ISRCTN21223142 https://doi.org/10.1186/ISRCTN21223142

Improving digital mental health services with and for national minority, Indigenous and refugee youth in Norway: The InvolveMENT research project protocol

Submission date
29/07/2024

Recruitment status
No longer recruiting

Registration date
19/09/2024

Overall study status
Ongoing

Last Edited
31/03/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Limited research exists on the mental health and service use among minority youth. The Norwegian government provides a public communication channel for youth, but it has not been adapted to meet the mental health needs of minority youthy. There is no research to determine the use, acceptability, effectiveness, cost-effectiveness and safety of digital services for minority youth in Norway.
Main aim: To improve the mental health of national minority, Indigenous and refugee youth.
Objectives: 1) Determine mental health and digital support needs, and possible barriers and facilitators to service use; (2) Assess use of and satisfaction with digital services to meet their mental health needs; (3) Explore their perspectives on digital mental health services; (4) Develop recommendations which can be used to adapt digital services to meet their needs and rights; and (5) Assess the use, acceptability, satisfaction, effectiveness, cost-effectiveness and safety of adapted services.

Who can participate?
Youth in the age range from 16-25 years who have a background as national minority, Indigenous or refugees. Phase 3 (co-design) age range 16-35 years.

What does the study involve?
1) A cohort study with cross-sectional online surveys to assess the mental health, wellbeing, digital support needs, utilization and satisfaction with digital services, and possible barriers and facilitators to service use
2) A qualitative study to explore youth perspectives on digital services for their mental health
3) A co-design study with youth, and healthcare and other professionals to develop proposals to adapt and improve the existing digital services
4) A randomized controlled trial (RCT) and a qualitative study to evaluate the adapted services.

What are the possible benefits and risks of participating?
This research project will improve existing digital services in order for them to enhance the accessibility and quality of digital health services, early interventions, reduce inequality in service provision for minority groups, and strengthen collaboration between youth, public and research organizations. Individual participants may benefit from the different types of support services offered online. No major risks are expected. However, in the event of deterioration of the mental health of participants, the project has developed safety procedures to outline how healthcare professionals should act when participants need increased support or treatment referral.

Where is the study run from?
The study is lead by the University of Stavanger (Norway) and data is collected nationally.

When is the study starting and how long is it expected to run for?
July 2023 to June 2027

Who is funding the study?
The study is funded by The Research Council of Norway, The University of Stavanger and UiT The Arctic University of Norway

Who is the main contact?
Prof. Petter Viksveen, petter.viksveen@uis.no

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
336307

Study information

Scientific Title
Improving digital mental health services with and for national minority, Indigenous and refugee youth in Norway: The InvolveMENT research project protocol

Acronym
InvolveMENT

Study objectives
For the randomised controlled trial, the study's alternative hypothesis is that adapted digital health services are more effective in meeting the mental health support needs of national minority, Indigenous, and refugee youth.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 01/11/2024, Regionaletisk komité (REC) (Universitetet i Bergen, Det medisinske fakultet, Postboks 7804, Bergen, 5020, Norway; +47 55589715; rek-vest@uib.no), ref: 780840

2. approved 01/11/2024, The Ethics Committee for Sami Health Research, Sakkyndig etisk komité for samisk helseforskning, Sámi dearvvašvuođadutkama áššedovdi etihkalaš lávdegoddi (Postboks 3, Karasjok, 9735, Norway; -; none@example.com), ref: 1133459/800166

3. approved 06/12/2024, Sikt – Norwegian Agency for Shared Services in Education and Research (Abels gate 5, Trondheim, 7030, Norway; -; none@example.com), ref: 374832

Study design
Multi-disciplinary multiphase multicentre mixed methods research design including: A) cross-sectional cohort study, B) qualitative study, C) co-design study, and D) evaluation study with pragmatic/unblinded RCT and qualitative phase.

Primary study design
Interventional

Study type(s)
Efficacy, Prevention, Quality of life

Health condition(s) or problem(s) studied
Digital mental health support for minority youth. Phase 3 age range 15 - 35 years.

Interventions
Observational: Cross-sectional cohort study with self-report online questionnaires.

RCT:
Intervention arm: Digital/online services which have been adapted to meet the mental health needs of minority youth.
Control arm: Digital/online services which have not been adapted to meet the mental health needs of minority youth.

The intervention period runs from the moment of implementation of adapted services, aimed to be from 6 months into the RCT. Services include information and answers to young persons'

questions; interactive self-help tools; chat or telephone services; or video consultations with a healthcare professional. It is up to each individual youth to decide which parts of the services they wish to use and how often they want to use them. Hence, the trial is at the pragmatic end of the Pragmatic Explanatory Continuum Indicator Summary (PRECIS) tool.

Randomization will take place using a digital randomization tool (e.g. RAND function in Microsoft Excel).

Intervention Type
Other

Primary outcome(s)
Self-reported symptoms of depression (PHQ-9/PHQ-A), measured at 12 months.

Key secondary outcome(s))
Current secondary outcome measures as of 31/03/2026:
Measured at 12 months into the RCT:
1. Generalized Anxiety short-form (GAD-2)
2. Children's Somatic Symptoms Inventory (CSSI)
3. The Flourishing Scale (psychological well-being)
4. EQ-5D

Previous secondary outcome measures as of 05/11/2024:
Measured at 12 months into the RCT:
1. Generalized Anxiety short-form (GAD-2)
2. Children's Somatic Symptoms Inventory (CSSI)
3. The Flourishing Scale (psychological well-being)
4. The World Health Organization Well-Being Index (WHO-5)

Previous secondary outcome measures:
Measured at 12 months into the RCT:
1. Generalized Anxiety short-form (GAD-2)
2. Short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS)
3. Children's Somatic Symptoms Inventory (CSSI)

Completion date
30/06/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 31/03/2026:
For cohort: Youth who identify as belonging to a national minority (Forrest Finns, Jewish, Kven /Norwegian Finns, Roma, Romani), Indigenous (Sami), or refugees (from Ukraine, the Horn of Africa, the Middle East, and surrounding countries). The cohort surveys 1 and 2 also include youth not belonging to these minority groups.
For RCT: Youth from the same minority groups as for the cohort, and who score from mild to moderately severe symptoms of depression on PHQ-9/PHQ-A.

Previous inclusion criteria:
For cohort: Youth who identify as belonging to a national minority (Forrest Finns, Jewish, Kven

/Norwegian Finns, Roma, Romani), Indigenous (Sami), or refugees (from The Horn of Africa, The Middle East, and surrounding countries)
For RCT: Youth from the same minority groups as for the cohort, and who score from mild to moderately severe symptoms of depression on PHQ-9/PHQ-A.

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
25 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Participants who score less than for mild or more than for moderately severe symptoms of depression on PHQ-9/PHQ-A.

Date of first enrolment
07/12/2024

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
Norway

Study participating centre
SHARE Centre for Resilience in Healthcare, Department of Quality and Health Technology, Faculty of Health Sciences, University of Stavanger
Postboks 8600 Forus
Stavanger
Norway
4036

Study participating centre
Regional Centre for Child, Youth Mental Health and Child Welfare North (RKBU Nord)
Postboks 6050 Stakkevollan
Tromsø
Norway
9037

Sponsor information

Organisation
University of Stavanger

ROR
https://ror.org/02qte9q33

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
Universitetet i Stavanger

Alternative Name(s)

University of Stavanger, UiS, NOR

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Norway

Funder Name
Universitetet i Tromsø

Alternative Name(s)
University of Tromsø, University of Tromso, University of Tromsø - The Arctic University of Norway, UiT The Arctic University of Norway, UiT Noregs arktiske universitet, The University of Tromsø – Norway's Arctic University, UiT Norway's Arctic University, UiT Norgga árktalaš universitehta, UiT

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Norway

Results and Publications

Individual participant data (IPD) sharing plan

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?
Participant information sheet	version 1	05/08/2024	05/08/2024	No	Yes
Participant information sheet	version 2	05/11/2024	18/12/2024	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes