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Does sleeping with a comfort item make a difference in how well kids sleep compared to not sleeping with a comfort item?

Submission date
11/12/2024

Recruitment status
No longer recruiting

Registration date
10/01/2025

Overall study status
Completed

Last Edited
07/10/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Randomised controlled trials are an important way to answer research questions and are the gold standard to decide if an intervention (like a new medicine or behaviour change) does what it is supposed to do. We think the public, especially kids, should understand what randomised trials are and why they matter. Having a better understanding of randomised trials and health research will also help children think critically about health information they encounter in their daily lives. We thought the best way to teach kids about trials would be to help them conduct one, as they have great ideas and can be great researchers!
The Kid's Trial is an online, randomised trial that invites kids between 7 and 12 years of age to co-create a trial with us and participate in the trial they create. Participating in The Kid's Trial will help children understand what randomised trials are and why they matter and help them think critically about health information they encounter in daily life.
In The Kid's Trial, children around the world were invited to send in low-risk, fun health questions they wanted to test. Children then voted for their favourite question and planned how to answer it. Their chosen question is, 'Does sleeping with a comfort item (for example, a soft toy or special blanket) make a difference in how well kids sleep compared to not sleeping with a comfort item?' We are now inviting kids worldwide to join this citizen-science randomised trial called the REST (Randomised Evaluation of Sleeping with a Toy or comfort item) trial.

Who can participate?
Any child around the world between 7 and 12 years of age who can access the study website and understand English

What does the study involve?
When kids (with their guardian's consent) agree to join the REST trial, they will randomly be put into one of two groups. The intervention, or 'try-it-out', group will sleep with a comfort item of their choice for 7 nights in a row. The control, or 'wait-and-see', group will not sleep with a comfort item for 7 nights in a row. A computer will decide who goes into which group randomly to make sure that everyone who joins the trial has a fair and equal chance to be in either group. After the trial, kids will fill out a survey where we will ask them about their sleep and how they

felt during the trial. The trial results will help the researchers understand if sleeping with a comfort item made a difference in how well kids slept.

What are the possible benefits and risks of participating?
Joining the REST trial could benefit kids by helping them learn about health research and randomised trials and improve their critical-thinking skills. The results will also help the researchers understand kids' sleep better.
Joining the REST trial shouldn't be risky for children or their parents or caregivers. There is a possibility that some children would like to be in a different group than the one that they are randomised to. Children can withdraw from the trial at any point, and no one will be upset by this.

Where is the study run from?
This study is based in the School of Nursing and Midwifery in the College of Medicine, Nursing, and Health Sciences, University of Galway, Galway, Ireland.

When is the study starting, and how long is it expected to run?
November 2021 to June 2025

Who is funding this study?
1. Health Research Board – Trials Methodology Research Network of Ireland
2. University of Galway (Ireland)

Who is the main contact?
Simone Lepage, s.lepage1@universityofgalway.ie

Study website
https://www.thekidstrial.ie/

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The Kid’s REST (Randomised Evaluation of Sleeping with a Toy or comfort item) Trial: an online, randomised trial of comfort item use on sleep quality in children

Acronym
The Kid’s REST Trial

Study objectives
Does sleeping with a comfort item (for example, a soft toy or special blanket) make a difference to how well kids (between the ages of 7 and 12 years of age) sleep compared to not sleeping with a comfort item?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/02/2023, University of Galway Research Ethics Committee (The Research Office, University of Galway, Galway, H91 TK33, Ireland; +353 (0)91 495312; ethics@universityofgalway.ie), ref: 2023.02.014

Study design
Online pragmatic superiority unblinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet

The participant information sheets can be found on the homepage https://www.thekidstrial.ie/ under the 'Parents' & Caregivers' Information Flipbook' and the 'Kids' Information Flipbook'.

Health condition(s) or problem(s) studied
Sleep-related impairment among primary-school-aged children

Interventions
Children can enrol in the trial and will be randomised to either the intervention group (sleeping with a comfort item) or the control group (sleeping without a comfort item) and do their trial at home for 7 days.

Both groups (intervention and control) will do the trial at home for 7 consecutive days. Participants will be randomised to their allocated group upon joining the trial in a 1:1 ratio. Due to the nature of the trial, blinding is not possible for either participants or researchers.
The intervention group (also called the 'try-it-out' group) will:
1. Choose one comfort item (the comfort item can be any item of choice that a child identifies, for example, a toy, blanket, or other item safe to sleep with) to sleep with for the duration of the trial before starting the trial
2. Sleep with the same comfort item each night for the duration of the trial
3. Start using their comfort when they start getting ready for bed (for example, if they normally read a book before bed, they should use their comfort item then and take it with them when they go to bed) each night for the duration of the trial
4. Sleep in their usual bed each night for the duration of the trial (if a child has more than one home, for example, a boarding school or multiple family homes, both will be considered their usual bed)
5. Keep everything else about their bedtime the same as usual

The control group (also called the 'wait-and-see' group) will:
1. Not sleep with any comfort items at night for the duration of the trial
2. Sleep in their usual bed each night for the duration of the trial (if a child has more than one home, for example, a boarding school or multiple family homes, both will be considered their usual bed)
3. Keep everything else about their bedtime the same as usual

Intervention Type
Behavioural

Primary outcome measure
Sleep-related impairment measured using the Patient-Reported Outcomes Measurement Information System (PROMIS) Pediatric Item Bank v1.0 – Sleep-Related Impairment- Short Form 4a at baseline (Pre-randomisation) and 1 day after trial completion (8 days post-randomisation). Sleep-related impairment is taken using a visual analogue scale (VAS).

Secondary outcome measures
Overall sleep quality is measured using the single-item Sleep Quality Scale (SQS) at baseline (pre-randomisation) and 1 day after trial completion (8 days post-randomisation). Sleep quality is measured using a visual analogue scale (VAS)

Overall study start date
01/11/2021

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Any child between 7 and 12 years of age
2. Any child who can understand enough English to understand the website and its contents
3. Any child who has access to the website
4. All children must have guardian consent

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
7 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
292

Key exclusion criteria
1. A child who does not have guardian consent
2. A child who is unable to understand and give assent

Date of first enrolment
13/01/2025

Date of final enrolment
15/09/2025

Locations

Countries of recruitment
Afghanistan

Albania

Algeria

American Samoa

Andorra

Angola

Anguilla

Antarctica

Antigua and Barbuda

Argentina

Armenia

Aruba

Australia

Austria

Azerbaijan

Bahamas

Bahrain

Bangladesh

Barbados

Belarus

Belgium

Belize

Benin

Bermuda

Bhutan

Bolivia

Bonaire Saint Eustatius and Saba

Bosnia and Herzegovina

Botswana

Bouvet Island

Brazil

British Indian Ocean Territory

Brunei Darussalam

Bulgaria

Burkina Faso

Burundi

Cabo Verde

Cambodia

Cameroon

Canada

Cayman Islands

Central African Republic

Chad

Chile

China

Christmas Island

Cocos (Keeling) Islands

Colombia

Comoros

Congo

Congo, Democratic Republic

Cook Islands

Costa Rica

Croatia

Cuba

Curaçao

Cyprus

Czech Republic

Côte d'Ivoire

Denmark

Djibouti

Dominica

Dominican Republic

Ecuador

Egypt

El Salvador

England

Equatorial Guinea

Eritrea

Estonia

Eswatini

Ethiopia

Falkland Islands

Faroe Islands

Fiji

Finland

France

French Guiana

French Polynesia

French Southern Territories

Gabon

Gambia

Georgia

Germany

Ghana

Gibraltar

Greece

Greenland

Grenada

Guadeloupe

Guam

Guatemala

Guernsey

Guinea

Guinea-Bissau

Guyana

Haiti

Heard Island and McDonald Islands

Holy See (Vatican City State)

Honduras

Hong Kong

Hungary

Iceland

India

Indonesia

Iran

Iraq

Ireland

Isle of Man

Israel

Italy

Jamaica

Japan

Jersey

Jordan

Kazakhstan

Kenya

Kiribati

Korea, North

Korea, South

Kosovo

Kuwait

Kyrgyzstan

Lao People's Democratic Republic

Latvia

Lebanon

Lesotho

Liberia

Libya

Liechtenstein

Lithuania

Luxembourg

Macao

Madagascar

Malawi

Malaysia

Maldives

Mali

Malta

Marshall Islands

Martinique

Mauritania

Mauritius

Mayotte

Mexico

Micronesia, Federated States of

Moldova

Monaco

Mongolia

Montenegro

Montserrat

Morocco

Mozambique

Myanmar

Namibia

Nauru

Nepal

Netherlands

New Caledonia

New Zealand

Nicaragua

Niger

Nigeria

Niue

Norfolk Island

North Macedonia

Northern Ireland

Northern Mariana Islands

Norway

Oman

Pakistan

Palau

Palestine, State of

Panama

Papua New Guinea

Paraguay

Peru

Philippines

Pitcairn

Poland

Portugal

Puerto Rico

Qatar

Romania

Russian Federation

Rwanda

Réunion

Saint Barthélemy

Saint Helena, Ascension and Tristan da Cunha

Saint Kitts and Nevis

Saint Lucia

Saint Martin (French part)

Saint Pierre and Miquelon

Saint Vincent and the Grenadines

Samoa

San Marino

Sao Tome and Principe

Saudi Arabia

Scotland

Senegal

Serbia

Seychelles

Sierra Leone

Singapore

Sint Maarten (Dutch part)

Slovakia

Slovenia

Solomon Islands

Somalia

South Africa

South Georgia and the South Sandwich Islands

South Sudan

Spain

Sri Lanka

Sudan

Suriname

Svalbard and Jan Mayen

Sweden

Switzerland

Syria

Taiwan

Tajikistan

Tanzania

Thailand

Timor-Leste

Togo

Tokelau

Tonga

Trinidad and Tobago

Tunisia

Turkmenistan

Turks and Caicos Islands

Tuvalu

Türkiye

Uganda

Ukraine

United Arab Emirates

United Kingdom

United States Minor Outlying Islands

United States of America

Uruguay

Uzbekistan

Vanuatu

Venezuela

Viet Nam

Virgin Islands, British

Virgin Islands, U.S.

Wales

Wallis and Futuna

Western Sahara

Yemen

Zambia

Zimbabwe

Åland Islands

Study participating centre
University of Galway
College of Medicine, Nursing, and Health Sciences
School of Nursing & Midwifery
Aras Moyola
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Sponsor information

Organisation
Trials Methodology Research Network

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Sponsor type
Research organisation

Website
https://www.hrb-tmrn.ie/

ROR
https://ror.org/05y8p4437

Organisation
Ollscoil na Gaillimhe – University of Galway

Sponsor details
College of Medicine, Nursing, and Health Sciences
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Sponsor type
University/education

Website
https://www.universityofgalway.ie/medicine-nursing-and-health-sciences/

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Funder Name
University of Galway

Alternative Name(s)
Coláiste na hOllscoile, Gaillimh, Ollscoil na hÉireann Gaillimh, Queen's College, Galway, University College, Galway, NUI Galway, National University of Ireland, Galway, National University of Ireland Galway, Ollscoil na Gaillimhe, National University of Ireland, Galway/NUI Galway, NUI Galway, OÉ Gaillimh

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Ireland

Results and Publications

Publication and dissemination plan
The researchers expect two publications to result from this research study. They plan to describe the processes used in the creation of the citizen science project, The Kid's Trial, in a peer-reviewed trials methodology journal. The second publication will describe the REST trial methods and results in a peer-reviewed journal.

The results of the trial will be presented at international conferences for trial methodology and clinical trials.

The researchers will also publish the results of the REST trial on their website and in a yet unknown method based on the final step of The Kid's Trial, where they will ask children how they would like to share their results.

Intention to publish date
01/06/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. The repository used is Open Science Framework (OSF): https://osf.io/tsre8/. The results shared will be those collected from participating kids in the REST trial and will be made available once the trial is complete and after full anonymisation of the data is complete. These records will remain in the OSF database. Parents of participants are aware that data will be published only after it is completely anonymised.

IPD sharing plan summary
Stored in publicly available repository