



The FRIENDS Programme: An evaluation of academic and emotional health outcomes

An outline evaluation strategy submitted to
the Education Endowment Foundation

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1. Introduction

We are extremely pleased to have the opportunity to lead this project, which complements our ongoing programme of research into school-based prevention of social, emotional and behavioural difficulties. Much of our portfolio is targeted at the primary sector, including the primary SEAL evaluation (Humphrey, Kalambouka, Wigelsworth, & Lendrum, 2010; Humphrey et al., 2010) and the more recent PATHS (Humphrey et al, 2015) and GBG trials (Humphrey et al, ongoing). Also relevant is our experience in implementation and process evaluation (Lendrum, Humphrey, & Wigelsworth, 2013), assessment of social, emotional and behavioural outcomes (Wigelsworth, Humphrey, Kalambouka, & Lendrum, 2010), and the use of cognitive behavioural therapy in schools (Squires & Caddick, 2012; Squires, 2014).

As a result of discussions between Manchester, Project Salus, and the EEF, we have expanded upon agreed elements of a final design, and have highlighted some key considerations that would benefit from further discussion, in order to finalise a mutually agreeable final design.

1.1 Evaluation team

We are confident that our evaluation team offers the optimal blend of methodological, subject, and practitioner knowledge and expertise needed for this project. The team members are:

Dr. Michael Wigelsworth (PI) will direct the study and ensure that it is completed to time and budget. Michael is leading the independent evaluation of the 'Inclusive' project, as well as the outcome components and associated publications of both the 'Promoting Alternative Thinking Strategies (PATHS)' and 'Good Behaviour Game' randomised control trials. He has specific expertise in evaluation trial design, including the measurement and assessment of outcome data, as demonstrated by his publication record (see link below).

<http://www.manchester.ac.uk/research/michael.wigelsworth/>

Dr. Garry Squires (Co-I) is both an academic researcher and a registered practitioner educational psychologist with expertise in the area of therapeutic interventions, specifically cognitive behaviour therapy (CBT). Garry has published over a dozen articles directly related to CBT interventions in schools and is currently a member of the British Psychological Society working party looking at delivering psychological therapies in schools and communities. Garry is currently a Co-I on the 'Good Behaviour Game' and 'PATHS' trials.

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Mrs. Elizabeth Birchinall (Co-I) has over 20 years' experience teaching in both in the secondary and primary sector. After extensive senior leadership experience as vice-principal of a large Manchester primary school, she is now programme director for our primary PGCE, which is currently the number 1 training provider (Good Teaching Guide, 2013), and is ranked as Ofsted grade 1. Liz is currently a Co-I on the 'Good Behaviour Game' trial.

1.2 Our understanding of the FRIENDS intervention, its purpose and its context

FRIENDS is a school-based, cognitive-behavioural preventative programme, designed to promote emotional resilience in order to prevent (or stabilise) the development of negative feelings of anxiety and depression; recognised as amongst the most common childhood disorders. It is suggested that by the age of 18, 1 in 10 children will have suffered from an anxiety disorder (Costello et al, 2003), with many more children experiencing serious symptoms that fall below clinical criteria for diagnosis. As FRIENDS contains universal, selective and indicated modes of delivery, it is intended to address all levels of prevention, early intervention, and treatment within a school setting.

FRIENDS has developed an impressive international evidence base since its official launch in 1991, with the positive results for anxiety and/or depression reduction in Australia (e.g. Lowry-Webster, Barrett, & Lock, 2003), Germany (Essau, Conradt, Sasagawa, & Ollendick, 2012), Mexico (Gallegos, Linan-Thompson, Stark, and Ruvalcaba, 2013), and recently, England (Stallard et al., 2014). FRIENDS is in use in at least 20 countries (including Ireland, where it forms part of the curriculum) and is currently endorsed by agencies such as the Substance Abuse and Mental Health Services Administration (who

have included it on their national registry of evidence-based programmes and practices). It is the only childhood anxiety prevention program acknowledged by the World Health Organization.

The FRIENDS programme consists of 10 weekly sessions, which aim to promote various protective factors, such as recognising physiological symptoms (e.g. session 2), emotional self-management (e.g. session 4), and supporting peer relationships (e.g. session 8). Indeed, the name of the programme is designed to help pupils recall and utilise the various skills taught in the sessions (**F**eelings; **R**emember to Relax; **I**nnner helpful thoughts; **E**xplore solutions and coping plans; **N**ow reward yourself; **D**o it every day; **S**tay strong inside). Each session is designed to last 60-75 minutes, but can also be conducted over two 30-35 minute periods instead. Additionally, there are two booster sessions that can be held approximately 1 to 3 months after completing the program, and two information sessions for parents of approximately 2 hours length each (though in correspondence with the EEF, we understand that this not a focus of this particular project). There have been significant revisions in the most recent editions of the FRIENDS programs (Barrett, Cooper, Guajardo, 2014), which now includes increased focus on addressing externalising symptoms.

Throughout various updates in content, the theoretical model underpinning FRIENDS can be consistently described as Cognitive Behaviour Therapy (CBT). The programme therefore teaches children skills in the cognitive (identify and challenge anxiety increasing cognitions), emotional (identify and manage anxiety), and behavioural (problem solve and face feared situations) domains. CBT has been described as the “gold standard” in the treatment of anxiety disorders (Otte, 2011, p.413), however, this recommendation has been largely based on clinical treatment in adults. Far less is known about the use of CBT when utilised as a preventative, universal intervention, especially within the English education system (Stallard, 2014). Findings from CBT use in children have tended to be community focused (Mychailyszyn et al., 2011) and/or been used with specialist populations, such as those identified with Autism Spectrum Disorder (e.g. Keehn, Lincoln, Brown, & Chavira, 2013). Indeed, Stallard was the first to report the outcomes of a universal cluster-randomised control trial of FRIENDS within English primary schools. Main effects were found for self-reported anxiety and depression scores, though no effects were found for the parent or teacher measures. These results bear further investigation, as the trial was not adequately powered to examine the subgroup of highly anxious pupils (therefore failing to fully consider differential gains in treatment vs. prevention), and there was little to no consideration of process evaluation. This is particularly important, as although Stallard noted that health professionals were, on average, more likely to generate greater effects than trained teachers, there is little in the way of empirical evidence to indicate why this might be so.

For the purposes of the current trial, ‘FRIENDS For Life’ is the specification version under evaluation. ‘FRIENDS for Life’ is one of three versions of the FRIENDS curriculum, designed specifically for ages 8-11 years (in contrast to FUN FRIENDS; ages 4-7, and My FRIENDS youth; ages 12-16). As the implementation of FRIENDS is encapsulated within an existing delivery team (Project Salus), there are minor adaptations and additions specific to the context. First, there a pre-implementation phase in which the delivery agent (commonly known as ‘coach’, or in this specific context, ‘project officer’) forms a relationship with a member of the school (see appendix 1). Second, parental lessons are not implemented in this specific context. Although part of the original intervention, parental sessions have not been identified as core component of the intervention and have been omitted. All other aspects of the intervention remained unchanged (see appendix 3).

1.3 The importance of who delivers FRIENDS

A key consideration in the implementation and delivery of FRIENDS is that of the intervention leader, specifically whether the intervention is delivered by a school or health professional (e.g. an undergraduate university degree in a relevant discipline and/or appropriate professional backgrounds such as, psychology or nursing). Trials have compared para/professional (e.g. school nurses) and teacher led delivery, though findings are mixed. For instance, Barrett and Turner (2001) found no difference between psychologist and teacher delivery, but conversely, Stallard (2014) notes an increased effectiveness when FRIENDS was delivered by ‘health facilitators’. No study of FRIENDS to date provides empirical evidence to indicate why such a difference might occur (though Stallard

hypotheses that implementer characteristics may be responsible). This element is worthy of further consideration given the implications for additional scale up and cost of the intervention. Although the study will not consider teachers as part of the programme delivery, there requires greater understanding of the mechanisms or process by which the programme is delivered – i.e. are we able to identify the components or features of the implementer and/or their delivery that can be attributed to success outcomes?

