

# The FRIENDS Programme: an evaluation of academic and emotional health outcomes

|  |   |   |
|--|---|---|
| <b>Submission date</b><br>04/11/2015   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>17/02/2016 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>02/07/2025       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

This one-year project will evaluate the effectiveness of a primary-school based intervention called FRIENDS. FRIENDS is designed to promote emotional resilience in order to prevent (or stabilise) the development of negative feelings of anxiety and depression, which are recognised as amongst the most common childhood disorders. FRIENDS is delivered both as a whole class programme, and also as a 'selective' or 'small group' intervention for particular pupils requiring additional support. 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, and is in use in at least 20 countries (including Ireland, where it forms part of the curriculum). It is the only childhood anxiety prevention program acknowledged by the World Health Organization. The project is important because research tells us that anxiety and depression are very common in children. It is suggested that by the age of 18, 1 in 10 children will have suffered from an anxiety disorder, with many more children experiencing serious symptoms that fall below clinical criteria for diagnosis. The aim of the FRIENDS curriculum is to prevent such problems before they occur, so it is important to see if, how, and why, and for who, the FRIENDS curriculum works for in English primary schools.

### Who can participate?

The study will take place in Kent Local Authority, so all children who are on a given participating school's full-time roll in year 5 at the start of the study will be considered as potential participants.

### What does the study involve?

About 80 schools are participating in the study. Within each school, we randomly allocate half of the year 5 classes to participate in FRIENDS and half of the year 5 classes to continue as normal. Classes allocated to FRIENDS attend 10 weekly FRIENDS sessions, including a 1 and 3 month 'booster' session. During this time, members of our team visit the schools to talk to the pupils and staff involved to try and understand how FRIENDS is delivered, and what participants think is good and bad about the way FRIENDS is delivered. At the end of the school year, schools are free to continue to implement FRIENDS. We take a range of measures at the start of the

FRIENDS programme (April 2016) and again in December to help us find out if FRIENDS is effective on range of outcomes, including emotional health, worry, wellbeing and behaviour. We also examine end of Key Stage 2 results to see if FRIENDS has helped with academic attainment.

What are the possible benefits and risks of participating?

The project presents the opportunity to participate in a large and rigorous educational research study which will help promote social and emotional wellbeing in education; furthermore, the survey data for each school is extremely useful for school planning and other requirements (e.g. school inspections). The surveys have been used in a range of studies before and have been carefully constructed for use in these types of research. Previous studies have found no reports of any adverse effects.

Where is the study run from?

The study will be conducted in primary schools in Kent.

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

August 2015 to December 2016.

Who is funding the study?

The Educational Endowment Foundation (UK).

Who is the main contact?

Dr Michael Wigelsworth

Michael.wigelsworth@manchester.ac.uk

## Contact information

### Type(s)

Public

### Contact name

Dr Michael Wigelsworth

### ORCID ID

<https://orcid.org/0000-0003-3361-6293>

### Contact details

University of Manchester

A6.3 Ellen Wilkinson Building

Oxford Road

Manchester

United Kingdom

M13 9PL

+44 (0)161 306 1763

Michael.wigelsworth@manchester.ac.uk

## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

### **Scientific Title**

Evaluating the efficacy of the FRIENDS programme in improving academic attainment and emotional health in primary-aged children in England: a cluster-randomised control trial

### **Acronym**

FRIENDS

### **Study objectives**

Primary outcomes

1. When compared to comparison classes, children in classes implementing FRIENDS over a ten-week period will demonstrate significant improvements in their:
  - 1.1. Academic attainment (as measured by their combined Maths and English Key Stage 2 scores)
  - 1.2. Self-rated worry

Secondary outcomes

2. When compared to comparison classes, children in classes implementing FRIENDS over a ten-week period will demonstrate significant improvements in their:
  - 2.1. Anxiety & depression
  - 2.2. Wellbeing
  - 2.3. Health-related quality of life
  - 2.4. Teacher-rated difficulties

Sub-group analysis

3. For RQs 1(a,b) & 2(a,b,c) there will be a significant differential effects on identified sub-groups of pupils:
  - 3.1. Pupils eligible for free school meals
  - 3.2. Pupils with elevated anxiety and/or depression at baseline

Implementation

4. Implementer and implementation outcomes will moderate programme outcomes

Validity of the logic model

5. Proximal changes in anxiety & depression and worry will be associated with improvements in academic attainment

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

University of Manchester's University Research Ethics Committee (UREC), 27/01/2015, ref: 16012

### **Study design**

Cluster-randomised control trial

### **Primary study design**

Interventional

### **Secondary study design**

Cluster randomised trial

### **Study setting(s)**

School

### **Study type(s)**

Prevention

### **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Worry, anxiety, depression

### **Interventions**

We will be approaching approximately 80 schools to participate in the research. The trial will be cluster-randomised, utilising matched-pair randomisation at the class level (utilising Key Stage 1 and baseline anxiety/depression scores for minimisation). Within each school, we will randomly allocate half of the year 5 classes to an intervention group and half of the year 5 classes to a comparison group. (This will mean that for most schools, one year 5 class will participate in FRIENDS, and one will continue as normal. Some smaller schools where there is only one year 5 class, will either receive the FRIENDS curriculum or a cash incentive instead).

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 (Feelings; Remember to Relax; Inner helpful thoughts; Explore solutions and coping plans; Now reward yourself; Do it every day; Stay 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. 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.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

1. Academic Attainment (as measured by combined Key Stage 2 English and Maths scores) - July 2016
2. Self-rated worry (as measured by the Penn State Worry Questionnaire for Children (PSWQ-C) - Jan-Mar 2016/December 2016

### **Secondary outcome measures**

1. Anxiety & depression (as measured by the Revised Children's Anxiety and Depression Scale (RCADS-30)) - Jan-Mar 2016/December 2016
2. Wellbeing (as measured by the Kidscreen 27) - Jan-Mar 2016/December 2016
3. Health-related quality of life (as measured by the Child Health Utility D9) - Jan-Mar 2016 /December 2016
4. Teacher-rated difficulties (as measured by the Strengths and Difficulties Questionnaire (SDQ)) - Jan-Mar 2016/December 2016

### **Overall study start date**

01/08/2015

### **Completion date**

31/12/2016

## **Eligibility**

### **Key inclusion criteria**

1. Born between 01/09/2004 and 31/08/2005 (within school year 5 for the 2015/2016 academic cohort)
2. Attending a mainstream state-funded primary school within Kent Local Authority
3. Primary school has not previously delivered FRIENDS

### **Participant type(s)**

Healthy volunteer

### **Age group**

Child

### **Sex**

Both

**Target number of participants**

3,300

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/01/2016

**Date of final enrolment**

29/02/2016

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre****University of Manchester**

Manchester Institute of Education

Oxford Road

Manchester

United Kingdom

M13 9PL

## **Sponsor information**

**Organisation**

University of Manchester (UK)

**Sponsor details**

Manchester Institute of Education

Oxford Road

Manchester

England

United Kingdom

M13 9PL

**Sponsor type**

University/education

**ROR**

<https://ror.org/027m9bs27>

# Funder(s)

## Funder type

Charity

## Funder Name

Educational Endowment Foundation (UK)

# Results and Publications

## Publication and dissemination plan

Intention is to publish at least one output for each of the study hypotheses noted in the trial protocol, primarily in peer-reviewed journals (but also potentially book chapters and other types of output). These will be published from 2016 onwards.

## Intention to publish date

31/12/2016

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Stored in repository

## Study outputs

| Output type                     | Details   | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | Secondary analysis of children at risk of anxiety disorders | 27/06/2025   | 02/07/2025 | Yes            | No              |