

Optimizing a Transdiagnostic Mental Health Intervention for Adolescents: Protocol for a Randomized Controlled Trial

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Abstract

Background

The increased mental health challenges among Norwegian youth places school nurses at the center stage for screening and preventive interventions. We co-designed and piloted an intervention (Kort) with and for Norwegian youth and school nurses. Kort consists of five common elements targeting emotion regulation (ER), which is associated with psychopathological development across disorders. Each element was identified through two systematic reviews of relevant mental health interventions targeting adolescent ER and subsequently modified to fit the Norwegian school health setting. The pilot indicated that Kort will reach satisfactory levels of feasibility, usability, and appropriateness to be implementable

to the school health setting once the elements have been refined in accordance with the pilot participants' feedback and other pilot data. In the present study, we will investigate the effect of each intervention element on proximal and distal outcomes relating to ER, mental health, and quality of life.

Design

The study consists of two successive randomized controlled trials of school nurses (N=100) and adolescents (N=300). We will employ a mixed-methods design combining intensive longitudinal data sampling with audio recordings and qualitative interviews.

Methods

The following data sources will be used to triangulate treatment effect: Youth: Daily diary experience sampling, pre-, post-, and follow-up measures, audio recordings of consultations, and qualitative interviews. School nurses: Audio recordings of consultations, standardized digital records about every session, and qualitative interviews. We aim to recruit 100 school nurses and 300 adolescents.

Results

The study will be initiated in November 2024, and we will successively recruit school nurses and youth until we have reached the prospected number of participants, until June 2026 at the latest. The results are expected to be published in 2027-2028.

Conclusion

This study will apply an innovative approach, combining diverse methods to investigate micro-processes involved in ER and enhance the understanding of ER strategies' role in mental health and well-being. The use of daily diary experience sampling enables investigations into the real-life complexities of adolescent emotion regulation. Pairing these observations with self-reported and observational fidelity assessments will enable a detailed understanding of how teenagers respond to the Kort elements on a day-to-day basis, and the discrete elements' impact on mental health outcomes.

Background

The Need for Interventions Preventing Adolescent Mental Disorders and Promoting Well-Being in School Health Services

Timely, targeted, and effective prevention of mental disorders and promotion of wellbeing for adolescents is at the very top of the Norwegian government's strategy for mental health (The Norwegian Ministry of Health and Care Services, 2023). An explicit responsibility is allocated to the school health services. The school health services are in a unique position as they have universal reach to all students. In Norway, we have recently observed disparities increase with regards to which (social, ethnic, and financial) groups access mental health care. This warrants solid competence about adolescent mental health in the school health setting. School health workers meet with a substantial number of adolescents (Moen & Skundberg-Kletthagen, 2018), and all 8th graders have a mandatory consultation with a school nurse. Unfortunately, our nation-wide survey showed that 72% of frontline health practitioners reported a lack of manualized and research-informed tools for addressing adolescent mental health. Therefore, we have co-developed and piloted the Kort intervention in collaboration with adolescents and school nurses.

The Kort intervention

Kort is a brief transdiagnostic intervention based on evidence-informed common elements (CEs) that have been tailored to the Norwegian school health setting (for students aged 12-20). The Kort CEs were selected based on two systematic reviews and meta-analyses (Helland et al., 2022; Mellblom et al., in review) that identified the empirical evidence on effective treatment practices targeting adolescent emotion regulation (ER). Emotion regulation can be defined as individuals' ability to handle their own and others' emotions in response to contextual demands, influencing their intensity, duration, and expression (Tull & Aldao, 2015). Individuals regulate emotional experiences through various strategies, using both adaptive and maladaptive approaches. The use of ER strategies is flexible; individuals usually use more than one kind of strategy at once, depending on their own abilities and on the context (Aldao et al., 2013). Difficulties in ER (i.e., dysregulation) are linked to diverse mental health problems such as anxiety, depression, eating disorders, conduct disorder, ADHD, and psychotic disorders (Aldao et al., 2016). Maladaptive ER strategies have been identified across diagnoses and the use of certain strategies (e.g., rumination, avoidance) can lead to the development and maintenance of general psychopathology (Cludius et al., 2020). Emotion regulation is therefore seen as a *transdiagnostic* process.

