within families. Promoting pro-social communication is a key short-term programme aim, which in line with the Social Development Model is hypothesized to lead to the prevention of alcohol misuse. In this exploratory trial we will collect data from parents (4 month follow-up) on family communication, to provide a broad estimate of potential effect sizes, and the feasibility and acceptability of doing so. Measures of parents' drinking will be piloted. Data will also be collected on parents' educational qualifications and socio-economic status so that intervention take-up can be assessed. Appendix 2 shows the CONSORT diagram for the study.

In summary, key study outcomes will be:

- Quality of programme implementation;
- Participant recruitment rate;
- Participant retention rate; and
- Feasibility and acceptability to participants of measuring:

i. Age of alcohol consumption initiation (pupils);
ii. Past month alcohol consumption frequency (pupils);
iii. Past month drunkenness (pupils);
iv. Pro-social communication in families (pupils and parents);
v. Parental drinking behaviours (parents); and
vi. Socio-economic status and educational background (pupils and parents)

5 Centre/school and/or participant selection

5.1 Inclusion criteria

Specific classes will participate in the trial in each school, normally from Years 5/6. All pupils in these classes will be eligible to participate in the trial. For children in intervention schools, participation in the KAT programme is not conditional on participation in the research. All pupils in the relevant classes will undertake KAT programme activities as part of their normal classroom work and their parents will be invited to attend the KAT fun events. We will seek to recruit all parents and children in classes which receive KAT regardless of the extent of individuals' participation in the programme.

5.2 Exclusion criteria

Pupils who do not give assent will not participate in the trial. Where parents/carers refuse consent for pupils' participation these pupils will not participate in the trial. Pupils who are absent at baseline and follow-up data collections will be excluded. Parents who are unable to communicate in English will be excluded.

6 Recruitment

6.1 Recruitment process

All schools in Newport county (South Wales) will be invited to participate in the trial by means of a standardised letter. This letter will be followed up by phone calls to each school until eight schools have been identified as being interested in participating. The Principal Investigator (JS) will visit each of these schools to explain the study and what schools' involvement will comprise, and to seek formal agreement from head teachers. The research team will discuss with each school which year groups and classes will participate in the study.

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In each school a member of the research team will speak to class groups who have been selected to take part in the study. Pupils will be provided with an oral description of the study and an information sheet, and have the chance to ask questions. Parents/carers will be sent two letters – a detailed information sheet, and a brief follow-up letter. These letters ask parents/carers to: return a reply slip to the research team with their contact details if they wish to participate in the study; and to contact the school if they do not wish their child to participate in the trial. Approximately one week later a member of the research team will visit the class, and ask pupils who are willing to participate to complete a written questionnaire. The front page of the questionnaire comprises an assent form for pupils to complete. In intervention schools we will seek to recruit all parents and children from the school classes that receive KAT, regardless of whether parents and children attend the family education evening.

6.2 Registration

Participants' personal details will be collected on paper and stored electronically. This information will be stored separately from questionnaire data.

6.3 Non-registration

Personal details of participants not selected for recruitment, or who decline to consent, will not be retained.

6.4 Withdrawal and loss to follow-up

School and individual participation is entirely voluntary and each may withdraw at any time without giving a reason, by informing the Principal Investigator or study manager that they do not wish to continue. Pupils who are absent for data collection will not be followed up.

An important aspect of the study is to assess retention rates at 4 months post intervention of pupils who complete baseline questionnaires and parents who express an interest in taking part in interviews.

7 Study/trial intervention

Control schools will continue with their normal activities, including any classroom work on alcohol or other substances. Process evaluation interviews with staff in control schools will identify normal practice in relation to both substance education and structures for involving parents in school life, and will examine any changes between baseline and follow up measures. The intervention will be delivered by school staff with the support of an educational consultant. The KAT programme will be of an estimated two weeks' intensity and includes three main components: (i) classroom work (delivered by teachers) on the effects of alcohol consumption, and preparation for a family education evening; (ii) the family education evening, delivered in school, and involving children and parents in activities addressing key health messages around alcohol; and (iii) a 'goody' bag to take home containing fun items and educational leaflets, and an educational DVD for families to watch together.

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8 Measures/assessment instruments

The primary research instruments are pupil questionnaires (self complete on paper in class) and telephone interviews with parents/carers.

Other research instruments used for the process evaluation include:

- Individual interviews;
- Focus groups; and
- Observation.

Questionnaires including measures of alcohol use will be completed by pupils under supervision in the classroom at baseline and approximately four months later.

Demographic data

At baseline, data will be collected from pupils on socio-economic status using the four-item Family Affluence Scale (FAS II) [43-45]. The FAS is used in the World Health Organization Health Behaviour of School-aged Children (HBSC) survey and in a sample of 8424 Irish schoolchildren was found to have a Cronbach's alpha of 0.401; to be significantly associated with parents' occupations; and to elicit a higher response rate than asking children to state their parents' occupations [46]. Another nine questions from the HBSC are used to collect baseline data on pupils' gender, age and ethnic background.

At four months post intervention the above questions will be asked of pupils who were absent from the baseline data collection as part of the follow-up. Data will also be collected from parents on household composition, educational qualifications and socio-economic status (using the National Statistics Social-economic Classification [NS-SEC]) [47] so that a profile of intervention take-up can be estimated.

Use of alcohol and tobacco

At baseline, a question asking whether pupils have ever had a proper drink is included. This has been used with children taking part in the randomised controlled trial of the Strengthening

Families Programme and is based on an ONS question. A second question from the HBSC survey is also used to ask whether children have ever been drunk. A question on smoking, drinking and drunkenness in the previous thirty days has been included to assess whether KAT has any impact on non-alcohol-related behaviour, and to include a measure of use during the previous thirty days in addition to the questions about "ever" use.

At four months post intervention, the questions used at baseline are repeated to measure pupils' alcohol use. The Daily Drinking Questionnaire is used to measure parents' alcohol use [48]. Two additional questions in the parents' questionnaire ask about any change in alcohol-related behaviour during the previous six months. These have been included following qualitative evidence from the pilot study of parental behaviour change following participation in KAT.

Family life and communication

At baseline, six questions about Family and Home Life from the Kidscreen 52 questionnaire are used:

> "This dimension examines the relationship with the parents and the atmosphere in the child's/adolescent's home. It explores the quality of the interaction between the child/adolescent and parent or carer, and the child's/adolescent's feelings towards parents/carers. Particular importance is attached to whether the child/adolescent feels loved and supported by the family, whether the atmosphere at home is comfortable or not and also if the child/adolescent feels treated fairly." [49]

Development and piloting studies demonstrated satisfactory reliability and validity for this dimension independently as well as for the questionnaire as a whole [50]. Ten questions are included to measure targeted parent-child communication about alcohol such as lecturing about alcohol use or giving advice on how to deal with offers of alcoholic drinks (Targeted Parent-Child Communication about Alcohol Scale [TPCCA]) [51]. The Family Activity scale (8 questions on what families do together) from the 2009 Health Behaviour in School-aged Children study questionnaire Welsh Assembly Government (Cardiff): Health Behaviour in School-aged Children (HBSC) Study in Wales (p.45) measures the frequencies of activities involving at least one parent and one child in a family. In terms of the Social Development Model, such activities may constitute opportunities for prosocial involvement. This scale is also used in the Project SFP Cymru trial of the Strengthening Families Programme 10-14 (SFP10-14).

At four months post intervention, we will use the Family Communication Scale [52] to measure the quality of communication between parents and children. The authors of the Family Communication Scale also devised the earlier Parent Adolescent Communication Scale (PACS) which measured both openness and problems in parent-adolescent communication [53]. A review of studies which used the PACS revealed that the subscale measuring openness was more predictive and this measure was used to develop the Family Communication Scale. The internal consistency reliability of the scale is .90 based on a US sample of 2,465 individuals and test re-test of .86. For this study, the advantages of using the Family Communication Scale rather than PACS are that it is only half as long (10 items instead of 20) and the same questions can be asked of parents and children. The authors also claim that it is suitable for use with a variety of family structures at different stages of family life. The Family Communication Scale will be used in both the questionnaire for parents and (with slight adaptation) the pupils' questionnaire.

A further measure of family communication specifically in relation to alcohol [54] will be used with both parents and pupils in preference to the Targeted Alcohol Communication Scale which presented some difficulty for pupils at baseline. Ennett et al. have validated parent and pupil versions of the scale [54].

The Family Activity Scale will be included in questionnaires for both parents and pupils and in intervention schools they will also be asked if they went to the KAT fun event and did the classwork (the latter question for pupils only).

9 Trial procedures

9.1 Piloting and testing

Recruitment, data collection and randomisation processes will be tested before use. Parents and young people from two schools (one in Newport, one in Penarth) will be asked to assist with piloting key research materials such as questionnaires. For 4-month follow-up questionnaires with pupils, this will include some method to check what pupils understand by the questions and how to answer them.

We will offer all families who provide data at follow-up a £15 gift voucher. Parents who are invited to take part in face to face interviews will have their travel expenses paid if necessary.

9.2 Data collection/assessment

In classes participating in the trial, pupils present on the day and consenting will be asked to complete a written questionnaire during classroom time, supervised by a member of the research team. Assistance will be provided by researchers or school staff for pupils with low literacy levels or for whom English is not their first language. The number of incomplete questionnaires will be recorded (defined as <50% of questions answered). Pupils will be asked to complete follow-up questionnaires at approximately 4 months after the intervention.

Telephone interviews will be conducted with parents at approximately 4 months post intervention by trained telephone interviewers based at Cardiff University.

The study's process evaluation will include observation of a selection of KAT lessons and the KAT family education evening. A sample of parents and young people from the intervention group schools will be invited to participate in discussion groups (pupils) and face to face interviews (parents/carers). School staff in intervention and control group schools will also be invited to participate in face to face interviews. Classroom preparation for the KAT education evening and the education evening itself will be observed in order to gain insight into the delivery of KAT and pupil and parent engagement in the programme. Notes will be taken during observation periods and written up as soon as possible. The observation will be used to inform interview questions and analyses. Teachers who delivered KAT will be invited to participate in semi-structured interviews to explore and understand their experiences of delivering KAT, school context influences, acceptability and implementation. Pupils will be asked to participate in focus groups to explore experiences and communication outcomes from participating in the KAT activities. Parents of the pupils will be invited to participate in interviews to explore family communication and their experiences of the education evening. All interviews and focus groups will be semi-structured with key issues to be addressed prompted through the use of topic guides (i.e. key topics or questions to be covered).

10 Statistical considerations

10.1 Randomisation

10.2 Schools will be randomly assigned to intervention and control in a 1:1 ratio. The schools will be stratified by size and free school meal entitlement (FSM) and these variables will be used to balance the randomisation. Optimal allocation will be used to carry out the randomisation. Here a balance algorithm is used when pre-defined sequence generation is required or when all units are randomised jointly. Data on school size and free school meal entitlement will be collected at recruitment and used to optimally balance the randomisation.

The total sample size of 8 schools is anticipated to equate to approximately 640 families, which with an estimated consent rate of 50% at baseline will achieve a sample of 320 families; 160 per group. As this is an exploratory trial, it is not powered to detect statistically significant intervention effects, unless these estimated effects are extremely large. The purpose of this exploratory trial is to assess the feasibility and acceptability of the intervention and of trial methods, and to provide estimates of key parameters such as potential effect sizes, recruitment and retention rates of the trial and participation rates of the programme, so that the value and optimal design of an effectiveness trial can be determined.

11 Analysis

11.1 Main analysis

Primary analyses will be on an intention to treat (ITT) basis using all randomised participants in the groups they were randomised to regardless of the intervention received.

Participant flow and recruitment

A major focus of the quantitative data analysis in this exploratory trial will be the ascertainment of consent, response rates, and retention rates for pupils, parents and schools. Summary statistics on consent, withdrawal and dropout will be collated for both trial arms and form the CONSORT [55] flow diagram for clinical trial reporting. The flow of clusters (schools) and individual pupils and their parents through each stage is to be illustrated in a diagram. Specifically, for each arm, the numbers of clusters and participants randomly assigned, receiving intended intervention, completing the study protocol, and analysed for the outcomes.

Baseline data

Appropriate descriptive summaries of baseline demographic and questionnaire data for pupils and parents from the two study arms will be tabulated. Descriptive summaries will also be produced for baseline data at cluster (school and household) level where appropriate.

Pupil outcomes (4 month follow-up)

Questionnaire data from the pupils will be analysed using a two-level generalised linear or logistic model (dependent on outcome), with responses from pupils nested within schools fitted using models adjusting for baseline data. Covariates included in the model will include those that were balanced on at randomisation (school size and FSM entitlement). As well as any differences between trial arms, estimates of intra-cluster correlations (ICCs) and broad indicators of effect size will be reported. This will help determine sample size calculations for a future definitive trial. Whilst we acknowledge that a household level cluster is present (siblings within a school), the number of these per school is likely to be very small and will not be incorporated.

Parent outcomes (4 month follow-up)

Data from parents will also provide some indication of variations between study schools. Data will be collected from both parents in two parent households where possible. Analyses will take account of this, including household as a random effect in any analyses of effect size using a three-level generalised model (parent, household, school).

Analyses of potential effect sizes on outcomes will include analysis of sensitivity to different assumptions about non-response.

Implementation feasibility

The feasibility of delivering KAT as part of an effectiveness trial will be addressed by the embedded process evaluation. This will further develop the theoretical model of how KAT works and examine implementation fidelity, programme reach and acceptability. Important functions of the process evaluation will be to examine school context, including provision of

other alcohol-focused education in both intervention and control schools, and to examine programme implementation, reach and acceptability of the programme in intervention schools. Interviews with programme deliverers, head teachers, parents (n= 5-10 per school) and focus groups with pupils (n= 1-2 groups per school) will identify and map the intervention as implemented and explore issues of acceptability. The interviews will draw on the framework for process evaluations of complex interventions outlined by Steckler and Linnan [56] that has been used in previous trials [57]. Interviews and focus groups will be conducted shortly after intervention delivery in schools. Interviews, focus groups and observation notes will be recorded and transcribed (with participants' permission) and imported into the data analysis package NVivo and subjected to thematic analysis. The data will be coded and assigned to themes which will be used to refine the initial coding framework of KAT that is developed from process evaluation literature, previous empirical research, field notes and interview questions. Feasibility of research methods and of school organisation will be assessed by observation in intervention schools using structured schedules, and through interviews with school staff and other delivery staff.

11.2 Sub-group & interim analysis

No formal subgroup analyses are planned. However, exploratory analysis of the impact of gender, social class, and ethnicity (if numbers permit) on the effect of the intervention could be carried out.

11.3 Cost effectiveness

To enable an economic evaluation to be conducted as part of a future effectiveness trial we will document in as much detail as possible the key cost and outcomes domains. We will seek to employ a partial-societal perspective and identify and measure 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 can be translated into financial costs will be considered based on the availability and suitability of appropriate unit costs. The primary and secondary outcomes will be 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. The feasibility of data collection instruments as part of an effectiveness trial will also form an important part of this feasibility study.

11.4 Data storage and retention

All work will be carried out in accordance with the requirements of the Data Protection Act 1998. In line with the Medical Research Council's guidance on Personal Information in Medical Research, we intend to retain all research data for 20 years after the end of the study. This is to allow further research to take place, and to allow any queries or concerns about the conduct of the study to be addressed. In order to maintain the accessibility of the data the files will be refreshed annually and upgraded if required. All electronic project data will be stored confidentially on password protected servers maintained on the Cardiff University Network

12 Study/trial closure

The end of the study/trial will be considered as the date on which the last participant has completed their follow-up assessment.

13 Regulatory issues

13.1 Ethical approval

Ethical approval for the study was given by the Cardiff School of Social Sciences Research Ethics Committee [SREC reference SREC/697] on 26 January 2011.

13.2 Consent

Each head teacher will be asked to sign a formal commitment for their school to take part in the study. The commitment will describe the roles and responsibilities of the school and the research team during the research period at the school. Individual teachers will be asked to give informed consent to take part in the research and will be assured that if they decide not to participate, their decision will be handled confidentially.

In each school a member of the research team will speak to class groups who have been selected to take part in the study. Pupils will be provided with an information sheet and an oral description of the study, and have the chance to ask questions. Parents/carers will be sent two letters – a detailed information sheet, and a brief follow-up letter. These letters ask parents/carers to: return a reply slip to the research team with their contact details if they wish to participate in the study; and to contact the school if they do not wish their child to participate in the trial. Approximately one week later a member of the research team will visit the class, and ask pupils who are willing to participate to complete a written questionnaire. The front page of the questionnaire comprises an assent form for pupils to complete.

Letters will be sent to parents/carers before telephone interviews seeking their written consent. For face-to-face interviews, written consent from parents/carers and school staff will be obtained at the time of the interview.

13.3 Confidentiality

The Chief Investigator and the research team will preserve the confidentiality of participants in accordance with the Data Protection Act 1998.

Data from questionnaires will be encrypted at the point of entry and stored in anonymised form, using participant identification numbers and a separate file containing the participant numbers and corresponding participant names will be held. Each participant will be allocated a numerical identifier. Index lists with study participant numbers and names will be held separately from the project data. Both files will be stored in secure password protected folders with restricted access.

The process evaluation will involve conducting interviews and focus groups. No individuals' names will be included in transcripts, but real names will be replaced with pseudonyms. A list of participant names and pseudonyms will be held in a separate location. Digital recordings of interviews/focus groups will be stored securely, and will be held separately from transcripts and information on participant identities. All focus-group participants will be asked to treat the discussion as strictly confidential. In reporting the results of the process evaluation, care will be taken to use quotations which do not reveal the identity of respondents.

All data, including audio recordings, will be encrypted whenever it is necessary; for example if data are transferred outside the secured server.

All data collected as part of the trial will be treated as confidential and will be viewed only by members of the trial team; anonymised data will be used wherever possible. The main circumstances under which the researchers would break confidentiality are where participants were at risk of serious harm. This would be most likely to occur as a result of a disclosure during a focus group, or if responses to questionnaires raised serious concerns regarding individuals' emotional wellbeing. All participants will be informed that if they disclose information about neglect, abuse, serious suicidal thoughts or self harm that we will pass this information on to an appropriate source; their consent for this will be sought prior to the collection of any data. The study will adhere to the Cardiff University policy on safeguarding children and vulnerable adults. All research participants will be informed of the circumstances under which confidentiality would have to be broken.

13.4 Indemnity

Cardiff University will provide indemnity and compensation in the event of a claim by, or on behalf of participants, for negligent harm as a result of the study design and/or in respect of the protocol authors/research team. Cardiff University does not provide compensation for non-negligent harm.

13.5 Study/trial sponsorship

Cardiff University will act as sponsor for the trial.

13.6 Funding

The trial is funded by the National Institute for Health Research Public Health Research Programme. The grant awarded is £193, 290.

14 Study/trial management

The study will have a full time trial manager, supported by the chief investigator (Dr Jeremy Segrott). They will meet weekly. The study will be managed by a Trial Management Group comprising the co-applicants on the original funding application, the process evaluation PhD student, and the DECIPHer Involving Young People Research Officer.

A stakeholders group for representatives of local delivery teams will be formed, including Gwent Police, the Welsh Government, schools, and the Healthy Schools team in Newport. This group will advise on the implementation and future development of the programme, and provide a way for key partners to be informed of developments with the trial.

15 Data monitoring & quality assurance

15.1 SSC (Study Steering Committee)

An independent Study Steering Committee will be formed, comprising:

- an independent chair;
- two other independent members;
- two member of the Study's Trial Management Group (including the PI); and
- a consumer representative (probably a head teacher from one of the study schools)

The study funder (NIHR) will be informed of all meetings and invited to attend.

15.2 DMC (Data Monitoring Committee)

A Data Monitoring Committee will not be created, and this decision is in line with guidance produced by the National Patient Safety Agency on DMCs (NPSA, 201). It is not necessary to establish a DMC because: a) the study is assessing intervention feasibility, not measuring its impact on health behaviours; b) because of this aim the trial protocol is unlikely to modified regardless of any interim data analysis; c) the risks associated with participation in the trial and the intervention are very low; and d) data are being collected over a short time period (4 months).

15 Publication policy

All publications and presentations relating to the study will be authorised by the Trial Management Group.

In line with the British Sociological Association's Authorship Guidelines [58], authorship of published trial reports and papers will be reserved for those who have made significant intellectual contribution to the research.

1) Everyone who is listed as an author should have made a substantial direct academic contribution (i.e. intellectual responsibility and substantive work) to at least two of the four main components of a typical scientific project or paper:
a) Conception or design.
b) Data collection and processing.
c) Analysis and interpretation of the data.
d) Writing substantial sections of the paper (e.g. synthesising findings in the literature review or the findings/results section).

2) Everyone who is listed as an author should have critically reviewed successive drafts of the paper and should approve the final version.

3) Everyone who is listed as author should be able to defend the paper as a whole (although not necessarily all the technical details).

All individuals who contribute to a report or paper without fulfilling the criteria for authorship will be named and their affiliation listed in an acknowledgement section, unless they explicitly request otherwise.

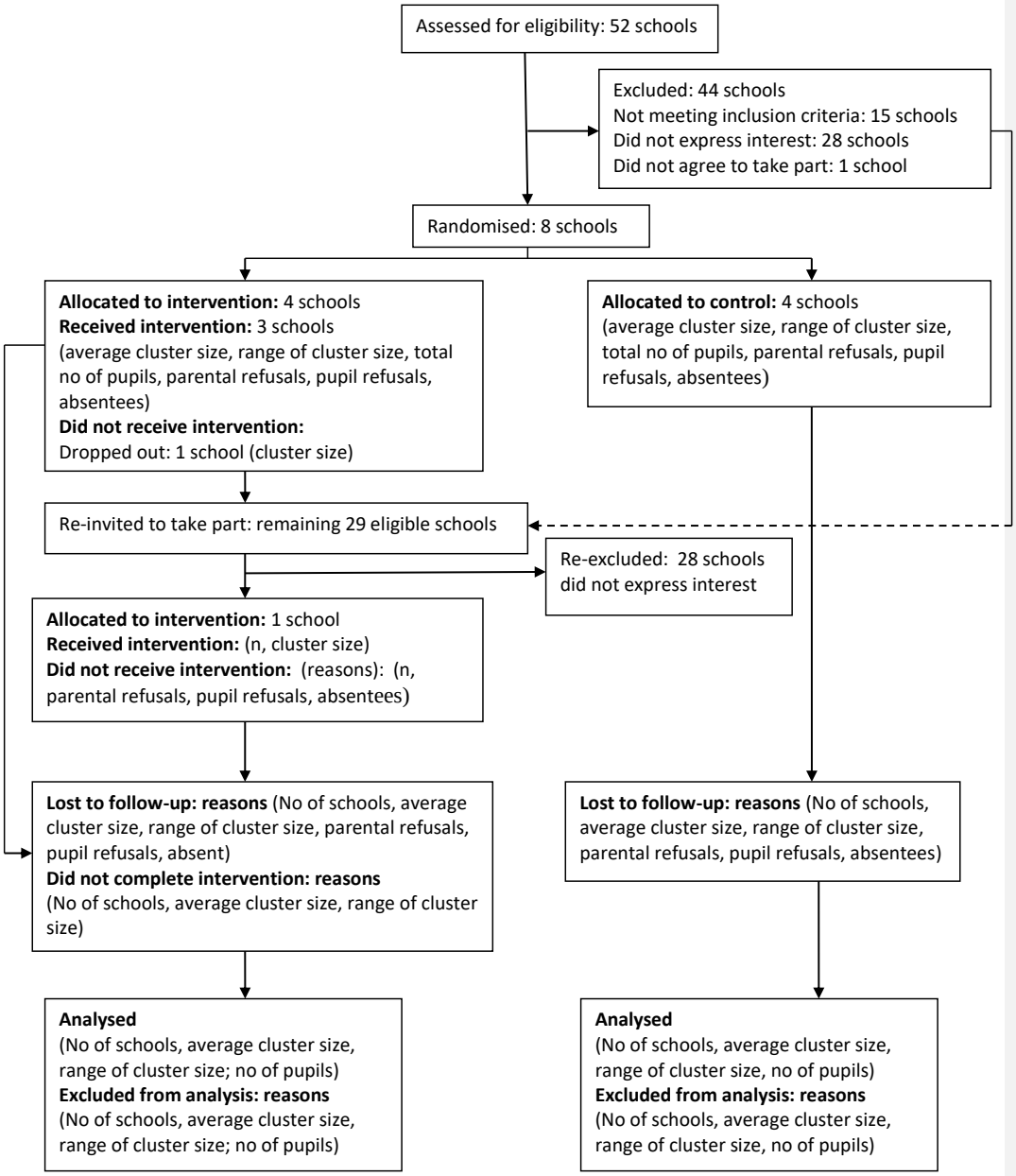
16 Milestones

Task/goal	***Date***
Recruitment of schools	Autumn 2011/January 2012
Baseline data collection (pupils only) via questionnaires	January 2012-March 2012
Finalise content of 4 month questionnaire (parents)	mid June 2012
Finalise content of 4 month questionnaire (pupils)	mid June 2012
Publish protocol	June/July 2012
4 month follow up data collection (pupils) via questionnaires	July-October 2012
4 month follow up data collection (parents) via telephone interviews	September/October 2012
Main analysis	October 2012-February 2013
Dissemination of results	March 2013-June 2013

Appendix 1: Logic model for KAT study

Inputs	**Outputs**		**Study outcomes**		
	Actions	Participants	Short-	Medium-	Long-
- Research staff & funding; - Education consultant; - KAT programme materials; - KAT logic model *. . .will enable us to . . . . .*	- Recruit & randomise schools; - Recruit parents & children; - Develop & pilot research tools; - Visit schools; - Write letters & information sheets for participants; - Observe KAT delivery; - Interview parents and school staff; - Conduct baseline & follow-up questionnaire surveys; - Hold focus groups with pupils; - Monitor costs; - Analyse data *. . . with . . .*	- 4 control schools - 4 intervention schools - Pupils & parents from each school *. . . in order to achieve . . .*	- Effective relationships with schools; - KAT class work; - KAT fun evenings *. . . which will enable us to . . .*	1. Estimate: (for KAT programme) - Quality of programme delivery - Reach, including equality of engagement across socio-economic groups and localities - Acceptability (for study) - Participant recruitment and retention rates (cluster and individual) - Feasibility and acceptability to participants of measuring: i. Age of alcohol consumption initiation (pupils) ii. Past month alcohol consumption frequency (pupils) iii. Past month drunkenness (pupils) iv. Pro-social communication in families (pupils and parents) v. Parental drinking behaviours (parents) vi. Socio-economic 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. 2. Pilot methods for assessing cost effectiveness as part of a future effectiveness trial *. . . and use these findings to . . .*	(for KAT programme) - Refine KAT logic model - Identify optimal delivery structures and systems (for study) - Determine whether to proceed with designing an effectiveness trial

Appendix 2: CONSORT diagram for KAT study



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