PROJECT TITLE

Treatment factors as predictors of outcome in video-based treatment for social anxiety disorder in youth.

1. Introduction

In 2021, the Norwegian government set a target of 15% virtual consultations for specialist health services (1). The following year the four regional health authorities launched a plan for 40% CO2e-emission by 2030, specifying 20% of consultations to be conducted by video or telephone before the year 2030 (2). Being the closest analogue to office delivered interventions (OD) among the digital interventions, video delivered (VD) interventions has the potential to reach young people with effective, acceptable, and sustainable mental health interventions. However, VD interventions have a surprisingly small evidence base, and this seems particularly true for studies in the youth population. Only a single pilot study with adolescents was identified from two recent reviews of studies using VD for mental health interventions (3, 4). Another review, specifically investigating cognitive behavior therapy (CBT) by VD treatment, excluded this age group because of lack of studies, but urged future studies to also include the younger age group (5).

Social anxiety disorder (SAD) is highly prevalent, with a life-time prevalence around 13%, and has an early onset with a median of 13 years (6). Untreated it usually follows a chronic course throughout the lifespan, with often serious consequences for mental health, education, work, and social life (7). Early and effective treatment for SAD is therefore of great importance for the youth population.

Over the past 15 years broad based cognitive behavioural therapy (CBT) programs designed to treat all common anxiety diagnoses have been offered to youth at Norwegian CAMHS, following studies documenting their effectiveness for various anxiety disorders (8). However, a study led by the PI of the current study found lower recovery rates for youth with SAD compared to other anxiety disorders (9). This finding was recently confirmed in a review and meta-analysis by other members of our consortium (10) and highlights the importance of conducting more research that can inform more effective treatments. For adults, a Cognitive Therapy (CT) manual specific for SAD has shown excellent effect in a range of studies after its introduction more than two decades ago (11). Another member of our consortium also reported a strong effect after adapting the adult manual to youth treated in a Norwegian Child and Adolescent Mental Health Service (CAMHS) setting (12). Recently, an official complete adolescent adaptation of the program has been developed by members of our consortium at Oxford University, with initial online delivered (OD) and video-delivered (VD) treatment showing very promising results for its effectiveness (13-15). This manual, named CT for SAD in Adolescents (CT-SAD-A) was therefore selected as the intervention for the current study comparing VD to traditional OD treatment for youth.

The current PhD study will investigate predictors of treatment outcome in CT-SAD-A in both video-delivered and traditional office delivered treatment, in a randomized controlled treatment (RCT) study using treatment factors as predictor variables (therapist competence, therapeutic alliance, and treatment credibility) that have previously been found to predict outcome in office delivered treatment. Therapist competence is defined as the level of the therapist's skills in delivering the treatment interventions (16) and will be measured by objective ratings of competence from videorecordings from the treatment. Competence in delivering cognitive therapy for SAD has been found to predict treatment outcome for adult patients (17). However, we do not have studies that investigate whether this is the case for adolescent patients, and there are no studies on the role of competence in video delivered cognitive therapy for SAD to date. Delivering treatment for adolescents may require specific competencies and there is a need for more research on this age population as SAD often debuts in adolescence. The therapeutic alliance, is defined as a collaborative bond and agreement on treatment goals between therapist and youth receiving treatment (18). In child and adolescent psychotherapy, meta-analyses have found therapeutic alliance to be associated

with small to medium effects on outcomes (18,19). However, there is a need for more research on the role of the therapeutic alliance in video-based treatment, which may require specific alliance building competencies, and also specifically with patients with SAD as a result of the lower recovery rates typically found in this patient population (9). In the current study, therapeutic alliance will be measured by self-report questionnaires from both therapist and patient. Treatment credibility refers to how believable, convincing, and logical an intervention is perceived to be (20). Treatment credibility has been found to predict treatment outcomes in internet-based treatments (21) and is a potential predictor for outcome in video-based treatment. In the current study, treatment credibility will be measured by a self-report questionnaire from patiens. Treatment outcome will be measured by standardized assessments and interviews (see section 3.1). With the increasing use of video-based treatment, the current study will add considerably to the literature by investigating the role of treatment factors as predictors of outcome in treatment of SAD in youths.

1.1. Impact on Patient Care

Investigating treatment factors as predictors of outcome in video-based treatment may result in developing a more effective treatment for social anxiety disorder (SAD), through targeted training of therapists and interventions aiming to increase treatment credibility. During the pandemic, the increase in youth anxiety disorders seen over the past decades has accelerated (22). Social isolation has potentially aggravated symptoms of SAD, with youth struggling to return to school and social activities. At the same time the Child and Adolescent Mental Health Service (CAMHS) suddenly had to switch from office delivered to video delivered consultations, to reach patients and their families during lockdown/quarantine. Increased use of video delivered consultations may represent a new way of reaching youth with effective interventions, also outside pandemics (23). As a digital intervention, it can be attractive to youth, lowering the barrier for seeking therapy, and being time-efficient for youth and families especially in rural areas. For society, increased use of video-delivered treatment may lead to lower climate footprint. Video delivery therefore holds the potential of benefits both to the individual and to society.

We will through this PhD study gain increased knowledge of treatment factors as predictors of outcome in delivering online video therapy for youth, which has not been subject to prior research. Findings may also be relevant to other mental disorders and age groups. This may have great impact, since the health authorities now asks for a substantial amount of health consultations to be offered by virtual means. An important outcome of the study will be to investigate components that can be targeted to produce better outcomes (e.g., therapist competence, therapeutic alliance, and treatment credibility). Existing anxiety treatment programs have been evaluated and implemented in many Norwegian CAMHS clinics, but these have been found to have insufficient effect on SAD (9). There is therefore a need to conduct research on more targeted treatments, like the one chosen for this study.

The RCT will also have a substantial impact on patient care through other work-packages (WPs) that will investigate other research questions than the current PhD project. These will investigate whether cognitive therapy for youth social disorder can be delivered with similar (non-inferior) effectiveness on- and offline, whether online video treatment format offers an economic advantage for patients, clinics, and the society, and whether it is perceived as safe and secure for young people and their families. This may then be offered as an evidence-based virtual intervention that can be delivered to the home or school of the youth in need for treatment. It may hold the potential to make therapy more available, lower the threshold for seeking therapy and reduce time for travel and time away from school and family. It may also contribute to the climate by reducing emission from transport. For some, the stigma still attached to identifying as a client of mental health services and as a patient, may be reduced through accessing the therapist from home. The RCT may therefore have several additional impacts on patient care by making effective treatments more accessible,

acceptable, and fairly distributed. This is important not only for mental disorders affecting the prospects of young people, but also to people in rural areas far from clinics.

2. Objectives and Goals/Milestones of the Project

In this multi-centre RCT, which is titled the "Covideo" study, we examine cognitive therapy (CT) for Social Anxiety Disorder (SAD) in adolescents, delivered by video (VD) or at the office (OD). The study has established one study center in each health region, recruiting therapists and patients from a CAMHS outpatient clinic and surrounding municipalities. The consortium behind the study includes members from all four regions. We have secured funding to run the study from KLINBEFORSK and have financing for three PhD's through three work packages (WP1, WP2, and WP3). The current application is for WP4 in the study.

The RCT, has four work packages (WPs), focusing on effectiveness, acceptability, sustainability, and predictors of outcome in the two delivery modes. The "Covideo" study aims to demonstrate that VD has comparable effectiveness to OD (WP1), is well accepted by patients and therapists (WP2), has economic and climate benefits for the society (WP3), and to identify predictors of treatment outcome (WP4).

The primary objective of the PhD project is to investigate predictors of both short-term and long-term outcome in VD and OD treatment for SAD in adolescents (WP4). The secondary objective is to establish psychometric properties for the therapist competence measure used in the study (24). We hypothesise that therapist competence, therapeutic alliance and treatment credibility will predict both short-term and long-term outcome in video-delivered treatment for youth. We also hypothesise that the psychometric properties of the measure used to assess therapist competence in OD can be replicated in VD (i.e., satisfactory interrater-reliability, internal consistency, and retest reliability).

By examining predictors of outcome in CT-SAD-A, the study will provide an evidence-base for a new targeted treatment for SAD in youth. This study will be the first full-scale RCT comparing VD to OD of psychotherapy to youth, and the first to investigate predictors of outcome for this intervention used as video-based treatment.

Overview of the four work packages (WPs):
<u>WP4: Treatment factors as predictors of outcome (therapist competence, therapeutic alliance, and treatment credibility) in VD relative to OD.</u>
Aim 1: Examine the psychometric properties of the Cognitive therapy competence scale for social phobia (CTCS-SP, 24) as a measure of therapist competence in video-delivered treatment.
Aim 2: Examine predictors of outcome in video-delivered and office delivered cognitive therapy for social phobia
We will examine therapist competence by assessing videotaped sessions from the treatment using a competence measure which has previously been psychometrically evaluated with adult patients. The PhD applicant will be involved in the scoring of treatment videos for competence ratings as part of the rater-team for the study. He will partake in regular project meetings with the research consortium. He will organize data for his research project and conduct data analyses for the three papers which comprise the PhD (see section 3.4 for publication plans). He will be supervised by a team of three researchers from the "Covideo" consortium. During the project period we aim to establish psychometric properties of the Cognitive therapy competence scale for social phobia (CTCS-SP, 24) and to investigate if the variables investigated as predictors are associated with short- and long-term outcomes.

<u>WP1: Effectiveness of VD relative to OD</u>
An RCT with noninferiority design of VD and OD with CT-SAD-A for SAD in youth.
Aim 1: Examine effectiveness based on symptom response and diagnostic recovery.

Aim 2: Examine potential moderators and mediators for therapy outcome.
Response and recovery rates are assessed pre/post and at 2- and 4-year follow-ups. Potential moderator and mediator variables are collected during the treatment period. We hypothesise that CT by VD will show non-inferior effectiveness.

WP2: Acceptability of VD relative to OD
Aim 1: Assess acceptability, safety, privacy, and technical problems.
Aim 2: Assess treatment barriers, compliance, and number of missed clinic appointments.
Structured questionnaires assessing barriers, are completed by youth. Interviews with youth, parents and clinicians focus on acceptability, safety, and compliance. Technical problems or challenges with performing therapeutic tasks during VD will be noted.

WP3: Sustainability of VD relative to OD
Aim 1: Analyse CO2e emissions from data on travel modes and distances.
Aim 2: Analyse cost-effectiveness of VD versus OD of CT-SAD-A.
To inform decision makers on whether VD should be a recommended therapeutic approach, we will examine sustainability from both climate and health economy perspectives. Data on travel modes and distances are analysed by a carbon footprint calculator. Costs will include travel costs for patients, absence from work for parents bringing them to OD therapy, extra equipment or training needed for VD delivery, and use of any additional health services. Data will also be collected by a pediatric generic preference-based measure of health-related quality of life, the CHU9D (25). We will present incremental cost-effectiveness ratio; that is differences in costs for VD and OD relative to differences in quality adjusted life-years (QALYs). Subsequent recommendations will depend on level of uncertainty and threshold value for health gain (26).

3. Feasibility

The PhD will be completed in 50% position over 6 years to ensure feasibility, as this period will allow for data collection and scoring of videos to be completed in line with the publication plan. Funding for the operational costs of the RCT has also been funded through KLINBEFORSK. More details are given in the Plan for milestones and dissemination (see section 3.4).

3.1. Study Design, Choice of Methodology and Analysis

Study design: The study is an RCT with a two-arms and non-inferiority design. Youth are randomized 1:1 to the two delivery modes, stratified by therapist. A wait-list comparison is not deemed acceptable as available CBT manuals have shown some effectiveness for SAD in youth.

Inclusion criteria: Age 14-18 years; SAD as primary diagnosis; no psychosis, moderate/severe depression, general learning disability or substance abuse, and < 20% school absence in past 3 months.

Recruitment and screening: We will recruit youth referred to CAMHS sites or seeking municipal services, but also by screening at high-schools with an established three-item symptom questionnaire (27).

Intervention: The CT-SAD-A will consist of 14 weekly 90-minutes individual therapy sessions, and a 6-months booster session.

Patients: Two hundred youth with SAD will be included during the planned two-year inclusion period.

Therapists and clinics: Therapists will be recruited both from CAMHS and municipal health services. At each of the four study centres we plan to have three therapists employed by CAMHS and three by

the municipalities. This will secure the needed number of at least 20 therapists for the study and allow us to compare therapy provision between these two service levels.

Therapist training: Members of our consortium (DMC and EL) who has developed the CT-SAD-A manual will provide therapy training. Therapists are required to treat at least one SAD patient by VD and one by OD, and also attend weekly supervision from an expert in our consortium (JMI). The expert (JMI) must approve of their competence before therapists are accepted into the study. Local coordinators will oversee recruitment, inclusion and therapies at the four study sites.

Technical equipment: The nationally approved "Join" system, delivered by the "Norsk Helsenett", will be used as video recording system, allowing for safe storage of recordings from VD and OD sessions.

Data storage: Videos from all therapy sessions are stored at the Service for Sensitive Data (TSD) by the University of Oslo, where also interview and data related to sustainability are stored. Clinical information collected online from youth and parents are stored in the Viedoc system, offered by the Clinical Trials Unit (CTU) at the regional research support facility. The system allows for automatic reminders of completion.

Data handling: Therapists and a project coordinator are automatically informed of measure completion, and in cases of "red flag" (see section 5: Ethical considerations for more information). Ratings are immediately accessible for therapist following completion.

Ratings of predictor variables: A random 15% of therapy sessions (n=420) will be extracted and assessed by raters for therapeutic competence, using the Cognitive therapy competence scale for social phobia (CTCS-SP, 24) which is a 16-item scale used to assess treatment videos. The scale has been found to have satisfactory interrater-reliability, internal consistency and retest reliability with adult patients (24). Therapeutic alliance (40) will be assessed by a 12-item self-reported alliance inventory named The Therapeutic Alliance Scale for Children – Child and Therapist versions (TASC C/T; 40) completed by the patient and therapist. TASC C/T has demonstrated satisfactory internal consistency in youth samples (40). Treatment credibility will be assessed by a 6-item self-report measure filled out by the patient which has demonstrated satisfactory internal consistency (41, see table 2 for all measures and assessment points).

Raters of competence: Raters with experience in using the treatment protocol will be recruited to rate competence based on videos of treatment. Interrater reliability will be examined, and funding to pay raters for the scoring of videos is funded through KLINBEFORSK.

Statistical analyses: The primary population will be the per-protocol population. Additional sensitivity analyses will be performed on the intention-to-treat population. The primary outcome will be analyzed in a mixed model framework, accounting for stratification factors and possible confounders. Intra class correlations (ICC) will be estimated to determine the degree of clustering related to the site and therapist levels in data. We plan to use latent growth curve modeling (LGM) on prediction models of youth- and parent-rated anxiety symptoms as outcome, and prediction models of loss of principal and all diagnoses will be based on the logistic regression.

Study sites: The following study sites are established at the following hospitals and regions: Innlandet (South-East); Førde (West); North-Trøndelag (Mid) - Northern Norway University Hospital (North).

Power calculation: Power was calculated for the primary outcome measure (Liebowitz Social Anxiety Scale Children/Adolescents self-report version (LSAS-CA; 28), with noninferiority design, and 1:1 patient allocation. Based on Hedman et al. (29), the non-inferiority margin was set at 10, with a

standard deviation of 18 based on our own data (unpublished). With these assumptions, and a confidence level of 95%, a sample of 144 subjects will result in 95% power. Inclusion of 200 patients allows for an estimated 20% pre/post attrition and 10% post/booster attrition.

Therapist number: With 20 therapists treating two patients per semester in year one, and three patients per semester in year 2, 200 patients receive treatment during the planned inclusion period.

Assessment of eligibility: A diagnosis of SAD is established by the Anxiety Disorders Interview Schedule 5 for Children and Parents (ADIS-5 C/P; 30). Comorbidity is examined by an online diagnostic interview, the Development and Well-being Assessment (DAWBA; 31). Three study group members (MA, GJW, ERH) are certified in the use of these interviews and will administer them by online video at pre-, post- and follow-ups, blind for treatment allocation. Participants who withdraw from the study will be asked to complete the outcome measures at withdrawal.

Table 1. SPIRIT table

Timepoint	Screening	Pre assessment	Start of treatment	Mid treatment	Post treatment	6 months booster	2 + 4-years follow-ups
Enrolment							
Eligibility	X	X					
Informed assent/consent		X					
Informed parental consent		X					
Clinical characteristics		X					
Random allocation		X					
Interventions							
Meeting the therapist			X				
CT-SAD-A video delivery			X	X	X		
CT-SAD-A office delivery			X	X	X		
Assessments							
Self-report measures		X	X	X	X	X	X
Parent report measures		X	X	X	X	X	X
Diagnostic interviews		X			X	X	X
Alliance, credibility & acceptability ratings			X		X		
Objective measures of competence based on video assessment					X		

Recent qualitative data from a study with the same intervention and similar measures (see Table 2), found that young people found measures acceptable, and therapists found them useful to tailor treatment and monitor progress (32). Still, we plan to pilot measure completion with Norwegian youth ahead of main study start.

Table 2. Measures for data collection

	Before/start treatment	Every session	Mid treatment	Post treatment	6 months booster	2 + 4 years follow-ups
Primary outcomes						
LSAS-CA-SR	X	X	X	X	X	X
ADIS Child/Parent	X			X		X
Secondary outcomes						
DAWBA online interview	X			X		X
RCADS CChild/Parent	X			X	X	X
SMFQ + one item	X	X	X	X	X	X
ASSWRS	X	X	X	X	X	X
Concentration	X		X	X	X	X
Social functioning Scale	X		X	X	X	X
Peer victimisation Scale	X		X	X	X	X
Focus of attention	X		X	X	X	X
Mediators						
CASCQ	X	X		X	X	X
CASBQ	X		X	X	X	X
Predictors						
TASC Child/Therapist	X	X	X	X	X	
CEQ	X					
Screening						
3-items SPIN	X					
School attendance	X					
Clinical utility						
Acceptability Interview				X		
Treatment barriers			X	X		

1: LSAS-CA-SR (28). 2: ADIS-C/P; anxiety diagnoses (30). 3: DAWBA; comorbidity (31). 4: Revised Child Anxiety & Depression Scale (RCADS, self/parent (33). 5: Short Mood and Feelings Questionnaire (SMFQ) (34). 6: Adolescent Social Summary Weekly Rating Scale (35). 7: Single item added to ASSWRS. 8: Relationship section of the ADIS-5 (30) 9: Peer victimization scale (36). 10: The Focus of Attention Questionnaire (37). 11: Child and Adolescent Social Cognitions Questionnaire (38). 12: Child and Adolescent Social Behaviour Questionnaire (39). 13: Therapeutic Alliance scale for Children (40). 14: Credibility of Therapy Scale (41). 15: Mini-SPIN (27). 16: School attendance youth/parent report. 17: Interviews & questionnaires for patients / parents / therapists (42). 18: Barriers to Treatment Participation Scale (43).

3.2 Organization and Collaboration

Regional coordinators will oversee recruitment and therapies at the four study sites. Main responsibility for the work packages is delegated to four resarchers: Ingul (WP1), Heiervang (WP2), Aas (WP3) and Bjåstad (WP4).

A Steering Committee (PI, co-PI Ingul, coordinators, and clinic heads) and a Scientific Advisory Board (SAB) with two national and two international external experts will be established. A study statistician from the Clinical Trial Unit (CTU) at Oslo University Hospital will follow the study from start to end. The consortium meets coordinators and therapists at biannual seminars. Written agreements, specifying contributions and rights of participating organizations, researchers and therapists will be developed. Any conflicts will be addressed to the Steering Committee and/or SAB.

The consortium consists of:

1) Einar R. Heiervang, MD, PhD, Principal Investigator and co-supervisor for PhD students, was Professor and Chair of Child and Adolescent Psychiatry at the University of Oslo for 12 years until 2023. He is a Consultant and Professor at Innlandet CAMHS. His research covers neurocognition, epidemiology and model evaluation, in addition to treatment research (including a previous RCT for youth anxiety).
2) Jo Magne Ingul, PhD, co-PI of the study, is Associate Professor at the Norwegian University of Science and Technology (NTNU). He has published on the effectiveness of the current treatment model for SAD adapted to the youth population, demonstrating large effects from regular IO treatment (12). Ingul provides weekly therapist supervision, and takes part in therapist training, planning, preparation, analyses and publication. He will be a co-supervisor for the PhD.
3) David M. Clark recently retired as Chair of Experimental Psychology at the University of Oxford, and Director of Oxford Centre for Anxiety Disorders and Trauma (OxCADAT). Clark co-developed the dominant CT manual for SAD in adults, recommended by NICE. He initiated and is the UK government's national advisor for the Improving Access to Psychological Therapies (IAPT) program. He also takes part in all aspects of the study.
4) Eleanor Leigh is a Medical Research Council Clinician Scientist Fellow at the University of Oxford. With Prof Emer Clark she developed the adolescent version of the treatment manual to be used in the study (CT-SAD-A) and conducted a study on an internet version of the manual. Together they provide therapist training. Leigh also takes part in all aspects of the study.
5) Aleksandra Alice Lønøy, is a student of Nursing and board member for the largest youth mental health organization in Norway (Mental Helse Ungdom). She acts as user representative and attends regular meetings of the consortium, also providing feedback on study measures, consent forms, interview guides and other aspects of the study.
6) Marianne Aalberg, PhD, Senior researcher and Head of the Child and Adolescent Section at the Department of Research and Development in Mental Health at Akershus University Hospital (Ahus). She has extensive experience in child anxiety treatment research and will contribute to eligibility assessments. She also takes part in all aspects of the study.
7) Jon Fauskanger Bjaastad, Clinical Psychologist, Doctor of Psychology (clinical), Director of Research at Division of Psychiatry, Stavanger University Hospital, is responsible for quality assessment of therapy sessions and is also involved in all parts of the study. He will be the main supervisor for the PhD.
8) Yngvild Arnesen, Clinical Psychologist, PhD student at the Arctic University of Norway and head of CAMHS at Northern Norway University Hospital, is also involved in all aspects of the study.
9) Gro Janne Wergeland, MD, PhD, is Professor of Child and Adolescent Psychiatry at the University of Bergen, and a Consultant at Haukeland University Hospital. Her thesis focused on effectiveness of a

generic anxiety program, in a study led by the current PI. She contributes on eligibility assessments and is also involved in all aspects of the study. She will be a co-supervisor for the PhD.

10) Helge Ruth, PhD applicant and Consultant at BUP Ålesund, Helse Møre og Romsdal. Helge is a medical doctor with considerable experience in anxiety treatment of youth and will be employed in a 50% PhD position at Stavanger University Hospital for the PhD project.

3.3 Budget

The main funding for running the current study of NOK 18,379 million comes from a national program for clinical treatment research (KLINBEFORSK), organized by the regional health authorities of Norway. Running costs for the study, as well as funding for the WP3 PhD, a postdoc position, and research assistants, is covered by this grant. The WP1 PhD and running costs for the pilot stage is funded by Innlandet Hospital Trust, while the WP2 PhD is co-funded by Innlandet Hospital and the Regional Health Authority for South/Eastern Norway. This current application is for the WP4 in the study, which comprises a PhD with three publications from the "Covideo" study.

3.4. Plan for Milestones and Dissemination

During the pilot stage that started in February 2022, three two-days training seminars with therapists have been conducted, and weekly group therapy supervision has been provided. The training seminars were recorded for use with new therapists coming into the study later. A two-year inclusion period is planned from January 2024, with 2- and 4-year follow-ups. We expect four PhD and a postdoc to produce at least 15-20 original papers from the study, which we aim to publish in high-ranking international peer-reviewed open-access journals. Findings will also be presented at conferences, to patients, the health service, and authorities.

For the current PhD application, we have the following publication plan:

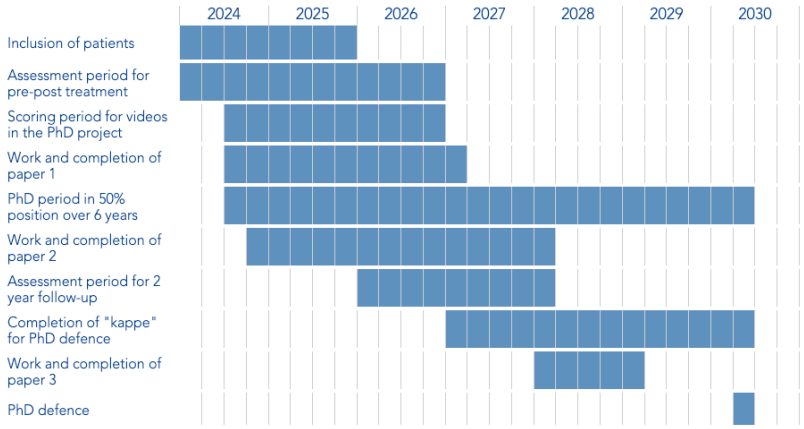
Publication 1: A psychometric evaluation of the Cognitive therapy competence scale for social phobia (CTCS-SP, 24) used in video-based treatment.

Publication 2: Competence, therapeutic alliance and treatment credibility as predictors of outcome in video-based treatment.

Publication 3: Competence, therapeutic alliance and treatment credibility as predictors of long-term outcome (2-years post treatment) in video-based treatment.

3.5 Plans for Implementation

Implementation of VD as a treatment delivery mode in CAMHS and municipalities is ongoing. Data on effectiveness, acceptability, sustainability, and predictors of outcome will speed up this process. Clinicians from the study will contribute to local implementation, and VD training throughout Norway will be arranged after the study provided positive results from the study. The CT-SAD-A manual will also be made available to services in all four health regions. Presentations at national and international conferences, meetings, and seminars, as well as dissemination through user organizations, will also be important for implementation in the PhD study period (see below).



4. User involvement

User involvement is considered critical to the research project as we need input from users regarding video-based treatment for youth, which is a relatively new field of study. The main supervisor for the PhD project has recently been a co-author on a publication on user involvement in Norwegian research projects (44) and results from this survey will inform our user involvement in the current study. The user representative, Aleksandra Lønøy, has previous experience in this role, and has contributed to planning and will be involved in the execution of the study, including recruitment, information and consent letters, and interview guides and questionnaires. She will also have important contributions in the dissemination phase, communicating to youth and the government.

5. Ethical Considerations

The study is approved by the Regional Committee for Medical and Health Research Ethics, and by the Data Protection Officer at Innlandet Hospital. The study involves children, and informed assent (below 16 years) or consent from youth and parents are required. Participants may withdraw at any time without negative consequences. Additional or alternative therapy will be offered in case of deterioration or insufficient effect.

Risk to participants is considered minimal. Significant distress during treatment has not occurred in previous case series, and participants are free to withdraw at any time. Close collaboration with parents is maintained throughout the study. Weekly reports on social anxiety and depressed mood are collected, and any sign of deterioration will be detected. An item on suicidality (item 19) is added to the Short Mood and Feelings Questionnaire (SMFQ; 34) from its long version, and any report of this is considered a "red flag" and is acted upon. If other deterioration or elevated risk is observed, appropriate procedures will be followed. Additional or alternative treatments may then be offered at participating clinics. Regarding risk to completion, inclusion of therapists and patients will go on until inclusion is complete. Training seminars are conducted regularly for new therapists on the manual and in technical procedures involved.

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