A MULTICENTRE CLUSTER RANDOMISED CONTROLLED TRIAL TO EVALUATE THE EFFECTIVENESS AND COST-EFFECTIVENESS OF KIVA TO REDUCE BULLYING IN PRIMARY SCHOOLS:

STAND TOGETHER

PROTOCOL VERSION 1.9 AND 20/11/2019

Sponsor:	Bangor University
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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the relevant trial regulations, GCP guidelines, and CTR's SOPs.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies from the trial as planned in this protocol will be explained.

Trial Sponsor:			
Name	**Position**	**Signature**	**Date**
Director:			
Name	**Signature**	**Date**	
Chief Investigator:			
Name	**Signature**	**Date**	

General Information This protocol describes the Stand Together trial and provides information about the procedures for entering participants into the trial. The protocol should not be used as a guide, or as an aide-memoire for other schools and pupils not enrolled in this trial. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the trial. Problems relating to the trial should be referred, in the first instance, to CTR

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Trial Co-ordination:

The Stand Together trial is being coordinated by the Centre for Trials Research (CTR), Cardiff University, a Clinical Research Collaboration (UKCRC) registered trials unit. This protocol has been developed by the Stand Together Trial Management Group (TMG). For **all queries** please contact the Stand Together team through the main trial email address.

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Contents

Glossary of abbreviations

AE	Adverse Event
CBSES	Challenging Behaviour Self-Efficacy Scale
CEIT	Children's Early Intervention Trust
CF	Consent Form
CHU-9D	Child Health Utility 9D
CI	Chief Investigator
CRF	Case Report Form
CSRI	Client Service Receipt Inventory
CTR	Centre for Trials Research
CTU	Clinical Trials Unit
CU	Cardiff University
EUCTD	European Union Clinical Trials Directive
FSM	Free school meals
GCP	Good Clinical Practice
GP	General practitioner
HE	Health Economics
HIFAMS	How I Feel About My School
IC	Informed consent
ICER	Incremental cost-effectiveness ratio
ICH	International Conference on Harmonization
IEC	Independent Ethics Committee
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number
KS2	Key Stage 2
MBI-ES	Maslach Burnout Inventory-Educators Survey
NIHR	National Institute of Health Research
NPD	National Pupil Database
OBVQ	Olweus Bully/Victim Questionnaire
PHR	Public Health Research
PI	Principal Investigator
PID	Participant identification number
PIS	Participant Information Sheet

PRQ	Participant Role Questionnaire
PS(H)E	Personal Social (Health) Education
QA	Quality Assurance
QC	Quality control
QL (QoL)	Quality of Life
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SEN	Special educational needs
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
TSDQ	Teacher Strengths and Difficulties Questionnaire
UP	Usual practice
WEMWS	Warwick-Edinburgh Mental Wellbeing Scale

1 Amendment History

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

Amendment No.	Protocol version no.	Date issued	Summary of changes made since previous version
1	1.9	20.11.2019	- Removal of linkage to social service data at Month 12 follow-up - Change of 'opt-out' form to 'right to object' form

2 Synopsis

Short title	A Multicentre Cluster Randomised-Controlled Trial to Evaluate the Effectiveness and Cost-Effectiveness of KiVa to Reduce Bullying in Primary Schools
Subtitle	Stand Together
Internal ref. no.	843
Development phase	N/A
Funder and ref.	National Institute for Health Research (NIHR) Public Health Research Programme (PHR) (PHR 17/92/11)
Trial design	Parallel-group, multicentre, two-arm, cluster RCT with process and economic evaluations
Trial participants	Key Stage 2 (KS2) pupils (aged 7-11 years)
Planned sample size	12 828 pupils
Planned number of sites	116 (58 intervention) primary schools in North Wales, the West Midlands, South East and South West England
Inclusion criteria	Mainstream, state primary schools (up to Year 6) with at least two KS2 classes
Exclusion criteria	• Mixed primary and secondary schools • Schools that deliver education through a language other than English or Welsh • Already implement a recognised anti-bullying programme that is considered to extend beyond a standard approach • Any school that has already implemented KiVa • Schools that cater solely for pupils with special educational needs (i.e., Special schools) • Schools without leadership that can guarantee project participation for the year of data collection/implementation
Intervention duration	12 months
Follow-up duration	12 months

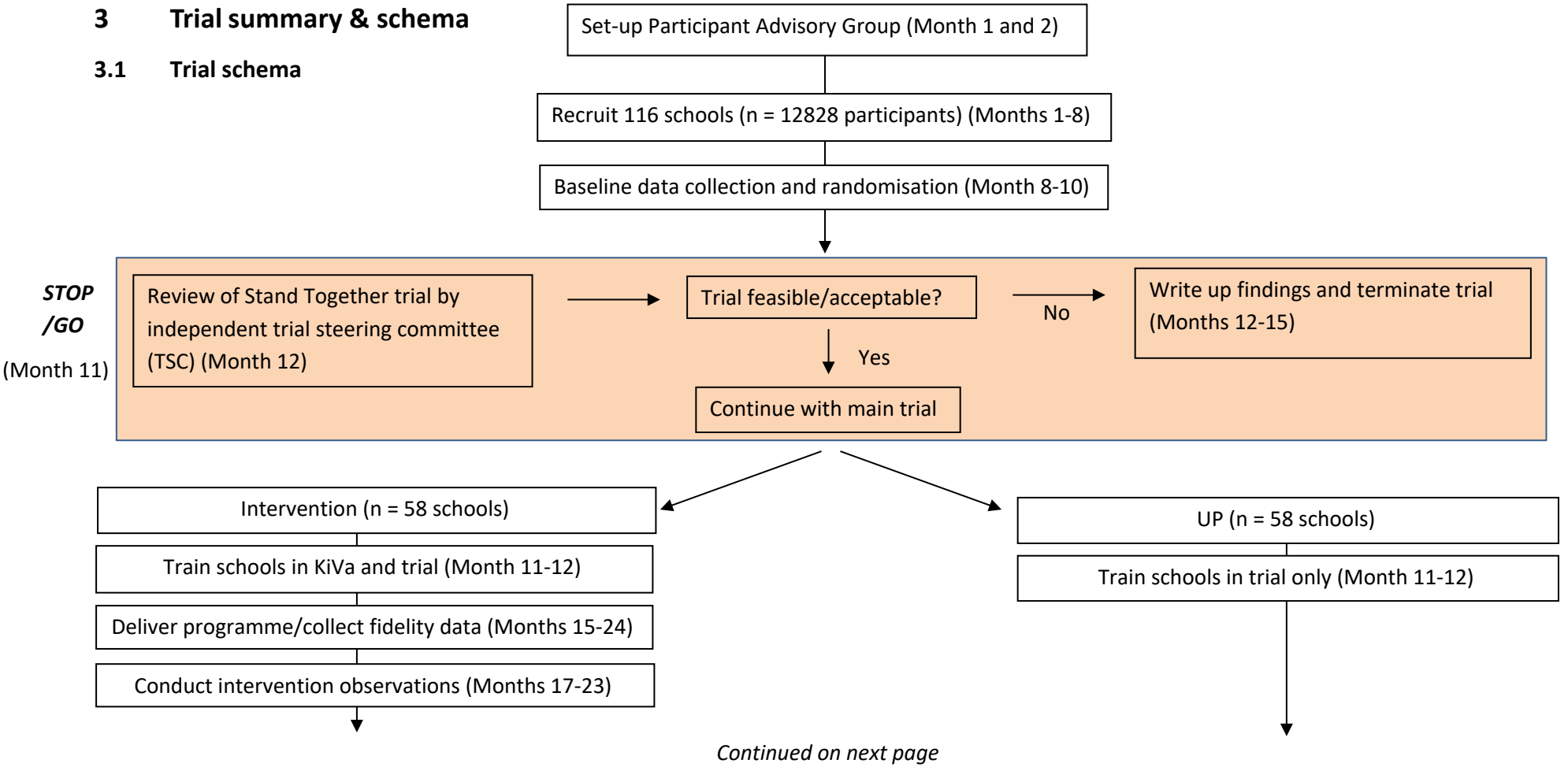
Planned trial period	July 2019 – March 2022 (33 months)
Primary objective	To investigate whether implementation of the KiVa programme over one academic year is more effective in reducing self-reported rate of bullying victimisation among pupils aged 7-11 years in UK primary schools than usual practice at 12 Month follow-up
Secondary objectives	To investigate whether delivery of the KiVa programme to KS2 pupils over one school year compared to usual practice: **1.** Is more effective at reducing the proportion of pupil self-reported bullying perpetration **2.** Is a more cost effective method of reducing pupil self-reported bullying victimisation **3.** Improves teacher-reported pupil behavioural **4.** Increases teacher self-efficacy in dealing with bullying **5.** Increases teacher mental wellbeing **6.** Decreases teacher burnout **7.** increases pupil wellbeing at school **8.** Increases pupil empathy **9.** Increases pupil self-efficacy in defending bullying
Tertiary/Exploratory objectives	**1.** To investigate the impact of the KiVa programme on school attendance, academic attainment and school exclusions. **2.** To examine participant roles in bullying and the potential impact of the KiVa programme on these roles. **3.** To determine whether the impact of KiVa vary by socio-economic status or gender. **4.** To explore KiVa implementation fidelity (lessons, indicated actions and schoolwide elements), factors that influence implementation and intervention mechanisms. **5.** To investigate schools' usual antibullying practices and how this may be impacted by KiVa implementation.

Primary outcomes	Pupil-level self-reported rate of bullying victimisation assessed using the Olweus Bully/Victim Questionnaire (OBVQ).
Secondary outcomes	**1.** The proportion of pupil self-reported bullying perpetration will be assessed using the OBVQ **2.** Cost effectiveness ratio (cost per incidence of bullying avoided using KiVa compared to Usual Practice (UP) will involve fully costing the implementation of the KiVa programme and assessing pupil-level self-reported bullying incidence using the OBVQ. Wider cost consequence analysis will involve fully costing the implementation of the KiVa programme and assessing child reported quality of life using the Child Health Utility 9D (CHU-9D), and frequency of child and/or parental contacts with the school and/or other services regarding bullying using the bespoke Client Receipt Service Inventory (CRSI) **3.** Teacher-reported pupil behavioural, hyperactive/inattentive, emotional, and peer problems and pro-social strengths will be assessed using the Teacher Strengths and Difficulties Questionnaire (TSDQ) **4.** Teacher self-efficacy in dealing with bullying incidents will be assessed using a modified version of the Challenging Behaviour Self-Efficacy Scale (CBSES) **5.** Teacher mental wellbeing will be assessed using the Warwick Edinburgh Mental Wellbeing Scale (WEMWS) **6.** Teacher burnout will be assessed using the Maslach Burnout Inventory - Educator Scale (MBI-ES) **7.** Subjective pupil wellbeing at school will be assessed using the How I Feel About My School (HIFAMS) questionnaire **8.** Pupil empathy will be assessed using the Empathy Toward Victim Scale **9.** Pupil self-efficacy in defending bullying will be assessed by averaging scores from three items of the Participant Role Questionnaire (PRQ) related to self-efficacy in defending bullying to give a single measure
Tertiary/Exploratory outcomes	**1.** School attendance records and KS2 Attainment, Absences and Exclusions datasets from the National Pupil Database (NPD) **2.** Participant roles related to bullying will be assessed using the PRQ

	3. KiVa implementation fidelity including: lesson implementation fidelity assessed by teacher-completed online Lesson Record Books, school-wide implementation assessed through a trial specific checklist completed by observers, reliability of teacher and school reporting of implementation through KiVa lesson observation and teacher fidelity rating measures completed by observer, and in-depth interviews conducted at eight intervention schools **4.** Intervention mechanisms and factors influencing implementation will be explored through focus groups and interviews with pupils and parent/carers of KiVa schools and through observation of lesson and school-wide delivery **5.** Schools' usual antibullying practices and will be determined by obtaining a copy of each school's antibullying policy, through completion of a trial specific proforma and through discussion with the schools' Headteacher
Intervention	KiVa (meaning 'nice' in Finnish and, 'Ki' and 'Va' beginning the Finnish words for 'against bullying') is an antibullying programme developed in Finland where it is has now been scaled up extensively. In this trial, KiVa will be delivered to KS2 pupils in intervention schools over one academic year. The core KiVa curriculum involves the delivery of class lessons (fortnightly or monthly depending on the school's timetable) delivered by class teachers who have received KiVa training from the school KiVa coordinator. Lessons cover definition of bullying, understanding and reflecting on emotions, group interactions processes, the mechanisms and consequences of bullying, group pressure, they also describe how bullying is affected by bystander behaviours and how to reduce different types of bullying, including cyberbullying, and support fellow pupils. KiVa lessons map onto over 50% of Welsh Personal Social Education (PSE) and English Personal Social Health Education (PSHE) curriculum. Confirmed incidents of bullying are addressed by the school's KiVa team using the KiVa scripted strategies and forms. KiVa is also implemented and visible schoolwide through whole school assemblies, KiVa vests worn by staff at break times to identify them as part of the school's KiVa team, and KiVa posters to increase the presence of the programme at the school.

3 Trial summary & schema

3.1 Trial schema



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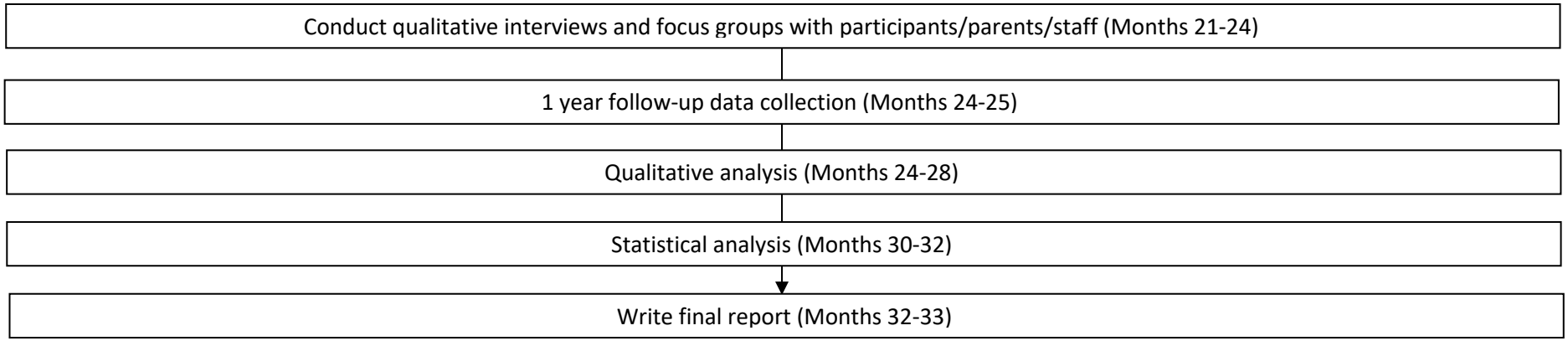

Figure 1. Stand Together trial flow diagram

3.2 Trial lay summary

3.2.1 Background

Bullying is an extremely important public mental health risk. Over 25% of UK children report being bullied at least weekly [1] and are more likely to experience depression and anxiety as children [2-4] and are at heightened risk of mental health issues in adolescence and adulthood [5]. In addition, bullying perpetration is linked to later violent behaviour and illicit drug use [6-7]. The Finnish KiVa school–based antibullying programme was highly effective in reducing several types of bullying including cyberbullying [8-10] and was consequently widely implemented in Finland. Two pilot studies in Wales have demonstrated school, teacher and pupil acceptability, and effectiveness [11-12], yet, KiVa still needs to be rigorously evaluated in the UK.

3.2.2 The trial

This trial will investigate whether implementation of the KiVa programme over one academic year is more effective in reducing reported bullying in UK primary schools than usual practice. One hundred and sixteen non-fee-paying primary schools (approximately 12 800 pupils) from four geographical areas (North Wales and Cheshire, the West Midlands and South East and South West England) will be recruited to the trial. Schools will be randomly split into two groups; half (n = 58) will implement KiVa with Key Stage 2 (KS2) pupils aged 7-11 years and half (n = 58) will form a UP group and continue with their usual antibullying practices. School size and level of deprivation as measured by Free School Meal (FSM) eligibility will be considered when allocating schools to a group. KiVa has dedicated 45-minute fortnightly lessons for pupils in years 3-6 (ages 7-11), posters, online games to play at home and/or school, whole school assemblies, parent information, designated trained staff to deal with confirmed bullying incidents and set procedures for use when bullying occurs. Class lessons teach an understanding of children's own and others' emotions and how to stand up against bullying and support victims.

3.2.3 Methods

Before the start of the 2020/21 academic year, KS2 pupils will complete questionnaires about their experience of bullying at school, how they feel about school and their general wellbeing. KS2 teachers will complete questionnaires about the behaviour of each pupil in their class, their confidence in dealing with bullying and the mental wellbeing. Pupils and teachers will complete these questionnaires towards the end of the 2020/21 academic year (May/June 2021). The study will be reporting whether there is a

reduction in the proportion of pupil self-reported bullying victimisation from the start to the end of the academic year and whether this reduction is greater within schools that delivered KiVa compared to schools that continued with their usual practice. To learn more about how KiVa lessons were delivered, the factors that influenced delivery, how it was delivered schoolwide and how it was received by participants, researchers will conduct interviews and focus groups with staff, pupils and parents in schools that delivered KiVa. Interviews will also be conducted with school staff from the control group to learn more about usual antibullying practices in UK primary schools. In addition, the cost of KiVa will be calculated and weighed up against any benefits in terms of reduced reported bullying, pupil quality of life and use of services related to bullying.

Trial findings will be disseminated through policy briefings, in press-releases, social media updates, via the creation of short audio-visual clips for schools and children and published in peer-reviewed academic journals and conference presentations.

4 Background

Bullying in childhood is one of the most tractable public mental health problems facing young people [13-14]. Bullying is generally defined as a pattern of 'unwanted, aggressive behaviour … that involves a real or perceived imbalance of power' [15]. The psychiatric morbidity arising from bullying is substantial; population studies suggest that 25-40% of mental health problems including depression, anxiety and self-harm in young adults may be attributable to childhood bullying [2-4]. Young people who are bullied are more likely to use mental health services in childhood and adolescence (odds ratio (OR) 2.53) and experience poor mental health up to age 50 (OR 1.30) [5]. During childhood, their use of school health services, primary care and specialist mental health service is increased. Bullying may also lead to school refusal and absenteeism [16] which can have serious impacts on educational attainment and employment prospects. Bullying perpetration also has negative impacts and is linked to later antisocial and violent behaviour and illegal drug use [6-7]. Thus, interventions that reduce bullying in schools can improve school attendance and behavioural problems and have the potential to substantially improve mental health and reduce depression, anxiety and self-harm in both childhood and adulthood.

UK school approaches to bullying vary widely and are rarely evidence based [17]. There is an urgent need to identify and scale up effective interventions across local and national school networks to address

bullying in schools, particularly in the early school years. This is also recognised by the Welsh Government as part of a national priority to improve levels of wellbeing in schools by Wales [18].

Systematic reviews consistently report that universal whole-school interventions, promoting schoolwide change, are most effective at reducing bullying [19-21] and are likely to provide a cost-effective and non-stigmatising approach to prevention [22]. KiVa is the most widely used bullying prevention programme across Europe. In a Finnish randomised controlled trial (RCT) (2007-2009) involving over 28,000 pupils in 234 schools, KiVa reduced bullying and victimisation significantly for 7 to 11 year-old pupils [19] across all forms of bullying, including verbal, physical, racist, and cyber- bullying [20] and reduced anxiety and depression [21]. KiVa has already been scaled up extensively in Finland, with over 90% of public schools enrolled. Since 2009, the national implementation was evaluated and has demonstrated positive although smaller effects than were found in the RCT [22].

4.1 Rationale for current trial

Finland has a very different education system to the UK, with negligible attainment differences between schools, no selection, tracking or streaming of students during their basic education, and highly educated primary school teachers with a mandatory five-year master's degree qualification [8]. Thus, it is not certain that intervention effects will transfer across to our different school contexts. Trials of the KiVa programme in Italy and the Netherlands [23-24] found that whilst KiVa did reduce levels of bullying and victimisation, effect sizes were variable. KiVa has yet to be rigorously evaluated in the UK. Our two pilot trials in Wales have demonstrated school, teacher and pupil acceptability and evidence of effectiveness [11-12] similar to that achieved in the broad roll out in Finland but with considerable variation across schools. However, there is still a need for a trial with independently collected data that is sufficiently powered to detect meaningful effects. Other issues regarding programme fidelity and the level of support needed within schools for the programme to be effective are still to be evaluated. It also remains to be tested whether KiVa will be effective across the social gradient, including in more socioeconomically disadvantaged schools and with socially disadvantaged children.

5 Trial objectives/endpoints and outcome measures

5.1 Primary objective

The aim of this trial is to investigate whether implementation of the KiVa programme over one academic year is more effective in reducing self-reported rate of bullying victimisation among pupils aged 7-11 years in UK primary schools than usual practice at 12 Month follow-up.

It is hypothesised that after one school year of implementation, KiVa will produce a 4% absolute reduction, or 22% relative reduction, in the proportion of pupil self-reported bullying victimisation from baseline.

5.2 Secondary objectives

To investigate whether delivery of the KiVa programme to KS2 pupils over one school year compared to usual practice:

1. Is more effective at reducing the proportion of pupil self-reported bullying perpetration
2. Is a more cost effective method of reducing pupil self-reported bullying victimisation
3. Improves teacher-reported pupil behavioural
4. Increases teacher self-efficacy in dealing with bullying
5. Increases teacher mental wellbeing
6. Decreases teacher burnout
7. Increases pupil wellbeing at school
8. Increases pupil empathy
9. Increases pupil self-efficacy in defending bullying

5.3 Tertiary/exploratory objectives

1. To investigate the impact of the KiVa programme on school attendance, academic attainment and school exclusions.
2. To examine participant roles in bullying and the potential impact of the KiVa programme on these roles.
3. To determine whether the impact of KiVa vary by socio-economic status or gender.

4. To explore KiVa implementation fidelity (lessons, indicated actions and schoolwide elements), factors that influence implementation and intervention mechanisms.
5. To investigate schools' usual antibullying practices and how this may be impacted by KiVa implementation.

5.4 Primary outcome measures

The primary outcome is the proportion of pupils self-reporting bullying victimisation and will be measured using the OBVQ [25]. In both the intervention and UP arms at Baseline and at 12 Month follow-up. This questionnaire measures the rate of total and different forms of bullying, including verbal, physical, relational and cyber-bullying. The OBVQ [25] has been used both in Finland and internationally for KiVa trials, enabling comparison across trials. The item that will be used to assess the primary objective is item 4, "How often have you been bullied at school in the past couple of months?" to which pupils may select one of the following responses: "I haven't been bullied at school in the past couple of month = 0", "it has only happened once or twice = 1", "2 or 3 times a month = 2", "about once a week = 3" or "several times a week = 4". The responses will be dichotomised so that a response of 2-4 will indicate bullying victimisation and responses 0-1 will indicate no bullying victimisation.

5.5 Secondary outcomes measure

5.5.1 Bullying perpetration

Pupil self-reported bullying perpetration will be assessed using the OBVQ [25] in both the intervention and UP arms at Baseline and 12 month follow-up. Pupils will respond to Item 4 which asks, "How often have you taken part in bullying another student(s) at school in the past couple of months?". Pupils will select one of the following responses, "I haven't bullied another student(s) at school in the past couple of months", "it has only happened once or twice", "2 or 3 times a month", "about once a week" or "several times a week".

5.5.2 Cost effectiveness

The implementation of the KiVa programme will be fully costed, including the completion of a KiVa Cost Diary by the schools' KiVa co-ordinator. Cost effectiveness ratio (the cost per Quality Adjusted Life Year (QALY) using KiVa compared to UP) will be determined by calculating costs of KiVa implementation, and pupil self-reported quality of life from the CHU-9D [26] will be used to calculate QALYS. A wider cost

consequence analysis will be conducted by collecting data on pupil self-reported incidences of bullying using the OBVQ [25] and through the CRSI which will collect data on the frequency of child and/or parental contacts with the school and/or other services e.g. GP, regarding bullying.

5.5.3 Pupil behaviour

KS2 teachers in both the intervention and UP arms will complete the TSDQ [27] at baseline and 12 Month follow-up. This is a 25-item screening instrument widely used in developmental, social, clinical and educational studies to detect behavioural, hyperactive/inattentive, emotional, and peer problems and pro-social strengths in children observed over the past six months. It is brief, quick to complete, and validated in national UK samples. The teacher version can be completed for children aged 4 to 17 years. It comprises five subscales (each with 5 items) assessing hyperactivity, conduct, emotional difficulties, peer relations and pro- social behaviour, respectively. The scales have good inter-item reliability (Cronbach's alpha = 0.63-0.82), and test-retest reliability (0.84).

5.5.4 Teacher self-efficacy in dealing with bullying

KS2 teachers in both the intervention and UP arms will complete the adapted CBSES [28] at Baseline and 12 Month follow-up. This five-item scale provides a domain-specific measure of teacher self-efficacy related to challenging behaviours and adapted to specifically refer to bullying behaviours.

5.5.5 Teacher mental wellbeing

KS2 teachers in both the intervention and UP arms will complete the WEMWBS [29] at baseline and 12 Month follow-up. This is a 14-item positively worded scale measuring adult mental wellbeing with good test-retest reliability (r = 0.83) and high internal consistency (Cronbach's alpha = 0.89).

5.5.6 Teacher burnout

KS2 teachers in both the intervention and UP arms will complete the MBI-ES [30] at Baseline and 12 Month follow-up. The MBI-ES [30] is an introspective 22 item psychological Inventory. It is a well-established scale, which uses a three-dimensional description of emotional exhaustion, depersonalisation, and personal accomplishment.

5.5.7 Subjective pupil wellbeing at school

KS2 pupils in both the intervention and UP arms will complete the How I Feel About My School (HIFAMS) survey [31] at Baseline and 12 Month follow-up. The HIFAMS [31] was developed at Exeter University for a similar school-based trial and is composed of seven items which asks pupils how they feel about school life. It has moderate re-test reliability (intra-class correlation coefficient = 0.62) and moderate internal consistency (Cronbach's alpha 0.62 to 0.67).

5.5.8 Pupil empathy

KS2 pupils in both the intervention and UP arms will complete the Empathy Toward Victim Scale at Baseline and 12 Month follow-up, which was constructed by the developer of KiVa, Professor Christina Salmivalli et al. [32]. This seven-item measure asks respondents to rate their level of empathy towards victims of bullying on a Likert scale anchored from 'never' (0) to always (3) and excellent internal consistency (Cronbach's α = 0.84) [32]. As it is posited as one of the mechanisms by which the KiVa programme reduces bullying, this data will be used to determine if changes in rates of bullying are mediated by changes in empathy.

5.5.9 Self-efficacy in dealing with bullying

KS2 pupils in both the intervention and UP arms will complete the PRQ [33] at Baseline and 12 Month follow-up. The scores from three items of this questionnaire will be averaged to give a measure of self-efficacy in defending bullying. As it is posited as another mechanism by which KiVa reduces bullying, this data will be used to determine if changes in rates of bullying are mediated by greater self-efficacy in defending bullying.

5.6 Tertiary/exploratory outcomes

5.6.1 School attendance, absences and exclusions

At baseline, schools will provide records of pupil-level authorised and unauthorised half-day absences. These data are routinely collected by schools for all pupils as a legal requirement. At 12 month follow-up, data from the Absence and Exclusion datasets will be requested from the National Pupil Database (NPD) for pupils in both the intervention and UP arms. At 12 Month follow-up, we will also request data from the KS2 attainment dataset from the NPD for pupils in both the intervention and UP arms.

5.6.2 Participant role in bullying

KS2 pupils in both the intervention and UP arms will complete the PRQ [33] at Baseline and 12 Month follow-up. The questionnaire identifies five scales that describe the different roles in bullying; the bully scale, the assistant scale, the reinforcer scale, the defender scale and the outsider scale. The respondent is asked to rate how often they behave in the ways described for each of the roles on a three-point scale (Never, Sometimes, Often).

5.6.3 SES and gender

At baseline, school-level FSM eligibility and gender will be obtained from the school and/or online databases such as http://statswales.gov.wales and https://www.gov.uk/search/research-and-statistics.

5.6.4 Intervention implementation and mechanisms

The fidelity data will help to interpret trial outcomes. For instance, if KiVa is not found to be effective this may be because of low levels of coverage. Understanding intervention mechanisms may also help to explain and understand trial outcomes e.g. we may observe unintended consequences of introducing KiVA into school systems. Process evaluation will also help to determine whether there are relationships between fidelity/quality of delivery and outcomes.

5.6.4.1 KiVa implementation fidelity

KiVa lesson implementation fidelity will be assessed in all intervention schools using online or paper-based Teacher Lesson Record Books completed by teachers after each KiVa lesson. KiVa Lesson Record Books will collect information on teacher number of lessons delivered (a proxy for intervention adherence), length of lessons, teacher preparation time, components delivered, lesson quality and student engagement. All intervention schools will complete a checklist to assess adherence to the schoolwide KiVa elements.

Fidelity will also be assessed through observations at a purposively sampled group of 16 intervention schools. For these schools, research assistants will also complete the Lesson Record book and checklist to assess reliability of teacher-reported lesson and schoolwide implementation fidelity. We will also collect redacted KiVa forms used for confirmed incidents of bullying.

5.6.4.2 Factors influencing KiVa implementation

Factors influencing KiVa implementation will be explored through in-depth interviews with teachers involved with KiVa delivery from eight intervention schools around 12 Month follow-up.

5.6.4.3 KiVa intervention mechanisms

Intervention mechanisms will be explored in focus groups with pupils and through one-on-one interviews with parents/carers of eight intervention schools around 12 Month follow-up. Parents/carers who are interviewed will be offered a £20 voucher as reimbursement for their time. Observation of lesson and school-wide delivery, and implementation of indicated actions will also be used to explore intervention mechanisms.

5.6.5 Usual antibullying practices

UP will be assessed in both intervention and control schools at Baseline and 12 Month follow-up by collecting a copy of the schools' bullying policy, interviews with the schools' Headteacher and through completion of a trial specific checklist.

6 Trial design and setting

This is a parallel-group, multicentre, two-arm, cluster RCT, with process and economic evaluations. One hundred and sixteen non-fee-paying primary schools will be recruited from four geographical areas coordinated through four Universities (hubs): North Wales (Bangor University), West Midlands (University of Warwick), South East England (University of Oxford) and South West England (University of Exeter). Schools (sites) will be randomised to receive KiVa over one academic year or continue with UP. The effectiveness and cost-effectiveness of KiVa will be assessed 24-months after randomisation.

6.1 Risk assessment

A Trial Risk Assessment has been completed to identify the potential hazards associated with the trial and to assess the likelihood of those hazards occurring and resulting in harm. This trial has been categorised as a low risk where the level of risk is comparable to the risk of usual antibullying practices in schools. A copy of the trial risk assessment may be requested from the CTR.

6.2 Participant risks

Potential risks of the intervention to participants are minimal. Some individuals might find aspects of the intervention content or research upsetting if they have experience with bullying victimisation or perpetration. Trial managers will work with schools to ensure a system is in place to enable appropriate support to be provided in such circumstances. Any potential for harmful effects due to the intervention itself will be explored via the collection and analysis of qualitative data to explore unintended consequences.

7 Site and Investigator selection

This trial will be carried out at participating primary schools within Wales and England. Headteachers who are interested in registering their school in the trial will sign an agreement to confirm that they have adequate resources to complete the trial.

Before any site can begin recruitment a Principal Investigator at each site must be identified. The following documents must be in place and copies sent to the Stand Together trial email account (see contact details on page 4):

- Favourable opinion from Main Ethics committee
- A signed Trial Agreement
- Current Curriculum Vitae and GCP training certificate of the Principal Investigator (PI)
- Completed Site Delegation Log and Roles and Responsibilities document
- Full contact details for all Site (Institution) personnel involved, indicating preferred contact
- A copy of the most recent approved version of the Participant Information Sheets and Consent Forms on host care organisation headed paper
- Returned copy of the Self-Evident Correction Log signed by the PI.

Upon receipt of all the above documents, the Trial Manager will send written confirmation to the Principal Investigator detailing that the centre is now ready to recruit participants into the trial. This letter/email must be filed in each site's Site File.

Occasionally during the trial, amendments may be made to the trial documentation listed above. CTR will issue the site with the latest version of the documents as soon as they become available. It is the responsibility of the CTR to ensure that they obtain ethics approval for the new documents.

Site initiation will be by teleconference.

8 Participant selection

Schools are eligible to participate in the trial if they meet all the following inclusion criteria and none of the exclusion criteria apply. All queries about participant eligibility should be directed to the Trial Manager before randomisation/registration.

8.1 Inclusion criteria

Mainstream, state primary schools (up to Year 6) with at least two KS2 classes.

8.2 Exclusion criteria

Ineligible schools are those that:

- Are mixed primary and secondary schools
- Delver education through a language other than English or Welsh
- Already implement a recognised anti-bullying programme that is considered to extend beyond a standard approach
- Have already implemented KiVa
- Cater solely for pupils with special educational needs (i.e., Special schools)
- Do not have leadership that can guarantee project participation for the year of data collection/implementation

9 Recruitment, Screening and registration

9.1 Identification of schools

A list of eligible schools in each geographical area will be identified by accessing publicly available information on the schools' or government website, from which the schools' contact details will also be obtained. Schools may also be identified through education conferences, Regional School Effectiveness and Improvement Service for North Wales, Birmingham Education Trust and the Schools Health Research

Network in Wales and Public Health leads for schools in local authorities in England. Schools' senior manager (deputy head, head of pastoral care) of eligible schools will be leafletted via email. All sites will be recruited in the area local to the hub to facilitate data collection and school required support.

9.2 Screening logs

A screening log of all ineligible and eligible but not consented/not approached schools will be kept at each hub so that any biases from differential recruitment will be detected. When at the hub, logs may contain identifiable information, but this **must** be redacted prior to being sent to the CTR. The screening log should be sent to the KiVa@cardiff.ac.uk every week (see section 19 for further detail on data monitoring/quality assurance).

9.3 Recruitment rates

Sites will be recruited at an expected rate of three per week per hub in order to reach the recruitment target of 116 schools by May 2020.

9.3.1 Progression criteria

Recruitment rates of schools and pupils across the four hubs will be used to determine trial feasibility. Progression to a full trial in all sites will dependent upon recruitment progress. Progression thresholds are set out below, with early cessation if the lower targets are not achieved. The decision to continue will be made at the end of May 2020. However, should the trial be terminated all interested schools will have the opportunity to be trained and implement KiVa on the same basis as all other schools across the UK.

Green (continue to full trial without modification):

- 90% or more of target schools recruited
- 80% or more eligible pupils recruited
- 90% or more baseline primary outcome collected
- 80% or more baseline secondary outcomes collected

Amber (remediable issues; proceed with caution): Review processes with the Trial Steering Committee and PPI group to see if we could improve before a recommendation is taken on progression.

- 80- 89% of schools recruited

- 60-79% eligible pupils recruited
- 80-89% baseline primary outcome collected
- 65-79% baseline secondary outcomes collected

Red: the TMG will consult with NIHR PHR for advice on how the trial should proceed

- Less than 69% schools recruited
- Less than 59% eligible pupils recruited
- Less than 79% baseline primary outcome collected
- Less than 64% baseline secondary outcome collected

9.4 Informed consent

To protect potential participants' (pupils' and parents') privacy, the school will disseminate information sheets, 'right to object' forms and consent forms to parents/carers on the researchers' behalf. Materials will be distributed using the schools' usual communication system. For instance, some schools will use electronic 'parent mail' and others may use paper newsletters. We will request that school uses alternative methods of contact to inform any parents/carers who do not receive information using normal communication systems. We will also ask the school to display trial information on schoolwide forums e.g. school bulletins to ensure that all parents/carers of KS2 children are informed about the trial and have been provided with an opportunity to complete a 'right to object' form.

Potential participants will be able to keep the information sheet (except for pupils; who will not be provided with a written information sheet) which will provide details of who to contact if they require further information about the research or bullying. The right of the potential participant to refuse to participate without giving reasons will be respected. Just prior to conducting the trial assessments, the researcher will inform all participants that they can withdraw their consent/assent up until the data has been collected and the interviews have been conducted. After this, data will not be able to be withdrawn as it will be pseudonymised.

9.4.1 Consent/assent obtained at Baseline

9.4.1.1 Headteacher

Headteachers will receive a leaflet which will provide information about the trial, what is involved, time commitment, costs, benefits and information on pupil privacy and safety. Headteachers will be directed to the Stand Together trial website if they wish to obtain more information. If the headteacher wishes to register their school in the trial, they will be required to agree to the terms stipulated in the agreement and provide their written consent.

9.4.1.2 Parents/carers

Information leaflets will be distributed to parents/carers of children at participating schools. Parents/carers will be informed that they have the 'right to object' to their child's data being collected and will be able to complete and return the 'right to object' form if they do not want their child to complete questionnaires to be used in the trial evaluation.

9.4.1.3 Pupils

As pupils are aged 7-11 years it is considered inappropriate to ask for written assent. Young children may not fully understand the significance of signing a document or even understand what a signature is. Therefore, we will seek verbal informed assent to collect questionnaire data (OBVQ [25], CHU-9D [26] and HIFAMS [31]) only from those pupils whose parent/carer did not return a 'right to object' form. On the day of data collection, a researcher will verbally inform pupils about the trial including what the trial is about, why they have been asked to participate, what they will be asked to do, how much time it will take and what to do if they become upset. Pupils will be given time to ask questions and it will be made clear that they don't have to participate if they don't want to and they do not need to give a reason. Signs of hesitation or distress will be taken to indicate that the pupil withdraws their assent. For those pupils who do not complete questionnaires, alternative arrangements will be provided to allow them to remain in the data collection environment to avoid embarrassment.

9.4.1.4 KS2 teachers and school KiVa team and coordinator

KS2 teachers will receive an information leaflet which will provide brief information about the trial, what is involved and information on pupil privacy and safety. Teachers will be informed that the school's Headteacher has already provided consent for their school to participate in the trial. Therefore, KS2

teachers will be required to deliver the intervention and associated documentation including TSDQ [27] data. Similarly, school administrators will need to provide school data if the headteacher has provided consent for the school to take part in the trial. Teachers may refuse to consent to provide MBI-ES [30], WEMWS [29] and CBSES [28] questionnaire data.

9.4.2 Consent/assent obtained at 12-Month follow-up

9.4.2.1 Parents/carers

Using the same distribution method as outlined in Section 9.4, parents and carers will receive an information leaflet requesting to provide consent to use additional information about their child to assist with the current trial's evaluation. This will include pupil-level data collected by the Department for Education and held on the NPD. Consent will also be sought to allow researchers to contact parents/carers in the future if there is a request to link children's trial data with other data. Consent will also be sought for parents to provide data about contact with the school about bullying by completing the bespoke Client Service Receipt Inventory (CSRI) [34]. Purposively selected parents and carers will receive an information leaflet about participating in qualitative interviews will also be asked to provide their written consent if they agree to take part. They will be informed that they will be offered a £20 voucher as reimbursement for their time.

9.4.2.2 Pupils

A purposively selected group of pupils will be invited to participate in a focus group. Prior to the focus group, a researcher will verbally inform pupils about trial including what the trial is about, why they have been asked to participate, what they will be asked to do and how much time is will take. Pupils will be given time to ask questions and it will be made clear that they don't have to participate if they don't want to and they do not need to give a reason. As indicated previously, it is not appropriate to seek written informed assent from pupils in this age group. Signs of hesitation or distress will be taken to indicate that the pupil withdraws their assent.

9.4.2.3 School staff

Purposively selected staff from KiVa and UP schools will receive an information leaflet about participating in qualitative interviews. They will also be asked to provide their written consent if they agree to take part.

9.5 Registration and Randomisation

9.5.1 Registration

Once school staff have expressed their interest in participating in the trial, a researcher will confirm the schools' eligibility using a standardised checklist. Once eligibility has been confirmed, Headteachers of eligible schools will be required to complete the Consent Form and Agreement. The school will be given a unique site ID and will be randomised to the intervention or UP arm.

9.5.2 Randomisation

Randomisation will be completed at school-level. Randomisation will be coordinated centrally by the CTR. The sampling frame will be prepared and held by the trial Data Manager. Within each of the four trial areas, schools will be organised into the four strata (based on median Free School Meal (FSM) strata and school size). Each school will be assigned an ID number, after which an independent CTR statistician will randomly allocate schools within each stratum to one of two arms using random block allocations. Further detail on this will be included in the randomisation protocol.

10 Withdrawal & lost to follow-up

10.1 Withdrawal

As it is the school's decision to take part in the trial and the Headteacher will provide their consent, parents will not be able to withdraw their children from receiving the intervention as KiVa will be part of the normal school PSE/PSHE provision. However, schools will have the right to withdraw consent for participation in the trial at any time. Individuals (school staff, pupils, parents/carers) will have the right to withdraw their consent for the collection and use of theirs's or their child's data in any aspect of the trial up until the data is collected. Participants will be informed that once data is collected, it cannot be withdrawn from the trial as all data will be pseudonymised by this stage. Distress or reluctance during pupil data collection will be assumed to indicate that the child wishes to withdraw consent to provide data at that time point. Participants' care from any services will not be affected at any time by declining to participate or withdrawing from the trial.

In all instances, schools and participants who consent and subsequently withdraw should complete a withdrawal form (used in the E-Pats trial; a group-based support intervention for parents with young

children who have learning disabilities) or the withdrawal form should be completed on the participant's behalf by the research assistant at the site based on information provided by the participant. School withdrawal forms should be sent to the sites' contact and then forwarded to the Trial Manager(s) in the CTR. Any queries relating to potential withdrawal of a school or participant should be forwarded to the Trial Manager(s) immediately.

10.2 Lost to follow up

The outcome measurements will be assessed at two time points. Baseline measures will be assessed prior to randomisation of schools into the two trial arms (control and intervention conditions, 58 schools [clusters] in each, see section 14.3, sample size). A second set of measurements will take place 12-months post randomisation as per the baseline protocol. As pupil level follow-up is affected by absence on the day of survey and pupil turnover in schools (estimated turnover for England is 6%), alternative times for data collection will be made for those who are absent to minimise attrition. Schools who complete the trial will have the opportunity to receive a monetary incentive to enhance retention (maximum £308 depending on what data is provided). Schools will also be advised that taking part in the trial may help Ofsted/Estyn inspections – especially in the areas of 'Personal Development' and 'Leadership and Management' (Ofsted), and 'Care, Support and Guidance' and 'Wellbeing and Attitudes to Learning' (Estyn).

11 Trial intervention

The KiVa antibullying programme for pupils aged 7 to 11 years was developed in 2006, by Prof. Christina Salmivalli and colleagues at the University of Turku, Finland, funded by the Ministry of Education and Culture. The word KiVa means 'nice' in Finnish and, 'Ki' and 'Va' begin the Finnish words for 'against bullying'. The KiVa programme content and rationale are informed by a Social Architecture Model of Bullying that demonstrates the significant role of bystanders in supporting or standing up against bullying [35]. KiVa is fully manualised (the programme manual includes background information, full implementation instructions, curriculum lesson plans, scripts for addressing highlighted bullying incidents, and forms for dealing with incidents).

11.1 Core curriculum

The core curriculum targets pupils in Years 3 and 4 (unit 1), and Years 5 and 6 (unit 2). Each unit contains ten structured ninety-minute lessons, typically split into two 45- minute lessons, delivered fortnightly throughout the school year. Lessons describe how bullying is affected by bystander behaviours and cover understanding and reflecting on emotions, group interactions processes, the mechanisms and consequences of bullying, group pressure and how to reduce different types of bullying, including cyberbullying, and support fellow pupils. The curriculum aims to create an emotionally and socially supportive setting that encourages pupil engagement via oral presentations, role-play, videos, group work, and whole class activities. KiVa covers over half of the PS(H)E provision in Wales and England. Online games to support learning can be played at home and/or school. Class lessons for all four years of KS2 pupils (aged 7-11 years) will be delivered by KS2 class teachers.

11.2 Indicated actions

Each school will have a dedicated KiVa team (2-3 staff members) who will be trained by accredited KiVa trainers to address confirmed bullying incidents using the KiVa structured and scripted process. Bullying incidents will be recorded in a designated KiVa logbook.

11.3 School-wide elements

Some intervention components are delivered across the whole school alongside delivery of the KiVa lesson curriculum to KS2 pupils. This includes universal actions to ensure that the entire school staff are knowledgeable about the KiVa programme and how it operates in the school. All school staff must know how to make a referral to the KiVa Team. The programme is introduced to all staff, parents, and pupils and is visible across the school with high visibility vests for break time supervisors (to identify the school's KiVa team), posters (to increase the presence of KiVa at the school) and a parent's guide. School launches are provided for staff and parents to inform and prepare them for the programme.

11.4 KiVa training

The Bangor based Children's Early Intervention Trust (CEIT) charity holds the UK KiVa dissemination contract and will co-ordinate KiVa training. KiVa materials, manuals, and online access are provided at the training (an annual re-registration fee payable to KiVa Finland is required for continued access to the online resources). There will be at least one accredited trainer per hub (both Warwick and Bangor already

have trainers and interest has already been generated at the two other sites). Two school staff members will attend a two-day training (ideally the KiVa coordinator and the KiVa Team lead) and co-ordinate the programme launch with all school staff, pupils and parents. They will train KS2 teachers in lesson delivery and all school staff in methods of reporting suspected bullying incidents. The KiVa team lead will train all school staff in methods of reporting suspected bullying. KiVa team members will ensure that someone is rapidly available, to assess referrals against KiVa bullying criteria and, if confirmed, to implement the indicated programme components including working with the victimised child's class teacher. Some referrals may not meet the definition of bullying and will be dealt with according to normal school procedures for disputes, misunderstanding and accidents.

12 Trial procedures

A summary of trial procedures is shown in Table 1 (Page 39).

12.1 Baseline data collection

12.1.1 School demographic data

For each school, postal code and school-level data including number of pupils enrolled, ethnicity and FSM eligibility will be obtained through publicly available online databases such as http://statswales.gov.wales and https://www.gov.uk/search/research-and-statistics. Number of KS2 pupils enrolled at the school, gender (class level) and special educational needs status (SENS) will be obtained from the schools.

12.1.2 Contacts with the school regarding bullying

The school will provide information about the frequency of contact the school has had with pupils and/or other parent/carer regarding bullying.

12.1.3 Usual antibullying practice

Headteachers will complete a proforma containing questions about the school's usual antibullying practices. The proforma will collect information about bullying prevention measures (lessons, assemblies, programmes), strategies for dealing with bullying incidents (whether incidents are recorded, who is involved, whether incidents are followed up), staff antibullying training and parental involvement in incidents of bullying. A copy of all schools' antibullying policy will be obtained online or from the

Headteacher. To supplement the written data, the researcher will obtain more information through discussion with the Headteacher.

12.1.4 Pupil and teacher self-report questionnaires

Research assistants will attend schools to administer and collect pupil and teacher questionnaires. Prior to data collection, the school will note the pupils whose parent/carer returned a 'right to object' form and will have made alternative arrangements to allow these pupils to remain in the data collection environment to avoid embarrassment. Pupils whose parent/carer did not return a 'right to object' form will complete self-report questionnaire data (OBVQ [25], HIFAMS [31] and CHU-9D [26]) on school grounds. Ideally the researcher will read the questionnaires aloud to the whole class to maximise completion rates and data quality. This approach will be field tested prior to data collection to determine feasibility. If it is not feasible, pupils will complete their questionnaires by themselves 'under exam conditions' and the field workers will walk around the room to identify those who are experiencing difficulty. The research assistant will discretely offer help to these participants. Irrespective of the approach, researchers will ensure not to use leading language or appear to be monitoring the participants' response. School staff may choose if they wish to be present during data collection. KS2 teachers will complete the TSDQ [27], CBSES [28], WEMWBS [29] and MBI-ES [30] at the same data collection timepoint.

Teachers and pupils will ideally complete CRFs electronically using encrypted tablet devices. There will be enough tablets for each child so that questionnaires can be completed as a class. However, if technical issues arise and prevent electronic data collection, paper CRFs will be completed instead. Completed paper questionnaires will be reviewed by field workers at each site as part of quality control. They will then be transferred to the CTR using Royal Mail Special Delivery post where they will be scanned and stored in pseudonymised form, using participant identification numbers (PID) and a non-unique identifier e.g. initials. PIDs and identifiable information i.e. participant names, will be stored in separate files. Both files will be stored in secure password protected folders.

12.2 Follow-up data collection

12.2.1 Pupil and teacher self-report questionnaires

At Month 12 follow-up KS2 pupils and teachers will complete the same questionnaires in the same method as described in Section 9.1.4. In addition, parent/carers will also complete the CSRI [34] which will provide data to be used in the health economics evaluation.

12.2.2 Linkage to routinely collected data

The Trial Manager will request access to the NPD close to the 12-month follow-up (data release dependent). This will include KS2 Attainment, Absence and Exclusions datasets. Participant identifiers (pupil name and date of birth) will be sent to the Department for Education using their secure data transfer system. Trial data will be linked to the NPD database. Identifiers will be removed, and researchers will access the linked data via a data safe haven.

Parents will also be asked to consent to be contacted by researchers in the future if there is a request to link children's trial data with other data.

12.2.3 Usual antibullying practice

At Month 12 follow-up, data on schools' usual antibullying practices will be obtained using the same method as described in Section 9.1.3. In addition, interviews will be conducted with teachers from three control schools. Interviews will be audio recorded and transcripts will be anonymised.

12.2.4 Process evaluation

12.2.4.1 KiVa implementation fidelity

Teachers in KiVa schools will complete an online or paper-based Teacher Lesson Record Books after each KiVa lesson. All intervention schools will complete a checklist to assess adherence to the schoolwide KiVa elements. Research assistants will observe intervention delivery in a purposively sampled group of 16 intervention schools. For these schools, research assistants will also complete the Lesson Record book and schoolwide checklist to assess reliability of teacher-reported lesson and schoolwide implementation fidelity.

12.2.4.2 Factors influencing KiVa implementation

Research assistants will conduct in-depth interviews with teachers involved with KiVa delivery from eight intervention schools around February/March 2021. These interviews will explore key factors influencing implementation of KiVA and how this varies across different school contexts.

12.2.4.3 KiVa intervention mechanisms

Research assistants will conduct focus groups with pupils and interviews with parents/carers of eight intervention schools around February/March 2021. Researchers will also observe class lessons and report on school-wide delivery and implementation of indicated actions. These data will enable us to understand: the extent to which key components of the intervention operate as intended; any unintended mechanisms; and ways in which KiVA interacts with school systems.

12.2.4.4 Usual antibullying practices

At Baseline, researchers will obtain a copy of each school's bullying policy either online or from the Headteacher. At Baseline and Month 12 follow-up, a trial specific proforma will be completed to identify what antibullying elements are in place at the school. Researchers will also obtain information through interviews with Headteachers.

13 Safety reporting

As SAEs have not been observed in previous trials implementing the KiVa programme, we do not plan to report SAE data in the current trial. A trial specific safeguarding procedure has been developed and details the procedures to be followed if a risk of harm to a child is disclosed or suspected. All field workers who visit schools will have enhanced DBS checks and will receive appropriate training. The name and contact details of each school's safeguarding lead will be documented at Baseline. Pupils will also be informed that if they disclose to a researcher information that causes concern about their health or safety, confidentiality may need to be broken to inform the school's safeguarding lead. All instances of reporting to the school will be documented in the TMF.

Table 1. Schedule of trial procedures.

Procedures	**Time point**			
	Screening/baseline (Feb-Apr 2020)	Pre-trial set-up (May-June 2020)	Trial period (Sep 20-Jun 2021)	Month 12 follow-up (Apr-Jun2021)
Eligibility assessment	x			
Informed consent/assent	x			x
Demographic data collection	x			
Usual antibullying practices	x			x
Randomisation		x		
KiVa training and school trial training		x		
Delivery of intervention/control condition			x	
Pupil and teacher questionnaire data collection	x			x
Linkage to routinely collected data				x
Focus groups/interviews				x

14 Statistical considerations

14.1 Randomisation

Cluster (schools) will be randomised in a 1:1 ratio to receive either the KiVa intervention or usual practice. Within each of the four study areas (North Wales and Cheshire, West Midlands, South East England, South West England), schools will be stratified on their size (number of KS2 students (years 3-6)) and the percentage of students eligible for FSM to ensure balance across arms on parental socioeconomic disadvantage. Randomisation of schools will occur after all schools within area and strata have been recruited and they will be informed of their allocation after baseline data have been collected. All schools will be assigned a site ID number, after which an independent CTR statistician, will randomly allocate recruited schools to Intervention or Control using computer generated random number block allocations. The independent CTU statistician will allocate KiVa or Usual practice to ID numbers and inform the designated intervention delivery team member in each area.

14.2 Blinding

Baseline data collection which will occur prior to randomisation. It is not possible for KiVA study participants (students), teachers, Trial Managers, the intervention delivery team or researchers involved in the process evaluation to be blind to intervention status. While it is intended that Month 12 follow-up data collection will be conducted blinded, researchers and field workers may be unblinded to randomisation as schoolwide components of the KiVa intervention may be visible e.g. KiVa posters and vests. The statistician analysing the primary and secondary outcome data and the health economists undertaking the economic analysis will remain blinded. Potential risks of the intervention to participants are minimal but in the case where unblinding is necessary, the allocation schedule will be available to the researchers either electronically via the independent CTR statistician's copy.

14.3 Sample size

The sample size calculation is based on data from the roll-out of KiVa in Finland where a reduction from 18% to 14% in rates of victimisation was observed [37]. A similar baseline rate of victimisation of 18% was obtained from a current UK based pre-post study of 41 schools [23]. An individual pupil level analysis correcting for clustering by school will be undertaken. To achieve a reduction from 18% at baseline to 14% (4% absolute reduction, 22% relative reduction), a total of 3,520 pupils are required to power an

individual level trial at 90% and a 5% significance level. This reduction equates to an effect size (odds ratio) of 1.35 which is of public health significance and is broadly in line with other effect estimates from KiVa and the wider literature on bullying and victimisation. The pooled odds ratio found in Ttofi's and Farrington's 2018 systematic review of bullying and victimization was 1.24 [6] and our effect size is mid-range of other relevant KiVa studies which range from 1.22 [11] to 1.47 [8]. The study will take account of clustering. In the Finnish study the school level intra-cluster correlation (ICC) for the comparison of KiVa and UP in self-reported victimization was 0.02 at the 12-month follow-up. An average cluster size of 111 pupils in years 3 to 5 is assumed. This is based on recruiting children from 3-year groups (years 3, 4, 5) with an average 27.8 pupils per class (based on 2018 KS2 figures from English schools), and an average 1.34 classes per year (based on the data from our UK KiVa pilot study where half of recruited schools had more than one class per year).

Assuming 111 pupils in years 3 to 5, an ICC of 0.02, and for one school dropout per arm, (10% pupil dropout due to either 'right to object' or loss to follow-up, based on data from a small Welsh BIG Lottery funded pilot RCT with 20 schools, led by the Dartington Social Research Unit), an 18% rate of victimisation, and a relative reduction of 22%, a trial involving 116 schools (58 per arm) would provide 90% power at a 5% significance level (a total of 12,828 pupils). In the Dartington trial matched pupil survey and attendance data were collected by unfunded school staff. For approximately 2500 pupils, matched measures completion at one year, across teacher rated SDQ', pupil survey data and attendance varied between 75 – 92% (mean 87.5%). This has been reported to the BIG lottery and a paper reporting this trial is under review. Since this was achieved with minimal funding and reliance on teachers to supervise the pupil survey and match data across two academic years, we are confident that with pupil data collection being undertaken by research staff it will be feasible to achieve the 90% rate. If a higher rate of victimisation and a larger effect size akin to the Finnish KiVa study of 1.47 is observed within the recruited schools then the sample size required will be lower and we will have more than the 90% power, given all other parameters (ICC, dropout) are held constant. 83% power can still be achieved if we find a smaller effect size akin to the pooled odds ratio of 1.24 (as per Ttofi et al.'s meta-analysis [6]) and the ICC is smaller at 0.01.

14.4 Missing, unused & spurious data

To investigate the impact of any missing outcome data on the trial conclusions, missing mechanisms will be explored, and appropriate imputation methods applied via sensitivity analyses. We will compare baseline characteristics and post-randomisation variables of pupils who have and have not completed primary outcome data. Multiple imputation will be performed to assess the impact of missing outcome data using the mi command in Stata. Imputation models will include outcomes (including pupil attendance), intervention arm, stratifying variables, and a main school effect to allow for clustering, as well as any appropriate baseline covariates. The main analyses will be repeated on the imputed datasets. As an added sensitivity analysis, a scenario-based imputation will be carried out such as best-worst case scenario assuming all lost to follow-up in the KiVa arm have been victimised and vice versa. Further details will be included in the statistical analysis plan (SAP), written prior to analysis.

14.5 Procedures for reporting deviation(s) from the original SAP

These will be submitted as substantial amendments where applicable and recorded in subsequent versions of the protocol and SAP.

14.6 Inclusion in analysis

Missing outcome data will not be replaced, and all main statistical analysis will be conducted on complete cases i.e. participants that provided data at baseline and 12 months.

15 Analysis

15.1 Main analysis

A detailed SAP will be written prior to analysis. The reporting of findings will be in accordance with the CONSORT guidelines for cluster RCTs and SPIRIT recommendations for reporting trials of interventions. Statistical analysis will be performed in R or Stata (version 13 or higher).

All analyses will be intention to treat (i.e. pupils will be analysed in the groups to which they were randomised, regardless of adherence to intervention) and missing outcome data will not be replaced (all main statistical analysis will be conducted on complete cases). Between-group comparisons will be presented with two-sided 95% confidence intervals (CIs). As the trial includes a reasonable number of

clusters, the analysis will be based on the individual pupil, allowing for clustering between pupils within school using robust standard errors. Analyses will control for the school level stratification variables (geographical area, school size, proportion of children eligible for FSM) and pupil characteristics (age, gender).

15.1.1 Primary outcome

Multilevel logistic regression models will be used to compare the proportion of pupils reporting victimisation at 12 months by arm, and results presented as odds ratios and 95% CIs. Intra-cluster correlations (ICCs) alongside 95% CIs will also be reported.

15.1.2 Secondary outcomes

Multilevel linear (continuous outcomes) and logistic (binary outcomes) regression models will be used to compare secondary outcomes.

15.1.3 Sub-group & interim analysis

Primary sub-group analyses will investigate the effect of the intervention on pupil gender and the proportion of pupils eligible for FSM. The interactions between the study arm and these variables will be modelled. The results of these exploratory analyses will be presented using confidence intervals. There will be no interim analyses.

15.2 Qualitative analysis

With appropriate consent, all interviews and focus groups will be audio-recorded, transcribed fully, and anonymised for analysis. Computer software (NVivo) will be used to manage the qualitative data and transcripts. Thematic analysis will be used to analyse the qualitative data (interviews, focus groups). Transcripts of interviews and focus groups will be coded and analysed using the process evaluation aims and objectives as an analytical framework within which to identify relevant themes. Findings from the qualitative analysis will be used to interpret quantitative assessments of implementation fidelity, including the ways in which these vary across schools, trial sites, and over time.

15.3 Cost effectiveness analysis

The delivery of the KiVa intervention will be fully costed. A cost diary will be completed by KiVa coordinators and will collect information on teacher time to deliver KiVa lessons and use of the online survey and set-up and co-ordination of pupils to games. We will liaise with CEIT, the UK KiVa programme trainers, to calculate the costs of training, supervision and resources. From a local authority (school) perspective, taking into account NICE guidance on economic evaluation of public health interventions and the effects of clustering, we will undertake a primary cost effectiveness analysis of the KiVa intervention, using pupil self-reported quality of life as the outcome effect. Cost and quality of life data will subsequently be combined to calculate an incremental cost-effectiveness ratio (ICER), which will demonstrate the cost per unit of effect (i.e. cost per QALY using KiVa compared to the control condition). We will also embed a wider cost consequence analysis [38] to explore self-reported bullying incidences using OBVQ data [25]. The questionnaires for the economic analysis will be completed at all measurement time points.

Economic evaluation: Intervention costs data (e.g. staff training, supervision & resources) including teacher lesson record books reporting time spent in preparation and lesson delivery will be gathered from teachers. Bullying incidence, CHU-9D [26], and a brief bespoke CSRI [34] relevant to the intervention under assessment will be used. The CRSI [34] will ask for frequency of additional services used by children (e.g. through the school's Special Educational Needs Co-ordinator/ team) and parental consultations with school staff regarding bullying. We will collect this school CSRI information at baseline and follow-up through records schools already hold, providing a pro-forma for schools to extract the relevant data. As part of the request for data linkage, consent will be requested from parents at the follow-up data collection point. At the follow-up parents in both trial arms will also be asked to consent to and complete a CSRI [34] for the 12 months preceding follow-up, which will enquire about children's' use of services such as child and adolescent mental health services, General Practitioner and nurse appointments, and productivity losses for parents to take time off work for these consultations. Additional service use data will be available via the routine data linkage aspect of the project (where parents provide consent for this), supplementing the two methods above. Resource use, using the described multiple data sources, will be costed using national unit costs [39-40]. A fully documented Health Economics Analysis Plan (HEAP) will be written, aligning with the SAP, which will be agreed by the co-applicants before data collection has

been completed. The cost- effectiveness analysis will be reported according to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS).

16 Data Management

In the first instance, researchers will aim to collect data electronically on encrypted tablet devices (one per participant). However, if there are technical issues or similar that inhibit this electronic data capture, paper CRFs will be used. Whichever method of data collection is used at baseline will be used at 12 month follow-up within that school, providing no technical issues arise.

16.1 Electronic CRFs

Pupil and teacher self-reported measures will be captured electronically on an encrypted tablet device via secure a web application, RedCap Cloud or Qualtrics, which are both compliant with electronic data security regulation. Prior to data collection, field workers will enter participants' unique PID and another non-unique identifier e.g. initials (pseudanonymisation), into the questionnaire and then give the tablet to the corresponding participant. A record of participants' names, PIDs and non-unique identifiers will be kept by the researcher in order to facilitate linkage of Baseline and 12 Month follow-up data. Data will be collected offline and will be uploaded to the secure RedCap Cloud/Qualtrics database by the research assistants once connected to secure, University internet at each hub. Data will be downloaded by delegated CTR trial staff from RedCap Cloud/Qualtrics database and stored as secure password protected files in pseudonymised form on Cardiff University's secure server.

16.1.1 Paper CRFs

In the instance where electronic data capture of pupil and teacher self-reported measures is not possible e.g. technical difficulties, data will be collected on paper CRFs. Prior to data collection, field workers will write participants' unique PID and another non-unique identifier e.g. initials, on the paper CRF then give the CRF to the corresponding participant. A record of participants' names, PIDs and non-unique identifiers will be kept by the researcher in order to facilitate linkage of Baseline and 12 month follow-up data.

As soon as possible after data collection, research assistants from each hub will check the questionnaires for completeness. The top copy of each completed paper CRF should be couriered from each hub to the CTR for data entry within four weeks of collecting data from all sites recruited by the hub. The remaining

copy is to be retained at the hub. Upon receipt of paper CRFs at the CTR, all data will be entered and transcribed by the trial team using a secure data management system. Data from questionnaires will be stored in pseudonymised form, using PIDs and a non-unique identifier e.g. initials. PIDs, non-unique identifiers and corresponding participant names will be held in separate files and will be stored in secure password protected folders. Refer to the trial data management plan for more details.

Parents/carers will complete a paper CSRI [33] questionnaire and send back to the CTR in an addressed, pre-paid envelop.

16.2 Data queries

All answered data queries and corrections should be signed off and dated by a delegated member of staff at the relevant participating hub. The completed data clarification form should be returned to the CTR and a copy retained at the site along with the participants' CRFs. The CTR will send reminders for any overdue data. It is the hub's responsibility to submit complete and accurate data in a timely manner. In accordance with the principles of GCP, the PI is responsible for ensuring accuracy, completeness, legibility and timeliness of the data reported to the CTR in the CRFs. CRF pages and data received by the CTR from participating trial sites will be checked for missing, illegible or unusual values (range checks) and consistency over time.

17 Protocol/GCP non-compliance

The Headteacher should report any non-compliance to the trial protocol or the conditions and principles of Good Clinical Practice to the researcher at their corresponding hub in writing as soon as they become aware of it. The researcher will then notify the Trial Manager at the CTR.

18 End of Trial definition

The end of the trial will be considered as the date on which the last participant has completed their follow-up assessment or qualitative component. The sponsor will notify the main Research Ethics Committee of the end of the trial within 90 days of its completion or within 15 days if the trial is terminated early.

19 Archiving

The TMF containing essential documents will be archived at an approved external storage facility for a minimum of 15 years. The CTR will archive the TMF on behalf of the Sponsor. Essential documents pertaining to the trial shall not be destroyed without permission from the Sponsor. Archiving and access to archive will be managed in accordance with the Standard Operating Procedures of the CTR.

20 Regulatory Considerations

20.1 Ethical and governance approval

Ethical approval for the trial will be obtained from the School of Psychology Ethics Committee at Bangor University prior to commencement. The Stand Together trial intervention is low risk and ethical approval was received in the pilot study and for previous work of this nature and so no ethical concerns are anticipated.

20.2 Data Protection

The CTR will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained. Data will be stored in a secure manner and will be registered in accordance with the General Data Protection Regulation 2016. The data custodian for this trial is Bangor University.

20.3 Indemnity

The Chief Investigator, local Investigators and coordinating centre do not hold insurance against claims for compensation for injury caused by participation in a trial and they cannot offer any indemnity.

20.4 Trial sponsorship

Bangor University will act as Sponsor for the trial. Delegated responsibilities will be assigned to the sites taking part in this trial.

20.5 Funding

The trial is funded by the National Institute for Health Research Public Health Research Programme. The grant awarded is £1,835,497.40.

21 Trial management

21.1 TMG (Trial Management Group)

The TMG will consist of the Chief Investigators (chairs), co-applicants, Trial Managers, PIs and research assistants from the CTR and other hubs, the CTR Data Manager and the CTR Trial Administrator. The role of the TMG will be to assist in the trial set up by providing specialist advice, input to and comments on the trial procedures and documents (information sheets, protocol etc). They will also advise on the promotion and the running of the trial and deal with any issues that arise. The group will meet, either face-to-face or using audio-conferencing facilities, at least quarterly throughout the course of the trial and if necessary, additional/more frequent meetings may occur particularly at crucial time points during the trial, for example during the set-up phase. TMG members will be required to sign up to the remit and conditions as set out in the TMG Charter.

21.2 TSC (Trial Steering Committee)

The TSC will meet annually and will include the chief investigators, an independent chair, and independent external members including: a Headteacher, staff of antibullying and youth health organisations and academics in psychology, mental health, statistics and health economics. The TSC will act as an independent strategic oversight body to ensure transparency and that relevant milestones are being met and will report back to the NIHR PHR Programme. TSC members will be required to sign up to the remit and conditions as set out in the TSC Charter.

21.3 DMC *(*Data Monitoring Committee)

Given the low risk nature of the trial, and the fact that there are no interim data collections scheduled, we will ask the TSC to act as DMC.

22 Quality Control and Assurance

22.1 Monitoring

The clinical trial Risk Assessment Form has been used to determine the intensity and focus of central and on-site monitoring activity in the Stand Together trial. Low monitoring levels will be employed and are fully documented in the trial monitoring plan. Investigators should agree to allow trial related monitoring,

including audits and regulatory inspections, by providing direct access to source data/documents as required. Participant consent for this will be obtained. Findings generated from on-site and central monitoring will be shared with the Sponsor, CI, PI & local R&D.

22.2 Audits & inspections

The trial may also be participant to inspection and audit by Bangor University under their remit as Sponsor.

23 Publication policy

A publications policy will be drafted and approved by the TMG. It will state principles for publication, describe a process for developing output, contain a map of intended outputs and specify a timeline for delivery. The publication policy will respect the rights of all contributors to be adequately represented in outputs (e.g. authorship and acknowledgments) and the trial to be appropriately acknowledged. Authorship of parallel studies initiated outside of the TMG will be according to the individuals involved in the project but must acknowledge the contribution of the TMG and the Trial Coordination Centre.

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