The MindMe study – Accessible mental health services

1.0 Introduction

Neurodevelopmental Disorders (NDD) are rising as major health concerns for youth. These individuals frequently face mental health challenges, often overlooked by clinicians and tools designed for neurotypical youth, leading professionals to depend on inaccurate measures and caregiver accounts. Consequently, there is a knowledge gap about mental health and risk factors in this group. Our project involves pioneering a digital tool tailored for those with cognitive challenges, with initial results highlighting its promise in accurate mental health evaluation. Building on this, the MindMe study seeks to transform assessments, emphasizing direc feedback from NDD individuals. This interdisciplinary initiative, recognized by global experts, champions a more inclusive, precise approach to mental health for the NDD community. This current project will examine mental health prevalence in NDD youth, identifying key social risks and evaluating the iSpe modules on depression, anxiety, and sleep. Our goal is to transform mental health services, integrate technology, reduce stigma, and elevate understanding of this group's unique challenges among stakeholders.

The project scope answers to Norwegian Government Reports and strategies[1-5]**,** addressing the need for inclusive mental health services, and the use of technology[6-8] to improve access and quality of treatment and care for youth. **One of the big societal challenges today is to facilitate the inclusion of young people with NDD and cognitive difficulties** in mental health services. The needs in this group are described in "Opptrappingsplan for psykisk helse (2023-2030)": *A common factor for these children is vulnerability, which can result in severe psychological and somatic complications if they do not receive proper adaptation and assistance*; "Et samfunn for alle": *The health- and care services should have good knowledge about people with disabilities and methods for how they can mobilize the users' own resources*; "På lik linje – Åtte løft for å realisere grunnleggende rettigheter for personer med utviklingshemning»: *Knowledge summary shows that only a minority of children with intellectual disabilities receive specific assistance in the healthcare system for their mental difficulties*; «Tjenester til personer med autismespektrumforstyrrelse og til personer med Tourettes syndrom»: *There is not equal access to specialized health services for the groups in Norway*. The Norwegian government ratified UN Convention on the Rights of People with Disabilities stats the obligation to: *Ensure that people with disabilities receive the healthcare services they need, especially due to their reduced functional abilities, including early assessment and intervention, as well as services to limit and prevent further disabilities, including among children and the elderly.*

State of the art and knowledge need

NDD encompass conditions such as autism spectrum disorder, global developmental delay and intellectual disabilities, attention deficit hyperactivity disorder (ADHD) and communication disorders[9]. **NDD is increasingly being recognized as a leading cause of morbidity in youth**[1,10]. Co-occurring mental disorders are more frequent in this population than in the general population[11]. Youth with NDD have a lower capacity to cope with mental and psychosocial challenges and have difficulty expressing and advocating their needs. Approximately 13% of the total population have borderline intellectual functioning (IQ 70-85) and 1-2 % of the population have intellectual disabilities[12]. Intellectual disability alone is rated as the third most costly disease in Norway[13]. Global cognitive impairment is frequent in substance use disorder (SUD), with an overrepresentation of youth (<24 years) having these challenges[14]. In clinical samples, the prevalence of NDD was found to be 55.5% in young patients referred for anxiety disorders [11]. This study did not include intellectual disabilities, learning disorders or communication disorder.

Research has repeatedly shown high prevalence of mental disorders in adults with NDD[15-18]. We have observed high frequency of psychotropic drug use from the age of 18[19]. Little is known about prevalence of mental disorders in youth with NDD, the age of debut, the impact of transition from youth to adulthood and social risk factors. **How to integrate the NDD youths' perspectives** in assessments of mental health problems and capturing meaningful changes in outcomes is currently an important focus area[20-22]. Services for the group are limited to a small number of highly trained clinicians, with the consequence that diagnosis and treatment are severely delayed. **Understanding the interplay between mental health issues and psychosocial risk factors** in NDD is particularly valuable for this group, where the complexities of their conditions often intertwine with mental health struggles[5]. Stressors such as social isolation due to difficulties in social interactions, communication challenges leading to frustration, and limited access to

appropriate educational and therapeutic resources may contribute. Understanding how these factors contribute to the development and exacerbation of mental health issues is crucial for effective intervention and support. Furthermore, the voices of these youths themselves are often marginalized in research and discourse about their own mental health. Their perspectives, experiences, and coping mechanisms deserve more attention, as they might hold the key to unlocking a deeper comprehension of the challenges they face and the most effective ways to assist them.

The need for early and valid identification of mental disorders in youth with NDD is highlighted as one of the 10 top research questions addressed from people with NDD, user organizations and professionals[20,23]. Very few mental health self-report measures have been developed for youth with NDD[20,22,24], and there is a total lack of evidence-based digital self-report tools. Consequently, the services must use measures developed for neurotypical youth, that do not communicate well with NDD individual's needs. The mental health care needs in people with NDD are thus often overlooked. Health professionals and researchers often must rely on proxy information (e.g., staff, caregiver, and teacher). Although objective indicators for mental ill health (e.g., behavioral equivalents such as increased frequency of crying, less smiling, reduced social participation etc.) can be reported by proxies, subjective indicators such as feelings, thoughts about life, well-being cannot be directly observed or understood[22,25,26]. Reliance on proxy reported symptoms of mental disorders has shown to underestimate the frequency of mental disorders in people with cognitive challenges[27]. Self-reporting and patient participation are particularly important in mental health assessment due to the subjective nature of these conditions. Clinicians, however, almost uniformly lack the expertise and tools to conduct a cognitively accessible assessment[22]. **Designing cognitively accessible self-report measures increases valid self-reporting significantly among individuals with cognitive challenges**[28-30]. By introducing valid mental health measures for this group to the services, patients can receive services at a lower service level and clinicians can better select which patients needs specialized treatment.

Inventory for Supported Psychological Evaluation (iSpe):

The research-based innovation project iSpe develops a comprehensive digital tool for the examination of mental disorders, based on the idea of a communication supported psychological evaluation. The iSpe is composed of a web-based application with a simple user interface. It integrates easily understood animations and innovative response options, for the screening and assessment of symptoms of mental disorders in people with cognitive challenges. Strategies employed to minimize the cognitive load and reduce biased responding include simplification of question content, simple phrasing, asking question about time in current state before past state and using pictures and animation to support the understanding of the item stem[29-31].

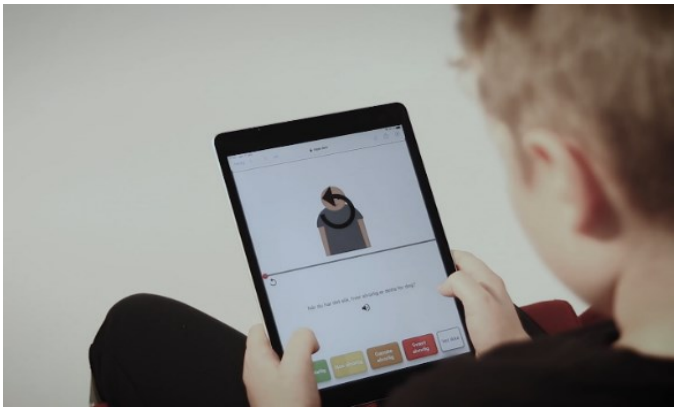

Fig. 1: iSpe applied in pilot study

Usability and feasibility of the iSpe: Several of its intended users have tested the iSpe as part of the development. The evaluation conducted showed that the application helped the participants to understand and convey complex emotional concepts and thoughts through the app. For younger participants the animations also functioned as a starting point for conversation about thoughts and feelings. As one young participant stated: "**It is much easier to tell about my feelings when I don't have to find their words**". To evaluate usability of iSpe, formal usability testing was conducted. The study concluded that the existing application is well adjusted for its purpose[33].

Analyses from our multicenter pilot study of the depression module show variability in symptom reports. Reaction time measures showed both item-to-item variability and indication of a learning curve, which gives new and exciting possibilities to innovative research in the field of psychometric assessments. Most therapists (88-94%) reported textual simplification and visual support to be useful for their client. Reports from patient interview following the assessment were positive. One patient reported: **"[I] really recognized myself in some of the videos or questions. The characters were good, the message came through very clearly**." Another patient said: "[I] think the examination was fun to participate in. Felt useful. The videos

were great". In general, patients and therapists talked about the iSpe in a positive way throughout the interview. Out of 24 patients and clients, 22 used words like "OK", "good", "fun", "exciting" and "all right". Several patients highlight they were able to express important thoughts and feelings. One patient said: "It was really okay to tell the tablet about thoughts and feelings. Gave a sense of calm. Good with examples and videos". There was significant correlation between therapist report and patient self-report, indicating that diagnostically the self-report questionnaire and the therapist questionnaire would place the same individuals in depressed vs. non-depressed categories. Overall, the multicenter study indicates good feasibility of the iSpe and the research protocol (Hove & Eilertsen, in progress).

1.1. Benefit for patient treatment

If successful, this research will provide a tailwind to research on the mental health of people with NDD. The project aims to answer to knowledge needs about mental health in NDD addressed by health authorities in Norway[1-8], clinicians, and researcher: Increase identification and accuracy of mental ill-health in youth with NDD, and by this facilitate correct treatment; inclusion and active participation of this group in research and the services; amplify flexibility, offering users location-independent healthcare services and reduced travel time; embrace digital technology to improve quality and efficiency of treatment; prioritize evidence-based mental health services by integrating healthcare development and research. Understanding risk factors can help patients, caregivers, and services to adopt a personalized approach to mental health. They can focus on specific aspects of their lifestyle or environment that might be contributing to their risk and make changes accordingly. Knowledge about the prevalence and risk factors can be useful in psychoeducation and caregiver information and reduce the fear and anxiety associated with mental disorders. Understanding the prevalence of mental disorders and their risk factors helps mental health services allocate their resources more effectively. Knowledge of risk factors allows services to develop preventive strategies that address the root causes of mental health issues. By targeting these risk factors, they can potentially reduce the overall incidence of disorders. **Health services will be able to provide services at a lower service level, which will increase service offers for this group and reduce the bourdon on highly specialized services with few specialists available (fig2).**

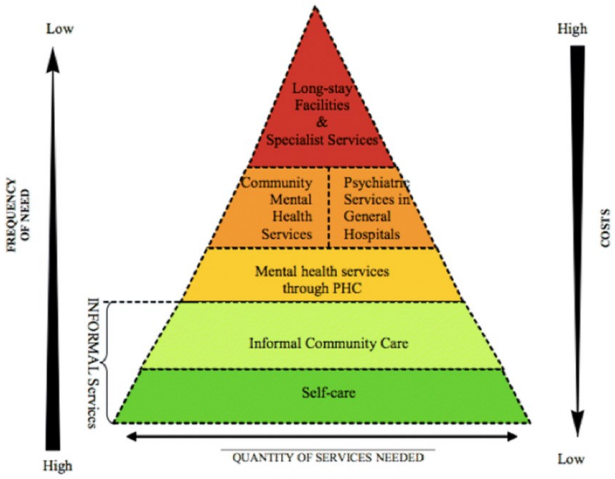

Fig. 2 The WHO Pyramid Framework

Valid diagnosis can be crucial for appropriate treatment. Acceptable reliability and validity are necessary features of a tool used in the healthcare system. With acceptable measures of reliability and validity, the application can be used in clinical and research contexts, and benefit both patients and therapists in the both the primary- and secondary mental health services. The MindMe study will if successful, pave the way for the development of more self-report measures in both mental health disorders as well as other health related outcomes. Patients and caregivers can track their progress over time using consistent and reliable psychometric measures. This helps them and their clinicians to understand whether the treatment is working and adjust if necessary. Patients, caregivers, and services can have confidence in their treatment plan when they know it's based on rigorous assessments. This can enhance their motivation to actively participate in their treatment.

The long-term vision is to transform mental health services, establish a blueprint for integrating technology and cognitive accessibility into mental health assessments, diminish the stigma associated with these conditions, and to increase awareness among all stakeholders regarding the challenges this population encounters. **The Norwegian Directory of Health project DIGIUNG, emphasize the need for digital inclusion of youth with cognitive challenges on their platform ung.no**.

Sustainability: The MindMe project can contribute to several United Nations (UN) Sustainable Development Goals, including: Goal 3: Good Health and Well-being: The project aligns with the goal of ensuring healthy lives and promoting well-being for all. Goal 4: Quality Education: Enhance communication and understanding of mental health experiences can contribute to inclusive and equitable quality

education by supporting individuals with communication or cognitive challenges. Goal 10: Reduced Inequalities: By addressing the specific needs of marginalized groups, the project contributes to reducing inequalities within society. Goal 17: Partnerships for the Goals: The collaboration between various partners, including healthcare organizations, academic institutions, and technology companies, demonstrates the project's commitment to fostering partnerships and collaborative efforts for sustainable development.