Emotion regulation is comprised of malleable skills associated with both good mental health, resilience, and psychopathological development. Therefore, ER is a suitable target for interventions promoting good mental health in adolescents. A recent meta-analysis assessing the effectiveness of interventions targeting ER found moderate effects in decreasing emotion dysregulation and small effects on improving ER (Moltrecht et al., 2021). Subsequently, decreases in emotion dysregulation were associated with improvements in mental health (Moltrecht et al., 2021). There has, however, been a dearth of research looking into what drives these effects, as in which specific elements of an intervention (i.e., discrete practices, processes, or principles) are effective for changing ER abilities. Helland et al. (2022) identified the active ingredients (i.e., effective common elements) of current interventions targeting ER in adolescence. Eleven potentially effective CEs (based on effect sizes above .20) were identified and six CEs were selected for inclusion in the co-design and pilot study of Kort. The six elements were:

1. Setting goals with the adolescent
2. Exploring emotions, thoughts, and reactions in the body and how they are connected
3. Exploring health promoting activities
4. Practicing exposure to emotions
5. Practicing psychological flexibility
6. Practicing mindfulness.

The Kort Pilot

The Kort pilot was a hybrid study investigating the implementability (feasibility and fit) of Kort in the real-life school health setting (Engell et al., in review). The pilot was conducted with 25 school nurses and 49 adolescents in the Eastern region of Norway between 2023-2024. The study was led by co-PIs Anneli Mellblom and John Kjøbli, funded by the Research Council of Norway (Ref. 326941), and approved by the Regional Committees for Medical and Health Research Ethics (Ref. 534396). The school nurses attended a three-day in-person training conducted by a school nurse specializing in clinical training, a clinical psychologist, and a clinical communication specialist. In addition, the school nurses were offered monthly digital guidance. Participants received training in all six elements and the Kort data collection scheme. A complex data collection infrastructure was also piloted in preparation for the current study. We collected data from participating adolescents for a mean of 53 days (range: 1-91). A mean of 2.3 adolescents were recruited by each school nurse.

School nurses received: 1) Pre- post and follow-up questionnaires about how feasible, suitable, and usable Kort and its elements were (i.e., implementability), 2) invitations to focus group interviews about the use and implementability of Kort, 3) access to a school nurse web portal for registering sessions with participating adolescent, (and the content of the sessions), and 4) the University of Oslo's Dictaphone app, used to record sessions with participating adolescents.

Participating adolescents were invited to respond to: a) pre-and post-questionnaires including measurements of demography, mental health and ER, b) daily diary questionnaires about ER strategies, ER exercises, and intensity of emotions, c) qualitative interviews about Kort and the data collection. In addition, 22 adolescents received a short form about intensity of emotions three times per day, in bursts of 4 days on/5days off. The purpose of this additional condition was to investigate how the two data collection schemes (of different intensities) were perceived by adolescents.

The Current Study

The current study will build on the Kort Pilot and employ a data-driven experimental design and a mixed-methods data collection system. The aim of the current study is to test the effect of each element in Kort compared to care as usual (CAU), and to identify differential effects between elements. The element Practicing exposure to emotions has been removed from Kort as the activities comprising the element were too resource-intensive for school nurses to practice with fidelity. The study will be conducted under co-PIs Anneli Mellblom and John Kjøbli and is the final study of the project entitled Early Prevention of Mental Health Problems: Co-Creating and Optimizing a Brief Evidence-Based Intervention for Adolescents (Kort) funded by the Research Council of Norway (326941).

The main research questions for this study are:

1. What is the effect of each of the individual 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?
 - a. **Four-armed RCT (main effects):** What is the effect of each Kort element on adolescents' emotion regulation, mental health, and quality of life, compared with the other elements and CAU.

- i. *Primary outcomes:* Difficulties in Emotion Regulation Scale (DERS), Behavior and Feeling Survey (BFS), Warwick-Edinburgh Mental Wellbeing Scales (WEMWBS). Secondary outcomes: sleep, loneliness, friendship, alcohol consumption
 - ii. *Moderators:* ethnicity, SES, age, gender, baseline problem load (e.g., BFS score)
 - b. **Microtrial 1 (main effects):** What is the effect of a single session using the two elements Psychoeducation and Setting goals on mental health literacy and health locus of control, compared with CAU
 - i. *Primary outcomes:* Mental health literacy, Multidimensional health locus of control
 - ii. *Secondary outcomes:* BFS
 - c. **Microtrial 2 (main effects):** What is the effect of each of the three elements Mindfulness, Positive activities (behavioral activation), and Psychological flexibility (cognitive restructuring) on their respective proximal outcomes, compared with the other elements and CAU (measured by visual inspection, within and between analyses, time-series variability aligned with introduction of respective elements)
 - i. *Primary outcomes:* Proximal outcomes T1-T4 (see Table 1, and Data Collection Blueprint for the Kort Study)
- 2. Through which mechanisms do the Kort elements affect adolescent mental health (Mediating effects)?
 - a. Does the self-reported use of any specific emotion regulation strategies mediate the Kort intervention effect on mental health and/or quality of life?
 - i. *Primary outcomes:* DERS, BFS, WEMWBS.
 - ii. *Mediators:* DD emotion regulation strategies
 - b. Which mediators might change the effect of the Kort elements on adolescent emotion regulation, mental health, and quality of life?
 - i. *Mediators:* Sleep, friendship, alcohol consumption, loneliness
 - ii. *Outcomes:* DERS, BFS, WEMWBS, proximal outcomes of each element (T1-T4, see Table 1, and Data Collection Blueprint for the Kort Study)
- 3. How is Kort perceived by school nurses and adolescents?

- a. Do adolescents practice the activities associated with each Kort element?
- b. Do adolescents find Kort practices and elements useful?
- c. Do school nurses find the Kort elements feasible and appropriate for their practice?

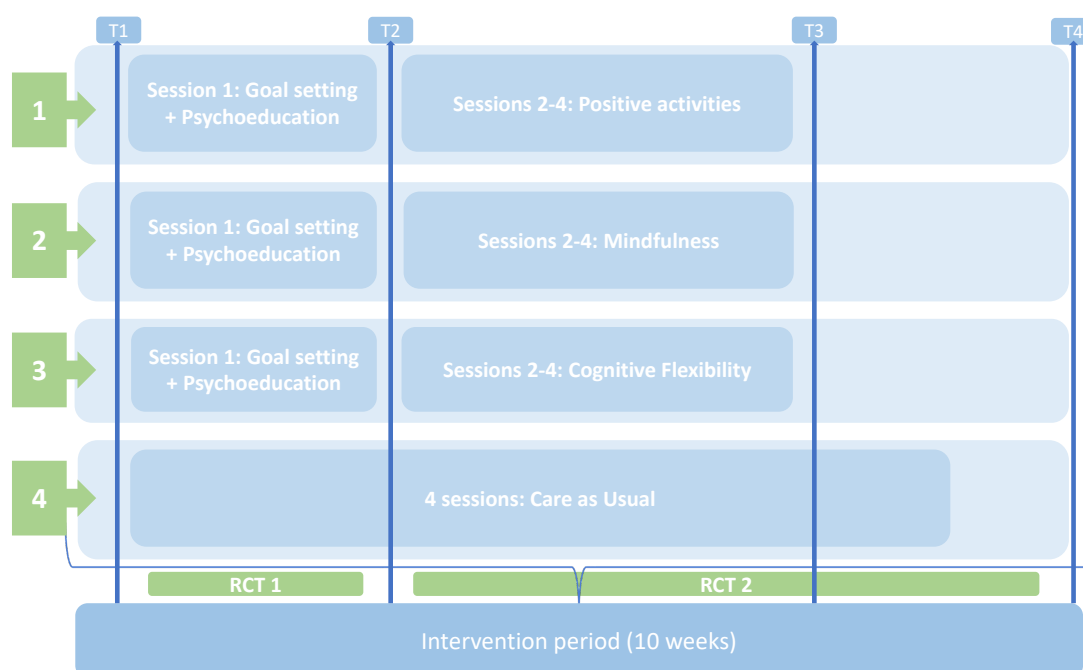
Methods

Study design

The design of the study is twofold and will consist of two successive randomized controlled trials (RCTs). Figure 1 displays the design, duration and conditions of the two RCTs. All participants will take part in both the RCTs. The RCTs are: 1) A micro trial comparing the elements Psychoeducation and Goal setting to Care as usual (1 session), and 2) A four-armed RCT comparing the elements Positive activities, Mindfulness, and Cognitive restructuring with each other and care as usual (min. 3 sessions).

Figure 1.

The Kort study design



Note. 1-4 indicates allocation to the four conditions. T1-T4 indicates the time when pre/post questionnaires are issued.

Setting

The study will be conducted in Norwegian school health services serving lower and upper secondary schools (grades 8-13). Most school health services consist of 1-4 school nurses

serving 1-4 schools. The school nurses are typically located at the schools and have a drop-in policy during school hours, during which the adolescents can visit them freely, depending on availability. While most school nurses do not have any formal training in consulting adolescents with mental health concerns, the adolescents who with them increasingly see them due to difficulties in coping with stress and emotions (Moen & Skundberg-Kletthagen, 2018).

Participants and criteria

We aim to recruit 100 school nurses serving lower and/or upper secondary school students. We will strive to recruit school nurses from urban and rural areas across Norway. Through the school nurses, we aim to recruit 300 adolescents aged 12-20 years. We have developed and tested a tailored web-based solution for ensuring informed consent form all participants (see appendices). For adolescents under the age of 16, we require consent from both caregivers (or confirmation that there is only one legal caregiver). Adolescents aged 16 or older will consent on their own behalf. The consent forms have been tailored to their target age groups, and previous iterations were approved by the Regional committees for medical and health research ethics (REK), and tested successfully with adolescents in the pilot study. Consent forms for caregivers are available in Norwegian and English. All consent forms are available as attachments to the ethical approval application form.

Recruitment

All school nurses who are prospective participants have been or will be recruited by Kort project team members (including WHO's Norwegian Healthy Cities network; Fremsam), or existing connections with school health services that participated in the Kort pilot study. All school nurses and their leaders are required to fill out a consent form, detailing what study participation entails and that participation is strictly voluntary. Each school nurse will be responsible for recruiting a minimum of 2 eligible adolescents to receive Kort and forwarding consent forms to the adolescents and one of their primary caregivers (if under 16 years of age). Adolescents may be recruited consecutively throughout the study period.

Ethics

The planned project is a randomized controlled trial of the element-based intervention Kort, delivered by school nurses to adolescents with mild to moderate mental health problems. Participation requires adolescents to spend time answering questions about their emotions and how they respond to them. This will be time-consuming, and some may experience it as

unpleasant. We have set up a compensation scheme for the adolescents. They will accumulate monetary compensations as they submit questionnaires. Each submitted questionnaire yields between 4-50 NOK, depending on the estimated time it takes to complete the questionnaire (see *Rewards for questionnaire completion* for details). The accumulated compensation will be awarded at the end of the trial period, in the form of a universal gift card. We evaluate this scheme as appropriate compensation for the adolescents' time, based on the adolescents' feedback about the Kort pilot data collection system. We expect the negative effects of participation to be minimal, as Kort is co-created and piloted with school nurses and adolescents to be safe, suitable, and appropriate for use with adolescents in school health settings. School nurses recruit adolescent participants and deliver the intervention. School nurses have the necessary competence to assess whether an adolescent requires treatment. In such cases, school nurses routinely refer adolescents to specialized health care agent and they will be instructed to continue to do so in during the Kort study period. Given that the school nurses who recruit adolescent participants will meet with them regularly throughout the trial period, they will be able to ascertain whether the adolescent is faring worse. Given that the adolescents we aim to recruit do not have clinical level mental disorders, we view the utility of the project as outweighing that of the inconvenience for participating adolescents.

Participating school nurses will be required to attend basic training and supervision sessions to learn how and when to deliver Kort. They will also be responsible for recruiting adolescents, report which elements they use in sessions with those adolescents and submit audio recordings of the sessions. This will be time-consuming and could therefore interfere with other tasks. However, school nurses have requested tools that are appropriate for use with adolescents with emotional problems and the Kort pilot has been highly successful in meeting school nurses' expectations. Therefore, study participation may increase their competence and enhance their capability to aid adolescents with emotional problems. In our assessment, these potential gains outweigh the liabilities associated with participation for school nurses.

All questionnaire data and audio recordings will be submitted directly to the project's workspace in Services for sensitive data's (tjenester for sensitive data; TSD) encrypted server. The TSD server is compatible with the requirements of the EU's General Data Protection Regulation for sensitive data storage. No data will be stored locally, and all data will be deindividualized in data files (i.e., each participant will be assigned a random ID number). The file containing personal information corresponding to the ID numbers will be stored

separately in a TSD folder and deleted in accordance with the date indicated by the Regional Committees for Medical and Health Research Ethics (REK). We will employ the same data management scheme as in the Kort pilot, as it has been tested, approved and used successfully.

Data Collection and Outcomes

The data collection infrastructure to be used in this study is an optimized version of the system that was used in the Kort pilot. Augmentations have been made to enhance the user experience (e.g., per adolescents' feedback, the order of items in the daily diary questionnaires will alternate to avoid response fatigue). Many of adolescents' questionnaires are prompted by school nurses' reports on a consultation. Therefore, we are launching a school nurse web-portal containing tasks and visual cues that may prevent or reduce report missingness. Table 1 depicts outcomes, instruments, and time points for adolescents to be enrolled in the study. T1 marks the start of the 10-week data sampling period. T2 occurs after the first Kort consultation, T3 after the fourth consultation, and T4 marks the end of the data sampling period (70 days after the first Kort consultation).

Implementability of the Kort intervention.

School nurses will report on the perceived implementability (acceptability, feasibility, appropriateness, usability) of the Kort intervention using the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), the Feasibility of Intervention Measure (FIM), and the Intervention usability scale pre- and post-intervention and follow up (T1 and T2).

Adolescents' Mental Health and Emotion Regulation.

We will measure adolescents' mental health using pre-test and post-test clinical measurements (T1-T4, between 34 and 125 items). Measures of adolescents' health and quality of life are administered at T1 and T4, and include measures of mental health (Behavior and Feelings survey, Weisz et al., 2019), well-being (Short Warwick-Edinburg Mental Well-Being Scale, Tennant et al., 2007), mindfulness (three subscales of the Five-Factor Mindfulness Questionnaire; Describing, Non-Reactivity, & Non-Judging, Dundas et al., 2013), cognitive fusion (Cognitive Fusion Questionnaire, Gillanders et al., 2014), self-compassion (two subscales of the Self-Compassion Scale for Youth, Neff et al., 2021; Self-kindness & Self-judging, Hughes et al., 2004), loneliness (the Three Item Loneliness Scale),

friendship (subscale for Peers and Social Support from KIDSCREEN-27, Andersen et al., 2016), mental health literacy (two self-developed items), functional impairment (two self-developed items asking to what extent mental health symptoms impact adolescents' daily lives), sleep and screen time use (seven self-developed items).

In addition, we will collect self-reported daily experiences of affect and emotion regulation strategies, using a Daily diary (DD) questionnaire (19 items total). The DD questionnaire consists of the Difficulties in Emotion Regulation Scale short form (DERS-SF; 7 items), the Positive and Negative Affect Scale (PANAS; 11 items) and one self-developed item about sleep quality. The DD questionnaire will be issued every evening at 7:00 p.m. during the 10-week data collection period (4:30 p.m. on Saturdays and Sundays). In addition, there will be an add-on questionnaire issued every Saturday, of the Behaviors and Feelings Survey (BFS; 12 items) and one self-made item about unusual events occurring over the past week. Finally, whenever a school nurse reports a session with an adolescent, that adolescent will receive 5 extra items about the working alliance with the nurse on their next DD. If the nurse reports that they used the element of their condition, the adolescent will receive between 1-5 additional items on their DD about the activities related to that element, every subsequent day for 5 days. These questions are dictated by the data collection system, in which the school nurses are randomized to one of four conditions (elements 3, 4, 5, or CAU). The randomization is fully automated and integrated to the data collection system. Table 1 depicts the experience sampling and measurement timepoints. Full documentation about instruments, items, translation, and references to psychometric properties is available in the additional file entitled Data Collection Blueprint for the Kort Study in the study protocol (ISRCTN13757428).

Table 1.

Outcomes, Instruments, and Time-Points for adolescents

Outcome	Instrument	Time- point					
		T1	T2	T3	T4	DD	WD
Mental Health literacy	Self-developed	x			x		
Emotion Regulation (Trait)	DERS-SF	x			x		
Personality	IPIP	x			x		
Mindfulness	FFMQ-15 ¹ MAAS ²	x	x	x	x		
Disordered Thinking/Cognitive Fusion	CFQ	x	x	x	x		

Well-being	SWEMWBS	x			x		
Everyday Functioning	Self-developed	x			x		
Loneliness	T-ILS	x			x		
Avoidance	CAMS	x			x		
Self-compassion	SCS-Y	x			x		
Working Alliance	WAI-SR		x	x			
Background/demographics	Self-developed	x			x		
Individual characteristics: Attitudes toward attending school, alcohol consumption, sleep quality, friendships	Self-developed	x			x		
Health Locus of Control	MHLCS	x			x		
Self-compassion	SCS-Y	x			x		
Emotions (State)	PANAS					x	
Emotion Regulation Strategies	Various sources					x	
Daily Sleep Quality	Self-developed					x	
Daily Emotions	PANAS					x	
Functional Emotion Regulation	Self-developed					x	
Adherence to Kort elements and activities	Self-developed						x
Emergent/Exceptional Events	Self-developed						x
Internalizing and Externalizing Symptoms	BFS						x

Note. A=Adolescent, DD=Daily diary. WD=Weekly diary (Saturdays only). ¹T1 and T4 only, ²T2 and T3 only

Table 2.

Outcomes, Instruments, and Time-Points for School Nurses

Outcome	Instrument	Time- point		
		T1	T2	CF
Background, demographics	Self-developed	x		
School Nurse Self-Efficacy	From the GuideMe study	x	x	
Readiness for implementation scale	MFE	x	x	
Measure of Innovation-Specific Implementation Intentions	MISH	x	x	
Measure of intervention acceptability, appropriateness and feasibility	AIM, IAM, FIM	x	x	
Intervention Usability Scale	IUS	x	x	
Working Alliance Inventory Short Form	WAI-SF			x
Perceived Usefulness of the Consultation	Self-developed			x

Use of Elements in Consultation	Self-developed			x
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Note. CF = Consultation Form (after each consultation)

Intervention Fidelity.

All school nurses will access a personal password protected Kort web-portal. In the portal, their personal dashboard displays their active participants (adolescents they have enrolled in the Kort study), and all relevant forms and activities related to each adolescent (e.g., prompts to set up sessions, how many sessions they have had, and a link to the fidelity and alliance questionnaire to be submitted after each session). All school nurses will submit a brief questionnaire indicating when they had a session with an adolescent that is enrolled in the study. This report prompts the working alliance items for that adolescents subsequent DD (see above). In addition, school nurses in conditions 1-3 will complete a brief dynamic questionnaire indicating which elements they have used in each session. These questions serve as an indicator of intervention fidelity, and whether the desired function of each element was achieved. The intervention fidelity questionnaire consists of between 3-13 items. School nurses in the CAU condition will report on working alliance only. All school nurses will take audio recordings of consultations with enrolled adolescents, using an end-to-end encrypted Dictaphone app (Nettskjema Dictaphone; University of Oslo, 2019). The audio recordings will be used to supplement the self-reported fidelity data, using a pre-defined fidelity coding framework (developed and tested in the Kort pilot).

Adolescents' and School nurses' Experiences with Kort and its Value.

To investigate adolescents' experiences with Kort and each element, we will invite a selection of adolescents from each of the four conditions to participate in individual interviews after T4. Similarly, to investigate school nurses' experiences with Kort and its clinical value, we will invite select school nurses to participate in follow-up focus group interviews at the end of the study.

Rewards for questionnaire completion.

The adolescents will accumulate monetary compensation for each completed questionnaire. Each adolescent their reward in the form of a universal gift certificate shortly after the 10-week study period. Each submitted Daily diary yields 5 NOK, and each completed weekend questionnaire yields 6 NOK. In addition, adolescents will be compensated with 60 NOK for completing T1, T2, T3 and T4. This amounts to a maximum reward of NOK 600 per adolescent. The compensation system and accumulated rewards will be available to the

adolescents through a gamified token system developed in collaboration with adolescents prior to the pilot. The graphic token system displays how many submissions they have completed and the accumulated value of the gift card. The adolescents can access this information through the questionnaire links they receive by SMS. The Norwegian Regional Committees for Medical and Health Research Ethics evaluated this reward system for the Kort pilot and found it appropriate for compensating adolescents for their time.

Data analysis

Quantitative Analyses.

We will be analyzing the data from the adolescents at the between and within level using appropriate intensive longitudinal analyses (e.g., multilevel modeling, dynamic structural equation modelling; DSEM), accounting for gender and age. Analyses will be informed by the conceptual model to investigate associations between the elements the adolescents receive and change in specific emotion regulation strategies. We will use repeated measures ANOVA to compare group pre and post means on adolescents' emotion regulation and mental health outcomes, and mixed models for testing multilevel associations between nurses' intervention fidelity and adolescents' outcomes. We will assess the extent of missingness and explore the possible reasons for missing data (e.g., missing not at random or missing at random). Given missingness at random, missingness in experience sampling data will be handled by implementing full information maximum likelihood. Missingness in pre and post data will be handled using multiple imputation. The percentage of compliance of intensive longitudinal data will also be assessed.

Qualitative analyses

The audio-recordings of consultations between school nurses and adolescents will be transcribed verbatim and coded for fidelity based on the "flexibility for function" conceptualization of fidelity. We will code quality in working towards core functions of intervention elements, and what components (i.e., activities and exercises) were used with adolescents in the consultation. We will also code which problems and concerns the adolescent brings to the consultations, how working goals are articulated, as well as communication structure and quality, and common relationship factors such as trust, alliance, and empathy. When coding alliance we will use the working alliance inventory- the observer (WAI-O; Horvath and Greenber, 1989). The interviews with adolescents will be transcribed verbatim and coded for their experiences with the intervention. We will analyze the transcribed interviews using inductive, reflexive thematic analysis (Clarke & Braun, 2017). The analysis

will use the six-phase process for data engagement, coding and theme development by Clarke & Braun (2017): 1) data familiarisation; 2) systematic data coding; 3) generating initial themes from coded and collated data; 4) developing and reviewing themes; 5) refining, defining and naming themes; 6) writing the report.

Mixed-methods analyses

Quantitative and qualitative results will be merged in tables, and results from each data source will be compared for convergence or divergence. Qualitative results will be used to complement the quantitative results to provide a more in-depth understanding of findings and mechanisms of change.

Power calculations and sample size

The current study entails two consecutive RCTs; first, a micro-trial (RCT 1) testing the effect of a single session of element 1 and 2 versus CAU, second, a four-armed RCT (RCT 2), testing the remaining three Kort elements against each other and CAU. All participants participate in both RCTs, as the Kort intervention is designed to give the elements in consecutive order. The sample size needs to be adequate to answer research questions for both RCT1 and RCT2. Power calculations for group comparisons both in RCT 1 and RCT 2 were performed in R through the pwr-package. In RCT 1, we expect an effect of Cohen's $d = 0.4$, given that we will measure proximal outcomes (e.g., ownership to one's own goals after having set goals for treatment, and mental health literacy after psychoeducation). Hence, given an alpha level of .05 and power of .80, a sample of 99 participants in each condition would be needed, indicating a need for 198 participants. In RCT 2, to detect a difference corresponding to a Cohen's $d = 0.5$, given an alpha level of .05 and power of .80, a sample of 64 participants in each condition would be needed. The Kort pilot indicated an expected level of 15% early dropout for the main study. Therefore, we will oversample by 15% and aim to recruit 75 adolescents for each of the four RCT-conditions, yielding a total sample of $n = 300$.

Ethical Considerations

For adolescents participating in the study, participation entails spending time every day on answering questionnaires. On four occasions during the course of the 10-week study period, they will be invited to respond to longer (10-20 minutes) questionnaires. While the data collection will be time-consuming, we have tailored it to accommodate the feedback we received about the data collection from adolescents in the Kort pilot (e.g., the daily diary questionnaires will be issued at 7 p.m. instead of at 9 p.m., and the sequencing of item scales

will vary to avoid tedious repetition). Adolescents will be compensated for their time using the compensation system that was tested in the pilot study (see details under Rewards for questionnaire completion).

We have implemented measures to avoid any unintended adverse outcomes or harmful effects from participation. Kort and the data collection infrastructure has been co-designed with school nurses and adolescents to ensure safety and suitability in school health environments. School nurses are qualified to evaluate whether an adolescent needs a mental health professional's assessment and have established procedures for making appropriate referrals. By meeting with the participating adolescents regularly during the study, school nurses can monitor and determine if their condition deteriorates. Given that the adolescents we plan to recruit do not exhibit clinical-level mental disorders, we believe the benefits of the project surpass any potential inconvenience for the participants.

Implementation of novel practices may have unintended consequences of positive, negative, or neutral effects. In the prospecting study, we have carefully assessed the potential consequences through systematic implementation planning informed by the implementation study conducted as part of the Kort pilot, and by continuously adapting our implementation strategies to emerging information (i.e., from follow-up conversations with school health service leaders whose employees participated in the Kort pilot and from preparing for a nation-wide scale up, where the training and local contexts require tailoring).

Unpredicted and unwanted consequences may still arise, and we take extra precautions to ensure that adolescent participants potential mental health needs are met in the following ways: 1) We will ensure that all school nurses are adequately trained in how and when to refer adolescents to specialized health services. As part of their day-to-day job, school nurses are familiar with their community service structure for emergency and specialized health care, such as community health centers for youth, general practitioners, school and/or pediatric mental health services, emergency rooms, and help lines/chat services. During the Kort training, we will bring this up in group discussions to raise awareness of this crucial knowledge.

2) We will instruct school nurses to detect and explore potential signs of increase in symptoms of mental disorders of illbeing in the adolescents they meet with. The training will include instructions on how to use the modules from the interventions to alleviate such symptoms, and when such symptoms may be beyond the scope of the Kort intervention.

3) Three members of the Kort project group are clinical psychologists with experience from specialized mental health services for adolescents. These persons will be part of the training and coaching of the school nurses, and they will be explicitly available for on-demand consultations with school nurses should they need guidance on how to aid an adolescent's mental health needs (e.g., consulting on who to refer an adolescent to, or debriefing after sessions revealing symptoms of serious mental disorder).

4) In all questionnaires for adolescent participants, project team member's contact information will be made available, along with the following statement (in Norwegian): *Do you need someone to talk to? The NGO Mental Health offers 24-hour free assistance lines. Call 116123, or use the chat service at <https://korspaahalsen.rodekors.no/>*

Furthermore, we have developed and tested a methodical monitoring system that ensures frequent data checks and communication between the project group, school nurses and their leaders. This entails both regular check-ins and on-demand aid in the form of individual coaching or leader-to leader support.

For participating school nurses, several activities could have potentially negative consequences, such as attending training and supervision sessions without the support of substitute nurses or additional time compensation. Additionally, nurses will be tasked with recruiting 2-10 adolescents, completing a fidelity measure after each consultation, and submitting audio recordings of these sessions. Learning and implementing new practices may be cognitively demanding, potentially interfering with other duties. Nonetheless, school nurses have requested suitable tools to assist adolescents with emotional challenges and to better structure their consultations. Kort has been co-developed with school nurses to enhance the efficiency of their consultations and preliminary pilot data suggests that it is successful in achieving this. Therefore, Kort could eventually free up additional capacity for school nurses. Participation in the study is voluntary, and nurses can withdraw at any time. We will also recommend withdrawal if we or their supervisors notice any excessive strain on their capacity due to the study. Overall, we believe that the benefits of enhancing nurses' abilities to support adolescents outweigh the potential drawbacks of participation.

Relevance for clinical practice

The findings from this study will contribute to the development of effective, scalable, and context-appropriate mental health interventions in Norwegian school health services. Our

findings may advance the field of adolescent mental health by uncovering mechanisms of change in ER and their associations with mental health outcomes.

Public contribution

The integration of data from youth, school nurses, and observational data (i.e., audio recordings of their sessions), corresponds with the co-design approach of developing and optimizing the intervention. Triangulation of these data enables detailed analyses about the relative effect of each element in the intervention, and their respective mechanisms of change. The results may be of utility to other intervention contexts, such as in the classroom, or other frontline or specialist health services working to promote good mental health in adolescents.

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