

1-2-3 Magic treatment for families with children with attention deficit hyperactivity disorder (ADHD)

Submission date 14/09/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/12/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/10/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Current plain English summary as of 23/02/2022:

Background and study aims

Children with attention deficit hyperactivity disorder (ADHD) are often unable to think coherently before reacting to situations (impulsivity). This can be tedious for parents/carers to manage and if not approached correctly can cause the situation to escalate instead of being neutralised. 1-2-3 Magic is a psychological behavioural intervention that equips parents with tools to manage problem behaviours. 1-2-3 Magic aims to educate parents/carers and even teachers about ADHD and also aids parents with effective strategies, such as communication skills, for handling their child's symptoms. 1-2-3 Magic also teaches parents to be confident in raising their child in order to build a healthy parent-child relationship. Although there are a few previous studies on 1-2-3 Magic, they do not observe the efficacy of 1-2-3 Magic specifically in children with ADHD. This research is important in improving the wellbeing of both children with ADHD and their parents/carers, in order to create a greater quality of life. 1-2-3 Magic teaches parents how to diffuse tantrums and negative behaviours and to encourage positive behaviours, this could improve home life, and the parent-child relationship can be mended. Theoretically, not only does 1-2-3 Magic improve wellbeing at home but also at school. If teachers are equipped with 1-2-3 Magic the classroom may be a safer environment for the children with ADHD and their peers. 1-2-3 Magic has already been used by different organisations, including some NHS trusts, but there has been no formal clinical trial conducted to evaluate the effectiveness especially for families with children diagnosed with ADHD in the UK.

This study will be the first to research the effectiveness of such an intervention in the UK specifically in families with children with ADHD. NICE guidelines recommendations for research regarding ADHD are "What is the clinical and cost-effectiveness, and optimum length, of a brief parent-training intervention for parents and carers of children and young people with attention deficit hyperactivity disorder (ADHD) aged 5 to 18 years?" Therefore this study falls into the NICE guideline recommendations.

Who can participate?

Parents of children aged 12 years old and under with diagnosed ADHD

What does the study involve?

Parents will attend six sessions of two and a half hours per session over a course of 6 weeks. The sessions will consist of training in behavioural management techniques using the key tools “1-2-3 Magic” and the “Evaluation tools on parenting.”

Parents of ADHD children will be recruited through the National Attention Deficit Disorder Information and Support Service (ADDISS). 100 participants will be randomly allocated into either group 1, 2 or 3. Follow-up time from the first to the last observation time for each person is 12 months. Each group will have the opportunity to attend the 1-2-3 Magic intervention with 3 months apart between each group. Group 1 will receive the intervention at month 1 while groups 2 and 3 will serve as control groups/wait-list groups. Groups 2 and 3 will receive standard care, including parent support groups, general advice, one-to-one consultations, resources, a wraparound service building relationships between parent and child, and psychoeducation for the parents while waiting to receive the intervention. At month 4, group 2 will receive intervention and group 3 will remain the control group. Finally, group 3 will also receive the intervention at month 7.

What are the possible benefits and risks of participating?

1-2-3 Magic is a psychological behavioural intervention that equips parents with tools to manage problem behaviours. 1-2-3 Magic aims to educate parents/carers and teachers about ADHD and aids parents with effective strategies, such as communication skills, for handling their child's symptoms. 1-2-3 Magic enables parental confidence in raising their child and building a healthy parent-child relationship.

Participants will receive a £5 Tesco voucher at 5 different timepoints upon completion of the outcome measurement questionnaires.

There are no risks of participating. All participants are waiting to be involved in this intervention in the first place, therefore this study allows them all a chance to participate, when previously they may have to wait for months to a year to join.

Where is the study run from?

1. University College London (UK)
2. ADDISS (UK)

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

September 2021 to May 2023

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Prof. Ian Wong
wongick@hku.hk

Previous plain English summary:

Background and study aims

Children with attention deficit hyperactivity disorder (ADHD) are often unable to think coherently before reacting to situations (impulsivity). This can be tedious for parents/carers to manage and if not approached correctly can cause the situation to escalate instead of being neutralised. 1-2-3 Magic is a psychological behavioural intervention that equips parents with tools to manage problem behaviours. 1-2-3 Magic aims to educate parents/carers and even teachers about ADHD and also aids parents with effective strategies, such as communication skills, for handling their child's symptoms. 1-2-3 Magic also teaches parents to be confident in

raising their child in order to build a healthy parent-child relationship. Although there are a few previous studies on 1-2-3 Magic, they do not observe the efficacy of 1-2-3 Magic specifically in children with ADHD. This research is important in improving the wellbeing of both children with ADHD and their parents/carers, in order to create a greater quality of life. 1-2-3 Magic teaches parents how to diffuse tantrums and negative behaviours and to encourage positive behaviours, this could improve home life, and the parent-child relationship can be mended. Theoretically, not only does 1-2-3 Magic improve wellbeing at home but also at school. If teachers are equipped with 1-2-3 Magic the classroom may be a safer environment for the children with ADHD and their peers. 1-2-3 Magic has already been used by different organisations, including some NHS trusts, but there has been no formal clinical trial conducted to evaluate the effectiveness especially for families with children diagnosed with ADHD in the UK.

This study will be the first to research the effectiveness of such an intervention in the UK specifically in families with children with ADHD. NICE guidelines recommendations for research regarding ADHD are "What is the clinical and cost-effectiveness, and optimum length, of a brief parent-training intervention for parents and carers of children and young people with attention deficit hyperactivity disorder (ADHD) aged 5 to 18 years?" Therefore this study falls into the NICE guideline recommendations.

Who can participate?

Parents of children with diagnosed ADHD, under the age of 12 years.

What does the study involve?

Parents will attend six sessions of two and a half hours per session over a course of 6 weeks. The sessions will consist of training in behavioural management techniques using the key tools "1-2-3 Magic" and the "Evaluation tools on parenting."

Parents of ADHD children will be recruited through the National Attention Deficit Disorder Information and Support Service (ADDISS). 84 participants will be randomly allocated into either group 1, 2 or 3. Follow-up time from the first to the last observation time for each person is 12 months. Each group will have the opportunity to attend the 1-2-3 Magic intervention with 3 months apart between each group. Group 1 will receive the intervention at month 1 while groups 2 and 3 will serve as control groups/wait-list groups. Groups 2 and 3 will receive standard care, including parent support groups, general advice, one-to-one consultations, resources, a wraparound service building relationships between parent and child, and psychoeducation for the parents while waiting to receive the intervention. At month 4, group 2 will receive intervention and group 3 will remain the control group. Finally, group 3 will also receive the intervention at month 7.

What are the possible benefits and risks of participating?

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Who is the main contact?
Prof. Ian Wong
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

19227/003

Study information

Scientific Title

A randomised wait-list controlled trial evaluating 1-2-3 Magic and its effectiveness on families with children with ADHD

Study objectives

1-2-3 Magic will reduce child problem behaviours, improve parenting self-efficacy and strengthen child-parent relationships.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 29/11/2021, University College London Research Ethics Committee (University College London, 2 Taviton St, London, WC1E 6BT, UK; +44 (0)20 7679 8717 ext: 28717; ethics@ucl.ac.uk), ref 19227/003

Study design

Randomized wait-list controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Behavioural parenting programme for parents with children with ADHD

Interventions

To test the effectiveness of the 1-2-3 Magic Programme administered online via Zoom, a randomised waiting-list controlled trial has been designed to evaluate whether 1-2-3 Magic can reduce parents' perceived severity of their child's symptoms of ADHD, thereby building parent confidence and improving familial relationships.

84 parents of children with diagnosed ADHD, under the age of 12, will attend six sessions of two and a half hours per session over a course of 6 weeks. The sessions will consist of training in behavioural management techniques using the key tools "1-2-3 Magic" and the "Evaluation tools on parenting."

The 1-2-3 Magic programme has a duration of 6 weeks, with one session per week.

Arm 1:

Arm 1 will start their intervention within the same month of the baseline and just after the baseline measurement in month 1. Arm 1 will complete questionnaires at six timepoints. Arm 1's baseline questionnaire will also pose as their pre-intervention questionnaire: baseline/month 1 (pre-intervention), 6 weeks after pre-intervention, month 3, month 6, month 9 and month 12.

Arm 2:

Arm 2 will start their intervention 3 months after the baseline in March 2022. Arm 2 serve as the control group for 3 months. Arm 2 will complete questionnaires at 6 timelines: baseline (month 1), month 3 (pre-intervention), 6 weeks after pre-intervention, months 6, months 9 and months 12.

Arm 3:

Arm 3 will start their intervention 6 months after the baseline, in July 2022. Arm 3 serve as the control group for 6 months. Arm 3 will complete questionnaires at 6 timelines: baseline (month 1), months 3, months 6 (pre-intervention), 6 weeks after pre-intervention, months 9 and months 12.

Randomisation will be conducted via online random allocators.

Intervention Type

Behavioural

Primary outcome measure

Parent self-efficacy measured through Tool to Measure Parenting Self-Efficacy (TOPSE) will be measured at the baseline session, before the first session (for arms 2 and 3), the last session of the programme and 6 months follow-up

Secondary outcome measures

Child disruptive behaviour through Eyberg Child Behaviour Inventory (ECBI) will be measured at the baseline session, before the first session (for arms 2 and 3), the last session of the programme and 6 months follow-up

Overall study start date

14/09/2021

Completion date

30/05/2023

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 25/07/2023:

1. Parents of children aged 12 years old and under
2. Parents of children with an official diagnosis of ADHD
3. Parents who speak, read, and write proficient English

Previous participant inclusion criteria:

1. Parents of children under the age of 12 years
2. Parents of children with an official diagnosis of ADHD
3. Parents who speak, read, and write proficient English

Participant type(s)

Mixed

Age group

Adult

Sex

Both

Target number of participants

100

Total final enrolment

100

Key exclusion criteria

Individual cannot read, write or speak proficient English

Date of first enrolment

01/12/2021

Date of final enrolment

31/03/2022

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

ADDISS

10th Floor

Hyde House

The Hyde
London
United Kingdom
NW9 6LH

Sponsor information

Organisation

University College London

Sponsor details

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Sponsor type

University/education

Website

<http://www.ucl.ac.uk/>

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

The main findings of this study will be submitted to peer-reviewed journals or other academic publications (e.g., PhD thesis) and presented at national and international conferences. Results will also be disseminated via ADDISS to their patients and practitioner network.

The researchers will send families a summary of the study results at the end of this project. This summary will give the overall results of this project – individual families will not be identified. Results will also be disseminated to the NHS so they can update their guidelines /recommendation regarding this intervention.

Intention to publish date

30/08/2023

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Recruitment methods	17/10/2023	23/10/2023	Yes	No