Prevention of anxiety and depression in school children
The development and testing of the new transdiagnostic EMOTION intervention

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Summary

Anxiety and depression are among the most common mental disorders affecting youth. The two disorders often co-occur and can cause significant distress and impairment. Having elevated symptom levels but not fulfilling the criteria for a disorder is even more common in youths. Experiencing elevated levels of anxious and depressive symptoms is associated with negative outcomes comparable to when fulfilling the criteria for a disorder and constitutes a risk factor for later development of disorders. Preventing internalizing problems in children from developing into disorders, could have important public health implications.

The main aims of this thesis were to develop a new transdiagnostic intervention targeting anxious and sad school children, to examine the feasibility of the program in a school setting and to perform an effectiveness evaluation of the intervention. Secondary aims were to examine the psychometric properties of the main outcome measures and to investigate associations between functional outcomes (quality of life and self-esteem) and primary outcome measures.

The work was performed in three steps, each with specific, but related aims. The results are reported in 4 papers, all published in or submitted to international scientific journals.

The main aims of the three steps were:

Step 1: A transdiagnostic intervention was developed with the aim of integrating common mechanisms of change targeting anxious or sad school children aged 8 – 12 years, resulting in the EMOTION: “Coping kids managing anxiety and depression” manual.

Step 2: The intervention was piloted in a small sample to examine feasibility and acceptability, including possible stigma (paper I).

Step 3: A randomized controlled trial was conducted. The aims were to evaluate the effectiveness of the intervention as indicated prevention, to examine the latent factor structure of main outcome measures and to investigate the associations of anxious and depressive symptoms to quality of life and self-esteem (paper II, III and IV).

The new transdiagnostic EMOTION manual developed in Step 1 was based on two well researched disorder specific treatments. Central components and common strategies when targeting anxious and sad children were included in the new program: a school-based intervention with 20 child group sessions over ten weeks. A parent component with eight parent group sessions was also part of the intervention. Manuals were developed to guide
group leaders from primary care conducting parent and child groups. The program was published in the US (Kendall, Stark, Martinsen, O'Neil, & Arora, 2013) and in Norway (Martinsen, Kendall, Stark, Rodriguez, & Arora, 2014).

The feasibility study (Step 2, paper I) was run in one school (n = 11 children). Results indicated that self-nomination and screening worked as a recruitment procedure with high attendance rates. High user satisfaction was reported in child groups and from group leaders. Parents reported moderate endorsement regarding personal usefulness and high endorsement of usefulness for children. Parents wanted fewer parent groups. Low stigma and increased coping were associated with participation in the intervention.

The effectiveness study (step 3; papers II, III, and IV) was run in 36 schools in three regions of Norway. The study had a clustered randomized designed where schools were randomized to intervention or control condition. Children and parents in the intervention condition received the EMOTION intervention, and the control condition received the attention they would otherwise get (TAU) (normal contact with school health nurse and family physician). Of the children completing screening (n = 1686), 873 children scored above cutoff and were invited to the study. The parents (n = 615) reported symptoms in their children via web-survey.

In paper II, children were categorized in at-risk groups according to their self-report (symptoms of anxiety only, depression only or reporting both anxious and depressive symptoms), and the associations of internalizing symptoms to self-reported quality of life and self-esteem were investigated. The at-risk groups reported significant differences in means regarding self-reported anxiety, depression, quality of life and self-esteem. Comparing the means reported in the at-risk groups, there was an increase in symptom levels when progressing from symptoms of either anxiety or depression, to comorbid symptoms; simultaneously mean self-reported quality of life and self-esteem decreased. Furthermore, the results also indicated statistically significant relations between quality of life, self-esteem and internalizing symptoms in the depression only group and the combined group, while not in the anxiety only group. Thus, depressive symptoms seemed to explain most of the variance in quality of life and self-esteem.

The latent factor structure originally proposed on the child anxiety measure (The Multidimensional Anxiety Scale for children - MASC-C) was examined and confirmed (paper III). Factor loadings on most subscales were good, but some factor loadings on the
Harm/Avoidance scale were low. Certain questions on this scale may therefore require modifications in the Norwegian version. The latent factor structure of the child depression measure (Short Mood and Feelings Questionnaire - SMFQ-C) was also examined. Results indicated a unidimensional factor structure with high internal consistency as originally suggested.

In paper IV, the effectiveness of the intervention was examined comparing the intervention condition to treatment as usual (TAU) in a school-based randomized controlled design. The intervention condition produced significant larger reductions in anxious and depressive symptoms compared to the control condition as reported by the children. For anxious symptoms, there were significant reductions in all subgroups (younger and older children, boys and girls), while for depressive symptoms, significant reductions were found for older children only. Parents reported significant reductions in their children’s depressive symptoms, but not in anxious symptoms. Parents generally reported lower symptom scores than their children did. The largest at-risk group recruited to the study reported symptoms of both anxiety and depression, hence a transdiagnostic approach targeting both symptom groups was supported.

Overall, the positive results from the effectiveness study indicate that the transdiagnostic EMOTION intervention is acceptable and feasible in a school setting. The current study lends support to the usefulness of a transdiagnostic approach to reduce symptoms of anxiety and depression in children.
**List of papers**

**Paper I**

**Paper II**
Self-reported quality of life and self-esteem in sad and anxious school children

**Paper III**

**Paper IV**
1 INTRODUCTION

The present thesis aimed to develop and test a new transdiagnostic intervention: the EMOTION “Coping Kids Managing Anxiety and Depression” program. This intervention is an indicated prevention program that targets children aged 8 – 12 years with symptoms of anxiety, depression or both. Anxiety and depression as internalizing disorders and their subthreshold presentations will first be presented. The associations of internalizing symptoms to the functional domains quality of life and self-esteem were also of interest as the functional domains could give an indication of severity in addition to symptom levels. The domains are therefore introduced before preventive approaches and the school setting as an important preventive arena is presented. Then the theoretical rationale for the EMOTION intervention, empirical evidence for cognitive behavioral therapy (CBT) for internalizing problems and a description of the intervention itself follows. The intervention was tested for feasibility and acceptability in a pilot study (paper I) that will be described below, but the main emphasis of this thesis is the randomized controlled study (paper II, III and IV). Methods, measures, statistical approaches and ethical considerations will mainly be related to this effectiveness study, also called ‘the main study’, but results from both studies will be presented and discussed. Methodological issues in the studies are discussed and possible future research directions are suggested before concluding this thesis.

First, some general background on internalizing problems in youth.

1.1 Internalizing problems in children

Recent research suggests that experiencing symptoms of mental disorders during lifetime is the norm rather than the exception (Schaefer et al., 2017), and approximately half of all individuals who will experience a mental disorder have the onset by age 14 (Kaufman, 2015). Internalizing disorders such as anxiety and depression are among the most common problems in youth that cause significant distress and impairment (Costello, Mustillo, Erkanli, Keeler, & Angold, 2003; Polanczyk, Salum, Sugaya, Caye, & Rohde, 2015). When taking into account the number of children with subthreshold symptoms (Polanczyk et al., 2015) and the impairment caused by such symptoms (Angold, Costello, Farmer, Burns, & Erkanli, 1999; Gonzalez-Tejera et al., 2005; Gotlib, Lewinsohn, & Seeley, 1995), the need for developing and testing new effective preventive interventions for symptomatic children becomes apparent.
Anxious feelings are natural and a normal part of childhood. Such feelings are often necessary reactions to stressful situations and may even enhance performance in some situations (Sandseter & Kennair, 2011). Typical fears in children move from concrete fears, such as being separated from caregivers in young children, to more abstract fears, such as evaluation in social situations, as children grow older (McLoone, Hudson, & Rapee, 2006; Pincus, 2012). The feared situations are related to the developmental phases of specific ages; however, when the reactions are excessive, age inappropriate and reduce daily functioning, the child may meet the criteria for an anxiety disorder (Muris, Merckelbach, Mayer, & Prins, 2000; Pincus, 2012). Anxiety disorders are among the most prevalent emotional disorders in childhood with prevalence rates reported between 2.4–17.0 % (Costello et al., 2003). A recent meta-analysis reported the worldwide pooled prevalence of any anxiety disorder in children at 6.5 % (Polanczyk et al., 2015). However, many children and adolescents have sub-threshold symptoms, i.e., symptoms below the clinical range and that do not meet all the criteria for a disorder. According to Balazs et al. (2013), the prevalence of subthreshold anxiety may affect up to 32 % of the youth population. Such symptoms may be difficult to detect, and parents and teachers may not recognize the child’s problems. Instead they may see the problems as part of normal development, healthy conscientiousness or in some cases as non-compliant behavior (McLoone et al., 2006). Symptoms may also be expressed differently at home and at school. At home the child may seek excessive reassurance, avoid developmentally appropriate situations, such as a sleep-over, or have somatic complaints; at school, the teachers may observe problems with concentrating, avoiding reading in class, or excessive absences from school (Ludwig, Lyon, & Ryan, 2015). In general, anxious symptoms become maladaptive and may require an intervention when they interfere with daily functioning and become persistent (Beesdo, Knappe, & Pine, 2009). Anxious symptoms in childhood are a risk factor for later adolescent anxiety disorders (Pine, 2007), and there are studies indicating that symptoms of anxiety may predict future depressive symptoms and depressive disorders (Goodwin, Fergusson, & Horwood, 2004; Keenan, Feng, Hipwell, & Klostermann, 2009; Kovacs & Lopez-Duran, 2010).

Sad feelings are also a normal part of childhood. When children experience loss or negative life events, the expected reactions are sad feelings. Depressive symptoms are therefore common in youth. When several symptoms are present most of the day nearly every day during the same two-week period, the child may however meet the criteria for a depressive episode (American Psychiatric Association, 2013). How a depressive episode is
expressed, may vary depending on the developmental stages of the child (Avenevoli & Steinberg, 2001). Somatic complaints typically decrease with age, whereas hypersomnia and reduced appetite increase during adolescence in girls (e.g., Kovacs, Obrosky, & Sherrill, 2003). Typical symptoms also include feelings of loneliness, the experience of not being good enough, and tiredness (American Psychiatric Association, 2013). According to Avenevoli and Steinberg (2001), insufficient attention to developmental differences in children may lead to the under-identification of clinical depression among young children. Prevalence estimates of depression range from 1–3 % in schoolchildren to 2-13 % in adolescents, indicating a dramatic increase in incidence in early adolescence (Angold, Erkanli, Silberg, Eaves, & Costello, 2002; Avenevoli, Knight, Kessler, & Merikangas, 2008; Merikangas, Nakamura, & Kessler, 2009). Subthreshold presentations of depression are important to target since these children report comparable functional impairment and many of the same negative outcomes as children having depressive disorders such as academic difficulties, substance abuse and social impairment (Gillham et al., 2007; Gonzalez-Tejera et al., 2005; Gotlib et al., 1995). According to Balazs et al. (2013), subthreshold depression may reach 29 % prevalence in adolescence, and the literature is consistent on the prognostic power of depressive symptoms in children to predict subsequent depressive disorders (Kovacs & Lopez-Duran, 2010). Studies have indicated that self-rated depressive symptoms in first-graders predicted a diagnosis of major depressive disorder between the 7th and 8th grades (Ialongo, Edelsohn, & Kellam, 2001), and depressive symptoms at age 9 predicted minor depression at age 10 or 11 (Keenan et al., 2008). Keenan et al. (2008) also reported that for each depressive symptom, the risk of a later disorder increased approximately twofold. Later research by the same investigators suggested that symptoms of depression in childhood are relatively stable and have a strong predictive value of pediatric depressive symptoms from childhood to early adolescence (Keenan et al., 2009). Youth who experience an episode of major depression also have a particularly high risk for becoming depressed again (Avenevoli et al., 2008; Zisook et al., 2007). Early intervention is thus important for children having internalizing symptoms.

There is a substantial degree of overlap between anxiety and depression in children; however, it appears that depression with coexisting anxiety is more common in children than is anxiety with coexisting depression (Axelson & Birmaher, 2001; Costello et al., 2003; Garber & Weersing, 2010). Anxiety symptoms and disorders have often been found to precede mood disorders (Avenevoli, Stolar, Li, Dierker, & Ries Merikangas, 2001; Chorpita & Daleiden, 2002; Cummings, Caporino, & Kendall, 2014), and anxiety has been suggested
as a risk factor in itself for the development of depressive symptoms and disorders (Bittner et al., 2004; Wittchen, Beesdo, Bittner, & Goodwin, 2003). Depressive symptoms may also increase the risk for later anxiety, and Pine, Cohen, Gurley, Brook, and Ma (1998) reported that major depressive disorder during adolescence predicted an increased risk for the development of generalized anxiety disorder. Depression and anxiety are the most common co-occurring conditions in youth (Avenevoli et al., 2008). Moreover, the prognosis for comorbid anxiety and depression is worse than for either disorder alone with a higher risk of recurrence, longer duration, greater impairment and less favorable response to treatments (Birmaher, Ryan, Williamson, & Brent, 1996; Ezpeleta, Domenech, & Angold, 2006).

Internalizing symptoms in children are often difficult to observe for parents and teachers (De Los Reyes et al., 2015; Villabø, Gere, Torgersen, March, & Kendall, 2012) and may lead to under-identification of problems (Avenevoli & Steinberg, 2001). Self-rating scales are therefore often used to determine symptom level and identifying high scoring samples as targets for interventions (Dierker et al., 2001). However, the phenomena are not directly observable, and interpretation of the items trying to measure anxious and depressive symptoms may vary depending on the developmental level of the child. The scales have furthermore often been translated from other languages and normed in different populations and cultures. Awareness of core features of the symptoms when identifying children at risk and tailoring the intervention to the child needs is more important in prevention initiatives than is diagnostic accuracy. However, ensuring that the measures have psychometric properties as originally proposed in different populations and age groups, is important when using scales for case identification and when evaluating the effectiveness of an intervention.

In summary, symptoms of anxiety and depression are prevalent problems with potentially detrimental consequences for the child and the family if the symptoms escalate and the problems develop into a disorder. The problems may be difficult to detect for adults, and self-report of symptoms is often used to identify children at risk. Even symptoms below the clinical range may render the child at risk for a negative trajectory and may be associated with impairment and lower levels of well-being (Klein, Shankman, Lewinsohn, & Seeley, 2009; Muris, 2006; Sadek & Bona, 2000). Preventing such problems from developing into disorders should be of primary importance.

Internalizing problems may interact negatively with functional domains such as quality of life and self-esteem. These domains will be introduced below before presenting different preventive approaches and CBT for internalizing problems.
1.2 Quality of life and self-esteem

Most quality of life definitions emphasize the child’s subjective satisfaction and assessment of their own wellbeing and functioning in everyday life (Bastiaansen, Koot, Ferdinand, & Verhulst, 2004; Post, 2014). Children with mental health problems have reported a lower quality of life compared to healthy children and those with a physical disorder (e.g., Sawyer et al., 2002). In a Norwegian study of children aged 8 – 15, the children with anxiety/depression reported a lower quality of life than did the ADHD group (Thaulow & Jozefiak, 2012). A study of quality of life in adolescents indicated that particularly anxiety symptoms, but also depressive symptoms, were negatively associated with quality of life (Stevanovic, 2013). A recent Norwegian study on anxious youth (12 – 17 years) reported that in participants with medium to high levels of anxiety symptoms, older age was strongly associated with poor overall quality of life (Raknes et al., 2017). Previous research has emphasized the usefulness of quality of life as a construct to provide important information about the child’s well-being beyond symptom measures (Jozefiak, Larsson, Wichstrom, Wallander, & Mattejat, 2010). These researchers suggested that for children with equal levels of mental health problems, quality of life measurement would add important information about the total severity of the child’s condition.

Low self-esteem is suggested as a possible risk factor for internalizing problems (de Jong, Sportel, de Hullu, & Nauta, 2012), and is also worth considering when targeting anxious and sad school children. Self-esteem is often characterized as an individual’s global evaluation of his or her overall worth as a person (A. E. Steiger, Allemand, Robins, & Fend, 2014). Higher levels of self-esteem have been correlated with improved coping and academic achievement, and lower levels have been correlated with negative outcomes such as substance abuse, loneliness, depression and social anxiety (Haney & Durlak, 1998). In cognitive vulnerability models of anxiety and depression, a negative self-view is considered a risk factor for the onset of disorders (Lonneke et al., 2014; van Tuijl, de Jong, Sportel, de Hullu, & Nauta, 2014). Research with adolescents and adults confirms this, finding that lower self-esteem is associated with higher levels of internalizing symptoms (e.g., de Jong et al., 2012; Ginsburg, La Greca, & Silverman, 1998). Sowislo and Orth (2013) suggested that low self-esteem predicts symptoms of both depression and anxiety. There is less knowledge whether these findings also are applicable to younger adolescents or children, however a study of Mexican-origin children found low self-esteem to be a prospective risk factor for depression in children aged 10 - 12 (Orth, Robins, Widaman, & Conger, 2014). Self-esteem is however changeable
(A. E. Steiger et al., 2014), and a meta-analysis (Haney & Durlak, 1998) concluded that it is possible to improve a youth’s self-esteem and to obtain positive changes in behaviors and academic performance if the intervention focuses particularly on changing self-esteem. Targeting low self-esteem in interventions for sad and anxious children could therefore be important.

Quality of life and self-esteem may provide information related to the severity of the child’s problems and potential risk factors in addition to information provided by symptom levels. The associations of internalizing symptoms to quality of life and self-esteem were therefore examined in the main study.

The high prevalence of internalizing symptoms and the possible negative development, highlight the importance of early intervention or prevention. Finding suitable arenas for identifying children at risk and providing empirically supported interventions are critical. Below, different preventive strategies and use of the school as an arena for reaching children at risk will be described. Then earlier findings on CBT for internalizing problems will be presented.

1.3 Prevention in a school setting
1.3.1 Prevention

Prevention aims to reduce the incidence of a targeted disorder or to prevent the further development of symptoms into a disorder prior to the typical increase in psychopathology (Gordon, 1987). Such efforts may be imperative because research has indicated that the path to enduring mental health begins in early development (Schaefer et al., 2017). Preventive initiatives are commonly categorized according to the targets of the intervention; in universal interventions all members of the population attend regardless of risk status (e.g., all children in a school or class), whereas targeted prevention (selective or indicated) addresses children who are identified as at risk (Mrazek & Haggerty, 1994). Selective programs recruit children based on a common risk factor for a defined problem or group (e.g., children of parents with psychopathology). Interventions are classified as indicated when offered to children reporting symptoms of a condition and who are considered at risk for future development of the disorder (Greenberg, 2010; Mrazek & Haggerty, 1994). As symptomatic children often are not in the mental health system (Essau, 2005; Fisak, Richard, & Mann, 2011), finding suitable arenas for identifying at-risk children and for conducting preventive interventions is imperative. Schools may be such an arena.
1.3.2 Schools as a preventive setting

In many countries children who receive mental health care do so in schools (Farmer, Burns, Phillips, Angold, & Costello, 2003; Lyon, Ludwig, Stoep, Gudmundsen, & McCauley, 2013). Although the primary aim of schools is to provide academic learning, research supports the relation between improved mental health and children’s academic competencies (Adelman & Taylor, 2010). Moreover, schools are primary settings where children display impairment (Ginsburg, Becker, Kingery, & Nichols, 2008) showing excessive avoidance, perfectionism or isolation from peers (Ludwig et al., 2015). Schools provide access to youth who may not otherwise seek treatment in a traditional mental health specialty clinic such as children with subclinical symptoms (Ryan & Warner, 2012) and is also a setting with opportunities to apply new coping skills. Schools are therefore considered an ideal arena for prevention (Masia-Warner, Nangle, & Hansen, 2006), and particularly in societies with predominantly public schooling, as in Norway. It is a realistic setting that can enhance generalizability of the skills learned (Mychailyszyn, Brodman, Read, & Kendall, 2012); moreover, school-based preventions may reduce barriers to treatment such as transportation and reduced stigma (Masia-Warner et al., 2006; Rapee & Spence, 2004). School-based interventions may also increase the chance of completing; according to Mennuti and Christner (2010), 96 % of families who were offered school-based mental health services followed through, whereas only 13 % referred to community-based clinics completed their treatment. Although there are several advantages of school-based interventions, challenges remain when conducting interventions in schools. School administrators who must use staff to recruit children to interventions may worry about resources, concerned parents who may not have identified the symptoms in their child and who may worry about possible stigma and missed class time are other possible challenges (Mychailyszyn et al., 2012). To some extent however, the schools must address the child’s problems with challenges in the classroom and possible absenteeism anyway. School personnel may therefore still welcome useful interventions.

There is extensive research on the effect of psychological therapies targeting anxiety and depression, and on school-based preventive interventions specifically. Findings from these studies could inform theoretical approach when developing a new intervention, and whether to conduct universal or indicated prevention when targeting anxious and sad children.

1.4 CBT for internalizing symptoms

The guiding theory behind the development of the EMOTION program was cognitive behavioral therapy (CBT) in which it is proposed that behavioral events, cognitive processes and emotional state influence behavior and behavioral change (Kendall, 2012b). The theory
has a problem-solving orientation and must be adapted to the child’s developmental level as the understanding and modification of emotions, cognitions and behaviors are central. Performance-based strategies and structured sessions are also a defining feature of CBT for children. Parents are involved to varying degrees, depending on the type of problem and levels of development (Kendall, 2012a). CBT for internalizing disorders and as a preventive approach has been extensively researched. A selection of recent meta-analyses and systematic reviews are presented in Table 1 below. In this table, the effects of psychological therapies targeting anxiety and depression and CBT as a preventive approach targeting symptomatic children are presented in separate sections. Within each section research regarding both problem areas will be examined first, then research targeting either anxiety or depression will be highlighted.
Table 1
Meta-analyses and systematic reviews; Effects of psychological therapies and preventive interventions in anxious and depressed youth

<table>
<thead>
<tr>
<th>Study</th>
<th>Studies/youth included</th>
<th>Disorders/problems</th>
<th>Approaches studied</th>
<th>Effect size Anx./Depr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weisz et al. (2017)</td>
<td>N = 447/30.431</td>
<td>Internalizing/externalizing anxiety</td>
<td>Usual care, CBT and others</td>
<td>0.61/0.29</td>
</tr>
<tr>
<td></td>
<td>N = 24</td>
<td></td>
<td>CBT</td>
<td>0.86</td>
</tr>
<tr>
<td>In-Albon &amp; Schneider (2007)</td>
<td>N = 24</td>
<td>Anxiety</td>
<td>CBT and others</td>
<td>Small to medium</td>
</tr>
<tr>
<td>Reynolds et al. (2012)</td>
<td>N = 55</td>
<td>Anxiety</td>
<td>CBT and others</td>
<td>0.34</td>
</tr>
<tr>
<td>Weisz et al. (2006)</td>
<td>N = 35</td>
<td>Depression</td>
<td>CBT and others</td>
<td>0.20/0.23</td>
</tr>
</tbody>
</table>

Effects of preventive interventions

<table>
<thead>
<tr>
<th>Study</th>
<th>Studies/youth included</th>
<th>Disorders/problems</th>
<th>Approaches studied</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Werner-Seidler et al. (2017)</td>
<td>N = 81/31.794</td>
<td>Anxiety &amp; depression</td>
<td>School-based prevention</td>
<td>0.20/0.23</td>
</tr>
<tr>
<td>Stockings et al. (2016)</td>
<td>N = 146/46.072</td>
<td>Anxiety &amp; depression</td>
<td>Universal, selective, indicated</td>
<td>Reductions in int. symptoms</td>
</tr>
<tr>
<td>Mychailyszyn et al. (2012)</td>
<td>N = 63/15.211</td>
<td>Anxiety and depression</td>
<td>CBT-based school prevention</td>
<td>0.50/0.30</td>
</tr>
<tr>
<td>Neil &amp; Christensen (2009)</td>
<td>N = 27</td>
<td>Anxiety</td>
<td>Universal, selective/indicated CBT and others</td>
<td>0.11 – 1.37</td>
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<td>Fisak et al. (2011)</td>
<td>N = 27</td>
<td>Anxiety</td>
<td></td>
<td>0.18</td>
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<tr>
<td>Teubert &amp; Pinquart (2011)</td>
<td>N = 65/5.713</td>
<td>Anxiety</td>
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<td>0.22</td>
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<tr>
<td>Stice et al. (2009)</td>
<td>N = 47</td>
<td>Depression</td>
<td></td>
<td>0.14</td>
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<tr>
<td>Calear &amp; Christensen (2010)</td>
<td>N = 42</td>
<td>Depression</td>
<td>School-based prevention/early intervention, mostly CBT</td>
<td>0.21- 1.40</td>
</tr>
<tr>
<td>Merry et al. (2011)</td>
<td>N = 53/14.406</td>
<td>Depression</td>
<td>Psychological and educational</td>
<td>Reduced risk of disorder</td>
</tr>
</tbody>
</table>

Note: The effect size (Cohen's d) is an index of size and direction of treatment effect in which 0.20 is considered small effect, 0.50 a medium effect, and 0.80 a large effect.

In the most recent meta-analysis listed in Table 1, the evidence of youth psychotherapy for internalizing and externalizing disorders over the last 50 years is summarized (Weisz et al., 2017). The study reported a mean posttreatment effect size (ES) of 0.46 for psychological therapies. A larger ES was reported for anxiety than for other problem areas, and the lowest ES was found for depression and multiple problems. According to Weisz et al. (2017) youth-focused behavioral treatments (including CBT) produced the most
robust evidence of beneficial effect, independent of informant. An European research team examined the effect of CBT interventions for anxiety disorders including only studies with a written study protocol; they found a large overall effect size across all treatments (In-Albon & Schneider, 2007). Also studying anxiety disorders, Reynolds, Wilson, Austin, and Hooper (2012) found CBT to produce moderate to large ES with passive control conditions and a small ES for active control conditions, whereas the effects of other types of psychotherapy were not significant. In an examination of the efficacy of psychotherapy for childhood depressive disorders, Weisz, McCarty, and Valeri (2006) investigated different types of therapies for depression in youth and found a lower effect size (0.34) than that in other meta-analyses of depression up to this date. The researchers did not find a significant difference in effect size between cognitive and other treatments.

In the next part of Table 1, the focus is on school based interventions, i.e., preventive approaches. Some research teams have investigated the effects of interventions with different theoretical orientations, others the effects on anxiety or depression separately or in combination. The effects of universal, selective and indicated prevention, respectively have also been reported in these studies.

Werner-Seidler, Perry, Calear, Newby, and Christensen (2017) reported beneficial (although small) effects on depressive and anxious symptoms compared to the control condition when examining all types of prevention programs. Stockings et al. (2016) investigated whether preventive programs could reduce internalizing symptoms and reported a reduction for both anxious and depressive symptoms. Mychailyszyn et al. (2012) examined school-based interventions with a CBT orientation for both problem areas and reported large effect sizes.

Studies examining the effects of interventions targeting anxiety only are also indicated in Table 1. Neil and Christensen (2009) performed a systematic review of 27 school-based prevention or early intervention programs and found effect sizes ranging from small to large. They suggested that the variation in effect sizes might be explained by program fidelity, leader support or relevant content. The type of intervention (CBT or others) did not produce significant differences in effect sizes in this study. Fisak et al. (2011) and Teubert and Pinquart (2011) reported a small effect size for prevention programs targeting anxiety. When Calear and Christensen (2010) examined school-based prevention/early interventions for depression only, most programs were based on CBT. The results were inconsistent: only 50% of the included studies reported a significant reduction in depression symptoms. Hence, they reported small to large effect sizes and suggested that the variation in effect size could be
explained by the type of preventive approach, including who led the groups and the control condition employed. When Stice and colleagues (2009) examined depressive preventive programs, 13 programs (41%) produced significant reductions in depressive symptoms, but with a low effect size. Merry et al. (2011) also focused on depression only and concluded that there was some evidence of preventive programs preventing the onset of disorders compared to no intervention.

Research presented in Table 1 may also give an indication as to how universal, selective and indicated interventions perform when targeting anxious and depressive problems. The results are mixed however. Several research teams have reported that selective or indicated interventions produce larger reductions than universal interventions (Calear & Christensen, 2010; Mychailyszyn et al., 2012; Stice et al., 2009; Teubert & Pinquart, 2011). Werner-Seidler et al. (2017) reported that targeted prevention performed better than universal interventions for depression but not for anxiety. Neil and Christensen (2009) reported positive results with universal and indicated approaches for anxiety. This was confirmed by Fisak et al. (2011) who also reported no significant differences between universal and targeted preventive programs for anxiety. When Merry et al. (2011) examined this issue in relation to depression, they found that selective and indicated interventions produced larger reductions than universal programs. However, when Stockings et al. (2016) examined the joint efficacy of universal, selective and indicated preventive interventions for anxiety and depression they found larger reductions in universal interventions than targeted interventions.

In summary, empirical evidence indicates that psychological therapies and school-based CBT for both anxiety and depression are promising. The results regarding universal vs targeted interventions are inconsistent, particularly so for anxiety. There is support for indicated approaches for depressive symptoms. Because the EMOTION program targets children presenting with both anxious and depressive symptoms, an indicated approach was chosen in the studies reported in this thesis.

Below, the rationale for transdiagnostic interventions will be presented before explaining the new CBT based transdiagnostic intervention: the EMOTION program.

1.5 Rationale for transdiagnostic interventions

In the meta-analyses and systematic reviews presented previously, the interventions were disorder specific (Mansell, Harvey, Watkins, & Shafran, 2009). Lately, transdiagnostic approaches in which similar conditions are targeted within one protocol, have been developed
Sauer-Zavala et al. (2017) suggested that transdiagnostic interventions can be split into three categories based on the rationale for the intervention: firstly, the guiding theory can be applied to a range of different problems; for example, CBT has been applied to many different problem areas and can demonstrate effects across many diagnoses (e.g., Weisz et al., 2017). A critique of this approach is that it is a “one-size fits all” way of thinking (Sauer-Zavala et al., 2017). Secondly, in a modular approach, the therapist selects interventions from a bank of evidence-based strategies to provide a tailor-made intervention for the presenting problem. With this approach, strategies are often presented sequentially, which may lengthen the treatment, and a clear strategy on how to select and sequence the modules are necessary. Lastly, the intervention may target shared mechanisms hypothesized to be maintaining factors or core deficits between the problem areas (McLaughlin & Nolen-Hoeksema, 2011; Sauer-Zavala et al., 2017). However, core mechanisms are unknown for many disorders (Sauer-Zavala et al., 2017).

The EMOTION intervention was developed with the third approach in mind: targeting common mechanisms of change for problems with common features. There are several rationales for targeting both problem areas within one protocol; the high comorbidity observed between anxiety and depression (e.g., Merikangas et al., 2009), the similarity of symptoms such as withdrawal/avoidance and cognitive distortions (e.g., Kendall et al., 2014), and the observation that effective interventions for anxiety and depression have a common structure and share many strategies such as relaxation, cognitive restructuring, problem solving and behavioral interventions (e.g., Kendall & Hedtke, 2006; Stark et al., 2007). Furthermore, findings in which single-disorder protocols target one of the disorders and reduce symptoms of the other also render support to the notion of shared underlying mechanisms for the two problems (Weisz, Jensen-Doss, & Hawley, 2006) and provide a rationale for targeting both problem areas simultaneously.

A diathesis-stress model hypothesized that in stressful situations, a combination of diathesis could result in anxiety, depression or both (Kendall et al., 2014). Possible common mechanisms were: information processing errors such as faulty core beliefs and deficits in problem solving, problems with emotion-regulation strategies, genetic predispositions and learning history (Kendall et al., 2014). Temperament or negative emotionality could also be a shared mechanism that may account for some of the shared variance between anxiety and
depression in youth (Barlow, 2000; Barrett, Duffy, Dadds, & Rapee, 2001; Garber & Weersing, 2010; Tully, Zajac, & Venning, 2009). Additionally, parental behavior, such as rejection and control, could play a role in both problem areas (McLeod, Weisz, & Wood, 2007; McLeod, Wood, & Weisz, 2007). Furthermore, similar neural dysfunction in relation to emotional stimuli has been suggested as a common mechanism (Kendall et al., 2014).

A transdiagnostic approach may be more effective when problems often co-occur, and it may reduce the need for training in multiple protocols and simplify forming of ideally sized groups. Potential disadvantages include the possible dilution of the approach compared to single disorder protocols. Although research on transdiagnostic approaches is underway (e.g., Chu et al., 2016; La Greca et al., 2016), little is still known about the effectiveness of transdiagnostic approaches targeting children. To our knowledge, the main study of the current thesis is the first large randomized controlled trial examining this issue. This thesis thus adds to the field by providing information regarding feasibility in a school setting and initial effects.

2 STEPS AND AIMS OF THE THESIS

The work in this thesis was completed in three steps, each with specific aims:

Step 1: Develop a transdiagnostic intervention.

Aim: Integrate common mechanisms of change for anxious and sad children in one protocol.

Step 2: Pilot the intervention.

Aim: Examine the feasibility and acceptability of the intervention.

Step 3: Conduct a randomized controlled study of the intervention.

Aim 1: Test initial effects of the intervention.

Aim 2: Examine primary outcome measures used for inclusion.

Aim 3: Investigate the associations between quality of life and self-esteem and internalizing symptoms.

An overview of the thesis with the timeline, steps and aims, development and revision of the manual and the papers produced by these initiatives is presented in Figure 1.
Figure 1 Overview of Thesis

**Steps/Studies/Aims**

**Step 1**
- Develop a transdiagnostic intervention
  - **Aim**: Integrate common mechanisms of change for anxious and sad children

**Step 2**
- Pilot the intervention
  - One school, n = 11
  - **Aim**: Examine feasibility and acceptability

**Step 3**
- Conduct a randomized controlled study
  - 36 schools, 3 regions, N = 695
  - **Aim 1**: Test initial effects of the intervention
  - **Aim 2**: Examine primary outcome measures
  - **Aim 3**: Investigate the associations of quality of life and self-esteem to internalizing symptoms

**Time**
- 2008
- 2011
- 2014
- 2015
- 2016

**Versions of the Emotion Manual**
- Pilot version
  - 20 child sessions, 2 individual 8 parent sessions

**First revision for RCT**
- 20 child sessions, 7 parent sessions

**Second revision after RCT**
- 16 - 20 child sessions, 5 parent sessions

**Paper 1**: Cognitive Behavioral Practice, (2016)
**Paper 2**: BMC Psychology (2016)
**Paper 4**: Journal of Consulting and Clinical Psychology (under review)

**Paper 1**
- Prevention of anxiety and depression in children: Acceptability and feasibility of the transdiagnostic EMOTION program

**Paper 2**
- Self-reported quality of life and self-esteem in sad and anxious school children

**Paper 3**
- The factor structure of MASC youth report in Norwegian school children

**Paper 4**
- Prevention of anxiety and depression in school-aged children: Effectiveness of the transdiagnostic EMOTION program
Step 1 THE DEVELOPMENT OF A TRANSDIAGNOSTIC INTERVENTION

The aim when developing the intervention was to integrate effective components from two well-researched disorder-specific treatments to create the new transdiagnostic EMOTION program. The disorder-specific programs were The Coping Cat program which primarily targets anxiety (Kendall & Hedtke, 2006), and The Action program which primarily targets depression (Stark et al., 2007). School children aged 8 to 12 reporting symptoms of anxiety and/or depression were the target group. The intervention was based on CBT principles, and which transdiagnostic strategies or core components to include in the new program were crucial decisions.

Important components in interventions targeting anxious and depressed youth have generally involved emotional learning, relaxation, cognitive restructuring, graded exposure and behavioral activation (Kendall & Hedtke, 2006; Stark et al., 2007). Furthermore, identified transdiagnostic mechanisms such as information processing, emotion-regulation strategies, behavioral interventions, learning history in addition to strategies suggested by experts in the field, guided decisions regarding content of the child-focused program. Parental involvement was another major consideration. Although parental behavior has been suggested as a factor for the development and maintenance of internalizing problems (McLeod, Weisz, et al., 2007; McLeod, Wood, et al., 2007), the effects of parental involvement in the treatment of anxious youth have been mixed. Some studies have indicated that including parents in the treatment is not essential to obtain a positive result (e.g., Kendall, Hudson, Gosch, Flannery-Schroeder, & Suveg, 2008; Reynolds et al., 2012), whereas others have reported a positive effect of parental involvement (e.g., Barrett, Rapee, Dadds, & Ryan, 1996). For depressed youth the role of parents will also vary according to the characteristics of the child and the family (Curry & Meyer, 2017), but there is evidence supporting a parental component when conducting child groups (Birmaher et al., 2007; David-Ferdon & Kaslow, 2008). A parental component was thus considered necessary and a possible transdiagnostic mechanism. Furthermore, because a negative self-view is considered a risk factor for both anxiety and depression (van Tuijl et al., 2014), and because self-esteem often decreases in early adolescence (Robins & Trzesniewski, 2005), and is changeable (A. E. Steiger et al., 2014), strategies for enhancing self-esteem were included in the EMOTION program. Twenty sessions targeting anxious and sad children were conducted in a group format to allow for
experiential and fun learning. See Figure 2 for an overview of the child and parent sessions related to common mechanisms.

Figure 2 EMOTION overview
Child and parent sessions and strategies to common mechanisms

<table>
<thead>
<tr>
<th>Child sessions/strategies</th>
<th>Common Mechanisms</th>
<th>Parent sessions/strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Motivation/goal setting, group cohesion, closing (S: 1, 3, 19, 20)</td>
<td>Collaborative relationship/focused approach</td>
<td>Motivation/goal setting/closing (S: 1, 7)</td>
</tr>
<tr>
<td>Coping through pleasant events/Emotion focused coping (S: 2, 4)</td>
<td>Emotion understanding and regulation</td>
<td>Identification of feelings/Emotion focused coping (S: 4)</td>
</tr>
<tr>
<td>Psychoeducation: Identification of feelings, how thoughts influence feelings (S: 3, 6)</td>
<td>Information processing errors</td>
<td>Problem-solving/ Cognitive restructuring (S: 5, 6)</td>
</tr>
<tr>
<td>Problem-solving/ Cognitive restructuring (S: 5, 7, 8, 9 &amp; 10 – 18)</td>
<td>Withdrawal/ behavioral learning</td>
<td>Exposure &amp; Behavioral activation/support (S: 4, 5)</td>
</tr>
<tr>
<td>Exposure &amp; Behavioral activation S: (10 – 18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Building a positive self-schema (S: 12 – 16)</td>
<td>Self-esteem</td>
<td>Positive parenting/ positive reinforcement/support (S: 2, 3)</td>
</tr>
<tr>
<td></td>
<td>Parental Behavior</td>
<td></td>
</tr>
</tbody>
</table>

Note: S = session number
Manuals were developed to guide group leaders recruited from primary care conducting parent and child groups. Parents and children received workbooks developed for the program. The program was published in the US (Kendall, Stark, Martinsen, O'Neil, & Arora, 2013) and in Norway (Martinsen, Kendall, Stark, Rodriguez, & Arora, 2014). Later revisions in both the US and Norwegian version were based on the Norwegian pilot study and the randomized controlled study to be explained later: see also Figure 1.

The EMOTION: “Coping kids managing anxiety and depression (Kendall et al., 2013) thus targeted symptomatic children aged 8 – 12 with their parents, both meeting in groups. The manual was structured with the first half of the program dedicated to skill building and the second half focusing on behavioral experiments, cognitive restructuring and enhancing self-esteem. Playful and experiential activities were emphasized in all sessions. Two child sessions a week for 10 weeks with two individual sessions to facilitate the development of specific goals for each child were included in this first version. The parents met in small groups for eight sessions. Every other parent session included the children. When the parents met alone, the goals were for the parents to learn the same strategies as the children, while also learning some skills aimed at parents only. When the parents and children met together, the goal was to interact and practice the skills they had learned separately.

This EMOTION manual was tested for feasibility and acceptability in a pilot study in the fall of 2011 (see paper I and section 4 below). Revisions were made to the manuals following the pilot study. The main changes were related to the number of sessions and increased coherence regarding the content and structure of the sessions. The revised version was then investigated in the main study (see paper IV and section 5).

4 Step 2 THE PILOT STUDY (Paper I)

The primary aim of the pilot study was to examine the feasibility and acceptability of the intervention as indicated by the results of the chosen recruitment procedure, attendance rates and satisfaction with the program. Satisfaction was reported by the children and parents after each session and after completion of the program. An important part of the feasibility study was also to evaluate possible stigma experienced by the children when participating because the study was conducted in a school setting with little room for anonymity.

A contract was signed with one rural school in which the intervention was piloted in fifth grade (9 to 10-year old children) during the fall of 2011 with group leaders from the local Educational-Psychological Services.
4.1 Methods

4.1.1 Recruitment

Because the EMOTION intervention targeted symptomatic children, a recruitment approach that identified at-risk children was necessary. We considered screening the entire grade level and having school nurses/counselors nominate children, however, the Regional Committee for Medical and Health Research Ethics (2011/536/REK South East) did not approve of this approach. A gateway approach was therefore administered where the program was first announced in a joint fifth grade meeting and presented at a parent meeting. The presentations were made age-appropriate, and the target group was emphasized: children who worried or were more anxious than their peers and their parents. Children who expressed interest and whose parents signed informed consent then completed self-report questionnaires of anxiety and depression, and the parents reported on internalizing symptoms. Children meeting inclusion criteria were invited to the pilot study.

4.1.2 Measures

An overview of measures used in the pilot study, is presented in Table 3 (Section 5.2). Only measures used to answer the aims of the study are described in detail. To screen for inclusion, the children completed the Multidimensional Anxiety Scale for Children (MASC-C, March, 1997) and the Children’s Depression Inventory (CDI, Kovacs, 1992): the parents described internalizing symptoms observed in their children using the Child Behavior Checklist (CBCL, Achenbach & Rescorla, 2001). User-satisfaction was measured after each session with three questions, and with the ACE Stigma and evaluation sheet (Rapee et al., 2006) after the intervention. This questionnaire also measured perceived stigma (for details, see section 5.2).

4.1.3 Inclusion and exclusion criteria

To be invited to the pilot study, the child or parents had to report symptoms between 0.5 – 2.0 over a chosen mean on measures of internalizing symptoms, see Table 3. Children reporting suicidal intent were excluded.

4.1.4 Sample characteristics

Of all the children in fifth grade, 38 % (22 children) signed up and completed the self-report measures. Only two children were invited based on parent report only. Of the children screened, 54.4 % (12 children) scored within the inclusion range and were invited to participate in the study. One child withdrew before the groups started, and 11 children forming two groups completed the intervention. For a flow chart of participants in the pilot study, see Appendix 1.
4.1.5 The intervention and training

Group leaders recruited from one primary care institution, attended a 5-day training prior to groups starting. The first three days focused on general CBT-principles and understanding anxiety and depression in children, while the last two days included a session by session training of the manuals and workbooks. Supervision was provided on a weekly basis by the first author of all papers.

Information regarding the recruitment procedures and feedback from group leaders, children and parents enhanced our knowledge of the acceptability and feasibility of the intervention. Results were reported in paper I and in section 7.1 of this thesis.

5 Step 3 THE RANDOMIZED CONTROLLED STUDY (Papers II, III & IV)

The primary aim of the main study was to establish whether the intervention had a significant effect on reducing symptoms of anxiety and/or depression when applied in a large selected sample of school children aged 8 – 12 years. The secondary aims were to examine the psychometric properties of the main outcome measures which was used for inclusion and to investigate associations between functional outcomes (quality of life and self-esteem) and primary outcome measures. This was an effectiveness study with group leaders running groups in addition to their usual workload. This real-world context ensured external validity, but it also implied being confronted by real-world problems which influenced the research project. The design, sample, measures and statistical methods in the main study are presented below.

5.1 Methods

5.1.1 A clustered randomized design

Randomized controlled trials represent the gold standard in evaluating health care interventions when designed appropriately (Schulz, Altman, & Moher, 2011). Core elements include random allocation to intervention and control groups, the participants being blinded to the condition they are in, and all intervention groups being treated identically (Sibbald & Roland, 1998). As observed by Ukoumunne, Gulliford, Chinn, Sterne, and Burney (1999), health interventions in schools are often implemented in clusters of individuals for both theoretical and practical reasons. As previously noted, the school setting was a natural arena for recruiting at-risk children in the current study. Furthermore, randomizing children to control and intervention conditions within the same school could possibly contaminate the results, and schools were therefore selected as the unit of randomization. To achieve a balance between study groups, schools with comparable sizes and within the same geographical area were therefore matched in pairs and the schools within each pair were randomized to the
control (TAU) and intervention (the EMOTION program) conditions. TAU included normal contact with the school health nurse or family physician. Hence, a clustered randomized design with restricted randomization was applied (Howick, 2011).

Both the intervention and control schools had short workshops in which school personnel were given information regarding typical symptoms in anxious and sad children how to assist these children in class.

5.1.2 Power-calculations

Power calculations were used to determine the number of participants in the main study. Although schools were the unit of randomization, the intervention was designed to change individual levels of anxious and depressive symptoms, thus creating the ‘unit of analysis problem’ (Ukoumunne et al., 1999). Standard statistical methods assume that individual responses are independent of one another; however, individuals within one cluster are often more similar to one another than individuals between clusters (Ukoumunne et al., 1999). Using standard statistical methods to assess power will in such cases often underestimate the sample size required. Methods to adjust the standard sample size calculation to account for both between-cluster variation and within cluster variation were thus applied. In the school interventions, three levels (school, class and individual) could be considered. When planning the study, however, only two levels (school and individual) were used because the children participating in the groups were often from several classes; therefore, the class level was not a unit of analysis.

To estimate the required sample size, we adjusted the power-calculations using the intraclass-correlation coefficient and the design effect (Deff), as recommended by Ukoumunne et al. (1999, pp. 31-32) to account for a multilevel approach. In addition to the significance level (0.05) and required power (0.80), we based the estimates on the following parameters: anticipated effect size in anxiety and depression: 0.35, and the intraclass correlation coefficient (ICC): 0.05 (Patras et al., 2016). Based on this estimation, at least 559 individuals and 23 schools were required, including both the control and intervention condition (see shaded area in Table 2).
Table 2. Number of participants and clusters required in the RCT

<table>
<thead>
<tr>
<th>Estimated ICC</th>
<th>Calculated DEFF</th>
<th>n</th>
<th>Number of schools</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00 – Base model</td>
<td>1</td>
<td>260</td>
<td>15</td>
</tr>
<tr>
<td>0.05 – Two-level model</td>
<td>2.15</td>
<td>559</td>
<td>23</td>
</tr>
</tbody>
</table>

Note: ICC = intraclass correlation coefficient; n = number of pupils; DEFF = Design effect = 1 + (nc – 1) *ICC, (nc = average number of individuals in a school = 24); The first value (260) is from Altman (1991), page 456, and the next figures are multiplied with the calculated DEFF value.

Then, the original power calculation (Table 2) was adjusted for uneven recruitment in the two conditions using the Welch t-test for two groups and accounting for the design effect. The updated estimated number of individuals necessary was 653, and the number of schools was increased to 36. In accordance with the Consolidated Standards of Reporting Trials (Consort) guidelines for clustered randomized trials (Campbell, Elbourne, & Altman, 2004), the flow of children through the study is described, see paper IV and Appendix II.

5.1.3 Informants

Which informants to include when recruiting children was an important consideration in the main study. Theoretical and practical issues in addition to knowledge gained from the pilot study played a part in this decision.

In psychological research, a multi-informant approach is often recommended (De Los Reyes et al., 2015; Rhew et al., 2010; Villabo, Gere, Torgersen, March, & Kendall, 2012). Agreement between symptoms reported by parents and by children, is however generally low (Kendall et al., 2014; Wei, Hoff, Villabo, et al., 2014). When screening many children for participation in the study, practical considerations also played a part regarding who to include in the screening process; while the children who had expressed interest could be reached directly at the school, the parents were to report symptoms via an e-mail link. With time constraints for the data collection and based on experience from the pilot study in which few children were recruited from parental report alone, child-report only was the basis for including participants in the main study. Parents would then be requested to provide baseline data of the included children.

5.1.4 Recruitment

The gateway recruitment approach adopted in the pilot study appeared acceptable, and a similar approach (illustrated in Figure 3) was used in the main study:

Stage I: The study was presented in the selected grade level for children using age-appropriate language and explicitly stating that we wanted to recruit children who considered themselves more anxious or sad than their peers. The children were given written information to bring
home and were encouraged to discuss participation with their parents. Simultaneously, the study was presented to the parents at parent meetings and by written information, in which voluntary participation and the importance of discussing participation with the children was emphasized. In the letter to parents, the last page provided alternatives regarding participation (yes/no), and the parents were asked to give their consent if they and their child wanted to participate in the study.

Stage II: Children whose parents had provided informed consent were invited to the screening, and electronically answered self-report measures of anxiety (MASC-C; March, 1997) and depression (SMFQ; Angold, Costello, Messer, & Pickles, 1995) during school hours (for more information on measures, see section 5.2).

Stage III: Only children who reported anxious and/or depressive symptoms of 1 SD or more above the chosen cut-off (for more information regarding the cut-off, see section 5.2.6) and their parents were invited to participate in the study. The parents of the children invited to the study, were then asked to answer a separate questionnaire via e-mail link.

In the first semester of the main study, the children and parents were informed about the study condition (intervention or control) of their school after having completed screening. For later semesters, the children and parents knew whether their school was an intervention or control school when signing up for the study.

Both parents and children would report symptom levels after the intervention/control period. A controlled pretest – posttest design for the child- and parent reports was thus used to measure change in symptom levels (see Figure 3 for a visual presentation of the recruitment approach, time of randomization and controlled pre-post design to measure change in symptoms).
Figure 3 Recruitment and pre-post design in the main study

**Stage I**
Study presented at schools in 3 regions

- 12 schools, 3 municipalities
  - Region North
- 12 schools, 3 municipalities
  - Region Mid
- 12 schools, 3 municipalities
  - Region East/South

**Stage II**
Screening/measuring symptoms
Child report

- Children interested and with informed consent screened
  - MASC/SMFQ

**Stage III**
Invitation to study
Parent report

- Children scoring 1 SD over the chosen cutoff were invited to participate

**Randomization**
Intervention/control

**Intervention/Control**

Children

- 10-week intervention
- 10-week control
- T1/C

Parents

- Parents of children invited to participate report on demographics & symptoms

- 10-week intervention
- 10-week control
- T1/P

**Measuring symptoms**
Child and parent report

- T2/C
- T2/P

1 semester * 5 (2.5 years)
5.1.5 Sample characteristics

The flow of children in the main study is illustrated according to Consort guidelines in Appendix II.

Of the total number of children informed about the study (n = 7322), 23.0 % (n = 1686 children) completed screening. Based on the screening results, 873 children were invited to participate in the study, 56.9 % were girls, the mean age was 9.64 years (SD = 0.93) and 97 % were of Norwegian origin. Only seven children (0.4 % of the children screened) were excluded from the study due to exclusion criteria (mental retardation, pervasive developmental disorders or not able to benefit from group intervention). Dropout was larger in the intervention condition compared to the control condition prior to groups starting; 67 children in the intervention condition compared to seven in the control condition. Reasons for dropout were not collected formally, but anecdotal reasons included the child not having significant problems and the parents not having time for group meetings. Furthermore, 71 children were excluded (randomly) due to group size limitations and some sites not being able to run several groups. Few children (n = 22 in both conditions) dropped out during the intervention period.

In total, 88.9 % (n = 615) of the parents whose children had been invited to the main study reported via web-survey on the child’s symptoms. Primarily mothers completed the survey (78.2 %). The parent sample consisted primarily of parents with a Norwegian, Nordic or Western-European background. Most of the parents were married (73.7 %), reported a household income above the median Norwegian income level (82.4 %), had higher education (66.8 %) and were employed full-time (74.9 %).

5.2 Measures

The selection of measures was based on the aims of the study, the psychometric properties of the Norwegian versions of relevant instruments and international research. According to Dierker et al. (2001), rating scales may be used to detect anxious and depressive symptoms in school children and were used for inclusion purposes. In addition, the measures chosen were easy to administer and widely used in similar studies. For an overview, see Table 3.
### Table 3
Measures in the pilot study and main study

<table>
<thead>
<tr>
<th>Measures</th>
<th>Inclusion criteria (IC): Mean + SD</th>
<th>Pilot*</th>
<th>RCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child report:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2,3,4 MASC-C</td>
<td>0.5 – 2 SD &gt; mean</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td></td>
<td>Girls: IC = 46 + 16 (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Boys: IC = 39 + 16 (SD)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2,4 SMFQ-C</td>
<td>More than 1 SD &gt; mean</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td></td>
<td>Girls/boys: IC = 3.8 + 3.6 (SD)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CDI*</td>
<td>0.5 – 2 SD &gt; mean</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td></td>
<td>Girls/boys: IC = 9 + 7 (SD)</td>
<td></td>
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<td>1 ACE Stigma and Evaluation sheet</td>
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<td>4 Demographic</td>
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<td>4 MASC-P</td>
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<td>User Satisfaction session by session*</td>
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Note: 1 = Measures reported in paper 1, 2 = measures reported in paper 2, 3 = measures reported in paper 3, 4 = measures reported in paper 4. * = measures used in the pilot

Below, the measures reported in this thesis and summarized in Table 3 will be described more closely.

#### 5.2.1 Anxious symptoms

The Multidimensional Anxiety Scale for Children (MASC-C/P)(March, 1997) provides both a child and parent version for reporting anxious symptoms. Both assess cognitive, emotional, physical and behavioral symptoms in youth between 8 and 19 years of age and both versions have 39 items. The measure includes four subscales: Physical Symptoms, Social Anxiety, Separation Anxiety/Panic and Harm Avoidance with the response options “0” for “never true”, “1” for “rarely true”, “2” for “sometimes true” and “3” for “often true”. The MASC-C has high retest reliability (March, Parker, Sullivan, Stallings, & Conners, 1997; March, Sullivan, & Parker, 1999) and good predictive and discriminative validity.
(Baldwin & Dadds, 2007; Dierker et al., 2001; Wood, Piacentini, Bergman, McCracken, & Barrios, 2002). Studies have also indicated good internal reliability within the four sub-scales (e.g., Baldwin & Dadds, 2007; March et al., 1997). In a Norwegian study, elevated scores were significantly associated with meeting the diagnostic criteria for both child- and parent reports (Villabo et al., 2012), and the factor structure of the parent questionnaire was consistent with the child version. The total anxiety score of the MASC-C/P was used to indicate the symptom-level of anxiety (March, 1997) and was used both for inclusion purposes (as a dichotomized variable indicating over/under the cut-off) and for measuring change (paper II, III and IV). Internal consistency of the MASC-C in the main study at T1 (n = 1686 children screened) was high with a Cronbach’s Alpha (α) = 0.91 and α = 0.90 for the parent report (n = 567). Because the MASC-C was one of the primary outcome measures in the main study and was used for inclusion purposes, more extensive examinations of the child measure, including its latent factor structure, were performed, see paper III.

5.2.2 Depressive symptoms

The Short Mood and Feelings Questionnaire (SMFQ C/P)(Angold et al., 1995) was used to assess depressive symptoms in the main study. The SMFQ is a brief 13-item scale that assesses cognitive, affective and behavioral-related symptoms of depression in children 8 to 18 years old; it has a parent and child version. Statements are rated as follows: “2” for “true”, “1” for “sometimes true”, or “0” for “not true”. In a study of 8 to 16 year-olds (Angold et al., 1995), the SMFQ-C discriminated clinically referred youth from unselected pediatric controls, and depressed youth from non-depressed youth. According to Angold et al. (2002), the measure correlates highly with more extensive measures such as the CDI (Kovacs, 1992). The measure has Norwegian norms for 8- to 15-year-olds, a high retest reliability (r = 0.8) and good content validity (Larsson, Ingul, Jozefiak, & Sund, 2016; Sund, Larsson, & Wichstrom, 2001). The scale was recommended for use when screening for depressive symptoms among youth (Angold et al., 1995). The total depression score of the SMFQ-C/P was used in the main study to indicate the symptom-level of depression and was used for both inclusion purposes (as a dichotomized variable indicating over/under the cut-off) and for measuring change (paper II and IV). The instrument demonstrated internal consistency for the total SMFQ scale, α = 0.87 for the child report and α = 0.88 for the parent report. Because the SMFQ-C was one of the primary outcome measures used for inclusion, its latent factor structure was also analyzed (see section 7.3).
5.2.3  KINDL

The KINDL (Kinder Lebensqualität Fragebogen) (Ravens-Sieberer & Bullinger) (www.kindl.org) was used to assess quality of life pre- and post-intervention in the main study as reported by the children. The KINDL was originally developed to assess health-related quality of life in youth aged 4 – 16 years and can be used in both clinical and healthy populations (Ravens-Sieberer, Erhart, Wille, & Bullinger, 2008). It consists of 24 items measuring physical and emotional wellbeing, self-esteem, and social functioning (family, friends and school). There are five answer options on a 1 – 5 scale in which “1” indicates “never” and “5” indicates “all the time”. A score can be calculated for all six dimensions; a total score indicating overall health-related quality of life is calculated as well. These scores were standardized to values between 0 and 100, with higher scores indicating a better quality of life. The standardization enabled comparisons with norm data (Ravens-Sieberer et al., 2013). The measure has good psychometric properties as measured in German children (Bullinger, Brutt, Erhart, & Ravens-Sieberer, 2008). A Norwegian version of the KINDL examined in a sample of children aged 8–16 years old, showed satisfactory internal consistency and retest reliability of the KINDL total quality of life scale (Jozefiak, Larsson, Wichstrom, Mattejat, & Ravens-Sieberer, 2008). The measure was used to examine the associations of quality of life to internalizing symptoms (paper II). The α in the current study was 0.90.

5.2.4  Self-esteem

The subscale Beck Self-concept Inventory for youth (BSCI-Y) from the Beck Youth Inventory-II (BSCI-Y) scale (Beck, Beck, Jolly, & Steer, 2005) was used to assess self-esteem pre- and post-intervention as reported by the children. The BSCI-Y measures self-concept in children between 7 to 18-year-olds using 20 items covering self-perceptions regarding competency, body image, relation to others and positive self-worth. The scale is considered useful for screening in schools (Beck et al., 2005). Statements are rated on a four-point scale: “1” for “never”, “2” for “sometimes”, “3” for “often” and “4” for “always”. Gender differences have been found, and the scale is divided into three age groups with different norms (Beck, Beck, Jolly, & Steer, 2012). In the main study, the total sum score based on all items was used. The Norwegian version of the scale was translated and adjusted to a Norwegian context indicating mean scores for age and gender (Beck et al., 2012). The mean raw scores for children aged 7 – 10 years old were 40.94 (SD 7.39) in girls and 41.62 (SD 7.63) in boys. The reliability of the Norwegian version was good (α in the 0.8 – 0.9 range).
The measure was used to examine the associations of self-esteem to internalizing symptoms (paper II), and the $\alpha$ in the main study was 0.92, which is considered good.

5.2.5 User satisfaction and stigma

Overall user satisfaction and participants’ experiences of stigmatization were measured following completion of the intervention in both the pilot and main study. The Norwegian translation of the ACE Stigma and evaluation sheet developed by Rapee et al. (2006) was used to assess overall user satisfaction and experience of stigma as reported by the children. This measure has 10 questions answered on a 10-point Likert scale ranging from “0” for “not at all” to “10” for “extremely”. Three questions focus on the extent to which the participants were embarrassed about participating in the program, were teased by others because they attended the program, and were criticized at home for participating in the program. The remaining seven questions were related to the children’s satisfaction with the program. The $\alpha$ was 0.69 post-intervention in the main study.

5.2.6 Inclusion and exclusion criteria

As summarized in Table 3, children reporting symptoms 1 SD above a chosen cut-off on anxiety or depression (no upper limit) were invited to participate in the main study. Given the variation in mean scores between boys and girls in unselected samples, we used gender specific cut-offs for anxiety (Olason, Sighvatsson, & Smami, 2004). The literature suggests using the same mean for boys and girls for the inclusion of depressive symptoms in children aged 8 - 12 years.

The following exclusion criteria were used: mental retardation, pervasive developmental disorder, and individual consideration of children who for different reasons would not benefit from a group intervention.

5.2.7 The intervention, training and supervision

In the intervention schools, the children participated in the EMOTION groups during or after school hours, whereas children in the control schools received the attention they would generally receive (contact with school health nurse and family physician). The revised version of the EMOTION program guided the group leaders running the sessions (see Figure 1 and description of the intervention in section 3). The children met twice a week for ten weeks (20 group sessions), and the parents met for 7 sessions.

Before the groups started, the group leaders recruited from primary care, attended a 3-day training, with the first day focusing on general CBT principles, and then worked through the manual session by session testing out the different strategies the last two days. The training
was provided by the same instructors (first and last author in paper IV), at all sites. The group leaders completed a checklist after each session to ensure fidelity within a flexible approach (Kendall, Gosch, Furr, & Sood, 2008), and 20% of the sessions were videotaped and rated for fidelity. Supervision was provided on a weekly basis when running the groups, and the supervisors were trained CBT therapists.

5.3 Statistical methods

The statistical methods used in this thesis is presented below, starting with an overview of the statistical methods pr. paper in Table 4.

Table 4 Statistical methods pr. paper

<table>
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<tr>
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<th>Paper I</th>
<th>Paper II</th>
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<th>Paper IV</th>
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<td>One-way Anova and Multiple Regression$^1$</td>
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<td>Confirmatory factor analyses (CFA)$^2$</td>
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<td>Multilevel methods$^3$</td>
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Note: $^1$ = SPSS, $^2$ = Mplus, $^3$ = R

5.3.1 One-way ANOVA and Multiple regression

The statistical package IBM SPSS; version 22 was used to provide descriptive information, and Cronbach’s alpha ($\alpha$) was used to test reliability. SPSS was also used to compare overall differences and pairwise comparisons between at-risk groups (post hoc tests). Post hoc tests are used to compare pairs of means after having found significant results from a one-way ANOVA controlling for the Family Wise error rate. Because the at-risk groups (anxiety only, depression only and anxiety and depression) were of unequal sizes, Hochberg’s GT2 test was used when comparing groups (Hochberg & Tamhane, 1987).

Multiple regression was used to predict the value of the dependent variable based on the value of two or more other variables. With multiple regression, the relative contribution of each of the predictors can be used to explain the total variance (the overall fit), and the relative contribution of each of the predictors to the total variance explained. The data were checked for assumptions underlying multiple regression. In paper II, quality of life and self-esteem were used as dependent variables, with anxious and depressive symptoms as the independent variables.

5.3.2 Latent factor analyses

Structural equation modeling (SEM) is a multivariate statistical analysis combining factor analysis and multiple regression analysis to examine the structural relationships.
between measured variables and latent constructs. This method assumes that the covariances between a set of observed variables can be explained by a smaller number of underlying latent factors (Hox & Bechger, 1998). The latent variable analyses in SEM provide scores where the error scores are accounted for, and thus latent factors are less biased than factors using composite scores.

Confirmatory factor analysis (CFA) is a hypothesis-driven type of latent variable analysis that examines the relationships between observed measures (indicators) and latent variables (factors) (T. A. Brown, 2006). In CFA, we have a hypothesis of the number of latent factors and the relationships between the latent factors and the observed variables based on past evidence and theory, and the confirmatory factor model is imposed on the data (T. A. Brown, 2006; Hox & Bechger, 1998). The purpose of structural equation modelling is to obtain estimates of the factor loadings and to assess the fit of the model, i.e., if the proposed model provides a good fit to the data. The acceptability of the specified model is evaluated by goodness-of-fit.

A latent factor analysis of the primary outcome measures for the children MASC-C (paper III) and SMFQ-C (see section 7.3) was performed using CFA with Mplus 7.0 statistical software. Since the variables were categorical, weighted least squares estimator (WLSMV) was used (Muthen & Muthen, 2012).

5.3.2.1 Model evaluation and fit-indices

The acceptability of the CFA solution should be estimated based on overall goodness-of-fit, specific points of ill fit and the interpretability, size and statistical significance of the model’s parameter estimates (T. A. Brown, 2006). An often used and recommended index is the Root Mean Square Error of Approximation (RMSEA; J. H. Steiger & Lind, 1980), which assesses the extent to which a model fits reasonably well, and is relatively insensitive to sample size (T. A. Brown, 2006). The RMSEA is an absolute measure of fit, and values < 0.05 suggest good model fit, whereas values < 0.08 suggest a reasonable model fit (M. W. Brown & Cudeck, 1993). Values < 0.10 are often used as the cut-off for poor fitting models (Kenny, 2015). Comparative fit indices evaluate the fit of a specified solution against a solution assuming no relationship among the variables. The Bentler’s Comparative fit index (CFI; Bentler, 1990) and the Tucker-Lewis Index (TLI; Tucker & Lewis, 1973) are both comparative indices, and both depend on the average size of the correlations in the data (Kenny, 2015). The CFI ranges between 0.0 to 1.0 with values closer to 1.0 indicating a good model fit. The TLI has features that compensate for the effect of model complexity including
a penalty for adding parameters that do not improve the model. Unlike the CFI, the TLI is non-normed, and values can thus fall outside the range of 0.0 to 1.0. However, the TLI is interpreted similar to the CFI, with values approaching 1.0 indicating a good model fit. The CFI and the TLI should be $> 0.95$ and ideally $> 0.97$. However, indices $\geq 0.90$ indicate that the model has adequate fit with the data, and between 0.90 – 0.95 are considered acceptable model fit (Bentler, 1995).

### 5.3.2.2 Measurement invariance

As different groups may perceive the same constructs differently, examining whether the constructs being studied have the same meaning in different subgroups may be important. The CFA provides a strong analytic framework for evaluating measurement models across groups (T. A. Brown, 2006). We therefore tested for measurement invariance by examining whether the primary outcome measure MASC-C had the same meaning for boys and girls and for children of different age groups. Cheung and Rensvold (2002) suggested that a change in CFI smaller than or equal to -0.01 indicates that the null hypothesis of invariance should not be rejected (Cheung & Rensvold, 2002). This measurement is independent of both model complexity and sample size.

### 5.3.3 Multilevel analyses

The main study had a clustered randomized design in which schools were the unit of randomization. Because clusters may contain individuals that are more similar to one another than individuals in other clusters (Ukoumunne et al., 1999), children attending one school could be assumed to be more similar than children attending other schools. The assumption that individual responses are independent of one another which underlies standard statistical methods, is thus violated (Donner, Birkett, & Buck, 1981). If the clustering levels are not accounted for when analyzing individual data that are clustered in groups, the significance of the intervention may be overestimated. The clustered design was therefore accounted for by using a multilevel approach.

We used mixed effects models, which are commonly used to describe the relationship between response variables and covariates in clustered data. This statistical approach incorporates both fixed and random effects. Fixed effects are parameters associated with the entire population or with repeatable levels of experimental factors, whereas random effects are associated with individual experimental units drawn at random from a population (Pinheiro & Bates, 2000).
We included random effects at the school level, the individual level, and within the individual for child data and parent data. Fixed effects included a time by randomization group interaction, and the analyses were adjusted for gender and age group (children in 3rd and 4th grade were classified as younger; children in 5th and 6th grade were classified as older).

In the main study, the standard deviation for random variation between schools was found to be too small to be reliably estimated for anxiety and for some subgroups of depression, and the models were therefore re-run without the school level for both child- and parent data.

Intention-to-treat analysis (ITT) was used. ITT analysis is considered the gold standard for assessing the superiority of an intervention in randomized trials, in which all randomized participants are analyzed in their randomized group (Yelland et al., 2015). ITT ignores noncompliance, protocol deviations, withdrawal, and anything that happens after randomization, and estimated effects using this method are considered conservative (Gupta, 2011). The estimation of mixed effects models used the R (The R Foundation for Statistical Computing, Vienna, Austria) package nlme.

5.4 Missing data
Due to electronic data collection, there were no single items missing for the participants.

6 ETHICAL CONSIDERATIONS
6.1 Children as target group and informed consent
The target group was 8 to 12-year-old school children and the interventions were conducted during school time. Important ethical considerations thus relate to informed consent from children and potential burden by participating in the study.

The Health Research Act was approved in Norway in 2009 with the purpose to promote ethically sound health research (Helseforskningsloven (The Health Research Act), 2015). This act has specific instructions regarding research on children. The main rule regarding consent (§ 13) states that consent must be obtained from participants in medical and health research, the consent must be informed, voluntary, expressed and documented; and the consent should be based on specific information about a concrete research project (Helseforskningsloven (The Health Research Act), 2015, p. 6). For subjects without the ability to provide informed consent, only minimal/insignificant risk is accepted. Along the same lines, the NESH-guidelines (De nasjonale forskningsetiske komiteene (NESH-guidelines, 2014, pp. 12-14) state that the person participating must receive all information necessary to understand the purpose of the research project, the consequences of participating
and the purpose. The information should be neutral and suitable to the participating subject. For participants who lack the competence to provide informed consent, the researcher has an even greater obligation to ensure the integrity of the participant (De nasjonale forskningsetiske komiteene (NESH-guidelines, 2014, p. 13). Children under 16 are such a group. The research project, including recruitment information, was approved by The Regional Committees for Medical and Health Research Ethics for both the pilot study (2011/536/ REK South East) and the main study (2013/1909/REK South East).

To comply with the above requirements, information letters and school presentations were carefully prepared for the children and their parents. The information was worded in an age-appropriate manner, and it was explicitly stated that the research project aimed to recruit children who considered themselves more anxious or sad than their peers and their parents. At school presentations, the children had the possibility to ask questions to clarify the purpose of the study. The children were also encouraged to discuss participation with their parents at home. The nature of the research project and the target group was even more explicitly stated in the written information provided to the parents. Voluntary participation, the importance of discussing participation with the children, and the possibility of withdrawal at any time was emphasized. To the extent possible, the study was presented at parent meetings. However, because parent meetings often are held up to half a year prior to the groups starting, it was not always possible to reach the parents through such meetings. Some parents therefore received written information only. In the letter to parents, the last page provided both alternatives (we want/do not want to participate in the study), the possibility of withdrawal was stated, and the parents were asked to give informed consent if they and the child wanted to participate in the study.

6.2 Potential stigma of participation

Both the Health Research Act, § 22 (Helseforskningsloven (The Health Research Act), 2015) and the Helsinki-declaration (World Medical Association, 2013, § 16) emphasize the importance of ensuring that the objective of the research project outweighs the risks and burdens to the research subjects. It is furthermore important to minimize possible identified risk.

The intervention was conducted during school time and included children reporting symptoms of anxiety or depression. Although delivering interventions in schools makes it possible to reach children who might not otherwise receive services, it is important to consider whether the intervention possibly imposes any burden on the children recruited to
participation. Experiencing stigma by expressing interest to participate (handing in the informed consent note) or by participating in groups during school hours where other children might identify who are participating in groups may be a burden. Experiencing stigma may also predict a negative response to preventive interventions (Moos, 2005) and may reduce the inclination to seek help for mental disorders (Issakidis & Andrews, 2002). Possible stigmatization is thus important to identify and evaluate. We have not identified studies that investigate the issue of stigmatization experienced by being selected for an indicated intervention. However, by being aware that stigmatization might be an issue, the presentation of the project was carefully worded using non-stigmatizing words (being sad or frustrated when negative events occurred and stressed or anxious rather than having anxiety and depression). Furthermore, all children were asked to return the consent note, even if they were not interested in participating. The argument for this procedure was that it would be less stigmatizing to hand in the note expressing interest to participate if all children did so.

Regarding experiencing stigma by participating in indicated interventions, Rapee et al (2006) reported that although self-reported stigma was low in their study, boys with more externalizing problems (in addition to their internalizing problems) regard participation in such interventions as more problematic. Evaluating stigma was thus considered important in the feasibility study (Paper I). There were several potential benefits of participating in the study: internalizing problems could be identified early, and the children could potentially experience a reduction in symptom levels due to participating in the intervention or receiving increased attention from caregivers after reporting the problems and improved coping skills. These potential benefits were evaluated to be higher than the potential risk. Nonetheless, we still paid attention to the possibility of stigma and, evaluated whether the children had such experiences. Despite attempting to minimize the risk of stigma, some children may still have found it stigmatizing to participate. This is a common dilemma in indicated prevention performed in a school setting.

7 RESULTS
7.1 Main findings: Paper I

The first paper based on the pilot study examined the acceptability and feasibility of the new transdiagnostic EMOTION intervention in one school with 11 children.

We had high attendance rates in the child groups (94 %) and acceptable attendance rates in the parent groups (75 %). In the session to session evaluations, the children and their
group leaders reported high user satisfaction (5.4 - 6 on a 7-point scale), and the parents reported moderate endorsement (4 on a 7-point scale) wanting fewer parent sessions. In the overall evaluation, the children reported the program to be very useful to them (mean scores between 8.3 and 9.5 on a 10-point Likert scale), and all group leaders wanted to run EMOTION groups again. The children reported low stigma associated with participation and increased coping. Mean scores on the three items evaluating stigma were between 1.1 to 1.7 on the scale where 0 was not at all, and 10 was extremely. The children reported a mean of 4.4 regarding their ability to cope with emotions prior to the program, and a mean of 9.7 after the program. Self-nomination with a screening procedure for recruitment worked well, with 38 % of the invited children wanting to participate. We thus concluded that the intervention was feasible and acceptable in a school setting.

7.2 Main findings: Paper II

In paper II, we wanted to examine the symptom expression of the children recruited to the main study as indicated by at-risk groups (anxiety only, depression only & anxiety and depression), in addition to the associations between these symptom-groups and the functional domains: quality of life and self-esteem. Baseline screening data (n = 915) after data collection in three semesters were analyzed.

The largest at-risk group recruited to the study after three semesters reported having symptoms of both anxiety and depression (n = 243, 26.6 % of children screened), while 15.4 % (n = 141) reported symptoms of depression only and 10.2 % (n = 93) reported anxious symptoms only. The at-risk groups reported significant differences in means regarding self-reported anxiety, depression, quality of life and self-esteem. Comparing the means reported in the at-risk groups, there was an increase in symptom levels when progressing from symptoms of either anxiety or depression, to comorbid symptoms; simultaneously self-reported quality of life and self-esteem decreased. In all at-risk groups, children reported quality of life 1 SD or more below the normative level (Ravens-Sieberer et al., 2008). In the at-risk groups depression only and in the combined group, self-esteem was reported 1 SD or more below the Norwegian normative group (Beck et al., 2012). The results also indicated statistically significant relationships between quality of life, self-esteem and internalizing symptoms in the depression only group and the combined group, while not for the anxiety only group. Thus, depressive symptoms seemed to explain most of the variance in quality of life and self-esteem. Significant age differences with older children reporting lower quality of life was only found in the combined symptom group.
We concluded that a transdiagnostic approach may be indicated as most children reported mixed symptomatology. Furthermore, quality of life and self-esteem may provide information about the severity of the problems for children with depressive symptoms or with comorbid symptoms in addition to symptom level.

7.3 Main findings: Paper III and examination of the SMFQ

The Multidimensional Anxiety Scale for Children (MASC-C) was used both for inclusion purposes and as a primary outcome measure; thus, it was important to examine the latent factor structure of the measure and determine whether the measure had comparable factor structure for gender and age (Paper III). Data based on all children screened in the main study (n = 1686) were analyzed; gender and age differences were also reported.

The four-factor structure was in general confirmed and was found to be consistent across gender and grade level. Factor loadings on most subscales were good, but some factor on the Harm/Avoidance scale were low. The items with the lowest factor loadings were the items: “I usually ask for permission” and “I try hard to obey my parents and teachers”. These two items were excluded from further analyses, and acceptable model fit was found (RMSEA = 0.045, CFI = 0.94 and TLI = 0.94). The internal consistency was high on all subscales (α of 0.72 – 0.86) except for the Harm/Avoidance scale (α = 0.61). Some features of this scale may therefore require modifications in the Norwegian version. Girls scored significantly higher than boys on all subscales, whereas the relationship with grade level (age) was not significant except for the Separation Anxiety subscale where younger children reported more symptoms than older children. Children reported higher symptom levels of anxiety (M = 51.92, SD 16.87) than found in other Nordic population-based samples, indicating that the sample was more anxious than their peers.

The SMFQ-C was also a primary outcome measure in the main study. A re-examination of some of the psychometric properties for the child version, including its latent factor structure, was of interest, although a separate paper was not published. A separate factor analysis was performed and is described below.

Using screening data from the main study (n = 1686), a confirmatory factor analysis (CFA) for the SMFQ-C using Mplus 7.0 software with the weighted least squares estimator (WLSMV, Muthen & Muthen, 2012) was performed. The suggested unidimensional structure of the measure was tested using the indices; RMSEA (RMSEA, J. H. Steiger & Lind, 1980), CFI (CFI, Bentler, 1990) and the TLI (TLI, Tucker & Lewis, 1973). Values for indicating
good fit are described in section 5.3.2.1. The results from this analysis indicated a good fit with values of RMSEA = 0.059, CFI = 0.97 and TLI = 0.97. Factor loadings were generally very good to good, with most factor loadings in the range 0.65 – 0.87; however, some factor loadings were in the fair range (0.43 – 0.45). As indicated in Paper IV (Table 1), children in this sample reported elevated levels of depressive symptoms compared to population means (Angold et al., 2002; Rhew et al., 2010). Hence, an indicated sample was recruited.

7.4 Main findings: paper IV

In paper IV, the EMOTION program was evaluated to determine whether the intervention produced larger reductions in symptoms of anxiety and depression than treatment as usual (TAU).

The results of the randomized controlled study showed that the intervention produced significant reductions in anxious and depressive symptoms as reported by children. Anxious symptoms were reduced by 11.83 points (p < 0.001) in the intervention condition compared to 4.62 points (p < 0.001) in the control condition, and there was a significant difference between the intervention- and control conditions post-intervention, with TAU scores 5.35 points higher in the control group than in the intervention group. This corresponds to a reduction of between 17.4 to 19.7 % in the intervention condition (depending on gender and age group) and a 7.0 to 8.0 % reduction in the control condition. For anxious symptoms, there was a significant reduction for all subgroups (younger and older children and boys and girls) where boys and older children had the largest reduction in symptom score. For depressive symptoms, the intervention produced a decrease of 2.31 points (p < 0.001) compared to a decrease of 1.50 points (p < 0.001) in TAU; the difference was significant. This corresponds to a reduction between 21.0 % to 25.0 % in the intervention condition and a 14.6 % to 17.6 % reduction in the control condition (depending on gender and age group). Significant reductions were found for older children in the subgroup analyses, where older children had a reduction of 3.30 points. As in earlier phases of the study, most children included reported symptoms of both anxiety and depression (49.4 %), whereas 30.0 % reported symptoms of depression only. The smallest at-risk group was the anxiety only group (20.6 %).

Parents reported markedly lower symptom levels (approximately 1 SD) than the children did. They also reported significant reductions in depressive symptoms of their children, where the intervention condition decreased more than the control condition. Parents in the intervention condition reported a decrease of 1.66 points (p < 0.001), compared to 0.36 points (p = 0.133) in the control condition. The parent reported reduction in anxious
symptoms was not significant. At-risk children with depressive symptoms thus benefitted from receiving a transdiagnostic intervention as reported by parents.

8 DISCUSSION

8.1 Main findings

The primary aims of the present thesis were to develop a new intervention targeting symptoms of both anxiety and depression in school-aged children and to investigate both the feasibility and effectiveness of the intervention. This was first tested in a pilot study in one school in Norway, followed by a large clustered randomized controlled trial involving 36 schools in three regions in Norway. The main findings from these studies will first be discussed, then methodological issues will be examined. Future research directions will follow, before concluding this thesis.

8.1.1 Initial effect evaluation of the EMOTION intervention (paper IV)

A major objective of the current thesis was to examine the effectiveness of the new transdiagnostic intervention in reducing symptoms of anxiety and depression as reported by children and their parents.

Although anxious symptoms decreased in both conditions as reported by the children, the intervention condition reported a significantly larger reduction in anxious symptoms compared to the control group (TAU). In general, the intervention condition reported a decrease of 17.4 to 19.7% (depending on which gender and age group was examined), whereas the control condition had a corresponding reduction of 7.0 to 8.0%. Subgroup analyses for gender and age groups consistently reported the same pattern, with the intervention condition having a significantly larger reduction than the control condition. Although effect size was not reported in paper IV due to the multilevel nature of the data, the significant reductions in child-reported anxiety pointed in the same direction as previous research on the effect of CBT for anxious children: Mychailyszyn et al. (2012) reported a medium-sized effect in school-based interventions with a CBT orientation, and programs targeting at-risk children yielded larger effects. Werner-Seidler et al. (2017) reported a smaller effect size when including different types of programs, although most had a CBT focus. This was consistent with the results reported by Teubert and Pinquart (2011) for anxiety problems. The finding that both older and younger children and girls and boys achieved significant reductions in anxious symptoms was found in both the current study and in previous reports (Gillham et al., 2006). Anxiousness is often more situation-specific (afraid of talking in class, being alone at home or fear of heights), and it may be easier for group
leaders to find meaningful goals and exercises to work with anxious symptoms for different ages and gender. Because anxious symptoms are a risk factor for later development of anxiety disorders and depressive symptoms (Kovacs & Lopez-Duran, 2010), symptom reductions may change an otherwise negative trajectory.

A significantly larger reduction in depressive symptoms occurred in the intervention condition (21% to 25%) than in the control condition (14.6% to 17.6%). Both groups reported, however, a decrease in symptoms. In the subgroup analyses, we found a significant reduction for older children who had a significantly larger reduction in the intervention condition than older children in the control condition. Similar findings were also reported by Stice et al. (2009). Interventions targeting depressive symptoms have typically reported lower response rates to CBT than interventions targeting anxious symptoms (e.g. Calear & Christensen, 2010; Mychailyszyn et al., 2012; Werner-Seidler et al., 2017). Depressive symptoms are often less situation-specific than anxious symptoms, such as having thoughts about not being as good as other children, having low energy and loneliness. Although group leaders may find it more difficult to engage and find concrete goals for sadder children, it appears they managed this with the older sad children. The sharp increase in depressive symptoms around 11 years of age may create greater room for improvement in older children (Merikangas & Avenevoli, 2002). In the current study, older children reported higher levels of depressive symptoms than younger children (see table 2, paper IV), which may explain the larger response in older children. Based on evidence of sub-clinical depressive symptoms as a strong prognostic factor for later developing depressive disorders (Kovacs & Lopes-Duran, 2010), reducing depressive symptoms and possibly delaying the onset of disorders may have important implications for the child, the family and for society.

In summary, we can conclude that the EMOTION program appears to have been effective in reducing symptoms of anxiety and depression as reported by the children.

Parents also reported a significant reduction in depressive symptoms with larger reductions in the intervention condition than in the control condition; however, this was not the case for parental report of anxious symptoms in their children. Parental involvement is well documented for interventions targeting depressed children (Costello et al., 2003). When a child was invited to the study after screening, parents may have become more aware of the child’s sadness and thus supported their child. As previously noted, the importance of parental involvement for child anxiety has produced mixed results: some studies indicate a positive effect of parental involvement, whereas others do not (Wei, Cummings, Villabo, & Kendall,
2014). It may be difficult for parents to observe internalizing symptoms (Comer & Kendall, 2004; Wei, Hoff, Villabø, et al., 2014) and hence report their children’s anxious symptoms accurately. Furthermore, some symptoms may be displayed in some contexts, but not in others (e.g., school vs home), also making it complicated for parents to identify the difficulties and to observe change (De Los Reyes et al., 2015). Divergent reporting of anxious symptoms from parents and children is common (Villabø et al., 2012). In the current study, parents initially reported symptoms of both anxiety and depression lower than their children, confirming that internalizing symptoms in children are difficult to detect even for adults close to the child.

Finally, most of the children recruited to the study reported elevated levels of both anxious and depressive symptoms, i.e. co-occurring symptoms. Mixed presentations in symptomatic children is typical in primary care, as stated in a report from WHO (Jamison, Creese, & Prentice, 1999); which was confirmed in the current study. Offering a transdiagnostic intervention targeting both problem areas can make it easier for primary health care professionals to meet the needs of many children by targeting both symptoms simultaneously. By using effective interventions, symptom levels may be reduced, which can have important public health implications and reduce the risk for a negative trajectory.

8.1.2 Psychometric properties of primary outcome measures (paper III)

Paper III examined the reliability and latent factor structure of the primary outcome measure for anxious symptoms, which was used both for inclusion purposes and to measure change in symptoms. The aim was to ensure that the measure worked well in this sample and that the factor structure was consistent with previous findings. We expected the four-factor structure of the MASC-C originally suggested by (March, 1997) to be replicated and comparable for gender and age.

The results indicated that the internal consistency for the total scale and for most subscales were good, whereas the subscale Harm/Avoidance scale was lower based on both the Cronbach’s alpha and the McDonald’s Omega coefficient (McDonald, 1999). Factor analysis revealed an acceptable overall fit with good factor loadings on most subscales and with a consistent factor structure across gender and age. On the Harm/Avoidance scale, however, some items related to seeking permission and obeying parents had low factor loadings. Problems with this sub-scale have been reported in other studies (Grills-Taquechel, Ollendick, & Fisak, 2008; van Gastel & Ferdinand, 2008; Villabø et al., 2012), which might be due to the subscale tapping into constructs such as Perfectionism and Anxious coping,
which is suggested to have less predictability of a specific anxiety disorder than the other subscales (Wei, Hoff, Villabo, et al., 2014). The Harm/Avoidance scale thus had limited cohesion. Modifying some questions in the Norwegian version to account better for the Norwegian culture could be beneficial. The nature of the sample was also examined when investigating the MASC-C. At-risk children were the target group, and it was interesting to investigate how the mean scores of this sample compared to the mean scores found in population samples. Children recruited to the main study expressed higher mean anxiety scores compared to normative groups both in Scandinavia and otherwise (March, 1997; Olason et al., 2004). Actually, the children in this sample scored closer to the mean scores in a Norwegian clinical sample (Villabø et al., 2012). The MASC-C was thus successful in screening for symptoms in at-risk children and as such seemed to have worked well in recruiting an indicated sample.

The factor structure of the SMFQ-C was later examined in the preparation of this thesis (see section 7.3) and results indicated a unidimensional factor structure with high internal consistency as originally suggested (Angold et al., 2002). The SMFQ-C was also successful in recruiting children with elevated symptom levels, as indicated in paper IV (Table 1).

8.1.3 Associations of quality of life and self-esteem to internalizing symptoms (paper II)

In paper II, we investigated the associations of quality of life and self-esteem to internalizing symptoms after categorizing the children in at-risk groups. We wanted to investigate whether information about quality of life could provide additional information about health service needs not detected by symptom levels alone? Furthermore, could the reported self-esteem improve our understanding of at-risk children?

The largest at-risk group identified after three semesters reported symptoms of both anxiety and depression followed by the at-risk group reporting symptoms of depression only and the smallest at-risk group reporting anxious symptoms only. In the current age group, we had expected the anxiety only group to be the largest at-risk group because population-based studies indicate that anxious problems are more common in this age group (Baumeister & Harter, 2007). The gradual increase in mean symptom scores when reporting anxiety or depression alone compared to reporting comorbid symptoms, and the corresponding decrease in mean reported quality of life and self-esteem give an indication of the higher burden for children having comorbid symptoms. Of all the at-risk groups, the combined group reported the lowest level of quality of life and self-esteem, which can be an indication of higher
problem severity. Less positive change could therefore be expected when children present with comorbid symptoms. Significant negative associations between symptoms of depression and the functional domains were found in the depression only and in the combined group, but not for the anxiety only group. Anxious symptoms may affect a narrower area of functioning (e.g., at home or at school) and may therefore not affect the child’s quality of life and self-esteem to the same extent. Our findings are contrary to Stevanovic (2013) and Raknes et al. (2017) who both reported a negative association between symptoms of anxiety and quality of life. Their samples were however with older youth or youth with a larger age span (8 – 18 years of age) and quality of life is found to decrease in adolescence. Previous studies have however reported that children with mental health problems report lower quality of life than the general child population (Jozefiak et al., 2010) and children with depressive disorders have more discomfort than children with other mental health problems (Sawyer et al., 2002). Our finding that symptoms of depression explained most of the variance in quality of life and self-esteem, supports the results from these studies. Screening for depressive symptoms and emphasizing therapeutic strategies targeting depressive symptoms specifically is therefore important in transdiagnostic interventions. Strategies to enhance self-esteem in children reporting depressive symptoms is also supported as low self-esteem is considered a risk-factor for further development of symptoms (van Tuijl et al., 2014).

8.1.4 The feasibility and acceptability of the intervention (paper I)

Step 2 aimed to investigate the acceptability and feasibility of the EMOTION program in a school setting after developing the first version of the EMOTION program (step 1). It was important to examine if recruitment approaches were acceptable and that participants were satisfied with the intervention. Ethical considerations were also a concern, and investigating possible stigma associated with participating in an indicated intervention was important.

Recruitment was based on self-nomination after receiving age-appropriate information, and both parents and children used rating scales to screen for symptoms in the pilot study. However, most children were recruited based on their own self-report. Self-recruitment using child self-report only was therefore seen as an acceptable recruitment strategy in the main study to follow.

The attendance rate was high in both child and parent groups (94 % and 75 %, respectively), which can be an indication of user satisfaction. Children and group leaders were very satisfied, and parents were moderately satisfied regarding personal usefulness and very satisfied regarding usefulness for their children. Children also reported relatively low stigma
and increased coping, and Mifsud and Rapee (2005) have argued that experienced stigma must be evaluated in relation to reported benefits. When Rapee et al. (2006) examined this issue further, they reported that increased stigma was associated aspects of the individuals (boys with externalizing problems) and with greater satisfaction for indicated programs compared to universal interventions. One could however speculate that perceived stigma could result in fewer boys expressing interest to participate (only two of 11 children in the pilot study).

Most parents wanted to reduce the number of parent sessions, and the level of parent involvement was an important consideration when revising the intervention. As discussed earlier, research on the importance of parental involvement is mixed for anxious children (e.g., Barrett, Dadds, & Rapee, 1996; Kendall, Hudson, et al., 2008; Reynolds et al., 2012); other research suggests that parents may be a factor for development and maintenance of internalizing problems and particularly depressive symptoms (Stark, Streusand, Prema, & Patel, 2012). However, the ideal number of parent sessions is difficult to determine when targeting symptomatic children. Parents may not be aware of the child’s problems and may therefore be less motivated to participate in an intervention. Conversely, studies have suggested that parent involvement may be important to support adaptive behavior and to generalize skills to the home context (Fisak et al., 2011; Spence & Shortt, 2007). Although a parent component was deemed necessary, parent feedback should be considered to increase user-friendliness of the intervention. The number of parent sessions was reduced from 8 to 7 after the pilot study and further reduced to 5 after the main study. Content was also adjusted based on feedback from the parents.

Information from group leaders indicated that the intensity of the intervention (20 child sessions) was a challenge when running the EMOTION groups in primary care. Reviews examining the optimal number of sessions, are not completely consistent: Werner-Seidler et al. (2017) reported the length of programs ranging from two to 40 sessions with most programs providing between 8 – 12 sessions in school-based prevention programs targeting anxiety and depression. Both Mychailyszyn et al. (2012) and Gillham et al. (2006) found that the duration of the intervention was not associated with a larger effect, whereas Reynolds et al. (2012) concluded that longer interventions achieved larger effect sizes than shorter interventions for children with anxiety symptoms. Weersing and Weisz (2002) found that youth receiving less than eight sessions had poorer effects than those with more sessions, and Spence and Shortt (2007) stated that low-dosage preventive interventions may not be
sufficient to produce lasting change. Finally, Stark et al. (2012) listed the benefits from having children meeting twice a week, which has some support from the adult literature: Cuijpers et al. (2013) concluded that having more sessions per week resulted in considerably larger effect sizes than fewer sessions per week. With this research in mind and the aim to enhance user friendliness, greater flexibility was incorporated when revising the intervention. Within each session, group leaders were encouraged to tailor the intervention to each child, with some optional and some required strategies. After the main study the total number of sessions in the manual was thus designed more flexible (16 – 20 sessions), with increased possibilities to tailor the intensity of the program to the characteristics of the group.

Content in the EMOTION manuals was revised based on feedback from the group leaders, parents and children after the studies. A joint parent and child session to focus on the child’s goal replaced the individual child sessions after the pilot; furthermore, increased focus on goal setting and more concrete exercises with less focus on writing were incorporated after the main study. Exposure and behavioral activation were re-conceptualized as behavioral experiments with a joint focus on approaching avoided situations to obtain new experience. The manual was thus developed using both knowledge from previous research, expert advice and user involvement to create a strong intervention.

8.2 Methodological issues

The present study has several strengths. Large sample size, no missing individual data and multilevel approach accounting for the clustering of data are within the standards suggested by The Society for Prevention Research (SPR) (Gottfredson et al., 2015). Although this study aimed to control for threats to internal validity, the findings presented in this thesis must be evaluated with methodological challenges and practical decisions within a real-world context in mind. Challenges relating to the cluster randomization and “blinding of conditions” will be discussed first. Then, the use of self-report measures, children as sole informants for recruitment, and the optimal cut-off for inclusion will be addressed. The issues relating to the representativeness of the sample and regression towards the mean are then discussed before suggesting future research and concluding this thesis.

8.2.1 Cluster randomization, selection and performance bias

Contamination between conditions if run within one school was a major consideration resulting in schools being the unit of randomization. Schools were matched based on geographical location, size and demographic factors and randomized to intervention or control condition after screening the children in the first semester. Schools once randomized to one
condition remained in this condition throughout the study. In the first semester, the families invited to the study were unaware of the status of the school (intervention or control). However, for recruitment in later semesters, the children and the parents knew that the children would be in the intervention/control condition if they were invited to the study after screening. Children and parents in the intervention condition may have shared information regarding the intervention with participants recruited in later semesters. In the control condition, children received treatment as usual. Parents, teachers, the school health nurse and the family physicians could have gained increased awareness of the child’s problems. Awareness of which condition they were in may have created two types of bias in later semesters:

a) Selection bias: resulting in a difference between the groups at baseline
b) Performance bias resulting in a “belief effect”

Selection bias: In an ideal randomized controlled situation, the parents and children in both conditions would be “blind” regarding which condition they would be assigned to (Cochrane, 2017). However, although randomization was correctly performed in the current randomized trial, “blinding” the participants regarding which condition they were in was not possible. The intervention condition consistently reported higher scores in both the child and parent reports in the intervention condition (see paper IV). We may thus not rule out selection bias in the current study.

Performance bias: According to Howick (2011), one confounding factor is also related to participants knowing they are being treated with the “real” intervention leading to a “belief effect”. Howick (2011) argues that caregivers may also be affected in a similar way where they believe the children receive the best intervention. This performance bias could contribute to greater symptom reduction in the intervention group.

8.2.2 Self-report in young children

In addition to methodological issues related to the randomization and blinding of conditions, the measures and informants used for inclusion also warrant attention.

Child vs other report: Based on the results from the pilot study, we used child self-report only for inclusion in the main study. As cited earlier, the literature typically recommends a multi-informant approach when assessing a child’s mental state (Wei, Hoff, Villabo, et al., 2014); however, informant disagreement is common, particularly for symptoms that are difficult to observe such as internalizing symptoms (De Los Reyes et al.,
2015; Villabø et al., 2012). In the pilot study, few children were recruited based on parental report alone. In the main study, parents also reported markedly lower symptom levels than their children. Relying on parental report alone would have included fewer children in the main study. However, not using parental report may fail to identify some children who could benefit from the intervention. Some parents wanted their child to participate because they believed their child to be sad or anxious, whereas the child self-reported low symptom levels. It is possible that these children would not have been very motivated to participate if included, and higher dropout could have been expected. The use of both parental, and child report, and possibly also nomination of children from other people knowledgeable of the child’s challenges (e.g., school health nurse and teachers) could have been beneficial.

Self-report in young children: using self-reports in young children also presents other challenges when using scales to measure a latent construct that is not directly observable, but where specific questions attempt to obtain knowledge about the construct. Using self-report places a heavy emphasis on the child’s comprehension of the language and the questions used. The developmental level of the child may influence the comprehension of language, and certain words may also carry different meaning in different cultures. Questionnaires may be translated without sufficient cultural adjustments, and even when adjusted according to cultural norms, some questions may be difficult for the child to understand. Furthermore, emotions may have different expressions and may be valued differently in different subgroups. In this study, the measures used for identifying the children’s symptom level for inclusion were based previous research indicating strong psychometric properties; some measures had also been evaluated in Norwegian samples (e.g., Richter & Sund, 2013; Villabø et al., 2012). A list of how to explain difficult questions was developed and used at the schools when screening the children. Awareness of these issues were the basis for performing psychometric evaluations of some features of the main outcome measures used in the main study. These evaluations primarily confirmed the factor structure from previous studies with high internal consistency. However, children may have had difficulties understanding some questions in the rating scales.

8.2.3 Cut-off for inclusion

Recruitment based on inclusion above a chosen cut-off is also worth discussing. We used the mean of a trait as a starting point for recruitment based on the assumption that certain traits are normally distributed in the general population; some individuals have more of certain traits, in this case being anxious or sad, than others. Although diagnostic interviews
have certain advantages over rating scales (Beesdo et al., 2009), using interviews when recruiting children in a school setting with administrative staff performing the screening was not an option. Rating scales in which symptoms can be placed on a continuum from having few symptoms to having many symptoms are considered appropriate to screen for inclusion in preventive settings (Dierker et al., 2001). However, the “correct” cut-off must be determined. What are the implications of choosing a high cut-off vs low cut-off regarding sensitivity and specificity? When do we have so much or so little of a characteristic that it becomes dysfunctional and in need of an intervention? How early is it acceptable to intervene to prevent negative development and to increase the likelihood of changing the trajectory in a more positive direction? Sadness and anxiousness are normal phenomena; however, early symptoms of anxiety and depression are clear predictors of later problems (e.g. Kovacs & Lopez-Duran, 2010).

In the pilot study, the cut-off was based on characteristics from a Nordic sample, and international research (Kamphaus & Frick, 2005; Olason et al., 2004) with a range of 0.5 – 2.0 SD above a population mean as the inclusion criteria. The main study used measures with Norwegian, Nordic or international norms for both anxious and depressive symptoms, (Angold et al., 2002; Olason et al., 2004; Rhew et al., 2010) and expert advice from Norwegian researchers to determine a suitable cut-off for an indicated sample. One SD above the population mean for anxious and depressive symptoms and no upper limit were determined as the appropriate cut-offs when recruiting symptomatic children (see also Table 3).

Not having an upper limit for inclusion implies including high-scoring children. This decision was based on experiences from the pilot study in which high scoring children were not invited to the study because they were expected to be referred to an outpatient clinic for further assessment/treatment. However, none of the high scoring children in the pilot study were referred, and to our knowledge, they did not receive any services for their problem. Including high scoring children in the main study hence resulted in a diverse sample with high and low scorers, some having comorbid problems and others not. A higher cut-off for inclusion (e.g., 1.5 instead of 1 SD) would increase the problem severity in the sample. Many children experiencing symptoms of anxiety and depression would then not have been invited to participate, and the cut-off would be closer to the considered clinical range. By choosing a lower cutoff (e.g., 0.5 as in the pilot), children with low problem loading would receive the intervention, and we would get closer to a universal prevention approach reaching children
with symptoms causing only small reductions in daily functioning. Finding the optimal cutoff is complex, and which children are reached/not reached with the chosen cut-off remains a dilemma.

8.2.4 Representativeness of sample

Another important question regards the representativeness of the sample. This study aimed to recruit a sample with higher problem severity than a population-based sample. This resulted in gateway procedure and information provided to parents and children specifying the target group. This raises issues regarding the generalizability of the findings.

In the current study, children who worried more or were more anxious than their peers were invited to the study when they met inclusion criteria. The sample was skewed because we did not screen all children in the targeted age group. The sample shows characteristics of anxious and depressive symptoms above the mean scores reported in normative studies (Olason et al., 2004; Rhew et al., 2010); thus, a subgroup with higher problem severity was recruited. Although, this approach is necessary in indicated prevention, it is not possible to generalize the results to a child population at large.

8.2.5 Regression towards the mean

In the main study, changes in pre- and post-intervention symptoms were measures of the presumed effect of the intervention. When recruiting participants classified as “at-risk” by exhibiting elevated levels of internalizing symptoms, regression towards the mean must be considered. According to Ostermann, Willich, and Lüdtke (2008), this phenomenon may occur “in situations of repeated measurements when extreme values are followed by measurements in the same subjects that are closer to the mean of the basic population”. High scoring individuals will tend to report values closer to the mean at the next measurement, and this may be interpreted inaccurately that the intervention caused the effect (Linden, 2013). Children naturally fluctuate in mood, and children reporting a high score in a screening procedure may be heavily influenced by a recent incident, e.g., a fight with friends or parents. Although measuring symptoms at more than one timepoint prior to starting the intervention would have been useful, multiple baselines would put extra pressure on the recruitment procedure and was not deemed feasible. We controlled for this problem by having a control group in the study; although both groups regressed towards the mean, the greater reduction in the intervention condition could possibly be attributed to the intervention provided.
9 FUTURE DIRECTIONS

Although the development of the EMOTION manual followed the deployment focused model (Weisz, Jensen, & McLeod, 2005) in which parents, children and group leader’s opinions have been incorporated in revisions of the manual and then tested, this process should continue. The revised and increasingly flexible version of the EMOTION program should be re-examined by other research teams. A long-term follow-up study, e.g., 5 years after the intervention, will also be important to examine whether the intervention has long-term preventive effects. To increase feasibility web-based approaches where some sessions are completed online, possibly incorporating feedback systems, could also be studied.

The intervention targets core mechanisms of change, and some have suggested that targeting these underlying mechanisms may result in more robust interventions (Sauer-Zavala et al, 2017). However, there is little empirical knowledge regarding common mechanisms, and future research should examine core mechanisms for change. The importance of a family component as a core mechanism in early intervention for anxious and sad children could be one interesting mechanism to examine in a future study. Such work could be conducted using innovative research designs such as factorial designs (Collins, Dziak, Kugler, & Trail, 2014). Such designs make it possible to study several intervention components simultaneously to determine which components would improve the intervention and could provide new knowledge (Dziak, Nahum-Shani, & Collins, 2012).

Although this thesis did not examine how having comorbid symptoms affects the response to the intervention, this could be an interesting future area of study. Will children reporting both anxious and depressive symptoms require a more extensive intervention than children reporting either symptom alone, or conversely, could children reporting either symptom alone suffice with a shorter intervention? A research team in Australia examined this issue regarding anxiety specifically and reported a similar response rate to CBT treatment regardless of having additional diagnoses (Rapee et al., 2013). However, they reported that children with comorbid conditions showed more severe symptom levels from the beginning and therefore remained more severe and impaired at the end of the treatment. They concluded that children with comorbid conditions may require more extensive treatment to obtain full improvement. We also found higher severity as reported by symptom levels and lower quality of life and self-esteem for children reporting both symptoms. The transdiagnostic perspective states that both symptom groups could be treated within the same protocol. It could however
be interesting to examine whether flexible versions (shorter or longer programs) for children presenting with different at-risk status could target the child’s needs even better.

The results from the current and previous studies on factors necessary for successful implementation provide crucial knowledge to transport the intervention into ordinary practice. Factors relating to organizational climate, leader support, and innovation fit in the organization running the intervention, are important factors to examine. Training leaders regarding the importance of implementing empirically supported interventions, could be one approach to improve organizational climate which should to be examined. Lastly, cost-benefit analyses of early interventions should be pursued when evaluating large-scale dissemination of a school-based preventive intervention.

10 CONCLUSION

The primary aims of this thesis were to develop and examine the feasibility of a new transdiagnostic intervention in a school setting and to perform an initial effectiveness evaluation of the intervention as an indicative approach. This is one of the first large studies world-wide to investigate a transdiagnostic approach targeting anxious and sad school children.

The current study lends support to the usefulness of a transdiagnostic approach to reduce symptoms of anxiety and depression in children. The initial effects indicate that the transdiagnostic EMOTION intervention provided larger reductions in child-reported symptoms of anxiety and depression and parent-reported symptoms of depression than in the control condition. Symptomatic children thus benefitted from the indicated intervention. With knowledge regarding the importance of subclinical symptoms of anxiety and depression in children, these reductions could be important to change the developmental trajectory in at-risk children.

Furthermore, our results suggest than many children have the burden of both anxious and depressive symptoms, and these children reported higher symptom scores compared to the children reporting either symptoms of anxiety or depression alone. While all at-risk groups reported lower quality of life than the norm group, the combined group reported lowest quality of life. Self-esteem was lower than the normative group when reporting comorbid symptoms or depressive symptoms only. Furthermore, significant associations between internalizing symptoms and the functional domains were found for the combined group and the depression only group, but not for the anxiety only group. Experiencing comorbid
symptoms may imply higher severity, which could have implications both for expected response to interventions and for the intensity of the intervention provided. Screening for possible depressive symptoms and providing strategies aiming at depressive symptoms especially appears to be important. A transdiagnostic approach can effectively work directly with both anxious and depressive symptoms and may therefore be useful for mental health professionals.

The results from the pilot study, indicated that the transdiagnostic EMOTION intervention was acceptable and feasible in a school setting with relatively low stigma reported from children. Parents, group leaders and children provided important feedback at this stage to enhance the user friendliness of the intervention. Lastly, the latent factor structure of the primary outcome measures was generally confirmed. The measures worked well and a sample with higher mean scores than found in normative populations were recruited.

Based on the positive results of the studies presented in this thesis, one may speculate whether new approaches (e.g., group based transdiagnostic interventions) may be indicated instead of or at least supplementary to more traditional individual single disorder approaches in preventive work. If comparable reductions in symptoms are gained by meeting with several children at once, this approach could be more efficient. Children could also receive more comprehensive interventions with time for experiential learning and practice. If policy makers want to prevent the onset of anxiety and depression in children, it may be worthwhile to provide sufficient doses when trying to prevent problems from developing. More children could possibly be reached by targeting both anxious and depressive symptoms in one protocol. New technologies could enhance feasibility in primary care and maintain the intensity of the intervention.

Developing efficient interventions targeting internalizing symptoms could have important public health implications. Interventions implemented in primary care should however have empirical support and be adjusted to the needs of the children, parents and providers.
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Appendix 1
Flow of children in Pilot Study

Pilot study
Fall 2011

Presentation of EMOTION program study at
Child meeting for fifth grade
(N = 57 children)
&
At Parent meetings

Parents completed provided informed consent and completed self-report measures of internalizing problems

Children expressing interest and with informed consent completed self-report measures of anxiety and depression
N = 22 children

Children scoring 0.5 – 2.0 SD above mean on self- or parent report invited to pilot
N = 12 children
1 child withdrew prior to intervention starting

Intervention period
10 weeks

Parents completing self-report measures, user-satisfaction, stigma

Children completing self-report measures, user-satisfaction, stigma
N = 11 children

Note. CDI = Children’s Depression Inventory (CDI; (Kovacs, 1992);
MASC-C = The Multidimensional Anxiety Scale for Children – child version (March, et al.,
Appendix II
Flowchart showing flow of children in the main study in accordance with Consort guidelines

36 schools participated
N= 7322 informed about study

Informed consent N = 1686 underwent screening for

36 schools, pairwise matched and randomly assigned to intervention or control group

18 schools allocated to intervention
N = 434 children

T1 Intervention (EC)
- n = 18 schools
- n = 296 started intervention
- Reasons:
  - n = 5 children excluded, exclusion criteria
  - n = 71 excluded due to lack of resources
  - n = 67 drop out pre intervention

18 schools allocated to control
N = 439 children

T1 Control (TAU)
- n = 18 schools
- n = 430 started control
- Reasons:
  - n = 2 children excluded, exclusion criteria
  - n = 7 drop out pre-intervention

18 schools allocated to intervention
N = 434 children

T2 Intervention (EC)
- n = 18 schools
- n = 266 answered T2
- n = 21 drop out during intervention, T2 not completed
- n = 9 missing

18 schools allocated to control
N = 439 children

T2 Control (TAU)
- n = 18 schools
- n = 428 answered T2
- n = 1 drop out during control, T2 not completed.
- n = 1 missing

Analysed

n = 18 schools
n = 358
Excluded from analysis:
- n= 71, excluded due to lack of resources
- n = 5, excluded, exclusion criteria

Analysed

n = 18 schools
n = 437
Excluded from analysis:
- n = 2 excluded, exclusion criteria
Paper I

Prevention of anxiety and depression in children: Acceptability and feasibility of the transdiagnostic EMOTION program.
Paper II

Self-reported quality of life and self-esteem in sad and anxious school children.
Self-reported quality of life and self-esteem in sad and anxious school children

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Abstract

Background: Anxiety and depressive symptoms are common in childhood, however problems in need of intervention may not be identified. Children at risk for developing more severe problems can be identified based on elevated symptom levels. Quality of life and self-esteem are important functional domains and may provide additional valuable information.

Methods: Schoolchildren (n = 915), aged 9–13, who considered themselves to be more anxious or sad than their peers, completed self-reports of anxiety (Multidimensional Anxiety Scale for children (MASC-C)), depression (The Short Mood and Feelings Questionnaire; SMFQ), quality of life (Kinder Lebensqualität Fragebogen; KINDL) and self-esteem (Beck self-concept inventory for youth (BSCI-Y) at baseline of a randomized controlled indicative study. Using multivariate analyses, we examined the relationships between internalizing symptoms, quality of life and self-esteem in three at-risk symptom groups. We also examined gender and age differences.

Results: 52.1% of the screened children scored above the defined at-risk level reporting elevated symptoms of either Anxiety and Depression (Combined group) (26.6%), Depression only (15.4%) or Anxiety only (10.2%). One-way ANOVA analysis showed significant mean differences between the symptom groups on self-reported quality of life and self-esteem. Regression analysis predicting quality of life and self-esteem showed that in the Depression only group and the Combined group, symptom levels were significantly associated with lower self-reported scores on both functional domains. In the Combined group, older children reported lower quality of life and self-esteem than younger children. Internalizing symptoms explained more of the variance in quality of life than in self-esteem. Symptoms of depression explained more of the variance than anxious symptoms. Female gender was associated with higher levels of internalizing symptoms, but there was no gender difference in quality of life and self-esteem.

Conclusion: Internalizing symptoms were associated with lower self-reported quality of life and self-esteem in children in the at-risk groups reporting depressive or depressive and anxious symptoms. A transdiagnostic approach targeting children with internalizing symptoms may be important as an early intervention to change a possible negative trajectory. Tailoring the strategies to the specific symptom pattern of the child will be important to improve self-esteem.

Trial registration: Trial registration in Clinical trials: NCT02340637, June 12, 2014.

Keywords: Quality of life, Self-esteem, Anxiety, Depression, Children at risk, Prevention

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Background

Internalizing disorders of anxiety and depression are common [1–4], often comorbid [5, 6] and have an impairing influence on children’s everyday lives and functioning [7–9]. Symptoms, even though not reaching a diagnostic level, may put the child at risk for later developing full disorders [10]. Thus, several studies have shown that self-reported depressive symptoms in children have a strong prognostic power to predict subsequent depressive disorders in youths [10–12]. Likewise, childhood anxiety symptoms are a risk factor for adolescent anxiety and depressive disorders [10, 12–15]. Elevated symptoms of anxiety or depression may also interfere with school functioning and academic achievement, and these associations seem to be bidirectional [16].

Prevalence rates of anxiety and depressive symptoms may vary with age. Although some studies suggest that the overall prevalence rates of fears and anxiety decrease from preadolescence into adulthood [17], other studies indicate that there are different developmental trajectories for specific anxiety symptoms, such as separation anxiety and social anxiety [3, 18]. There also seems to be distinct gender differences, with females reporting more fears than males [17, 19]. Anxiety is often found to precede depression [7] and children showing mixed symptomatology may thus have had the problems for a longer time than having anxiety only. Furthermore, depressive symptoms in girls age 14–15 seem to increase more rapidly than for boys at the same age [20–22]. Both anxiety and depression may be precursors for other difficulties [8, 23] and even not qualifying for a full disorder, such symptoms may reduce daily functioning [24].

It should however be kept in mind that anxious or sad feelings are also normal aspects of life. For intervention purposes it is therefore necessary to differentiate between children at risk for developing psychopathology from children showing normal variations of feelings. Not providing service leaves early symptoms unattended and thereby runs the risk that children suffering from internalizing symptoms miss receiving adequate early help [22, 25–28]. Collecting children’s self-report of anxious and depressive symptoms is one way of identifying children in need of preventive interventions.

For some children elevated levels of symptoms of anxiety and depression may over time be associated with functional impairment and lower levels of well-being [29–31]. Quality of life and self-esteem are among the domains that in combination with elevated levels of internalizing symptoms could imply higher problem severity and thus indicate an at-risk sub sample of children that may be in need of indicated preventive efforts [32].

According to Mattejat et al. [33], quality of life can be defined as “a subjective perception of well-being and satisfaction that can best be evaluated by the child according to his or her own experience within several life domains”. The concept thus emphasizes a child’s subjective satisfaction with his or her functioning in everyday life [34]. During the last decade, a number of studies have addressed quality of life in children and adolescents with mental health problems [32, 34, 35]. A general finding is that children with mental health problems report lower quality of life compared to healthy children as well as those with a physical disorder [36, 37]. In a clinically based Norwegian study with children aged 8–15, those with anxiety/depression reported lower quality of life than did the AD/HD group [35]. Bastiaansen and colleagues [34] found that anxiety disorders had a negative impact on quality of life similar to children with externalizing disorders and mood disorders.

Does quality of life add incrementally to the identification of health service needs that are not detected by symptoms alone? The results of one study [29] indicated that children in outpatient services reported significantly lower quality of life than children in the community with the same level of emotional and behavioral problems. The investigators concluded that for children with equal levels of mental health problems, quality of life measurement would add important information about the total severity of the condition and hence the need for an intervention.

Self-esteem can be described as an individual’s global evaluation of his or her overall worth as a person [38]. While some have argued that self-esteem and depression can be joined under the construct of negative emotionality as they share a large proportion of variance [39], others emphasize factors to the contrary and have argued for the importance of distinguishing between the two constructs [40]. In cognitive vulnerability models of anxiety and depression, a negative self-view is considered a risk factor that may increase the likelihood for onset of disorders [41]. Adolescence is a sensitive time with many developmental challenges, and research suggests that self-esteem decreases during these years, especially for girls [42, 43].

According to van Tuijl and colleagues [41], research on adolescent and adult samples has consistently suggested lower self-esteem in individuals with higher levels of depression and anxiety symptoms, e.g. [41, 44]. Furthermore, findings from a meta-analysis supported that low self-esteem is predictive of symptoms of depression and anxiety [45]. There is less knowledge on younger children, but a study of Mexican-origin children found low self-esteem to be a prospective risk factor of depression for children aged 10–12 [46]. Steiger and colleagues [38] emphasize the malleability of self-esteem during the adolescent years. It may be important for preventive interventions to target low self-esteem either indirectly through the negative self-related thoughts consistent with the symptomatology of anxiety and/or depression or directly through working with improving self-esteem.
Examining how symptoms of anxiety and depression are related to the child's functioning by assessing self-reported quality of life and self-esteem may thus improve our understanding of at-risk children. By focusing especially on symptomatic sub-groups, we can determine if there are differential relations between symptom level and quality of life and self-esteem for children with different combinations of problems. Maybe having some symptoms imply higher problem severity, pointing at the importance of intervening for specific subgroups. If self-esteem is affected, this could also point at the importance of focusing on self-esteem in indicated interventions.

The present study examined symptoms of anxiety and depression at baseline as reported by a self-selected sample of school children aged 9–12 years. Children were invited to participate in the pretest by having information about the study presented in class and in appropriate letters to children and parents. Children were screened for participation in the randomized controlled trial studying the effect of a targeted preventive intervention to reduce symptoms of anxiety and depression in children. Children exhibiting symptoms of anxiety, depression or both above a normative mean, were included in the RCT condition. The mean scores and standard deviations for inclusion on self-reported symptoms was based on population studies using unselected samples [48, 49]. Analyses in the present paper were also based on the same at-risk sample.

The associations of internalizing symptoms with self-reported quality of life and self-esteem were evaluated, controlled for gender and grade level in the three different at-risk groups (i.e. children having symptoms of Anxiety only, Depression only or Combined (Anxiety and Depression). We hypothesized that there would be significant differences in means between the at-risk groups with regard to self-reported quality of life, self-esteem, anxiety, and depression and that having symptoms of both disorders would imply higher symptom levels and lower self-reported quality of life and self-esteem than having symptoms of either depression or anxiety alone. We also assumed that older children and girls would report lower quality of life and self-esteem across symptom groups.

Based on earlier findings it was furthermore hypothesized that elevated symptoms of either anxiety or depression would be negatively associated with quality of life and with self-esteem. In addition, having symptoms of both disorders concurrently was expected to have a stronger relationship with quality of life and self-esteem than having symptoms of either alone.

**Method**

**Recruitment procedure**

School children were recruited from primary schools after an open invitation to municipalities in urban and rural areas of Norway. The schools had agreed to participate in a randomized controlled study aiming to reduce the levels of anxious and/or depressive symptoms among school children through a new transdiagnostic group intervention based on cognitive behavioral therapy. Identification of children at risk for developing disorders requires a screening procedure. This procedure must be acceptable to the ethical board, the school administration, to parents and their children. Since screening entire age groups of children for symptoms is neither usual nor seen as acceptable in Norway, the children and their parents were informed about the study at school and in parent meetings. It was emphasized that the target group for the study were children who believed they were more anxious and sad than their peers and their parents. Children expressing interest and who had informed consent from their parents were then invited to screening. The child's scoring of 1 SD or more on symptoms of anxiety, depression or both, was considered the inclusion criteria for further participation in the RCT condition. The mean scores and standard deviations for inclusion on self-reported symptoms was based on population studies using unselected samples [48, 49]. Only the screened children with scores above the cutoff at pretest (n = 477) were included in the present study. The sample on which the current study is based was thus recruited from a subgroup of the total population, and should therefore have more problems than the normal population of children in this age group. In indicated prevention, this is however a necessary recruitment procedure as we want to target children who have a certain level of specific problems.

**Participants**

In participating primary schools (n = 30) a total of 4,315 children in 4th–6th grade (9–12 years of age) and their parents were invited. The number of children screened were n = 915, and the analysis representing baseline data are based on the at-risk samples (n = 477) scoring 1 SD or more on symptoms of anxiety, depression or both. For details of the RCT go to https://clinicaltrials.gov/ct2/show/NCT02340637, Trial registration: NCT02340637, June 12, 2014.

**Measures**

Multidimensional Anxiety Scale for Children (MASC-C). Anxiety symptoms were measured by the MASC-C [50], a 39-item, child self-report, assessing anxiety in youth between 8 and 19 years. The measure has four subscales: Physical Symptoms, Social Anxiety, Separation Anxiety/Panic and Harm Avoidance. The response options are “0” for "never true about me", “1” for “rarely true about me”, “2” for “sometimes true about me” and “3” for “often true about me”. The MASC-C has high retest reliability [51, 52], and good predictive and discriminative validity [53–55]. Elevated scores are significantly
associated with meeting diagnostic criteria in a Norwegian sample [56]. In this study, the total anxiety score of the MASC-C was used to indicate symptom-level of anxiety [50]. The total anxiety score was also used as a dichotomized variable, indicating whether the child scored above the defined cutoff or not. Given the variation in mean scores between boys and girls in unselected samples, we used gender specific cutoffs for anxiety [49], MASC-C girls; X = 46 (SD 15), 1 SD above mean; ≥ 61 points, MASC -C boys; X = 39 (SD 15), 1 SD above mean; ≥ 54 points. Internal consistency of the MASC-C in the present study was high with Cronbach’s Alpha 0.91.

Short Mood and Feelings Questionnaire (SMFQ). Depressive symptoms were assessed by the SMFQ [57], a brief 13-items scale assessing cognitive, affective and behavioral-related symptoms of depression in children 8 to 18 years. Statements are rated as being either “true” (2), “sometimes true” (1), or not true (0). In a study of 8–16 years-olds [57] the SMFQ discriminated clinically referred youth from unselected pediatric controls, and depressed youth from non-depressed youth. The measure has recently demonstrated Norwegian norms for 8 to 15 year olds, high retest reliability (r = 0.8) and good content validity [22, 58]. A full-scale sum score was created as the sum of all the individual values [57]. In addition, a dichotomized variable was used, indicating whether the child scored above the decided cutoff or not.

The literature suggests the same mean to be used for boys and girls for inclusion of depressive symptoms in this age-group [47, 48]. SMFQ cut-off: X = 3.8 (SD 3.6), 1 SD above mean; ≥ 7 points. Internal consistency of the SMFQ in the current study, Cronbach’s alpha, was 0.94.

Beck Youth Inventory-II (BSCI-Y). Self-esteem was assessed using a subscale of the BSCI-Y [59]. The BSCI-Y measures self-concept in children between 7 and 18 years using 20 items, and is considered useful for screening in schools [59]. The self-concept inventory measures the child’s perception of self, body image, competence and relation to others. Statements are rated on a four-point scale, “1” for “never”, “2” for “sometimes”, “3” for “often” and “4” for “always”. Gender differences have been found, and the scale is divided into three age groups with different norms [60]. The total sum score based on all items was used [59]. The inventory has Norwegian norms and the reliability of the Norwegian version was high (Cronbach’s alpha in the 0.8–0.9 range). Cronbach’s alpha in the current study was 0.93.

KINDL (Kinder Lebensqualität Fragebogen) [61] http://www.kindl.org/. The KINDL was used to assess quality of life. The KINDL was developed for epidemiological use in children and adolescents aged 4–16 years. It consists of 24 items and measures physical and emotional wellbeing, self-esteem, and social functioning (family, friends and school) on a 1–5 scale where 1 indicates “never” and 5 indicates “all the time”. The KINDL questionnaire is analyzed by adding the item responses marked on each subscale, transforming the scores to standardized scores enables comparisons to be made with norm data [62]. A mean of 81.9, SD 9.07 is reported from a normative sample of school children (n = 846) [63]. In a study with children aged 8–16 years, a Norwegian version of the KINDL showed satisfactory internal consistency and retest reliability of the KINDL total quality of life scale [64]. Cronbach’s alpha in the current study was 0.89.

Associations between the measures were expected as they measure related constructs. To investigate this issue, the strength of the relationships between the constructs were calculated using Pearson’s correlation, see Table 1. All associations were significant at p < .001. The moderate degree of associations however indicated that they still measure different concepts. The relatively weak correlation (r = .353) between the independent variables (anxiety and depression) indicated low risk of multi-collinearity in the regression analysis.

The children screened was categorized into 3 at-risk groups depending on their scores on symptoms of anxiety and depression: the Anxiety only group scored ≥ 1 SD above the normative mean on anxiety symptoms only, the Depression only group scored ≥ 1 SD above the normative mean on depressive symptoms only, and the Combined group scored ≥ 1 SD above the normative mean on both anxious and depressive symptoms.

Statistics
One-way between groups analysis of variance (ANOVA) (the statistical package IBM SPSS; version 22) compared the overall as well as the contrast differences in mean scores on quality of life, self-esteem, anxiety and depression within the at-risk groups. Multiple regression analysis assessed the degree of relationship between anxiety and depression on quality of life and self-esteem, controlling for gender and grade-level within each symptom group.

Results
All children screened were n = 915, of them 53.7 % (n = 491) were girls.

| Table 1 | Correlations between anxiety, depression, quality of life and self-esteem |
|---------|-----------------|-----------------|-----------------|
|         | Anxiety (MASC-C) | Depression (SMFQ) | Quality of life (KINDL) |
| Depression (SMFQ) | .353* | | |
| Quality of life (KINDL) | | .430** | .635** |
| Self-esteem (BSCI-Y) | | | .282* |

Note: N = 477, KINDL Kinder Lebensqualität Fragebogen, BSCI-Y Beck youth inventory-II-self-concept scale, MASC-C the multidimensional anxiety scale for children – child version, SMFQ the SMFQ (The Short Mood and Feelings Questionnaire); ** p < .001
More than half (52.1 %, n = 477) of the full sample scored >1 SD above the cutoff on symptoms of anxiety, depression or both. There were more girls (n = 277, 58.1 %) than boys (n = 200, 41.9 %) in the at-risk sample. The largest at-risk group (n = 243, 26.6 %) were children reporting symptoms of both anxiety and depression (the Combined group), 15.4 % (n = 141) reported symptoms of Depression only and 10.2 % (n = 93) reported symptoms of Anxiety only, see Table 2.

**Group and gender differences**

One-way between groups ANOVAs were conducted to examine if there were significant overall differences in means between the at-risk groups with regard to self-reported quality of life, self-esteem, anxiety, and depression. Hochberg GT2 was used in the contrast analysis as the groups were of different sizes, and the differences between the groups are indicated in Table 2.

We found a significant overall difference in self-reported mean scores on quality of life in the groups F (474, 2) = 76.6, p < .001. Children reporting both anxiety and depression (the Combined group) reported significantly lower quality of life than children in the Depression only group did (MCombined = 55.5 vs MDepression only = 63.9, p < .001). The children in the Depression only group reported significantly lower quality of life than the Anxiety only group (MDepression only = 63.9, vs MAnxiety only = 71.3, p < .001, GT2 = 7.5, p < .001). There was also an overall significant difference in means between the groups with regard to self-reported self-esteem F (474, 2) = 38.6, p < .001. Children in the Depression Only group reported significant lower self-esteem compared to children in the Anxiety only group (MDepression only = 36.4, vs MAnxiety only = 41.4, p < .001, GT2 = 4.9, p < .001) and between the Combined group and the Depression only group there was also a significant difference with the Combined group reporting lower self-esteem than the Depression only group (MCombined = 32.1, vs MDepression only = 36.4, p < .001, GT2 = 4.3, p < .001).

In addition, we found a significant overall difference in mean symptom level of anxiety, F (474, 2) = 270.7, p < .001. Post hoc analyses of contrast effects indicated a significant difference between self-reported anxiety in the Combined group compared to the Anxiety only group (MCombined = 71.6 vs MAnxiety only = 65.2, p < .001, GT2 = −6.5, p < .001). The Depression group also self-reported on anxiety symptoms, and as expected they reported significantly lower anxiety scores than the Anxiety only group (MDepression only = 48.5 vs MAnxiety only = 65.2, p < .001, GT2 = 16.7, p < .001). Self-reported mean scores on depression were also significantly different across the groups F (474, 2) = 184.5, p < .001. Scores in the Combined group was significantly higher than in the Depression only group (MCombined = 12.6 vs MDepression only = 9.7, p < .001, GT2 = −2.9, p < .001). The Anxiety only group also reported on symptoms of depression, and their depression scores were significantly lower than in the Depression only group (MDepression only = 12.6 vs MAnxiety only = 3.9, p < .001, GT2 = −5.8, p < .001).

We found significant gender differences in mean scores in self-reported anxiety in the Anxiety only group F (1, 91) = 18.2, p < .001, and in the Combined group F (1, 241) = 39.4, p < .001 with girls reporting higher levels of anxiety than boys did. Also children in the Depression only group reported on anxiety symptoms and with gender differences F (1139) = 45.1, p < .001. In the Combined group, there was furthermore a significant effect of gender on depression F (1, 241) = 11.2, p < .001, on Quality of Life F (1241) = 10.8, p < .001 and on self-reported Self-esteem F (1241) = 10.5, p < .05 where girls reported higher levels of symptoms of depression, and lower quality of life and self-esteem. In the Depression only group there was no significant difference in scores between boys and girls with regard to quality of life, self-esteem and depression.

**Table 2** Gender and group differences in self-reported quality of life, self-esteem, anxiety and depression

<table>
<thead>
<tr>
<th></th>
<th>Anxiety only (1)</th>
<th>Depression only (2)</th>
<th>Anxiety and depression (3)</th>
<th>Hochberg GT2 Diff. bw groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N: boys =45; girls =48</td>
<td>N: boys =60; girls =81</td>
<td>N: boys =95; girls =148</td>
<td></td>
</tr>
<tr>
<td>Quality of life (KINDL)</td>
<td>M</td>
<td>SD</td>
<td>95 % CI</td>
<td>M</td>
</tr>
<tr>
<td>Boys</td>
<td>73.4*</td>
<td>7.6</td>
<td>(71.1; 75.6)</td>
<td>65.1</td>
</tr>
<tr>
<td>Girls</td>
<td>69.5</td>
<td>8.0</td>
<td>(67.1; 71.8)</td>
<td>63.0</td>
</tr>
<tr>
<td>Self-esteem (BSCI-Y)</td>
<td>Boys</td>
<td>42.2</td>
<td>7.0</td>
<td>(40.1; 44.3)</td>
</tr>
<tr>
<td>Girls</td>
<td>40.7</td>
<td>9.1</td>
<td>(38.0; 43.3)</td>
<td>35.4</td>
</tr>
<tr>
<td>Anxiety (MASC-C)</td>
<td>Boys</td>
<td>61.8</td>
<td>7.0</td>
<td>(59.7; 63.9)</td>
</tr>
<tr>
<td>Girls</td>
<td>68.3**</td>
<td>7.6</td>
<td>(66.1; 70.5)</td>
<td>51.9**</td>
</tr>
<tr>
<td>Depression (SMFQ)</td>
<td>Boys</td>
<td>4.2</td>
<td>1.7</td>
<td>(3.7; 4.7)</td>
</tr>
<tr>
<td>Girls</td>
<td>3.7</td>
<td>1.8</td>
<td>(3.2; 4.2)</td>
<td>9.9</td>
</tr>
</tbody>
</table>

Note: N = 477. KINDL, kinder Lebensqualität Fragebogen, BSCI-Y Beck youth inventory-II-self-concept scale, MASC-C the multidimensional anxiety scale for children – child version, SMFQ the SMFQ (The Short Mood and Feelings Questionnaire); *p < .05, **p < .001 for gender differences, *** Hochberg GT2 indicates only significant differences at p < .001.
Anxiety and depression in relation to quality of life and self-esteem
Separate multiple regression analyses were performed within the at-risk groups predicting quality of life and self-esteem apart using symptoms of anxiety and depression as dimensional independent variables. Analyses were controlled for gender and grade level.

Quality of life
Examining the sample in relation to quality of life, there was a statistical significant relation between self-reported symptoms of depression and quality of life in the Depression only group (β = -.45, p < .001) and in the Combined group with a standardized beta for symptoms of anxiety (β = -.32, p < .001), and for depression (β = -.36, p < .001), see Table 3 below. Symptoms of depression explained most of the variance, Part² = 20.3 % in the Depression Only group, and Part² = 9.7 % in the Combined group. In the Combined group, symptoms of anxiety explained 6.9 % of the variance in quality of life. Grade level was statistically significant in Combined group at the p < .05 level, where older children reported lower quality of life than younger children did. Gender was not significantly related to quality of life in any of the at-risk groups.

In the Anxiety only group, the relation between anxiety symptom level, grade level and quality of life was not significant.

There was a clear tendency that the Combined model explained most of the variance in Quality of life with 38 %, (F (238, 4) = 36.43, p < .001). The model for Depression only explained 23 % (F (137, 3) = 13.45, p < .001) and the Anxiety only model 9 %, (F (88, 3) = 3.03, p < .05).

Self-esteem
Examining symptom levels in the at-risk groups with regard to self-esteem, there was a significant relation between symptoms of depression and self-esteem (β = -.34, p < .001) in the Depression only group and in the Combined group (β = -.34, p < .001), see Table 4. In both groups, symptoms of depression explained most of the variance: Part² = 11.6 % and Part ² = 8.4 % respectively. Grade level was only significant in the Combined group (β = -.15, p < .05) with the oldest children scoring lowest on self-esteem. Gender was not significantly related to self-esteem in any of the at-risk groups.

There were no significant relations between the Anxiety only group and self-esteem.

The model explained 22.1 % of the variance in self-esteem in the Combined group (F (238, 4) = 16.9, p < .001) with symptoms of depression explaining most of the included independent variables (8.4 %). The model for the group Depression only explained 14.9 % of the variance in self-esteem (F (137, 3) = 7.9, p < .001), while there was a non-significant relation between anxiety and self-esteem F (88, 3) = .56, n.s.).

Additional analyses indicated no interaction effect between symptoms of anxiety and depression on quality of life or self-esteem.

Discussion
The present study examined self-reported internalizing symptoms in a sample of children aged 9–12 years in relation to self-reported quality of life and self-esteem controlled for grade level and gender. The children were recruited as part of a randomized controlled intervention trial to be run in schools and baseline measures were used. We examined self-reported quality of life and self-esteem in relation to symptoms of anxiety and depression and discuss if such functional domains may give additional indications of how internalizing symptoms may have differential impact on different at-risk groups.

The children were considered to be at risk for developing further problems if they scored 1 SD or more above a normative mean based on unselected or population samples in other studies on symptoms of anxiety, depression or both. In this study most children reported symptoms of both anxiety and depression, while children reporting anxiety only was the smallest at-risk group. This is different from population based studies where anxiety problems usually are the most common emotional problem for this age group [2]. Our main finding regarding the associations with the two functional domains was that

| Table 3 Standard multiple regression analysis for at-risk groups on quality of life |
|----------------------------------------|-----------------|-----------------|-----------------|-----------------|
|                                       | Quality of life | Anxiety only (n = 92) | Depression only (n = 141) | Anxiety & depression (n = 243) |
|                                       | Std β          | 95 % CI          | Part²          | Std β          | 95 % CI          | Part²          | Std β          | 95 % CI          | Part²          |
| Anxiety (MASC-C)                      | -.11           | (3, -1)          | .9 %           |                |                |                |                |                |                |
| Depression (SMFQ)                     |                |                  |                | -.32**         | (-5, -2)        | 6.9 %           |                |                |                |
| Grade level                           | -.17           | (-4.5, 4)        | 2.9 %          | -.14           | (-4.7, -1.7)   | 1.9 %           | -.13*          | (-4.4, -5)     | 1.6 %           |
| Gender                                | -.21           | (-6.9, -2)       | 3.7 %          | -.06           | (-4.2, 1.9)    | 0.3 %           | .01            | (-3.0, 2.4)    |                |
| R²                                    | .094           | R² = .228        | R² = .380      |                |                |                |                |                |

Note: Quality of life: KINDL kinder Lebensqualität Fragebogen; MASC-C the multidimensional anxiety scale for children – child version, SMFQ the SMFQ (The Short Mood and Feelings Questionnaire) * p < .05, ** p < .001, Part² = effect size
when progressing from the Anxiety only group, to the Depression only group and finally to the Combined group, there was a gradual increase in anxious and depressive symptoms and a decrease in quality of life and self-esteem. In multivariate analyses, significant associations were found between symptoms of depression as well as comorbid anxiety and depression and self-reported quality of life and self-esteem. This was according to our hypothesis. There was however a significant difference between the symptom groups Anxiety Only and Depression only where having depressive symptoms only indicated lower quality of life and self-esteem than having anxiety symptoms only. The symptoms level of the Anxiety only group was not significantly related to the two functional domains, despite that the mean score on quality of life was more than one SD below the normative sample of the measure [63]. When targeting both anxiety and depression in a transdiagnostic intervention, it may thus be important to emphasize therapeutic strategies targeting symptoms of depression especially both with regard to time spent and tailoring them to the characteristics of the individual child as these symptoms appear to be closely related to the severity experienced by the children.

Symptoms of depression explained most of the variance in relation to quality of life. Symptoms of depression like low mood, anhedonia and lowered energy might set a spiral of experiencing lower quality of life in many areas, both because depressive symptoms are associated with less activity and less joy, and because having a high level of depressive symptoms might distort the child’s conception of him- or herself, the context and the future. Only in the Combined group, older children reported significantly lower quality of life than younger children. We did not find a significant effect of gender in any of the other symptom groups which was contrary to our hypothesis, namely that girls would report lower quality of life than boys would. Other studies have reported gender differences in quality of life, with girls showing a greater decrease than boys did [64, 65], but this was not replicated in our study.

Symptoms of anxiety alone (the Anxiety only group) did not gain a significant relation to the children’s experience of life quality. This finding indicates that having more or less anxiety within the at-risk range is not necessarily associated with quality of life. Anxiety symptoms may affect more specific domains, and does not affect the quality of life to the same extent as when having depressive symptoms. The Anxiety only group was also the smallest at-risk group in the study, which may have influenced our results. Restriction of range could also be a factor to consider, however the variance in the symptom scores of Anxiety only group were acceptable compared to the Combined group. We thus found partial support for our hypothesis; having high levels of symptoms in both domains had a stronger negative impact on quality of life than having symptoms of anxiety alone.

According to Jozefiak and colleagues [32] the child’s self-reported quality of life may be an important indicator of the child’s well-being that can provide us with information regarding the child’s need for health services to a greater extent than symptom level alone. Based on the current sample, it appears that symptoms of depression alone, and symptoms of depression and anxiety together was significantly associated with the child’s quality of life and as such may indicate higher problem severity in need of intervention. When both symptom groups are targeted in a united preventive intervention, as less positive change may be expected in these groups compared to the Anxiety only group as implied by higher problem severity. As anxiety also is found to often precede depression in children [7], it may be hypothesized that children with a mixed symptom presentation have had their problems longer and hence is more difficult to change.

There were significant associations between symptoms of depression and self-esteem in the Depression only group and in the Combined group. This was according to our hypothesis. We found significant age differences as indicated by grade level only in the Combined group, older children reporting lower self-esteem than younger children did. There were no significant effects of gender. Children who reported symptoms of Depression only or both Anxiety and depression, reported self-esteem in the lower than average, to much lower range [59] which is an indication of severity.

### Table 4 Standard multiple regression analysis for at-risk groups on self-esteem

<table>
<thead>
<tr>
<th>Anxiety only (n = 92)</th>
<th>Depression only (n = 141)</th>
<th>Anxiety &amp; depression (n = 245)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>β</strong></td>
<td><strong>95% CI</strong></td>
<td><strong>Part</strong></td>
</tr>
<tr>
<td>Anxiety (MASC-C)</td>
<td>-0.09 (−0.1, 0.3)</td>
<td><strong>.8 %</strong></td>
</tr>
<tr>
<td>Depression (SMFQ)</td>
<td>-0.34** (−1.4, −0.5)</td>
<td><strong>11.6 %</strong></td>
</tr>
<tr>
<td>Grade level</td>
<td>-0.04 (−0.3, 0.2)</td>
<td><strong>.2 %</strong></td>
</tr>
<tr>
<td>Gender</td>
<td>-0.14 (−0.5, 0.16)</td>
<td><strong>1.5 %</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>R²:0.019</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>R²:1.49</strong></td>
</tr>
</tbody>
</table>

Note: Self-esteem: BSCI-Y Beck youth inventory-II self-concept scale, MASC-C the multidimensional anxiety scale for children – child version, SMFQ the SMFQ (The Short Mood and Feelings Questionnaire) * p < .05, ** p < .001, Part = effect size
Earlier studies have indicated that self-esteem decrease with increasing age and also that gender differences in self-esteem increase with increasing age [60]. Our findings with regard to gender may be explained by the fact that the children in this study were in the lower age range. Symptoms of depression explained most of the variance in both the Depression only and in the Combined group. Depressive symptoms thus seem to be related to a negative self-perception. This is not surprising as depression often is characterized by a negative global self-evaluation, which is also central in the concept of self-esteem of a person [38]. There is, however, support for viewing self-esteem and depression as separate constructs [40].

In the Anxiety only group, there were no significant relations between symptoms of anxiety, gender, grade level and self-esteem. This result may indicate that anxiety affects a narrower area of functioning and thus does not threaten the global self-evaluation of the child.

Our study suggests that symptoms of anxiety and/or depression are negatively related to the child’s self-perception. The importance of working to enhance a child’s self-evaluation in these at-risk groups especially is supported by existing research as low self-esteem is a risk factor for developing symptoms of anxiety and depression [41, 44]. The fact that self-esteem often decreases even more during adolescence [42], and the possibility of improving self-esteem by suitable interventions [38], makes focusing on this aspect important in interventions targeting children with internalizing symptoms.

Lastly it is worth mentioning that the current study took place in a school setting. Previous studies have pointed at the association between mental health problems and school functioning, more specifically by reducing learning capacities, increasing risk for absenteeism and academic underachievement [16]. Such problems may again influence mental health negatively. These reciprocal, negative associations are important indicators for the necessity in reaching these children with suitable and effective interventions.

Our study extends earlier research by showing that there exists a relationship between symptom levels and quality of life and self-esteem for children with depressive symptoms and for children having both depressive and anxious symptoms. This indicates the importance of always screening for depressive symptoms in preventive work and in treatment of internalizing symptoms. Assessing how such symptoms influence the child’s self-reported quality of life may give important additional information about problem severity.

We would argue that the present findings make it plausible to intervene for children who are at-risk, although not disordered, as they report lower quality of life and reduced self-esteem with increasing symptomatology. Both national [26] and international research [25, 66] have documented that children with internalizing disorders are not receiving the needed services. While many of the children reporting symptoms of anxiety and/or depression in this study would not qualify for a diagnosis, there is ample research indicating that even having fewer symptoms of anxiety and depression may render the children at risk for developing more serious problems [10]. It is also possible that some of the high-scoring children in the present sample could qualify for a disorder although this was not the focus in this study. We would therefore argue that experiencing high levels of internalizing symptoms indicate that the child could be a target for preventive efforts. The results concerning the different severity level in both the Depression only and in the Combined group on the one hand compared to the Anxiety only group on the other hand might have implications for expected change of a common indicative program, and might have implications for the emphasis given to specific interventions in such an intervention.

**Strengths and limitations**

The present study has several strengths and limitations. The sample was geographically diverse and from small and large schools in both urban and rural areas. There were few missing data, and the screening measures had good psychometric properties.

While we intended a full screening of the entire target population, this was not acceptable to the ethical committee and not according to cultural norms in Norway. The sample was therefore self-selected based on the children’s own experience of being sad or anxious, and the children being screened most probably has a higher problem loading than the general child population this age.

While recruiting the children from a school setting has its advantages, some children might not be reached by the recruitment method used in this study (children with certain problems, e.g. socially anxious children, migrant children with a different cultural background).

The rating scales used are brief and cost-effective and identifies children in need of services [54] and it has been argued that self-report of internalizing difficulties can be superior to other/parent report [67]. However, inclusion of other informants of child symptoms may nevertheless add to the accurate identification of children in need. Lastly, although the cutoff scores were based on an acceptable rationale, the selection based on different means for including children to the study could have influenced the results.

**Conclusion**

Schoolchildren wanted to participate in a study targeting symptomatic children with regard to anxiety and depression, and approximately half of the screened children self-reported high levels of symptoms of anxiety, depression or both. The largest at-risk group comprised of children self-reporting both depressive and anxious symptoms.
High levels of depressive symptoms and the combination of anxious and depressive symptoms were associated with reduced quality of life and self-esteem, but not symptoms of anxiety alone. A transdiagnostic approach targeting both symptom groups may be promising as a preventive or early intervention approach. Focus on enhancing self-esteem could be important in such an intervention especially so for children with depressive or mixed symptomatology. In addition, tailoring the transdiagnostic intervention might be important to get sufficient attention to children with specific challenges related to depressive or mixed symptomatology.

Abbreviations
BSCL-Y: Beck youth inventory-II questionnaire, self-concept scale; KINDL: Kinder Lebensqualitat Fragebogen questionnaire; MASC-C: Multidimensional anxiety scale for children questionnaire; SMFQ: Short mood and feelings questionnaire

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The dataset will be made available on request to the corresponding author.

Authors’ contributions
KM contributed to the study design, data collection, statistical analysis, and interpretation of data and the writing of the paper. SPN contributed to the study design, interpretation of data and the revising of the manuscript. SH contributed to the study design, statistical analysis, interpretation of data and the revising of the manuscript. TW contributed to the statistical analysis, interpretation of data and the revising of the manuscript. AMS contributed to the study design, interpretation of data and the revising of the manuscript. PCK contributed to the study design, interpretation of data and the revising of the manuscript. All authors read and approved the final manuscript.

Competing interests
The authors declare that they have no competing interests, and all authors have approved the manuscript for publication.

Consent for publication
All parents have signed consent to publish on the dataset.

Ethics approval and consent to participate
The study was approved by the Regional Ethics committee, Region South and East Norway, 2013/1909/REK sør-øst. All parents have signed consent to participate in the study.

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