1.4 Effects on academic attainment

Given the primary purpose of the FRIENDS programme as a cognitive-behavioural preventative programme, there has been no prior consideration regarding its direct impact on academic attainment. However, there is clear evidence linking depression, worry and heightened anxiety with poorer academic attainment (Keogh, Bond, & Flaxman, 2006; Owens, Stevenson, & Hadwin, 2012), though it is important to distinguish between generalised, chronic anxiety and depression, and the more situational and acute test anxiety (e.g. Putwain, Connors, & Symes, 2010).

This suggests that, if examining the influence of FRIENDS on attainment, work is required on empirically validating a logic model for the intervention, in order to include academic attainment. A-priori pathways could be empirically tested as part of an evaluation protocol in order to demonstrate the relationship between proximal (i.e. anxiety) and distal (i.e. attainment) variables. The proposed study would therefore be the first to empirically examine the direct impact of FRIENDS on children's academic attainment.

As a final note, we believe that the current societal and education policy context is ideal for a trial of this type. There are serious concerns in UK society regarding the health-related burden of child mental health and the considerable associated economic and societal costs (Belfer, 2008). The mental health of children and young people is being increasingly recognised as a global priority. FRIENDS aligns closely with previous calls for early intervention both within the academy (e.g. Levitt, Saka, Romanelli, & Hoagwood, 2007) and from a policy perspective, as the current Education Secretary had made early intervention for mental health and wellbeing in children a priority and focus for the government (Department for Education, 2015b).

2. Evaluation strategy

Given the relatively short nature of the intervention (i.e. 10 weeks) and the minimal risk of contamination due to external delivery, the trial will be cluster-randomised, utilising matched pair randomisation at the class level, (utilising KS1 and baseline anxiety/depression scores (see section 2.5) for minimisation). We feel that this design offers the best balance between cost-effectiveness, power, and attractiveness (i.e. reduced attrition) to participating schools. The version of FRIENDS being implemented will be 'FRIENDS for life'.

2.1 Target sample

The trial will comprise of a single cohort of year 5 pupils from state-funded primary schools (e.g. community, foundation, or academy) who have not previously implemented FRIENDS. As the trial is designed to examine FRIENDS in the general school population, special schools are excluded from recruitment.

2.2. Stage of Trial

A small number of trials have shown FRIENDS to be effective in a UK setting, including a recent cluster-randomised control trial (Stallard et al. 2005; Stallard et al., 2007; Stallard et al., 2013). However, no study has yet examined academic attainment as a programme outcome, and implementation in an

effectiveness trial should take place in “at least three areas” (EEF, 2015). Therefore, the study has been designated by the EEF as ‘efficacy’. This has relevance for the current trial in two main areas; recruitment, and monitoring of implementation (see 2.5 ‘assessment of implementation and process’ for further discussion of implementation).

Regarding recruitment, there is a need to ensure a sufficient and co-operative number of schools in order to test the intervention components. However, as Salus will be using existing networks and contacts as part of the trial recruitment, it is important that FRIENDS is being examined rather than any common service or product provided by Salus. Receipt of service(s) from Salus would not necessarily preclude participation in the study (indeed, research notes the importance of existing infrastructure (Elliot & Mihalic, 2004; Spoth et al., 2004) but we would be keen to include schools from a variety of ‘starting positions’. In order to do this, we propose that Manchester and Salus work closely on ensuring an expansive and unbiased recruitment strategy, utilising all possible avenues. This will include a stratified sampling strategy to accurately represent the wider socio-demographic distribution in Kent Local Authority.

Manchester will provide all relevant technical details and documentation of the evaluation strategy, personnel and assistance at specific recruitment events (where possible), and will liaise with Salus regarding memoranda of agreement, baseline data collection, and informing schools of their allocation after randomisation.

2.3 Approach to randomisation

As above, the trial will be cluster-randomised, utilising matched pair randomisation at the class level, utilising KS1 and baseline ‘Revised-Child Anxiety and Depression’ scores for minimisation (see section 2.5 ‘assessment of outcomes’).

For each participating school:

- Single form entry: Randomly allocated to receive either FRIENDS, or £1000 (delivered at the end of the academic year)
- Double form entry: Random allocation of one class to receive FRIENDS, one class to serve as usual practice
- Triple form entry: Random allocation of either one or two classes to receive FRIENDS, with remaining classes to serve as usual practice.
 - one class to receive FRIENDS, one class to
- Four form entry: Random allocation of 2 classes to receive FRIENDS, two classes to serve as usual practice.

Regarding split classes (e.g. a merged year 4/5 class), this would be treated as a class of 15 year 5 pupils (assuming a class size of 30), and will be treated as such in the randomisation procedure. We will then monitor how schools decide to deliver the intervention.

All schools will be excluded from purchasing FRIENDS for use with the usual practice classes and/or their year 6 classes in the subsequent academic year (i.e. the original cohort).

A traditional concern of designs of this type is the expectation of the control group (or, in this context, more accurately referred to as ‘usual practice’ - UP) to seek “off-study” treatment, however in the current proposal, the evaluators have control over this behaviour (i.e. we will be able to ensure that as a condition of participation, any changes to practice are monitored). Similarly, as part of the collection of baseline data, we will be able to secure class lists for the project officer to compare when delivering the intervention, to ensure the schools are compliant with the randomisation process.

We will enlist the services of the Manchester Academic Health Science Centre Clinical Trials Unit (MAHSC-CTU) to complete the randomisation, to ensure an independent process, free from bias.

2.4 Power and sample size (PASS)

It is worth noting that although the following PASS calculations are based on detecting changes in attainment, this is a theoretically plausible *distal* consequence of the intervention. This is likely to mean the study is overpowered to detect the *proximal* effects of anxiety, depression, and worry. However, there are a small number of factors that mitigate this risk. For instance, the ICC for attainment is greater for that than anxiety, and there is strong cause to ensure subgroup differences (i.e. heightened levels of baseline anxiety) are included in the analysis.

As noted earlier, there is limited extant data on the impact of FRIENDS on attainment; therefore arriving at a precise effect size to use in our power calculations is difficult. Although a number of reviews have examined the effects CBT based intervention with children (e.g. Ishikawa, Okajima, Matsuoka, & Sakano, 2007; Cartwright-Hatton, Roberts, Chitsabesan, Fothergill, & Harrington, 2004), these have not included attainment as an outcome.

A further consideration is changes to the KS2 examination currently being introduced. In the summer term of 2016, children in year 2 and year 6 will undertake revised SATS examinations, reflecting the new national curriculum (Department for Education, 2014). The new examinations will be marked externally, cover reading, grammar and punctuation (including spelling), maths, and science (selected sample only). Scaled scores will be provided, and can be compared to national averages. For the trial cohort, KS1 examination (i.e. pre-test covariate) is based on the 'old' system, whereas the KS2 examination (i.e. post-test) will be based on the 'new' system. Although data will become available regarding the correlation between these two systems, this will not be available until after the trial has started and the protocol published. Therefore, power calculations do not include controlling for academic pre-test data (i.e. KS1).

Therefore, we have powered the study for a minimal detectable effect size (MDES) of 0.10. This represents a pragmatic limit in terms of a practical demonstration of effect, and is close to prior discussion relating to upper thresholds of available implementation resources:

All calculations assume: $N=28$ per cluster (Department for Education, 2015a); ICC (class level) = 0.17^1 , Power=0.8, Alpha=.05,² proportion of single form entry = 51%³, overall 10% attrition

MDES	Number of pupils	Number of classes	Approx. number of schools (of which are single form entry)
0.10	3,300	110	77 (55)

2.5 Assessment of outcomes

In discussion with the EEF, the following measures have been approved:

Attainment: The primary academic outcome measure will be KS2 Maths and English combined, as measured by the standardised curriculum tests conducted in July 2017. KS1 scores will be used as the baseline co-variate.

Non-academic outcomes: The primary non-academic outcome will be self-rated 'worry' as measured by the *Penn State Worry Questionnaire for Children (PSWQ-C)* (Meyer, Miller, Metzger, & Borkovec, 1990).

Secondary non-academic outcomes will be:

- Self-rated change in 'total anxiety and depression' score as measured by the *Revised Child Anxiety and Depression Scale (RCADS 30)* (Ebesutani et al., 2012)

¹ Estimate drawn from the largest academic ICC (KS2 results in writing) from the PATHS trial

² Although we would expect attrition to be low given the study design, we have included a conservative estimate drawn from previous trials (e.g. PATHS) with a loss of 9% in a C-RCT design.

³ Based on approximate data of Kent school sizes, provided by Salus

- Teacher rated difficulties (emotional symptoms) as measured by the *Strengths and Difficulties Questionnaire (SDQ)*.
- Teacher rated difficulties (conduct problems) as measured by the *Strengths and Difficulties Questionnaire (SDQ)*.
-

(note – online licensing agreements mean teachers will complete all 25 items of the SDQ)

Non academic outcomes will be measured at pre-test (Jan-Feb 2016) to facilitate randomisation, and again at post-test (December 2016).

We will liaise with both schools and Salus to maximise responses. For instance, discussing possible penalties for non-return of teacher data (for instance, a minimal return rate is required for allocation to the trial), creating and linking project websites, etc.

2.6 Assessment of implementation and process

Previous process evaluations of FRIENDS have typically been very limited, restricted to adherence to protocol, responsiveness, and limited study of acceptability (e.g. Kusters et al., 2012; Stallard et al., 2013). We would argue that this gap in knowledge is problematic for the continued scale up of the programme. Understanding implementation is vital for several reasons, not least that variability can affect outcomes (Humphrey, 2013). This has particular relevance to proposed study given the flexibility in delivery, as FRIENDS can be implemented at the universal, selective, or indicated level of prevention within a school. Understanding how and why schools vary their implementation, and what effect this might have on outcomes is vital.

Self-report from implementers: This role of implementer is of particular relevance to FRIENDS, given that differences in effect between teacher and external delivery has been hypothetically attributed to this element (Stallard, 2010), and has been noted as a factor in similar trials (Lendrum, Humphrey, & Wigelsworth, 2013). Accordingly, project officers will be asked to return brief reports from each of their delivery sessions, using an agreed pro-forma. Requested information will include categorical indicators of attendance, timing and length of the session, and pupil’s responsiveness (i.e. interest and enthusiasm) to the class. Self-report data will then be used as a basis to briefly interview project officers in terms of perceived feasibility, acceptability and utility of the programme by the school and pupils. We would also seek to understand and clarify whether any adaptation to the programme had been made by project officers, for instance, whether the follow up sessions are consistent with the booster sessions in the original programme. Similarly, we would capture decisions around small group (e.g. criteria for selection). Finally, we would ask project officers to complete a short battery of brief socio-demographic and attitudinal measures to be considered alongside implementation and outcome data.

Independent observations of implementation: Addressing concerns of demand characteristics and impression management (Humphrey, 2013), we add rigour and objectivity to self-report data by studying the implementation of the intervention through direct observations of the class as research demonstrates this to be much more closely related to intervention outcomes (Domitrovich, Gest, Jones, Gill, & DeRousie, 2010). Observations will be carried out by trained researchers, which will allow us to moderate self-report data and include implementation variability in the analyses (e.g. to what extent do implementation factors affect outcomes). Previous projects have employed custom quantitative assessment tools, and we would seek to replicate this approach using a bespoke pro-forma. We feel that observing each project officer for two sessions (ideally in two different schools), offers a good balance between cost and rigour.

Longitudinal case studies of implementation: As the project specification identifies flexibility in the intended delivery of the intervention (whether some children receive additional support through small group work) we would be keen to capture case studies of implementation, including the reasons

and criteria for how small groups are selected, why these are seen as beneficial, and to explore the wider context influencing these decisions (e.g. perceptions of social validity, acceptability and feasibility, and whether there is evidence of any displacement (e.g. if FRIENDS displaces something else that is equally effective) through document analysis, observations, and multi-informant interviews. E.g. senior leadership team / head teacher, class teacher, and pupil focus groups. We would employ a maximum variation approach in consultation with Salus to select approximately 8-10 willing case study schools. We would provisionally seek to select schools on the basis of location (urban /rural), relative affluence, pupil turnover, attainment, and any history of working collaboratively with Salus.

Usual practice survey: A critical consideration in the implementation of the FRIENDS curriculum is the extent to which it displaces, alters, or enables existing practice, both related, and independent to the programmes objectives (e.g. FRIENDS may replace other class-based mental health initiatives, or be used to link and supplement other programmes (e.g. anti-bullying). This information will be captured through a questionnaire completed by school staff (either SLT and/or SENCO), detailing any current provision (to assess the unique contribution of FRIENDS. This survey will include a request for CAMHS referral data to assess possible pupil-level changes in school provision. This survey will be repeated the following year to establish whether there are any changes post-intervention.

2.7 Assessment of Costs

For the base design, we would obtain up-to-date figures from Project Salus for the cost of the intervention and its delivery, and briefly survey the implementers as to any additional fixed (i.e. one-off) or variable (i.e. per pupil) costs incurred during delivery (e.g. photocopying of materials, any travel, any additional consultation directly relating to FRIENDS, etc) as per the EEF guidance on cost evaluation (EEF evaluators conference, 2015).. This will enable us to report on the start-up cost, 1 year, and 3 year running costs of implementing FRIENDS.

2.8 Analytical Strategy

We will conduct intention-to-treat (ITT) analyses for all pupils using hierarchical linear modelling to take into account the clustered and hierarchical nature of the study dataset. Effect sizes will be reported using Hedge's *g* (Cohen's *d* bias corrected) and accompanied by 95% confidence intervals as per EEF specifications. The Primary outcome will be KS2 Maths and English combined, as measured by the standardised curriculum tests conducted in July 2017. KS1 scores will be used as the baseline co-variate. Results will be converted into 'month progress'

We will also conduct ITT analyses for the instruments listed in section 2.5, specifically: Worry (as measured by the PSWQ-C), Anxiety/Depression (as measured by the RCADS- 30), and teacher rated emotional and conduct difficulties (as measured by the SDQ).

Several a-priori sub-group analyses have been agreed:

- Pupils eligible for Free School Meals (FSM)
- Those identified as 'at risk' at baseline - pupils scoring in the top 20% on the PSWQ-C.
- Pupils who also attended additional small group work as part of Project Salus's implementation plans (see appendix 1)

We will also model outcome data by implementation variability, and investigate temporal relations between outcome variables that might provide empirical evidence for the underlying logic model to the intervention. In this instance, we would make of structural equation modelling (SEM); specifically, multilevel path analysis (Shiple, 2009).

2.8 Ethics and Registration

All trial documentation and procedures have been reviewed and approved by Manchester's University Research Ethics Committee (committee 3) – reference number 16012. The trial was also prospectively register with the ISRCTN: reference number SRCTN13721202.

4. Timescale

	Trial Management	Project Delivery	Process Evaluation
Aug	Ethical Clearance Finalise trial protocol		
Sep			
Oct		Contact with schools	
Nov			
Dec			
2016			
Jan	Service agreements & Baseline collection		
Feb			
Mar	Follow up window (ensure against attrition) Scoring of baseline data Randomisation		
April		Intervention begins	Observations Interviews Case study data
May			
Jun			
Jul			
Aug			
Sep		Booster 1	
Oct			
Nov		Booster 2	
Dec	Post-test (non-academic)		
2017			
Jan			
Feb			
Mar			
April			
May			
Jun			
Jul		KS2 Testing	
Aug			
Sep			
Oct			
Nov			
Dec			

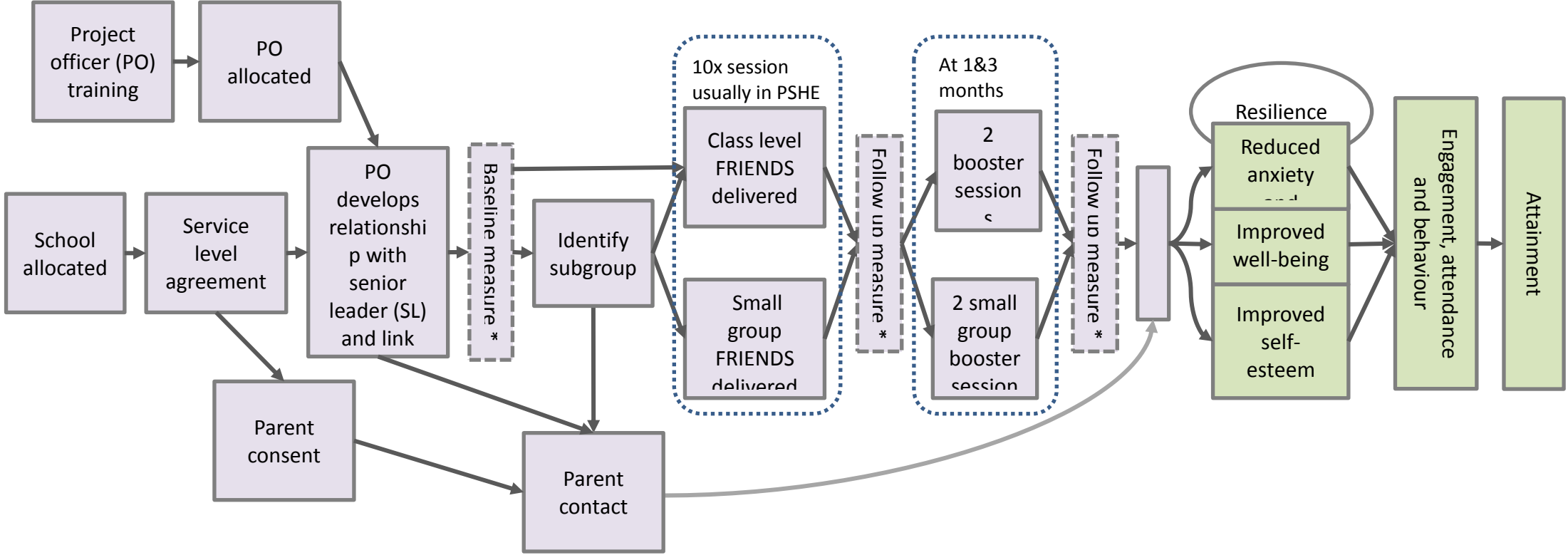
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Appendix 1: Draft logic model – SALUS FRIENDS intervention



*Stirling belonging, SDQ, attainment, attendance and behaviour

Appendix 2 – School breakdown

Average distribution of class entry across Kent

1 class entry	51%
2 class entry	27%
3 class entry	17%
4 class entry	4%

Appendix 3 - Intervention Description

Adapted from the template for intervention description and replication (TIDieR) checklist and guide (Hoffman et al, 2014).

1. Brief name:

FRIENDS For Life.

2. Why: describe any rationale, theory, or goal of the elements essential to the intervention

FRIENDS is a school-based, cognitive-behavioural preventative programme, designed to promote emotional resilience in order to prevent (or stabilise) the development of negative feelings of anxiety and depression.

The theoretical model underpinning FRIENDS can be consistently described as Cognitive Behaviour Therapy (CBT). The programme therefore teaches children skills in the cognitive (identify and challenge anxiety increasing cognitions), emotional (identify and manage anxiety), and behavioural (problem solve and face feared situations) domains.

3. What (materials): describe any physical or informational materials used in the intervention, including those provided to participants, used in intervention delivery, and/or training of intervention providers

The FRIENDS curriculum is manualised.

Group leaders manual: There are highly specified lesson plans for each session provided in the 'group leader's manual'. It is expected that the group leader (i.e. delivery agent - known in this trial as a 'Project Officer') delivers the session as specified in the manual. The manual provides objectives, an agenda, and major learning outcomes for each of the ten sessions. Specific scripts and a breakdown of each session are provided, and time to complete specified (as little as 2 minutes for warm up activities).

'Activity book for children': An additional booklet is provided which contains sheets that directly relate to the group leaders manual. It is recommended each child is provided a workbook, but photocopies can be prepared in advance of the session and distributed when needed. There are additional sheets to take home to work on activities as homework.

Additional class materials such as whiteboard markers, name tags, pictures for a collage activity, are listed by session if required.

4. What (procedures): Describe each of the procedures, activities and/or processes used in the intervention, including any enabling or support activities

The agenda for each session is highly specified. Each session in the manual has an agenda, which specifies the specific activities and time they should take to do, in 5-10 minute increments. Specific scripts are provided at points to introduce specific learning goals or activities.

5. Who provides: For each intervention provider (e.g. teacher, psychologist, youth worker), describe their expertise, background and any specific training given)

Each session is delivered by a group leader. This is an individual who has received FRIENDS training. The group leader can be teacher in the classroom or an external delivery agent. In the context of the current trial, group leaders (known as 'Project Officers') are external delivery agents, employed by Project Salus. They are not known to the schools.

The FRIENDS manual provides the option for older children to act as Assistant Group Leaders. It is recommended that if this is implemented, that the older children receive in-school training to understand the purpose of the FRIENDS curriculum.

6. Who receives: Provide a description of the target population for the intervention

FRIENDS for Life is a whole class intervention. The group leader delivers the curriculum to every pupil in the class, for each of the 10 sessions.

7. How: Describe the mode(s) of delivery (e.g. face to face) of the intervention and whether it is provided individually or in a group

FRIENDS is delivered in class, like a normal lesson, but with the option of an external implementer.

Small groups: FRIENDS may also be implemented as a small-group for selected anxious pupils. The precise number and criteria for small group work is decided by the teacher. In such cases, the curriculum is run as specified in the manual, but with a smaller group.

8. Where: Describe the type(s) of location(s) where the intervention occurs, including any necessary infrastructure or relevant features

FRIENDS takes place in a class setting, with no change to the layout or setup of the class. Some of the activities involve movement around the class (e.g. swapping group membership).

9. When and how much: Describe the number of times the intervention is to be delivered and over what period of time including (if applicable) the number of sessions, their schedule, and their duration, intensity or dose

The FRIENDS programme consists of 10 weekly sessions, which aim to promote various protective factors. Each session is mandatory and should be delivered as specified in the handbook (see below). Each session is designed to last 60-75 minutes, but can also be conducted over two 30-35 minute periods instead.

10. Tailoring: If the intervention is planned to be personalised or adapted, then describe what, why, when and how

Some options are provided for project officers to elect from – for instance, session 7 activities 2 recommends a guest speaker, but if one is unavailable, then the alternative for pupils to write a letter to that person instead.

In the instance of the current evaluation, an optional parental information session has been omitted. This element of the intervention does not form part of the core intervention.

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