# A transdiagnostic mental health intervention for adolescents in the Norwegian school health services

<b>Submission date</b> 19/09/2024	Recruitment status	[X] Prospectively registered		
19/09/2024	Recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
04/10/2024	Ongoing	Results		
Last Edited	Condition category	Individual participant data		
10/06/2025	Mental and Behavioural Disorders	[X] Record updated in last year		

#### Plain English summary of protocol

Background and study aims

Many young people in Norway face challenges with their mental health, and school nurses play a key role in supporting them. To help with this, we have developed an intervention called Kort (which means "Brief" in Norwegian), designed together with young people and school nurses. Kort aims to improve how young people manage their emotions, which can reduce the risk of developing mental health problems. The intervention focuses on five key strategies: setting goals, learning about emotions (psychoeducation), mindfulness, changing negative thoughts (cognitive restructuring), and encouraging positive activities.

The study will explore how well each of these strategies works in improving emotion regulation and overall mental health in young people.

#### Who can participate?

The study will involve 100 school nurses and 300 adolescents aged 12-18 years from across Norway. The young people taking part will have contacted their school nurse because they are struggling with difficult emotions, thoughts, or stress.

# What does the study involve?

If you take part in this study, you will receive the Kort intervention over a period of 10 weeks, with at least four sessions with your school nurse. The sessions will take place at your school.

You will also be asked to complete a daily questionnaire on your phone about how you are feeling. This will take just a few minutes each day. In addition to daily questionnaires, you will also be asked to complete some longer questionnaires before and after the 10-week period, and possibly take part in interviews about your experience.

Each completed questionnaire will earn you tokens, which you can collect and later exchange for a digital gift card.

What are the possible benefits and risks of participating?

Participating in this study gives you the chance to learn new ways to manage stress, difficult thoughts, and emotions. You will also be contributing to research that could help improve mental health support for other young people in the future.

As with any study, there are some risks. You may find it challenging to talk about your emotions or complete daily questionnaires. However, you can always choose to skip a question or stop participating at any time.

Where is the study run from?

The study is being run by the Centre for Child and Adolescent Mental Health in Oslo, Norway.

When is the study starting and how long is it expected to run for? The study was in planning in January 2023. We will continue to recruit participants until June 2026, with the results expected to be published in 2026-2027.

Who is funding the study?

The study is funded by the Research Council of Norway.

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#### Study website

https://kort.rbup.no/

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# Additional identifiers

# EudraCT/CTIS number

Nil known

#### **IRAS** number

# ClinicalTrials.gov number

Nil known

# Secondary identifying numbers

326941

# Study information

#### Scientific Title

Optimizing a transdiagnostic mental health intervention for adolescents: a randomized controlled trial of Kort in Norwegian school health services

#### **Study objectives**

Primary research question:

What is the individual effect of each of the Kort elements (i.e., Setting goals with the adolescent, Exploring emotions, thoughts, and reactions in the body and how they are connected, Exploring health promoting activities, Practicing psychological flexibility, Practicing mindfulness.) on adolescent emotion regulation?

#### Secondary research questions:

- 1. What is the individual effect of each of the Kort elements (i.e., Setting goals with the adolescent, Exploring emotions, thoughts, and reactions in the body and how they are connected, Exploring health promoting activities, Practicing psychological flexibility, Practicing mindfulness.) on adolescent emotion regulation?
- 2. Through which emotion regulation strategies do the Kort elements affect adolescent mental health?
- 3. Do Kort elements change emotion regulation differently for any subgroups (e.g., age group, gender, problem load)?
- 4. How is Kort perceived by school nurses and adolescents?

# Ethics approval required

Ethics approval required

# Ethics approval(s)

- 1. Approved 27/09/2024, Regional Committees for Medical and Health Research Ethics (Kongens gate 14, Oslo, 0153, Norway; +47 23 31 83 00; post@forskningsetikk.no), ref: 755856
- 2. Approved 19/09/2024, Norwegian Agency for Shared Services in Education and Research (PO 5782 Torgarden, Trondheim, 7437, Norway; +47 73 98 40 40; postmottak@sikt.no), ref: 333366

# Study design

Multicentre interventional randomized controlled trial

#### Primary study design

Interventional

# Secondary study design

Cluster randomised trial

#### Study setting(s)

School

# Study type(s)

Prevention, Quality of life, Efficacy

#### Participant information sheet

See study outputs table

#### Health condition(s) or problem(s) studied

Prevention of mental health problems and promotion of well-being in adolescents aged 12-18 years who consult with a school nurse due to emotional challenges

#### **Interventions**

The Kort intervention targets emotion regulation in adolescents and is tailored to be delivered by school nurses in the Norwegian school health setting. Kort consists of five treatment elements, two of which are to be delivered in the first session (goal setting and psychoeducation about thoughts, feelings and sensations in the body).

School nurses will be randomized to provide one of the three remaining elements (cognitive restructuring, positive activities, og mindfulness), or care as usual (CAU).

A block randomization scheme is applied using the following criteria: 1) each block has its own training site and dates. 2) for each block, a minimum of 4 school nurses must be allocated to each condition. 3) school nurses who work in the same school are allocated to the same condition (to avoid contamination).

The school nurses recruit adolescents who approach the school nurse due to emotional difficulties (e.g., stress, challenging thoughts, feelings, or emotions). The adolescents receive the intervention elements or CAU, based on their school nurse's allocation.

#### Intervention Type

Behavioural

#### Primary outcome measure

#### Adolescents:

Adolescents receive digital questionnaires every day during the trial period (71 days). They receive a baseline questionnaire on day 1 (T1), questionnaires measuring proximal outcomes of target intervention elements after the first and second session with the school nurse (T2 and T3, respectively, and a post-questionnaire after the intervention period (T4). In addition, adolescents receive daily diary questionnaires (DD) and weekend questionnaires (WW). The outcomes and measures are as follows:

- 1. Mental Health literacy is measured using a self-developed questionnaire at T1, T2, T3, and T4
- 2. Emotion regulation (trait) is measured by the Difficulties in emotion regulation scale short form (DERS-SF) at T1, T3, and T4
- 3. Emotion regulation (state) is measured using a daily self-developed questionnaire (DD)
- 4. Emotions and emotional intensity are measured using Positive and Negative Affect Schedule (PANAS-SF), daily (DD)
- 5. Mindfulness is measured using the Five Facet Mindfulness Questionnaire (FFMQ-15) and the the Mindful Attention Awareness Scale (MAAS) at T1, T2, T3, and T4
- 6. Disordered thinking/cognitive fusion is measured using the Cognitive Fusion Questionnaire (CFQ) at T1 and T4
- 7. Internalizing and externalizing symptoms are measured using Behavior and Feelings Survey (BFS) at T1 and T4
- 8. Well-being is measured using the Short Warwick-Edinburgh Mental Wellbeing Scale

#### (SWEMWBS) at T1 and T4

- 9. Functional impairment is measured using a self-developed questionnaire at T1 and T4
- 10. Loneliness is measured by the Three-item loneliness scale (T-ILS) at T1 and T4
- 11. General mental Health is measured by the Behaviors and Feelings Scale (BFS) at WW
- 12. Avoidance is measured by Child Avoidance Measure-Self Report (CAMS) at T1, T4 and DD
- 13. Working alliance is measured by the Working Alliance Inventory short revised (WAI-SR) at T2, T3, and T4

#### School nurses:

School nurses fill out digital questionnaires about each adolescent after each session. The questionnaires are tailored to the intervention elements, and are all self-developed. They contain items measuring:

- 1. The school nurse's assessment of whether the session was useful for the adolescent, in general
- 2.The school nurse's assessment of the perceived value and achieved functions of each of the intervention elements and activities that were applied in that session (i.e., Setting goals and assessing goal attainment, exploring how thoughts, feelings and bodily sensations are connected, exploring challenging thought patterns and practicing identification and modification of them, planning and scheduling positive activities, practicing mindfulness exercises).

#### Secondary outcome measures

- 1. Self-compassion is measured by Self-compassion scale youth version (SCS-Y) at T1, T4 and DD
- 2. Sleep is measured by a single self-developed item at T1 and T4
- 3. Friendships is measured by a self-developed questionnaire at T1 and T4
- 4. School attendance and alcohol consumption is measured by a self-developed questionnaire at T1 and T4

# Overall study start date

01/01/2023

#### Completion date

30/06/2026

# **Eligibility**

#### Key inclusion criteria

- 1. Adolescents (12-18 years) who seek help from a school nurse due to challenges with emotions, thoughts, feelings, or stress
- 2. School nurses, or other health professionals (20-80 years) who work in the lower or upper secondary school health services, and who routinely have consultations with adolescents

# Participant type(s)

Health professional, Service user

#### Age group

Mixed

#### Lower age limit

12 Years

#### Upper age limit

80 Years

#### Sex

Both

# Target number of participants

400

#### Key exclusion criteria

- 1. Adolescents who consult with school nurses due to concerns about somatic problems
- 2. Adolescents who have clinical level mental disorders warranting specialized mental health care
- 3. Health nurses who are not currently employed in a upper or lower school health service (e.g., works at a community health centre for youth)

#### Date of first enrolment

21/11/2024

#### Date of final enrolment

30/06/2026

# Locations

#### Countries of recruitment

Norway

# Study participating centre Lesja skole

Norway 2665

# Study participating centre Vinstra ungdomsskole

Norway 2640

# Study participating centre Ringebu ungdomsskole

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Study participating centre Lom ungdomsskole Norway 2686

Study participating centre Dokka ungdomsskole Norway 2870

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Study participating centre Create VGS Norway 2615

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Study participating centre Vestby ungdomsskole Norway 1540

Study participating centre Asker VGS Norway 1386

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Study participating centre Bakkeløkka ungdomsskole Norway 1454

Study participating centre Gystadmarka ungdomsskole Norway 2069

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#### Sponsor type

Government

#### Website

https://www.rbup.no/about-us

#### Organisation

Norwegian Institute for Public Health

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Government

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Fremsam

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Other

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# Funder(s)

#### Funder type

Government

#### **Funder Name**

Norges Forskningsråd

#### Alternative Name(s)

Forskningsrådet, Norwegian Research Council, Research Council of Norway

#### Funding Body Type

Government organisation

# **Funding Body Subtype**

National government

#### Location

Norway

# **Results and Publications**

#### Publication and dissemination plan

Results will be made available:

- For participants and the general public through the project website and project members' social media platforms
- For school health professionals through local and/or domestic congresses, and through the host institution's teaching curriculum
- For the research community through several publications in open access peer-reviewed international journals, as well as Norwegian language journals

#### Intention to publish date

01/06/2027

# Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the study will be stored in a publicly available repository by Sikt – the Norwegian Agency for Shared Services in Education and Research (https://www.sikt.no/en/find-data). All quantitative data described in the protocol will be deidentified and uploaded by December 2027 and will be available indefinitely.

#### 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			19/09/2024	No	Yes
Other files			11/03/2025	No	No
Protocol file			11/03/2025	No	No