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GuideMe - An evaluation project in school health services

Submission date	Recruitment status	[X] Prospectively registered
09/07/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/08/2022	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/06/2024	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
A national guideline with best practice recommendations for school health services in Norway was launched in 2017. To promote healthy life skills and identify students in need of follow-up, the guideline strongly recommends individual consultations with all 8th graders and increased cooperation with schools. Implementation of guidelines and practice change is a challenge in many sectors. Researchers have therefore co-created an implementation tool (SchoolHealth) together with practitioners, students, and other stakeholders consisting of three discrete implementation strategies:
1. Digital dialogue and administration tool
2. Dialogue support
3. School cooperation

The overall objectives of the current study are to help the service implement the guideline recommendations and reach its goals. The study expects to increase knowledge about effective implementation mechanisms and adolescent user pathways in health and welfare services.
The project will evaluate and optimize the SchoolHealth tool by studying the three strategies' effectiveness on guideline fidelity and the extent to which fidelity helps reach guideline goals by using a hybrid evaluation design with a factorial experiment. We will also compare SchoolHealth with a similar Danish tool. In order to understand the importance of participation in the study over time, data received from pupils will be linked with data from national patient and population registers. Data collected will also be compared with existing population-based studies in Norway and Denmark.

Who can participate?
Students, school nurses and school personnel

What does the study involve?
The schools will be randomly selected to test different combinations of these three components. This means that a school gets none, one or more of the components. Regardless of the experimental group, participants will complete questionnaires at baseline, after the 8th-grade consultation, and 6 months post-consultation. Students, school nurses, and school personnel will be invited to individual and focus group interviews after consultations. By

participating in the study, the informants will help with identifying successful strategies for implementing a guideline that can support adolescents in a life phase vital for future health and wellbeing. If successful, SchoolHealth will facilitate health promotion in schools, more effective youth services and systematic cooperation with schools The study will yield valuable knowledge about implementation strategies and service use, increase evidence-based practice, and promote cooperation between Nordic countries.

What are the possible benefits and risks of participating?
The risks of participating in the study are small because individual consultations with all 8th-grade students and cooperation with schools are part of the school nurse's ordinary job. The aim of the study is to support this work. Thus, some school nurses may be more skilled and supported in implementing the 8th-grade health consultation and cooperate systematically with the school. Each participant will be asked to answer questions about implementation and user satisfaction. Students will also be asked about their mental health, quality of life and health behaviour, which may cause a degree of discomfort. However, all students will have an individual consultation with the school nurse. In addition, all students will be encouraged to contact the school nurse if they feel worried after answering the questions.

Where is the study run from?
The Regional Center for Child and Adolescent Mental Health, Eastern and Southern Norway (Regionsenter for barn og unges psykiek helse Øst og Sør; Norway)

When is the study starting and how long is it expected to run for?
June 2021 to May 2026

Who is funding the study?
The Research Council of Norway (Norges Forskningsråd; Norway)

Who is the main contact?
Dr Åse Sagatun National project manager (Norway)
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
RCN Project Number: 320097

Study information

Scientific Title
Guideline effectiveness and implementation mechanisms in school health services

Acronym
GuideMe

Study objectives
Primary research questions:
1. What is the effectiveness of elements in the SchoolHealth tool on fidelity to the recommendations for:
1.1. The individual 8th-grade consultations (consultations completed, recommended topics addressed, user involvement, quality, and adaptations)?
1.2. Cooperation with schools (e.g., systematic cooperation, nurses teaching in groups or classes, tailored group interventions in collaboration with schools)?
2. What is the effectiveness of elements in the SchoolHealth tool on:
2.1. The school nurses' work-related self-efficacy and relations with students?
2.2. Assisting school nurses in identifying vulnerable students?
2.3. Student's health literacy, general self-efficacy, health behavior and quality of life?
2.4. School climate and student's school attendance?
2.5. How are possible effects mediated by fidelity to the guideline?
Secondary research questions:
3. What are the differences/similarities between the SchoolHealth tool and the equivalent

Danish dialogue tool?
4. Regarding self-reported health status:
4.1. What are the associations between self-reported health status and user pathways in health- and welfare services in Norway (contacts with primary and secondary health care)?
4.2. How is self-reported health associated with use of the school health services in Norway and Denmark?
5. Regarding implementation elements:
5.1. How are implementation elements, implementation determinants, and guideline fidelity associated?
5.2. How are implementation elements, organizational- and implementation climate, perceptions about the guideline, and implementation leadership associated with guideline fidelity and effects?
6. Based on the results of the study; what are the cost-benefit of the optimized version of the SchoolHealth tool?
We will also document and publish experiences with co-creating the SchoolHealth tool and designing the study, as well as use and user experiences with the SchoolHealth web dialogue

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/02/2022, Regional Committees for Medical and Health Research Ethics South (REK) and East C (Gullhaugveien 1-3, 0484 Oslo, Norway; +47 22 84 55 11; rek-sorost@medisin.uio.no), ref: 397998. The Regional Ethics Review Board concluded that the study does not require ethics approval as it falls outside the scope of the Health Research Act, cf. section 2, under Norway's law.

Study design
Multicenter hybrid-design randomized factorial-experiment population-based study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Promotion of the life skills, health and quality of life in 8th-grade students, and the identification of students in need of follow-up

Interventions
The ‘SchoolHealth’ tool consists of the following three components:
1. Web dialogue: A digital health information form that pupils complete before their health-promoting consultations. Pupils answer questions about their health and health habits, such as screen use and well-being at school, as well as questions about stressful life events. The school nurses can access the forms in connection with their day-to-day work. Summarised, anonymous reports are generated on areas that schools and the school health services can cooperate about, such as screen use, well-being at school, health and health habits.
2. Dialogue guide: A competence development package for school nurses, where the aim is to

improve the quality of the health dialogue with 1st-year pupils in lower secondary school.
3. School cooperation: A competence development package for teachers, head teachers and school nurses, where the aim is to strengthen their cooperation.

The schools will be randomly selected to test different combinations of these three components. This means that a school gets none, one or more of the components. The different combinations constitute eight different experimental groups. The randomisation process will be done in R statistical software.
A school participates for one school year and 40 schools will be invited over a two-school year period. A total of about 2000 students, 70 nurses and 60 school personnel will be invited. Data collection in schools will start in autumn 2022 and end in spring 2024.
Students, school nurses, and school personnel will complete questionnaires at baseline, after the 8th-grade consultation, and 6 months post-consultation.
Students, school nurses, and school personnel will be invited to individual and focus group interviews after consultations.
In Denmark, we will conduct focus group interviews with school nurses, school personnel, and teams implementing BørnUngeLiv.dk. We will also conduct individual interviews with school nurses and school personnel.
Linking of data with the national register will be done before December 2032. Then all personally identifiable information will be deleted.
Associations between self-reported health status, intervention group and user pathways in health- and welfare services will be investigated by linking student questionnaires in the current study with national register data follow-up (e.g., follow-up by the school health services, the general practitioner and referrals to outpatient clinics).
To compare self-reported health and use of the school health service, data from the current study will be compared with existing population studies in Norway (UngHUNT) and Denmark (BørnUngeLiv.dk).

Intervention Type
Other

Primary outcome(s)
1. Fidelity to recommendations in the guideline will be indexed by three constructs: Adherence to guidelines, adaptations to guidelines, and quality in using guidelines. Questions are tailored according to the National guideline for school health services
1.1. To measure fidelity to the recommendation of the individual 8th-grade consultation, questions on e.g., completed consultations, topics addressed, user involvement, quality, and adaptations will be answered by students and school nurses at T2 (after the consultations). School health nurses also report adaptations to guidelines through open-ended questions (free text) in the post-consultation questionnaire (T2)
1.2. To assess fidelity to the recommendation on cooperation with schools, questions on e.g., systematic cooperation, knowledge about each other’s framework conditions, nurses teaching in groups or classes and group interventions in collaboration with schools, will be answerey nurses and school personnel at the beginning of the school year (T1) and at the end of the school year (T3)
2. The school nurses' work-related self-efficacy and relations with students:
2.1. Work-related self-efficacy will be answered by nurses at T1 and T3
2.2. Nurse-student relation answered by students by an 8-item questionnaire about user satisfaction and relations at T2
2.3. Nurses by a self-developed questionnaire at T2
3. For the identification of vulnerable students a combination of several questionnaires will be

used:
3.1. Students' self-reported mental health at T1 and T3
3.2. Students' self-reported physical health using the Children's Somatic Symptoms Inventory (CSSI-8) at T1 and T3
3.3. Students' self-reported health habits (see below) at T1 and T3
3.4. Students' self-reported Quality of life measured using Kidscreen-27 at T1 and T3
3.5. Students' self-reported trauma measured using Child and Adolescent Trauma Screen at T1
3.6. School nurses' registration of students' function measured using self-developed questions at T2
3.7. School nurses' registration of student follow-up measured using self-developed questions from T2 to T3
4. Student's health literacy, general self-efficacy, health behaviour and quality of life measured using:
4.1. The Health Literacy for School-Aged Children (HLSAC) instrument at T1, T2 and T3
4.2. The General Self-Efficacy Scale, short version (GSE-5) answered by students at T1, T2 and T3
4.3. Student's self-reported health behaviour (i.e., physical activity, sleep, nutrition, screen activities) at T1 and T3
5. School climate and student's school attendance measured using:
5.1. Self-developed questionnaire answered by students at T1 and T3

Qualitative interviews will be used to measure the experiences of school nurses, students, and school personnel with the different implementation strategies/elements in SchoolHealth

Semi-structured, individual- and focus group interviews with open-ended questions will be carried out with school nurses, students, and school personnel. Follow-up questions will be used if necessary. The interviews will take place after the individual consultations with 8th graders and at the end of the school year.

Timepoints:
T1 = The beginning of the school year
T2 = After the consultations
T3 = The end of the school year

Key secondary outcome(s))

1. Differences/similarities between SchoolHealth and the equivalent Danish dialog tool (BørnUngeLiv.dk) measured using qualitative semi-structured focus group interviews with school nurses and personnel implementing BørnUngeLiv.dk, and individual interviews with school nurses and school personnel in Denmark and Norway between timepoint T2 and T3
2. User pathways in health- and welfare services will be provided by National registry data. This includes contacts with (including time/date and diagnoses):
2.1. School health services (The Norwegian Registry for Primary Health Care)
2.2. General practitioners (The Norwegian Registry for Primary Health Care)
2.3. Physiotherapists (The Norwegian Registry for Primary Health Care)
2.4. Specialized healthcare services (including psychiatric care) (The Norwegian Patient Register (NPR))
During years before and after (to date, according to availability of data) 1) participation in SchoolHealth and 2) participation in the Young-HUNT survey.
3. Self-reported use of the school health services and self-reported health will be assessed using questionnaire data at T1 from:
3.1. The GuideMe study/SchoolHealth
3.2. Existing population studies in Norway: The youth part of The Trøndelag Health Study (The HUNT Study) - Young-HUNT 3 (2006-2008) and Young-HUNT 4 (2017-2019).

3.3. BørnUngeLiv.dk in Denmark.
4. Implementation determinants will be measured using:
4.1 The Implementation Climate Scale, ICS will be answered by nurses and their leaders at T1 and T3
4.2. The Implementation Leadership Scale, ILS will be answered by nurses and their leaders at T1 and T3
5. Implementability of guidelines will be assessed using the following three scales:
5.1. Feasibility of Intervention Measure (FIM) answered by nurses and their leaders at T1 and T3
5.2. Acceptability of Intervention Measure (AIM), answered by nurses and their leaders at T1 and T3
5.3 Intervention Appropriateness Measure (IAM) will be answered by nurses and their leaders at T1 and T3
6. Cost-effectiveness of SchoolHealth using measures of short- and long-term costs and effects of the intervention within (e.g., healthcare utilization measures and utilities) and outside (e.g. school attendance, grades, participation in extracurricular activities) the healthcare sector up to 2032. Models and measures suitable for economic evaluation in primary health care services are lacking, and development of these is planned as a part of the study.

Timepoints:
T1 = The beginning of the school year
T2 = After the consultations
T3 = The end of the school year

Completion date
31/05/2026

Eligibility

Key inclusion criteria
1. Normal population of 8th-grade students (aged 13 to 14 years old)
2. Public health nurses in the School health service (aged 23 to 70 years old)
3. Upper secondary school personnel/teachers (aged 23 to 70 years old)

Participant type(s)
Health professional, Learner/student, Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
13 years

Upper age limit
70 years

Sex
All

Key exclusion criteria
Students who for any reason are not able to answer the questions in the web-based health information form

Date of first enrolment
01/09/2022

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
Norway

Study participating centre
Regional centre of child and adolescent mental health (RBUP), Eastern and Southern Norway
Postboks 4623
Nydalen
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NO- 0405

Study participating centre
Norwegian University of Science and Technology (NTNU)
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Study participating centre
VID Specialized University
P.O. Box 184 Vinderen
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Sponsor information

Organisation
The Research Council of Norway

ROR
https://ror.org/00epmv149

Funder(s)

Funder type
Research council

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

Funder Name
Regionsenter for barn og unges psykiek helse Øst og Sør

Funder Name
Norges Teknisk-Naturvitenskapelige Universitet(Norwegian University of Science and Technology)

Alternative Name(s)
Norwegian University of Science and Technology, The Norwegian University for Technology an Sciences, Universidad Noruega de Ciencia y Tecnología, NTNU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Norway

Funder Name
VID Specialized University

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		15/11/2023	16/11/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes