

Creating a fun and engaging storybook to help children more effectively manage their emotions

Submission date 22/05/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/05/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/07/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Autobiographical memory shapes our self-identity, self-esteem and wellbeing. Conversely, 'memory biases', the tendency to retrieve negative over positive memories from the past and future, and 'over-general memories', the difficulty recalling memories of specific events, are linked with poor mental health. As these memory styles increase risk for later mental health difficulties, they could be a potential target for interventions promoting wellbeing. The aim of this study is to investigate whether a storybook intervention co-produced by research and clinical scientists, a children's artist, and children aged 6-9 years old (and their parents), can teach children (and their parents/guardians) more 'helpful' memory styles.

Who can participate?

Children aged 6-9 years

What does the study involve?

Participants are randomly allocated to one of two groups, who receive either the intervention or control storybook. Both storybooks contain the same pictures and format and consist of a story, rationale and six exercises to be completed over a period of 3 weeks. Through a story about a central character, the intervention storybook includes information on how maladaptive responses to negative memories (such as avoidance) are unhelpful and suggests alternative positive responses (such as building detailed memories). It also provides information on building detailed positive future images. The text of the control storybook differs so that content on memory processes is not included. Feedback is solicited from children and parents/guardians.

What are the possible benefits and risks of participating?

It is not yet certain whether taking part will be of benefit to participants, but they will help to work out how best to support children, parents and teachers. There are no known risks for taking part in this study, but it is possible that talking about events in the past may make a child feel sad, and there will always be someone available for them to talk to and who can help.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
June 2017 to December 2020

Who is funding the study?
British Academy (UK)

Who is the main contact?
Dr Victoria Pile
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Improving cognitive health and wellbeing in children: increasing the specificity of future positive memories and past negative memories using storybook narratives and character illustrations

Study objectives

The aim of this study is to investigate the acceptability, feasibility and preliminary effectiveness of a storybook intervention targetting memory processes in children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Psychiatry, Nursing and Midwifery Research Ethics Subcommittee of the College Research Ethics Committee (CREC) at King's College London, 23/05/2018, ref: HR-16/17-4115

Study design

Interventional feasibility randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Depression and anxiety

Interventions

Children will be randomly allocated to receive the storybook ("My Memory Forest") or control intervention. Both will contain the same pictures and format. Both the storybooks will consist of a story, rationale and 6 exercises to be completed over a period of three weeks. Through a story about a central character, "My Memory Forest" includes information on how maladaptive responses to negative memories (such as avoidance) are unhelpful and suggests alternative positive responses (such as building detailed memories). It also provides information on building detailed positive future images. The text of the control book will differ so that content on memory processes is not included.

Intervention Type

Other

Primary outcome measure

Feasibility and acceptability of the intervention are assessed by recording numbers of eligible participants, recruitment rate, retention rate, outcome measure completion rate, data completeness, data on adherence/compliance, and feedback questionnaires

Secondary outcome measures

All measures are administered pre and post intervention unless otherwise stated

Child measures:

1. Depression is measured using the Center for Epidemiological Studies-Depression (CES-D)
2. Anxiety is measured using the social anxiety, generalised anxiety and separation anxiety subscales on the Spence Children's Anxiety Scale (SCAS)
3. Self-esteem is measured using the Rosenberg self-esteem scale
4. Memory specificity is measured using the Autobiographical Memory Task pre and post-intervention
5. Mental imagery for future events is measured using the Prospective Imagery Task
6. Participants will be asked to complete positive and negative mood ratings before and after completing each exercise

Parent report:

1. Internalising symptoms (for the child) will be measured using the subscales of the Strengths and Difficulties Questionnaire (SDQ)
2. Depression is measured using the Patient Health Questionnaire (PHQ-9)
3. Anxiety is measured using the Generalised Anxiety Disorder Assessment (GAD-7)
4. Mental imagery for future events is measured using the Prospective Imagery Task

Overall study start date

30/06/2017

Completion date

31/12/2020

Eligibility

Key inclusion criteria

Children aged 6-9 years

Participant type(s)

All

Age group

Child

Lower age limit

6 Years

Upper age limit

9 Years

Sex

Both

Target number of participants

56

Key exclusion criteria

1. Child/caregiver has insufficient English language ability to complete the questionnaire measures and intervention
2. Child has severe learning disability or sensory impairment

Date of first enrolment

30/05/2018

Date of final enrolment

05/06/2020

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

King's College London

Institute of Psychiatry, Psychology and Neuroscience

London

United Kingdom

SE5 8AF

Sponsor information**Organisation**

King's College London

Sponsor details

Guy's Campus

London

England

United Kingdom

SE1 4UL

Sponsor type

University/education

Website

<https://www.kcl.ac.uk/index.aspx>

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Research organisation

Funder Name

British Academy

Alternative Name(s)

The British Academy

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

1. Planned publication of outcomes to peer-reviewed journal within a year from end of trial
2. Dissemination via conferences and to schools/NHS services at a local level
3. Protocol will be available on request

Intention to publish date

31/12/2021

Individual participant data (IPD) sharing plan

It is planned to make individual participant data available on publication of the associated study results, via a publicly-available data repository such as Open Science Framework. Data made available will be the research data reported in the publication, with the exception of any data that could compromise participant anonymity.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	feasibility results				

Results article	24/06/2021	05/07/2021	Yes	No
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