Fear of intra-oral injections among 10–16-year-olds

Assessment, prevalence and treatment

Karin Goplerud Berge

Dissertation for the degree of philosophiae doctor (PhD)

at the University of Bergen

2016

Dissertation date: November 25th.

Year: 2016

Title: Fear of intra-oral injections among 10-16-year-olds: Assessment, prevalence and treatment

Author: Karin G. Berge

Print: AIT Bjerch AS / University of Bergen

Scientific environment

- Department of Clinical Dentistry, The Faculty of Medicine and Dentistry, University of Bergen, Bergen, Norway

- Oral Health Centre of Expertise in Western Norway-Hordaland, Bergen, Norway.

Acknowledgements

The work presented in this thesis was a collaboration between Department of Clinical Dentistry, University of Bergen, and Oral Health Centre of Expertise in Western Norway, Hordaland (OHCE-W, Hordaland), carried out during 2013-2016. I would like to express my gratitude for the financial support provided by OHCE-W Hordaland, in addition to a project grant from L. Meltzers Høyskolefond.

The thesis is within the joint fields of dentistry and psychology, and through joining our forces we can reach far in our attempt to help fearful dental patients. The work behind this thesis is a collaboration in which I am incredibly grateful for having the opportunity to take part. There are a lot of people who have helped me in order to reach this goal, and I would like to express my sincere gratitude.

First and foremost I would like to thank my three supervisors for making this thesis possible. My sincere and deep gratitude goes to my main supervisor Associate Professor Marit Slåttelid Skeie. I am indebted for your invaluable guidance, hard work, and your thorough and detailed comments. You have been available to an extent that exceeds all expectations. You have always encouraged me to progress, and generously shared your knowledge and compassion.

Furthermore, I want to express my warm and deep gratitude to my co-supervisors Dr. Maren Lillehaug Agdal and Dr. Margrethe Vika. When I first started to work at the Center for Odontophobia, seeing the way you worked, and the way you treated the patients inspired me deeply, and is the reason that I wanted to work within this field. Your knowledge within the field and passion for the patients are inspiring. From the very first day you included me in all aspects of your work, and generously shared your broad knowledge. To have the opportunity to work and learn from some of the leading clinicians and researches within the field, whom I admire both professionally and personally, has been invaluable to me. You have constantly encouraged me and guided me in order to progress both as a clinician and a researcher. I find myself privileged to have had the three of you as my supervisors.

I want to warmly thank all the schools participating in this research project, and all the pupils sharing their dental experiences. Further, I would like to thank all the patients who have challenged their fears. Their contribution hopefully helps us improve and further develop the treatment.

Furthermore I would like to express my gratitude to OHCE-W, Hordaland, and the leader Professor Ellen Berggreen, for providing me with the necessary work conditions, facilitating the work behind this thesis.

I would also like to gratefully thank Professor Stein Atle Lie, co-author in Paper 1, for invaluable statistical guidance, and for laughing with me and not at me by all my questions.

I also owe much gratitude to Jana Ingebrigtsen, Rim Bertz, Jofrid Bjørkvik, Anne Karin Haga and all the rest of my colleagues at the Center for Odontophobia. Your contribution to the research project has been essential. Moreover sharing your high competence gained from long clinical experience working with fearful patients has taught me so much.

Ingfrid Brattabø, what should I have done without you by my side at the office? I am forever grateful for your support, and for us having so much fun along with the frustrations. Your insightful views have been invaluable to me, and your passion for the work an inspiration!

Elwalid Nasir, Manal Mustafa and Anne Skåtøy, a warm thank you for shearing fruitful discussions, good laughs and coffee, and for providing such a great atmosphere at the office.

To my fellow PhD colleagues Elisabeth Schilbred Eriksen, Elisabeth Grut Gil and Ferda Gülcan, thank you for all the support, interesting scientific discussions and necessary coffee breaks.

I would also like to express my gratitude to the dental assistants and dentists at the Clinic of Paediatric Dentistry for facilitating and performing the behavioural tests in Study II.

Furthermore, I would like to warmly thank June Indrevik for administrational guidance and general problem solving, and Randi Sundfjord for punching all the data in Study I.

My friend and psychologist Pia, a warm thank you for sharing your knowledge of psychology and giving me perspectives on my work, but most of all for being an unconditionally supportive friend. Furthermore, my friends Ingrid, Kari, Agnes, Trine, Siri, Linn and Ingvill, thank you for inspiration and endless support. For bringing me lunch, for always helping me on short notice when I desperately needed help with tables or figures not behaving the way I wanted them to, and always encouraging me to keep on going.

My parents, thank you for all the love and support. You have given me the confidence to embark this project, but also to see the importance of other aspects of life.

Peter, takk for at du er verdens aller beste person!

Abbreviations

AT	Applied tension
AUC	Area under the curve
BAT	Behavioural avoidance test
BII phobia	Blood-injury-injection phobia
BIP	Blood-injury phobia
CBT	Cognitive Behavioural Therapy
CFSS-DS	Children's Fear Survey Schedule-Dental Subscale
DSM-5	Diagnostic and Statistical Manual of Mental Disorders 5th edition
E-OIP	Extra-oral injection phobia
IOIF-s	Intra-Oral Injection Fear scale
I-OIP	Intra-oral injection phobia
IP	Injection phobia
IS-c	Injection Phobia Scale for children
ITG	Immediate Treatment Group
ITT	Intention-to-treat
MQ-c	Mutilation Questionnaire for children
PDS	Public Dental Service
RCT	Randomized Controlled Trial
ROC	Receiver Operating Characteristics
WCG	Waitlist-Control Group

Abstract

Background: Intra-oral injections are common procedures within dentistry, performed in order to avoid procedural pain. Nevertheless, little is known about the prevalence of high intra-oral injection fear, or treatment of intra-oral injection phobia among children and adolescents. **Aims:** The overall aims were to gain more knowledge about the prevalence of high intra-oral injection fear among children and adolescents, to validate the novel Intra-Oral Injection Fear scale (IOIF-s), to clarify the overlap between intra-oral injection fear and dental fear, and to explore the possible effectiveness of cognitive behavior therapy (CBT) among children and adolescents with formally diagnosed intra-oral injection phobia (I-OIP). **Methods:** The study comprised two parts, both carried out in Hordaland County, Norway. Study I was a cross-sectional study among 1460 10- to 16-year old pupils. Data were collected by use of questionnaires, including the novel IOIF-s. Study II was a randomized and controlled treatment study in 67 patients within the same age group, fulfilling the DSM-5 criteria for I-OIP. The patients were randomly assigned to either an immediate treatment group receiving CBT, or a waitlist-control group. The treatment was performed by dentists specially trained in CBT. Subjective and behavioural measures of effectiveness of the treatment were assessed. **Results:** Crohnbach's alpha of the IOIF-s was 0.95. Further the IOIF-s was found to discriminate between participants with and without I-OIP. In total 13.9% of the children reported high fear of intra-oral injections based on the IOIF-s. A strong association between fear of intra-oral injections and dental fear was revealed. CBT had significant effect compared to no treatment both measured subjectively by self-report scales, and behaviourally by receiving intra-oral injections. **Conclusions:** The IOIF-s has satisfying psychometric properties in terms of reliability and validity. Further, high intra-oral injection fear was found to be prevalent among the targeted age group, and is associated with avoidance of necessary dental treatment. CBT performed by specially trained dentists is an efficient treatment among children and adolescents diagnosed with intra-oral injections.

List of publications

This thesis is based upon three papers:

1. Berge KG, Vika M, Agdal ML, Lie SA, Skeie MS. Reliability, validity and cut-off score of the Intra-Oral Injection Fear scale, Int J Paediatr Dent. 2016 May 27.doi: 10.1111/ipd.12237.

2. Berge KG, Agdal ML, Vika M, Skeie MS. High fear of intra-oral injections: prevalence and relationship to dental fear and dental avoidance among 10-16-year-old children. 2016 Eur J Oral Sci. In press.

3. Berge KG, Agdal ML, Vika M, Skeie MS. Treatment of intra-oral injection phobia: a randomized clinical trial among 10- to 16-year-olds. (Submitted manuscript)

Contents

1.0 INTRODUCTION

Intra-oral injection phobia is a subgroup of the blood-injury-injection phobia, one of the five specific phobias classified in the Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5) (1). Within dentistry, intra-oral injections are common procedures, performed in order to avoid procedural pain. Pain and anticipation of painful dental experiences are found to be predictors for the development of dental fear (2). Sufficient pain control in relation to dental treatment in children is therefore of vital importance. Intra-oral injections are found to be among the most fear-provoking stimuli for children in a dental setting (3, 4). Nevertheless, little is known about the prevalence of high intra-oral injection fear among children and adolescents. This may partly be due to the absence of psychometric measurement tools assessing the intra-oral injection fear. Furthermore, in the young population little is known about the consequences of high fear of intra-oral injections, or the association between intra-oral injection fear and dental fear. Even though blood-injury-injection phobia may have its onset in childhood (5-7), there is a lack of evidence based interventions for children and adolescents suffering from intra-oral injection phobia.

This thesis concerns assessment, prevalence and treatment of intra-oral injection phobia in children and adolescents. Psychometric properties and applicability of a novel self-report scale assessing intra-oral injection fear will be evaluated. The prevalence of high intra-oral injection fear is examined, as well as the overlap between high intra-oral injection fear and high dental fear. Furthermore, the consequences of high fear of intra-oral injections in terms of avoidance of dental treatment requiring intra-oral injections will be discussed. Finally, the effectiveness of 5-sessions of cognitive behaviour therapy (CBT) performed by specially trained dentists, is explored in a sample of children and adolescents with formally diagnosed intra-oral injection phobia.

1.1 Fear, anxiety and phobia, definitions

Fear, anxiety and phobia are related emotions and are often used interchangeably in literature. The function of the rather similar emotional experiences **fear** and **anxiety** is to generate adequate adaptive responses when exposed to threats, danger and motivational conflicts (8). The feared object is suggested to be characterized as "real", "objective" and "known", whereas the anxiety provoking object is described as "unclear or uncertain" (9). The core point of anxiety has been described as a sense of uncontrollability (10). Depending on the context, the responses of fear and anxiety are usually mild, short-term and reasonable (11). By activation of the autonomic nervous system, the fear/anxiety response exhibits four types of symptoms that facilitate the "fight-or flight" response, enabling either immediate escape or attack of feared stimuli (12). The *physiological* or *somatic* symptoms, as a consequence of arousal of the sympathetic nervous system, include adrenaline secretion, increased perspiration, increased heart rate and muscle tension. *Emotional* symptoms are displayed essentially in terms of fearfulness and apprehension. Furthermore, *cognitive* symptoms include anticipation of harm, fear of losing control and finally *behavioural* symptoms such as avoidance or escape from feared situations (11, 13). To summarize, the terms fear and anxiety display the same physiological responses. However, as described by Barlow, fear is a reaction to a present triggering stimuli or the danger imminent, whereas anxiety is future-oriented and corresponds to a threat that has not yet occurred (9).

In anxiety disorders, the frequency and intensity of fear/anxiety responses are out of proportion to the situations that trigger them and the responses interfere with daily life. Although these distinctions are often not very sharp, delineations can be made between an adaptive response to a threat, which can be termed *adaptive fear* and a *maladaptive anxiety* response (11). In adaptive fear, individual cognitions and concerns are realistic given the circumstances, the amount of fear experienced is in proportion to the reality of the threat and the fear response subsides when the threat ends. In maladaptive anxiety, on the other hand, individual concerns are unrealistic,

the fear experienced is out of proportion and the concern persists when the threat ends.

Anxiety disorders take a number of different forms, including phobic disorders. **Phobias** are exaggerated and irrational fears of certain objects or situations (1). Hence, when the fear/anxiety response reaches extreme levels, and significant distress and impairment of functioning is reported, the state may be defined as a phobia, classified in the Diagnostic and Statistical Manual of Mental Disorders -5 (DSM-5) as an anxiety disorder (1). Individuals with phobias recognize their fear as irrational, yet their solution is often to make attempts to avoid the feared situation or object.

Phobia is a clinical diagnosis that can only be diagnosed by trained professionals such as psychologists or physicians. A thorough evaluation should include a structured or a semi-structured interview, self-report measures and behavioural assessments (14). In epidemiologic studies, self-report instruments with cut-off scores are often utilized to separate a subclinical from a clinical fear level, or to separate low-, mild- and high fear levels (15). Differences in measurement methods, study designs, study samples, the informant assessed (*e.g.,* child, parent, observer), cut-off scores and the terms used may cause inconsistent prevalence figures (15, 16). In the data obtained and collected for the present thesis, the term "fear" is used to assess fear and anxiety levels, whereas the term "phobia" is used only when an individual is diagnosed by a clinical psychologist.

1.2 Specific phobia

The anxiety disorder, specific phobia, is defined as a "marked and persistent fear that is excessive or unreasonable, cued by the presence of anticipation of a specific object or situation." (1). Specific phobias fall into one of five categories: 1) animal type, 2) natural environment type, 3) situational type, 4) blood-injection-injury type and 5) others. Although the different specific phobias possess similar dimensions, they differ

in several aspects including age of onset, focus on apprehension, sex composition, timing of the phobic response and type of physiological reaction during exposure (17). The following criteria are needed to meet the diagnostic criteria for a specific phobia diagnosis according to the DSM-5 (300.29) (1):

A. *Marked fear or anxiety about a specific object or situation (e.g., flying, heights, animals, receiving an injection, or seeing blood). Note: In children, the fear or anxiety may be expressed by crying, tantrums, freezing, or clinging.*

B. *The phobic object or situation almost always provokes immediate fear or anxiety.*

C. *The phobic object or situation is actively avoided or endured with intense fear or anxiety.*

D. *The fear or anxiety is out of proportion to the actual danger posed by the specific object or situation and to the sociocultural context.*

E. *The fear, anxiety or avoidance is persistent, typically lasting for 6 months or more.*

F. *The fear, anxiety, or avoidance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.*

G. *The disturbance is not better explained by the symptoms of another mental disorder, including fear, anxiety, and avoidance of situations associated with panic-like symptoms or other incapacitating symptoms (as in agoraphobia); objects or situations related to obsessions (as in obsessive-compulsive disorder); reminders of traumatic events (as in posttraumatic stress disorder); separation from home or attachment figures (as in separation anxiety disorder); or social situations (as in social anxiety disorder).*

Excessive fears of specific objects or situations are common in young children. However, often the phobia diagnosis is not applicable as the degree of impairment is only mild and transitory and thus considered developmentally appropriate (1, 18). As

these fears in children may be transient, the DSM-5 describes the duration of symptoms of typically 6 months or more to diagnose a child with specific phobia. Furthermore, children in contrast to adults are less capable of recognizing their fear as irrational and excessive. Young children typically are not able to understand the concept of avoidance. Accordingly, additional information should be sought from significant others. Crying, freezing, tantrums or clinging may express fear and anxiety in a young child. The prevalence rates of specific phobias are approximately 5% in younger children and approximately 16% in 13- to 17-year-olds (14).

1.2.1 Blood-injury-injection phobia

Individuals with blood-injury-injection (BII) phobia are characterized by extreme and excessive fear and avoidance cued by seeing blood or injuries or by seeing or receiving injections or other invasive medical procedures. It has been suggested that individuals with BII types phobias may be especially internally focused on their fear and seem concerned about sensations indicating impending faintness (14). BII phobia can be divided in two main subgroups: blood-injury phobia (BIP) and injection phobia (IP) (19). It has been shown that IP can further be divided into separate, sometimes overlapping conditions, namely extra-oral IP (E-OIP) and intra-oral IP (I-OIP) (20).

BII phobia has a complex and multifactorial aetiology. Factors involved in the development and maintenance of the phobia include negative learning experiences, aberrant brain processes, temperament (behavioural inhibition), learning experiences, evolutionary preparedness, avoidance and cognitive biases (20-22).

The tendency for individuals with BII phobia to be associated with fainting in the phobic situation is one of the most distinct features compared to other specific phobias (6, 19). However, it has been debated whether this feature is representative of the whole population of individuals with BII phobia (23, 24). A diphasic physiological response is mediated by the sympathetic nervous system, manifested by

an initial increase in heart rate and blood pressure. This typical physiological fear response is followed by a sharp drop in heart rate and blood pressure due to activation of the parasympathetic nervous system, possibly leading to fainting (19, 23, 25). From an evolutionary perspective, the drop in blood pressure and fainting may represent an adaptive response to injury and excessive blood loss (14). The frequency estimates of fainting associated with BII stimuli are inconsistent. Öst found that approximately 70% of individuals with blood phobia experienced this response at times, whereas the corresponding proportion in individuals with IP was 56% (19). However, a study among 60 BII phobia participants reported that only 20% showed diphasic responses when exposed to surgery (23).Vika et al. reported that among 18-year-olds, 15.9% nearly fainted, whereas 1.7% fainted in relation to dental injections (26). In contrast to other phobias, individuals with BII phobia in some studies have reported a strong family history with a biologically predisposed autonomic response leading to a tendency to faint (27, 28). A significant familial aggregation of blood fear has been reported, indicating a possible genetic inheritance (19, 28, 29). A possible mediator for fainting associated with BII stimuli, especially for the blood phobia subtype, is disgust (30). The basic emotion of disgust is reported in relation to the trigger in individuals with BII phobia and is characterized by activation of the parasympathetic nervous system, manifesting in nausea, dizziness and fainting (31).

The onset of BII phobia is usually prior to 10 years of age (5-7) and the lifetime prevalence is reported to vary approximately 3.0%-4.5% (6, 7, 17, 32). A study by Oosterink et al. found the prevalence of subgroups of BII phobia to be as follows: blood phobia 1.0%, injury phobia 0.8% and injection phobia 1.1% (33). In some studies, females are found to report BII phobia more often than males (6, 34), but the sex differences are more inconsistent, and not as prominent, as in other specific phobias (1, 33, 35). There is a lack of knowledge of equivalent prevalence figures in BII phobia among children.

1.2.1.1 Intra-oral injection phobia

Characteristic for the subtype I-OIP is the extreme and excessive fear of intra-oral injections or situations or stimuli associated with intra-oral injections (20). Triggers may include seeing the syringe/needle, the feeling of being anaesthetized, sensations of swelling gums, fear of allergic reactions and seeing a picture of a syringe. Intra-oral injections are mainly used for local anaesthesia during dental treatment to prevent procedural pain. Hence, avoidance of intra-oral injections due to fear may cause individuals to undergo painful dental procedures or avoid dental treatment that requires local anaesthesia. Negative or painful dental experiences or anticipated fear of them are found to be predictors for developing dental fear and anxiety (2, 36, 37).

Studies have found intra-oral injections to be among the most fear-provoking stimuli related to the dental setting (3, 38, 39). Dutch children reported that the prevalence of fear of needles related to dental treatment decreased with increasing age (40). Among 10- to 11-year-olds, the prevalence was 11% compared to 19% among 4-6-year-olds. However, this study is based on the response to a single item and does not cover different aspects of the fear response. In a large sample of 18-year-olds, during their last intra-oral injection 17% experienced a high level of fear (26). Of those reporting high fear of injections during their last dental or medical injection, 8.1% were highly fearful of both intra- and extra-oral injections, and the prevalence was higher among girls than boys. Additionally, if they knew that an intra-oral injection was required 3.3% reported avoidance of dental treatment. Correspondingly, 4.6% of students and staff at the University of Washington avoided intra-oral injections due to fear (41).