2. Objectives and aims

The project's overarching goal is to discern prevalence of mental and behavioral health in clinical samples of youth with NDD and their associated social risk factors. A secondary aim is it to evaluate the psychometric properties and clinical utility of the iSpe depression, anxiety, and sleep modules in our target groups. See 2.1 for clearly defined, concrete, and verifiable sub-goals.

2.1 Research questions and hypotheses, theoretical approach, and methodology

RQ1 – Mental health and social risk factors in NDD
#RQ1.1: What is the prevalence of mental disorders among youth and young adults with NDD? *Methods:* Examine frequency of symptoms of mental disorders through self-reported, proxy reported and therapist diagnostic evaluation. Descriptive statistics and analysis of variance (e.g., ANOVA or Friedman test) will be used to analyze prevalence (CI95%) and variation of reported number of symptoms between responses. Self-reported symptoms of depression, anxiety and sleep disorders in the target group will be compared to self-reported symptoms of these disorders in non-NDD patients. *Expected results:* We expect to find a higher prevalence of mental disorders in youth and young adults with NDD compared to non-NDD, and more self-report symptoms compared to proxy- and therapist symptom reports.
#RQ1.2 What are the key social risk factors contributing to mental health challenges among youth with neurodevelopmental disorders (NDD)? *Methods*: Level of social support, family functioning, peer relationships, bullying and victimization, social integration and stressful life events will be applied as predictors in a regression model with mental disorder as dependent variable, adjusting for level of functioning, gender, and age. When feasible, self-report measure will be applied using relevant iSpe modules. Otherwise, proxy reports will be used. *Expected results*: We expect to unveil key social risk factors that play a significant role in contributing to mental health challenges among youth and young adults with NDD.
RQ2 – Reliability and validity
#RQ2.1: Are the iSpe modules sensitive and specific as diagnostic measures? *Methods*: Examine the tool's sensitivity, specificity and positive and negative predictive values measured in comparison with the clinical diagnostic interview with the Norwegian translation of the MINI Pluss modules for depression, anxiety, and insomnia. *Expected results*: We expect to find the iSpe-modules to be useful when validated against gold standard methods (sensitivity + specificity >1.5)[34].
#RQ2.2: How do the iSpe modules correlate with validated assessment tools (concurrent validity)? *Methods*: Informant iSpe-reported symptoms of depression, anxiety and insomnia, and the severity of these symptoms, in comparison to informants reports from the Depression and Anxiety Stress Scale (all participants), Psychopathology in Adults with Intellectual Disabilities Checklist (participants with learning disability) and Psychopathology in Autism Checklist (participants with autism). *Expected results*: We expect to find substantial intra class correlation (ICC) and/or Gwets AC values (icc/Gwets AC= .61 - .80) between iSpe score and checklist scores[35].
#RQ2.3: What is the internal consistency and test-retest reliability of the patient reported iSpe modules? *Methods*: Test-retest regime for iSpe modules with retest after 14 days, using intraclass correlation (ICC) with a 2- way mixed-effects model. We assume little or no change in the participants' mental health condition within this time period[36].

Expected results: We assume that each of the modules are homogeneous dimensions and expect to find acceptable internal consistency (alpha value .70 - .90) for the iSpe as a research and clinical tool (35). We expect test-retest reliability of the two iSpe tests administered within 2 weeks to be excellent (icc/Gwets AC>.75)[37].
RQ3 – Self-reporting mental health
#RQ3.1: Are some symptoms more difficult for the respondent to self-report than other symptoms, and how is it associated with cognitive functioning? *Methods:* Reaction time (RT), measured in the iSpe test, serve as proxy for difficulties with answering questions about symptoms. We will use regression analysis with RT as dependent variable, WISC/WAIS and Vineland verbal indexes as predictors, other WISC/WAIS and Vineland indexes, age and gender as adjustment variable, and linear mixed effect models (e.g., random intercepts for individual measures). *Expected results:* We expect to identify verbal ability and skills to predict RT measures, adjusting for ability and skills indexed, age and gender, with explained variance at medium strength and significance level .025 to reject the null hypothesis that symptoms are equally easy/difficult to answer.
#RQ3.2: What predicts the therapist's perceived benefit of self-reports vs proxy reported symptoms in people with cognitive challenges? *Methods:* We will use regression models with WAIS and Vineland indexes as predictors and questionnaire information about perceived benefit of self-reported and proxy reported symptoms as outcome measure. *Expected results:* We expect to find WAIS and Vineland communication indexes as predictors for therapists' perceived benefit of patient- and proxy report of symptoms, adjusting for other WAIS and Vineland indexes, age and gender as adjustment variable, and linear mixed effect models (e.g. random intercepts for individual measures).

3. Execution of the study

3.1 Study design, method, and statistics

Design: We will employ a cross-sectional design, commonly adopted approach for investigating the prevalence of mental disorders and social risk factors, and for studying the psychometric properties of assessment tools. This design is efficient; offering a point-in-time estimate of the occurrence of these conditions valuable for public health planning and intervention development; providing insights into variations in prevalence rates or psychometric properties across different demographics. Additionally, this design will help generate hypotheses about potential associations between variables. Crucially, findings derived from cross-sectional analyses can serve as a foundation, steering the trajectory of future research, including comprehensive longitudinal studies.

Participants: We plan invite all individuals (age 13-24 years old) referred to recruiting units to participate in the study. Specifically, patients with NDD will undergo an examination using the iSpe self-reporting tool. Inclusion criteria for the iSpe tool is having mild intellectual disability, learning disabilities [e.g., IQ 70-85], developmental disabilities [e.g., autism spectrum disorder] or language/verbal disorder. Exclusion criteria is a) having a full-scale IQ<60, b) unstable psychotic and bipolar state (conditions in remission is not exclusion criteria), c) severe visual impairment or blindness. Data from non-NDD patient assessed with standard self-report measure of depression, anxiety and/or sleep disorders will be collected through medical journal.

Recruiting sites: Participants will be recruited from the following sites: **Helse Fonna HF**: Mental Health Unit for people with Learning or Developmental Disabilities (LDD); Department of Child Psychiatry Haugesund; Haugaland DPS. **Helse Stavanger**: Mobilt innsatsteam. **Helse Bergen**: Kronstad DPS; Child inpatient unit. **Blå kors:** Clinic Haugaland.

The outpatient unit LDD has the highest volume of annually referred patients with learning disabilities or autism and mental disorders in Helse Fonna HF. They receive approximately 130 referrals each year, and roughly 80 of these are eligible for the study. From Department of Child Psychiatry, we anticipate 40 eligible patients annually. From Haugaland DPS, we expect around 25 eligible patients each year. Other project partners have indicated that at least 20 patients should be eligible for the study from each unit annually. These figures suggest a conservative estimate of approximately 180 eligible patients on an annual

basis. When we consider our sample size/power estimation (details provided see below) and factor in an expected participation rate of 65%, our data collection is projected to last about two years. By this time, we anticipate having included approximately 200-230 participants.

Statistical plan and power analyses*:* Sample size and statistical power have been meticulously determined and confirmed by our in-house statistician. Sample size estimate RQ1: Given the absence of known effect sizes, offering a precise sample size calculation is challenging. But as an approximation, and assuming a medium effect size (Cohen's $f^2 = 0.15$), setting an alpha of 0.05, and six predictor variables, a desired power of 0.80, and accounting for an average correlation among predictors of 0.5, we will require around 200 participants. Sample size estimate RQ2: In our clinical sample, the prevalence of these disorders is conservatively expected to be at least 30% for each of the three disorders. With a sample size of 200 participants, we expect to identify sensitivity and specificity at a 95% precision level for RQ2.1. Expecting a correlation coefficient about .7 between the comparison instruments and iSpe in the current study and accepting a confidence interval +/- .2 (SE=.1), a sample size of 90 participants is needed at minimum for RQ2.2. According to the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN), less than 30 participants, 30 to 49 participants, 50 to 99 participants, and greater than 100 participants denote poor, fair, good, and excellent methodological quality for test-retest analysis respectively as a rule of thumb. Myung et al[36] suggest using a 1:5.37 item to sample size ratio in ICC test-retest reliability analysis. Number of symptom items in the iSpe modules range from 17 (depression) to 27 (agoraphobia). Using the suggested ratio, a sample size of 145 participants indicates excellent methodological quality for the test-retest analysis in RQ2.3. Sample size estimate RQ3**:** There is a strong correlation between reaction time means and general mental ability, which increases with age[38]. We have not found studies investigating the correlation between reaction time and adaptive behavior scores, but IQ has been shown to explain .47 of the variances in Vineland composite adaptive behaviors score[39]. Assuming a medium effect size, a sample size of 100 is needed in RQ3 for a regression analysis with two predictor variables at a significance level .025 (after a Bonferroni adjustment for 2 predictors).

Instruments

Level of functioning: The Hayes Ability Screening Index (HASI), Wechsler intelligence measures (WISC-V/WAIS-IV) and the Vineland Adaptive Behavior Scale (Vineland-III) are clinical tools that will be administered by health professional to verify and index cognitive challenges in the participants. The selection of instruments depends on age and clinical relevance for the participants.

Developmental disabilities: The Social Communication Questionnaire (SCQ) will be used to screen for symptoms of autism spectrum disorders. The Child Communication Checklist 2 (CCC-2) will be used to screen for language disorders. The CCC-2 also include measures indicative for autism spectrum disorder.

Depression, anxiety, and sleep disorders: Information regarding depression, anxiety and sleep disorders in young adult participants are collected using the corresponding modules in The MINI Pluss interview (version 7.0.2), and with the KIDDIE-SADS for youth. Both the patient and proxy interview will be conducted. Additional data on mental disorders will be collected through the Depression and Anxiety Stress Scales (DASS), Psychopathology in Adults with Intellectual Disabilities (P-AID) and Psychopathology in Autism Checklist (PAC). The DASS has been validated in clinical samples[40]. The P-AID and PAC have been validated in people with intellectual disabilities and autism respectively[41,42]. Additional tools may be incorporated to align with the assessment package of collaborating units (e.g., according to "Nasjonalt pasientforløp").

Questionnaire: Patient demographic including gender, medical, mental health history, therapist experience with cognitive challenges. Self-reported social risk factors will be collected using the iSpe questionnaires Friends, Family, Coping and joy, Collaboration and interaction, Somatic health, and Future (see fig 2).

Fig. 3 From iSpe Friends modul

Usability Evaluation: An interview guide for the collection of user experience and usability of the iSpe has been developed and tested in

a pilot study. The system usability score (SUS)[43] will be used for the collection of quantitative data about usability of the iSpe modules.

Procedure

Those who agree to participate will undergo an ordinary mental health assessment at the unit, including the assessments described above and proxy report of symptoms. The patient's therapist will examine the participant's mental health. The iSpe web-application will be administered on iPads. The iSpe assessments are administrated at the therapists' office, at home or at inpatient units, dependent on the patients' needs or will. The participant can at his or her own will or need, bring support persons/parents to assist them. All assessments will, in accordance with requirements in the Norwegian "Nasjonalt pasientforløp", take place within six to twelve weeks after the initial consultation. The patients' therapist is blind to the results from the iSpe assessment when evaluating the presence of mental health symptoms and disorders. Patients that agree to participate in the study, who are already enrolled in the service, will have a reexamination with the study assessment package. Decision of the presence or not of a diagnosis will be based on two expert diagnosticians who independently derive diagnoses based on all available information except from the iSpe modules, and who resolve any disagreements by consensus.

Risk management: Sample size (low risk): Being able to include all the participants needed for sufficient power in hypothesis testing. Findings from the pilot study and the sample size and power estimation indicates that the project is realistically feasible with a data collection period of two years. We will continuously monitor the data flow in our sample size and power estimation and take measures to increase activity in our program if inclusion of patients is lower than expected. Digital self-report and data security (low risk): The iSpe-web app comprises non-sensitive information as movie and sound files, pictures, and questions etc. For handling sensitive data, the project will use the solutions developed by Helse Vest ICT with Microsoft Azure as platform for collecting, storing, analyzing, and sharing sensitive data in compliance with the Norwegian privacy regulation.

3.2. Organization and collaboration

The project is anchored in Helse Fonna HF, is administrated by the Research and Innovation department, and is executed in partnership with the Department of Mental Health. Key partners in this research project also collaborate with the iSpe innovation project and/or the multicenter pilot study. Partners and recruiting sites have firmly established collaboration within their health trust in association with the iSpe.

The project manager, **senior researcher and specialist in psychology Oddbjørn Hove**, is leading the research group on a day-to-day basis. He is founder and manager both the iSpe-project and several projects related to the development of the iSpe and MindMe: User front-end and Creator app; iSpe-modules for depression, anxiety, and insomnia; co-produced and supervised the development of seven iSpe-modules for psychosocial risk factors with Helse Stavanger and Stavanger municipality; iSpe multicenter pilot study; established the MindMe co-production forum; supervised and conducted data collection with youth for a master thesis about complex word identification in Norwegian; co-supervised the NTNU bachelor projects: Parameterized Animation to Support Mental Health Screening, and the iSpe – Smartwatch project. Currently leading projects: i) Person-centered tailoring of assessment in NDD, collaborating with the NHS organization CANDIDD (UK), ii) MindMe dashboard prototype, collaborating with UX-design Helse Vest ICT, and iii) Explore and document the feasibility of SMART on FHIR, collaborating with Helse Vest ICT and Western Norway University of Applied Sciences (HVL).

Hove founded the outpatient services within mental health for people with NDD in 2004, and is head of office for this service in Helse Fonna HF. The outpatient service is responsible for supervision to specialist mental health services in the Helse Vest region on topics related to mental health in in people with NDD. He has initiated and managed several quality improvement projects in the unit. Besides his own research and innovation projects, he actively participates in a national multi-center intervention study lead by NevSom. He has in-depth knowledge of both the clinical and research field of mental health in people with cognitive challenges, and the implementation of research results in clinical practice. As part of his PhD, he developed several mental health checklists for people with intellectual disabilities, implemented in both Helse Fonna and Helse Bergen.

The main scientific group comprises in addition to Hove, Børge Sivertsen (PhD) at the Norwegian Institute of Public Health and Silje Eilertsen (PhD) at Haugaland DPS, Helse Fonna. Sivertsen is a senior researcher, a

professor of both psychology and psychiatry, and is also an accredited specialist in sleep medicine. He has published widely about mental health across all age groups and has extensive experience with use of register data. Sivertsen has led over 18 large-scale projects, and he has published over 290 academic papers in top-tier international journals, with an h-index of 69. He was ranked 12th amongst the top 500 producing researchers across all disciplines in Norway between 2019-2022. Sivertsen will supervise on epidemiologic research. **Our expanded research group** comprises Professor Sujeet Jaydeokar (CANDDID, NHS trust UK), Professor Helge Molde, Associate professor and specialist in neuropsychology Marit Therese Schmid, specialist in SUD psychology Kirsten Braatveit (PhD), Specialist in clinical psychology Ingvild Aase (PhD), biostatistician Jörg Assmus (PhD), Nina Agnethe Grytten Torkildsen (PhD), and user participant Emberland (see eSøknad for descriptions). All collaborators have been involved in the planning of the MindMe study.

3.3. Budget

See «eSøknad»

3.4. Plan for activity and dissemination

Activity schedule	2024	2025	2026	2027	2028
Pretraining and data collection					
Setting up data collection					
Revise information letter and re-apply REK					
Staff training in data administration; data collection					
Data analysis and preparation of papers					
Update literature review					
Study board discussion and analysis of results					
Data analysis					
Writing and publishing papers					
Paper 1 & 2 – Mental health and risk factors					
Paper 3 – Psychometric properties of the iSpe					
Paper 4 – Clinical utility of self-report					
Communication and dissemination (incl. e-learning course)					
Network and PPI activity					
PPI meeting					
Meeting with data collectors and scientific partners					
Social media activity: project status and activities					

Measures for communication and exploitation

Public health care and patients: Arrange events and meetings where researchers in the research group will present their projects and will be available for individual questions. We have started a web site for the iSpe project where we will present material from both the innovation- and research project in addition to general information about cognitive challenges and mental health. Project news and updates published on the web site will be distributed on various social medias[1].

Researchers and clinicians: Presentations at national and international conferences, open access publication in journals, and workshops on (1) research-based innovation, (2) human-centered design and (3) mental health in NDD.

Clinical research network*:* The projects aim to establish a multi-disciplinary PPI and research network on mental health in people with cognitive challenges that includes R&D project members from the iSpe-project and the MindMe study, members from regional specialist services, Universities, municipalities, user organizations and end users. The main aim for the research network will be to stimulate collaboration on clinical research and development within the field. We will arrange 1-2 meetings annually.

3.5. Plan for implementation

We have applied Health pilot funding at the Norwegian Research Council to realize the project, in collaboration with among others youwell AS, Helse Vest ICT, DIPS, Directory of ehealth, Norwegian Directory of Health (Livshendelse: Alvorlig sykt barn), Directory of Digitalization (UU-tilsynet), State Child

[1] https://www.facebook.com/mindme.no/

Unit, national competence centers and several clinical departments and municipalities in the Helse Vest region.

Plan for communication and dissemination is central to the implementation of research finding from the project. To incorporate research into clinical practice we plan to develop guidelines and protocols for mental health professionals to integrate the research findings into their assessment and treatment practices and offer training sessions and workshops to clinicians on how to use the iSpe modules effectively and interpret the results. An e-learning course about mental health and risk rick factors in NDD will be developed, that also will serve as protocol for the utilization of the iSpe tool.

The innovation level in the project is high. The development of the iSpe platform represents a significant technological innovation. The creation of self-reporting modules for mental health assessment tailored to individuals with NDD is novel. The project's research methodology is innovative through the utilization of reaction time as a proxy is a creative way to assess the challenges individuals with cognitive impairments may face. The integration of iSpe modules into clinical practice and the creation of guidelines for mental health professionals reflect innovative efforts to improve service quality. The project's emphasis on involving patients, caregivers, and mental health professionals in the development and refinement of tools demonstrates an innovative user-centered approach. The project's engagement with policymakers and advocacy groups showcases an innovative strategy for driving systemic change in mental health services. By presenting research findings and advocating for policy changes, the project aims to influence the structure and allocation of resources within the mental health system.

4. User involvement

Main users in this project are youth with NDD, caregivers and specialist mental health professionals. **Users have been involved thru the MindMe co-creation forum** established in 2022. The forum comprises participants from The Youth advisory board Helse Fonna, Fagforbundets fellesorganisasjon, ADHD foreningen and privat resource persons. End users with NDD and caregivers will be invited to participate in the project thru presentations on seminars arranged by Norsk Forbund for utviklingshemmede and Autismeforeningen. The first meeting with Autismeforeningen is scheduled in October. The Youth advisory board have reviewed the research protocol for stigmatizing labeling of target groups, the usefulness of research question, the procedure for data collection, measures of communication and user involvement. They will continue to contribute with reviews of information and consent letters, and disseminations of results. Nevrosysmed and the MindMe project will share experiences with strategic and operational user involvement throughout the project period. Collaboration includes exploring knowledge and materials to promote further inclusion and participation of users with cognitive impairments.

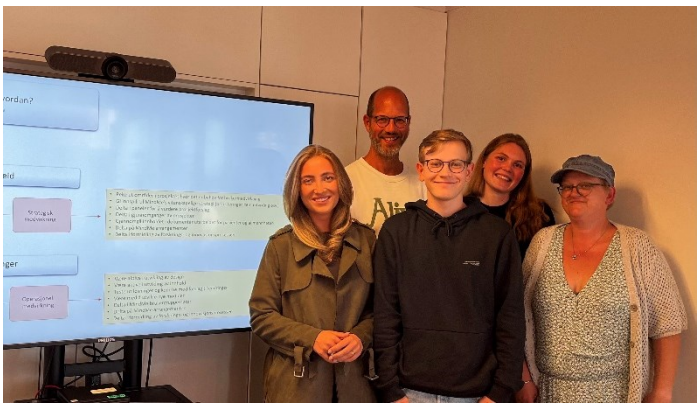

Fig. 4 MindMe Co-creation forum

5. Ethic

The pilot study was approved by REC (177214) and DPO. We will re-apply REC and DPO for approval of the present study. The pilot study was approved by the DPO in collaborating health trust. They will re-apply for DPO approval of the present study.

6. References

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