

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.

Published: 07-05-2025

Last updated: 16-05-2025

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57463

Source

ToetsingOnline

Brief title

The Girls United Study

Condition

- Other condition

Synonym

corumination, internalizing symptoms and disorders (depression/anxiety)

Health condition

corumneren, internaliserende symptomen en stoornissen (depressie/angst)

Research involving

Human

Sponsors and support

Primary sponsor: Hogeschool Rotterdam

Source(s) of monetary or material Support: NRO/Citylab010/SIA KIEM

Intervention

Keyword: co-rumination, internalizing problems, prevention, RCT

Outcome measures

Primary outcome

Self-reported co-rumination

Secondary outcome

Secondary outcome measures are self-reported anxiety symptoms, self-reported depression symptoms, self-reported friendship quality, self-reported positive and negative affect, interpersonal responses to positive affect, self-reported anxiety symptoms, self-reported self-worth.

Study description

Background summary

Research shows that young adolescent girls who engage in excessive, speculative, and negatively focused discussions with friends about interpersonal problems and worries * a behaviour also known as co-rumination* face a greater risk of developing internalizing symptoms (i.e., depression and anxiety) and reduced friendship quality. Currently there are no school-based prevention programs available that specifically address high levels of co-rumination in young adolescent girls aged 10-12-years old. Mindfulness training, with a focus on present-moment awareness, appreciation, gratitude, and awareness of the dynamics between thoughts, emotions, bodily sensations, and impulses, can be helpful for girls who engage in repetitive and judgmental

negative interactions. To address this need, we developed a blended, mindfulness and psycho-education prevention program called Girls United and the current cluster Randomized Controlled Trial will test program's effectiveness in primarily reducing co-rumination and secondarily internalizing problems. Girls United aims to teach mindfulness skills at a dyadic level, i.e., between two close female friends and thereby helps young girls prone to co-rumination incorporate these techniques into their daily lives. This evidence-based prevention program will then be implemented across Dutch mainstream primary schools.

Study objective

The primary aim of the cluster Randomized Controlled Trial (cRCT) is to evaluate the effectiveness of the Girls United prevention program on self- and parent-reported mental health outcomes in a sample of max 320 young adolescent girls aged 10 to 12 (attending mainstream primary schools in the Netherlands) displaying high levels of self-reported co-rumination. Additionally, the study aims to identify the mechanisms of change of the program.

Study design

The Girls United cluster Randomised Controlled Trial has two arms: (1) an intervention condition in which max 80 girls* friendship dyads (n = max 160 with high levels of self-reported co-rumination) will receive the Girls United program for 14 weeks, and (2) a control condition in which max 80 girls* friendship dyads (n = max 160 with high levels of self-reported co-rumination) will receive teaching-and-care-as-usual (TAU). The intervention will be offered in two consecutive cohorts during academic year 2025/2026 and 2026/2027. Randomisation will take place at the classroom level.

Intervention

The Girls United prevention program aims to foster social-emotional-behavioral self-regulation within a supportive close-friendship context through incorporation of both dyadic and individual experiential 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.

Study burden and risks

The study is expected to pose minimal burden and risks for participating girls, as it does not interfere or disrupt their regular education practices and focuses on naturally occurring interactions and activities within their close friendships. Additionally, the study provides an opportunity for participants to contribute to research aimed at enhancing understanding and preventing excessive co-rumination and internalizing issues in adolescent girls.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Children (2-11 years)

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 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 (Loan, Symonds, Vargas-Chanes & Fridley, 2003).

Exclusion criteria

Exclusion criteria at participant/girl level:

1) 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	11-04-2025
Enrollment:	1000
Type:	Anticipated

Ethics review

Approved WMO	
Date:	07-05-2025
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL88776.100.25