The hitherto lack of an adequate assessment tool for intra-oral injection fear may be one of the reasons for the inconsistent and absent prevalence of figures in children and adolescents. A scale assessing injection fear, referred to as the Injection Phobia Scale for children (IS-c), is an 18-item rating scale designed for self-reporting of injection fear in children and adolescents (42). However, only one item covers intra-oral injection fear, and the remaining items mainly cover situations related to

extra-oral injections such as blood samples and vaccines. Similarly, the widely used Children's Fear Survey Schedule - Dental Subscale (CFSS-DS), a scale used for measuring dental fear in children has only one item covering fear of intra-oral injections (43). This lack of a proper assessment tool led a research group at the University of Bergen, Norway to develop the Intra-Oral Injection Fear scale (IOIF-s) for children and adolescents. The research group drafting the novel IOIF-s included Professor Lars Göran Öst (psychologist), Professor Magne Raadal (dentist), Professor Erik Skaret (dentist) and Margrethe Vika (psychologist, PhD).

The early onset of BII phobia, in addition to the associated negative consequences of I-OIP, illustrates the need for early and correct identification.

1.2.1.2 Dental phobia

Dental phobia refers to extreme or excessive fear of dental treatment procedures or associated stimuli, leading to avoidance of necessary dental treatment or endurance of dental procedures with intense fear. Pain related to the dental situation, especially in combination with a sense of lack of control, is shown to considerably increase the risk of a high level of dental fear (2, 36, 44). Common negative cognitions include pain experienced as intolerable, loss of control, being subject to negative behaviour from the dentist, feeling ashamed in the treatment situation, invasive procedures and sights and sounds of stimuli (3, 45, 46). Avoidance of dental treatment due to fear may cause more extensive treatment problems including pain, which in turn may lead to maintenance or aggravation of the fear (47).

The prevalence estimates of a high level of dental fear in children vary greatly, partly due to differences regarding age groups studied, informants assessed (child *vs* proxy), study designs, measuring tools, cut-off scores, geography, culture and terms utilized. This often makes prevalence comparisons challenging or impossible. However, the prevalence of high dental fear has been reported to be between 3.3% and 20.6%, with girls often, but not always, displaying proportionally more

fearfulness than boys (2, 48-50). Although the results are inconsistent (48), some studies have revealed decreasing dental fear with increasing age (4, 51). However, the associations are not always very strong.

1.3 Overlap between subtypes of BII phobias and dental phobia

Dental treatment includes invasive medical procedures, and dental phobia is categorized in the DSM-5 as part of BII phobia (1). This classification is debated however, as research is inconsistent (17), and accumulating evidence suggests that dental phobia should be considered a specific phobia independent of the BII phobia subtype (38, 52-54). In the World Health Organization diagnostic manual, known as the International Classification of Disorders (ICD-10), dental phobia is categorized as a specific phobia (F40.2) (55). Further sub classification of the specific phobia category similar to the DSM-5 does not occur.

Le Beau et al. concluded that dental phobia and BII phobia shared more similarities than differences (17). A Dutch study, however, assessing the relationship between dental phobia and either BII phobia or avoidance of BII related stimuli among dental patients, concluded that there were only weak nonsignificant correlations between these constructs (38). However, 57% of the patients with dental phobia could also be classified as individuals with BII phobia. Hence, the relationship between BII phobia subtypes and dental phobia is still unclarified. By looking at BII phobia and dental phobia as separate conditions, substantial but varying estimates of overlap have been documented.

The overlap between dental fear and BII fears seems more often to be reported with a larger proportion of the dentally fearful individuals being fearful of injections than fearful of blood. In a study by Öst it was found that 18.6% and 8.6% of those characterized with IP and blood phobia, respectively, also had a high level of dental fear (19). However, in this relatively small proportion of individuals with blood- and injection phobias with dental fear, the fear was found to be mediated by fear of

injections during dental treatment. In a similar study, but in non-diagnosed adults, it was concluded that although blood-injury fear was found to be a significant component of dental fear, the overall contribution was small (56). Poulton et al. revealed that among dentally fearful individuals (not diagnosed by psychologists), 10% reported a comorbid fear of blood, whereas 53% reported a comorbid fear of injections (57). Further it was indicated that dentally fearful individuals who were also fearful of injections were at especially high risk of adverse oral health outcomes. These findings are further supported by de Jongh et al., who reported that high proportions of individuals with dental phobia feared dental procedures such as "receiving anaesthetic injections" (39.0%), whereas only a small proportion feared the sight of blood (7.3%) (38).

In a sample of Norwegian 18-year-olds, dentally fearful individuals scored significantly higher on the scales assessing blood-injury and injection fear compared to individuals who were not dentally fearful (58). The authors stated that this indicated a relationship between BII phobia and dental phobia and suggested that BII phobia may be a background factor causing some individuals to become dentally anxious when exposed to dental injections. This relationship needs to be further explored, as research in this area is lacking in children.

1.4 Treatment

Cognitive behaviour therapy (CBT) is considered an evidence-based and effective treatment for specific phobia in children and adolescents (59-61). Usually, CBT for a specific phobia is brief and time-limited and involves 8-11 weekly sessions (62). Nevertheless, Öst has shown that specific phobias can be treated in a single 3-hour treatment session, referred to as "one session treatment (OST)" (63). OST is now also considered a well-established treatment for children and adolescents (64). The treatment involves exposure-based therapy including hierarchical presentation of the feared stimulus, psychoeducation, participant modelling and targeting catastrophe cognitions by the child (63).

However, children and adolescents with BII phobia are highly underrepresented or excluded in many treatment studies of specific phobia. The exclusion has partly been explained by poor treatment response and a more complex clinical presentation, making children with BII phobia more difficult to engage in exposure therapy (59, 60). Öst et al. included 60 adolescents with specific phobias, 12 with IP and 2 with blood phobia (61). The adolescents with BII phobia revealed a significantly less favourable treatment response. Another controlled trial involving 43 7- to 17-year-olds diagnosed with specific phobia, of which 6 had BII phobia, found exposure treatment to be superior compared to a waitlist control (65). However, in this study the treatment outcomes for the different specific phobias were not examined separately.

A modified and individualized OST approach for BII phobia in children has been described in a study by Oar et al. (22). The modifications performed to enhance treatment outcomes for BII phobia in children and adolescence included addressing the roles of pain, disgust and fainting. Furthermore, the efficacy of this modified OST in a sample of 24 8- to 18-year-olds with BII phobia was also examined in a controlled trial (66). After treatment, 33.3% of the participants did not meet the criteria for a diagnosis, whereas following a 4-week electronic based therapy maintenance program, 62.5% did not meet the diagnostic criteria at 3-month follow-up. However, none of the individuals with BII phobia were explicitly diagnosed with the subtype I-OIP.

To the best of our knowledge, there are no randomized controlled studies exploring the effect of CBT among children and adolescents diagnosed with I-OIP. A literature search in PubMed revealed that few studies have focused on intra-oral injections at all (Table 1). However, 89% of adults with I-OIP were successfully treated by CBT in a randomized controlled study by Vika et al. (67). This study employed collaboration between clinical psychologists and dentists specially trained in CBT for I-OIP and dental phobia. Because of the lack of knowledge of treatment of I-OIP in children and the early onset of BII phobia in general, combined with the substantial consequences, interventional studies are greatly needed.

Table 1. The table displays the results from an electronic literature search from PubMed, performed 15th Aug, 2016. Inclusion criteria were reviewed published articles, written in English from Aug 15th 1986 to Aug 15th 2016. The search algorithm was (intra oral injection fear OR intra oral injection anxiety OR intra oral injection phobia OR dental injection fear OR dental injection anxiety OR dental injection phobia OR needle injection fear OR needle injection anxiety OR needle injection phobia) AND (child OR children). The number of Titles/Abstracts originally identified was 3. After excluding articles not covering children and adolescents up to the age of 16, and not considering specific intra-oral injections, only the 3 articles remained (the first ones in the table). Seven articles were also identified through hand search.

Author	Country	Year	Age group	Focus of interest	Objectives
Taylor GD & Campell C	United Kingdom	2015	Paediatric patients	Needle desensitization.	A description of needle desensitization for paediatric patients.
Kuscu OO & Akyuz S	Turkey	2008	9–13 years	Electronic computerized devise.	To investigate the influence of anxiety and type of dental injection, a plastic syringe or an electronic computerized device, on the pain perceived by children.
Majstorovic M & Veerkamp JS	The Netherlands	2004	4 - 11 years	Needle phobia. Dental anxiety.	To explain the nature of needle phobia and its relationship in dental phobic children with evidence on age-related differences.
Al-Namankany A et al.	USA	2014	6-12 years	Video modelling. Dental injection anxiety.	To investigate if video modelling can influence a child's anxiety before administration of dental injections
Nieuwenhuizen J et al.	The Netherlands	2012	4-6 years	Comuter-controlled local analgesic delivery system. Dental anxiety.	To compare two different computer-controlled local analgesic delivery systems in terms of pain and stress reaction.
Krekmanova L et al.	Sweden	2009	8-19 years	Dental anxiety. Painful dental injections.	To study everyday- and dental pain experiences in relation to gender, age and dental anxiety.
Versloot J et al.	The Netherlands	2008	4-11 years	Dental anxiety. Children's behaviour before and during local anaesthesia injection.	To examine the levels of dental anxiety and earlier experience with dental injections and the possible influence on children's behaviour before and during a local anaesthesia injection.
Bågesund M & Tabrizi P	Sweden	2008	10.3-18.8 years	Pain control. Anxiety level.	To evaluate the effectiveness of intraoral topical anaesthetics
Weinstein P et al.	USA	2003	7-9 years	Videotaped intervention. Anxiety of the pain of dental injections.	To assess a videotape used to enhance child perceived control in a dental setting.
Rosenberg ES	USA	2002	13-80 years	Computer-controlled anesthetic delivery.	To evaluate level of anxiety an pain associated with computer-driven anaesthetic delivery

1.5 Aim

The overall aims of the thesis were to gain more knowledge about the prevalence of high fear of intra-oral injections among children and adolescents, the overlap between intra-oral injection fear and dental fear, and to explore the possible effectiveness of CBT among children and adolescents with formally diagnosed I-OIP when performed by specially trained dentists.

More specific aims were:

In a general population of 10- to 16-year-olds:

- Evaluate the usefulness (reliability and validity) of a new self-report scale assessing fears of intra-oral injections.
- Assess the prevalence of self-perceived high fear of receiving intra-oral injections.
- Estimate the prevalence of high BII fear subtypes.
- Explore the overlap between fear of intra-oral injections and dental fear.
- Evaluate the possible consequences of fear of intra-oral injections in terms of avoidance of dental care.

In a sample of children and adolescents with formally diagnosed I-OIP (DSM-5):

- Evaluate the effectiveness of cognitive behaviour therapy (CBT) when performed by specially trained dentists.

2.0 MATERIALS AND METHODS

This thesis is based on two different studies conducted in Hordaland County, Norway. Study I was a cross-sectional questionnaire study (population study). Study II was a randomized controlled treatment study with a 1-year follow-up design. Paper 1 is based on data from both Study I and Study II. Paper 2 is based on Study I, and Paper 3 is based on Study II.

2.1 Sample size calculation and sample selection

2.1.1 Study I

A pilot study reporting a 6% prevalence of high fear of intra-oral injection formed the basis for the sample size calculation. Additionally, an absolute precision of 2% with a 95% confidence interval yielded a sample size of 550 pupils. A sample size of 1100 was needed to detect differences in prevalence between the two age groups (10- to 12-year-old pupils *vs* 13- to 16-year-old pupils) and between sexes. The final sample size was set to 1400, assuming an anticipated drop-out rate. The total population of 10- to 16-year-old pupils in Hordaland County at the time of the study was approximately 44000 according to Statistics Norway (68).

As classical conditioning is found to be one of the main aetiological factors in BII phobia (69, 70), sampling was performed on the basis of public dental clinics to minimize the effect of single dentists treating all pupils in the area. The pubic dental clinics in Hordaland County were arranged and listed from largest to smallest. According to the list, public elementary schools belonging to the catchment areas of the largest public dental clinics were first invited to the study. The schools in the catchment areas of the subsequent public dental clinics of the list were then invited. When the required sample size was reached, the selection of schools stopped.

2.1.2 Study II

Because empirical data to support a power analysis was lacking, the following power analysis calculation was performed: An active treatment group (Group I) was compared to a waitlist-control group (Group II), which was put on a waitlist for 5 weeks before being enrolled for treatment (Paper 3, Figure 1). An estimated effect size (Cohen's d) of least 0.80 was utilized. Furthermore, a significance level of 0.05 and a power of 80% led to a required group size of 26 patients (71). Previous findings in CBT studies of specific phobias in children reported an estimated attrition rate of approximately 10% (72), yielding a total sample size of at least 60 patients. Consequently, a final sample size was set to 68, yielding 34 patients in the immediate treatment group (ITG, Group I) and 34 patients in the waitlist-control group (WCG, Group II).

All patients were enrolled consecutively from the group of patients referred for treatment to the Centre for Odontophobia within the study enrolment interval (Aug. 2013- June 2015). These patients were referred from the Public Dental Service (PDS), as they were not able to receive intra-oral injections. The inclusion criteria were: a) 10- to 16-years-old; b) a primary diagnosis of I-OIP according to the DSM-5 criteria (1); c) acceptance of comorbidities with other phobias as either secondary diagnoses or co-primary diagnoses with I-OIP; d) willingness to try exposure treatment; and e) willingness to participate in the study for a period of 1 year. Exclusion criteria included disorders including primary depression, drug or alcohol abuse, cognitive developmental disorder or psychotic symptoms.

2.2 Study design and procedure

2.2.1 Study I

Data collection for this cross-sectional questionnaire study was conducted between Jan. 2014 and March 2015 and was completed by the pupils in their respective classrooms (45 min) while supervised by the first author. Prior to the study, an

information sheet for the parents/guardians was distributed by the teacher to the pupils and was also sent to the parents/guardians by e-mail. Optional participation and the opportunity to opt out were emphasized, whereas the purpose and anonymity of the study was outlined. From both the children and their guardians informed passive consent was obtained. The pupils received a short standard oral introduction outlining the content of the questionnaire, its anonymity and that participation was not mandatory, given by the first author on the day of investigation. The questionnaire (Appendix I) included information of age and sex, single questions concerning experience with intra-oral injections and avoidance of intra-oral injections, in addition to four psychometric self-report instruments: 1) the Intra-Oral Injection Fear scale (IOIF-s) (73); 2) the Children's Fear Survey Schedule- Dental Subscale (CFSS-DS) (43, 74); 3) the Injection Phobia Scale for children (IS-c) (42) and 4) the Mutilation Questionnaire for children (MQ-c) (42).

2.2.2 Study II

This randomized controlled trial was conducted at the Centre for Odontophobia, Oral Health Centre of Expertise in Western Norway, Hordaland, between 2013 and 2016. The patients were met by one of the two clinical psychologist in the waiting room prior to completion of the psychometric self-report instruments IOIF-s (73), CFSS-DS (43, 74), IS-c (42) and MQ-c (42). Subsequently, a semi-structured diagnostic interview was conducted by the psychologists. Following the interview, patients underwent a behaviour avoidance test (BAT) after which they promptly completed the questionnaire denoted "Cognitions during the BAT".

The randomization process was eventually performed in which the patients withdrew a sealed, numbered and opaque envelope randomly allocating them into either a treatment group (Group I) or a control group (Group II). Treatment started the following week for the immediate treatment group (Group I/ITG), pursuing one session per week for 5 weeks (Paper 3, Figure 1). The waitlist-control group (Group II /WCG) had a new appointment with the psychologist after 5 weeks on a waitlist.

They were re-examined by the psychologist with respect to any possible effect (the four psychometric self-report instruments were completed, followed by the BAT and "Cognitions during the BAT") prior to eventually being allocated to treatment and further included in the treatment group for post-treatment and 1-year follow-up assessment. At post-treatment and at 1-year follow-up, all patients (from both groups) underwent a short interview by a psychologist, completed the same set of psychometric self-report instruments and underwent the BAT including completion of the "Cognitions during the BAT" questionnaire. Promptly after post-treatment assessments, patients were scheduled for an appointment with a regular dentist at their local PDS clinic. An epicrisis describing the conducted CBT treatment and recommendations for future dental treatment was attached to the patients' digital PDS journal. Data regarding success of receiving intra-oral injections, both during the CBT performed by the specially trained dentists and during the 1-year follow-up period with the regular dentist were obtained from the PDS journal. Due to ethical reasons dental treatment (*e.g.,* drilling, extractions) following intra-oral injections received as part of the CBT, was conducted for the patients that were capable within the 5 sessions.

Four dentists were performing the treatment, all being specially trained and accredited in CBT for I-OIP according to the manual for one-session treatment, modified for 5 sessions (61, 63, 67). Three of the dentists had been evaluated and approved by Professor Öst, based on videotaped treatment sessions. The fourth dentists had equivalently been evaluated and approved according to the same criteria by one of the clinical psychologists, securing standardized CBT training.

2.3 Instruments and measures

2.3.1 Psychological measures

2.3.1.1 Intra-oral injection fear

The Intra Oral Injection Fear scale (IOIF-s) is a 12-item psychometric self-report instrument in Norwegian assessing fear of intra-oral injections in children (Appendix I). Each response is scored from 1 to 5 (1 = not afraid at all, 5 = very afraid) with a sum score ranging from 12 to 60.

A Visual Analogue Scale (VAS) was used to evaluate self-perceived fear of intra-oral injections (0 = no fear at all; 10 = terrified).

2.3.1.2 Dental fear

The Children's Fear Survey Schedule–Dental Subscale (CFSS-DS) is a 15-item validated psychometric self-report instrument measuring dental fear in children (43, 74). Each response is scored from 1 to 5 (1 = not afraid at all, 5 = very afraid) with a sum score ranging from 15 to 75. The validated cut-off score of 38 was used to indicate high dental fear (16, 48).

2.3.1.3 Fear of injections

The Injection Phobia Scale for children (IS-c) is an 18-item psychometric self-report instrument assessing fear of injections. Each response option ranged from 0 to 4 (0 = not afraid at all, 4 = very afraid) (42). The sum score ranged from 0 to 72. No cut-off score was validated.

2.3.1.4 Blood-injury fear

The Mutilation Questionnaire for children (MQ-c) is a 15-item psychometric self-report instrument assessing blood and injury fear (42) with five response alternatives for each item ranging from 0 to 4 (0 = not afraid at all, 4 = very afraid). The sum score ranges from 0 to 60. No cut-of score was validated.

2.3.2 Diagnostic interview

Intra-oral injection phobia was diagnosed by a semi-structured diagnostic interview (lasting 1-1.5 hours) performed by a clinical psychologist according to the DSM-5 criteria for BII phobia (1). Psychoeducation and behavioural analysis were conducted as part of the diagnostic interview, including a brief description of the treatment method and its rationale.

2.3.3 Behavioural measures

2.3.3.1 Behavioural Avoidance Test

The behavioural avoidance test (BAT) consists of 13 steps progressively approaching exposure to an intra-oral injection (Paper 3, Table 1). External dentists blinded to the assessment point and group affiliation performed the BATs. An oral introduction was given to the dentists on how to perform the test. The dentists were also given a written manual. Furthermore, the dentists were informed about the importance of standardization and the rationale for the test. The psychologists informed the patients about the rationale for the test, conveying that each step was to be verbally explained by the dentist. They were further informed that they freely could ask any question during the test or discontinue the test at any point. Termination of the test could be signaled either verbally or by showing a "No" card. A test was considered a successful intra-oral injection if patients completed at least step 10 ("putting a few drops of anaesthesia").

2.3.3.2 Cognitions during the BAT

"Cognitions during the BAT" assessed the frequency of 5 negative and 5 positive thoughts on a 5-point Likert scale (0 = Never, 4 = Very often). The negative thoughts are *"I can't do this", "I'm going to fail", "I'll faint", "I need to get out of this situation"* and *"I can't stand this".* The positive thoughts are *"I have control over the situation", "It's going well – better than I thought it would", "It's not as unpleasant as I thought"," I feel calm and safe"* and *"I'm satisfied with myself"*(75).

2.3.3.3 Ability to receive intra-oral injections

Information on whether the patients were able to receive "successful" intra-oral injections during the CBT treatment was obtained by the dental records in the journal made by the dentist performing the treatment (Study II). A "successful" intra-oral injection corresponded with completion of at least step 10 of the BAT, in line with ideal treatment goals. Similarly, information about "successful" intra-oral injections during the 1-year follow-up period at the local dentist was obtained from the PDS journal.

2.3.3.4 Time since last intra-oral injection

The participants were asked when they received their last intra-oral injection at the dentist (< 1 year ago, ≥1 year ago, never received or cannot remember having received one) (Study I).

2.3.3.5 Avoidance of intra-oral injections

The participants were asked to estimate how sure they were of being able to cope with dental treatment knowing that an intra-oral injection was required ("definitely", "probably", "probably not", "certainly not") (Study I).

2.4 Treatment

The applied treatment in Study II was cognitive behavioural therapy (CBT) modified for 5 sessions in children, each with a maximum duration of 1 hour as delineated by professor Öst (61, 63, 67). Adjustments for maturation and developmental level of each individual patient were made. Further, the modifications for treatment of I-OIP included addressing its unique or typical characteristics; the pain sensation, the feeling of disgust and the vaso-vagal response/fainting. Education regarding the association between pain and fear was conducted. Fearful patients have been found to report more pain during dental injections than less fearful patients, thus by reducing the level of fear the perception of pain is reduced (76). Establishing a good therapeutic relationship with a common understanding of the importance of joint and balanced contribution was among the main principles for treatment. Furthermore, the patients underwent gradual and controlled *in vivo* exposure to a hierarchy of fear-provoking steps connected to dental injections (Paper 3, Table 2). The element of pain may lead to more graduated exposure steps. During exposure, the patients' catastrophic thoughts and fear symptoms were elicited to explore what happens when they are exposed to fear-provoking situations. For patients experiencing the feeling of disgust, disgust eliciting exposure tasks were exerted. The dentist helped the patients with cognitive restructuring of the thoughts, feelings and fear symptoms. In each treatment session, sub-goals were pursued (Paper 3, Table 2). In patients with a tendency to faint, applied tension was used (77, 78).

2.5 Construction of variables

2.5.1 Study I

The variable, "Avoiders" were handled differently in Paper 1 and Paper 2. For validation of the IOIF-s (Paper 1), when asked if they were able to cope with dental treatment knowing that an intra-oral injection was required, Avoiders were defined as those responding "certainly not" whereas Non-avoiders were those responding "definitely". The responses "probably not" and "probably" were excluded to avoid ambiguous answers during validation of the IOIF-s.

In Paper 2, Avoiders were defined as those responding "certainly not" or "probably not" whereas Non-avoiders were those responding "definitely" or "probably" when asked if they were able to cope with dental treatment knowing that an intra-oral injection was required. This dichotomized variable was constructed for logistic regression analysis (Paper 2, Table 5 and 6), where the dependent variable was "Avoiders" (1)/"Non-avoiders" (0). Independent variables also underwent dichotomization. Dichotomization of the variable, "High/Not high fear of intra-oral injections" was based on the sum score achieved on the IOIF-s, "High fear" (> sum score 38 (1)), "Low fear" (≤sum score 38 (0)). The variable, "High/Not high dental fear" was similarly based on the sum score achieved on the CFSS-DS, where "High dental fear" (>sum score 38 (1)) and "Low dental fear" (≤sum score 38 (0)). The variable, "Sex" was "Girls" (1) and "Boys" (0), and the variable, "Age" was categorized into "Youngest" (10-12 years (0)) and "Oldest" (13-16 years (1)). The variable, "Experience with intra-oral injections" was dichotomized into "Yes" (1) and "No" (0). Participants who responded as having received intra-oral injections " <1 year ago" or "≥1 year ago" were coded "Yes" (1). Participants responding, "never received or can't remember having received intra-oral injections" were coded as "No" (0).

2.6 Ethical Considerations

Ethical approvals from Regional Committees for Medical and Health Research Ethics in Norway (REK, 2010/63-3) were obtained for both Study I and Study II. Study II was additionally registered at clinicaltrials.gov (NCT02083432). Permission to conduct the questionnaire study at schools was obtained from the educational authorities and school administrations in each municipality, in addition to informed passive consent from both the pupils and their guardians (Study I) (Appendix II). Informed written consent from patients and their guardians was collected (Study II) (Appendix III).

2.7 Statistics

Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS), version 22.0 (Paper 1 and 2) and 23.0 (Paper 3) (IBM, Armonk, NY, USA). Sum scores on the scales were calculated, and sum scores for individuals with missing information on 20% or fewer items were hence imputed and the missing values replaced using the mean of the other values. The exception was the "Cognitions during the BAT", where no missing questions was required for computing the sum-score.

Leven's test for equality of variances was conducted for the ANOVAs and the t-tests. When the assumption of equal variances was violated, the Welch test not assuming homogeneity of variances was conducted. Effect size (eta squared) was calculated for differences in mean sum scores between groups based on the following guidelines: 0.01=small effect, 0.06=medium effect and 0.14=large effect (79). Analyses performed are shown in Table 2.

In Paper 1, internal consistency reliability of the IOIF-s was analysed by Cronbach's alpha, Alpha if Item Deleted, Corrected Item-Total correlation and the Inter-Item Correlation coefficients. The Intra Class Correlation (ICC) coefficient was used for test-retest analyses. Furthermore, to assess validity, the independent sample

t-test was used in comparison with the IOIF-s sum score data between those not diagnosed with intra-oral injection phobia (Sample I) and those diagnosed with intra-oral injection phobia (Sample II). Additionally, an independent sample *t*-test was used to compare differences in the IOIF-s sum score between "Avoiders" and "Non-avoiders". Relationships between bivariate variables (between the IOIF-s and the MQ-c, IS-c, CFSS-DS and the single question rating self-perceived fear of intra-oral injections) were analysed with Spearman's correlation coefficients. To further emphasize validity, Principal Component Analysis (PCA) with oblimin rotation was performed to identify the underlying structure of the IOIF-s. The number of components retained was guided by three decision rules: 1) Kaiser's criterion (Eigenvalues above 1); 2) inspection of the scree plot (the number of components above the change of shape of the plot were retained) and 3) by use of parallel analysis (80) (components with eigenvalues exceeding the values obtained from corresponding random data sets were considered separate components). A Receiver Operating Characteristics (ROC) curve was used to determine the most discriminant IOIF-s cut-off score (Paper 1, Fig. 1). This was done in order to separate those with I-OIP from all others, with the best balance between sensitivity and specificity (81).

In Paper 2, one-way analysis of variance (ANOVA) was used to analyse group differences. To assess relationships and differences between groups of subjects with a high level of fear of intra-oral injections and those with a high level of dental fear, Chi-square tests with Yates Continuity Correction were employed. Furthermore, logistic regression models were utilized to assess associations between the dependent and independent variables. Bivariate and multiple (standard) analyses were conducted, yielding Odds Ratios (ORs) with 95% Confidence Intervals (CIs). Pearson's correlation coefficients were conducted to assess multicollinearity between the independent variables.

In Paper 3, a mixed between-within subjects ANOVA for repeated measures was used to test whether treatment was better than wait-list control by comparing the ITG with the WCG. The factors were group (ITG and WCG) and time (pre- and post-treatment/waitlist). Additional sensitivity analyses were performed to examine the

impact of drop-outs following the intention-to-treat (ITT) principles, using the last observation carried forward to post-treatment/post-waitlist. To combine the WCG with the ITG, two further analyses were made comparing the immediate and the delayed treatment groups within each condition: 1) independent sample *t*-tests between pre-treatment scores in the ITG and the WCG and 2) paired sample *t*-tests of score changes in the WCG (degree of change from pre- to post-waitlist). The immediate and delayed treatment groups were combined for further analyses if no significant differences were found. To analyse time changes (pre- and post- treatment and at 1-year follow-up), paired sample *t*-tests were used.

Table 2. Statistical tests applied in the thesis.

Statistics and methods used	Paper 1	Paper 2	Paper 3
Principal Component Analysis	+		
Chi-square statistics		+	
Cronbach's alpha	+		
Alpha if Item Deleted	+		
Inter-Item Correlation coefficients	+		
Corrected Item-Total correlation	+		
Intra Class Correlation coefficient	+		
Effect size statistics	+	+	+
Logistic regression (OR)		+	
Paired sample t-test			+
Independent-sample *t*-test	+		+
One-way ANOVA		+	
Repeated measure ANOVA (mixed between-within subjects)			+
Spearman's rank correlation coefficient	+		
Pearson correlation coefficient	+	+	
ROC-curves (receiver operating curves)	+		

3.0 RESULTS

3.1 Participants

3.1.1 Study I

In total, 1460 pupils aged 10- to 16 years were invited to participate in the study. Because 19 pupils declined to participate in the study, the final sample consisted of 1441 pupils (Paper 1, Table 1), yielding a response rate of 98.7%. Furthermore, 13 had not completed the question regarding sex and in the remaining sample, 50.9% were girls (727 girls and 701 boys) (Paper 2, Table 1). The mean age of the participants was 12.7 years (SD=1.9). Altogether, 31 schools participated in the study (33.7% of the invited schools).

3.1.2 Study II

In total, 67 patients (39 of which were girls) (Table 3) were enrolled in the study within the time limit for enrolment. The mean age of the participants was 12.2 years (SD=2.0, age range 10-16). In total, 58 patients completed the CBT treatment and attended the accompanying post assessments, whereas 4 patients in the immediate treatment group (ITG) did not complete treatment and 5 patients dropped out of the waitlist control group (WCG), yielding a response rate completing the treatment of 86.6%. Furthermore, 54 patients attended the 1-year follow-up assessments, whereas 4 of the patients completing the post-treatment assessments failed to appear (response rate 80.6%) (Paper 3, Figure 1).

One patient that discontinued the CBT was, by conjoint judgement between dentist and patient/guardian, scheduled for further dental treatment under general anaesthesia as the patient did not respond sufficiently to the CBT. Another patient was found to need more treatment sessions at the psychologist prior to the CBT. Hence these patients were considered drop-outs from the study. The remaining 11 drop-outs were due to unknown reasons. Furthermore, of the patients considered

drop-outs, 2 were diagnosed with respectively Attention Deficit Hyperactivity Disorder (ADHD) and Asperger syndrome, and 2 were enrolled in psychiatric out-patient clinics for unknown reasons. Among the remaining sample completing the treatment and follow-up assessments, 4 were diagnosed with ADHD whereas 2 patients were under further consideration by psychologists due to attention, concentration and behavioural problems. Additionally, 1 patient was after fulfilling treatment and during the 1-year follow-up diagnosed with Asperger syndrome.

Table 3. Distribution of participants according to sex and age (Sample II).

Age (yr)	Girls	Boys	Total
10	10	5	15
11	6	7	13
12	7	5	12
13	4	5	9
14	5	2	7
15	7	1	8
16	0	3	3
Totalt	**39**	**28**	**67**

3.2 Results, papers

3.2.1 Paper 1 (Study I and Study II)

3.2.1.1 Reliability

The internal consistency reliability of the items in the IOIF-s yielded a Cronbach's Alpha coefficient of 0.95. The test-retest revealed an ICC of 0.79 (95% CI: 0.53-0.90). Furthermore, the corrected item-total coefficient ranged from 0.59 to 0.88 (Paper 1, Table 2), whereas the inter-item correlations ranged from 0.38 to 0.86 (Paper 1, Table 3). The results yielded satisfying reliability.

3.2.1.2 Validity

Validity was shown in that the IOIF-s discriminated significantly between the participants with and without a diagnosed I-OIP (participants in Study I and Study II). Furthermore, the IOIF-s total score was found to discriminate significantly between non-avoiders and avoiders of intra-oral injections, supporting the construct validity of the scale.

The correlation coefficient between the sum score of the IOIF-s and the participant single question rating of self-perceived fear of intra-oral injections was significant (rho=0.78, p<0.001). Furthermore, the IOIF-s was associated with other survey instruments of similar construct. A significant correlation was found between the sum scores of the IOIF-s and IS-c (rho=0.83, p<0.001), and between the sum scores of the IOIF-s and MQ-c (rho=0.65, p<0.001). A significantly stronger correlation was found between the IOIF-s and IS-c than between the IOIF-s and the MQ-c (Z=10.94, p<0.001).

Principal Component Analysis of the IOIF-s revealed a two-component solution characterized as "Contact Fear" and "Distal Fear". Examination of the content of the items found that the "Contact Fear" items all shared the common characteristics of actual contact with the intra-oral injection. The "Distal fear" items

shared the characteristics of all being indirectly or remotely related to contact with intra-oral injections. This two-component solution was supported by the fact that these components revealed eigenvalues exceeding 1 (7.7 and 1.02, respectively) (Paper 1, Table 4). The structure matrix providing information about the correlation between variables and factors and the unrotated loadings (Component Matrix) is presented in Table 4. With 0.4 as a basis for salient loading, inspection of the pattern matrix revealed no items with loadings on multiple components, whereas both components had items with salient loadings. In total, 72.7% of the total scale variance (64.2% and 8.5%, respectively) was accounted for by the two components. The scree plot indicated a break after the second component (Figure 1). Parallel analysis revealed one component with eigenvalues exceeding the corresponding criterion value for a randomly generated data matrix of the same size. The first random eigenvalue generated by the parallel analysis was 1.15 and the second value was 1.11. The latter value slightly exceeded the second eigenvalue (1.02) generated by the PCA.

Table 4. Structure and Component matrix for the IOIF-scale. Rotation converged
in 5 iterations (Sample I).

|	Structure Matrix		Component Matrix	
	Comp. 1	**Comp. 2**	**Comp. 1**	**Comp. 2**
Item:				
IOIF item 8	.923	.592	.896	-.221
IOIF item 2	.914	.552	.878	-.262
IOIF item 1	.907	.581	.881	-.217
IOIF item 7	.886	.553	.855	-.231
IOIF item 11	.861	.593	.848	-.154
IOIF item 3	.768	.687	.804	.065
IOIF item 10	.766	.451	.731	-.234
IOIF item 9	.765	.632	.786	-.002
IOIF item 4	.756	.681	.793	.071
IOIF item 5	.604	.881	.735	.488
IOIF item 6	.511	.849	.653	.546
IOIF item 12	.597	.820	.711	.418
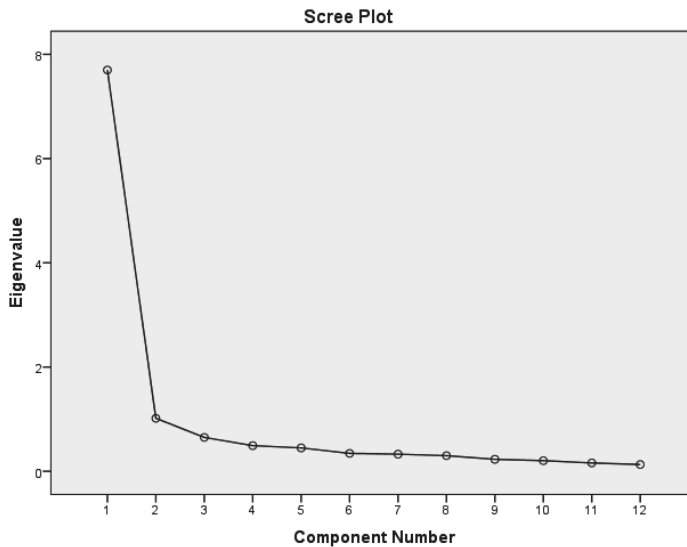
Figure 1. Scree plot**:** Each of the eigenvalues of the components plotted

3.2.1.3 Receiver Operating Characteristics

The Receiver Operating Characteristics (ROC) curve, used to determine the most discriminant IOIF-s cut-off score, indicated that a cut-off score of 38< was appropriate (Paper 1, Fig. 1). The ROC-curve revealed that by dichotomizing the IOIF-s at a cut-off score of 38, I-OIP was detected with a sensitivity of 0.61 and a specificity of 0.85, and an Area Under the Curve (AUC) of 0.73 (95% CI:0.66;0.80 $p < 0.001$).

3.2.2 Paper 2 (Study I)

3.2.2.1 Prevalence of BII fear and dental fear

A total of 59.4% of the children could remember having received an intra-oral injection at some point, and 31.1% could remember an injection within the past year. The mean scores for the scales IOIF-s (27.5 and 19.7), CFSS-DS (28.3 and 22.3), MQ-c (17.3 and 10.2) and IS-c (18.4 and 9.7) were significantly higher for girls compared to boys (Paper 2, Table 2). However, among those who scored above cut-off at the IOIF-s, no significant sex differences were found. Furthermore, the mean IOIF-s sum score revealed significantly higher values for the youngest age group (10-13 years) compared to the oldest (14-16 years), with respective means of 24.7 and 22.5. However, the effect-size analyses revealed that the age difference was small. In total, 13.9% of the children reported high intra-oral injection fear, including 21.1% of girls and 6.4% of boys. The corresponding percentages for dental fear were 11.7%, including 17.1% for girls and 6.4% for boys. There were significant associations between those who scored above the cut-off and girls on both the IOIF-s and the CFSS-DS.

3.2.2.2 Overlap between intra-oral injection fear and dental fear

A significant relationship was found between fear of intra-oral injections and dental fear. Of the children reporting high fear of intra-oral injections, 57.7% also reported high dental fear, while 66.3% of those reporting high dental fear also reported high fear of intra-oral injections. In total, 7.9% of children reported both high fear of intra-oral injections and high dental fear.

3.2.2.3 Avoidance of intra-oral injections

When an intra-oral injection was needed, 10.6% reported that they probably would avoid dental treatment. The reported OR values in bivariate analyses for intra-oral injection fear, dental fear and experience with intra-oral injections were 12.7, 10.5 and 0.4, respectively, and each was significantly associated with Avoiders (Paper 2, Table 5). In multiple regression analysis, high intra-oral injection fear was found to predict avoidance of dental treatment with a peak OR of 6.5 (Paper 2, Table 6).

3.2.3 Paper 3 (Study II)

3.2.3.1 Immediate treatment group (ITG) vs waitlist-control group (WLC)

The results showed that CBT had a significant effect compared to no treatment, on all self-report measures (Paper 3, Table 3), except for positive thoughts, in which neither of the groups revealed a significant effect. The results of the ITT analysis yielded no differences in significance level apart from three exceptions. At the IS-c, the significance level at the group effect was altered from not significant to a significance level of $p<0.05$, whereas regarding the BAT and negative thoughts, the significance level at the group effect was altered from $p<0.01$ to $p<0.05$.

3.2.3.2 The effect of CBT in the group as a whole

In the group as a whole, a significant reduction from pre- to post-treatment was found on all four psychometric instruments (Figure 2). The results for the IOIF-s, CFSS-DS and IS-c were maintained from post-treatment to 1-year follow-up, whereas the MQ-c revealed further significant reduction. Furthermore, significantly more steps of the BAT were completed post-treatment compared to pre-treatment for the group as a whole, and the effect was maintained from post-treatment to follow-up. Similarly, treatment significantly reduced the frequency of negative thoughts from pre- to post-treatment, whereas the positive thoughts remained unchanged. The results were maintained at 1-year follow-up.
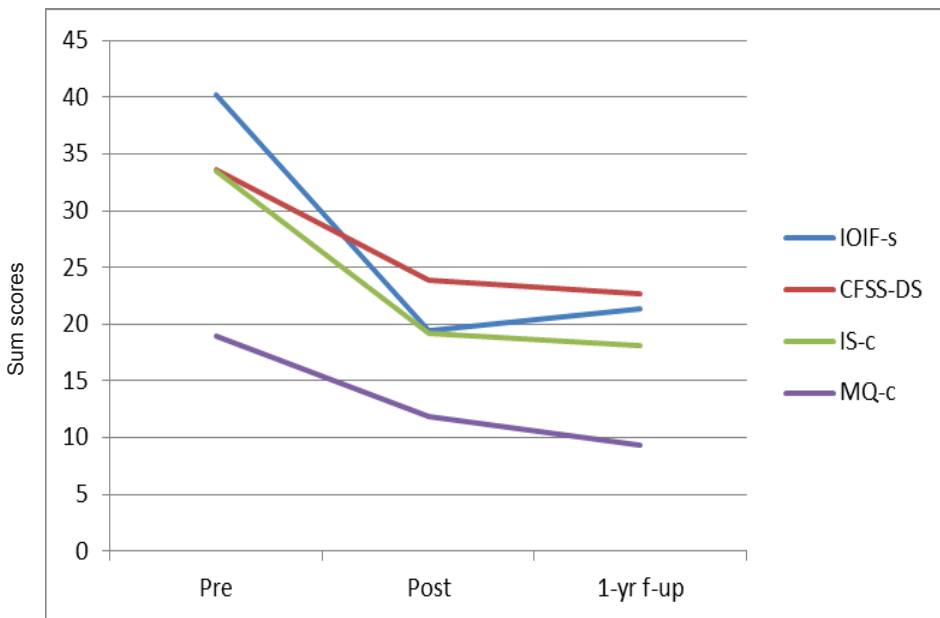

Figure 2. Study II: Mean sum scores of the Intra-Oral Injection Fear scale (IOIF-s), Children's Fear Survey Schedule-Dental Subscale (CFSS-DS), Injection Phobia Scale for children (IS-c) and Mutilation Questionnaire for children (MQ-c) according to assessment time; pre-treatment (Pre), post-treatment (Post) and at 1-year follow-up (1-yr f-up)

3.2.3.3 Ability to receive intra-oral injections

Of the 67 patients originally enrolled in the study, 70.1% managed to receive intra-oral injections during CBT treatment. Another 14.9% managed to have a few drops of anaesthesia injected in submucosa, but not the fully required amount. After completing the CBT, 49 of the patients were in need of further dental treatment at their local dental clinic. Of these patients, 69.4% managed to receive the necessary intra-oral injections at their local dentist in the PDS during the follow-up year.

4.0 DISCUSSION

4.1 Methodological considerations

4.1.1 Sample size and representativeness

4.1.1.1 Study I

The high response rate among the pupils strengthened the representativeness of data for Hordaland County, even though a strike among teachers led many of the schools to decline participation. As the teacher strike reached a national level and affected public elementary schools regardless of area and demographic characteristics, it can be assumed that the impact on outcome measures was probably limited. The standardized procedure in which the survey was conducted, further added support to the representativeness. Nevertheless, the sample was limited to only one Norwegian county and thus was not representative of all Norwegian pupils within this age range. The structure of the public dental service (PDS) and the public school system in the county is based on national guidelines. The PDS in Norway is free of charge for all children within this age range, and approximately 97.5% of all children attend public elementary schools (82). It is therefore reasonable to believe that the results are indicative of the situation for the targeted age group in Norway. Only 19 pupils declined to participate in the study, yielding a high response rate at the individual level within the schools. This could partly be explained by use of informed passive consent rather than written consent. This type of consent highly limits selection bias, but introduces some ethical issues. However, permission to use passive consent was granted by the ethics committee (REK) as the questionnaire was of a character such that ethical integrity was ensured.

A similar study with focus on BII phobia randomized the study population by municipality classes (26). As classical conditioning is known to be one of the most important factors in the acquisition of BII phobia (13, 69, 70), the present study sampling was instead based on public dental clinics. Schools belonging to the

catchment areas of the largest public dental clinic were first invited, as the intention was to minimize the effect of single dentists treating all pupils in one area. Nevertheless, all six municipality classes present in Hordaland County were represented in the final sample. The participating school classes within each school were selected by the respective headmasters and teachers in each school. This selection was based on availability and convenience that particular day, thus leaving the selection not truly random, but rather somewhat arbitrary. Another limitation was the fact that the data were analysed with the single pupil as the entity for analyses. Although the pupils were sitting at their respective desks in classrooms while completing the questionnaires, the analysis did not take into account the possible influence that pupils have on each other. However, the fact that the author was present in the classroom to give the standard introduction about the questionnaire and study most likely increased the reliability of the study. The author's main impression was that the pupils participated mostly in a conscientious manner.

As a relatively large sample was required to detect differences among sex and the two selected age groups, significant results were followed by effect size statistics. Because the effect size indicates the magnitude of the effect, this step was taken to limit relevance of statistically significant results that were not clinically relevant due to the large sample size (71).

4.1.1.2 Study II

Despite the relatively small sample size, power analysis confirmed that there was adequate power to detect differences between the treatment group and the control group (71). In terms of sample size and power, this study was in line with other CBT studies (67, 83, 84).

The patients were all referred from the PDS because they were not able to receive the intra-oral injections required to undergo necessary dental treatment. The patients were not self-referred, and 97.9% of all children (aged 1-18,

2014) in Norway, regardless of socioeconomic background were under regular supervision of PDS (85). Hence, there are reasons to believe that the sample of Study II, to some extent, can be indicative for children with I-OIP in the general population of Hordaland. A limitation to this statement is that some of the phobic children may be compelled through dental treatment by the dentist or parents against their will. Furthermore, the dentist may have postponed further dental treatment until the child has matured so that children were not being referred to the Centre for Odontophobia. Additionally, children and/or guardians may have declined the offer of referral for cognitive behaviour therapy (CBT). However, it was a prerequisite before treatment with general anaesthesia that all guardians/dentists either had considered or had attempted referral of children to the Centre for Odontophobia.

Because ethical considerations made it impossible to recruit patients either for a control condition that implied no treatment or for a condition of known ineffectiveness, the patients were allocated to a five-week long waitlist (Waitlist-Control Group). The time for which treatment was withheld was chosen as it corresponded to the duration of treatment for the patients in the Immediate Treatment Group (ITG). It was hypothesized that 5 weeks of CBT would result in reduced fear of intra-oral injection among the ITG. Therefore, any reduction in fear within 5 weeks among the Waitlist-Control Group (WCG) would be valuable information regarding the actual effect of CBT. Additionally, 5 weeks was regarded appropriate as the patients would probably not remember their answers between the first and the second assessment. Accordingly, the replicate measurement should be independent of the first measurement. Furthermore, the relatively short amount of time between the assessments limits the time in which patients may be influenced by external factors which may influence their phobia (86). The WCG was implemented because previous research has shown that the rate of significant remissions from specific phobias was found to be very low without any exposure to the phobic stimuli (87, 88). In general, the design with a WCG is considered to be an accepted design for clinical treatment studies (86).

A strength of the study was that there were four dentists who carried out the CBT, who all had underwent calibration procedures for the specific study. Furthermore, two psychologists performed the interviews.

4.1.2 Instruments and measures

4.1.2.1 Assessing intra-oral injection fear, Intra-Oral Injection Fear scale (IOIF-s)

The BII phobia has been reported to have an onset prior to 10 years of age (5-7). The early onset, combined with the consequences of avoidance of intra-oral injections such as poor pain control during dental treatment, contributes to dental fear (89-92). Hence, the need for early and correct identification of intra-oral injection fear was emphasized. The satisfying psychometric properties in terms of reliability and validity of the IOIF-s made it useful for evaluation of intra-oral injection fear both at a population and at an individual level.

To identify the underlying structure of the IOIF-s and to summarize the data using a smaller set of factors or components, a principal component analysis (PCA) was conducted. PCA was chosen rather than a confirmatory factor analysis, as the latter is applied when a hypothesis exists about expected factor structures. The PCA is one of the methods preferred if the purpose is to explore the data without a prior hypothesis or model. This was the case, as the IOIF-s was not known to be based on a theoretical assumption of specific separate dimensions and no prior factor structure model existed. Oblique rotation was performed as it was considered that if more than one component were revealed, they could be correlated. Using an oblique rotation method is recommended in psychological research as it is reasonable to expect correlations between components (93). Although indistinct demarcations were found by the PCA, a two-dimensional structure was revealed, consisting of "Contact Fear" and "Distal fear". The former accounted for the strongest part of intra-oral injection fear (Paper 1, Table 4). A one-component structure also had to be considered due to the somewhat indistinct demarcations. However, an overall

evaluation of the PCA in combination with theoretical coherence favoured the two-component structure. The strength of the component loadings and the high communalities increase the certainty of the results of the PCA, indicating that the components are stable (94). A similar two-component structure, labelled "Contact Fear" and "Distal Fear" have been found in two other scales assessing, respectively injection fear in children (IS-c) and Injection Phobia Scale-Anxiety (IPS-Anx), assessing injection fear in adults (42, 95).

The cut-off value was chosen for the IOIF-s to separate persons with high intra-oral injection fear from persons with low- and moderate- intra-oral injection fear. This cut-off value demonstrated moderate discriminative properties. The area under the curve (AUC) can be interpreted as the probability that the test will yield a score in the elevated/abnormal range for a randomly chosen person who has been diagnosed with intra-oral injection phobia compared to a randomly chosen person who has not been correspondingly diagnosed. The AUC of 0.73-0.87 revealed in Paper 1 corresponds to a moderate level (81, 96). Although a cut-off point nearest the upper left corner results in the smallest overall error rate, other factors may make it preferable to adjust this point (81). In this case, the cut-off point was increased. As a consequence, the specificity was increased while the sensitivity was decreased. From a clinical and research perspective, it can be argued that specificity in this case is more important with respect to the nature of fear, anxiety and phobia (1, 11), which emanate from a continuum. A lower cut-off value would increase both the sensitivity and the likelihood of Type 1 error. All patients diagnosed with intra-oral injection phobia by the psychologist in Study II scored above 38 on the IOIF-s (mean score 40.1) before treatment, which further supported the cut-off value chosen. A limitation of the chosen cut-off value is that the number of participants in Study II assessed by a psychologist was relatively small, whereas the participants in Study I, which was a large sample with a high response rate, were not assessed by a psychologist. A larger diagnosed sample in which all participants were assessed by a psychologist for diagnosis with or without intra-oral injection phobia, might have altered the results of the ROC curve and thereby the cut-off point (81). Additionally, validating the cut-off

scores according to child and adolescent ages and sex could further improve the validity of the cut-off score (16, 81). This should be focused on in further studies.

      A method used for determining cut-off scores in psychometric measures is a value one standard deviation (SD) above the mean as the cut-off score for self-reported fear in children (97). For the IOIF-s, that would imply a cut-off score of 34.9, which is lower than the standard cut-off score revealed in Paper 1. However, this method provides no information about the scale sensitivity and specificity. Due to these factors, the cut-off score chosen for the IOIF-s seems to be a relevant standard cut-off score to detect those in need for special attention. Nonetheless, it should be interpreted with caution.

4.1.2.2 Dental fear and BII fear

The CFSS-DS is a validated psychometric instrument for assessing dental fear in children which has been widely used, and found to have good reliability and validity in different populations, including that of Scandinavia (4, 43, 74, 98, 99). The instrument may be used in two different versions, either by self-rating by the child or by parental ratings. Self-ratings by the children were used in this thesis to strengthen the reliability and validity, as scales completed by parents/guardians have shown moderate agreement between child and parental ratings on self-reports (16). For the child version, cut-off scores between 37 and 42 have been used (16, 48, 100). In the present thesis, the score above 38 was chosen for both Study I and II, similar to the cut-off score used in a Swedish study (containing a small sample with child self-ratings) (16). Another study used one standard deviation (SD) above the mean as a cut-off value when children completed the CFSS-DS (97). If this method had been used in the present study, it would have lowered the cut-off value and consequently would have increased the prevalence of dental fear. Furthermore, different cut-off scores by age and sex for the parent rated CFSS-DS scale have revealed cut-off scores lower than the standard cut-off scores (16). Accordingly, the use of standard

cut-off scores in the prevalence estimation of dental fear might have underestimated the fear level.

The IS-c and MQ-c assessing fear of injections and blood-injury fear in children, respectively, were constructed and validated in a Swedish sample of 8- to 17-year-old children and adolescents (N=677). In the study, norm data were obtained and psychometric properties were evaluated (42). Both scales had excellent psychometric properties and were found to be appropriate for use both in research and as a clinical tool. A limitation was that the scales did not have a validated cut-off score for measuring a high level of fear.

The IS-c, MQ-c and CFSS-DS were all in Norwegian. The Norwegian versions were based on the Swedish versions, as the two Scandinavian languages are closely related to each other. The scales had been translated from Swedish to Norwegian and were then back-translated.

Even though psychometric self-report scales are recommended for assessing fear in children, and widely used, the validity of using self-reported scales in 10- to 16-year-olds must be interpreted with caution. Their responses depend not only on their age, but also on their stages of development in cognitive, social and emotional terms (101).

4.1.2.3 Behavioural Avoidance Test

The BAT (Paper 3, Table 1) was used to measure behavioural changes, and has previously been used in adults (67). Similar versions adapted for specific phobias including other BII phobias have been utilized for both children and adults (66, 70). As avoidance is known to be one among other important diagnostic criteria of a phobia, measures of change in avoidance behaviour are considered useful for assessing this disorder. However, the BAT used in this study involved the invasive and possibly painful procedure of intra-oral injection. Combined with the lack of an established therapeutic alliance to the external dentist, the test may be experienced

differently for children than for adults, possibly due to differences in cognitive development. As trust and a therapeutic alliance are key aspects during CBT (63, 101), further research should evaluate whether the BAT for intra-oral injection phobia in children is developmentally appropriate.

4.1.2.4 Cognitions during the BAT

The "Cognitions during the BAT" was assessed in order to evaluate cognitive changes that occurred together with behavioural alterations after teatment. Although the reliability and validity of the "Cognitions during the BAT" was found satisfactory in adults (67), the questionnaire was not necessarily developmentally appropriate for children. One may speculate as to whether some of the youngest children may have had difficulties differentiating between the present situation and future events when responding to the questionnaire. This could possibly have led to conservative results of the positive and negative cognitions during the test.

4.1.2.5 Time since last intra-oral injection

The variable "time since last intra-oral injection" introduces possible recall bias. Therefore, the response options <1 year ago and ≥1 year ago were combined, yielding the variable "experiences with dental injections". The response options were dichotomized into "yes" and "no", to limit recall bias and increase reliability. Most of the pupils (59.4%) (Study I) could remember having experienced an intra-oral injection. Correspondingly, the PDS in Hordaland County reported the percentage of 10- to 16-year-olds in 2014with no prior caries experience to be approximately 47%. This percentage adds support to the validity of the pupils reported experience with intra-oral injections. However, among those who reported not having experienced an intra-oral injection or those who did not recall one, some may actually have received intra-oral injections. The recollections by these children may be influenced by a variety of factors. If the situation was not perceived as particularly fearsome, the

children could have forgotten about it. On the other hand, if the situation was perceived as extremely fearsome, some children could have supplanted the experience or could have dissociated, resulting in not remembering the intra-oral injection experience (13).

4.1.2.6 Avoidance

Avoidance is one of the most important behavioural measures associated with a specific phobia (1). Within Paper 2 it was determined to include those who probably or certainly would not be able to cope with dental treatment if an intra-oral injection was needed. Self-reports, especially on behaviour and particularly among children, should be interpreted with caution. Social desirability biases may occur as some children tend to answer questionnaires according to what is considered "preferable" (102), possibly causing them to under-report avoidance. The anonymity of the study was outlined in attempt to limit this effect. Furthermore, completing the questionnaire in a classroom, at a distance from the actual exposure to intra-oral injections in a dental clinic, may be a challenging transfer of context for the youngest children. The youngest children are more dependent on their parents'/guardians' decisions concerning dental appointments and treatment, which may have influenced their response to this question. This variable was therefore targeting the treatment situation involving the intra-oral injection rather than attendance at the treatment session, which the children are perhaps not in the position to avoid. However, this approximation may introduce some biases, such as possibly including patients more afraid of dental procedures other than intra-oral injections (*e.g.,* drilling). Nevertheless, this variable probably represents one of the closest approaches for assessing self-reported avoidance of intra-oral injections among young children.

4.2 Prevalence of high intra-oral injection fear

High intra-oral injection fear based on the IOIF-s was found to be prevalent among 10- to 16-year-olds in Hordaland County. In Study I, there was a significant tendency toward declining intra-oral injection fear with increasing age. The effect size statistics, on the other hand, showed that the magnitude of the differences was small, implying no strong clinically relevant age influence (71). Previous studies on BII fear/phobia and dental fear/phobia in children have shown an inconsistent age effect. Several studies have shown dental fear to decrease with increasing age (4, 40, 74, 97, 100, 103, 104). However, as in Study I, some of these associations were not very strong or the effect size was not calculated. Other studies did not reveal any age differences (105, 106). Furthermore, the sampling procedures may introduce biases (102), as may *e.g.,* different cut-off scores and different informants (child vs proxy), making it challenging to compare the results (107).

An important factor for interpretation of the results is the element of developmental change and maturation of cognitive abilities over time. The results may be influenced by the age range from which the study samples are obtained and may be dependent on the breadth of the age range. Studies have found that cognitive maturation is not necessarily linear over time (108), causing the age range to become particularly important when interpreting results and comparing studies. In Study I, a larger sample size allowing us to look at differences between each separate age group could have influenced the result.

Significant sex differences were found on all four psychometric scales. Some of the aetiological factors found to affect and possibly explain some of these sex differences include biological factors, vulnerability and environmental influences (109). The results revealed in Study I are in line with previous studies of BII fear and dental fear in children and adolescents, in which girls were found to exhibit both more and a greater intensity of fears than boys (48, 110). However, other studies did not reveal any significant sex differences (4, 104). Additionally, girls and boys have been found to disclose emotions differently. