

Exploratory trial of the Kids Adults Together (KAT) Programme

Submission date 01/08/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/10/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 04/12/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Kids, Adults Together (KAT) is a school-based programme which seeks to prevent alcohol misuse by strengthening communication and improving relationships in families. The aim is determine the value and feasibility of conducting a full effectiveness trial of the Kids, Adults Together Programme. The studys findings will provide evidence to guide a decision about whether the programme should be tested further in a larger study, to find out if taking part in the KAT programme could reduce the number of young people harmed by alcohol misuse. This study will also provide evidence on best practice for any planned trial.

Who can participate?

Children aged 8-11, their parents, and school staff, from eight primary schools in a UK city.

What does the study involve?

Schools will be involved in the study over two school terms. Four schools will run the KAT programme in addition to their usual lessons and the other four schools will continue with their usual lessons. Which schools will run KAT will be decided by a randomisation process, which is like tossing a coin.

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 work covers the effects of alcohol consumption and preparation for a family fun event. The KAT fun event lasts about one hour and involves children and parents in activities addressing key health messages around alcohol. Children are given a goody bag to take home, containing a DVD for families to watch together and other materials which may be used over an indefinite period. Before the KAT programme begins, pupils in all schools will be asked to complete a questionnaire. About six months later, after the KAT programme has been run in four of the schools, the pupils in all eight schools will be asked to complete a second questionnaire and their parents will be invited to take part in interviews. Questions in the interviews and questionnaires will cover alcohol use; and family communication and activities. Researchers will also observe the classroom preparation and fun evenings and ask pupils, parents and school staff what it was like to be involved in KAT and what they think of it.

At the end of the study we will calculate what percentage of pupils, parents and schools consented to take part, and continued to take part, out of all those who were invited to get

involved in both the research and the KAT programme. We will use questionnaire data from pupils to estimate how many schools and pupils would need to take part in a larger study. The usefulness of methods (such as interviews and questionnaires) chosen to conduct the research will be assessed, alongside a calculation of costs of running KAT and an evaluation of methods for keeping accounts. The study will also report on the ways in which schools organised the programme and whether school staff, pupils and parents considered the KAT programme, and the research methods, to be satisfactory.

What are the possible benefits and risks of participating?

Parents, children and teachers will learn more about alcohol and become more aware of the personal and social effects of alcohol misuse. There will be no immediate benefit to research participants from schools which do not run the programme. But there should be future benefits to the general public because the results of the study are expected to influence decisions about the best use of research funding.

The main risk of taking part is that the KAT programme, and researchers questions about alcohol consumption, may raise participants concern about their own or others alcohol use. Researchers will be prepared to help participants to obtain appropriate support and if necessary to follow child protection procedures.

Where is the study run from?

School of Social Sciences at Cardiff University

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

Recruitment started in November 2011. Participants will be enrolled on the study for a period of six months. The study will be completed by 31 August 2013.

Who is funding the study?

National Institute for Health Research (NIHR)

Who is the main contact?

Dr. Jeremy Segrott

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Study website

<http://drjeremysegrott.weebly.com/kat-project.html>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

10/3002/03

Study information

Scientific Title

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

Acronym

KAT

Study objectives

Primary objectives:

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

Secondary objectives:

1. Refine the theoretical model of the intervention
2. Assess the feasibility and acceptability of the intervention
3. Identify the major barriers and facilitators to implementing the intervention
4. Identify optimal delivery structures and systems for the KAT programme post-trial
5. Establish intervention participation rates and reach, including equality of engagement across socio-economic groups and localities
6. Determine the most efficient ways of engaging parents, children and teachers in the focus groups, interviews and questionnaire surveys
7. Assess trial recruitment and retention rates
8. Identify potential effect sizes that are likely to be detected as part of an effectiveness trial and an appropriate sample size
9. Determine the feasibility, suitability and cost of the proposed methods for measurement of the primary and secondary outcomes
10. Determine the best research approaches and the most appropriate methods for conducting a process evaluation of KAT
11. Identify the costs of delivering KAT, and pilot methods for assessing cost effectiveness as part of a future effectiveness trial
12. Establish what structures, resources and partnerships are necessary for a definitive trial to take place

More details can be found at http://www.phr.nihr.ac.uk/funded_projects/10_3002_03.asp

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cardiff University School of Social Sciences Research Ethics Committee, 28 February 2011 ref: SREC/697

Study design

Phase 2 single-centre exploratory cluster randomised controlled trial with nested process evaluation.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

<http://drjeremysegrott.weebly.com/kat-project.html>

Health condition(s) or problem(s) studied

UK children start drinking at a young age and the amount they drink has increased. More youngsters in the UK misuse alcohol than in most other European countries. People who start drinking at a younger age are more likely to have problems with alcohol when they get older.

Interventions

The intervention is the Kids, Adults Together (KAT) Programme: primary school-based classwork and family activities designed to promote pro-social communication between parents and their children. KAT is a complex intervention with three components: (i) classroom work which addresses the effects of alcohol consumption and involves preparation for a family fun event; (ii) the family fun event, 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 after the fun event. The classroom work takes up to a week of classroom time but may be spaced over a longer period. The family fun evening lasts 1-2 hours and is a single event.

Schools in the control group will continue with any existing alcohol-related lessons/school activities. Schools in the intervention group are free to continue with such activities and we expect the study to ascertain how KAT may be integrated or cross-referenced with other school work.

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:

1. Individual interviews
2. Focus groups
3. Observation

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

The studys 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 focus 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 observations and written up as soon as possible. The observations 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 fFocus groups with pupils will to explore experiences and communication outcomes from participating in the KAT activities. Parents of the pupils will be invited to participate in interviews toInterviews with parents will 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. keys topics or questions to be covered).

Intervention Type

Other

Phase

Phase II

Primary outcome measure

In a potential effectiveness trial the primary outcome would be young people's age of first drinking alcohol (2 years past baseline). In this exploratory trial we will pilot the feasibility and acceptability of collecting these data from pupils at 6 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 10-14) 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 any eventual effectiveness trial of KAT, and will also be used to identify rates of prevalence of key drinking behaviours in KATs 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, which will allow estimation of alcohol outcomes and their intra-cluster correlation at school level (Currie et al., 2008).

In summary, key study outcomes will be:

1. Quality of programme implementation
2. Participant recruitment rates
3. Participant retention rates
4. Feasibility and acceptability to participants of measuring:

- 4.1. Age of alcohol consumption initiation (pupils)
- 4.2. Past month alcohol consumption frequency (pupils)
- 4.3. Past month drunkenness (pupils)
- 4.4. Pro-social communication in families (pupils and parents)
- 4.5. Parental drinking behaviours (parents)
- 4.6 Socio-economic status and educational background (pupils and parents)

Secondary outcome measures

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 (4-6 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 from parents on educational qualifications and socio-economic status so that intervention take-up can be assessed.

Overall study start date

01/02/2012

Completion date

31/10/2012

Eligibility

Key inclusion criteria

Schools:

- 1. Primary schools in Newport, Gwent, UK
- 2. English medium
- 3. Commitment from head teacher

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. In intervention schools all pupils in the relevant classes will undertake KAT programme activities as part of their normal classroom work. Pupils will participate in the KAT programme regardless of whether they and/or their parents/carers participate in the trial. Parents and children will be invited to attend the fun events regardless of whether they participate in the trial.

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 fun event.

Children:

- 1. Members of classes in Years 4, 5 and 6 at primary school (mostly 9-11 years old)
- 2. Ability to communicate in English (with support if necessary)
- 3. Assent from children to take part
- 4. Parents do not object to child(ren)s participation

Parents:

- 1. Child has taken part in school
- 2. Consent to take part
- 3. Ability to communicate in English (with support if necessary)

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

Children from 240 families; 80-100 of the childrens parents

Key exclusion criteria

Schools:

Welsh (or other non-English) medium

Children:

1. Absent from school during data collection
2. Unable to communicate in English
3. Parental refusal for child to take part

Parents:

1. Child has not taken part in school
2. Unable to communicate in English
3. Not contactable by phone

Date of first enrolment

01/02/2012

Date of final enrolment

31/10/2012

Locations**Countries of recruitment**

United Kingdom

Wales

Study participating centre

Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement (DECIPHer)

Cardiff

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CF10 3BD

Sponsor information

Organisation

Cardiff University (UK)

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Sponsor type

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Funder(s)**Funder type**

Government

Funder Name

National Institute for Health Research - Public Health Research Programme (UK) ref:10/3002/03

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2015		Yes	No