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

Submission date	Recruitment status	<ul><li>[X] Prospectively registered</li><li>Protocol</li></ul>		
11/12/2024	No longer recruiting			
Registration date	Overall study status	Statistical analysis plan		
10/01/2025	Completed	☐ Results		
Last Edited	Condition category	Individual participant data		
07/10/2025	Mental and Behavioural Disorders	[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 cocreate 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

# Contact information

# Type(s)

Public, Scientific, Principal investigator

### Contact name

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# Additional identifiers

# Clinical Trials Information System (CTIS)

Nil known

# ClinicalTrials.gov (NCT)

Nil known

# Protocol serial number

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

# Study type(s)

Treatment

# 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(s)

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).

# Key secondary outcome(s))

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

# 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

# Healthy volunteers allowed

No

# Age group

# Child Lower age limit 7 years

# Upper age limit

12 years

### Sex

All

# 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

**United Kingdom** 

England

Northern Ireland

Scotland

Wales

Afghanistan

Åland Islands

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
Equatorial Guinea
Eritrea
Estonia
Eswatini
Ethiopia
Falkland Islands
Faroe Islands
Fiji
Fiji Finland
-
Finland
Finland France
Finland France French Guiana
Finland France French Guiana French Polynesia
Finland France French Guiana French Polynesia French Southern Territories
Finland France French Guiana French Polynesia French Southern Territories Gabon
Finland France French Guiana French Polynesia French Southern Territories Gabon Gambia
Finland France French Guiana French Polynesia French Southern Territories Gabon Gambia Georgia
Finland France French Guiana French Polynesia French Southern Territories Gabon Gambia Georgia Germany

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
Могоссо
Mozambique
Myanmar
Namibia
Nauru
Nepal
Netherlands
New Caledonia
New Zealand
Nicaragua
Niger
Nigeria
Niue
Norfolk Island

North Macedonia
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
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



Virgin Islands, U.S.
Wallis and Futuna
Western Sahara

Yemen

Zambia

Zimbabwe

# Study participating centre University of Galway

College of Medicine, Nursing, and Health Sciences School of Nursing & Midwifery Aras Moyola Upper Newcastle Road Galway Ireland H91 HX31

# Sponsor information

# Organisation

Trials Methodology Research Network

### **ROR**

https://ror.org/05y8p4437

# Organisation

Ollscoil na Gaillimhe – University of Galway

# **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**

# 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

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes