iCanCope with Pain™ Norway

Cultural translation and feasibility testing of the Norwegian *iCanCope with Pain*™ app aimed at reducing pain and improving health-related quality of life in a school-based population of adolescents with persistent pain

Erik Grasaas

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List of papers

Paper I

Grasaas E, Fegran L, Helseth S, Stinson J, Martinez S, Lalloo C, Haraldstad K. *iCanCope with Pain*: Cultural Adaptation and Usability Testing of a Self-Management App for Adolescents with Persistent Pain in Norway. Journal of Medical Internet Research 2019.

Paper II

Grasaas E, Helseth S, Fegran L, Stinson J, Småstuen M, Haraldstad K. Health-Related Quality of Life in Adolescents with Persistent Pain and the Mediating Role of Self-Efficacy. Health and Quality of Life Outcomes 2020.

Paper III

Grasaas E, Fegran L, Helseth S, Stinson J, Småstuen M, Lalloo C, Haraldstad K. App-based Intervention Among Adolescents with Persistent Pain: A Pilot Feasibility Randomized Controlled Trial. BMC Pilot and Feasibility Studies.

Abbreviations

Application (app)
Behavioral Activation Therapy (BA)
Cognitive Behavioral Therapy (CBT)
General Linear Model (GLM)
General Self-Efficacy (GSE)
General Self-Efficacy Questionnaire (GSEQ)
Health-Related Quality of Life (HRQOL)
Hospital Anxiety and Depression Scale Questionnaire (HADS)
International Association for the Study of Pain (IASP)
International Classification of Diseases (ICD)
Internet-delivered Cognitive Behavioral Therapy (iCBT)
International Physical Activity Questionnaire (IPAQ-SF)
Lübeck Pain-Screening Questionnaire (LPQ)
Nord-Trøndelag Health Survey (HUNT)
Patients' Global Impression of Change Scale (PGIC)
Perceived Social Support from Friends (PSS-FR)
Quality of Life (QOL)
Randomized Controlled Trial (RCT)
Socioeconomic Status (SES)
Social Cognitive Theory (SCT)
Visual Analogue Scale (VAS)

Summary

Background: Persistent pain has a high prevalence among adolescents. Pain has been shown to reduce all aspects of the adolescent's health-related quality of life (HRQOL). Available pain-coping applications (apps) are rarely scientifically evaluated nor have health personnel in their development. Thus, there is a need to provide coping strategies in evidence- and theory-based app interventions aimed at reducing pain and increasing HRQOL among adolescents with persistent pain.

The *iCanCope with Pain*™ app is originally from Canada and based on theory, identified healthcare needs and current best practices for pain self-management. There was a need for ensuring the app was appropriate for a school-based population of Norwegian adolescents with persistent pain. Hence, Paper I described the translation and cultural adaptation of the app into the Norwegian context and evaluated the app's usability. The findings from Paper I secured a fundamental platform for further feasibility testing on a larger scale. Given the limited research evidence regarding the underlying mechanisms between pain and HRQOL in adolescents with persistent pain, Paper II described the experience of pain, HRQOL and self-efficacy among this study sample; and explored the association between pain intensity and HRQOL testing for self-efficacy as a possible mediator. Finally, in Paper III we determined the feasibility and explored possible differences in outcomes between the intervention and control groups of an 8-week intervention using the Norwegian *iCanCope with Pain*™ app. Two papers have been published in peer-reviewed journals and one paper submitted, which together have established a coherence in research toward the overall objective of this thesis.

Objective: To adapt culturally and determine the feasibility of the *iCanCope with Pain*™ app and examine pain and HRQOL in a school-based population of adolescents with persistent pain.

Methods: Paper I applied a phased approach, wherein phase 1 included translation and cultural adaptation of the app into the Norwegian context. This process used an expert panel of researchers and target group representatives, who were responsible for linguistic quality assurance and assessment. In phases 2 and 3, the app's usability was

tested. For phase 2, assessments of usability and user experiences included observation, the think-aloud method, audiovisual recordings, questionnaires and individual interviews in a laboratory setting. For phase 3, assessment of usability and user experience over a two-week home-based test included questionnaires and individual end-user interviews. Overall, app usability was determined based on ease of use, efficiency and user satisfaction. Further, in Paper II, 78 adolescents participated, aged 16–19 years old with persistent pain and were recruited from five high schools in Southern Norway. All participants completed an electronic survey consisting of the Lübeck Pain Questionnaire (LPQ), which included the Visual Analogue Scale (VAS) measuring pain intensity, the General Self-Efficacy Questionnaire (GSEQ) and the KIDSCREEN-52 Questionnaire measuring HRQOL. In Paper III, 73 adolescents with persistent pain participated. Participants were randomized into two groups using simple randomization. The intervention group received the Norwegian *iCanCope with Pain*™ app incorporated with five components: (I) symptom trackers, (II) goal setting, (III) coping toolbox, (IV) social support and (V) age-appropriate pain education. An active parallel comparable group received the app containing only component (I). Participants completed an electronic survey before and after the 8-week intervention period.

Results: The cultural translation provided findings necessary for further evaluation by revealing that the end users did not report any misunderstandings or discrepancies with the words or phrasing of the translated and culturally adapted app. Further, the participants in the lab- and home-based usability tests found the app self-explanatory and easy to use, with high average usability satisfaction scores of 82 and 89 out of 100, respectively. However, one end user commented that the app served as a reminder of their pain. In Paper II, all participants reported multiple pain locations, wherein headache was most commonly reported (88.5%). Mean pain intensity (VAS) of the sample was 5.4 (SD = 1.8), higher for girls 5.7 than boys 4.2 (Mean difference 1.55). The association between pain intensity and the HRQOL subscales physical well-being, psychological well-being, mood, self-perception, autonomy and school environment were mediated by self-efficacy. The highest degree of mediation and thus the largest indirect effect was estimated for the physical well-being HRQOL subscale (67%). The findings from Paper III revealed that an app-based intervention in a school-based population of adolescents resulted in a high attrition rate (62%) and low engagement.

Intention-to-treat analyses revealed no significant differences in outcomes between the groups (all *P*-values = 0.05). Although a large effect size (d = .91) was revealed for the Hospital Anxiety and Depression Scale Questionnaire (HADS) subscale of depression, herein the intervention group reported lower postmeasures (6.2, SD 3.49) than the control group (9.6, SD 3.95).

Conclusions: High usability satisfaction and only minor errors cumulatively indicated that no changes to the app were needed before the pilot feasibility randomized controlled trial (RCT), with the exception of facilitating user interaction within the social support feature. Furthermore, examination of the underlying mechanisms between pain and HRQOL highlighted the importance of promoting self-efficacy to increase HRQOL in future interventions by revealing that about half of the reduction in several HRQOL subscales was explained by the mediating variable self-efficacy. High attrition and low engagement of the pilot feasibility RCT indicate the need for a change in the trial design. Still, this study exceeds previous research by determining the feasibility and explores outcomes between groups using a self-management app in a school-based population of adolescents with persistent pain and provides estimates for calculation of sample sizes in future app-based intervention.

1.0 Rationale for the thesis

There are several reasons for providing research on this specific topic. First and foremost, persistent pain in adolescence is recognized as a growing public health problem worldwide due to its high prevalence [1, 2]. Second, persistent pain is well known to impact all aspects of adolescents' everyday life and their families [3, 4]. Third, persistent pain in adolescence is a major economic concern for the society because pain in adolescence is reported to persist into adulthood [5]. Further, many adolescents in pain do not seem to know where to seek coping information or know what to do when they are in pain [6]. Moreover, during recent years, adolescents have reported an increase in stress and psychosocial complaints and reported a lower HRQOL, especially among girls [3, 7, 8], which indicates that the need for coping strategies in adolescence is of current interest.

The systematic review by King and colleagues examined the epidemiology of persistent pain in children and adolescents, and reported that persistent pain not related to any disease is common; however, the exact prevalence varies among studies [2]. Nevertheless, Swain and colleagues estimated the prevalence of headache, stomachache or backache in an international survey of pain in adolescents by including data of a total of 404,206 participants, wherein headache was most commonly reported (54.1%) as pain at least monthly for the last 6 months [1]. Persistent pain is prevalent in about 20% to 35% of adolescents in Western countries but may vary depending on each study's classification of persistent pain, the study sample, age variation or pain measurements. Nevertheless, it seems to increase with age and be more prevalent in girls than in boys [9-13]

Persistent pain can negatively impact all aspects of HRQOL, which includes physical, psychological, social and economic relations [2, 14]. Thus, the adolescent's everyday life is affected in many ways, and given the cyclic nature of pain, planning social activities and attending school every day may be a challenge [15]. Previous studies report that adolescents in pain may experience role-loss due to periods of isolation from peers [16-18]. Pain is often referred to as a vicious circle [16] because it may negatively amplify other aspects of life and vice versa. For instance, previous studies have reported that pain may reduce

physical activity levels and reduce the quality of sleep, which again may negatively influence our health. Hence, physical activity levels and sleep disturbance may interact as both causes and consequences of pain [6, 19, 20]. A Danish study of twins revealed that persistent low back pain in adolescence increased the risk of pain in adulthood by 3.5 times and when adolescents experienced persistent multisite pain, such as combined headache and low back pain, the risk of pain later in life increased even further [21]. Thus, a significant proportion of adolescents with persistent pain are likely to experience pain that persists into adulthood with corresponding higher risks of psychosocial and socioeconomic distress and mental disorders [22-24].

Pain causes some of the highest costs in modern societies. Therefore, reducing pain in adolescence is important. Persistent pain is considered to have a greater economic impact than most other health conditions [25, 26] because it reduces productivity and increases the risks of leaving the job market. In the Norwegian population, results from the global burden of diseases showed that low back and neck pain is the largest single cause of disease burden measured as disability-adjusted life years [27]. Further, according to health surveys conducted in the northern parts of Norway, about 50% of cases of disability benefits are due to persistent pain conditions [28, 29]. Hence, providing cost-efficient coping strategies in adolescence may be an essential preventive initiative from an economic perspective.

Previous studies have indicated that many adolescents do not seem to know what to do when they are in pain and that many rely on their parents' knowledge and coping experiences [6, 30, 31]. Notably, the Internet is becoming a source of advice for the younger generation regarding pain coping for everyday pain [6]. Nowadays, mobile phones have continuous access to the Internet and are integrated with apps, which seem to be a preferred way to receive digital health information [32-34]. This might be especially relevant for those adolescents that experience barriers with traditional therapies [35-39]. Knowing the majority of pain apps available for the public are not scientifically evaluated [40], there is clearly a need for research on evidence- and theory-based app interventions aiming to reduce pain and increase HRQOL among adolescents with persistent pain.

2.0 Theoretical framework

2.1 Persistent pain

In general, when addressing pain, it is important to emphasize that expressing pain through a short definition is a challenge because pain is often complex and thus viewed through a biopsychosocial model [41]. The biopsychosocial model provides an understanding of how pain is influenced by several interacting factors by including both biological and psychosocial aspects. For instance, pain may be affected by stressful memory processes, the fear of pain or even thinking of pain may trigger the pain experience [42]. The biopsychological viewpoint is considered to provide the most complete understanding of pain [41]. The International Association for the Study of Pain (IASP) has incorporated the biopsychosocial view and defined pain as: "*an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage*" [43]. Nevertheless, it should not be neglected that pain is a subjective phenomenon. Thus, to understand truly the pain experience, McCaffery's pain definition should be highlighted because it focuses on the subjective experience: "*Pain is whatever the experiencing person says it is, existing whenever he says it does*" [44].

In a clinical update in the IASP [45], Finley and colleagues categorized pain in children and adolescents as everyday pain, short-term pain, recurrent or disease-related pain. In the context of a school-based population of adolescents with pain with no known underlying pathological condition responsible for the pain experience, both everyday pain and recurrent pain are of relevance. Everyday pain is typical minor bruises [6], which are commonly experienced in adolescence in sports and other activities and defined by Eccleston as "*pain that is clinically unimportant that arises from normal everyday activity. Pain functions to interrupt current concerns and promote problem solving typically in the form of escape, pain management, or request for assistance*." Although this type of pain is not medically significant, it provides an opportunity for learning about how to cope with pain early in life [46, 47].

Further, recurrent pain is a term that includes the experience of pain in connection to duration or frequency. Long-lasting pain is often referred to as

chronic, recurrent or persistent pain. Pathophysiology of persistent pain is often referred to as an unknown (idiopathic) condition, the pain experience may include elements of nociceptive pain (i.e., pain from peripheral nerve endings), neuropathic pain (injury or dysfunction of the somatosensory system) or psychosocial-emotional pain [19, 48]. To date, there is no definitive explanation of the underlying pathophysiology of persistent pain in adolescence.

There are often inconsistencies in the literature in terms of classification of persistent pain, and for many years there had not been a standardized classification of persistent pain. However, in 2015, an IASP Task Force classified chronic pain as persistent or recurrent pain lasting more than 3 months [49]. The Task Force based their work on the current scientific evidence and the biopsychosocial model and made an important distinction between chronic primary pain and chronic secondary pain. Herein, chronic primary pain represents chronic pain as a disease in itself. Chronic secondary pain is chronic pain where the pain is a symptom of an underlying condition. As a result, the International Classification of Diseases (ICD-11) included this systematic presentation of persistent pain, which was later adopted by the World Health Organization in May 2019.

Chronic primary pain by the ICD-11 is classified as: "*pain in 1 or more anatomic regions that persists or recurs for longer than 3 months and is associated with significant emotional distress or significant functional disability (interference with activities of daily life and participation in social roles) and that cannot be better explained by another chronic pain condition. This is a new phenomenological definition, created because the etiology is unknown for many forms of chronic pain. Common conditions such as, e.g., back pain that is neither identified as musculoskeletal or neuropathic pain, chronic widespread pain, fibromyalgia, and irritable bowel syndrome will be found in this section and biological findings contributing to the pain problem may or may not be present*."

Ultimately, given the ICD definition, several terms are appropriate for expressing long-lasting pain in adolescence. However, we found the use of persistent pain to be the most appropriate term for a school-based population.

2.2 Prevalence of persistent pain

The prevalence of persistent pain among adolescents varies in the literature. The substantial variation may be due to different operational definitions of persistent pain, pain measurements, study groups, age variation, sample size or other methods, which together make comparison a challenge [1]. Already, in the first comprehensive review of pain epidemiology in children and adolescents, by Goodman and McGrath in 1991 [50], the challenge of comparing prevalence rates across studies was identified, such as the disagreement regarding the definition of various types of pain. However, the recent ICD-11 [49] finally provided a standardized definition, from which future research will benefit.

To illustrate the substantial variation of pain prevalence, in the systematic review by King and colleagues, which included 32 studies on persistent pain in children and adolescents in a school-based population, the prevalence across the studies ranged from 8% to 83% for headache; 4% to 53% for abdominal pain and 4% to 40% for multisite pain [2]. The review reported higher prevalence rates in girls than in boys and an increase of pain with age for most pain types. Further, a recent review from 2019 investigated the prevalence of self-reported persistent pain among younger adolescents using data evidence from 42 countries (n=214,283) [51]. The findings revealed that the overall proportion of adolescents reporting weekly pain during the last 6 months was as high as 44.2%. Further, adolescents' age and sex were strong predictors for reporting pain, and the most consistent findings indicated that the prevalence increases with age and that multisite pain was more prevalent in girls across all countries.

Most cross-sectional studies on adolescents with persistent pain define pain as symptoms that occur weekly for 3 or 6 months [10, 11, 52-55]. Data from a health survey conducted in northern parts of Norway (HUNT) revealed a high persistent idiopathic pain prevalence of 33% (weekly pain for the last 3 months) among adolescents aged 13–18 years [10]. Taking into account the possible reasons for discrepancies across epidemiological prevalence studies, still, the overall consensus of the literature is that prevalence of persistent pain among adolescents is high, headache is most commonly reported, more prevalent in girls than in boys, increases with age and should be considered as an important health concern [1, 2, 51].

2.3 Health-related quality of life

The concept of health-related quality of life (HRQOL) derives from "quality of life" (QOL), which is a concept that is used differently in the literature and reported to be hard to define [56, 57]. Some refer to QOL as well-being, health status, satisfaction with life or happiness, and the concept is generally accepted as multidimensional [58]. However, QOL does not reflect the patient-reported outcome, which is an outcome measured in absolute terms (e.g., severity of symptoms or of a disease), often as an alteration from previous assessments [59]. The QOL concept is recognized as a subjective phenomenon, such as the subjective well-being based on the person's own beliefs and expectations [60]. It suggested that most people are familiar with the term "quality of life," and thus it is common to have an intuitive understanding of the concept, which means QOL seems to mean different things to different people due to their own understanding and perception [59].

The United Nations have stated in their sustainable development goals (goal 3): to ensure healthy lives and promote well-being for all at all ages [61], and the overall sustainable development of well-being is reported to be related to attributes such as health, family and safety [62]. However, in the context of adolescents with persistent pain, it is important to assess which dimensions of well-being are most relevant [59]. Norwegian adolescents have reported that QOL is about good circles in life, including being together with good friends, positive self-image and family relations [63]. These dimensions, such as physiological, psychological and social well-being are suggested to be highly relevant to assess in adolescence [64]. One of the important domains of QOL is health. The HRQOL is a relevant measure in connection to pain because pain is known to impact all aspects of life [14, 65, 66]. Therefore, the study of HRQOL may give an overall indication of how well life is perceived among adolescents living with persistent pain.

Instruments measuring HRQOL can provide essential information on a person's health status, and provide a better basis for improving and promoting health [67]. Thus, HRQOL serves as a framework that is considered especially relevant within health promotion, given a positive focus on the individual perception of resources rather than problems [67]. A recent systematic review by Haraldstad et

al. [68], which assessed the QOL in medical and health research, concluded that the majority of studies within the field have conceptual and methodological challenges. Nevertheless, QOL is considered to be an essential end point in health research in different patient groups and study designs [68].

It is reported that the perception of health is related to maturity [69]. Therefore, the questions regarding if children and adolescents can report their own HRQOL has been raised [69]. However, when entering adolescence, research evidence shows that adolescents can reflect on their own life, health and well-being [70]. However, HRQOL instruments should be sensitive to changes that might happen during adolescence, which emphasizes the importance of using validated instruments for measuring HRQOL [69]. Several validated and designed HRQOL instruments have been developed for children and adolescents, such as the Child Health and Illness Profile, the KIDSCREEN-52, the KINDL and the Pediatric Quality of Life Inventory; wherein, the KIDSCREEN-52 has been shown to have the best structural validity [71]. According to Ravens-Sieberer and Bullinger, the developers of the KIDSCREEN approach for measuring the HRQOL, HRQOL is defined as: "*a psychological construct that describes the physical, mental, social, psychological and functional aspects of well-being and function from a personal perspective*" [72]. Moreover, the KIDSCREEN-52 includes dimensions such as school, bullying and family, which are especially important in adolescence [73].

Several studies have examined the association between pain and HRQOL among adolescents and the research evidence indicates that persistent pain is associated with reduced HRQOL [4, 14, 19, 65, 74]. In a school-based population of adolescents, girls have reported lower HRQOL than boys [3, 8]. Notably, both genders decrease their HRQOL during the 3 years in high school [8]. Further, adolescents in pain have reported feeling down and have lower QOL because they felt like life just passed them by due to not participating in activities as healthy adolescents [4, 75].

A Norwegian study showed that pain in children and adolescents was associated with lower HRQOL demonstrated by reduced scores for all 10 subscales of the KIDSCREEN-52 questionnaire, but had the greatest impact on the HRQOL subscales of self-perception, psychological well-being, mood, relationship with

parents and school environment [3]. Further, findings indicate that adolescents with persistent pain do not only report significantly lower HRQOL than population-based normative data but also compared with data of adolescents with other chronic illnesses [14].

2.4 Self-efficacy

Self-efficacy refers to "how well one can execute courses of action required to deal with prospective situations" [76]. Bandura [77, 78] has described the concept of self-efficacy as a self-regulatory mechanism by which it is possible to change as a result of being motivated by others or through goal setting and education. The self-regulatory mechanisms of self-efficacy indicate the degree of confidence, and thus the ability to exert control over a given goal or behavior [79]. Self-efficacy may predict a change in behavior because it reflects circumstances surrounding the given goal, often presented as a challenge in sociostructural factors [80].

Bandura [80] argues that self-efficacy will, directly and indirectly, influence our behavior (Figure 1). The direct structural path between self-efficacy and behavior indicates the direct influence because self-efficacy is considered a major predictor for behavior change. Further, self-efficacy could through its impacts on goals, outcome expectations and perceptions of sociostructural factors facilitate indirectly promoting a change in behavior (Figure 1) [80].

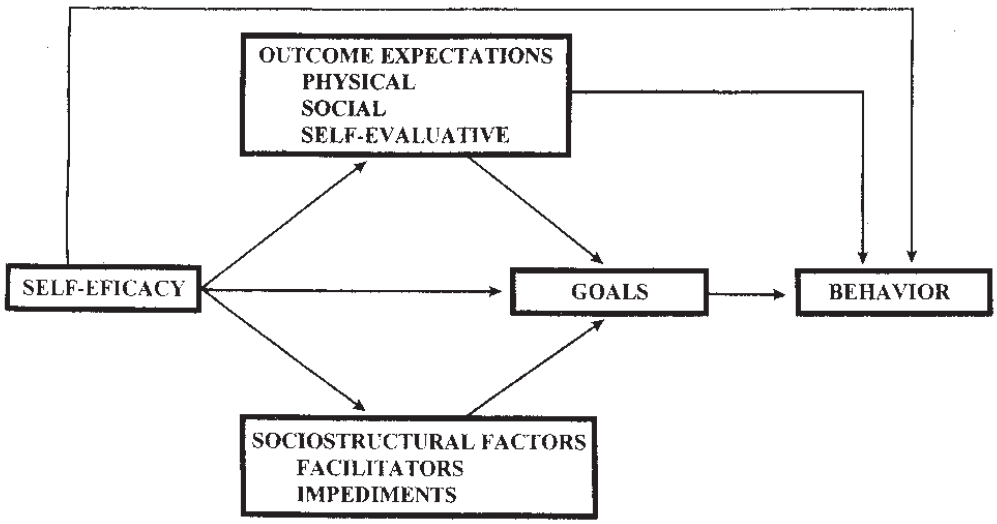


Figure 1. The structural paths of self-efficacy through its impacts on goals, outcome expectations and perception of sociostructural factors to promote behavior according to Bandura [80] (Permission to reuse from the publisher).

Given that self-efficacy is considered a major predictor for behavior change, Bandura has presented possible approaches that may increase self-efficacy [79]. According to Bandura, self-efficacy is underpinned by four components: (1) Performance accomplishments (learning through personal experience). (2) Vicarious experiences (learning through observations of others). (3) Verbal persuasion (learning through encouragement). (4) A person's physiological state (learning that physiological reactions such as increased heartbeats and sweaty palms may influence a person's belief and thus self-efficacy). Notably, these suggested determinants are in overall accordance with an updated systematic review with meta-analyses examining the best way to increase self-efficacy and promote healthy behavior [81]. Therein, findings showed that vicarious experience and feedback from peers (i.e., peer support) are most effective.

In the context of adolescence, an increase in self-efficacy has been shown to positively impact QOL [82, 83]. It is reported that an increase in self-efficacy may help to reduce stress and thereby increase the QOL [82, 83]. In young adolescents, a higher degree of self-efficacy has been shown to be related to higher HRQOL scores and improved school performance [84, 85]. Self-efficacy has been associated with several positive health outcomes for adolescents with chronic pain, including higher self-esteem and acceptance, and lower disability and somatic symptoms [86, 87].

2.5 Holistic model for understanding pain and HRQOL

To grasp the understanding of pain and HRQOL in adolescence, we have chosen to view this in the light of the holistic empirical model for the biobehavioral investigation of pediatric pain by Varni et al. [88] (Figure 2). The model illustrates that pain may arise from several conditions (precipitants), such as from disease, injury, stress or procedures and that intervening variables will influence pain and HRQOL, thereby providing arguments for theory- and evidence-based interventions aiming to reduce pain and increase HRQOL in adolescence.

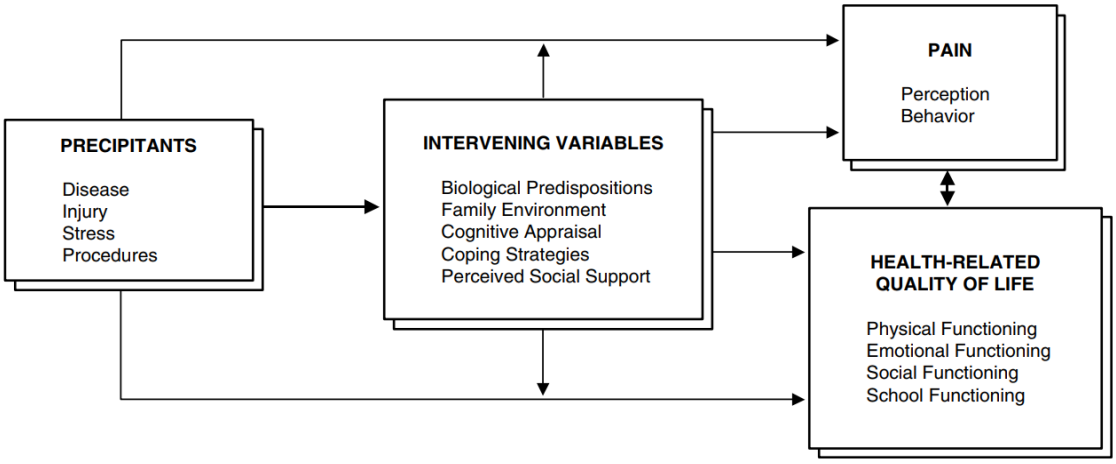


Figure 2. A holistic model for understanding pain in adolescence (Permission to reuse from the author).

Stress and high demands in adolescence

Pain may arise for several reasons. Although several factors may act as a contributing cause to persistent pain in adolescence, highlighting stress as a potential cause (Figure 2) seems highly relevant for understanding the pain experience in adolescence. Research evidence suggests stress may manifest within the musculoskeletal system, wherein a Norwegian study by Østerås and colleagues showed that adolescents in pain reported higher levels of perceived stress, which also explained some of the variation in pain intensity (VAS) and number of pain sites [12]. In a qualitative study, Norwegian adolescents reported that stress was the cause of their pain experience [89]. It has been suggested that adolescence is a time of many important independent decisions in life, which may cause stress [90]. The Norwegian Young data survey, which is conducted close to every year among Norwegian adolescents in junior high and high schools, has since 2010 shown an increase in stress and psychosocial aspects, especially among girls [7]. In the recent Young data survey, about half of the Norwegian adolescents in high schools seem to have concerns like “everything feels like a struggle” or they feel like they are “worrying too much” [7]. Moreover, it is suggested that adolescents perceive higher levels of stress due to changes and trends in society. Expectations of a successful appearance in social media and general high demands of being successful in every aspect of life have been suggested to be related to the pain experience in adolescence [91, 92]. In Norwegian high schools, two-thirds of the girls and one-third of the boys have

reported being often or very often stressed by schoolwork [93]. Pain in adolescence has been suggested to influence school absence [9, 94-96].

Biological predispositions. Genetic factors seem to contribute to the understanding of pain as an intervening variable (Figure 2). In a systematic review of twin studies, around 50% of the risk for developing migraine, tension-type headache or chronic widespread pain seems to be related to genetic factors [5]. Research evidence indicates that there seems to be a shared biological sensitivity, often expressed as "pain vulnerability," "pain sensitivity" or "central sensitivity syndrome" [97-99]. Further, other studies have argued that pain may arise and continue for generations, also due to cultural and environmental factors such as how pain is expressed and pain-coping strategies [100-102]. Other well-known risk factors for persistent pain are sleep problems, obesity, inactivity, anxiety and depression, which may be shown to be associated with an increased prevalence of persistent pain and/or an increased sensitivity [103-107]. Further, stress factors in school, such as too much homework, harassment by peers or being treated poorly by teachers, were associated with psychosomatic pain [107-109]. Feelings such as sadness, nervousness, irritability or unsafe were also reported to be associated with psychosomatic pain in adolescence [108].

Family environment and perceived social support

According to an empirical analysis of the Norwegian Young data surveys, never before have so many adolescents reported that they feel lonely [93]. This is a concern, given both friends and family functioning and relations may influence the pain experience in adolescence. It is widely believed that social support facilitates coping by establishing helpful networks and relationships and is important in healthy activities' promotion [110, 111]. Social support may include both quantitative (e.g., number of friends) and subjective (e.g., network appraisal) dimensions [112]. Further, social support is reported to not only affect mental health and physical health but the mortality risk [113].

Lewandowski and colleagues examined in their systematic review the family functioning of adolescents with persistent pain, and showed in their overall findings that families of adolescents with persistent pain generally have poorer family functioning than healthy families [114]. A qualitative study has suggested that Norwegian adolescents talk about pain as a way to describe difficult feelings

and that pain is a kind of warning symptom for troubled life, wherein pain reduced their ability to manage everyday life, made social settings difficult and in general hampered the possibility for success [89]. Further, it is interesting that adolescents from a school-based population with headaches have reported higher depression levels than adolescents from a clinical setting with headaches [115]. Previous studies have indicated that adolescents in a school-based setting are largely left alone and that they tend to feel a lack of support [6, 16, 116], which may contribute to an increased pain experience [117].

School attendance is important in an adolescent's everyday life, in terms of education but also regarding social support and interaction. Persistent pain in adolescence has been shown to increase the number of school days absent [9, 94-96]. A study by Rohde and colleagues investigated how Norwegian school teachers experienced persistent pain among adolescents in their school setting [118], wherein the teachers report that physical pain may be a gate opener to other underlying psychological or social factors. In addition, teachers report that adolescents have limited experience managing pain and use more painkillers now than before. A previous study reported that the teachers themselves may also commonly experience the feeling that they are not adequately equipped to handle situations where adolescents struggle with persistent pain [119]. Further, the psychosocial health of Norwegian adolescents is reported to be strongly associated with dropouts in high school due to suggested reasons such as a decrease in self-efficacy, motivation and self-perception [120]. Providing theory- and evidence-based strategies to manage pain in Norwegian adolescents seems to be important for preventing dropouts, which is associated with both unemployment and disability benefits [121-123]. In addition, both Norwegian and international studies have suggested that pain in adolescence may cause pain problems and other negative aspects later in life [22, 23, 124, 125].

Ultimately, adolescents with persistent pain tend to derive from families with lower socioeconomic status (SES), which is reported as a predictor for both health and pain. Several studies have shown that low SES is associated with a higher risk of pain, and several other negative aspects of life [126-128]. A recent Norwegian study from 2018 found that health complaints are more frequent among adolescents from families with lower SES [129].

Cognitive appraisal and coping strategies

Success in coping ability depends on individuals' willingness to undertake and maintain required behaviors [130]. Hence, individual-level theories tend to focus on cognitive factors, including beliefs, attitudes and expectations with an overall objective to maximize positive health outcomes. There are several psychological theories and psychotherapies represented in the literature with different techniques for pain management and coping [131]. Therefore, this final section will present the most relevant underlying psychological theories and psychotherapies in connection to pain management and coping interventions in adolescence.

The concept of self-management embraces both cognitive appraisal and coping strategies (Figure 2) and is based on the notion that it will improve well-being [132]. Self-management is a naturally occurring concept in interventions aiming to increase well-being and promote healthy behavior. Therein, adolescents need to take responsibility for their own situation and is often comprised of relaxation techniques, promoting physical activity, social support, mindfulness, imagery techniques, coping-skills training and cognitive behavioral therapy [133].

Cognitive behavioral therapy (CBT) is often considered the preferred intervention for several conditions, including pain management [94]. CBT is a form of psychotherapy originally conceptualized by Aaron Beck [134] and is explained as "*a time-sensitive, structured, present-oriented psychotherapy directed toward solving current problems and teaching clients skills to modify dysfunctional thinking and behavior*." CBT focuses on the interrelations among thoughts, feelings and behaviors [135]. Hence, adolescents may work on focusing on developing personal coping strategies to solve current problems and change unhelpful cognitive patterns (e.g., thoughts, beliefs and attitudes), behaviors and emotion regulation, and ultimately provide a solid basis for coping with and understanding their health condition [135]. According to the review by Eccleston and colleagues, the research evidence for effectiveness is strongest for CBT with a focus on cognitive coping strategies and behavioral rehearsal [66]. The utilization of a cognitive approach by being aware of our thoughts and their influences on our feelings and behavior, and thus acknowledge the fact that we cannot change the appearing thoughts, but we may change how we process them, which may be an important coping tool [136]. Notably, given that the adolescents

are in a critical time of transition, wherein readiness to change, acceptance and independence may vary. In addition, because parents and caregiving persons will often find their own personal ways for management of adolescents' pain—thus effective cognitive rehearsal is essential [137, 138].

Behavioral activation therapy (BA) was originally used by Peter Lewisohn to treat mood disorders, especially depressions, and is reported to be efficacious for reinforcing engagement with meaningful activity [139, 140]. BA focuses on a persons' daily life by targeting different behaviors, such as increasing engagement in activities related to pleasure or mastery and reducing activities that uphold or increase the risk for depression [141]. BA is based on the approach of allowing persons to learn how to cope with their depression by an increase in positive awareness in terms of goal setting and by tracking one's own emotions. BA may allow adolescents to track their daily symptoms in real time, which may help them to recognize their pain patterns better, further, helping them to identify and to be aware of potential pain triggers. Hence, by tracking symptoms over time, they are able to monitor fluctuations in their pain and thus increase their understanding of their health condition [37, 142]. Originally, Lewisohn argued that BA was based on the belief that depression was mainly behavioral dependent and based on a limitation in social relationships [143]. However, modern psychological interventions commonly include and overlap both behavioral and cognitive approaches, such as CBT. Indeed, BA is reported to be one of the main predictors and reasons why CBT is shown as effective [144].

Social cognitive theory (SCT), developed by Albert Bandura, has influenced our understanding of human behavior [80]. According to Bandura, a new behavior depends on the "reciprocal determinism," which is referred to as the interaction between our existing behavior, our personal factors and our social and physical environment [79]. SCT is based on key concepts explaining our individual behavior, such as outcome expectations, efficacy expectations or incentives [130]. Outcome expectations are related to the belief about whether a given behavior will result in a specific outcome and efficacy expectations are related to the belief about our capability to perform the behavior that results in a specific outcome. Interestingly, both concepts build on a person's beliefs and the perceptions of the connection between behavior and outcome and may not be considered "true" capabilities [130]. Still, the concept of efficacy outcomes is

reported to be essential for goal setting and thereby improving pain and functioning [145]. Bandura argues that the efficacy outcomes will predict people's emotional reactions, such as anxiety and distress [128].

SCT is originally based on social learning theory. Albert Bandura conducted a well-known study in 1961 called the Bobo experiment; therein, children were exposed to both violent and aggressive behavior [146]. The example highlights the fact that promoting healthy behavior requires providing positive youth development, herein including positive engagement, enhancing outcome expectations and efficacy expectations, providing coping strategies, social support, which together seem to be important components for an intervention strategy. Moreover, SCT suggests that adolescents' performance or behavior may also be influenced by their social and physical interactions, meaning support by their peers, parents and teachers.

Taken together, adolescence is a demanding time of transition, wherein the prevalence of pain and stress experience is high, especially among girls. Several aspects may influence the adolescent's everyday life. Given the stressful everyday life of adolescents, it is important to provide coping strategies that may help to increase the adolescent's interpretation of the situation and thus, the interpretation of the extent to which the situation is perceived as stressful or not, which is a key component in cognitive appraisal and rehearsal [147]. Thus, from a research point of view, it is important to increase the research evidence by understanding the adolescent's experiences, identify relevant intervening factors and possible causes of pain in adolescence, and thereby provide appropriate theory- and evidence-based self-management interventions.

3.0 Previous pain management interventions

Pain management research in adolescence is in ongoing development. The traditional approach is comprised of individual face-to-face psychological interventions in combination with pharmacological and physical treatment [148]. Harrison et al. [149] revealed in their updated review (2019) of best evidence for the rehabilitation of chronic pediatric pain that there is evidence supporting individual outpatient interventions, multicomponent treatment packages and interdisciplinary outpatient packages, indicating interventions may include a range in concepts, support and ways to deliver treatment.

Although traditional psychological interventions, which are face-to-face delivered, are reported to be effective in reducing frequency or intensity of pain in children and adolescents [150], there are some disadvantages because many adolescents may not have a trained therapist available and/or such sessions include high costs. Therefore, several studies have investigated the effect of self-administered versus therapist-administered interventions [94, 151, 152]. Findings revealed that both interventions are effective in reducing pain among adolescents. Research evidence indicates that remotely delivered self-management interventions are efficacious in reducing pain intensity and severity in adolescents, wherein the treatment has a comparable effect to traditional face-to-face interventions [152, 153]. Thus, there are several suggested advantages by delivering self-management interventions remotely (e.g., via telephone, CD-ROM, websites or apps), such as they are delivered in a cost-efficient format and have removed or reduced barriers to access intervention from a geographical perspective [154].

Still, remotely delivered self-management interventions require both time and energy from the adolescents in their already stressful everyday life, which could be a challenge. Adolescents report being comfortable with using smartphones and apps [155]. Although providing interventions in their preferred platform for communication could trigger their level of engagement, it could also lead to distractions.

3.1 Remotely delivered self-management interventions for adolescents with persistent pain

In 1992, McGrath and colleagues evaluated in a randomized controlled trial (RCT) the efficacy and efficiency of a predominantly self-administered intervention in adolescents with migraine (aged 11–18 years: N=87) and found that self-administered and clinic treatment were equally effective and superior to a control treatment. Plus, the self-administered intervention was substantially more cost-efficient [156]. Previous studies have shown self-management programs may also be remotely delivered through computer-based programs (CD-ROM). In the randomized controlled studies by Conelly et al. (aged 7–12 years: N=37) and Rapoff et al. (aged 7–13: N=35), the effect of a self-guided CD-ROM program ("Headstrong") containing cognitive-behavioral self-management strategies was evaluated. Both studies revealed lower pain severity in the intervention group posttreatment [157, 158]. Cottrell and colleagues showed in their assessment of telephone-administered behavioral treatment for adolescents with migraine (aged 12–17 years: N=34), that the ones randomly assigned to the two-month telephone-administered program showed clinically meaningful reductions in headache parameters and improvements in QOL [159]. Further, Stinson and colleagues showed in their pilot RCT that combining an Internet-based self-management program with telephone support for adolescents with arthritis (aged 12–18 years: N=46), reduced pain and increased disease-specific knowledge [160].

Several studies and reviews could indicate a reduction in pain intensity, frequency or severity and/or improvements in HRQOL using Internet-delivered self-management interventions in children and adolescents with persistent pain [94, 161-165]. Voerman and colleagues demonstrated a significant reduction in pain intensity and improvements in QOL subscales: general behavior, mental health, family activities and health using the first Dutch guided Internet-delivered self-help intervention for adolescents with persistent pain (aged 12–17 years: N=69). Palermo and colleagues demonstrated first in 2009 a significant reduction in pain intensity and activity limitations among adolescents after an Internet-delivered family CBT intervention (aged 11–17 years: N=48) and again in 2016 (aged 11–17 years: N=273). Hicks and colleagues found a significant reduction in pain intensity, but no difference in the QOL using an online psychological

intervention for pediatric recurrent pain (aged 9–16 years: N=47). Trautmann and Kroner-Herwig demonstrated in the first German guided Internet-delivered self-help intervention for adolescents with persistent pain (aged 10–18: N=65) a significant reduction in pain frequency and duration, but no significant reduction in pain intensity or in the quality of life.

Although adolescents report that they are comfortable with technology and often use the Internet as a source of advice to gain knowledge on how to cope with pain [6, 145, 166], the preferred way of communication and interaction is often performed via mobile apps [155]. An explosion of mobile apps has occurred to track health data and may change the approach to pain management [167]. Considerable evidence indicates that electronic assessments are superior to paper-and-pencil diaries in terms of user-friendliness, satisfaction, reliability and validity [168-170]. The continuous availability and accessibility from apps may minimize the recall bias, and thus apps are considered to be "state of the art" assessment methods for pain measures and other health outcomes [171, 172].

3.2 App-based self-management intervention to cope with pain

A systematic review of the literature by Majeed-Ariss et al. [34] on the effectiveness of mobile apps designed to support adolescents' management of their physical chronic or long-term conditions revealed that the key finding was the paucity of evidence-based apps that exist, in contrast to the thousands of apps available for the public, which are not evidence-based or user or professional informed. Thus, they were unable to evaluate the effectiveness of apps in this regard. Further, the review paves the way for future evidence-based apps with rigorous development. Similar findings were revealed in the review of patient-targeted smartphone applications for pain management by Lalloo et al., which found that of the 279 apps available for the public: only 8% of these had included healthcare professionals during their development and only one app had undergone scientific evaluation [40]. Nevertheless, the most recent systematic review examining the benefits of apps in pain management by Turnheer et al. [173] concluded that pain management apps may be beneficial for patients, particularly in an out-clinic setting, wherein different patient groups have reported a reduction in pain levels using self-management apps as a way of receiving coping skills. For instance, in a randomized clinical trial for pediatric sickle-cell patients, findings revealed that using mobile phones, combined with

CBT coping-skills training, increased coping and reduced pain intensity [174]. Further, the short-term results of a digital multidisciplinary pain self-management app significantly reduced user-reported pain levels in patients with low back pain [175]. In adolescents with cancer, a real-time pain management app called *Pain Squad+* was found to be feasible and improve pain-related outcomes [176]. A multicenter observational study of patients with chronic pain showed that using the app *Music Care* significantly reduced pain and anxiety [177].

On this basis, little is known of app-based interventions aiming at reducing pain and improving HRQOL among adolescents in a school-based population with persistent pain. To our knowledge, this doctoral thesis is the first to culturally adapt and determine the feasibility of a self-management app aiming at reducing pain and improving HRQOL in a school-based population of adolescents with persistent pain in Norway.

4.0 Aims of the thesis

The aim of this thesis was to culturally adapt and determine the feasibility of the *iCanCope with Pain*™ app and examine pain and HRQOL among a school-based population of adolescents with persistent pain. The specific aims of the separate papers were as follows:

1) To describe the translation and cultural adaptation of the app into the Norwegian context and evaluate the app's usability (Paper I).

2) To describe the experience of pain, HRQOL and self-efficacy; and to explore the association between pain intensity and HRQOL, testing for self-efficacy as a possible mediator in adolescents with persistent pain (Paper II).

3) To determine the feasibility of an 8-week app-based self-management intervention in a school-based population of adolescents with persistent pain aimed at reducing pain and improving HRQOL. Secondary, to explore possible differences in outcomes between the intervention and control groups (Paper III).

5.0 Methods

The doctoral thesis is comprised of three interrelated papers (Table 1). Paper I used a phased approach to accommodate the app into the Norwegian context and provided insight in requirements and needs from the end-user perspective, which provides a basis for pilot feasibility testing with a larger sample of adolescents with persistent pain and the possibility to explore possible differences in outcomes between groups (Paper III). Paper II tested for underlying mechanisms in the association between pain intensity and HRQOL by testing the role of self-efficacy as a possible mediator and thus revealing the relevance of promoting self-efficacy in interventions aiming to improve HRQOL.

Table 1. Methods and outcomes of the three interrelated papers.

Paper I	Paper II	Paper III
Methods: -Phase 1: Cultural translation -Phase 2: Laboratory usability test (n=6) -Phase 3: Field usability test (n=5)	**Methods:** A cross-sectional study design A school-based sample of adolescents with persistent pain (n=78)	**Methods:** A pilot feasibility RCT study design A school-based sample of adolescents with persistent pain (n=73)
Outcomes: Ease of use Effectiveness Satisfaction	**Outcomes:** Description and association of pain, HRQOL and self-efficacy as a mediator	**Outcomes:** Feasibility testing and possible differences in outcomes between groups

5.1 Study design

This doctoral topic was addressed using different methods with the intention of providing the most appropriate prerequisites for answering the specific aims and the overall objective. To conduct a cultural translation of the app into the Norwegian context and evaluate the app's usability, we chose to use a phased approach. Phase 1 includes translation and cultural adaptation of the app into the Norwegian context. In phases 2 and 3, the app's usability is tested in laboratory and field settings, respectively.

In addition, the original *iCanCope with Pain*™ program is based on a user-centered design method [37], which is an iterative problem-solving process focusing on knowing the user, the context of use and the tasks for which he or she uses the product [178]. Although the *iCanCope with Pain*™ program [37] builds on identifying need assessments of Canadian adolescents, we ensured by thorough cultural translation and usability tests that the self-management app was adapted and appropriate for Norwegian adolescents.

To examine the underlying mechanisms between pain and HRQOL, a cross-sectional study design was conducted. Data for this study were collected at baseline during an intervention study that aimed to help reduce pain and promote HRQOL in Norwegian adolescents with persistent pain using the *iCanCope with Pain*™ app. Finally, to determine the feasibility of an 8-week app-based self-management intervention in a school-based population of adolescents with persistent pain, an RCT design with two parallel groups was conducted. The intervention group received the *iCanCope with Pain*™ app comprised of all the evidence- and theory-based features. The active comparable group received a control app that included only symptom trackers (component I).

5.2 Study sample and setting

To ensure a thorough translation and cultural adaptation procedure (Paper I), a convenience sampling of adolescents was chosen to ensure the app was suitable for their age group. Therein, the user-involvement included two adolescents (aged 17 years) in phase 1 and six adolescents (aged 17–18 years) who served as participants in the laboratory usability test (phase 2). Moreover, participants in phase 2 were gender-balanced and used both iOS and Android operating systems. Five participants (aged 16–18 years) in phase 3 were end users and followed the same inclusion as Papers II and III. These five adolescents were also gender-balanced and used both operating systems, and were included in baseline measures (Paper II, n=78), but were not allowed to participate in the pilot RCT trial (Paper III, n=73).

The study was conducted in southern Norway in 2018, wherein we asked the five largest government-funded high schools within an area of 10 miles to participate (an area of about 100,000 inhabitants). No high schools were excluded or refused to participate. The attending adolescents were representative of different levels of

SES. We included 16–19-year-old adolescents with persistent pain (weekly pain lasting three months or more) who were able to read and understand Norwegian and used their own smartphones. We excluded adolescents with cognitive disabilities because of their inability to understand how to use the *iCanCope with Pain*™ app, goal setting and/or library readings. Adolescents with a pain of pathological or medical origin (e.g., arthritis/oncology patients) were also excluded because the program was not specifically designed for these patient groups.

Prior to the recruitment procedure, and as stated in Paper I, the app would be used in an upcoming RCT. Therefore, we initially aimed to have the statistical power and thus be able to estimate definitive effects in a full RCT. Our original power estimates were performed using G*Power 3.1 [179], wherein the estimated sample size was 64 per group based on a medium effect size of 0.5 or 52 per group based on a large effect size, both with an alpha value of 0.5 and a power 0.80 using a two-sided *t* test [180]. Because the research evidence indicated a 50% reduction in pain intensity among Internet-delivered self-management programs for adolescents with persistent pain [154], we believed a medium to large effect size was appropriate to use.

5.3 Recruitment procedure

The recruitment procedure started with contacting the county education chief, who informed the respective high schools of the project and gave permission to contact the management at each school. The first author visited the five high schools, gave information to all teachers and management, and later informed about the study in each classroom (about 150 classrooms), wherein the adolescents were free to ask any questions. We wanted to ensure anonymity and confidentiality. Therefore, the adolescents received a written brochure in the classroom with an attached e-mail address generated for this purpose only. Information was also available at the high schools' homepage (Appendix I). The researcher provided an oral presentation in the classroom. The oral presentation and written information included the inclusion/exclusion criteria of the study. If adolescents experienced persistent pain and wanted to participate in the study, they could send an e-mail to the corresponding e-mail address.

5.4 Data collection

Data were obtained from usability testing in two phases (phases 2 and 3). During phase 2, the convenience sample signed a written informed consent in paper form prior to laboratory usability testing (Appendix II). The usability was assessed using both qualitative and quantitative data. The qualitative data were collected using individual interviews, which followed a semi-structured interview guide (Appendix III) with 14 questions. The preparation and transcribing process followed guidelines for qualitative interviews [181, 182]. Further, the content analysis process and presenting data were in accordance with the deductive approach explained by Elo et al. [183]. To ensure that the participants spoke freely, most questions were open-ended, and all questions allowed for follow-up questions like "Why do you think that?" or "Can you tell me a bit more about that?" Further, observation, the think-aloud method and audiovisual recordings provided the measures ease of use and efficiency by assessing the participants performing each of the predefined tasks because we were able to assess if the participants completed the tasks (ease of use) and we could assess the time spent on each task (efficiency). The System Usability Scale (SUS) Questionnaire (Appendix IV) was administered and provided the satisfaction measure of the Norwegian version of the *iCanCope with Pain*™ app. Further, all participants created a mock user profile when interacting with the app to ensure nonidentifiable information throughout the process. During phase 3, five end users conducted a 2-week home-based test to evaluate user experiences with the app over time and to identify additional user needs. An electronic survey (Survey Exact) with an implemented informed consent was conducted prior to testing (Appendix V).

The electronic survey tool used in our study consecutively distributed our outcome measures (next paragraph) set for Papers II and III. The adolescents were free to end the electronic survey at any time and most questions included a neutral response, which resulted in no missing data. The electronic survey was pretested in phase 3 during the 2-week home-based test.

The electronic survey provided the data (baseline measures) for Paper II. When the electronic survey was completed, all eligible participants received an e-mail with their corresponding username, password and a short PowerPoint

presentation about downloading and using the app (Paper III). An admin webpage was used to generate all usernames and passwords. A simple randomization procedure was performed by two researchers using a computer-generated randomization list and thus, blinded to the researcher. After the 8-week intervention period, a link to the online postintervention questionnaire was sent to each participant's e-mail address. Throughout the study, all participants were included in the arm (intervention or control) in which they were originally randomized using the intention-to-treat approach regardless of their app use.

5.5 Translation procedure

For the cultural translation of the app (phase 1) in Paper I, we used a two-stage approach based on the principles of good practice for the translation and cultural adaptation explained by Wild et al. [184]. Therein, the first stage included the age-appropriate pain education library and the second stage the software interface text. Further, we translated the three following instruments based on the same standardized procedure [184]: Perceived Social Support From Friends (PSS-FR), Pain Self-efficacy Questionnaire (PSEQ) or Patients' Global Impression of Change Scale (PGIC). The procedure comprises several steps, namely, a forward translation to Norwegian independently conducted by three native Norwegian experts within the field. Then, compared and merged into one version and translated back to English by a professional translator (native American). Afterward, the Norwegian and English versions were compared, and grammar inconsistencies or discrepancies were addressed by the research team and proofreading was performed. Further, the instruments were pretested in phase 3 (Paper I) by the end users, wherein the adolescents were asked how they experienced the instruments and if they had any comments about the phrasing or substantial understanding of the instruments. They reported it was easy to understand and no comments regarding potential improvements, and thus, we considered that there was no need for changes after phase 3.

5.6 Outcome measures

The usability was assessed by quantitative and qualitative data, which provided the measures ease of use, efficiency and satisfaction of the Norwegian version of the *iCanCope with Pain*™ app. We followed the guidelines by the International Organization for Standardization (ISO) for evaluating usability in terms of ease of use (effectiveness), efficiency and satisfaction [185].

Ease of use. Each participant completed 10 predefined tasks. Each task corresponded to the five components in the app. The ease of use and technical errors were evaluated based on the number of completed tasks and total errors. Herein, a completed task was defined as a task successfully achieved by the participant [186].

Efficiency. The app efficiency was evaluated based on the time needed to achieve the tasks. Efficiency was expressed as the mean task completion time [186].

Satisfaction. The SUS Questionnaire was used to evaluate user satisfaction. SUS consists of 10 open-ended polarity-balanced questions with a five-point Likert scale for responses (Appendix IV). The total average scores were categorized based on the adjective ratings of Bangor et al. [187], as shown in Figure 3.

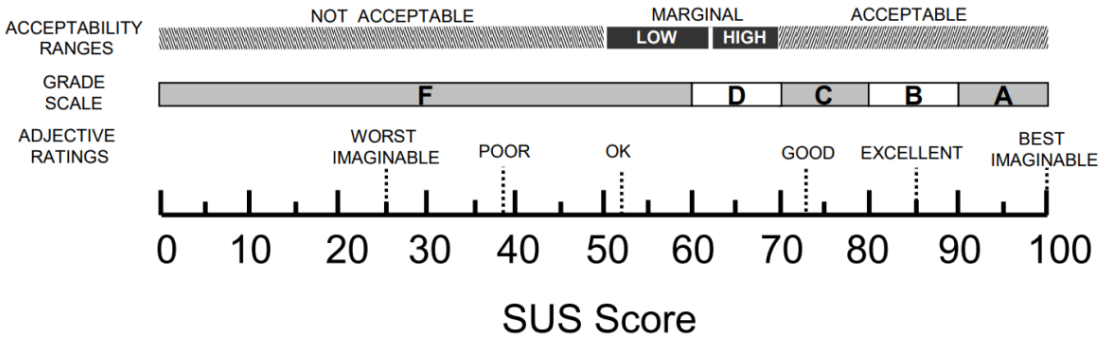


Figure 3. Adjective ratings, acceptability ranges and school grading scales, in relation to the average System Usability Scale (SUS) score (Permission to reuse by author and publisher).

Additional measures included identifying the users' needs and technical issues, to refine the app for use in an upcoming trial with a larger sample size.

The following outcome measures were included in the electronic survey, wherein the first part contained sociodemographic information such as age, gender and parental education. Parental education levels were used as a proxy for SES.

Pain (Papers II and III). To assess pain, the Norwegian translated version of the LPQ was administered (Appendix VI), which includes the Visual Analogue Scale (VAS) for pain intensity at the present moment ranging from 0 (no pain) to 10 (worst pain imaginable) [9]. VAS is a well-known measure of pain intensity and

found to be both valid and reliable, also including digital use [32, 188, 189]. Pain duration was measured in three categories as pain lasting more than 3 months, more than 6 months or more than 12 months. Pain frequency refers to how often pain was experienced and categorized as daily pain, several times a week or once a week. Pain location refers to specific body regions of pain. Multisite pain was defined as pain in at least two of the following predefined regions: head, ears, teeth, throat, chest, back, stomach, reproduction organs, arms, legs or other places.

HRQOL (Papers II and III) was measured with the Norwegian version of KIDSCREEN-52 (Appendix VII), which is the first cross-cultural multidimensional instrument that is validated in several countries and shown to have high structural validity [18, 67, 71, 190]. The questionnaire consists of 52 items with a 1–5 Likert scale based on 10 subscales: physical well-being (five items), psychological well-being (six items), moods and emotions (seven items), self-perception (five items), autonomy (five items), parent relations (six items), social support and peers (six items), school environment (six items), bullying (three items) and financial resources (three items) [191]. We followed the KIDSCREEN manual and transformed negative questions into positive [190]. Then, data were transformed linearly to a 0–100-point scale, where the lowest possible HRQOL was 0 and the highest HRQOL was 100.

Self-efficacy (Papers II and III) was measured with the Norwegian version (Appendix VIII) of the General Perceived Self-Efficacy (GSE) Scale short-form [192]. The short form of the GSE Scale is found to be both valid and reliable [193]. GSE is often defined as the global confidence in one's ability across a wide range of demanding and novel situations [194]. All items use a 1–4-point scale, where 1 refers to the lowest GSE and 4 the highest. Hence, the total score of the five GSE items ranges from 5 (lowest) to 20 (highest total score), where higher scores indicate higher GSE.

The feasibility (Paper III) was measured by (1) attrition rates and (2) level of engagement (interactions with the app). Second, the focus was on exploring possible differences in outcomes between the groups. The outcome measures of pain, HRQOL and GSE, as described were included (Paper III) and supplemented by the following outcome measures:

Perceived Social Support From Friends (PSS-FR) questionnaire was measured with a Norwegian version (Appendix IX) to measure adolescents' social support levels [195]. Internal consistency was 0.84 (Cronbach's alpha). PSS-FR has been shown to be a valid and reliable instrument among adolescents. The PSS-FR comprises 20 statements of feelings and experiences that occur to most people in their everyday relationship with friends [195, 196]. There are three options for each statement: Yes, No and Don't know, these measures were divided into numeric categories, Yes = 1, No and Don't know = 0. Hence, a total score from 0 to 20, where higher values represent a better outcome.

Pain Self-efficacy Questionnaire (PSEQ) was measured with a Norwegian version (Appendix X) to measure how confidently the adolescents performed a range of activities described, despite their pain [197]. The internal consistency was 0.93 (Cronbach's alpha). PSEQ consists of 10 items with a seven-point Likert scale, where 0 = not at all confident and 6 = completely confident. The PSEQ is reported to have satisfactory psychometric properties for a heterogeneous group of persistent pain patients [197]. The total score ranged from 0 to 60, wherein higher scores indicated higher self-efficacy beliefs and better outcomes.

Anxiety and depression levels among the adolescents were measured with the Norwegian version (Appendix XI) of the Hospital Anxiety and Depression Scale Questionnaire (HADS) [198]. HADS is a well-known and validated method for assessing the symptom severity of anxiety disorders and depression [199]. The HADS total score (HADS-T) consists of two different subscales with a total of 14 items. There is one subscale for anxiety (HADS-A) and one subscale for depression (HADS-D). Each subscale consists of seven items with a Likert scale from 0 to 3. Thus, each subscale ranges from 0 to 21, and when the subscales are combined the total HADS score ranges from 0 to 42. Herein, lower values represent a better outcome.

Patients' Global Impression of Change Scale (PGIC) was measured with a Norwegian version (Appendix XII), allowing the participants to self-assess their change in symptoms after the intervention. The PGIC consists of one question

and thus internal consistency was not applicable. Further, the PGIC is a validated scale for interpreting the subjective outcome measure of an intervention [200].

Finally, **Physical activity** was measured with the short form of the International Physical Activity Questionnaire (IPAQ-SF) [201]. IPAQ (Appendix XIII) was originally developed as a standardized instrument for activity levels in different populations and tested for reliability and validity [201-203]. The questionnaire consists of a seven-item "a 7-day recall" self-reported form [201]. The total physical activity level includes intensity, duration and frequency of physical activity.

5.7 The iCanCope with Pain™ app

The *iCanCope with Pain*™ app consists of five evidence- and theory-based features (Figure 4). Features I to IV were based on psychological theories and psychotherapies and provided the following functions: (I) symptom trackers for pain, sleep, mood, physical function and social function; (II) goal setting to improve pain and function; (III) a coping toolbox of pain self-management strategies; (IV) social support. Component V is the corresponding pain education library.

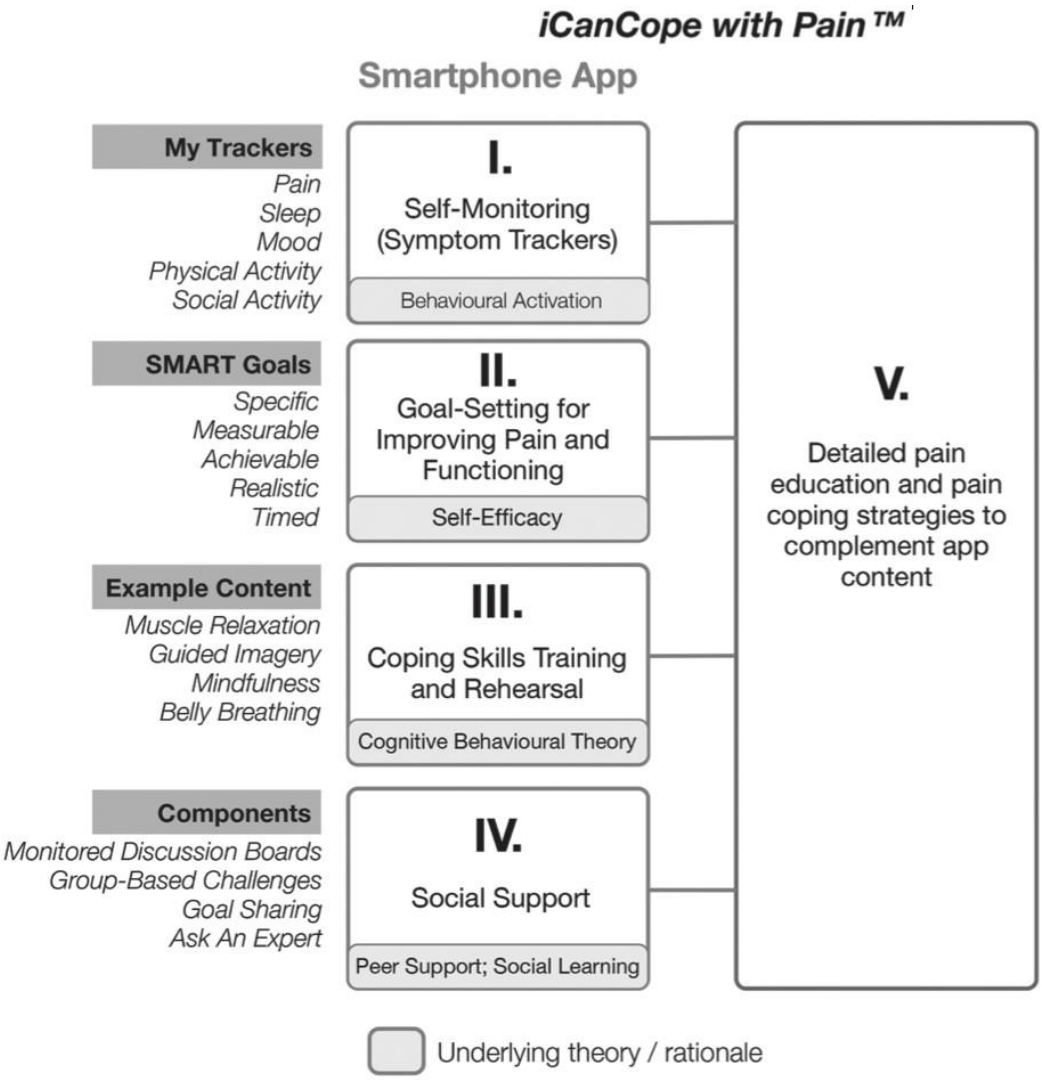


Figure 4. Conceptual framework showing the theories underlying the Norwegian *iCanCope with Pain*™ app for adolescents with persistent pain. Published as the original Canadian illustration (Permission to reuse by author and publisher).

Component I

My trackers are integrated as a daily check-in functionality in the app, which allows adolescents to rate their level of pain intensity, pain interference, mood, physical activity, sleep quality and energy.

Component II

Goal setting was designed to enhance self-efficacy and thereby improve pain and functioning [145]. The development of the app's goals feature was consistent with the SMART framework—specific, measurable, achievable, realistic and timed [204]. Thorough formulation of a SMART goal is necessary for success; thus, this method provides a useful standardized tool for adolescents to write and

express their own goals in the app. The app also provided adolescents with reminders and positive feedback on their progress in reaching their goals.

Component III
Personalized self-management instruction was designed to increase coping skills and rehearsal, thus promoting positive changes in behavior, and hopefully pain itself [37]. This component provides several coping strategies to manage pain, including muscle relaxation, CBT, guided imagery, mindfulness and abdominal breathing. The training was personalized based on each adolescent's goals. In other words, the component of the app aims to provide pain management strategies that help adolescents during everyday life, despite their pain [136].

Components IV and V
In the social support feature in the app (component IV), the adolescents receive *questions of the day* in monitored discussion boards. Finally, component V is an age-appropriate pain education library, which is integrated together with the coping-skills training (component III) in the app.

Given that the app is currently part of an ongoing RCT in other countries and is thus not publicly available, only screenshots from component I are available for publication. Therefore, the presented screenshots in Appendix XIV are all from the daily check-in (component I).

5.8 Analysis

In all papers, the statistical analyses were conducted using SPSS version 25 (IBM Corp., Armonk, NY) for Windows, wherein categorical variables are presented as frequency and percentage and continuous variables were described by the mean and standard deviation with corresponding effect size in Paper III.

Paper I
The data collected (e.g., Internet-server data, observations, audiovisual recordings and interviews) corresponded to the five components (features) in the app. Quantitative laboratory usability test (e.g., task completion, time, errors) measures were evaluated based on users' interactions with the app and to assess the app's ease of use and efficiency. Satisfaction was assessed in both usability tests using quantitative data from the SUS questionnaire (10 questions, each

scored from 0 to 40 points). Herein, the scores were transformed and converted to a 0 to 100 range (multiplying by 2.5). The scores were categorized adjectivally [187].

Both usability tests followed the same interview guide (Appendix III), comprising 14 questions. The five predefined theory-based app components (i.e., self-monitoring, goal setting, coping-skills training, social support and pain education library) were the basis for developing a structured categorization matrix using deductive content analysis [183]. Data were coded according to eight predefined categories, which comprised the five components, potential improvements, usage considerations and coping (Table 2). Herein, subcategories were developed as part of the deductive content analysis [183]. Interview responses were transcribed verbatim using NVivo for Windows (QSR International Pty. Ltd., version 12, 2018).

Table 2. Structured categorization matrix

	Hvordan opplever ungdommer brukervennlighet av den norske versjonen av *iCanCope with Pain?*
Bibliotek	
Fellesgruppe	
Målsetting	
Mestring av smerter	
Daglig registrering	
Forbedringer	
Brukervennlighet	
Mestring	

Paper II

Mediation analysis followed the PROCESS macro bootstrapping method developed for SPSS by Hayes [205]. The mediation effect was regarded as significant if the 95% confidence interval (CI) for this effect did not include zero. We used SES as a covariate in the mediation analysis. Moreover, we provided a

correlation matrix between self-efficacy and HRQOL subscales calculated using Pearson correlations.

To present the mediation effects as a percentage, the indirect and direct effects were separately divided by the total effect and multiplied by 100. *P*-values < 0.05 were considered significant and all tests were two-sided. According to Preacher and Hayes, an indirect effect does no longer impose evidence of a simple association between the dependent and independent variables as a precondition [206]. Hence, we included all HRQOL subscales in the mediation analysis as depicted in Figure 5:

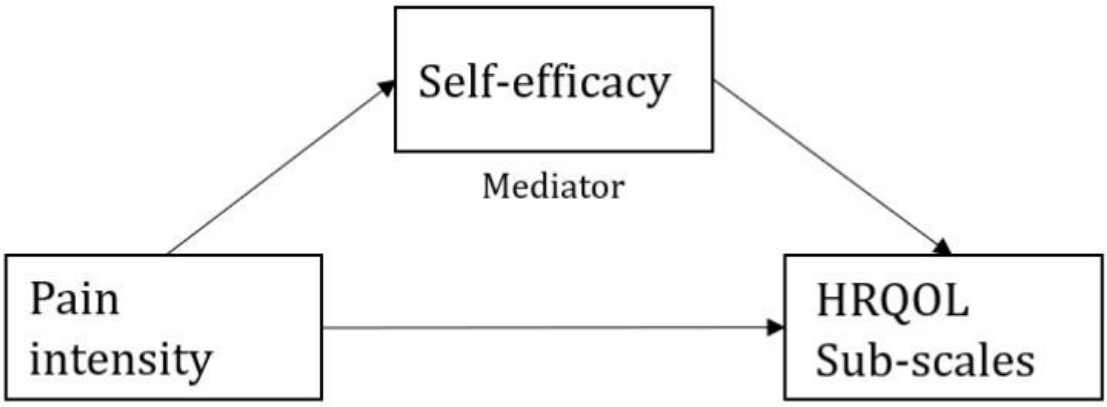


Figure 5. Schematic of our mediation model.

Paper III

Crude comparisons at baseline between the intervention and control groups were performed using *t* tests for continuous variables and chi-square tests for categorical variables. We conducted separate analyses for each outcome. Rates of attrition were calculated. The app engagement parameter was determined by the total number of interactions with the app's check-in feature (available in both groups). All participants were included in the final analysis according to the arm (intervention or control) in which they originally were randomized using the intention-to-treat approach. The general linear model (GLM) was fitted to explore possible differences in outcomes between the groups. In the GLM model, the postmeasures were entered as the dependent variable and compared between the treatment groups using baseline score as a covariate. Effect sizes were determined and expressed using Cohen's d, where 0.2 indicates a small effect, 0.5 indicates a medium effect and 0.8 indicates a large effect [207]. *P*-values <

0.05 were considered as statistically significant because our study was considered exploratory.

5.9 Ethics

Given that our study population includes adolescents with persistent pain, which usually has an unconfirmed etiology with no underlying pathological condition or apparent single explanation, several ethical considerations were assessed during this study. First and foremost, all participation was voluntary, in agreement with the Helsinki Declaration and participants provided written informed consent before participating in the study. They were aware that they could withdraw without a reason at any time during the study, in which case their data would be deleted and destroyed, and that the confidentiality and anonymity of their data were ensured at all times.

During the recruitment procedure, we wanted to provide information about the project and the corresponding e-mail address on different platforms. Meaning, the first author gave information that, if they wanted to participate, they could enroll whenever they liked, and the generated e-mail address was available on the classrooms' whiteboards, schools' homepage and in a written brochure with the respective high school's nurse. Thus, no teacher or classmates were aware of their participation in the study. In addition, given the older adolescents tend to report the highest prevalence of persistent pain in Norway (16–18 years) and some might not want to include their parents in their health problems, we chose to set 16 years as the lowest age limit. Norwegian adolescents at the age of 16 years are responsible for their own medical health and may participate in health-promoting studies without parental permission [208]. Moreover, we cooperated with school health nurses in the schools, who were available if the adolescents had questions or concerns regarding the intervention.

The study was approved by the Norwegian Regional Committee for Medical Research Ethics South-East-B (REK reference 2017/350) (Appendix XV). As an expression of gratitude, participants in usability tests received a gift card. Moreover, because adolescents report high demands and many report stress in connection to homework, we were aware of the risk of high attrition at T1 (postmeasures). Thus, we contacted REK and asked to provide gift cards also for participants who completed T1, however, that request was rejected. Furthermore,

we conducted a thorough assessment of the privacy and security demands prior to testing, which included an interdisciplinary team (researchers, persons in IT, privacy and security). Even though this study was conducted prior to the General Data Protection Regulation, we were still aware of risks by storing data. Thus, we chose to instruct all participants to create a mock user profile throughout the studies. By using a mock profile, there is no identifiable information stored in the app, which resulted in lower risks regarding privacy and security.

During the intervention period, the research team monitored the social support feature (discussion boards) by using the app to ensure no inappropriate posts were made. In addition, we checked an admin webpage during the entire intervention period. If any participants felt that any of the posts made by others were inappropriate, they were able to flag the relevant post. Then, the flags were alerted on the admin webpage. However, no flags were made during the intervention period by any of the participants. Nevertheless, because we were not able to control the posts made in advance, we considered this as an essential initiative. Hence, we could act and remove a participant from the social support feature, if necessary.

The *iCanCope with Pain*™ Norway trial was registered in Clinical Trials.gov (ID: NCT03551977). Ideally, we could have completed the trial registration before the first participant enrolled in the project.

6.0 Results

6.1 Paper I

In the first phase of Paper I, the participants did not report having any misunderstanding about or found discrepancies with the words or phrasing (e.g., meaning or activities) of the translated and culturally adapted pain education library or software text in the app, in either usability test. In addition, participant interviews and debriefings in the field usability test (phase 3) were conducted to ensure credibility and understanding of the translated text from an end-user perspective. Overall, the participants found the app easy to understand and interpret and found the phrasing suitable for their age group.

In the second phase, user-satisfaction scores (SUS) were measured in the laboratory usability test. The SUS revealed an average score of 82 out of 100, categorized as *good* and just below *excellent* [187]. Each participant completed all 10 predefined tasks, indicating a high ease of use. The predefined tasks were completed within the stipulated time frame. Efficiency scores are presented in Figure 6 as the mean time in seconds for the completion of each of the 10 predefined tasks related to the five components in the app (I to V).

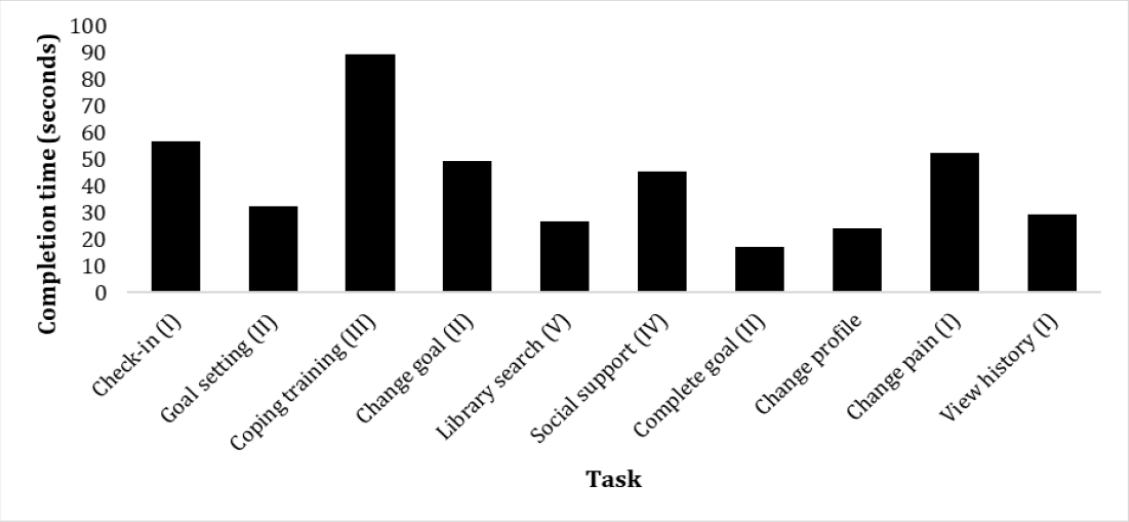


Figure 6. Mean completion time in seconds (0 to 100) for each laboratory usability test task (N=6).

In the third phase, the average user-satisfaction score for the field usability test score was 89 out of 100 and thus categorized as *excellent* [187]. In terms of

sociability, the participants reported that, in theory, this was a promising idea that would allow them to share their experiences and motivate each other within a social support group. However, only one of the participants made posts to this functionality. This participant explained how this feature could have been improved. For instance, the ability to switch to a single chat option with a healthcare professional (i.e., physical therapist) or create groups with other adolescents who experience similar types of pain. Further, the participant reported that questions in the social support function should focus on pain-coping strategies.

6.2 Paper II

In total, 78 adolescents with persistent pain participated in the study. The majority (62, 79.5%) were girls and 16 (20.5%) were boys. The participants were aged 16 (26.9%), 17 (29.5%), 18 (26.9%) or 19 (16.7%) years old. The mean pain intensity (VAS) score in the study sample was 5.4 (SD 1.8). Girls reported higher mean pain intensity scores than boys (5.7 [SD 1.8] versus 4.2 [SD 1.9]), respectively. Almost half of the participants (48.7%) reported pain lasting more than 12 months, and about one-third with reported daily pain (29.5%). All participants reported multisite pain, and half of the participants (51.3%) reported pain in locations other than the 10 predefined locations; in this unspecified category, pain in the shoulder(s), neck and hip was most frequently reported.

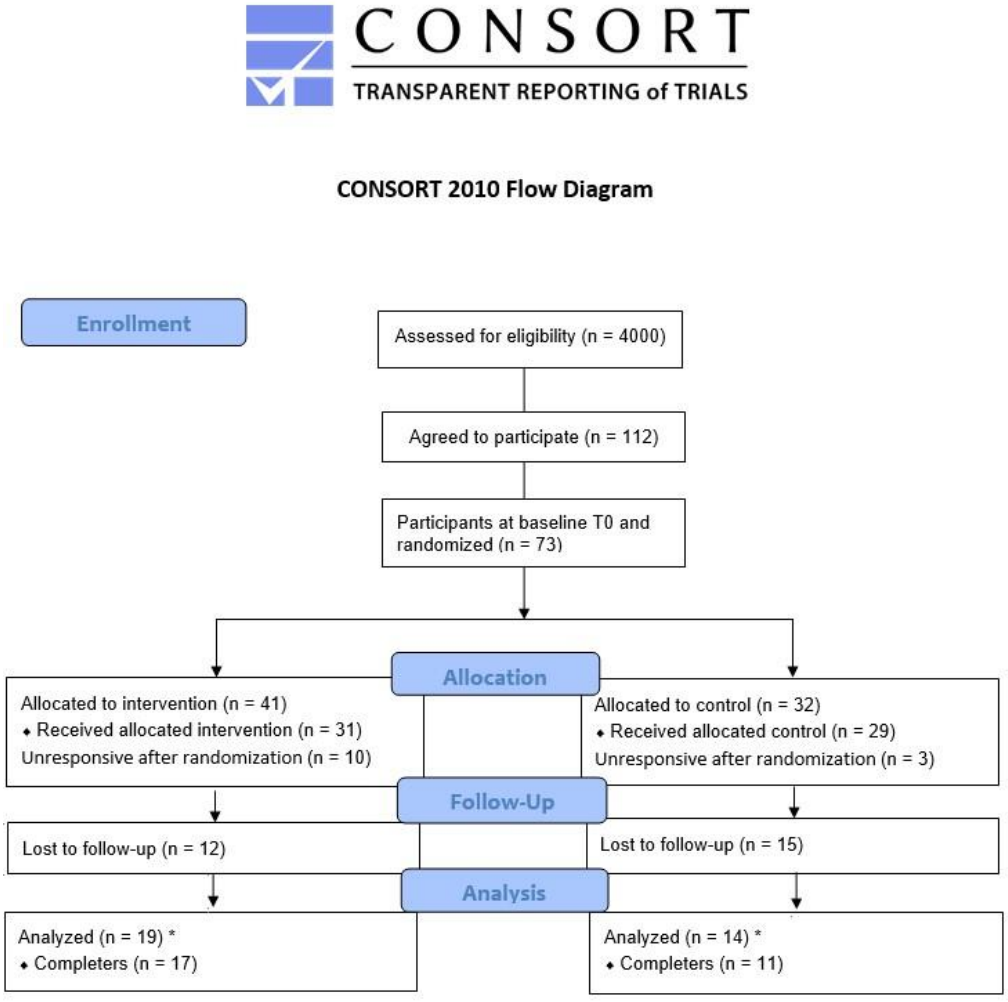
The participants scored low on several HRQOL subscales, with scores ranging from 45.2 (SD 21.0) to 91.0 (SD 13.3) on a 0–100 scale. Boys reported higher scores than girls for all HRQOL subscales except financial resources. The largest gender difference was shown for the HRQOL subscale mood, where girls reported a mean score of 54.9 (SD 21.3) compared with 73.7 (SD 15.6) for boys. The participants reported a mean GSE score of 13.5 (SD 3.3), with girls scoring 13.2 (SD 3.3) and boys 14.8 (SD 3.2).

The findings revealed that all HRQOL subscales were negatively associated with pain intensity. Further, a significant indirect effect was found for the HRQOL subscales physical well-being (B = –2.05; 95% CI [–3.64 to –0.56]), psychological well-being (B = –1.30; 95% CI [–2.96 to –0.20]), mood (B = –1.34; 95% CI [–3.08 to –0.19]), self-perception (B = –1.85; 95% CI [–3.65 to –

0.50]), autonomy (B = –0.87; 95% CI [–2.12 to –0.03]) and school environment (B = –0.92; 95% CI [–2.73 to –0.01]). Physical well-being had the highest indirect effect (67%) among the respective HRQOL subscales.

6.3 Paper III

112 adolescents agreed to participate by e-mail (Figure 7). Seventy-three participants were randomly assigned to two groups. Of the 73 participating adolescents, a total of 28 participants (38%) completed the postquestionnaire, resulting in an attrition rate of 62%.



* Completers answered all items in the postquestionnaire. All available data analyzed.

Figure 7. CONSORT flow diagram of the progression of participants through phases for the pilot feasibility RCT.

Second, the adolescents' interactions with the app were analyzed to explore the level of engagement with the app. The daily check-ins for symptom tracking (I)

in the app were used by both groups and were categorized as low engagement. Participants in the control group conducted a median of 9 (range 1 to 56) check-ins for symptom tracking (I) during the study period. The intervention group conducted a median of 6 (range 2 to 52) check-ins for symptom tracking (I).

Given that there were no significant differences in demographic variables or in outcomes between the ones completing the study (n=33, VAS 5.4, SD 1.9) and the ones who dropped out (n=40, VAS 5.7, SD 2.0), missing at random was assumed. Baseline-adjusted intention-to-treat (ITT) analyses were computed to explore possible group differences on outcomes, pain intensity, HRQOL, self-efficacy, pain self-efficacy, social support and HADS. No significant group effects were revealed (all *P*-values > 0.05). However, HADS and HADS-D (depression) revealed a medium (d = 0.53) and large effect size (d = 0.91), respectively.

7.0 Discussion

The following paragraphs will discuss methodological considerations, the main findings and future directions.

7.1 Methodological considerations

First, using a theory- and evidence-based app provided us with a solid basis for future work, by allowing Norwegian adolescents to test and experience a well-tested rigorous framework that represents a major strength of this thesis, especially given the lack of scientifically evaluated pain management apps available for adolescents [40, 173]. However, on the other hand, the components of the original *iCanCope with Pain*™ program are based on needs assessments from Canadian adolescents recruited from chronic pain clinics [37], not a school-based population of adolescents with persistent pain in Norway.

The present thesis utilized both quantitative and qualitative data in Paper I. The combination of methods should be considered as a strength of Paper I because it may provide a greater understanding in usability tests [185, 186, 209]. Moreover, it is reported that qualitative and quantitative strategies should not be considered incompatible but as a complementary approach [210]. We found conducting a deductive content analysis to be the most appropriate approach because it is recommended in cases where the researcher wishes to retest data in a new context [211], wherein data naturally matched the predefined categories of a structured categorization matrix. The collected data were coded according to eight predefined categories, herein the categories were each of the five components of the app (I–V), along with potential improvements, usage considerations and coping. The predefined categories were considered ideal for ensuring a systematic assessment. Because the pilot feasibility RCT consisted of two parallel arms with two different versions of the *iCanCope with Pain*™ app, wherein the intervention group received all five components of the app and the active comparable group received only component I. A systematic assessment of the usability and user experience of each component were therefore of great value.

7.1.1 Study samples

In Paper I, to ensure a thorough cultural translation (phase 1) and assess technical usability aspects (phase 2), a convenience sampling of adolescents was used [212]. We considered that Norwegian adolescents within the age group would provide valid data even though they probably were not in pain. The participants assessed if the app was suitable for their age group (phase 1) and evaluated the system usability in laboratory settings (phase 2). We did not ask if these adolescents were in pain. However, they tended to relate their use of the app in a more hypothetical manner. The focus was to assess the age-appropriateness of the cultural translation and technical usability aspects. Therefore, we chose to not include adolescents with persistent pain (end users) in phases 1 and 2, even though it is reported that end users provide the most valuable feedback [213].

About 4000 adolescents from a school-based population were approached to participate. Based on research evidence of the prevalence of persistent pain [9-12, 129], we predicted that about one-quarter of the approached adolescents would be eligible. An advantage of this study recruitment procedure is that the researcher provided the information and ensured that the adolescents received the same information in each classroom, which strengthened the reliability and probably reduced possible bias in enrolment.

A major limitation of the thesis is the total study sample size, which indicates a threat to the validity because the risk of bias increased. Our initial power calculations could have been performed differently [214], such as only expecting a small effect size (d) that was clinically worthwhile to detect because there were no prior app-based studies with the same aim in this specific population. Other adjustments could have been an adjustment of the alpha value to 0.025 instead of 0.05, given that our aim included two outcomes: reducing pain and promoting HRQOL. Such adjustments would have provided us with the need for a large sample size to evaluate effects in an RCT. Further, knowing adolescents are a difficult population to recruit [215], we could also have added an expectation of attrition. Further, we could have provided reminders using multiple platforms as recommended in online trials [216]. That we only used e-mail as a communication platform should be considered a limitation. Given the rapid

development of apps, there were probably other appropriate platforms to communicate with adolescents or at least using a traditional text message.

7.1.2 Study design

In Paper I, the *iCanCope with Pain*™ app was translated and culturally adapted into the Norwegian language and cultural context. Phase 1 required a multistep approach, including input by an interdisciplinary group to ensure thorough translation and adaptation. During phases 2 and 3, the app's usability was evaluated. The participation of adolescents with persistent pain (end users) in phase 3 strengthened this study design because they tested the app in the context of use after we had evaluated the satisfaction, ease of use and effectiveness (phase 2), as recommended [185].

Our measured baseline provided us with cross-sectional data. In cross-sectional study designs, no causal relationships may be identified. However, we consider that our findings shed new light on the underlying mechanisms of the association between pain and HRQOL in a sample from a school-based population of adolescents. Further, the study design provides a snapshot of the characteristics, frequency of the targeted data at a specific time point within the study sample [217]. The highest validity and accuracy of epidemiological data is achieved when including the entire population. However, because this is not feasible in most cases, it is important to clearly define the subgroups with inclusion and exclusion criteria. By using a cross-sectional study design, it becomes possible to examine the burden of the study sample, examine associations with other variables and explore underlying mechanisms [217].

RCTs are considered the gold standard for interventions aiming to evaluate effects [218, 219]. To date, our study is the first to include a feasibility RCT design in a school-based population of adolescents with persistent pain using an app aimed at reducing pain and improving HRQOL. Even though this current study experienced an unexpectedly high attrition and loss to follow-up, making it difficult to evaluate the effects, the sample size was in accordance with Hertzog's recommendations (10–40 responders per group) for pilot studies [220], which allows for exploring the impacts of outcomes and the possibility to provide estimates for future definitive trials. Still, the gold standard aside, bias might

occur in RCTs due to the allocation of study participants, missing outcomes, measurement methods, reporting of results and conflict of interest [221]. We strove to keep all potential biases to a minimum in every step of the trial, by reliable enrollment procedure, blinding the researcher assessing the data during allocation and following the ITT approach. Further, our electronic survey provided us with no missing data in the completed questionnaires, and thus we strove to maintain the internal validity [219]. Further, there are some fundamental advantages of comparing outcomes with a control group, in terms of taking into consideration the Hawthorne effect, defined as a change of behavior in response to the awareness of taking part in a study and the well-known placebo effect, wherein an improvement may occur after receiving a treatment with no therapeutic value [222]. Moreover, the outcomes in RCTs should be useful for the applied study population and healthcare providers and should be put in context with current research evidence by providing a new updated piece to the never-ending puzzle (e.g., external validity). Although research evidence indicates that support provides better effect than no support in Internet-delivered psychological interventions trials [223], we were interested in evaluating the preliminary effects of the *iCanCope with Pain*™ app itself.

7.1.3 Data collection and outcome variables

In phase 1 (Paper I), given there are several previously described translation and cultural adaptation techniques with different strengths and weaknesses, it seems that being transparent in each step when collecting data is considered essential [224]. In the subsequent phases, the user experience and usability were assessed by quantitative and qualitative data obtained by the think-aloud method, audiovisual recordings, questionnaires and individual interviews.

The think-aloud method was used due to its high value in evaluating usability flaws and to gather information about the system usability and used during tasks to confirm when participants started and ended each of the predefined tasks, thereby providing valuable insight into users' thoughts and actions [225]. The verbalization of the participants' thoughts gave insight into each component of the app. However, not all participants found it natural to verbalize the task as they were performing it, which may have influenced task efficiency because of higher cognitive loads. This may call into question the reliability and validity of

these data [226]. Further, there are some concerns by implementing the think-aloud method because not only is there an increase in the cognitive load for the participant but the verbalized information is subjective [225]. Hence, having a sufficient number of participants using the think-aloud method is crucial. Because Paper I had six participants conducting the think-aloud method (phase 2), it should be considered as a strength because only approximately four subjects are considered to be enough for providing a rich source of data using this method [227]. Still, the recommended sample size may depend on the skills of the participants, number of iterations planned for the design and financial or other impacts of the use of the system [227].

Although the think-aloud method was performed with enough participants, these adolescents were not in pain and research indicates that a usability test should preferably include users who will use the system in the future [225]. However, we included end users (i.e., adolescents with persistent pain) during the two-week home-based test (phase 3), wherein a concurrent think-aloud method was not feasible. Nevertheless, the use of a concurrent think-aloud method (in live settings) is considered to generate more valuable usability information than conducting a retrospective think-aloud method condition [228]. Finally, a strength of the study is the fact that we followed the ISO for evaluating the usability, the think-aloud method helped provide the outcome measures ease of use (effectiveness) and efficiency, which are considered essential in usability evaluation [186].

The SUS is known to be a quick and dirty scale for measuring the perceived usability of various computer systems [229]. It is very simple to use and administer, which may explain why SUS is used in nearly 8000 studies according to Google Scholar. SUS evaluates the user satisfaction of a system and is not only simple to use but is also regarded as a free, validated and reliable test measurement [230]. Bangor and colleagues presented a meta-analysis comprised of nearly 10 years' worth of SUS data. The findings showed that the SUS is a highly robust and versatile tool for measuring the usability of a system [231]. On the other hand, SUS must not be mistaken for an objective measure of usability and should not be the only measure in a usability assessment [186]. We considered the use of SUS to be a valid and reliable method for assessing the satisfaction of use, especially given the fact that the total score of SUS is possible

to interpret as adjective ratings, such as “good” or “excellent,” which makes it an understandable measure of user satisfaction of a system.

Individual interviews were chosen for collecting the qualitative data and provided insight into the user experiences of the *iCanCope with Pain*™ app. In qualitative healthcare research, an interview is the most common method for data collection [232]. By conducting individual interviews, each adolescent was able to elaborate and speak freely [182]. Thus, this current method thoroughly assessed each participant experience and provided a solid data collection. Interviews as a qualitative method are reported to provide a “deeper” understanding of the experience than quantitative methods such as questionnaires [232]. Further, semi-structured interviews are often preferred within healthcare research [233] because they provide some guidance on topics and categories to talk about. In the preparation phase, we selected the most relevant categories [181] and prepared a categorization matrix [183]. The semi-structured approach helped to discover information that is important to the participants, which had not initially been thought of from our researcher point of view [232]. Even though some questions were not open-ended, when asking follow-up questions like “Why do you think that?” the participant often spoke more freely. Because pain may be related to sensitive matters and the fact that we promised anonymity for the end users (phase 3), group interviews were not considered appropriate, even though they might be less time-consuming and also provide a rich understanding of participants’ experiences [234].

In Paper II, we used translated and validated instruments assessing pain, self-efficacy and HRQOL, which should be considered as a major strength. Despite standardized and validated questionnaires, there is always a risk of bias when assessing symptoms using self-report questionnaires [235]. For instance, the use of self-report questionnaires may overestimate the prevalence of a condition because they may blur the distinction between low and high prevalence [236]. Before providing consideration in connection to each of the administered instruments, it should be emphasized that the data collection was conducted through an electronic survey, called Survey Exact. There are some methodological considerations in connection to using an e-mail reporting system among adolescents. Because we experienced a high attrition after the registration, it could be in connection to e-mail as a reporting system. It should be considered

a limitation that we only used e-mail to communicate because this probably is not the preferred platform for communication among adolescents. On the other hand, all the registered adolescents initially sent an e-mail to enroll in the project, so they were likely aware and familiar with the use. To exemplify the ongoing development of the *iCanCope with Pain*™ app, recent updates allow the participants (in Canada) to download the app from Appstore or Google Play Store, access the app, and answer the questionnaires within the app (baseline measures). Hence, the data collection is within the same electronic platform, and probably a more suitable approach, especially among adolescents.

The Norwegian version of the LPQ was administered for assessing pain among a school-based population of adolescents for several reasons. The questionnaire has been used within the same study population in Norway [9], making it easier to compare findings. Further, it is among very few validated Norwegian translated questionnaires regarding pain assessment. Moreover, we did not find any other pain questionnaires validated for our specific age group. In addition, the LPQ includes the VAS, which is found to be both valid and reliable, also including digital use [188]. However, there is only one measure of pain intensity "at this present moment," not an average score for the pain intensity during the last day or week. Given the cyclic nature of pain, it is a limitation that we were not able to examine if the pain intensity "at this present moment" coincided with the "average" scores. Finally, the pain location questions refer to a 3-month recall period, which might be a long period for adolescents to remember and may have reduced the validity of the data.

In this study, the KIDSCREEN-52 was administered to assess HRQOL, which was chosen based on the fact it was validated for Norwegian adolescents [18] and had been previously used in research among a school-based population of adolescents [3]. KIDSCREEN-52 has been shown to have the best structural validity compared with several HRQOL questionnaires [71]; using the KIDSCREEN-52 should be considered as a major strength. Still, it is important to be aware that the KIDSCREEN-52 does not provide a total score for HRQOL, instead, it is comprised of 10 subscales.

To assess self-efficacy, the Norwegian five-item short version of the GSE revised and translated by Røysamb and colleagues (1998) was administered [192]. Using

translated and validated questionnaires are as stated, a strength of this study. However, the short form (five items) of GSE might provide even better psychometric properties than the original 10-item version [193]. Hence, we considered that the short form provided sufficient data of the participants' GSE and given the total time of the electronic survey was approximately 20 minutes, it was probably an advantage to not administer too many comparable questions within the same topic, in terms of preserving the participants' motivation, and thus the validity of the data.

In Paper III, the primary outcomes of the pilot feasibility RCT were drop-out rates and the level of engagement. These outcomes will be further considered in the discussion of the main findings. To explore possible differences in outcomes between groups, we administered the following questionnaires based on several methodological considerations.

To measure the adolescents' social support levels, we chose to translate the PSS-FR questionnaire [195]. The primary reason was to be able to compare our findings with the original Canadian English ongoing feasibility study. The same argument is applicable for both the PGIC and PSEQ. Meaning, these questionnaires had not undergone earlier translations, which could be considered a limitation of use. Nevertheless, it should be considered a strength that we conducted a rigorous procedure, including an interdisciplinary team, with two independent forward translators, an English native speaking back translator, researchers within the field and end-users' debriefing (as part of phase 3 in Paper I). Thus, we have performed a transparent and recommended procedure [184]. For the translated questionnaires, we found satisfactory Cronbach's alpha scores of 0.84 and 0.93 for PSS-FR and PSEQ, respectively, indicating a high internal consistency reliability. PGIC consists of only one question, and thus, internal consistency is not applicable.

We chose to use the translated and validated Norwegian version of the HADS [198]. Although anxiety and depression are common during adolescence and often associated with persistent pain, previous Internet-delivered self-management interventions for adolescents with persistent pain do not tend to focus on this topic [154]. Because our study population derives from a school-

based setting, include HADS should be considered both a strength and a relevant tool.

We intended to measure physical activity using the IPAQ-SF [201]. However, we used an adult version that consists of plain text for answering questions regarding physical activity, which resulted in invalid data. This should be considered as a limitation and indicates the importance of age-appropriate questionnaires to obtain valid data. Thus, the total physical activity level, which includes frequency, duration and intensity was not possible to assess. On this basis, we were not able to report these findings in Paper III.

Ultimately, when addressing our questionnaires (electronic survey) from a bigger perspective, and given that 10 adolescents started the postquestionnaire but did not finish, this could indicate that the electronic survey was too comprehensive.

7.1.4 Choice of data analysis

To ensure a systematic approach to the features of the *iCanCope with Pain*™ app, a deductive content analysis was conducted because we wanted to retest the app's features (I–V) in a new context [183]. Data were condensed using predefined categories as recommended in a deductive approach [183]. The predefined approach allowed for allocating data to the same categorical structure, thus providing data within each of the app's features (I–V). Data from the Internet server followed the same allocation of data (features I–V), providing us with further insight into the participants' use of each feature. Moreover, given the predefined tasks of usability testing also corresponded to the specific categories (features I–V), herein we used observation, the think-aloud method and audiovisual recordings to assess if the task was completed (ease of use) and the task completion time (efficiency), and to assess errors. Combining both qualitative and quantitative data provided a greater understanding of how the adolescents experienced using the *iCanCope with Pain*™ app [210]. The interpretation of the results of analysis and the conclusion from the findings were reviewed by co-authors and supervisors.

Mediation analyses in health research are increasing and are commonly used [237]. However, we found that there are several data analysis choices in

connection to evaluating the mediation effect, and thus, determine the indirect effect. Although it is reported that mediation tests agree more than they disagree [238], it should be considered a strength of this study that we used the bootstrapping method of Andrew Hayes [239]. The bootstrapping sampling method provides an increase in power compared with other tests that evaluate the indirect effect, such as the Sobel test [240], which is recommended in large samples. Furthermore, by computing samples repeatedly and randomly thousands of times, the bootstrapping method provides applicable point estimates and confidence intervals even for data that consist of small sample sizes [239]. In this current study, given that our study variables were normally distributed, the total effect is therefore equal to the sum of the direct and indirect effects (in linear systems) [239].

However, we did not consider statistical analyses of gender statistically meaningful based on the limited sample size and the homogeneity of the sample (Paper II). Thus, we considered it appropriate to focus on the outcome for the whole population rather than to focus on gender differences. Given the multiple end points, we should have recruited a larger sample size. On the other hand, we have put considerable effort into the recruitment process and tried to enroll all eligible individuals and the distribution of gender is typical within the study population [9-12, 129]. Moreover, the aim of our study was to describe the adolescent population and present our mediation model, not necessarily show that all the suggested causal paths are statistically significant. Further, several of the revealed associations are statistically significant, thus the study was by definition sufficiently powered.

The greatest threat to the validity of this study is the high attrition during the app-based intervention that naturally influenced the loss of power and risks of possible bias. When experiencing a high attrition rate, it is important to assess if a selective dropout did occur. If the participants drop out because they found the app to be a nonpreferred method for coping, such a reminder that they were in pain [241], or that they dropped out because they felt worse, then, an unreal relationship may occur between the groups, which is called type 1 error [242]. This statistical phenomenon may occur when a significant relationship is shown between two variables, however, there is no actual connection in real life and thus known as an incorrect rejection of a true null hypothesis. In our study, we

did not have any data of the dropouts, except their baseline measures, which did not reveal any differences in demographics or in outcomes between the completers and the dropouts. Further, because our study was clearly underpowered, there is a risk for type 2 error as well [242], perhaps there was an actual connection in real life for some study variables, but was biased by the limited sample size and high attrition.

Contrary to our expectations, the differences in changes in pain and HRQOL (Paper III) were lower than anticipated. Based on our findings: using a two-way means test to demonstrate that we would need n=699 in each group to reach the level of statistical significance for pain intensity gives an important insight into the planning of future definitive trials. Because of the high attrition rate and loss to follow-up, in addition to 10 participants only partially completing the postquestionnaire, we considered using the last observation carried forward for the imputation of data (meaning baseline measures) as part of the ITT approach. However, the imputation of data is a controversial topic, and we chose to analyze only the available data following the ITT approach, wherein the randomized participants were analyzed according to the group they were originally assigned, regardless of the participants' use of the *iCanCope with Pain*™ app [243]. Compared with per-protocol analysis (only include the completing participants who have received treatment), following the ITT principle should be considered a strength from a statistical point of view [244].

7.2 Discussion of main findings

This section will discuss the main findings in relation to theory, including the holistic empirical model for the biobehavioral investigation of pediatric pain by Varni et al. [88] (Figure 2) and current research evidence.

Overall, our main findings revealed that the *iCanCope with Pain*™ app is a thoroughly well-tested app, with high satisfaction, ease of use and effectiveness among Norwegian adolescents. Still, there are components of the app, such as the social support feature, that seem to be more applicable in theory than in practice. Further, our baseline data revealed that up to 67% of the reduction in the association between pain intensity and HRQOL subscale scores was explained by the mediating variable, self-efficacy. Finally, the feasibility testing of an app-based self-management intervention in a school-based population of adolescents

with persistent pain revealed high treatment attrition and low level of engagement.

7.2.1 The cultural translation and usability testing

We used a transparent two-stage approach consisting of 10 steps to conduct a cultural translation of the *iCanCope with Pain*™ content into Norwegian [184]. Transparency in the translation procedure is considered essential because it strengthens the validity and reliability of the procedure [184, 224]. The thorough multistep approach used herein is recommended when culturally translating instruments into clinical practice [245], and may explain why the participants found no discrepancies in phrasing or words. Further, given that the articles in the library originally were addressed to adolescents, the English Canadian text was not only easy to read but also short and concise, often with understandable bullet points. This may explain why the Norwegian participants reported that the app text was suitable for their age group. Adolescents in Norway or in Canada seem to be quite alike in terms of what is considered everyday activities and sports. Meaning, we did not need to add new activities and there seems to be a cross-cultural equivalence [246].

Obviously, the original Canadian *iCanCope with Pain*™ program underwent rigorous testing [37]; the preparatory work may explain why we did not find any need for user training or technical issues. Still, there were naturally minor technical issues along the way before the Norwegian server was operational. During developmental updates of the Norwegian *iCanCope with Pain*™ app, such as including new screenshots (with adjusted text size), there were ongoing improvements over time. In other words, our findings may also be in connection with our thorough preparatory work before conducting usability tests. The importance of thorough interdisciplinary collaboration, including performing pretests and assessing both protocols and technology in detail beforehand should be highlighted.

An important finding of the usability testing was that the highest score of the user satisfaction was found among the participants (adolescents with persistent pain) who interacted with the app over time in their natural home environments. The finding is important because end users are known to provide the most valuable feedback [213], and the app is intended to be used in the home environment. In

addition, the participants scored very high on the SUS scale (89 out of 100), expressed as somewhere between "excellent" and "best imaginable" [187]. In context to the research literature, the average score of the SUS from over 500 studies is 68 out of 100. Meaning, scores above 68 should be considered above average and scores below should be considered below average [247]. Our study provided two independent user-satisfaction evaluations of 82 and 89 out of 100 (phases 2 and 3, respectively), indicating that the Norwegian *iCanCope with Pain*™ app is a system with reliable high user satisfaction.

Our participants reported appreciating that they were able to access the app from home after school and learn from psychological strategies in the app, which were the most popular articles. Given that many Norwegian adolescents worry too much [7], the app may provide coping strategies and information compared with other information online, which are not theory- and evidence-based. It seems like the adolescents prefer to read about coping strategies compared with sharing experiences within the social support feature regarding pain. Our participants reported they liked the idea of an app component that allows them to seek social support, however, this feature was rarely used. Adolescents have reported that they prefer to use a mobile phone app for relationship support, which was reported to not be influenced by gender, age or any other background characteristic [248]. Instead, the support feature seems to be influenced by the user needs and the appropriateness of app content [248]. One possible explanation may be that the study sample might have a lack of identity in terms of pain and the user needs could be more specific and personalized. Thus, maybe it would have been easier to share if the participants experienced the same type of pain, pain in the same location or close to the same pain intensity levels. Patients with chronic pain have reported that personalization is an important element in e-Health interventions [249]. However, findings also suggest that such interventions help in the distraction of pain, regardless of their pain intensity levels [249].

7.2.2 Pain, HRQOL and self-efficacy

Our descriptive data revealed high pain intensity levels of 5.4 in our study sample. Although the pain intensity level could be considered severe [250], the finding is in accordance with Norwegian epidemiological data, revealing similar mean pain intensity scores (4.5) for adolescents in pain [12]. Our descriptive data

revealed findings that are important to discuss because they provide the characteristics of the study sample, adolescents with persistent pain from a school-based population. For instance, all participants reported multisite pain. In the context of the research literature, a school-based survey revealed among Norwegian adolescents that multisite pain is associated with mental health problems and thus increases the risk of mental health disorders [24]. Further, it reported that mental problems and stress are equally related across genders among Norwegian adolescents in pain [251], however, girls tend to report higher levels of stress and mental problems than boys [7]. In light of the biobehavioral model of pediatric pain by Varni et al. [88], a depicted connection appears directly between stress and pain, thereby indicating stress as a direct cause of pain. A recent review examined stress as an etiology of persistent pain in children and found that stress elicits neurobiological mechanisms [252]. Stress as a cause of pain is in fact suggested by Norwegian adolescents [89]. It is logical to assume that stress and worrying can cause pain because psychosocial aspects have been shown to manifest in the musculoskeletal system as persistent pain [253]. However, opposite directions should be considered because these are purely associations, stress may also be a consequence of pain. For instance, it is reported the high level of perceived stress in Norwegian adolescents with pain could be explained by the variation in pain intensity levels [12].

Moreover, our findings revealed that girls reported higher scores for pain intensity (VAS 5.7) than boys (VAS 4.2) and more frequent pain of longer duration, which is in accordance with the literature [3, 10, 129, 254]. Further, our findings revealed that a school-based population of adolescents with persistent pain has impaired HRQOL. The research evidence provides a clear indication that pain is well known to affect HRQOL negatively [3, 4, 14, 19, 65, 255-257], and there seems to be a tendency for gender differences. For instance, the typical gender difference in HRQOL is not present in children. Data from 12 European countries (n = 21,590) showed no gender difference in HRQOL of young children; however, with increasing age, HRQOL in girls declined significantly compared with that in boys [258]. In Norway, girls tend to report lower HRQOL than boys in adolescence [3, 8], which is in accordance with our findings. However, there seems to be no significant difference between the changes in boys' and girls' decline in HRQOL during 3 years in high school [8], indicating

the gender difference seems to increase from early adolescence and follow to late adolescence.

An important finding for this current study was that enhancing self-efficacy seems to be an important intervention strategy when aiming to improve HRQOL in a school-based population of adolescents with persistent pain, despite research evidence indicating that pain in adolescence may be prevented or reduced with a wide approach of both physical, psychological and pharmacological management [259]. In many cases, treating the pain itself is difficult. Thus, interventions seem to focus on providing pain management strategies in terms of coping-skills training and rehearsal and promoting positive behavior change [37]. In other words, because of the complexity of pain, the approach to pain management may include focusing on positive resources and strategies rather than focusing on the pain itself. Thereof, it is necessary to take a holistic perspective into account (Figure 2) because it may help to understand the intervening variables needed to optimize the approach to pain management. Herein, coping strategies often comprise the concept of self-efficacy because self-efficacy is regarded as a self-regulatory mechanism that is possible to change and is recognized as a major predictor for behavior change [81]. In connection with our findings, which revealed self-efficacy as a mediator in the association between pain and several HRQOL subscales, these together provide initiatives for focusing on enhancing self-efficacy in future pain interventions.

The highest indirect effect of self-efficacy was found in the association between pain and the HRQOL subscale physical well-being, which is especially interesting. The HRQOL subscale physical well-being does not represent physical activity levels but is theorized as the subjective perception of physical well-being of the person’s own beliefs and expectations [60]. However, a strong association has been reported between self-perceived physical function and physical performance in adults [260]. In adolescence, lower self-perception of physical fitness is associated with lower psychosomatic health symptoms [261]. Because self-efficacy may be regarded as confidence in the ability to perform a given task [79], it is understandable that the degree of self-efficacy may explain the reduction of the HRQOL subscale physical well-being because the adolescents probably feel less confident in their perception of physical well-being when the pain intensity increases. Although self-efficacy is a well-known

determinant for a healthy lifestyle and physical function in the general population [262, 263], it is interesting that it explains two-thirds of the reduction in HRQOL subscale physical well-being in a school-based population of adolescents.

7.2.3 Feasibility testing of the *iCanCope with Pain*™

Our findings revealed high attrition rates of an app-based intervention among the adolescents throughout the trial. A total of 112 school-based adolescents agreed by e-mail to participate and stated they were in pain; however, only 73 participants completed baseline measures. After the baseline measures, 13 participants did not receive the allocated intervention, meaning they did not use the app. All eligible participants received a username and password with a corresponding PowerPoint presentation. However, these findings may indicate the need for changes, possibly by having a more facilitated onboarding process (helping the adolescents to use the app). On the other hand, we did not register any technical issues or adolescents contacting us with problems of use, and the onboarding process was also pretested.

The finding of a high attrition rate is in line with Voerman et al. [161] who experienced both a high rate of attrition and loss to follow-up after an Internet-delivered self-help program for adolescents with persistent pain. Interestingly, one of the suggested possible explanations for the high attrition and loss to follow-up was that the adolescents viewed the questionnaire as homework, and thus, were not interested in additional time-consuming work [161]. Taken into consideration that 10 participants in this current study started on the postquestionnaire but did not complete it could indicate that it might have felt like homework or at least it felt too time-consuming.

It is interesting that the level of engagement was high during a two-week home-based test (Paper I). However, when adolescents recruited from the same study sample tested the app in an 8-week pilot feasibility RCT (Paper III), the level of engagement was categorized as low. These findings are in contrast to Lalloo et al. [264], who found that the intervention and control groups were both categorized as high-moderate engagement using the symptom tracking feature (I) of the *iCanCope with Pain*™ app. The differences in the level of engagement may be due to the difference in the study sample, such as a school-based

population versus a clinical sample with regular support with a healthcare team. Support in Internet-based therapy is reported to be more effective than without support [223]. It should be mentioned that not all clinicians recommend tracking pain symptoms as part of an intervention [136] because of their belief that self-monitoring may provide too much focus on pain, and thus provide the opposite of the preferred effect. Hence, only one of the five daily check-in questions in the *iCanCope with Pain*™ app is related to pain [37].

Further, adolescents in the two-week home-based test (Paper I) knew that they were to see the researcher after the test period, which may have motivated or influenced the level of engagement. Or it could be that the adolescents after 1–2 weeks already had the feeling that they knew what the app had to offer. Meaning, the components (features) in the app comprised a static infrastructure, except from user interactions within the social support feature, there are not any new or dynamic features/articles presented during the intervention period. Traditional self-management interventions have a duration period for 8–10 weeks [66, 133], thereby providing several different modules within the given timeframe, often with a new module every week. One might argue that the level of surprise or keeping the participants motivated over time might be difficult with an app comprised of a static infrastructure.

The findings of a low level of engagement in our study should be viewed in light of recent research evidence and the holistic biobehavioral model of Varni et al. [88]. A natural concept occurring in research is the dose–response or exposure–response relationship, which indicates that the magnitude of the dose often proportionally influences the response in outcome [265]. However, despite the dose–response relationship, recent Internet-delivered interventions among adolescents with persistent pain have reported that the adolescents' level of engagement was not related to the outcome variables [266, 267]. Law et al. [267] indicated that a family-based CBT for persistent pain delivered through the Internet improved the adolescents' disability, parent-protective behavior and parent distress immediately after posttreatment, after 6-month follow-up and at 12-month follow-up. Interestingly, the analysis showed that higher parent distress at baseline predicted less improvement in child disability over 12 months, which indicates that the parent distress may increase the risk of poor response in the long term in pain interventions among adolescents with persistent pain.

Moreover, in a recent study by Alberts et al. [266], the engagement in an Internet-delivered cognitive-behavioral program for adolescents with persistent pain and their parents was examined. The findings indicated that parental engagement predicted the activity limitations scores at posttreatment for the adolescent. However, contrary to their expectations, the adolescents' level of engagement was not predictive for the treatment outcomes, indicating the important role of parental engagement and family environment. We do not have any data on parent distress level or parental engagement; however, these aspects should not be neglected because they may be important for adolescents' improvement in pain management interventions. Hence, the intervening variable family environment as illustrated in the holistic model by Varni et al. [88] seems to influence the response in the outcome, perhaps more than the adolescents' own level of engagement.

In the context of pain interventions using smartphone apps, the same trend is reported. Adult persistent pain patients compared a smartphone app with or without two-way messaging. The findings revealed that the two-way messaging feature moderately improved the level of engagement and compliance with daily assessments, however, there were no significant differences in pain outcomes between the groups [268]. Notably, the study stated the need for continued research to understand ways to optimize the use of apps [268]. This could indicate that the level of engagement may not alone be the best predictor for the response in outcomes in app-based interventions.

Despite the agreement in the literature that pain negatively affects HRQOL [3, 4, 14, 19, 65, 255-257], there are some discrepancies in the association between pain and HRQOL in a previously reported intervention study. Hicks and colleagues [164] reported a significant reduction of pain after an Internet-delivered psychological treatment program for children and adolescents with persistent pain, wherein participants were recruited from high schools and not from chronic pain clinics. They expected HRQOL to improve with a concomitant decrease in pain; however, they did not find any significant difference in HRQOL scores across groups at any time of measurement (posttreatment and 3-month follow-up) [164]. A possible explanation for the lack of change was hypothesized to be related inclusion of a school-based study population rather than a referred clinical sample, which could explain that other intervening

variables (Figure 2) rather than pain intensity levels may influence the HRQOL in a school-based population of adolescents with persistent pain. Still, it is suggested that the effectiveness of coping strategies may vary depending on the participants' level of pain, wherein higher pain intensity levels at baseline may provide a better basis and act as a favorable basis for improvement [116, 149]. Our study sample had relatively high pain intensity levels at baseline, indicating that a favorable basis for improvement was present. However, no significant differences between groups was revealed.

An important finding of this study was the medium and large effect size found for the HADS total score and subscale of depression, respectively. Our baseline data revealed a high mean depression score of 8.9 and 10.1 for the control and intervention groups, respectively. The original scoring classified scores between 0 and 7 as within the normal range of depression score, however, discrepancies regarding optimal cut-off have been reported [269]. The articles *coping with fatigue* and *distraction techniques* were among the most liked articles, which indicate the adolescents' interest in these topics. Given that the estimates for future trials revealed that the lowest sample size to reach statistical significance was the HADS subscale of depression, this could indicate future app intervention comprised of a school-based sample of adolescents with persistent pain could benefit by a focus on reducing depression symptoms.

There may be several mechanisms explaining the large effect size found for the HADS subscale of depression in this study population. The intervention group had access to components II–V, herein we have examined their interactions with the app (e.g., number of goals, number of liked articles and activity within the social support feature). Still, we do not have information about how many minutes the participants spent on each article nor their experience in this regard. Even though an article is not liked, this does not necessarily indicate that it is not of great importance for adolescents. Most articles within the age-appropriate library consist of either coping-related strategies or articles promoting physical activity, which are both beneficial for mental health [270, 271], and may explain why adolescents with persistent pain with relatively high levels of depression scores reported lower depression scores at postintervention.

Recent research evidence by Harrison et al. [149] examining the best evidence for the rehabilitation of persistent pain among adolescents emphasizes the need for including an intensive interdisciplinary pain management approach. However, we have throughout this thesis intended to evaluate the Norwegian *iCanCope with Pain*™ app and its preliminary impacts, with the ongoing link to practical implications because, if a self-management app should be publicly available (with no support), it should be tested using the same approach. Nevertheless, our findings indicate a need to change the trial design including using multiple platforms for communication, helping with the onboarding process, possibly with an interdisciplinary approach could help to improve participant retention by, for instance, aiding to set up relevant goals, help understand the adolescent's pain patterns and provide additional and personalized information and support.

7.3 Future directions

Mobile communication technology is the fastest-growing sector of the communication industry, with over 7 billion registered users worldwide [167]. Estimates revealed that by 2020, more than four out of five phones will be smartphones capable of running sophisticated apps [272]. Although recent systematic reviews indicate that several patient groups may benefit from mobile apps in pain management [173], little is known of the long-term effect among adolescents with persistent pain, emphasizing the need for further definitive full-scale RCTs. Furthermore, because apps may be both a cost-efficient approach and remove barriers to access the intervention [154], studies examining cost-effectiveness should be conducted. Finally, given the high prevalence and increase in pain experience in recent years among adolescents in a school-based population, evaluating self-management apps as a preventive initiative should also be considered.

In terms of Internet-delivered self-management programs, two systematic reviews and meta-analysis concluded that the current quality of research evidence is very low, but has a promising potential to be successful on the clinical effect and socioeconomic benefits, but studies are needed to increase the confidence in this potentially promising field [154, 273]. Further, there are a few Internet-delivered RCTs aiming to reduce pain among adolescents with persistent pain [161-164, 274, 275] and pilot RCTs with preliminary results [276, 277].

However, the sample size is low in all studies (ranging from N=33 to N=69), except in the study by Palermo et al. (2016), which shows methodological strength with a relatively large sample size of 273 participants. Further, the control group undertook an Internet-delivered pain education program and was compared with the iCBT intervention group, wherein the control group was equalized in time, attention and computer usage and thus, not a passive control group [162]. There is a need for further full-scale definitive RCTs remotely delivered by Internet/mobile apps to evaluate the effect of self-management programs for adolescents with persistent pain compared with passive and active controls and other interventions.

It is reported in a longitudinal trial of smartphone pain applications for persistent pain patients that future development and use of smartphone pain apps should have strategies to make the program more engaging over time, and thus improve the motivation because satisfaction ratings seem to diminish over time [278]. In a meta-analysis of RCTs, the overall results indicated that smartphone devices are a promising self-management tool [279], however, e-Health interventions still have inadequate evidence to evaluate the medium- to long-term effects of such interventions, and the potential reduction of incidence of disorders [280]. Therefore, more research is needed to evaluate the medium- to long-term effects.

In the context of cost-effectiveness, Law et al. [281] recently examined the effect of adjunctive iCBT intervention or adjunctive Internet education on healthcare-related economic costs in a cohort of adolescents with persistent pain in the United States. Both groups' healthcare expenditures significantly decreased from the year before the intervention to the year after the intervention. Although the findings indicated that the rate of change in healthcare costs over time did not significantly differ between the two groups, more studies are needed to examine this important economic perspective.

In this new area of research, there is a need for both higher quality and quantity of research evidence. Murray et al. [282] recently published a paper investigating who benefits most from Internet-delivered CBT interventions among adolescents with persistent pain and found that younger adolescents will benefit more than older adolescents and adolescents having parents with low distress will especially benefit [282]. In addition, a few general predictions such as sleep quality and

higher pain intensity were also important for outcome improvements. Still, there are many uncertainties about who benefits most from app-based interventions in a school-based population of adolescents with persistent pain. Research should strive to apply best practice, theory and evidence through appropriate and accessible platforms and further evaluate the efficacy, effectiveness and cost-effectiveness in the long term.

8.0 Conclusions and practical implications

Testing of the Norwegian *iCanCope with Pain*™ app revealed high user satisfaction, ease of use, efficiency and only minor errors cumulatively indicating that no changes to the app were needed, except for facilitating user interaction within the social support feature. These findings provide a promising basis for a further app-based evaluation on a larger scale.

Adolescents with persistent pain report impaired HRQOL, which consequently affected all aspects of their everyday life and indicated the need for future targeted interventions. Our findings revealed that up to 67% of the reduction in the HRQOL subscale psychological well-being was explained by the mediating variable, self-efficacy. These data provide insight into the underlying mechanisms of the associations between pain and HRQOL in a school-based population of adolescents and have important implications for the future practice of pain management interventions, which should aim to increase HRQOL by promoting self-efficacy. Teachers and healthcare nurses should be aware of targeting self-efficacy as a strategy to increase HRQOL.

This study exceeds previous research by testing the feasibility of an app-based self-management intervention in a school-based population of adolescents with persistent pain in Norway. High treatment attrition and low level of engagement indicated the need for changes in trial design, and thus, future trials should consider using multiple platforms for communication and forms of support to improve participant retention. Nevertheless, our findings provide estimates for the calculation of sample sizes in future app-based interventions. Future larger and full-scale definitive trials are needed to evaluate the effect of app-based self-management intervention aiming to reduce pain and improve HRQOL in a school-based population of adolescents.

9.0 References

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Paper I

Original Paper

iCanCope With Pain: Cultural Adaptation and Usability Testing of a Self-Management App for Adolescents With Persistent Pain in Norway

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Abstract

Background: Persistent or chronic pain is a common health problem among adolescents. Thus, it is important that they receive evidence-based strategies for symptom management. *iCanCope with Pain* is a mobile phone app designed to help adolescents cope with chronic pain. The app comprises 5 evidence- and theory-based features: (I) symptom trackers for pain, sleep, mood, physical function, and energy; (II) goal setting to improve pain and function; (III) a coping toolbox of pain self-management strategies; (IV) social support; and (V) age-appropriate pain education. The *iCanCope with Pain* app is based on theory, identified health care needs, and current best practices for pain self-management.

Objective: The objectives of this study were to describe the translation and cultural adaptation of the app into the Norwegian context and evaluate the app's usability using a phased approach.

Methods: Phase 1 included translation and cultural adaptation of the app into the Norwegian context. This process used an expert panel of researchers and target group representatives who were responsible for the linguistic quality assurance and assessment. In phases 2 and 3 the app's usability was tested. For phase 2, the assessments of usability and user experiences included observation, the think aloud method, audiovisual recordings, questionnaires, and individual interviews in a laboratory setting. For phase 3, the assessment of usability and user experience over a 2-week home-based test included questionnaires and individual end-user interviews. Overall, app usability was determined based on ease of use, efficiency, and user satisfaction. Qualitative data were analyzed using deductive content analysis. Descriptive statistics were calculated for quantitative data.

Results: End users did not report any misunderstandings or discrepancies with the words or phrasing of the translated and culturally adapted app. Participants in both the laboratory- and home-based usability tests found the app self-explanatory and reported that all 5 of its features were easy to use. All tasks were completed within the allocated time frame (ie, efficiency), with few errors. Overall System Usability Scale scores were high, with average scores of 82 and 89 out of 100 from laboratory- and field-based tests, respectively. Participants liked the idea of a social support function (feature IV), although qualitative and internet server data revealed that this feature was rarely used.

Conclusions: This study described the cultural and linguistic adaptation and usability testing of the Norwegian version of the *iCanCope with Pain* app. High user satisfaction, ease of use, efficiency, and only minor errors cumulatively indicated that no

changes to the app were needed, with the exception of facilitating user interaction within the social support feature. The app will be used in an upcoming randomized controlled trial with a larger sample.

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KEYWORDS

health; self-management; adolescent; chronic pain; translating; mobile app

Introduction

Background

The prevalence of persistent or chronic pain in nonclinical adolescent populations is increasing and has become recognized as a growing health problem [1-3]. Chronic pain is commonly defined as pain lasting more than 3 months [4]. Previous studies have revealed high prevalence rates (approximately 15% to 35% [5-7]) of chronic pain among adolescents, which increases with age and can negatively impact all aspects of their lives. The consequences include reduced health-related quality of life and physical activity and higher risk for psychosocial problems such as stress, anxiety, and depression [8-11]. Thus, interventions focused on coping and symptom management strategies are needed to prevent adolescents' pain conditions from continuing into their young adulthoods [12,13].

An increasing number of self-management interventions have been developed and are associated with reduced chronic pain among both children and adolescents [14]. Self-management interventions often comprise behavioral therapies and types of cognitive behavioral therapy (CBT), which may include coping skills training, imagery techniques, biofeedback, relaxation, and other symptom management strategies [15]. CBT is effective among chronic pain patients and is thus the preferred intervention for adolescents with different health disorders [16,17]. In their systematic review of the literature in this area, Fisher et al showed that self-management interventions are accessible through computer-based programs or mobile phone apps, and that such interventions may reduce chronic pain intensity among children and adolescents [15].

Adolescents are comfortable using computerized technologies and have reported that internet-delivered self-management interventions are their preferred methods for gaining information about chronic pain and pain coping skills [18,19]. However, many of the available Web-based interventions and apps have not undergone scientific evaluation. For instance, Lalloo et al [20] found a total of 279 apps that focused on pain self-management; only 8% of these had included health care professionals during their development and only 1 had undergone scientific evaluation. Thus, it is important to emphasize that adolescents should receive evidence-based content, including strategies to manage chronic pain conditions, from apps.

The iCanCope With Pain App

The *iCanCope with Pain* app is an evidence- and theory-based pain self-management app [21] that was developed by Dr Stinson and Lalloo, in collaboration with the Centre for Global eHealth Innovation at University Health Network in Toronto, Canada. The app's content was developed by an interdisciplinary team of pediatric chronic pain experts and is based on empirically identified health care needs and current best practices for pain self-management [21]. The app is currently part of an ongoing randomized controlled trial and is thus not publicly available.

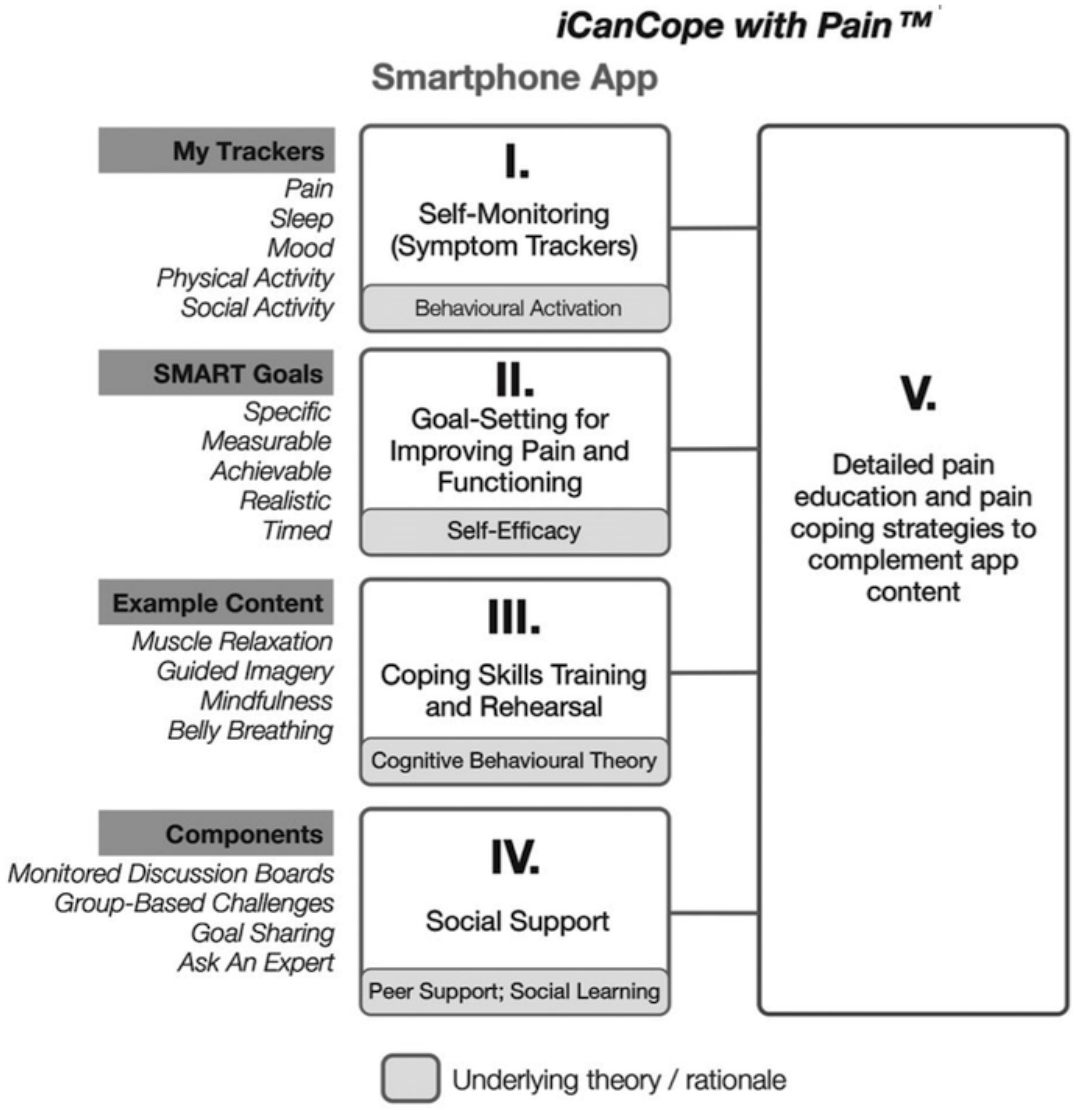
Theoretical Framework

The *iCanCope with Pain* app comprises 5 evidence- and theory-based features: (I) symptom trackers for pain, sleep, mood, physical function, and social function; (II) goal setting to improve pain and function; (III) a coping toolbox of pain self-management strategies; (IV) social support; and (V) age-appropriate pain education. Features I to IV were based on psychological theories and psychotherapies; component V is a pain education library (Figure 1).

Component I is based on behavioral activation therapy, which was originally developed to treat mood disorders and is efficacious for reinforcing engagement with, and motivation for, meaningful activity [22,23]. Allowing adolescents to track and self-monitor their daily symptoms in real time helps them to better recognize their pain patterns and set goals to improve their symptoms. It may also help them identify and be aware of their pain triggers; by tracking symptoms over time, adolescents can also monitor fluctuations in their pain [21,24]. My trackers are integrated as a daily check-in functionality in the app, wherein the adolescents can rate their level of pain intensity, pain interference, mood, physical activity, sleep quality, and energy.

Component II is based on social cognitive theory, originally called social learning theory developed by Albert Bandura, which has influenced our understanding of human behavior [25]. The theory suggests that adolescents' performance or behavior is influenced by their beliefs (cognition) and support by their peers, parents, and teachers. Bandura argues that self-efficacy is the most suitable approach to affecting cognition [26]. Self-efficacy refers to "how well one can execute courses of action required to deal with prospective situations" [27]. Thus, component II was designed to enhance self-efficacy and thereby improve pain and functioning [19]. The development of the app's goals feature was consistent with the SMART framework—specific, measurable, achievable, realistic, and timed [28,29]. Thorough formulation and evaluation of a goal is necessary for success; thus, this method provides a useful standardized tool for users to write and express their own goals in the app.

Figure 1. Conceptual framework showing the theories underlying the Norwegian iCanCope with Pain app for adolescents with persistent pain. Published as the original Canadian illustration. Source: Stinson et al. Used with permission by the original publishers [21].



Component III is based on CBT, with a focus on the interrelations among thoughts, feelings, and behaviors [30]. Consistent with this, adolescents can focus on developing personal coping strategies to solve current problems and change unhelpful cognitive patterns (eg, thoughts, beliefs, and attitudes), behaviors, and emotion regulation [30]. Thus, the aim of component III is personalized self-management instruction in terms of coping skills training and rehearsal, to promote positive changes in mood, behavior, and ultimately pain itself [21]. This component provides several coping strategies to manage pain, including muscle relaxation, guided imagery, mindfulness, and abdominal breathing. In other words, the CBT component of the app aims to provide pain management strategies that help adolescents during everyday life, despite their pain [31].

Component IV, social support, includes both quantitative (eg, number of friends) and subjective (eg, network appraisal) dimensions [32], both of which affect mental health, physical health, and mortality risk, and thus influence health throughout the lifespan [33]. Social support theory and peer support are strongly related to self-efficacy (component II) and healthy activities promotion [34]. Although numerous self-efficacy promotion methods exist, Ashford et al's review [35] showed that vicarious experience (ie, social modeling) and feedback from peers (ie, peer support) are most effective. In the social support feature in the app, the adolescents receive *questions of the day* in monitored discussion boards. Finally, component V is a pain education library, which is integrated together with the coping skills training (component III) in the app.

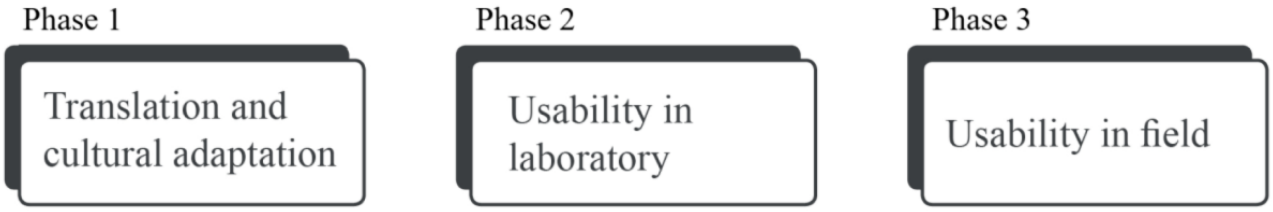
The primary objectives of this paper are to describe the translation and cultural adaptation of the app into the Norwegian context and to evaluate its usability using a phased approach. The phased approach assessed the translated and culturally adapted app's usability and users' experiences with its ease of use, efficiency, satisfaction, and sociability. An additional objective was to identify the users' needs and technical issues, to refine the app for use in a planned prospective randomized controlled trial with a larger adolescent sample.

Methods

Design

During phase 1, the *iCanCope with Pain* app was translated and culturally adapted into the Norwegian language and cultural context. This required a multistep approach, including input by an interdisciplinary group to ensure thorough translation and adaptation. During phases 2 and 3, the app's usability was evaluated. Phase 2 was conducted in a laboratory setting and phase 3 in participants' homes during a 2-week period. Figure 2 illustrates the overall protocol.

Figure 2. Norwegian iCanCope with Pain app translation and usability testing.



Participants

Participants were recruited from a high school in Southern Norway. During phase 1, 2 representatives from the target group (both aged 17 years) participated to ensure that the app translation and cultural adaptation were appropriate for their age group. During phase 2, 6 adolescents (aged 17 to 18 years) were recruited for a laboratory-based usability test. During phase 3, 5 adolescents (aged 16 to 18 years) were recruited for a 2-week home-based test to evaluate user experiences with the app over time and to identify additional user needs. Both usability tests were gender-balanced and included users of both Android and iOS operating systems to best represent the target group for an upcoming clinical trial. The inclusion and exclusion criteria for the phase 3 end-user group were also consistent with those planned for the upcoming clinical trial. We included 16- to 19-year-old adolescents with persistent pain (weekly pain lasting 3 or more months based on subjective reporting) who were able to read and understand Norwegian and owned a mobile phone. Adolescents with cognitive disability or diseases were excluded because of their inability to correctly understand the *iCanCope with Pain* app, goal setting, or library readings. Adolescents with painful health conditions from a pathological or medical origin (eg, hematology/oncology patients) were excluded as the program was not specifically designed for these patient groups.

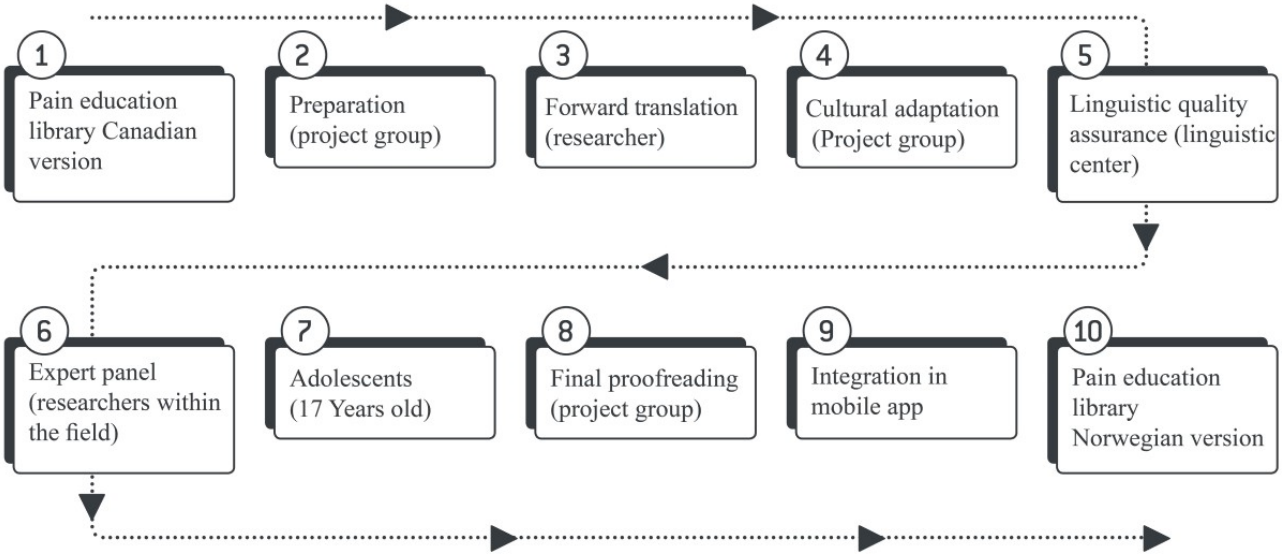
Phase 1: Translation and Cultural Adaptation

A 2-stage approach was used for language and cultural adaptation of the original Canadian *iCanCope with Pain* app [21] to the Norwegian context, based on the principles of good practice for translation and cultural adaptation explained by Wild et al [36]. The first stage addressed the age-appropriate pain education library and the second stage addressed the software interface text of all features.

Pain Education Library

The first stage was a 10-step process to ensure quality translation and adaptation of the age-appropriate pain education library to a Norwegian context, as illustrated in Figure 3. The first steps (1 to 4) were conducted by the project group and first author; these steps comprised preparation and forward-translation to Norwegian, followed by cultural adaptation, in which typical Canadian names, sports, and sayings were replaced with Norwegian versions (eg, dragon boat racing is not well-known in Norway). Quality assurance (step 5) was carried out by native Norwegian and English speakers at the linguistic service center at the University of Agder (UiA). In this step, the original Canadian English version was compared with the translated Norwegian version to assess linguistic equivalency and correct spelling. In addition, an expert panel of researchers within the field of pain ensured (step 6) that the 2 versions were conceptually equivalent. Furthermore, 2 adolescents assessed the pain education library (step 7) to ensure that its content was clear and easy to understand by their age group. A final proofreading (step 8) was conducted before formatting (step 9) each article in the pain education library as HTML to be added (step 10) to the Norwegian *iCanCope with Pain* app.

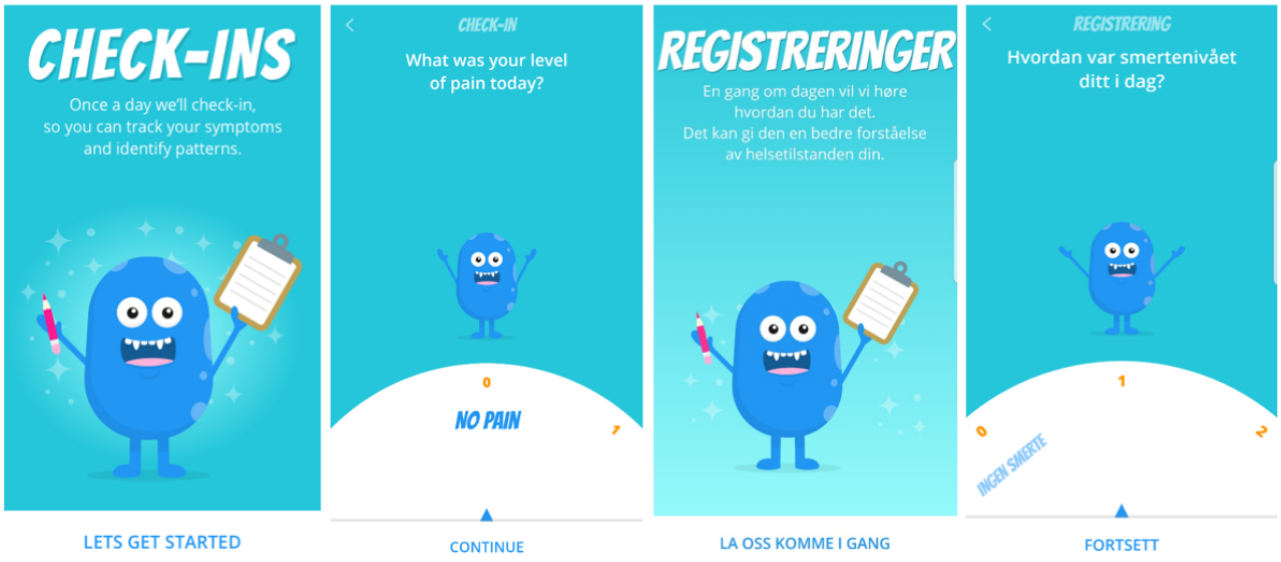
Figure 3. The 10 steps of translation and cultural adaptation of the iCanCope with Pain app's pain education library.



Software Interface Text

The second stage also followed the principles set forth by Wild et al to ensure credibility and understanding [36] and included another 10 steps: (step 1) preparation; (step 2) forward translation; (step 3) reconciliation; (step 4) back translation; (step 5) back translation review; (step 6) harmonization; (step 7) cognitive debriefing; (step 8) review of cognitive debriefing results and finalization; (step 9) proofreading; and (step 10) final report. The software interface text was prepared and translated into Norwegian by the authors (steps 1 and 2, respectively), then merged into a common version (step 3), and translated and validated back into English by personnel at the linguistic service center (steps 4 and 5, respectively). A comparison of multiple language versions was not possible as the *iCanCope with Pain* app was only available in the Canadian English language of the original version (step 6). A cognitive debriefing was conducted with the end users after the usability field test (phase 3) to check its understandability and cultural relevance (step 7). Review of the cognitive debriefing, proofreading, and final report were assessed by the project group (steps 8, 9, and 10, respectively). The Norwegian software interface text was then integrated into the *iCanCope withPain* app by the Centre for Global eHealth Innovation (Canada), with adjustments to user interface size and layout to accommodate different word lengths for various screen sizes and forms. See Figure 4 for example comparisons of the Norwegian and Canadian software interfaces.

Figure 4. Screenshots of the Norwegian and Canadian user interface versions of the iCanCope with Pain app. Published with permission from the Centre for Global eHealth Innovation (Canada).



Phase 2: Usability Test in Laboratory Setting

Before the laboratory usability test, 2 pretests were used to assess the protocol, logistics, and technology, and to determine the amount of time the tests would take, the number of participants needed, the number of tasks, and the level of app complexity. The 10 resulting predefined tasks had a stipulated time frame of approximately 1 min per task.

The task tests were carried out at the UiA laboratory facilities over 2 days with 6 adolescent participants. The laboratory facilities house control and test rooms are separated with a 1-way mirror (facility details have been previously reported by Gerdes et al) [37]. Each participant participated individually and spent approximately 60 min on research team–administered tests. Each test was conducted according to the pretested protocol, in order of: (1) 10 predefined tasks; (2) System Usability Scale (SUS) questionnaire [38]; and (3) interview. We have followed the definition by the International Organization for Standardization (ISO) by evaluating the usability in terms of the ease of use (effectiveness), efficiency, and satisfaction. The official ISO 9241-11 definition of usability is: "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" [39].

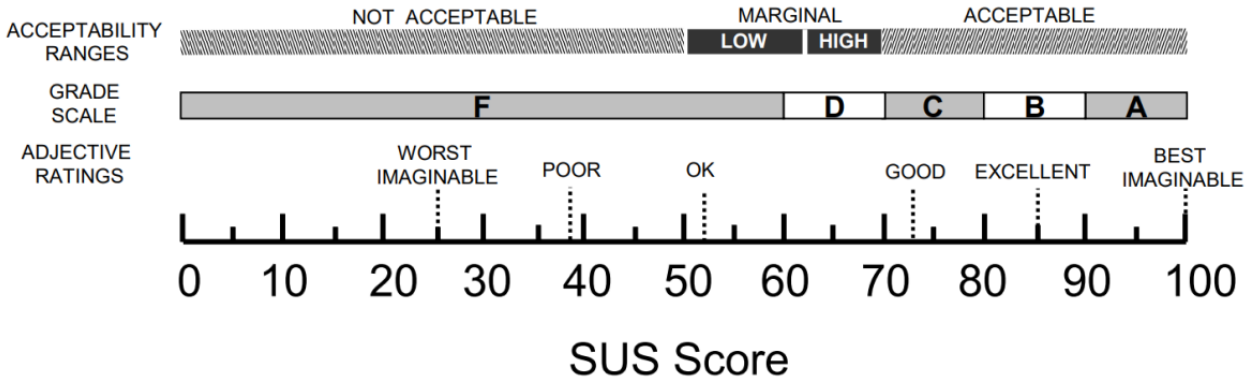
Ten Predefined Tasks

Each participant completed 10 predefined tasks corresponding to the 5 app components (Figure 1): (1) conduct a daily check-in; (2) create a goal; (3) coping skill training; (4) change goal; (5) library search; (6) create a post in the social support group; (7) complete a goal; (8) change user profile; (9) change pain area and symptoms; and (10) view history of daily check-in. The tasks were presented to each participant on a sheet of paper. Participants could ask for help at any time, in which case help was interpreted as a moderator intervention, tabulated, and annotated. Participants also performed the think aloud (TA) method [40] while solving tasks. In the TA, participants verbalize what they are thinking as they perform a task. This method is frequently used to gain insight into users' thoughts during a usability test [40]. Observations and audio and visual recordings were collected using a set of cameras and microphones that recorded the user interface, running commentary, and physical interactions with the app. A minimum of 2 researchers were present during each test. The ease of use and technical errors were evaluated based on the number of completed tasks and total errors. A completed task was defined as a task successfully achieved by the participant [41]. An error was defined as an incorrect selection, gesture, or landing on a screen triggered by a participant. The app efficiency was evaluated based on the time needed to achieve the tasks, expressed as the mean task completion time [41].

System Usability Scale Questionnaire

The SUS questionnaire was used to evaluate user satisfaction and comprised 10 open-ended polarity-balanced questions with a 5-point Likert scale for responses. The average scores were categorized based on the adjective ratings [42], as shown in Figure 5.

Figure 5. Adjective ratings, acceptability ranges, and school grading scales, in relation to the average System Usability Scale (SUS) score. Source: Bangor et al. Used with permission by the original publishers [42].



Interview

Finally, individual posttest semistructured interviews were conducted to assess user experiences with the app. The interview guide included 14 open-ended questions based on the 5 app components (Figure 1) and 3 additional categories for potential improvements, usage considerations, and coping. These predefined categories were considered ideal for ensuring a systematic assessment of the app and thus created a basis for the structured categorization matrix.

Phase 3: Field Usability Test

A total of 5 adolescents with persistent pain tested the Norwegian *iCanCope with Pain* app continuously over a period of 2 weeks to assess user experience over time and to identify any need for further assistance while using the app. The participants answered an electronic survey that was equivalent to the baseline questionnaires (which will also be included in the upcoming clinical trial) to ensure that they fulfilled the inclusion criteria (eg, the Lübeck Pain questionnaire [7] for assuring the presence of pain and pain experience for 3 or more months). A detailed description of each questionnaire is available at ClinicalTrials.gov using ID NCT03551977. Each participant received an email with their username and password and an accompanying brief written introduction to the app's features. Participants were also given a researcher's phone number and email address, in case they needed technical assistance at any time during their 2-week participation. Participants were asked to download the app from the App Store or Google Play for their iOS- or Android-based mobile phone, respectively, after which they were to start the app and log in. User experience was assessed at the end of the 2 weeks using the SUS questionnaire and individual semistructured interviews.

Data Analysis

The data collected (eg, internet server data, observation, audiovisual recordings, and interviews) corresponded to the 5 app components. Quantitative laboratory usability test (eg, task

completion, time, errors) measures were evaluated based on users' interactions with the app and to assess the app's ease of use and efficiency. In both usability tests, quantitative data from the SUS questionnaire (10 questions, each scored from 0 to 4 points) were transformed by multiplying by 2.5 to convert scores to a 0 to 100 range and were categorized adjectivally [42]. Descriptive statistics were analyzed using IBM SPSS Statistics for Windows, version 25.0 (IBM Corp). Both usability tests followed the same semistructured interview guide, comprising 14 open-ended questions. The 5 predefined theory-based app components (ie, self-monitoring, goal setting, coping skills training, social support, and pain education library) were the basis for developing a structured categorization matrix using deductive content analysis [43]. The collected data were coded according to 8 predefined categories, including the 5 components, potential improvements, usage considerations, and coping. Interview responses were transcribed verbatim using NVivo for Windows (QSR International Pty Ltd, version 12, 2018).

Ethics

The study was approved by the Norwegian Regional Committee for Medical Research Ethics South-East-B (REK reference 2017/350). Participants were informed verbally and in writing that their participation was voluntary, that they could withdraw at any time without a reason (in which case their data would be deleted and destroyed), and that confidentiality and anonymity of their data were ensured at all times. Participants signed informed consent forms before participating.

Results

Phase 1: Translation and Cultural Adaptation

The participants did not report having any misunderstanding about or finding discrepancies with the words or phrasing (eg, meaning or activities) of the translated and culturally adapted pain education library, in either usability test. In addition, participant interviews and debriefings in the field usability test (phase 3) were conducted to ensure credibility and understanding of the software interface text. Overall, the participants found the software interface text, which comprised single words and short sentences, easy to understand and interpret, and found the phrasing suitable for their age group.

Phase 2: Laboratory Usability Test

Participants successfully downloaded the Norwegian version of *the iCanCope with Pain* app and logged in using their mobile phones. After logging in, participants created a mock user profile. They reported finding it easy to perform a daily check-in and liked the idea of monitoring pain patterns, which could contribute to a better understanding of their pain experience. The continuous presence of the avatar figure that changed both face and body expressions according to a numeric scale during registration and feedback made the app easy to use and self-explanatory. However, there were also comments that the profile's avatar *looked a bit childish*. These participants found it motivating to set goals and read articles in the library section based on those goals. All participants reported that they would recommend the app to others and appreciated the range of pain coping strategies. One participant said:

> *Hmm, actually it seems like it [the app] has control. So, there is a lot of information. I did not understand at first how an app may help with pain when I first heard about it, but I get it now when I see what it is, yes.*

Participants in the laboratory usability test did not make any suggestions regarding how the app could be improved; thus, no adjustments were made before the home-based usability test.

User Satisfaction

User satisfaction scores (0 to 100) in the laboratory usability test are shown in Table 1. The average score was 82 out of 100, categorized as *good* and just below *excellent* [42]. The color-based visualization scheme is a modified version of that recommended by Smaradottir et al [44], wherein green represents a positive response, yellow a neutral response, and red a negative response.

Table 1. System Usability Scale questionnaire scores from the laboratory usability test.

Questions	P1[a]	P2	P3	P4	P5	P6	Mean (SD)
I think that I would like to use this app frequently	3[b]	3[b]	3[b]	3[b]	4[c]	4[c]	3.3 (0.5)
I found this app unnecessarily complex	2[c]	2[c]	2[c]	1[c]	2[c]	1[c]	1.6 (0.5)
I thought this app was easy to use	5[c]	4[c]	4[c]	4[c]	4[c]	5[c]	4.3 (0.5)
I think I would need assistance to be able to use this app	1[c]	3[b]	1[c]	1[c]	2[c]	4[d]	2 (1.3)
I found the various functions in this app to be well integrated	5[c]	5[c]	4[c]	4[c]	3[b]	5[c]	4.3 (0.8)
I thought there was too much inconsistency in this app	2[c]	2[c]	2[c]	1[c]	1[c]	1[c]	1.5 (0.5)
I imagine that most people would learn to use this app very quickly	4[c]	5[c]	3[b]	5[c]	5[c]	4[c]	4.3 (0.8)
I found this app very cumbersome/awkward to use	1[c]	2[c]	2[c]	1[c]	1[c]	1[c]	1.3 (0.5)
I felt very confident using this app	5[c]	4[c]	3[b]	5[c]	5[c]	4[c]	4.3 (0.8)
I needed to learn a lot before I could get going with this app	1[c]	3[b]	1[c]	1[c]	2[c]	1[c]	1.5 (0.8)
Scores	87.5	72.5	75	90	82.5	85	__[e]
Average	82	—	—	—	—	—	—

[a]Px: participant x.

[b]Neutral response: neither agree nor disagree.

[c]Positive response: agree or strongly agree for positive questions; disagree or strongly disagree for negative questions.

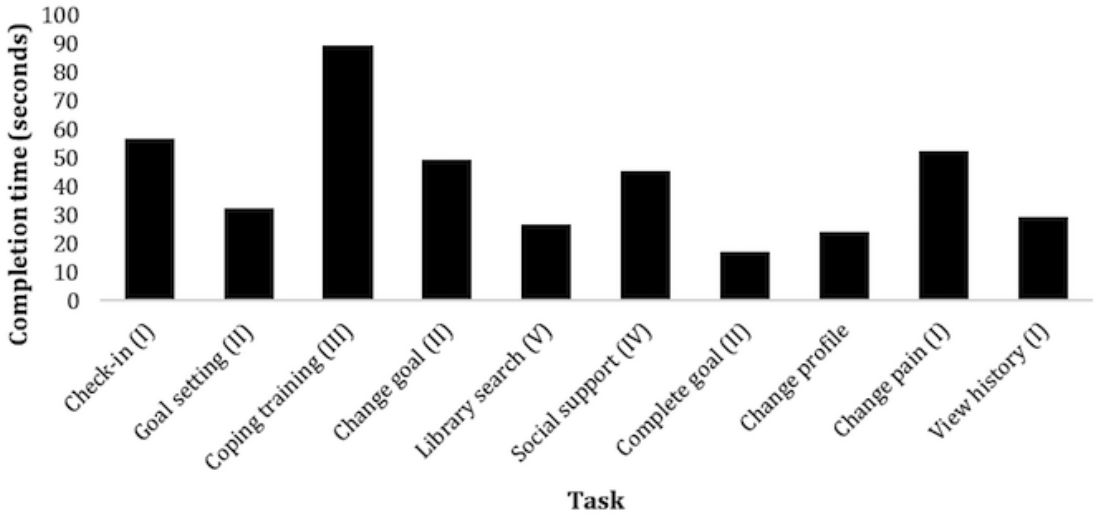
[d]Negative response: agree or strongly agree for negative questions; disagree or strongly disagree for positive questions.

[e]Not applicable.

Ease of Use and Efficiency

Each participant completed all 10 predefined tasks. As participants progressed through the tasks, some unwanted screen landings or touches were registered as errors. The predefined tasks were completed within the stipulated time frame. Task 3 was expected to be more time consuming as it required the participants to first find a specific article about coping, read the article quietly to themselves, and then read the preferred information bullet points aloud. Efficiency scores are presented in Figure 6 as the mean time in seconds for the completion of each of the 10 predefined tasks related to the 5 app components (I to V).

Figure 6. Mean completion time in seconds (0 to 100) for each laboratory usability test task (N=6).



Phase 3: Field Usability Test

The daily check-in (ie, self-registration) feature is intended to give users insight into, and an overview of, how they are coping with pain. In total, 4 of the 5 participants used the daily check-in almost every day, primarily after school, with an average of 10.5 check-ins during the 14 testing days. One participant commented, “It [check-in functionality] was a reason for using the app every day” and that “I will miss doing it.” However, 1 participant only used the daily check-in twice and explained in the interview that this was because the app became a reminder

of the pain; even positive feedback from the avatar figure *Copey* after a daily check-in was interpreted as negative by this participant, as it was either *too positive* or *just a reminder that I struggled*. Participants created an average of 2.2 goals during the test period. Most goals were related to physical activities, such as participation in soccer practice or burning 200 kcal by running. They also created goals regarding sleep and energy. The participants reported that they appreciated the ability to set goals, said it was a motivating feature, and found it easier to achieve goals when they were written down. The library provided age-appropriate information and pain coping strategies; the participants found this easy to use and interesting, as it offered articles and exercises. One participant reported, "There was a lot of variation in the articles, and I even read about things that I had not related to with my type of pain..." Another participant mentioned that he/she liked using the app in private settings, as he/she did not want to go to a psychologist. Participants favored articles related to CBT, distraction techniques, and help with developing a treatment plan. None of the participants asked for additional help or experienced any technical issues during the test period; thus, no technical issues, help, or user training needs were identified.

User Satisfaction

The average user satisfaction score (0 to 100) for the field usability test is shown in Table 2. Participants' average score was 89, categorized as *excellent* and below *best imaginable* [42].

Table 2. System Usability Scale questionnaire scores from the field usability test.

Questions	P1[a]	P2	P3	P4	P5	Mean (SD)
I think that I would like to use this app frequently	4[b]	2[c]	5[b]	3[d]	4[b]	3.6 (1.1)
I found this app unnecessarily complex	1[b]	2[b]	1[b]	1[b]	2[b]	1.4 (0.5)
I thought this app was easy to use	5[b]	5[b]	5[b]	5[b]	5[b]	5 (0)
I think that I would need assistance to be able to use this app	1[b]	1[b]	1[b]	1[b]	1[b]	1 (0)
I found the various functions in this app were well integrated	5[b]	4[b]	5[b]	5[b]	5[b]	4.8 (0.4)
I thought there was too much inconsistency in this app	2[b]	3[d]	1[b]	1[b]	2[b]	1.8 (0.8)
I would imagine that most people would learn to use this app very quickly	5[b]	5[b]	5[b]	5[b]	5[b]	5 (0)
I found this app very cumbersome/awkward to use	1[b]	1[b]	1[b]	1[b]	1[b]	1 (0)
I felt very confident using this app	3[d]	2[c]	5[b]	4[b]	5[b]	3.8 (1.3)
I needed to learn a lot of things before I could get going with this app	1[b]	2[b]	1[b]	2[b]	1[b]	1.4 (0.5)
Scores	90	72.5	100	90	92.5	__[e]
Average	89	—	—	—	—	—

[a]Px: participant x.

[b]Positive response: agree or strongly agree for positive questions; disagree or strongly disagree for negative questions.

[c]Negative response: agree or strongly agree for negative questions; disagree or strongly disagree for positive questions.

[d]Neutral response: neither agree nor disagree.

[e]Not applicable.

Sociability

Sociability refers to the app's ability to facilitate user interactions with peers [45]. All participants reported that, in theory, this was a promising idea that would allow them to share their experiences and motivate each other within a social support group. However, only one of the participants made posts to this functionality. This participant explained how this feature could have been improved, including switching to a single chat option with a health care professional (ie, physical therapist), options to create groups with other adolescents who experience similar types of pain, and that questions in the community function should focus on pain coping strategies. No changes were made to refine the app for the upcoming clinical trial on this basis, except to facilitate interaction with peers in the community function.

Discussion

Principal Findings

Here, we have described the process of translation and cultural adaptation of the *iCanCope with Pain* app into a Norwegian context, and outcomes of 2 usability tests. Our adolescent study participants did not report having any misunderstanding of or finding discrepancies within the words or phrasing of the translated and culturally adapted app. The laboratory usability tests showed that all 10 predefined tasks were completed within the allocated time frame (ie, were efficient) and were reported to be easy to use. Furthermore, both usability tests showed that the app was self-explanatory, with high satisfaction scores. One home-based usability test participant reported that the app became a reminder of their pain. The community functionality

(social support) in the app was rarely used. No technical issues, help, or user training needs were identified.

A 2-stage multistep approach was considered necessary to culturally adapt the app content. The thorough approach used herein may explain why participants found the Norwegian *iCanCope with Pain* app text suitable for their age group, with no discrepancies in phrasing or words. Although several translation and cultural adaptation techniques have been previously described, with different strengths and weaknesses, a transparent and thoroughly described procedure is essential [46]. Nevertheless, 8 steps have been recommended as a minimum when conducting a stepwise translation and adapting instruments intended for a clinical context [47]. In addition, the concept of functional equivalence in cross-cultural research involving adolescents [48] is particularly important; for example, adolescents might engage in different behaviors and understand meanings differently across diverse cultures. Nevertheless, no misunderstandings regarding activities or meanings were reported in this study.

The original Canadian *iCanCope with Pain* app underwent rigorous development and testing through a user-centered design for adolescents with chronic pain, based on their unique health care needs [21]. Furthermore, the *iCanCope with Pain* app is currently under evaluation for use by those with other health conditions, such as arthritis and sickle cells disease [49]. Such preparatory work should be highlighted as it may explain why we failed to identify any technical issues or the need for any additional user assistance or training in either of our usability tests. In addition, this may explain why we found high user satisfaction in both usability tests, with the highest scores among the participants who interacted with the app over time in their natural home environments. These participants reported that they were able to relate specifically to the different app components and thus provided the most valuable feedback from an end-user perspective [50,51].

Despite the participants' reports that they liked the idea of an app component that would allow them to seek social or peer support, this functionality was rarely used. Nevertheless, research has shown the advantages of peer support delivered via apps, which may provide effective interventions and alleviate stress within other health care systems [52]. Forgeron et al concluded their systematic review by noting that adolescents with chronic pain have peer relationship deficiencies [53]; however, we expect that the rare use of social support in this study was more likely because of our low number of participants. Regardless, social (or peer) support plays a protective role for adolescents with chronic pain and is important for their social development [54].

The app was designed for a generic target group of adolescents with persistent pain originating from different etiologies. Our participants reported appreciating that they were able to access the app from home after school and learn from psychological strategies in the app, which were the most popular articles. Given the free time of adolescents may be limited, measures such as high efficiency (tasks completed within the allocated time frame) and ease of use might be of great importance, by not taking much of the adolescents' free time. Accessibility of the internet, with options for what, when, and where to read, and creating their own goals could be beneficial for adolescents who might be in a stressful stage of life with school and everyday activities, and for those who may find traditional psychological therapies delivered by adults more difficult [55]. One participant in our study mentioned that he/she did not want to go to a psychologist, possibly reflecting adolescents' perceived stigma with psychotherapy that has been previously reported [21,55,56]. Mobile phones may have several advantages compared with traditional face-to-face treatments, including their 24/7 availability, pocket size, interactive nature, and flexible programming [57]. However, 1 participant in our study also stated that the app served as a pain reminder and thus was a nonpreferred coping approach. Consistent with this comment, technology and apps for coping may not be suitable methods for empowering all adolescents who experience persistent pain [21].

Limitations

Several study limitations must be considered. TA was used during tasks to confirm when participants started and ended each of the predefined tasks, providing valuable insight into users' thoughts and actions [40]. However, not all participants found it natural to verbalize the task as they were performing it, which may have influenced task efficiency because of higher cognitive loads. This may call into question the reliability and validity of these data [58]. Another limitation is that we used convenience sampling of the adolescents, who conducted the translation and cultural adaptation procedure (phase 1) and who served as participants in the laboratory usability test (phase 2). Furthermore, only 2 adolescents were included in phase 1. These adolescents might have related their use of the app in a more hypothetical manner. Ideally, all participants should have been end users, who are known to provide the most valuable feedback [40]. However, recruiting end users was only possible in the final study phase (phase 3) as the first 2 phases were conducted before recruitment for the randomized controlled trial. Participants suggested several potentially valuable improvements that were not feasible. For example, including health care support would make the app a class 2 medical device, and creating groups based on different pain areas was limited by funding and did not correspond with the upcoming trial design. Finally, the app was originally developed and user-tested by groups with a relatively larger age range [21,49] than was used in this study, suggesting that our assessments may not generalize to a larger population. However, our sample was recruited specifically to match the criteria for the upcoming trial, to which they likely generalize.

Conclusions

This study presented the process of language and cultural adaptation and 2 usability tests for the Norwegian version of the *iCanCope with Pain* app. High user satisfaction, ease of use, efficiency, and only minor errors cumulatively indicated that no changes to the app were needed, with the exception of facilitating user interaction with peers within the social support feature. Despite this, iterative usability testing was fundamental to ensuring that the app is cross-culturally valid and easy to use,

before it is used in an upcoming randomized controlled trial with a larger sample.

Acknowledgments

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Authors' Contributions

KH, LF, SH, and JS developed the project protocol and contributed to the study design. SM and EG were responsible for usability tests. EG, CL, KH, LF, and SH were responsible for the translation and cultural adaptation and data analysis. All authors contributed to the manuscript preparation and approved its final version.

Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy
ISO: International Organization for Standardization
SUS: System Usability Scale
TA: think aloud
UiA: University of Agder

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Paper II

Health and Quality of Life Outcomes

RESEARCH Open Access

Health-related quality of life in adolescents with persistent pain and the mediating role of self-efficacy: a cross-sectional study

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Abstract

Background: Persistent pain has a high prevalence among adolescents. Pain has been shown to reduce all aspects of the adolescent's health-related quality of life (HRQOL). In adult patients with pain, self-efficacy has been shown to mediate the relationship between pain intensity, disability and depression. However, little is known about whether self-efficacy acts as a mediating variable in the relationship between persistent pain and HRQOL sub-scale scores in a school-based population of adolescents.

Objectives: To describe the experience of pain, HRQOL and self-efficacy, and to explore the association between pain intensity, general self-efficacy and HRQOL in adolescents with persistent pain by testing self-efficacy as a possible mediator.

Methods: The study participants were 78 adolescents with persistent pain, aged 16–19 years, who were recruited from five high schools in southern Norway. All participants completed an electronic survey consisting of the Lubeck Pain Questionnaire, which included a visual analogue scale (VAS) measuring pain intensity, the General Self-Efficacy Scale (GSE) and the KIDSCREEN-52 Questionnaire measuring HRQOL. Statistical analyses were conducted using the PROCESS macro for SPSS developed by Andrew Hayes.

Results: All participants reported pain in multiple locations, of which the head was most common (88.5%). Mean (SD) pain intensity score of the participants was 5.4 (1.8). The study sample had poor HRQOL, with mean (SD) scores for several sub-scales ranging from 45.2 (21.0) to 91.0 (13.3) on a 0–100 scale. The associations between pain intensity and the HRQOL sub-scales of physical well-being, psychological well-being, mood, self-perception, autonomy and school environment were mediated by self-efficacy. The highest degree of mediation and, thus, the largest indirect effect was estimated for the HRQOL sub-scale physical well-being (67.2%).

Conclusions: This school-based sample of adolescents with persistent pain had impaired HRQOL. Up to 67% of the reduction in the HRQOL sub-scale scores for physical well-being, psychological well-being, mood, self-perception, autonomy and school environment could be explained by the mediating variable self-efficacy. Thus, future pain-management interventions that aim to increase HRQOL in school-based populations of adolescents with persistent pain should consider promoting self-efficacy and providing more targeted interventions.

Trial registration: ClinicalTrials.gov ID NCT03551977.

Keywords: Adolescents, Health-related quality of life, Persistent pain, Self-efficacy, Mediation

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Introduction

Persistent or chronic pain among adolescents is recognized as a global growing health problem. Headache, abdominal pain and back pain are most commonly reported, but these frequently coexist with persistent pain at multiple locations [1, 2]. Pain in adolescence is often complex, may have no clear cause and can include cycles of flares [3]. Chronic pain is defined as persistent or recurrent pain lasting more than 3 months [4]. Internationally comparable data indicate that persistent pain is highly prevalent among adolescents [5]. Research indicates that the prevalence of persistent pain among adolescents in Western countries ranges from 20 to 35%, is clearly higher in girls than in boys and increases with age [6–11]. The national annual Young-data surveys have revealed an increase in psychosocial complaints among Norwegian adolescents attending high schools, herein about half of the adolescents have concerns like "everything feels like a struggle" [12]. Further, Norwegian adolescents have reported that the feeling of stress and struggle may be a contributing factor to their pain experience [13]. However, persistent pain in a school-based (non-clinical) population of adolescents usually has an unconfirmed aetiology with no underlying pathological condition or apparent single explanation [14]. Thus, further insight into the complexity of pain associations in adolescence is needed.

Persistent pain in adolescence has several consequences. Short-term consequences may include absence from school and social activities, resulting in periods of isolation from peers and role loss, which may explain why adolescents with pain tend to have fewer friends compared with healthy adolescents [3, 15, 16]. In addition, pain that begins in adolescence may have long-term consequences if the adolescents enter adulthood suffering persistent pain, which carries risks of psychosocial and socio-economic distress [17, 18] Other long-term consequences include higher levels of perceived stress, sleep disturbance, reduced physical activity and overall reduced health-related quality of life (HRQOL), which all negatively affect different aspects of the adolescent's everyday life [19, 20].

HRQOL is a multidimensional concept that includes physical, psychological, social and spiritual aspects of life [21]. The concept of HRQOL is often used when assessing how pain can influence the daily life of adolescents, because pain impacts all aspects of life [22, 23]. Several studies that examined the association between pain and HRQOL among adolescents showed that persistent pain is associated with reduced HRQOL [10, 20, 22–25]. There are several questionnaires that measure HRQOL, of which KIDSCREEN-52 has been shown to have the best structural validity [26]. However, there is limited research investigating HRQOL and pain in a school-based population of adolescents using the 10 sub-scales of the KIDSCREEN-52 questionnaire [27]. A Norwegian study showed that pain in children and adolescents was associated with lower HRQOL demonstrated by reduced scores for all 10 sub-scales of the KIDSCREEN-52 questionnaire, but had the greatest effect on the HRQOL sub-scales of self-perception, psychological well-being, mood, relationship with parents and school environment [27]. Further research on pain and HRQOL in a school-based sample of adolescents is needed to explore whether this association can be explained by underlying mechanisms or is related purely to the pain itself.

Self-efficacy, defined by Albert Bandura as "one's beliefs in one's capability to organize and execute the courses of action required to achieve given results", is well-known to affect a person's cognition [28, 29]. In adults, general self-efficacy (GSE) has been shown to positively impact QOL by reducing stress and, thereby, increasing QOL [30, 31]. In young adolescents, a higher degree of self-efficacy has been shown to be related to higher HRQOL scores [32], and has been associated with several positive health outcomes for adolescents with chronic pain, including higher self-esteem and acceptance, and lower disability and somatic symptoms [33, 34]. In a sample of adolescents with chronic headache, higher self-efficacy was associated with improved school performance and lower disability [35].

Previous research evidence has shown that self-efficacy acts as an underlying mechanism by mediating the relationship between pain-related fear and school-related disability in adolescents with chronic headache [36]. In adults with chronic pain, self-efficacy was found to be a mediator of the relationship between pain intensity, disability and depression [37]. Bandura has proposed that self-efficacy might act as a mediator between stressful experiences and outcomes such as well-being [38]. However, no study has investigated whether self-efficacy acts as a possible mediator of the relationship between pain and HRQOL in a school-based sample of adolescents.

Thus, the purpose of this study was to describe the pain experience (intensity, frequency, duration and location), HRQOL and GSE in a sample from a school-based population of adolescents with persistent pain, and to assess possible associations between pain intensity, GSE and HRQOL. We hypothesized that pain intensity is negatively associated with HRQOL, and that self-efficacy plays a role as a mediator.

Methods

Design and aim

Data for this cross-sectional study were collected at baseline during an intervention study that aimed to help reduce pain and promote HRQOL in Norwegian adolescents with persistent pain using a smartphone application called iCanCope with Pain™.

Setting of the study

The study was conducted in southern Norway in 2018. All government-funded high schools within an area of 10 miles, were invited to participate. The area includes about 100,000 habitants. No high schools were excluded or disagreed to participate. The parents of the attending adolescents had varied level of education, here used as a proxy for socio-economic status, thus we consider our sample to be representative of a population of adolescents with different levels of socioeconomic status (SES). We included 16–19-year-old adolescents with persistent pain (weekly pain lasting 3 months or more) who were able to read and understand Norwegian and used their own smartphones. Adolescents with cognitive disabilities were excluded because of their inability to understand how to use the *iCanCope with Pain* application, goal setting and/or library readings. Adolescents with pain of pathological or medical origin (e.g., arthritis/oncology patients) were excluded because the program was not specifically designed for these patient groups.

Procedure

The primary author visited all high schools and informed each class about the study. To ensure anonymity and confidentiality, adolescents received oral and written information in the classroom with an attached email address generated solely for the purpose of this study. Information was also available on the high schools' websites. Those who wanted to participate in the study could send an email to the research study email address. The data collection period lasted 3 months. All participation was voluntary, and participants provided written informed consent before participating in the study. They were aware that they could withdraw without a reason at any time during the study, in which case their data would be deleted and destroyed, and that the confidentiality and anonymity of their data were ensured at all times. The study was approved by the Norwegian Regional Committee for Medical Research Ethics South-East-B (REK reference 2017/350).

Measures

The electronic survey tool used in our study was designed to consecutively administer the following respective questionnaires. The adolescents were free to end the electronic survey at any time. Most questions included a neutral option, thus resulting in all items being answered. The electronic survey was pre-tested [39]. The first page of the survey contained demographics information such as age, gender and parental education. Parental education levels were used to indicate the participants' socioeconomic status (SES).

Pain

To assess pain, the Norwegian version of the Lübeck Pain-Screening Questionnaire (LPQ) was administered, which has demonstrated satisfactory content validity and high internal consistency (Cronbach's alfa 0.92) [6]. The LPQ aims to identify both the presence and consequences of pain with a recall period of 3 months. For the present study, pain intensity was digitally measured using a visual analog scale (VAS) ranging from 0 (no pain) to 10 (worst pain imaginable). This VAS is a well-known measure of pain intensity, has been found to be both valid and reliable [40, 41], and has been validated for digital use [42]. Pain duration was recorded in three categories: pain lasting more than 3 months, more than 6 months or more than 12 months. Pain frequency was defined as how often pain was experienced and was categorized as daily pain, several times a week or once a week. Pain location referred to pain in specific body regions. Multi-site pain was defined as pain in a least two of the following predefined regions used by the LPQ: head, ears, teeth, throat, chest, back, stomach, reproductive organs (pain during menstruation), arms, legs or other locations.

HRQOL

To assess HRQOL, the Norwegian-translated and validated version of KIDSCREEN-52 was administered [16]. The KIDSCREEN-52 questionnaire is a cross-cultural multi-dimensional instrument that has been validated in several countries with internal consistency above 0.80 (Cronbach's alfa) for all dimensions [16, 43, 44], and consists of 52 questions using a 1–5 Likert scale grouped into 10 sub-scales comprised of different numbers of items: physical well-being (five items), psychological well-being (six items), moods and emotions (seven items), self-perception (five items), autonomy (five items), relationship with parents (six items), social support (six items), school environment (six items), bullying (three items) and financial resources (three items) [45]. Next, we followed the KIDSCREEN manual and transformed negative questions into positives [43], after which the data were transformed to a linear 0–100-point scale, where the lowest possible HRQOL scored 0 and the highest HRQOL scored 100.

Self-efficacy

To assess self-efficacy, the Norwegian 5-item version of the General Perceived Self-Efficacy Scale (GSE) revised and translated by Røysamb and colleagues (1998) was administered [46]. The GSE scale originally included 10 items and was developed by Jerusalem and Schwarzer [47]. The short form of the GSE scale has also been found to be valid and reliable with satisfactory internal consistency (Cronbach's alfa 0.82) [48, 49]. GSE is a psychometric scale developed to identify a person's

optimistic self-belief in coping, often defined as one's global confidence in one's ability across a wide range of demanding and novel situations [47]. In the independent versions of GSE, all items use a 1–4-point scale, where 1 refers to the lowest GSE and 4 the highest. Hence, the total score for the five GSE items ranges from 5 (lowest) to 20 (highest total score), where higher scores indicate higher GSE.

Statistical analyses

The statistical analyses were conducted using IBM SPSS Statistics for Windows (version 25.0; IBM Corp., Armonk, NY). Demographic data were described using descriptive measures. The study variables pain intensity, GSE and 9 out of 10 HRQOL sub-scales had skewness values of ±0.5 and kurtosis values of ± 1, which indicated that these variables are approximately normally distributed. Continuous variables were described by mean and standard deviation, and categorical variables by frequency and percentage. Mediation analysis was conducted using the PROCESS macro bootstrapping method developed for SPSS by Hayes [50], herein we entered SES as a covariate. The mediation effect was regarded as statistically significant if the 95% confidence interval (CI) for this effect did not include zero. Further, a linear regression of the mediator (self-efficacy) on pain was conducted. A correlation matrix between self-efficacy and HRQOL subscales was constructed using Pearson correlations. Finally, we conducted linear regression of HRQOL on both self-efficacy (indirect path) and pain (direct path). The indirect and direct effects were separately divided by the total effect and multiplied by 100 to be presented as a percentage. *P*-values < 0.05 were considered significant and all tests were two-sided. According to Preacher and Hayes, a significant indirect effect does no longer impose evidence of a simple association between the dependent and independent variable as a precondition for a mediation analysis [51]. Hence, all HRQOL sub-scales were included.

We proceeded using the mediation model depicted in Fig. 1.

Results

Participants

About 4000 adolescents from a school-based population were approached to participate, and based on the previous evidence of the prevalence of persistent pain [2, 6–8, 10, 11], we predicted that about one quarter of the approached adolescents would be eligible. One hundred and seventeen adolescents registered for the study by sending an email to the study email address, of whom 83 provided informed consent and completed the baseline questionnaires. We do not have any data for the 34 adolescents who did not continue after registration. Five adolescents were excluded because they did not meet the inclusion criteria (i.e., pain presence). In total, 78 adolescents with persistent pain participated in the study. The majority (62, 79.5%) were girls and 16 (20.5%) were boys. The participants were aged 16 (26.9%), 17 (29.5%), 18 (26.9%) or 19 (16.7%) years old.

Descriptive data for study variables: pain intensity, HRQOL and GSE

Mean (SD) pain intensity (VAS) score in the study sample was 5.4 (1.8) (Table 1). Girls reported higher mean (SD) pain intensity scores than boys (5.7 [1.8] versus 4.2 [1.9], respectively). The participants' mean (SD) scores ranged from 45.2 (21.0) to 91.0 (13.3) on a 0–100 scale for the HRQOL sub-scales. Boys reported higher scores than girls for all HRQOL sub-scales except financial resources (see Table 1). The largest gender difference was shown for the HRQOL sub-scale mood, where girls reported a mean (SD) score of 54.9 (21.3) compared with 73.7 (15.6) for boys. The participants reported a mean (SD) GSE score of 13.5 (3.3), with girls scoring 13.2 (3.3) and boys 14.8 (3.2).

Pain duration, frequency and location

The participants were all affected by the location of pain, and all participants reported multi-site pain during the 3 months recall period (details in Table 2). Almost half of the participants (48.7%) reported pain lasting more than 12 months, with 29.5% reporting daily pain and 46.2% experiencing pain several times a week. More than

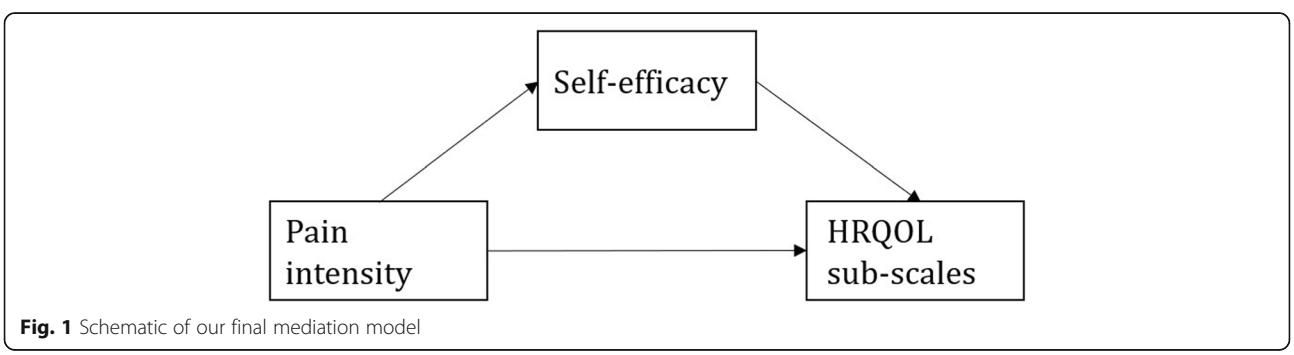

Fig. 1 Schematic of our final mediation model

Table 1 Characteristics of the participants: pain, self-efficacy and HRQOL sub-scale scores

Study variable	All ($n = 78$) mean (SD)	Girls ($n = 62$) mean (SD)	Boys ($n = 16$) mean (SD)
Pain intensity	5.42 (1.88)	5.74 (1.75)	4.19 (1.90)
Self-efficacy	13.54 (3.30)	13.21 (3.29)	14.81 (3.17)
KIDSCREEN subscale			
Physical well-being	45.19 (20.99)	41.37 (18.56)	60.00 (23.80)
Psychological well-being	56.09 (22.23)	53.02 (21.93)	67.97 (19.76)
Mood	58.74 (21.56)	54.90 (21.29)	73.66 (15.64)
Self-perception	45.71 (23.16)	43.06 (22.96)	55.94 (21.62)
Autonomy	59.23 (18.90)	55.73 (18.64)	72.81 (13.16)
Relationship with parents	65.01 (24.41)	64.38 (24.80)	67.45 (23.43)
Financial resources	70.61 (26.85)	71.24 (27.23)	68.23 (26.03)
Social support	60.52 (20.60)	58.67 (20.83)	67.71 (18.54)
School environment	54.75 (20.03)	52.02 (18.32)	65.36 (23.31)
Bullying	91.03 (13.34)	90.99 (14.02)	91.15 (10.74)

half of the participants (51.3%) reported pain at locations other than the 10 pre-defined locations; in this unspecified category, pain in shoulder(s), neck and hip was most frequently reported. Headache was most commonly reported by the participants (88.5%), herein 95.2% of the girls and 62.5% of the boys reported headache (Table 2).

Associations between pain intensity, HRQOL sub-scale scores and GSE

Scores for all the HRQOL sub-scales and GSE were negatively associated with pain intensity. Pain intensity was a significant predictor of the scores for the HRQOL sub-scales physical well-being (B = −2.81), psychological well-being (B = − 4.55), mood (B = − 3.62), self-perception (B = − 4.13), social support by peers (B = − 3.26) and school environment (B = − 3.18) (Table 3).

Table 2 Counts and percentage of bodily regions affected by pain within the 3-month recall period for all participants and stratified by gender

Pain region	All ($n = 78$)	Girls ($n = 62$)	Boys ($n = 16$)
Head	69 (88.5%)	59 (95.2%)	10 (62.5%)
Teeth	15 (19.2%)	14 (22.6%)	1 (6.3%)
Ears	14 (17.9%)	14 (22.6%)	0
Throat	35 (44.9%)	32 (51.6%)	3 (18.8%)
Back	49 (62.8%)	40 (64.5%)	9 (56.3%)
Chest	21 (26.9%)	18 (29.0%)	3 (18.8%)
Stomach	50 (64.1%)	45 (72.6%)	5 (31.3%)
Reproductive organs	50 (64.1%)	50 (80.6%)	0
Arms	12 (15.4%)	8 (12.9%)	4 (25.0%)
Legs	30 (38.5%)	27 (43.5%)	3 (18.8%)
Other	40 (51.3%)	33 (53.2%)	7 (43.8%)

Table 3 Linear regressions of pain intensity (independent) on HRQOL sub-scales (dependent) and on GSE (dependent)

Variable	B	95% CI	*P* value
Physical well-being	−2.81	−5.27 to −0.34	0.02
Psychological well-being	−4.55	−7.04 to − 2.0.6	< 0.01
Mood	− 3.62	− 6.10 to − 1.14	< 0.01
Self-perception	−4.13	−6.78 to − 1.49	< 0.01
Autonomy	−1.74	− 4.00 to 0.52	0.12
Relationship with parents	−2.47	−5.39 to 0.44	0.09
Financial resources	−1.06	−4.31 to 2.20	0.52
Social support	−3.18	−5.56 to −0.79	0.01
School environment	−3.26	−5.57 to − 0.95	< 0.01
Bullying	−0.87	−2.48 to 0.74	0.29
GSE	−0.63	−1.01 to −2.56	< 0.01

CI confidence interval

We examined the association between self-efficacy (mediator) and HRQOL sub-scale scores (dependent variables), which revealed a non-significant relationship between self-efficacy and the HRQOL sub-scale social support. Estimates of the correlation matrix between HRQOL sub-scales and self-efficacy are listed in Table 4 and revealed an overall low to moderate correlations. The strongest correlation was found between HRQOL sub-scale physical well-being and self-efficacy of 0.538.

Mediation of self-efficacy on the relationship between pain intensity and selected HRQOL sub-scale scores

The mediation effect was performed using the PROCESS macro developed by Hayes [41], herein we controlled for SES (entered as a covariate). A significant indirect effect was found for the HRQOL sub-scales: physical well-being (B = − 2.05; 95% CI [− 3.64 to − 0.56]), psychological well-being (B = − 1.30; 95% CI [− 2.96 to − 0.20]), mood (B = − 1.34; 95% CI [− 3.08 to − 0.19]), self-perception (B = − 1.85; 95% CI [− 3.65 to − 0.50]),

Table 4 Estimates of the correlation matrix between HRQOL and self-efficacy

HRQOL sub-scales	Self-efficacy
Physical well-being	0.538
Psychological well-being	0.414
Mood	0.407
Self-perception	0.490
Autonomy	0.269
Relationship with parents	0.184
Financial resources	0.048
Social support	0.208
School environment	0.327
Bullying	0.010

autonomy (B = – 0.87; 95% CI [– 2.12 to – 0.03]) and school environment (B = – 0.92; 95% CI [– 2.73 to – 0.01]). Non-standardized estimates of the Bs of the associated variables are shown in Fig. 2. The direct paths (C′) between pain intensity and physical well-being, mood and school environment were no longer significant, which indicated that these associations were completely mediated by self-efficacy.

Approximately half of the reductions in HRQOL subscale scores for physical well-being, psychological well-being, mood, self-perception, autonomy and school environment was explained by the mediating variable (indirect effect). Physical well-being had the highest indirect effect (67.2%) among the HRQOL sub-scales (Table 5). The calculation of direct and indirect effect as percentages was not was not applicable for the HRQOL sub-scale bullying due to opposite directions of these effects.

Discussion

This study described the pain experience (intensity, frequency, duration and location) of adolescents with persistent pain, assessed the association between pain intensity, GSE and HRQOL, and tested self-efficacy as a possible mediator of pain. Our findings demonstrated that the participants were affected by the intensity, duration, frequency and locations of their experienced pain. Pain intensity was associated with impairments in the scores for several sub-scales of HRQOL and GSE. Further, GSE was a significant mediator between pain intensity and the HRQOL sub-scales of physical well-being, psychological well-being, mood, self-perception, autonomy and school environment. Up to 67% of the reduction in these respective HRQOL sub-scales was explained by the mediating variable (indirect effect).

Considering that the study sample was recruited from a school-based setting, and that headaches were the most commonly reported pain (88.5%), the overall presence of pain could be categorized as severe, with a mean pain intensity score of 5.4 (VAS) [52]. However, epidemiological studies have reported similar mean pain intensity scores ranging from 4.5 to 5.6 [2, 8]. Our data also revealed several gender differences: girls reported higher scores for pain intensity (VAS 5.7) compared with boys (VAS 4.2). Although all participants experienced persistent multi-site pain, girls reported pain in a greater number of body regions. These findings are consistent with the literature showing that headache is the most

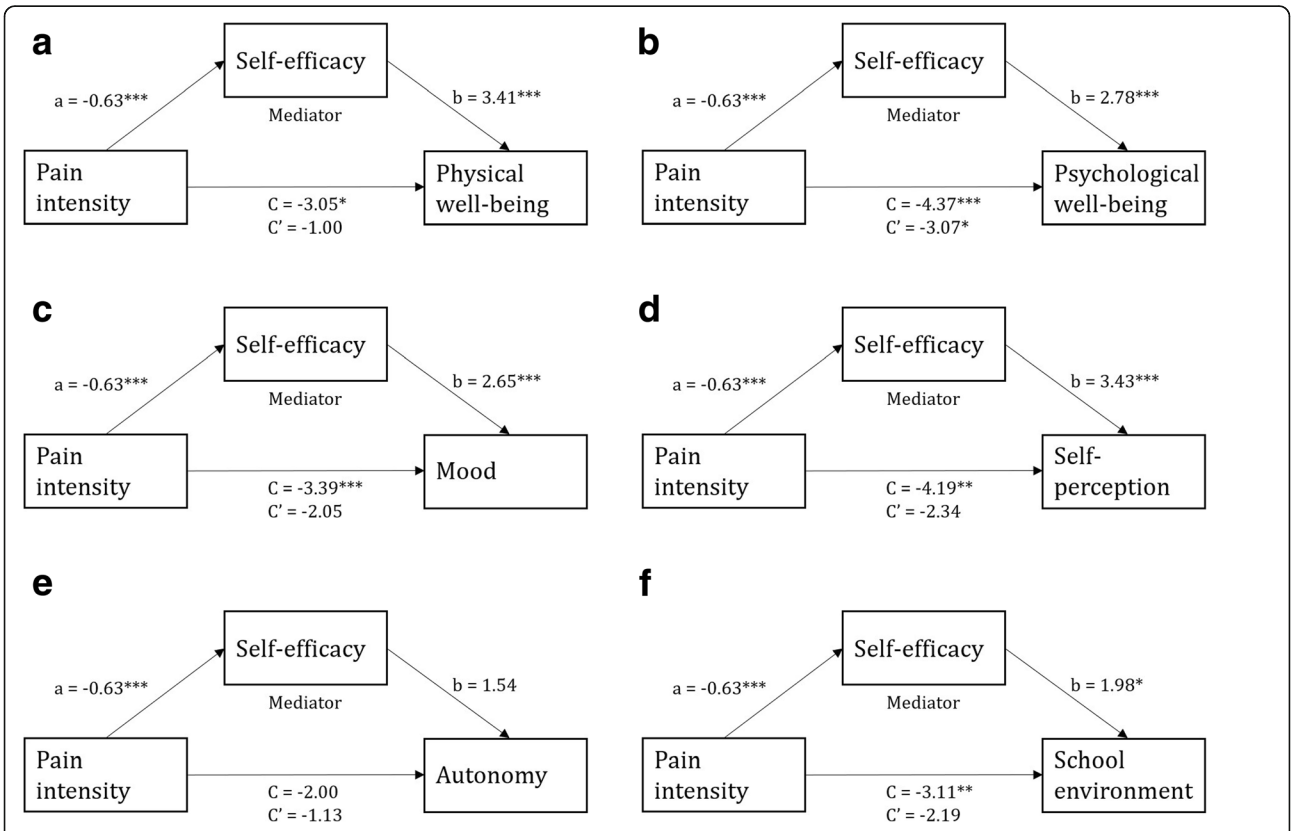

Fig. 2 Mediation by self-efficacy of the association between pain intensity and the scores for HRQOL sub-scales **a** physical well-being, **b** psychological well-being, **c** mood, **d** self-perception, **e** autonomy and **f** school environment; $p < 0.05$*, $p < 0.01$** and $p < 0.001$***. Path a and b depict the indirect effects through the mediator. Path C represents the total effect and C' the direct path

Table 5 Reduction in HRQOL sub-scales explained by the direct (pain intensity) and indirect (self-efficacy) effects presented as percentage (%)

HRQOL sub-scales:	Direct effect (%)	Indirect effect (%)
Physical well-being	32.8	67.2*
Psychological well-being	70.3	29.7*
Mood	60.5	39.5*
Self-perception	55.8	44.2*
Autonomy	56.5	43.5*
Relationship with parents	74.6	25.4
Financial relationship	86.2	13.8
Social support	85.7	14.3
School environment	70.4	29.6*
Bullying	–	–

$p < 0.05$*

commonly reported type of pain, and that girls in late adolescence seem to experience more intense and frequent pain of longer duration than that experienced by boys, and more often have pain in multiple sites [7, 9, 11, 27]. Because pain is known to impact HRQOL, our findings predictably identified a gender difference in HRQOL sub-scale scores, with generally higher scores for boys than for girls. Higher HRQOL in adolescence in boys compared with girls is consistent with previous reports [53–56]. Data from 12 European countries ($n = 21$, 590) showed no gender difference in HRQOL of young children; however, with increasing age, HRQOL in girls declined significantly compared with that in boys [56]. However, given that our study population was considered homogenous with respect to age, we were not able to perform any statistical inference concerning age.

Our findings revealed that pain intensity was negatively associated with all sub-scales of HRQOL and GSE, and that the participants generally reported low scores for HRQOL. However, in our regression analyses of pain intensity (independent) and sub-scales of HRQOL (dependent), the non-standardized estimates of B explained the difference in HRQOL in our study with that reported in an earlier published study, which used 10 sub-scales of KIDSCREEN-52 in a school-based population of children and adolescents ($n = 1099$) [27]. In this earlier school survey, the most impaired sub-scales of HRQOL for adolescents with persistent pain were psychological well-being, mood, self-perception, autonomy and school environment; this was generally consistent with our findings. However, unlike the earlier study, we did not identify any significant relationship between pain intensity and the HRQOL sub-scale autonomy, while our data showed a significant relationship between pain intensity and the scores for the HRQOL sub-scales of physical well-being and social support. These findings may relate to those of previous studies, which showed that persistent pain may result in periods of isolation from peers and, thus, absence from school, everyday physical activities and other social activities [3, 15]. Adolescents have reported that one of the most important things for their quality of life is to be social together with friends [57], and children and adolescents with persistent pain are commonly reported to have reduced social functioning and reduced physical activity levels [9, 58–60].

We hypothesized that self-efficacy would play a role as a possible mediator between pain and HRQOL. Interestingly, self-efficacy, a well-known approach to evaluating effects on a person's cognition, did not only mediate the relationship between pain intensity and scores for HRQOL sub-scales connected with the adolescent's perception of themselves, such as psychological well-being, mood and self-perception, but we showed that a reduction in self-efficacy also appeared to play a role in other HRQOL sub-scales, such as school environment. These findings are consistent with previous research that has shown that higher scores for self-efficacy in adolescents with chronic pain were associated with improved school functioning and lower school-related disability [35, 36]. Further, earlier studies showed that higher self-efficacy positively influences academic achievement and the likelihood of remaining in school [61]. Moreover, the highest indirect effect was found for the HRQOL sub-scale physical well-being, which is an important finding given that a reduction in physical well-being in adolescence is an indication of an impaired physical activity level, which is considered as a key component of a healthy lifestyle, herein self-efficacy is identified as a determinant for physical activity [62, 63]. A systemic review with meta-analyses by Ashford and colleagues discussed numerous ways to change self-efficacy, and reported that interventions, including feedback on past performance, feedback on performance compared with others and vicarious experience (role model), produced the highest levels of self-efficacy [64]. Bandura [65, 66] defined the concept of self-efficacy as a self-regulatory mechanism by which it is possible to change as a result of being motivated by others or through goal-setting and education. Thus, enhancing self-efficacy seems to be an important intervention strategy when aiming to improve HRQOL in adolescents with persistent pain.

Strengths and limitations

All data analysed were cross-sectional, so no causal relationships could be identified. We could not test statistically the possible effect of gender due to the limited sample size and the homogeneity of the sample (a great

majority were girls). Moreover, we were not able to control for other possible confounders as medication use. Hence, larger samples are recommended in future studies. The mediation model seeks to identify underlying mechanisms between observed associations but is of exploratory nature. Thus, this current meditation model is based on our assumptions and understanding of this research area, e.g. we can only assume causality and direction of the direct and indirect effect. Our findings are exploratory and should be verified and replicated in future and large studies and may only be generalized to a school-based population of adolescents with persistent and weekly pain. The effects may be over-estimated due to the shared source of variance. However, we consider that our findings shed new light on the underlying mechanisms of the association between pain and HRQOL in a sample from a school-based population of adolescents. We do not have any data regarding the 34 individuals who initially enrolled but were lost after registration; thus, the recruited adolescents might be those who were most interested because they had more severe pain. Hence, the findings may not be generalizable to the general population. A strength of the study is that we used well-validated questionnaires; however, the instrument for self-reported pain measures (LPQ) had a 3-month recall period for pain location, which might be a long period for adolescents to remember and may have reduced the validity of the data. In contrast, KIDSCREEN-52 used a 1-week recall period, which has been shown to be advantageous [16, 67].

Clinical implications

Our findings provide new insight by showing that the association between pain intensity and HRQOL in a school-based sample of adolescents with persistent pain was explained by the mediating variable self-efficacy. Thus, this study extends previous assumptions and empirical research and shows that in future interventions for pain management, promoting self-efficacy could be beneficial for HRQOL. Given that research evidence has identified numerous ways to change self-efficacy [64–66], these findings may contribute to the design of more effective pain-management interventions that promote HRQOL in adolescents with persistent pain. Finally, regarding the adolescents' school environment, teachers and health care nurses should be aware of targeting self-efficacy as a strategy to increase HRQOL.

Conclusions

This study suggested that a school-based sample of adolescents with persistent pain had impaired HRQOL, which consequently affected all aspects of their everyday life and indicated the need for future targeted interventions. Our findings revealed that up to 67% of the reduction in the HRQOL sub-scale scores for physical well-being, psychological well-being, mood, self-perception, autonomy and school environment was explained by the mediating variable, self-efficacy. These data provide insight to the underlying mechanisms of the associations between pain and HRQOL in adolescents and have important implications for the future practice of pain management interventions, which should aim to increase HRQOL by promoting self-efficacy.

Abbreviations

GSE: General self-efficacy; HRQOL: Health-related quality of life; LPQ: Lübeck Pain-Screening Questionnaire; VAS: Visual Analog Scale

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Authors' contributions

KH, LF, SH and JS developed the project protocol. EG was responsible for the recruitment, and data analysis together with MS. All authors contributed to manuscript preparation and approved its final version.

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The participants received oral and written information and provided written informed consent before participating in the study. The study was approved by the Norwegian Regional Committee for Medical Research Ethics South-East-B (REK reference 2017/350).

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

Paper III

App-based Intervention among Adolescents with Persistent Pain: A Pilot Feasibility Randomized Controlled Trial

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Abstract

Background: Persistent pain in adolescence adversely affects everyday life and is an important public health problem. The primary aim was to determine the feasibility of an 8-week app-based self-management intervention to reduce pain and improve health-related quality of life in a community-based population of adolescents with persistent pain. A secondary aim was to explore differences in health outcomes between the intervention and control groups.

Methods: A sample of 73 adolescents aged 16–19 years with persistent pain from a community-based population were randomized into 2 groups. The intervention group received the Norwegian culturally adapted version of the *iCanCope with Pain*™ app, which includes symptom tracking, goal setting, self-management strategies, and social support. The attention control group received a symptom tracking app. Feasibility was assessed as attrition rates and level of engagement (interactions with the app). The secondary outcomes included pain intensity, health-related quality of life, self-efficacy, pain self-efficacy, perceived social support from friends, anxiety and depression, and patient global impression. Statistical analyses were conducted using SPSS.

Results: Demographic and baseline outcome variables did not differ between the 2 groups. No differences were found between the participants completing the study and those who withdrew. Twenty-eight adolescents completed the intervention as planned (62% attrition). Both groups had a low level of app engagement. Intention-to-treat analysis (n = 19 + 14) showed no significant differences in outcomes between groups. However, the large effect size (Cohen's d = .9) for depression suggested a lower depression score in the intervention group.

Conclusions: High treatment attrition and low engagement indicate the need for changes in trial design in a full-scale randomized controlled trial to improve participant retention.

Trial registration: The iCanCope with Pain Norway trial was retrospectively registered in Clinical Trials.gov (ID: NCT03551977). Registered 6 June 2018. https://clinicaltrials.gov/ct2/show/NCT03551977.

Keywords: chronic pain; adolescent; randomized controlled trial; mobile applications; self-management

Key messages regarding feasibility

1) This study builds on an earlier cultural adaptation and is the first study to determine the feasibility of a self-management app aiming at reducing pain and improve HRQOL in a school-based population of adolescents with persistent pain in Norway.

2) The high treatment attrition and low engagement rates observed indicate the need for some changes in trial design in a full-scale randomized controlled trial to improve participant retention.

3) Possible changes in trial design could be including personal support and use of additional electronic platforms for communication with participants. Nevertheless, our findings provide estimates for calculation of sample sizes in future app-based intervention trials of school-based adolescents with persistent pain.

Background

Persistent pain in adolescents adversely affects everyday life and is an important public health problem [1]. Pain lasting ≥3 months is classified as persistent/chronic pain [2] and is prevalent in about 20–35% of adolescents in Western countries [3–7]. Previous studies have reported impaired health-related quality of life (HRQOL) in adolescents with persistent pain compared with those without pain [8,9]. Adolescents in pain often do not know where to seek information or how to cope with pain [10,11]. The Internet has become a source of advice and provides self-management skills for younger people to cope with pain [10].

Systematic reviews indicate that Internet-delivered self-management interventions can help reduce pain and/or improve HRQOL in children and adolescents with persistent pain [12,13]. However, most adolescents in these studies were recruited from a clinical setting, where the adolescents already are undergoing treatment. Because some adolescents experience barriers when accessing traditional therapies, such as talking in groups or with health personnel [14], some might prefer remotely delivered interventions for coping with pain.

The use of smartphone applications (apps) may be preferred for receiving digital health information, and hundreds of pain management apps are available for the public [15]. A systematic review of the benefits of apps for pain management in different age and patient groups concluded that pain management apps may be beneficial for patients, particularly in community-based settings [16]. However, most pain apps available for the public have not been evaluated scientifically [17]. There is a need for research on evidence- and theory-based app interventions aimed at reducing pain and increasing HRQOL among a school-based population of adolescents with persistent pain.

Researchers in collaboration with eHealth Innovation at University Health Network (Toronto, Canada) developed an evidence- and theory-based pain self-management app for adolescents called *iCanCope with Pain*^{TM} [14]. We have translated and culturally adapted the English-language *iCanCope with Pain*^{TM} app into the Norwegian context and evaluated the app's usability in laboratory settings and in the field [18]. We found that end users reported high usability and satisfaction with only minor errors. These findings suggested that few changes were needed in the app before a pilot trial could proceed.

The purpose of this study was to determine the feasibility of the Norwegian *iCanCope with Pain*^{TM} app in an 8-week pilot randomized controlled trial (RCT) aimed at reducing pain and improving HRQOL in a school-based population of adolescents with persistent pain. The primary aim was to determine the trial feasibility in terms of participant attrition rates and level of engagement with the app. The secondary aim was to determine the impact of the intervention on pain intensity, HRQOL, self-efficacy, pain self-efficacy, perceived social support from friends, anxiety and depression, and patient global impression. We hypothesized that adolescents receiving a mobile phone app containing strategies for coping better with pain would experience improvements in outcomes compared with adolescents receiving an attention control app.

Methods

Design

This present study used a pilot RCT design with 2 parallel groups. The intervention group received the *iCanCope with Pain*^{TM} app comprising 4 evidence- and theory-based features: (I) symptom trackers for pain intensity, pain interference, sleep, mood, physical activity, and energy; (II) goal setting to improve pain and function; (III) a toolbox of pain education and self-management strategies; and (IV) peer-based social support via a monitored community

forum. The attention control group received an app that included symptom trackers only. Both groups were asked to use the respective apps for 8 weeks. Outcome measures were examined at the baseline (T0) and after the intervention (T1).

Participants

The study was conducted in Southern Norway in 2018. Five government-funded high schools were invited to participate, and all agreed. Eligible individuals were adolescents aged 16–19 years with self-reported persistent pain, defined as weekly pain lasting 3 months or longer. They were able to read and understand Norwegian and had their own smartphone (iPhone or Android). Adolescents with cognitive disability were excluded because of their inability to understand how to use the *iCanCope with Pain*^{TM} app independently. Adolescents with a diagnosis of a pathological or medical origin (e.g., oncology patients) were excluded because the program was not designed specifically for these pain conditions.

Procedure

The first author visited the 5 high schools and explained the study in each classroom. To ensure anonymity and confidentiality, adolescents received a written brochure with an attached email address generated for this purpose only. Information was also available on the websites of each participating high school. Both the oral presentation in the classroom and written information included the inclusion and exclusion criteria of the study. Any adolescents who experienced persistent pain and wanted to participate in the study were instructed to send an email to the corresponding study email address. When the baseline questionnaire was completed, the last author sent the eligible participants their corresponding username, password, and a short PowerPoint presentation about downloading and using the app. The first author was blinded to the simple randomization procedure performed by the last author using a computer-generated randomization list and the generated coding sheets. After

the 8-week intervention period, a link to the online postintervention questionnaire was sent to each participant's email address.

Outcomes

The primary outcome of this study was the feasibility of using the Norwegian *iCanCope with Pain*^{TM} app in a school-based population of adolescents with persistent pain measured. Specific feasibility outcomes were:

1. Attrition rate was defined as the percentage of participants who failed to complete the final measures.
2. App engagement was measured as the total number of completed symptom check-ins (feature I) over the study period.

The secondary study outcomes, focused on preliminary effectiveness, were:

Pain was assessed using the Lübeck Pain-Screening Questionnaire (LPQ), which has, as a measure of internal consistency, a Cronbach's alpha of 0.92 [3]. The LPQ includes a visual analogue scale (VAS) for participants to assess their pain intensity at the present moment, and the score ranged from 0 (no pain) to 10 (worst pain imaginable) [3]. The VAS slider is often used as a measure of pain intensity and has been found to be both valid and reliable, including its digital use [19].

HRQOL was measured using KIDSCREEN-52, which is a cross-cultural multidimensional instrument that has been validated in several countries; the internal consistency, as measured by Cronbach's alpha, is >0.80 for all dimensions [20–22]. The questionnaire includes 52 items grouped into 10 subscales, which are scored using a 1–5 Likert scale. The electronic format of the survey ensured that all items required answers, which resulted in no missing data. We followed the KIDSCREEN manual and transferred

negative questions into positive [20]. The data were then transformed linearly to a 0–100-point scale, where 0 indicated the lowest and 100 indicated the highest HRQOL.

Self-efficacy was measured using the General Perceived Self-Efficacy Scale short form (GSE) [23]. The short form has been found to be both valid and reliable and has a satisfactory internal consistency of 0.82 [24]. The GSE is often expressed as the global confidence in one's ability across a wide range of demanding and novel situations [25]. All items use a 1–4-point scale, where 1 refers to the lowest GSE and 4 the highest, giving a total score from 5 to 20.

Anxiety and depression were measured using the Hospital Anxiety and Depression Scale Questionnaire (HADS) [26]. The HADS is a validated method for assessing the symptom severity of anxiety disorders and depression, and it has a satisfactory internal consistency of 0.77–0.89 [27]. The HADS total score (HADS-T) is based on 14 items separated into 2 subscales: anxiety and depression (HADS-D). Each subscale comprises 7 items that are rated on a Likert scale of 0–3. The total for each subscale is 0–21, and the total HADS score is 0–42. Lower values reflect less anxiety and depression.

The following three instruments were translated into Norwegian based on the principles of good practice for translation and cultural adaptation explained by Wild et al. [28].

Perceived social support was measured using the Perceived Social Support – Friends Scale (PSS-Fr) questionnaire to measure adolescents' social support levels [29]. The internal consistency was 0.84 (Cronbach's alpha). The PSS-Fr has been shown to be a valid and reliable instrument among adolescents. It includes 20 statements that refer to feelings and experiences that occur to most people at one time or another in their relationships with friends [29]. There are 3 answers for each statement: Yes, No, and Don't know. These measures were

categorized numerically as Yes = 1 and No and Don't know = 0. They yielded a total scale of 0–20, where higher values represent greater perceived social support.

Pain self-efficacy was measured using the Pain Self-Efficacy Questionnaire (PSEQ) to assess how confidently the adolescents performed a range of activities described despite their pain [30]. The internal consistency was 0.93 (Cronbach's alpha). The PSEQ includes 10 items rated on a 7-point Likert scale, where 0 = not at all confident and 6 = completely confident, which gives a total score of 0–60. The PSEQ has been shown to have satisfying psychometric properties [30].

Global impression of change was measured using the Patients' Global Impression of Change Scale (PGIC), which asks participants to self-assess their change in symptoms after the intervention. The PGIC includes 1 question (internal consistency not applicable) and is a validated scale for interpreting the subjective outcome measure of an intervention [31].

Ethics

The study was approved by the Norwegian Regional Committee for Medical Research Ethics South-East-B (REK reference 2017/350). All participants received oral and written information and signed an informed consent before participating in the study. They were aware that they could withdraw at any time during the study without a reason and that confidentiality and anonymity of their data were ensured at all times. The adolescents did not receive any compensation for participation.

Data analysis

All statistical analyses were conducted using SPSS version 25 for Windows (IBM Corp). Baseline categorical data (T0) are presented as frequencies and percentages. Continuous data are presented as mean, standard deviation (SD), and effect size (Cohen's d). Comparisons between the intervention and control groups at T0 were performed using *t* tests for continuous

variables and chi-squared tests for categorical variables. Separate analyses were conducted for each outcome.

Rates of attrition were calculated as participants completed the post-questionnaire (T1) divided by the number of participants at T0. Completion of daily symptom check-ins was used as a proxy for app engagement. Operational definitions were used to categorize check-in engagement over the 8-week (55-day) study period: low engagement, ≤24% (≤13/55 reports); low-moderate engagement, 25–49% (14 to 27/55 reports); high-moderate engagement, 50–75% (28 to 41/55 reports); and high engagement, 76–100% (42 to 55/55 reports) [32].

All app interactions were measured separately for each feature and are presented as the median and range and as frequencies and percentages for categorical data. All participants were included in the final analysis following the intention-to-treat (ITT) protocol. A general linear model was fitted to explore possible differences in outcomes between the groups. In this model, the post intervention measures were entered as the dependent variables, and these were compared between the treatment groups using the T0 score as the covariate. Effect sizes were determined and are expressed as Cohen's d as follows: 0.2, small effect; 0.5, medium effect; and 0.8, large effect [33]. *p* values <.05 were considered to be significant.

Results

Sample characteristics

Participants at T0 included 73 adolescents aged 16 to 19 years with persistent pain. Most participants were female with multisite pain, in an average of 4.4 pain sites. Almost half of the participants reported pain lasting more than 12 months (47%), about one-third reported having pain daily (27%), and almost half experienced pain several times a week (47%). The characteristics of the sample, both overall and by groups, including pain location, at T0 are

presented in Table 1. The intervention and control groups did not differ at T0 on demographic and outcome measures (Tables 1–3).

Table 1

Characteristics of the sample (N = 73) at T0

Demographic characteristics	Total N = 73 N (%)	Intervention N = 41 N (%)	Control N = 32 N (%)
Sex (female)	60 (82.2)	36 (87.8)	24 (75.0)
Age	17.4 (1.0)	17.5 (1.0)	17.3 (1.0)
Pain location			
Head	64 (87.7)	37 (90.2)	27 (84.4)
Teeth	14 (19.2)	7 (17.1)	7 (21.9)
Ears	13 (17.8)	10 (24.4)	3 (9.3)
Throat	33 (45.2)	21 (51.2)	12 (37.5)
Back	45 (61.6)	25 (61.0)	20 (62.5)
Chest	20 (27.4)	13 (31.7)	7 (21.9)
Abdomen	47 (64.4)	29 (70.7)	18 (56.3)
Reproductive tract	48 (65.8)	28 (68.3)	20 (62.5)
Arms	10 (13.7)	5 (12.2)	5 (15.6)
Legs	27 (37.0)	13 (31.7)	14 (43.8)

Feasibility analyses

Figure 1 provides a CONSORT flow diagram of participants through the study [34] and for the corresponding checklist [35], see Additional file 1. Of the estimated 4000 adolescents who were approached in the schools, about one-quarter were considered eligible based on previous prevalence rates of persistent pain in Western countries [3–7]. A total of 112 adolescents agreed by email to participate and stated they were in pain, however only 73

participants completed the measures at T0 and were randomized into either control or intervention group. A total of 28 participants (38%) completed the postintervention questionnaire (T1); 17 (23%) were in the intervention group and 11 (15%) the control group, which produced an attrition rate of 62%.

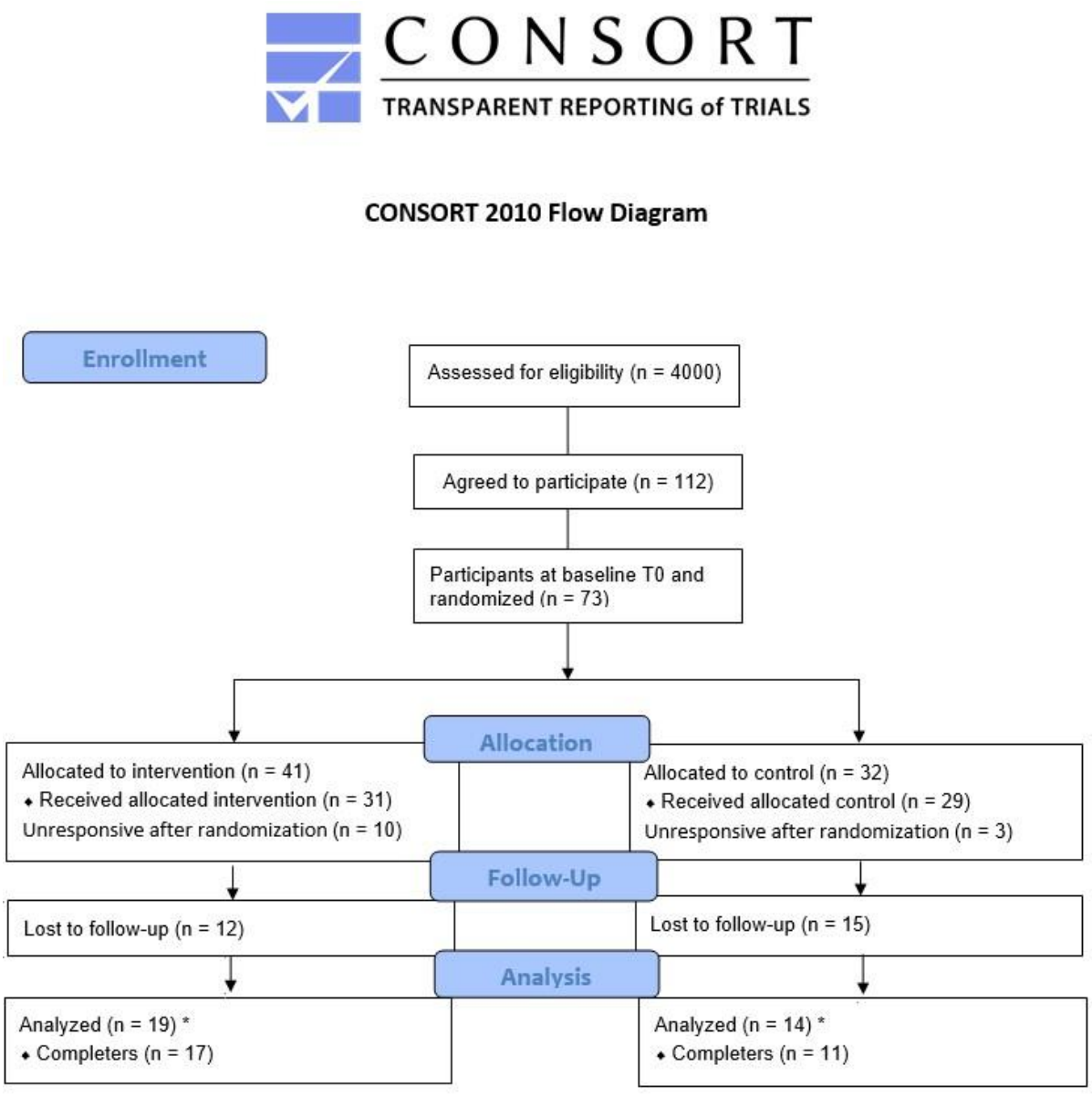

Figure 1. CONSORT flow diagram. *Completers answered all items in the postintervention questionnaire.

Next, the adolescents' interactions with the app were analyzed to explore their level of engagement. The daily check-ins for symptom tracking (I) in the app were used by both groups and were categorized as low engagement. Participants in the control group (n=29) conducted a median of 9 (range 1–56) check-ins for symptom tracking (I) during the study period distributed as follows: low (80%), low-moderate (10%), high-moderate (7%) and high (3%). The intervention group (n=31) used all features (I–IV) and conducted a median of 6 (range 2–52) check-ins for symptom tracking (I) distributed as follows: low (74%), low-moderate (13%), high-moderate (10%) and high (3%). The goalsetting feature (II) was used most frequently to set up physical activity goals (43%), such as walking or running, followed by goals related to mood (21%), energy (13%), sleep (13%), and social activities (10%). A median of 3 goals (range 1–156) were set up by the participants (intervention group). The toolbox of pain education and self-management strategies (III) comprised 91 articles, and 8 participants favored 24 of these articles. Articles about coping with fatigue and yoga were most frequently favored, followed by distraction techniques, healthy eating, strength training, and tips for developing a treatment plan. The social support feature (IV) was rarely used. No technical issues were registered.

Preliminary Effectiveness

The demographic and the outcomes variables did not differ significantly between the participants who completed the study (n = 33, pain intensity 5.4, SD 1.9) and those who later dropped out (n = 40, pain intensity 5.7, SD 2.0).

As anticipated, the scores for all 10 subscales of HRQOL were higher at T1 than at T0 in the intervention group (Table 2). Baseline-adjusted ITT analyses were used to identify possible group differences on pain intensity and HRQOL subscales but showed no significant differences (all $p > .05$).

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Table 2 about here

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No significant group effects were found for the T0-adjusted ITT analyses of self-efficacy, pain self-efficacy, social support, and HADS (all $p > .05$). As shown in Table 3, HADS had a medium effect size (d = .53) and HADS-D had a large effect size (d = .91).

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Table 3 about here

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The self-assessed level of change in symptoms from T0 to T1 showed that about half of the adolescents in both the intervention group (47%) and control group (55%) reported "no change" or "almost the same" since T0 (Figure 2). One-third of the adolescents in the intervention group (n = 6) reported that they felt moderately better or better since T0, whereas only 9% (n = 1) in the control group reported this improvement.

Figure 2. Changes in symptoms since the beginning of the intervention.

Discussion

This study examined the feasibility of the Norwegian *iCanCope with Pain*^{TM} app in an 8-week pilot feasibility RCT among adolescents with persistent pain in a school-based population. We found high attrition rates and a low level of engagement with symptom check-ins, which indicate the need for change in trial design in a future full-scale RCT to improve participant retention.

Despite being underpinned by rigorous adaptation and usability testing [18], this school-based study sample had unexpectedly high attrition rates (62%). High treatment attrition is not uncommon for remotely delivered internet pain management interventions for adolescents with persistent pain [36]. Attrition and loss to follow-up are more common for online trials than for conventional trials, probably because of fewer interactions or less support than in traditional face-to-face trials [37]. For instance, the use of both postal and telephone reminders for follow-up seems to be more effective than texting reminders for follow-up [37]. Given we only used email as a corresponding electronic platform, might have influenced to the lack of response. Another possible explanation for the high attrition rates in our study may be that the app changed the pain experience, as shown by worsening or improving symptoms. Thus, the cyclic nature of persistent pain in adolescence may help explain why some dropped out when feeling better or other to discontinue when feeling worse. Some participants might have perceived the app as a nonpreferred coping method. However, the high attrition rate was not due to technical issues as no technical requests were reported during the intervention period.

Further, the lack of support may be important for several reasons. Support by health-care personnel was one suggestion for improving the usability of the Norwegian *iCanCope with Pain*™ [18]. Studies have shown that adolescents in pain do not know where to seek coping information, and many rely on adults such as their parents [10,11]. In a meta-analysis, Spek and colleagues found that Internet-based therapy with therapist support is more effective than Internet-based therapy without any support [38]. These findings are in line with a recent review that examined the best evidence for rehabilitation of persistent pain among children and adolescents, which found that multidisciplinary interventions that include an intensive interdisciplinary pain management approach are important [39].

In our study, low engagement was revealed by the adolescents as the few check-ins of symptom tracking (I) in both groups. These findings contrast with those in a recent study by Lalloo et al. [32], who assessed a clinical sample of adolescents in pain recruited from tertiary care centers and reported that the intervention and control groups conducted on average 33.8 and 36 registrations, respectively, and that both were categorized as high-moderate engagement. Differences in engagement between our study and that by Lalloo et al. may relate to difference in samples. For example, our study sample was a school-based population of adolescents with persistent pain, who did not receive support and did not have a clear diagnosis. By contrast, the study sample of Lalloo et al. comprised adolescents recruited from pain clinics and tertiary care centers in ongoing treatment courses who received support and had regular interactions with an interdisciplinary health-care team. Although the frequency of check-in registrations was found similar in the 2 groups in our study, only 1 participant in the control group reported that he or she felt moderately better or better since the beginning of the intervention compared with 6 participants in the intervention group. This finding suggests that other components in the app (II–IV) may be important for pain management.

The ITT analyses (n = 19 + 14) revealed no significant differences in outcomes between groups. Still, an important finding was the medium effect size for the HADS total score and large effect size for the HAD-D score. Given that the most liked articles focused on coping with fatigue and distraction techniques, these findings suggest that these adolescents with persistent pain found the app to be a relevant tool for learning about cognitive and mental coping strategies. The high mean depression score in this school-based population is in line with previous work that indicated that school-based non-referred adolescents with recurrent headache reported higher depressive symptoms compared with clinically referred adolescents with recurrent headache [40].

Our study has strength and limitations. We found an unexpected high attrition rate that naturally influenced the loss of power and the risk for bias. We, therefore, compared outcomes between participants who completed the study and those who later dropped out. This was a pilot feasibility RCT, and the sample size was consistent with Hertzog's recommendations (10–40 responders per group) for pilot studies [41] to allow for exploration of outcomes and the opportunity to estimate the number needed for future definitive trials. A strength of this pilot study is its RCT design combined with assessment of the feasibility of using a rigorously developed, culturally adapted, and well-tested app, which is both theory and evidence based. Given that this was a feasibility study and considered exploratory, we did not consider that adjustments for multiple testing and providing *p* values on demographics were appropriate. Finally, all participants attended the 8-week intervention during the same period from mid-April to mid-June in 2018. This means that the postintervention measurements coincided with the participants' examination period, which may have induced a higher stress level. We do not know whether this factor affected the attrition rates or any other outcomes.

Conclusions

High treatment attrition and low engagement rates indicated need for some changes in trial design in a full-scale RCT to improve participant retention. Possible changes in trial design could be including personal support and use of additional electronic platforms for communication with participants. Nevertheless, our findings provide estimates for calculation of sample sizes in future app-based intervention trials of school-based adolescents with persistent pain.

List of abbreviations

General Perceived Self-Efficacy Scale (GSE)

Hospital Anxiety and Depression Scale Questionnaire (HADS)

HADS depression score (HADS-D)

HADS total score (HADS-T)

Health-related quality of life (HRQOL)

Intention-to-treat (ITT)

Lübeck Pain-Screening Questionnaire (LPQ)

Patients' Global Impression of Change Scale (PGIC)

Pain Self-Efficacy Questionnaire (PSEQ)

Perceived Social Support – Friends Scale (PSS-Fr)

Randomized controlled trial (RCT)

Standard deviation (SD)

Visual Analog Scale (VAS)

Declarations

Ethics approval and consent to participate

The participants received oral and written information and provided written informed consent before participating in the study. The study was approved by the Norwegian Regional Committee for Medical Research Ethics South-East-B (REK reference 2017/350).

Consent for publication

Not applicable.

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

None.

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Authors' Contributions

KH, LF, SH, and JS developed the project protocol. CL provided information and practical assessments for preparing and conducting this current study in Norway. EG was responsible for the recruitment. The data analysis was conducted by EG and MS. All authors contributed to manuscript preparation and approved its final version.

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41. Hertzog MA. Considerations in determining sample size for pilot studies. Res Nurs Health 2008;31(2):180–91.

519 **Table 2**

520 Unadjusted descriptive statistics for pain and HRQOL for both groups

Outcomes	Control group Mean [SD]	Intervention group Mean [SD]	Effect size (Cohen's d)
Pain intensity			
Before intervention T0	5.5 [1.9]	5.4 [1.9]	
After intervention T1[a]	5.1 [1.65]	5.3 [2.45]	.08
HRQOL			
Physical well-being			
T0	50.0 [19.43]	41.6 [21.55]	
T1[b]	48.9 [17.56]	52.4 [25.56]	.16
Psychological well-being			
T0	54.5 [20.4]	56.8 [23.1]	
T1[b]	63.9 [23.71]	65.9 [20.74]	.10
Mood			
T0	61.6 [18.81]	55.4 [22.72]	
T1[b]	68.4 [16.98]	69.7 [20.05]	.07
Self-perception			
T0	46.1 [22.64]	45.7 [23.04]	
T1[b]	56.8 [24.46]	56.5 [23.37]	.01
Autonomy			
T0	61.6 [17.80]	56.6 [20.23]	
T1[b]	65.7 [15.67]	62.9 [24.05]	.14
Parents' relationship			
T0	61.2 [23.44]	68.1 [24.64]	
T1[b]	65.8 [28.92]	72.1 [26.18]	.23
Social support			

T0	56.6 [23.69]	63.3 [18.40]	
T1[b]	66.7 [17.75]	69.1 [20.68]	.13
School environment			
T0	52.7 [20.32]	55.0 [19.77]	
T1[b]	57.4 [28.50]	69.1 [16.74]	.49

[a] Control group n = 14, intervention group n = 19

[b] Control group n = 14, intervention group n = 17

Table 3

Unadjusted descriptive statistics on self-efficacy, pain self-efficacy, social support, and HADS scores for both groups

Secondary outcomes	Control group Mean [SD]	Intervention group Mean [SD]	Effect size (Cohen's d)
Self-efficacy			
Pre-intervention T0	13.9 [3.03]	13.0 [3.42]	
Post-intervention T1[c]	14.2 [3.02]	14.9 [3.59]	.22
HADS-T			
T0	15.2 [6.14]	16.7 [6.58]	
T1[c]	15.0 [5.93]	11.7 [6.31]	.53
HADS-A			
T0	6.3 [2.97]	6.7 [3.74]	
T1[c]	5.4 [3.25]	5.5 [3.91]	.02
HADS-D			
T0	8.9 [3.86]	10.1 [4.14]	
T1[c]	9.6 [3.95]	6.2 [3.49]	.91
Perceived social support			
T0	10.3 [2.80]	10.5 [3.24]	
T1[d]	10.2 [3.38]	10.5 [4.35]	.09
Pain self-efficacy			

T0		44.4 [11.56]	41.3 [11.37]	
T1[e]		48.3 [8.50]	44.5 [14.12]	.32

[c] Control group n = 13, intervention group n = 17

[d] Control group n = 12, intervention group n = 17

[e] Control group n = 11, intervention group n = 17

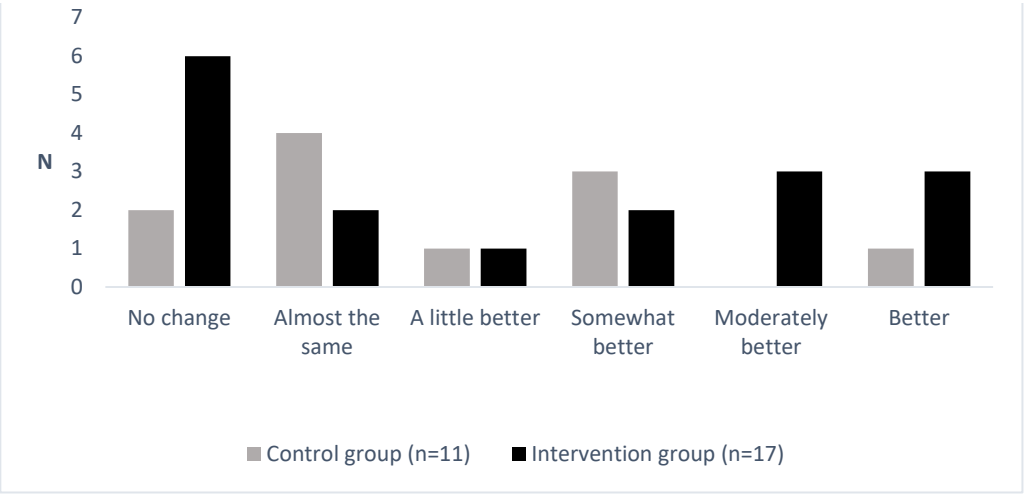

7
6
5
4
3
2
1
0
N
No change
Almost the same
A little better
Somewhat better
Moderately better
Better
Control group (n=11)
Intervention group (n=17)

Figure 2.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1 of 24
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2 of 24
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4 of 24 to 5 of 24
	2b	Specific objectives or research questions for pilot trial	5 of 24
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5 of 24
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	Not applicable
Participants	4a	Eligibility criteria for participants	6 of 24
	4b	Settings and locations where the data were collected	6 of 24
	4c	How participants were identified and consented	6 of 24
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5 of 24 to 6 of 24
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	7 of 24 8 of 24 9 of 24
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	Not applicable
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	Not applicable
Sample size	7a	Rationale for numbers in the pilot trial	11 of 24 17 of 24
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6 of 24
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	6 of 24

Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6 of 24
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6 of 24
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6 of 24
	11b	If relevant, description of the similarity of interventions	Not applicable
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	9 of 24 10 of 24
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	11 of 24
	13b	For each group, losses and exclusions after randomisation, together with reasons	12 of 24
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6 of 24
	14b	Why the pilot trial ended or was stopped	6 of 24
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	11 of 24
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	11 of 24 to 14 of 24
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	11 of 24 to 14 of 24
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	11 of 24 to 14 of 24
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
	19a	If relevant, other important unintended consequences	Not applicable
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	14 of 24 to 17 of 24
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	14 of 24 to 17 of 24
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	14 of 24 to 17 of 24

	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	17 of 24
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	2 of 24
Protocol	24	Where the pilot trial protocol can be accessed, if available	Not available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	19 of 24
	26	Ethical approval or approval by research review committee, confirmed with reference number	18 of 24

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix I

FORSKNINGSPROSJEKTET

iCanCope with Pain

TRENGER DELTAKERE!

Vi ønsker deltakere til et forskningsprosjekt som tester effekten av å bruke en app som heter iCanCope with Pain.

HVEM KAN VÆRE MED?
Vi vil gjerne komme i kontakt med ungdommer i videregående skole som har mye smerter.

Det kan være hodepine, vondt i skuldre eller mage, eller andre typer hverdagssmerter. For å delta må du ha hatt ukentlige smerter som har vart mer enn 3 måneder og du må ha din egen iPhone/smarttelefon.

Ungdommer som opplever smerter på grunn av alvorlige medisinske diagnoser som f.eks. kreft, kan ikke være med i dette forskningsprosjektet siden app'en ikke er utviklet for denne gruppen.

OM PROSJEKTET
I dette prosjektet ønsker vi å finne ut om det å bruke en internettbasert app kan bidra til bedre mestring av smerter. Vi ønsker å se om bruk av app'en kan redusere smerteplagene og gjøre hverdagen bedre.

Hvis du vil delta i studien får du mulighet til å teste ut iCanCope with Pain app'en i 8 uker. Før du starter skal du fylle ut et samtykke/spørreskjema og du vil motta nødvendig informasjon for å kunne laste ned og bruke app'en. Etter du er ferdig med perioden fyller du igjen ut spørreskjemaet. Noen deltakere vil bli spurt om å være med i et gruppeintervju.

Husk at ingen utenom forskeren vil få vite hva du svarer på spørreskjemaene og ingen vil kunne gjenkjenne svarene dine ved en senere anledning.

OM ICANCOPE WITH PAIN
iCanCope with Pain er en internettbasert app som kan bidra til bedre mestring av smerter.

Denne app'en gir deg mulighet til daglig registrering av smerte, søvn, humør, fysisk aktivitet og sosialt slik at du kan følge med på hvordan du har det over tid.

INTERESSERT?
Ta kontakt på:
mestre.smerte@uia.no
eller snakk med helsesøster på skolen din.

UNIVERSITETET I AGDER

Appendix II

Samtykke til deltakelse i brukertesting

Bakgrunn og formål
Mange unge har ofte smerter som hodepine, vondt i magen eller andre «vondter». Slike smerter kan gå utover dagliglivet og aktiviteter. I den forbindelse er det utviklet en app - *iCanCope with Pain.* Vi ønsker å finne ut om denne app'en kan bidra til bedre mestring av smerter blant ungdom.

Hensikten med brukertesting er å se hvordan det oppleves å bruke app'en, og om den har feil eller mangler. Vi ønsker derfor at ungdommer i den aktuelle aldersgruppen tester ut app'en under observerbare forhold, og gir tilbakemelding på opplevelsen av å bruke app'en.

Hva innebærer deltakelse i brukertesting?
Deltakelse i brukertesting innebærer at du prøver ut app'en under observerbare forhold i ca 1 time. Det er ønskelig at du besvarer et spørreskjema, og er med på en kort samtale etter testingen. Alle data som du registrerer i app'en skal være fiktive (oppdiktede). Dette vil skje ved UIA Grimstad. Data registres i form av notater og lyd/filmopptak. Brukertestingen er 12. og 13. desember 2017. Transportkostnader vil dekkes, og mat og drikke serves i pausen. Du vil få et gavekort på 300 kr.

Hva skjer med informasjonen om deg?
Informasjonen du gir vil brukes til å rette opp eventuelle feil og mangler ved app'en.

Alle personopplysninger vil bli behandlet konfidensielt. Alle deltakere for et eget av-identifiserbart brukernavn og passord. Kun forsker, databehandler og veiledere vil ha tilgang på datamaterialet. Etter deltakelse i prosjektet vil alle personopplysninger bli anonymisert og slettet. Det vil ikke være mulig å gjenkjenne deltakere i senere publikasjoner.

Frivillig deltakelse
Det er frivillig å delta i brukertesting og du kan når som helst trekke ditt samtykke uten å oppgi noen grunn. Dersom du trekker deg, vil alle opplysninger om deg bli slettet. Det er ingen konsekvenser ved å trekke seg.

Dersom du har spørsmål ta kontakt med doktorgradsstipendiat Erik Grasaas på telefon 97524422 eller erik.grasaas@uia.no.

Prosjektleder er Kristin Haraldstad, telefon 38142267 eller kristin.haraldstad@uia.no.

Samtykke til deltakelse

Jeg har mottatt informasjon om brukertesting i lab, og er villig til å delta og teste ut app'en «iCanCope with Pain» under observerbare forhold.

(Signert av deltaker, dato)

Appendix III

1. Hva er ditt inntrykk etter du nå har prøvd ut den norske versjonen av app`en i 2 uker?

2. Hva likte du best med denne app'en?

3. Hva likte du minst med denne app'en?

4. Likte du å utføre daglig registrering?

5. Likte du muligheten til å sette deg mål i app`en?

6. Likte du muligheten til å bruke biblioteket i app`en?

7. Likte du muligheten til en fellesgruppe i app'en?

8. Hva kunne eventuelt bidratt til å forbedre denne app'en? Nå har du jo vært inne på flere ting allerede, men har du noe du tenker på?

9. Ville du ha anbefalt denne måten å lære mestring på for andre?

10. I hvilke situasjoner ville du fått brukt for denne app'en?

11. Hvor ofte tror du at du ville benyttet deg av denne app'en?

12. Er det noe du syns mangler i app`en av innhold eller funksjoner?

13. Hvis du skal beskrive app`en til en venn i en setning eller to – hva ville du sagt?

14. Andre siste kommentarer?

Appendix IV

Noen spørsmål om systemet du har brukt.

Vennligst sett kryss i kun en rute pr. spørsmål.

	Sterkt uenig				Sterkt enig
1. Jeg kunne tenke meg å bruke dette systemet ofte.	1	2	3	4	5
2. Jeg synes systemet var unødvendig komplisert.	1	2	3	4	5
3. Jeg synes systemet var lett å bruke.	1	2	3	4	5
4. Jeg tror jeg vil måtte trenge hjelp fra en person med teknisk kunnskap for å kunne bruke dette systemet.	1	2	3	4	5
5. Jeg syntes at de forskjellige delene av systemet hang godt sammen.	1	2	3	4	5
6. Jeg syntes det var for mye inkonsistens i systemet. (Det virket "ulogisk")	1	2	3	4	5
7. Jeg vil anta at folk flest kan lære seg dette systemet veldig raskt.	1	2	3	4	5
8. Jeg synes systemet var veldig vanskelig å bruke	1	2	3	4	5
9. Jeg følte meg sikker da jeg brukte systemet.	1	2	3	4	5
10. Jeg trenger å lære meg mye før jeg kan komme i gang med å bruke dette systemet på egen hånd.	1	2	3	4	5

Appendix V

Selvhjelpsapplikasjonen icancope with pain

Bakgrunn og hensikt
Dette er et doktorgradsprosjekt ved Universitet i Agder. Deltakerne kommer fra ulike videregående skoler på Sørlandet. Undersøkelser viser at det i dag er mange unge som ofte har smerter som hodepine, vondt i magen eller andre «vondter». I denne forbindelse er det i Canada utviklet en app – iCanCope with Pain – som har til hensikt å fremme mestring og livskvalitet. Vi ønsker å finne ut om en norsk versjon av denne app'en kan bidra til å fremme mestring av smerter blant ungdom. For å vurdere effekten av «iCanCope with Pain» app'en er det laget to versjoner med noe ulikt innhold. Det er helt tilfeldig hvilken versjon du får prøve ut.

Hva innebærer studien?
Deltakelse i studien innebærer å teste ut en tilfeldig versjon av «iCanCope with Pain» app'en i 8 uker. Før du blir med i prosjektet må du lese dette informasjonsskrivet, gi ditt samtykke og besvare et spørreskjema. Etter 8 uker blir du bedt om å svare på samme spørreskjema en gang til.
Etter at du har svart på spørreskjema, vil du motta en link på e-post som gir deg muligheten til å laste ned app'en sammen med en beskrivelse om hvordan den brukes. Første gangen du registrerer deg på app'en vil det ta omkring 10 minutter. Det er ønskelig at du hver dag i denne 8 ukers perioden svarer på noen faste spørsmål om smerte, fysisk aktivitet, søvn, sosial aktivitet og humør på app'en. Det vil ta under 2 minutter daglig å svare på spørsmålene.

Hvis det oppstår noe feil med app'en, så er prosjektleder Kristin Haraldstad tilgjengelig for tekniske henvendelser.

Hva skjer med prøvene og informasjonen om deg?
Alle personopplysninger vil bli behandlet konfidensielt. Du får ditt eget brukernavn og passord. Kun forsker, databehandler og veiledere vil ha tilgang på opplysningene (datamaterialet). Etter deltakelse i prosjektet vil alle personopplysninger bli anonymisert. Resultater fra prosjektet vil bli publisert i ulike tidsskrift, men det vil ikke være mulig å gjenkjenne noen deltakere.

HUSK: Bruk kun ditt tildelte brukernavn eller lag et fiktivt navn. For din egen sikkerhet - aldri bruk eget navn eller oppgi andre personidentifiserbare opplysninger når du bruker app'en.

Deltakelse
Det er frivillig å delta i studien, og du kan når som helst trekke deg uten å oppgi noen grunn. Dersom du trekker deg, vil alle opplysninger om deg bli anonymisert. Det er ingen konsekvenser ved å trekke seg fra studien.

Prosjektleder: Kristin Haraldstad, 1. amanuensis UiA.
Epost: kristin.haraldstad@uia.no Tlf: 38142267

PhD stipendiat: Erik Grasaas, UiA
Epost: erik.grasaas@uia.no Tlf: 38141703

Samtykke:
Jeg har mottatt og forstått informasjon om studien. Jeg samtykker, og er villig til å delta på 8 ukers testing av app'en «iCanCope with Pain».

- ○ JA

‹ › Neste

Appendix VI

1. **Har du hatt smerter (vondt noen steder) de siste tre månedene?**

A ○ Nei, jeg har ikke hatt smerter (hatt vondt).

B ○ Ja, jeg har hatt smerter (hatt vondt)

2. **Har du hatt noen av disse smertene i løpet av de tre siste månedene?**

		Ja	Nei
	Vondt i hodet	○	○
	Vondt i ryggen	○	○
	Vondt i øret	○	○
	Vondt i magen	○	○
	Vondt i armen(e)	○	○
	Vondt i beinet	○	○
	Vondt i brystet	○	○
	Vondt i halsen	○	○
	Vondt i tennene	○	○
	Gjelder jenter: *Menstruasjonssmerter*	○	○
	Vondt andre steder Hvor_____	○	○

3. Hvor har du hatt mest vondt?

_____

4. **Hvor lenge har du hatt vondt på denne måten?**

Bare en gang. ○ Mer enn 3 måneder ○

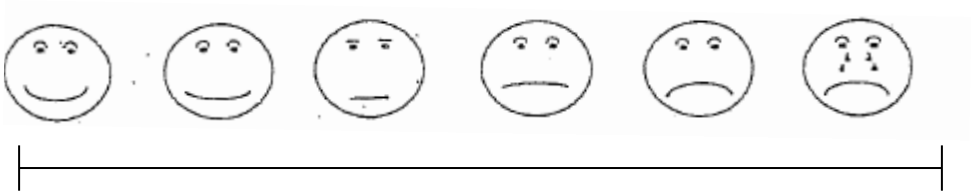
Mindre enn en måned	○	Mer enn 6 måneder	○
Mellom 1 og 3 måneder	○	Mer enn 12 måneder	○

Hvor ofte har du hatt denne smerten (hatt vondt på denne måten) de tre siste månedene?

5.

Mindre enn èn gang i måneden	○	1 gang i uka	○
1 gang i måneden	○	Flere ganger i uka	○
2-3 ganger I måneden	○	Hver dag	○

6. **Hvor sterk er denne smerten vanligvis?**



Nesten ikke følbar smerte

Den sterkeste smerte som kan tenkes

På grunn av disse smertene-

7.

	Aldri	Av og til	ofte	Alltid
Har jeg brukt medisiner	○	○	○	○
Har jeg vært hos legen	○	○	○	○
Har jeg vært borte fra skolen	○	○	○	○
Kunne jeg ikke være sammen med venner	○	○	○	○
Hadde jeg dårlig matlyst/spiste jeg ikke	○	○	○	○

Hadde jeg problemer med å sove	○	○	○	○
Kunne jeg ikke drive med fritidsaktivitetene mine	○	○	○	○
Kunne ikke foreldrene/en av foreldrene mine gå på jobb	○	○	○	○
Måtte jeg legge meg/ta det med ro	○	○	○	○
Var det noe annet jeg ikke kunne gjøre _____ *(hva?)*	○	○	○	○
Har jeg gjort følgende _____ *(hva?)*	○	○	○	○

Hva tror du selv er årsaken til disse smertene (grunnen til at du har vondt)?

8.

Værskifte	○	Bråk/høy musikk	○
Irritasjon/krangling	○	Familiesituasjonen	○
Skolesituasjonen	○	PC	○
Opphisselse	○	Skolearbeidet	○
Tristhet	○	Ikke noe spesielt	○
For lite søvn	○	En ny situasjon	○
Forkjølelse	○	Fysisk anstrengelse/ sport	○
TV-titting	○	Mat/søtsaker	○
Ensomhet/følte meg alene	○	For jenter: *Menstruasjon*	○
Vet ikke	○	Annet_____	○

Når fikk du disse smertene for første gang?

9.

Etter en skade/ et uhell	○	Etter å ha byttet skole	○
Etter en medisinsk behandling/operasjon	○	Etter skilsmisse/separasjon hos foreldre	○
Etter et dødsfall I familien	○	Hos jenter: I forbindelse med menstruasjon	○
Etter en flytting	○	Vet ikke	○
Etter en sykdom/i forbindelse med en sykdom	○	Etter noe annet	○
Etter fysisk anstrengelse/sport	○	_____ *(hva?)*	

10. **Finnes det en årsak og/eller medisinsk diagnose til smertene dine?**

Nei ○ Vet ikke ○ Ja ○ _____ *(hvilken?)*

11. **Har du en eller flere kroniske sykdommer? (for eksempel høysnue, allergi)?**

'Nei ○ Vet ikke ○ Ja ○ _____ *(hvilken?)*

12. **Er det noen i familien din som har ofte smerter, eller alltid smerter?**

'Nei ○ Vet ikke ○ Ja ○ _____ *(hvem?)*

Appendix VII

1. Til vanlig, hvordan vil du si at helsen din er?

- ○ veldig bra
- ○ bra
- ○ ganske bra
- ○ dårlig

Når du tenker på den siste uka…

	Ikke I det hele tatt	litt	ganske	veldig	I høy grad
2. Har du følt deg frisk og sprek?	○	○	○	○	○
3. Har du vært fysisk aktiv (for eksempel løpt, klatret, syklet)?	○	○	○	○	○
4. Har du kunnet løpe bra?	○	○	○	○	○

Når du tenker på den siste uka.

	Aldri	Sjelden	Ganske ofte	Veldig ofte	Alltid
5. Har du følt deg full av energi?	○	○	○	○	○

Når du tenker på den siste uka...

	Ikke i det hele tatt	Litt	Ganske	Veldig	I høy grad
1. Har livet ditt vært bra?	○	○	○	○	○
2. Har du vært glad for at du lever?	○	○	○	○	○
3. Har du følt deg fornøyd med livet ditt?	○	○	○	○	○

Når du tenker på den siste uka...

	Aldri	Sjelden	Ganske ofte	Veldig ofte	Alltid
4. Har du vært i godt humør?	○	○	○	○	○

5.	Har du følt deg glad?	○	○	○	○	○
6.	Har du hatt det gøy?	○	○	○	○	○

Når du tenker på den siste uka...

		Aldri	Sjelden	Ganske ofte	Veldig ofte	Alltid
1.	Har du følt at alt du gjør blir feil?	○	○	○	○	○
2.	Har du følt deg trist?	○	○	○	○	○
3.	Har du følt deg så ille/elendig at du ikke har villet gjøre noe?	○	○	○	○	○
4.	Har du følt at alt i livet ditt går galt?	○	○	○	○	○
5.	Har du vært skikkelig lei?	○	○	○	○	○
6.	Har du følt deg ensom?	○	○	○	○	○
7.	Har du følt deg presset?	○	○	○	○	○

Når du tenker på den siste uka...

		Aldri	Sjelden	Ganske ofte	Veldig ofte	Alltid
1.	Har du vært fornøyd med deg selv slik du er?	○	○	○	○	○
2.	Har du vært fornøyd med klærne dine?	○	○	○	○	○
3.	Har du vært bekymret for utseendet ditt?	○	○	○	○	○
4.	Har du vært sjalu på andre jenters eller gutters utseende?	○	○	○	○	○
5.	Ville du gjerne forandre noe ved kroppen din?	○	○	○	○	○

	Når du tenker på den siste uka ...	Aldri	Sjelden	Ganske ofte	Veldig ofte	Alltid
1.	Har du hatt nok tid for deg selv?	○	○	○	○	○
2.	Har du kunnet gjøre de tingene du ønsker i fritiden din?	○	○	○	○	○
3.	Har du hatt nok muligheter til å være ute?	○	○	○	○	○
4.	Har du hatt nok tid til å være sammen med venner?	○	○	○	○	○
5.	Har du kunnet velge hva du vil gjøre i fritiden din?	○	○	○	○	○

	Når du tenker på den siste uka...	Ikke i det hele tatt	Litt	Ganske	Veldig	I høy grad
1.	Har moren/faren din forstått deg?	○	○	○	○	○
2.	Har du følt at moren/faren din er glad I deg?	○	○	○	○	○

	Når du tenker på den siste uka...	Aldri	Sjelden	Ganske ofte	Veldig ofte	Alltid
3.	Har du vært glad hjemme?	○	○	○	○	○
4.	Har moren/faren din hatt nok tid til deg?	○	○	○	○	○
5.	Har moren/faren din behandlet deg rettferdig?	○	○	○	○	○
6.	Har du kunnet snakke med moren/faren din når du har lyst?	○	○	○	○	○

	Når du tenker på den siste uka...	Aldri	Sjelden	Ganske ofte	Veldig ofte	Alltid
1.	Har du hatt nok penger til å gjøre de samme tingene som vennene dine?	○	○	○	○	○
2.	Har du hatt nok penger til det du trenger?	○	○	○	○	○

	Når du tenker på den siste uka...	Ikke I det hele tatt	litt	ganske	veldig	I høy grad
3.	Har du hatt nok penger til å gjøre ting sammen med vennene dine?	○	○	○	○	○

	Når du tenker på den siste uka...	Aldri	Sjelden	Ganske ofte	Veldig ofte	Alltid
1.	Har du vært sammen med vennene dine?	○	○	○	○	○
2.	Har du gjort ting sammen med andre jenter og gutter?	○	○	○	○	○
3.	Har du hatt det gøy sammen med vennene dine?	○	○	○	○	○
4.	Har du og vennene dine hjulpet hverandre?	○	○	○	○	○
5.	Har du kunnet snakke med vennene dine om alt?	○	○	○	○	○
6.	Har du kunnet stole på vennene dine?	○	○	○	○	○

	Når du tenker på den siste uka...	Ikke i det hele tatt	Litt	Ganske	Veldig	I høy grad
1.	Har du vært glad på skolen?	○	○	○	○	○

2.	Har du klart deg bra på skolen?	○	○	○	○	○
3.	Har du vært fornøyd med lærerne dine?	○	○	○	○	○

	Når du tenker på den siste uka...	Aldri	Sjelden	Ganske ofte	Veldig ofte	Alltid
4.	Har du klart å følge med på skolen?	○	○	○	○	○
5.	Har du likt å være på skolen?	○	○	○	○	○
6.	Har du kommet godt ut av det med lærerne dine?	○	○	○	○	○

	Når du tenker på den siste uka...	Aldri	Sjelden	Ganske ofte	Veldig ofte	Alltid
1.	Har du vært redd for andre jenter og gutter?	○	○	○	○	○
2.	Har du blitt ertet av andre jenter og gutter?	○	○	○	○	○
3.	Har du blitt mobbet av andre jenter og gutter?	○	○	○	○	○

Appendix VIII

UNIVERSITETET I AGDER
FAKULTET FOR HELSE- OG IDRETTSVITENSKAP

Mestringstro

	Ikke riktig	Litt riktig	Nesten riktig	Helt riktig
1) Jeg klarer alltid å løse vanskelige problemer hvis jeg prøver hardt nok.	○	○	○	○
2) Hvis noen motarbeider meg, så kan jeg finne måter og veier for å få det som jeg vil.	○	○	○	○
3) Jeg er sikker på at jeg kan mestre uventede hendelser	○	○	○	○
4) Jeg er rolig når jeg møter vanskeligheter fordi jeg stoler på min evne til å klare meg	○	○	○	○
5) Dersom jeg er i knipe, finner jeg vanligvis en løsning	○	○	○	○

Neste

Appendix IX

UNIVERSITETET I AGDER
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Instruksjoner: Påstandene som følger handler om følelser og erfaringer de fleste har hatt en eller flere ganger i forhold til venner. For hver påstand er det tre mulige svar; Ja, Nei, Vet ikke.

Vennligst velg et svar for hver påstand.

Opplevd sosial støtte fra venner

	Ja	Nei	Vet ikke
Vennene mine gir meg den moralske støtten jeg trenger.	○	○	○
De fleste andre har et nærmere forhold til vennene sine enn jeg har.	○	○	○
Vennene mine liker å høre på hva jeg tenker	○	○	○
Noen venner kommer til meg når de har problemer eller trenger råd.	○	○	○
Jeg stoler på vennene mine når det gjelder å få emosjonell støtte.	○	○	○
Hvis en eller flere av vennene mine var bekymret for meg, så ville jeg bare holdt det for meg selv.	○	○	○
Jeg føler at jeg står litt utenfor i vennegjengen min	○	○	○
Jeg har en venn jeg kan gå til dersom jeg er lei meg uten at det føles ubehagelig etterpå	○	○	○
Vennene mine og jeg er veldig åpne om hva vi tenker om ting	○	○	○
Vennene mine bryr seg om mine personlige behov	○	○	○

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	Ja	Nei	Vet ikke
Vennene mine kommer til meg for å få emosjonell støtte	○	○	○
Vennene mine er gode til å hjelpe meg å løse problemer	○	○	○
Jeg har et dypt fortrolig forhold til flere venner	○	○	○
Vennene mine får gode ideèr om hvordan de kan gjøre noe for meg	○	○	○
Jeg blir ukomfortabel når jeg betror meg til venner	○	○	○
Vennene mine ønsker å være være sammen med meg.	○	○	○
Jeg tror at vennene mine føler jeg er god til å hjelpe dem med å løse problemer	○	○	○
Jeg har ikke et like nært forhold til en venn som andre har til sine venner	○	○	○
Jeg har nettopp fått en god idé fra en venn om hvordan jeg kan gjøre noe	○	○	○
Jeg skulle ønske at vennene mine var veldig annerledes	○	○	○

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Appendix X

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Vennligst beskriv hvor komfortabel du er med å gjøre følgende ting selv om du har smerter.
Velg et tall på skalaen, der 0 = ikke komfortabel i det hele tatt og 6 = fullstendig komfortabel

Husk, dette spørreskjemaet er ikke ute etter om du har gjort disse tingene eller ikke, men hvor komfortabel du er med å gjøre dette selv om du har smerter.

For eksempel:
Ikke komfortabel i det hele tatt = 0
Fullstendig komfortabel = 6

Jeg kan ha glede av ting selv om jeg har smerter	
Jeg kan gjøre det meste av husarbeid (f.eks. rydde, ta oppvasken, o.l) selv om jeg har smerter	
Jeg kan være sosial med venner og familie så ofte som jeg pleier selv om jeg har smerter.	
Jeg kan håndtere smerter i de fleste situasjoner	
Jeg kan gjøre ulikt type arbeid selv om jeg har smerter ("arbeid" inkluderer husarbeid, betalt og ubetalt arbeid)	
Jeg kan fremdeles gjøre mange av de tingene jeg liker å gjøre, slik som hobbyer og fritidsaktiviteter selv om jeg har smerter	
Jeg kan håndtere smerter uten bruk av medikamenter	
Jeg kan fortsatt oppnå de fleste av målene i livet mitt på selv om jeg har smerter.	
Jeg kan ha en vanlig, normal livsstil selv om jeg har smerter	
Jeg kan gradvis bli mer aktiv selv om jeg har smerter	

Neste

Appendix XI

Psykisk helse

Jeg føler meg urolig og nervøs ○ Mesteparten av tiden ○ Mye av tiden ○ Fra tid til annen ○ Ikke i det hele tatt

Jeg gleder meg fortsatt over tingene slik jeg pleide før ○ Avgjort like mye ○ Ikke fullt så mye ○ Bare lite grann ○ Ikke i det hele tatt

Jeg har en urofølelse som om noe forferdelig vil skje ○ Ja, og noe svært ille ○ Ja, ikke så veldig ille ○ Litt, bekymrer meg lite ○ Ikke i det hele tatt

Jeg kan le og se det morsomme i situasjoner ○ Like mye nå som før ○ Ikke like mye nå som før ○ Avgjort ikke som før ○ Ikke i det hele tatt

Jeg har hodet fullt av bekymringer ○ Veldig ofte ○ Ganske ofte ○ Av og til ○ En gang i blant

Jeg er i godt humør ○ Aldri ○ Noen ganger ○ Ganske ofte ○ For det meste

Jeg kan sitte i fred og ro og kjenne meg avslappet ○ Ja, helt klart ○ Vanligvis ○ Ikke så ofte ○ Ikke i det hele tatt

Jeg føler meg som om alt går langsommere ○ Nesten hele tiden ○ Svært ofte ○ Fra tid til annen ○ Ikke i det hele tatt

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Jeg føler meg urolig som om jeg har sommerfugler i magen ○ Ikke i det hele tatt ○ Fra tid til annen ○ Ganske ofte ○ Svært ofte

Jeg bryr meg ikke lenger om hvordan jeg ser ut ○ Ja, jeg har sluttet å bry meg ○ Ikke som jeg burde ○ Kan hende ikke nok ○ Bryr meg som før

Jeg er rastløs som om jeg stadig må være aktiv ○ Uten tvil svært mye ○ Ganske mye ○ Ikke så veldig mye ○ Ikke i det hele tatt

Jeg ser med glede frem til hendelser og ting ○ Like mye som før ○ Heller mindre enn før ○ Avgjort mindre enn før ○ Nesten ikke i det hele tatt

Jeg kan plutselig få en følelse av panikk ○ Uten tvil svært ofte ○ Ganske ofte ○ Ikke så veldig ofte ○ Ikke i det hele tatt

Jeg kan glede meg over gode bøker, radio og TV ○ Ofte ○ Fra tid til annen ○ Ikke så ofte ○ Svært sjelden

Neste

Appendix XII

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Siden du startet å bruke app'en, hvordan vil du beskrive endring (hvis det finnes) i aktivitet, symptomer, følelser og generell livskvalitet relatert til smertene dine? Vennligst velg det tallet som passer best med den grad av endring du har opplevd siden du startet å bruke app'en i forbindelse med smertene dine.

- Ingen bedring
- Nesten det samme
- Litt bedre
- Noe bedre
- Moderat bedre
- Bedre
- Mye bedre

Forklaring
1= Ingen endring (eller tilstanden har blitt verre)
2 = Nesten det samme, omtrent ingen endring
3= Litt bedre, men ingen merkbar endring
4= Noe bedre, men endringen har ikke vært av betydning
5= Moderat bedre og en liten, men merkbar endring
6= Bedre, en betydelig forbedring som har gjort en forskjell
7 = Mye bedre, en betydelig forbedring som har gjort en stor forskjell

< > Avslutt

Appendix XIII

UNIVERSITETET I AGDER
FAKULTET FOR HELSE- OG IDRETTSVITENSKAP

Fysisk aktivitet

Tenk all meget anstrengende aktivitet du har drevet med de siste 7 dagene. Meget anstrengende aktivitet er aktivitet som krever hard innsats og får deg til å puste mye mer enn vanlig. Ta bare med aktiviteter som varer minimum 10 minutter i strekk.

Hvor mange dager i løpet av de siste 7 dagene har du drevet med meget anstrengende fysisk aktivitet som tunge løft, gravearbeid, aerobics, løp eller rask sykling? -- Velg --

Hvor lang tid brukte du vanligvis på meget anstrengende fysisk aktivitet på en av disse dagene? Oppgi i timer og minutter for en dag

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Tenk på all middels anstrengende aktivitet du har drevet med de siste syv dagene. Middels anstrengende aktivitet er aktivitet som krever moderat innsats og får deg til å puste litt mer enn vanlig. Ta bare med aktiviteter som varer minst 10 minutter i strekk.

Hvor mange dager i løpet av de siste 7 dagene har du drevet med middels anstrengende fysisk aktivitet som å bære lette ting, jogge eller sykle i moderat tempo? Ikke ta med gange. -- Velg --

Hvor lang tid brukte du vanligvis på middels anstrengende fysisk aktivitet på en av disse dagene? Oppgi i timer og minutter for en dag

Tenk på tiden du har brukt på å gå de siste 7 dagene. Dette inkluderer gange på jobb og hjemme, gange fra et sted til et annet eller gange som du gjør på tur eller som trening på fritiden.

Hvor mange dager i løpet av de siste 7 dagene gikk du i minst 10 minutter i strekk? -- Velg --

Hvor lang tid brukte du vanligvis på å gå en av disse dagene? Oppgi i timer og minutter for en dag

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Det neste spørsmålet omfatter all tid du tilbrakte sittende på ukedagene i løpet av de siste 7 dagene. Inkluder tid du har brukt på å sitte på jobb, hjemme, på kurs og på fritiden. Dette kan tilsvare tiden du sitter ved et arbeidsbord, hos venner, mens du leser, eller sitter eller ligger for å se på TV.

Hvor lang tid brukte du på å sitte på en vanlig hverdag i løpet av de siste 7 dagene? Oppgi i timer og minutter for en dag.

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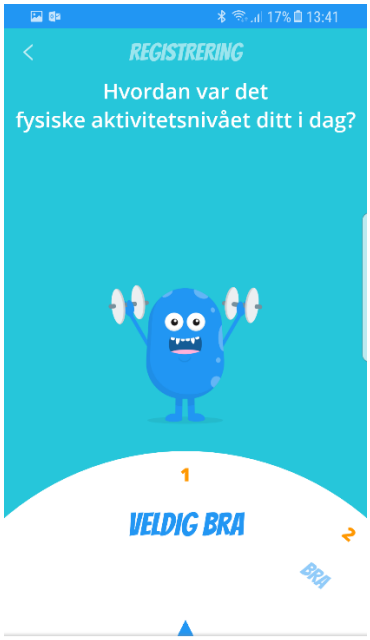
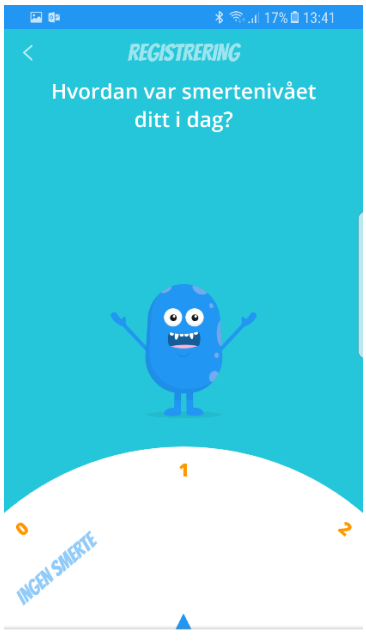
Appendix XIV

LA OSS KOMME I GANG



FORTSETT

FORTSETT



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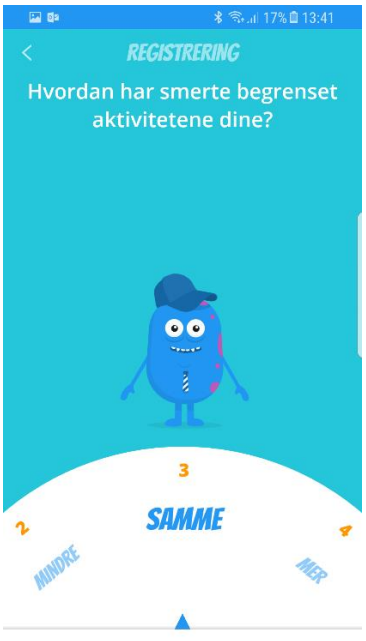

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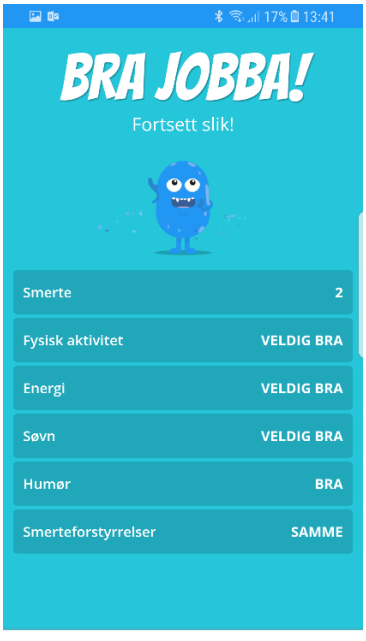

FERDIG

Appendix XV

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Hege Holde Andersson	22845514	29.06.2017	2017/350 REK sør-øst B
			Deres dato:	Deres referanse:
			11.05.2017	

Vår referanse må oppgis ved alle henvendelser

Kristin Haraldstad
Universitetet i Agder

2017/350 Ungdom og mestring av smerter - iCanCope with Pain

Forskningsansvarlig: Universitetet i Agder
Prosjektleder: Kristin Haraldstad

Vi viser til tilbakemelding på ovennevnte forskningsprosjekt. Tilbakemeldingen ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst) i møtet 07.06.2017. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10.

Prosjektleders prosjektbeskrivelse
"iCanCope with Pain - en app - som skal bidra til mestring av smerter hos ungdom. Hovedformål: 1) å tilpasse iCanCope with Pain til norske forhold, 2) å undersøke om norsk versjon av iCanCope with Pain kan bidra til å fremme mestring og livskvalitet hos ungdom med smerter. 1: Hvordan opplever ungdommer brukervennlighet av den norske versjonen av iCanCope with Pain i laboratorium og ved pilottest? Brukertesting av den norske versjonen av iCanCope with Pain hos ungdom med smerte. Dette skal gjennomføres i laboratorium og ved 2 ukers pilottest der data samles inn ved intervju og spørreskjema. 2: Hvilken sammenheng er det mellom smerter, mestring, fysisk aktivitet og livskvalitet hos ungdom med smerter? En tverrsnittsstudie der baseline data samles inn ved spørreskjema 3: Kan bruk av app'en iCanCope with Pain bidra til å fremme mestring og livskvalitet hos ungdom med smerter? En RCT studie der data samles inn ved spørreskjema besvart før og etter en 8 ukers intervensjonsperiode."

Saksgang
Komiteen behandlet første gang prosjektet i møtet 22.03.2017. I brev datert 21.04.2017 skrev komiteen:

*«**Komiteens vurdering***
Den foreliggende informasjonen er ikke tilstrekkelig til at komiteen kan fatte en avgjørelse.

Slik komiteen leser søknad og protokoll er det ikke samsvar i det som oppgis i forhold til studiens formål. Det referers til ulike oppdelinger av studien, i søknadsskjema og protokoll. På bakgrunn av dette ber komiteen om at studiens formål presiseres og samkjøres i protokoll og søknadskjema.

Rekruttering
Det skal rekrutteres ungdommer mellom 16 og 18 år med kroniske smerter. De må kunne norsk og ha smarttelefon. De rekrutteres fra videregående skoler i Kristiansand. Det er imidlertid uklart for komiteen hvor mange deltagere man skal rekruttere. Det oppgis at endelig styrkeberegning vil gjøres i samarbeid med en statistiker tilknyttet UiA, og antall forskningsdeltakere vil være avhengig av hvor stor effekt som kan forventes. Komiteen ber om en nærmere redegjørelse for hvor mange elever man tenker å rekruttere og over hvor langt tidsrom man skal rekruttere.

Komiteens beslutning
Vedtak i saken utsettes. Komiteen tar stilling til prosjektet ved mottatt svar.»

Prosjektleders tilbakemelding
Komiteen mottok prosjektleders tilbakemelding 11.05.2017. I tilbakemeldingen skriver prosjektleder at man nå har presisert studiens formål og oppdelinger, og samkjørt dette i søknadsskjema og prosjektprotokoll. Videre skriver prosjektleder at hovedformålet med studien er 1) å tilpasse iCanCope with Pain til norske forhold, og 2) å redusere smerter og fremme livskvalitet hos ungdom med smerter ved bruk av den norske versjonen av iCanCope with Pain app'en. Forskningsspørsmålene er tredelt: 1) Hvordan opplever ungdommer brukervennlighet av den norske versjonen av iCanCope with Pain i laoratorium og ved (2 ukers) pilottest? 2) Hvilken sammenheng er det mellom smerter, mesteringsforvetninger og livskvalitet hos ungdom med smerter? (etablerer en baseline basert på spørreskjema) og 3) Kan bruk av app'en iCanCope with Pain bidra til å redusere smerter og fremme livskvalitet hos ungdom med smerter (RCT studie med spørreskjema før og etter 8 ukers intervensjonsperiode). Det er nå gjort styrkeberegning og det skal rekrutteres 120 deltakere over ett år.

Komiteens vurdering
Komiteen mener prosjektleder har svart tilfredsstillende på de merknader komiteen hadde. Slik prosjektet nå foreligger, har komiteen ingen innvendinger til at det gjennomføres.

Vedtak
Komiteen godkjenner prosjektet i henhold til helseforskningsloven § 9 og § 33.

Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden.

Tillatelsen gjelder til 31.12.2020. Av dokumentasjonshensyn skal opplysningene likevel bevares inntil 31.12.2025. Opplysningene skal lagres avidentifisert, dvs. atskilt i en nøkkel- og en opplysningsfil. Opplysningene skal deretter slettes eller anonymiseres, senest innen et halvt år fra denne dato.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder *«Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren»*

Sluttmelding og søknad om prosjektendring
Dersom det skal gjøres endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK. Prosjektet skal sende sluttmelding på eget skjema, se helseforskningsloven § 12, senest et halvt år etter prosjektslutt.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningslovens § 28 flg. Klagen sendes til REK sør-øst B. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst B, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Komiteens avgjørelse var enstemmig.

Med vennlig hilsen

Grete Dyb
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leder REK sør-øst B

Hege Holde Andersson
komitésekretær