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Girls United cluster randomized controlled trial

Submission date
18/01/2025

Recruitment status
No longer recruiting

Registration date
04/03/2025

Overall study status
Ongoing

Last Edited
13/05/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This study focuses on young adolescent girls who often talk excessively and negatively with their close friends about their problems, a behavior known as co-rumination. This can lead to depression, anxiety, and lower friendship quality. The study aims to test a new school-based program called Girls United, which combines mindfulness training and psycho-education to help reduce co-rumination and improve mental health and well-being.

Who can participate?
Girls aged 10 to 12 years old, attending mainstream primary schools in the Netherlands, who show high levels of co-rumination, can participate. The study involves 160 pairs of close friends (dyads).

What does the study involve?
Participants will be divided into two groups. One group will receive the Girls United program for 14 weeks, which includes weekly online lessons on mindfulness and psycho-education. The other group will continue with their usual school activities. The program aims to help girls develop better emotional regulation and improve their friendships.

What are the possible benefits and risks of participating?
The study is expected to have minimal risks and will not disrupt regular school activities. Participants may benefit from improved mental health, better emotional regulation, and stronger friendships. They will also contribute to important research on preventing co-rumination and internalizing issues in young girls.

Where is the study run from?
The study is run by Rotterdam University of Applied Sciences in the Netherlands.

When is the study starting and how long is it expected to run for?
The study started in January 2021 and is expected to run until December 2027.

Who is funding the study?
Nationaal Regieorgaan Praktijkgericht Onderzoek SIA (Netherlannds)

Who is the main contact?
Patricia Vuijk, p.vuijk@hr.nl.

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SVB/ RAAK.PRO04.005

Study information

Scientific Title
Effectiveness of an integrated, blended mindfulness- and psycho-education program for the prevention of co-rumination and internalizing problems in Dutch primary school girls: A cluster Randomized Controlled Trial

Acronym
GirlsUnited

Study objectives
Current study hypothesis as of 14/04/2025:

1. Girls in the intervention group will have a greater reduction in co-rumination (primary outcome) about distress and difficult emotions and feelings, (and thereby) internalizing

symptoms (depression/anxiety, secondary outcome) and negative affect (secondary outcomes) during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.
2. Girls in the intervention group will have less dyadic depression contagion, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.
3. Girls in the intervention group will demonstrate less dyadic anxiety contagion during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.
4. Girls in the intervention group will experience better friendship quality, higher levels of positive affect and higher levels of interpersonal responses to positive affect, during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.
5. The hypothesized intervention effects on co-rumination will be mediated by the development of mindfulness and emotion regulation skills during the intervention period, immediately after the intervention period and after one-year follow-up.
6. Girls in the intervention group will experience greater feelings of self-worth and will show less health care use during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.

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Previous study hypothesis:

1. Girls in the intervention group will have a greater reduction in co-rumination about distress and difficult emotions and feelings, (and thereby) internalizing symptoms and negative affect during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.
2. Girls in the intervention group will have a later onset of depressive symptoms or a later onset of depressive disorder and less dyadic depression contagion, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.
3. Girls in the intervention group will demonstrate a later onset of anxiety symptoms or a later onset of anxiety disorder and less dyadic anxiety contagion during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.
4. Girls in the intervention group will experience better friendship quality, higher levels of positive affect and higher levels of interpersonal responses to positive affect, during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.
5. The hypothesized intervention effects on co-rumination will be mediated by the development of mindfulness and emotion regulation skills during the intervention period, immediately after the intervention period and after one-year follow-up.
6. The hypothesized intervention effects on co-rumination will be moderated by self-control: girls with more developed self-control skills will demonstrate greater intervention effects immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.
7. Girls in the intervention group will experience less stress symptoms, less anhedonic symptoms, greater feelings of self-worth and will show less health care use during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 07/05/2025, MEC-U (Koekoekslaan 1, Nieuwegein, 3435 CM, Netherlands; +31 883208784; info@mec-u.nl), ref: 25.006

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Co-rumination and internalizing problems in Dutch primary school girls

Interventions
The Girls United prevention program aims to foster social-emotional-behavioural self-regulation within a supportive close-friendship context through incorporation of both dyadic and individual experiential mindfulness-based learning. Developed between 2020 and 2023 using the Intervention Mapping Approach for health promotion planning, the program includes 14 weekly online lessons delivered by trained facilitators. These lessons integrate psychoeducation and mindfulness practices, guiding participants in using the application App yourself Happy app within their friendship dyads. The program's aim is to support 160 Dutch girls (80 dyads) aged 10 to 12 who are at high risk, helping them shift from maladaptive to adaptive emotion regulation patterns in their daily interactions. This approach encourages the benefits of close, intimate friendships while introducing healthy alternatives to excessive co-rumination.In the control condition, girls receive unchanged any regular care and regular education.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 14/04/2025:

1. Self-reported co-rumination measured using CRQ-Short at T0, T1, T2, T3, T4 and T5.

Baseline measure (T0): Sept 2025 (Cohort 1) & Feb 2026 (Cohort 2)
T1 measure: Nov 2025 (Cohort 1) & April 2026 (Cohort 2)
T2 measure: Jan 2026 (Cohort 1) & June 2026 (Cohort 2)
T3 measure: March 2026 (Cohort 1) & Oct 2026 (Cohort 2)
T4 measure : May 2026 (Cohort 1) & Dec 2026 (Cohort 2)
Follow-up measure (T5): May 2027 (Cohort 1) & Dec 2027 (Cohort 2)

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Previous primary outcome measure:

1. Self-reported risk for (early onset) depression measured using CDI-2 at T0, T1, T2, T3, T4 and T5.
2. Self-reported co-rumination measured using CRQ-Short at T0, T1, T2, T3, T4 and T5.

Baseline measure (T0): Sept 2025 (Cohort 1) & Feb 2026 (Cohort 2)
T1 measure: Nov 2025 (Cohort 1) & April 2026 (Cohort 2)
T2 measure: Jan 2026 (Cohort 1) & June 2026 (Cohort 2)
T3 measure: March 2026 (Cohort 1) & Oct 2026 (Cohort 2)
T4 measure : May 2026 (Cohort 1) & Dec 2026 (Cohort 2)
Follow-up measure (T5): May 2027 (Cohort 1) & Dec 2027 (Cohort 2)

Key secondary outcome(s))
Current secondary outcome measures as of 14/04/2025:

1. Self- and friend-reported friendship quality measured using the NRI at T0, T1, T2, T3, T4 and T5.
2. Self-reported positive and negative affect measured using the PANAS-C at T0, T1, T2, T3, T4 and T5.
3. Self-reported interpersonal responses to positive affect measured using the CoDEQ at T0, T1, T2, T3, T4 and T5.
4. Self-reported anhedonic symptoms measured using the LASS at T0, T1, T2, T3, T4 and T5.
5. Self-reported anxiety symptoms measured using the RCADS at T0, T1, T2, T3, T4 and T5.
6. Self-reported self-worth measured using the CBSK at T0, T1, T2, T3, T4 and T5.
7. Self-reported stress measured using the Stress Vragenlijst voor Kinderen at T0, T1, T2, T3, T4 and T5.
8. Self-reported risk for (early onset) depression measured using CDI-2 at T0, T1, T2, T3, T4 and T5.

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Previous secondary outcome measures:

1. Self- and friend-reported friendship quality measured using the NRI at T0, T1, T2, T3, T4 and T5.
2. Self-reported positive and negative affect measured using the PANAS-C at T0, T1, T2, T3, T4 and T5.
3. Self-reported interpersonal responses to positive affect measured using the CoDEQ at T0, T1, T2, T3, T4 and T5.
4. Self-reported anhedonic symptoms measured using the LASS at T0, T1, T2, T3, T4 and T5.
5. Self-reported anxiety symptoms measured using the RCADS at T0, T1, T2, T3, T4 and T5.
6. Self-reported self-worth measured using the CBSK at T0, T1, T2, T3, T4 and T5.
7. Self-reported stress measured using the Stress Vragenlijst voor Kinderen at T0, T1, T2, T3, T4 and T5.

Completion date
31/12/2027

Eligibility

Key inclusion criteria

To be eligible for inclusion, a participant/girl must meet all of the following criteria:
1. Aged 10 to 12 years.
2. Visiting a primary school of RiBA, BLICK op Onderwijs, and Scholennetwerk BSI (i.e., collaborative school network).
3. Attending 5th or 6th grade of mainstream upper primary education in academic year 2025 /2026 or 2026/2027.
4. Being a cisgender woman or being a transgender woman.
5. Having a good or best friend (being a cisgender woman or being a transgender woman) at the same school.

To be eligible for inclusion, a dyad/girls must meet the following inclusion criteria:
By lack of an official cut-off score for high co-rumination levels, we will base our inclusion on a distribution-based technique. That is, we will include friendship dyads of which at least one of the two girls, or both girls, have a score above the median co-rumination screening score of the cohort on the Co-rumination Questionnaire-Short (Hankin, Stone & Wright, 2010). This will result in a sample of the 50% highest scoring girls on co-rumination. Note that a distribution-based technique is a common-used technique to select a high-risk population of clinical significance in the absence of meaningful clinical cut-offs (Sloan, Symonds, Vargas-Chanes & Fridley, 2003).

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 years

Upper age limit
12 years

Sex
Female

Key exclusion criteria
Exclusion criteria at participant/girl level:
1. Following and/or participating in an another individual or group-based mindfulness-based training in academic year 2025/2026 or 2026/2027.

Exclusion criteria at the school level (to mitigate any risk of difficulties in trial implementation):
1. Not having a headteacher in academic year 2025/2026 or 2026/2027.
2. Judged as ‘inadequate’ during the most recent school inspection by the Dutch Inspectorate of Education.
3. Implementing another mindfulness-based intervention in academic year 2025/2026 or 2026 /2027.

Date of first enrolment
01/06/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Netherlands

Study participating centre
Rotterdam University of Applied Sciences
Rochussenstraat 198
Rotterdam
Netherlands
3015 EK

Sponsor information

Organisation
Rotterdam University of Applied Sciences

ROR
https://ror.org/0481e1q24

Funder(s)

Funder type
Government

Funder Name
Nationaal Regieorgaan Praktijkgericht Onderzoek SIA

Alternative Name(s)
Nationaal Regieorgaan Praktijkgericht Onderzoek, National Board of Practice-Oriented Research SIA, National Board of Practice-Oriented Research, Regieorgaan SIA, NRPO-SIA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be stored in a non-publicly available repository ResearchDrive.
- The App yourself Happy app collects personal data. YipYip has developed the app. YipYip is a Dutch company but engages a sub-processor where personal data collected by the app is hosted: Google Cloud Platform. The company is based in the United States, but the servers where the data is are hosted in the Netherlands. YipYip has made appropriate agreements with Google regarding the processing of personal data. To be able to monitor the implementation of the training program, the PI and both PhD-students will receive a login link with a personal login-code to access this data file. Data will be stored under a pseudonym. The keyfile which links the participants to their pseudonyms will only be accessible by the PI and the PhD-students.
- Questionnaires. Questionnaire data will be collected using Qualtrics. No physical data (e.g., paper questionnaires) will be collected, used, or stored. All data will be stored on Research Drive.
- The training sessions will be recorded with BigBlueButton for training and intervision purposes but only when the parents/main caretakers
provided their approval on the informed consent form. The videorecordings will be automatically transported to Research Drive by
BigBlueButton. Nobody but the PI and the two main researchers have access to the videorecordings.

The study targets female adolescents aged 10-12 years. Parents or main caretakers must provide written consent, but only if their child is willing to participate. Twelve-year-olds must also sign an IC form, in addition to obtaining consent from their parents or main caretakers. Signed IC from both parents or main caretakers is essential for participation.

The data will be accompanied by a short overview of the instruments and constructs used (.pdf format) for each of the phases of the study. This gives an at-a-glance overview of the available data. (instrument names, constructs, scales and subscales, admitted waves, expected N, etc.). For a more in-depth overview of the data, a codebook (.pdf format) will be created. (instruction text, variable labels, value labels, variable info, calculated variables, syntax, references, etc.). Data gathered during the school data collection and implementation study will be accompanied by a digital logbook per person per training session. This logbook contains some general information (name, date, schoolId/classId, etc.) and a checklist (checklists for all tasks, and open text fields to allow the trainers to write down comments). This data will be transported to an encrypted MS Access database (.accdb) and the digital files will be removed after ten years.

Data minimization and anonymization
A minimal set of information is collected to be able to put into perspective the research question, following the data minimization principle. Identifying data will be pseudonymized before they are analyzed, so: no names will be used, only an artificial identifier (string of digits). Furthermore, other identifying data, age and education are de-identified, by not using absolute values, but broader categories, which prevent an inference attack from revealing disclosed information, but generalizing the identifying information.

Anonymization/pseudonymization and storage
Collection and processing of personal data for the purpose of the research project will be carried out exclusively by the PI, the data manager and PhD-students. The keys will be known only to the PI and the PhD-students. De-anonymization may occur only for the purpose of assessment of scientific integrity and upon a request thereto by a competent authority (CA). All research data is stored on Research Drive.

Sharing during research
In order to facilitate co-operative research over long-distance and only if necessary, with regard to the purpose of the research project, research data including personal data may be shared among the PI and all researchers (including the data manager). Data linked to published papers will be made openly available minus any data that can be considered personal data (video data). For the purpose of sharing pseudonymized research data over distance, researchers will use ResearchDrive or the Dutch cloud service SURFdrive. SURFdrive is designed especially for higher education and research purposes and offers researchers and staff an easy way to share and synchronize files within a secure community cloud with ample storage capacity. All SURFdrive information security protocols meet high standards. The Dutch Legal Framework for Cloud Services serves as a guideline for all service-related agreements. SURFdrive complies with Dutch and European privacy legislation. In addition, access to SURFdrive is password protected and designated folders can be password protected. Communication to and from SURFdrive is encrypted. If shared via SURFdrive, files that contain personal data are placed in designated and password protected folders. In addition, such shared files will be encrypted. Keys to encrypted shared files are held by the PI and secondary researchers.

Sharing after research
When the study is completed, the underlying research data may be shared with third parties for the purposes of reproduction, reuse or assessment of scientific integrity. The sharing of research data connected to a publication is subjected to contractual obligations with the publisher. Data linked to published papers will be made openly available minus any data that can be considered personal data. The sharing of research data with third parties will be carried out with the use of DANS Easy. DANS Easy is certified with Data Seal of Approval and World Data System and uses persistent identifiers to make data FAIR. Files that contain personal data will not be stored on DANS Easy unless they are anonymized and/or pseudonymized. Files that contain personal data will be stored in DarkStore, an offline archive for storing sensitive information/data without a persistent identifier. Files stored in DarkStore will not be shared with third parties, unless the purpose of reproduction, reuse or assessment of scientific integrity justifies otherwise. In that event such files may be released subject to identification of the requestor accompanied by a purpose statement and approval by the CA of Rotterdam University of Applied Sciences.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 4.0	30/04/2025	13/05/2025	No	No