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

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

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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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Prevention, Quality of life, Efficacy

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(s)

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 (CFO) 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).

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

12 years

Upper age limit

80 years

Sex

All

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 recruitmentNorway

Study participating centre Lesja skole Norway 2665

Study participating centre Vinstra ungdomsskole Norway 2640

Study participating centre Ringebu ungdomsskole Norway 2630

Study participating centre Heidal skole Norway 2676

Study participating centre Otta ungdomsskole Norway 2670

Study participating centre Gausdal VGS Norway 2651

Study participating centre Lillehammer VGS Norway 2609

Study participating centre Hammartun barne- og ungdomsskole Norway 2609

Study participating centre Lom ungdomsskole Norway 2686

Study participating centre Dokka ungdomsskole Norway 2870

Study participating centre Skreia ungdomsskole Norway 2848

Study participating centre NTG ungdomsskole Norway 2618

Study participating centre NTG videregående skole Norway 2618

Study participating centre Åretta ungdomsskole Norway 2613

Study participating centre Skjåk barne- og ungdomsskole Norway 2690

Study participating centre Sjåk videregående skole Norway 2686

Study participating centre Lom ungdomsskole Norway 2686

Study participating centre Dokka VGS Norway 2870

Study participating centre Vågå ungdomsskole Norway 2680

Study participating centre Smestad ungdomsskole Norway 2619

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Study participating centre Nord-Gudbrandsdal videregående skole avd. Otta Norway 2670

Study participating centre Søndre Land ungdomsskole Norway 2860

Study participating centre Lena ungdomsskole Norway 2850

Study participating centre Lena – Valle VGS Norway 2850

Study participating centre Solvang skole Norway 2636

Study participating centre Akademiet VGS Norway 6004

Spjelkavik VGS

Norway 6011

Study participating centre Spjelkavik ungdomsskole Norway 6011

Study participating centre Ålesund VGS Norway 6008

Study participating centre Spjelkavik ungdomsskole Norway 6011

Study participating centre Skarbøvik ungdomsskole Norway 6006

Study participating centre Eide ungdomsskole Norway 6490

Study participating centre Ulstein ungdomsskoleNorway
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Study participating centre Sula ungdomsskule Norway 6039

Study participating centre Ulstein VGS Norway 6065

Study participating centre Fræna ungdomsskole Norway 6440

Study participating centre Blindheim ungdomsskole Norway 6011

Study participating centre Bud barne og ungdomsskole Norway 6430

Study participating centre Hustad barne og ungdomsskole Norway 6444

Hustadvika VGS

Norway 6440

Study participating centre Borgund VGS

Norway 6011

Study participating centre

Fusa VGS

Norway 5640

Study participating centre Voss ungdomsskole

Norway 5700

Study participating centre Sotra VGS

Norway 5353

Study participating centre

Hop VGS

Norway 5307

Study participating centre Ravnanger ungdomsskole

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Study participating centre Fusa ungdomsskole Norway 5640

Study participating centre Nore neset ungdomsskole Norway 5217

Study participating centre Voss VGS Norway 5710

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Study participating centre Voss gymnas Norway 5700

Study participating centre Fjell ungdomsskole Norway 5353

Study participating centre Kleppestø ungdomsskole Norway 5300

Study participating centre Askøy VGS Norway 5300

Study participating centre Vormsund ungdomsskole Norway 2160

Study participating centre Nesodden VGS Norway 1459

Vesong ungdomsskole Norway 2040

Study participating centre Grevlingen ungdomsskole Norway 1555

Study participating centre Vestby ungdomsskole Norway 1540

Study participating centre Asker VGS Norway 1386

Study participating centre Nannestad ungdomsskole Norway 2030

Study participating centre Nannestad VGS Norway 2030

Study participating centre Bakkeløkka ungdomsskole Norway 1454

Gystadmarka ungdomsskole

Norway 2069

Study participating centre Jessheim VGS

Norway 2066

Study participating centre Nesbru VGS

Norway 1396

Study participating centre Røyken VGS

Norway 3440

Study participating centre Bleiker VGS

Norway 1387

Study participating centre Runni ungdomsskole

Norway 2150

Study participating centre Rakkestad ungdomsskole

Norway 1890

Nes VGS

Norway 2150

Study participating centre Uvdal skole Norway

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Study participating centre Rødberg skole

Norway 3630

Study participating centre Veggli skole Norway

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Study participating centre Edvar Munch VGS

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Study participating centre Vestby VGS

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Study participating centre Bodø VGS

Norway 8005

Bodin VGS

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Study participating centre Valle skule Norway 6260

Study participating centre Bykle skule Norway 4754

Study participating centre Setesdal VGS Norway 4747

Study participating centre Gressvik ungdomsskole Norway 1621

Study participating centre Vestbygda ungdomsskole Norway 1626

Study participating centre Kvernhuset ungdomsskole Norway 1615

Glemmen VGS

Norway 1605

Study participating centre Haugeåsen ungdomsskole Norway 1663

Study participating centre Borge ungdomsskole Norway 1654

Study participating centre Risum ungdomsskole Norway 1769

Study participating centre Halden VGS Norway 1772

Sponsor information

Organisation

Centre for Child and Adolescent Mental Health, Eastern and Southern Norway

Organisation

Norwegian Institute for Public Health

Organisation

Fremsam

Funder(s)

Funder type

Government

Funder Name

Norges Forskningsråd

Alternative Name(s)

Forskningsrådet, Norwegian Research Council, Research Council of Norway, The Research Council of Norway

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Norway

Results and Publications

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? |
|--|-------------------------------|--------------|------------|----------------|-----------------|
| Other files | | | 11/03/2025 | No | No |
| $\underline{\textbf{Participant information sheet}}$ | | | 19/09/2024 | | Yes |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| <u>Protocol file</u> | | | 11/03/2025 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |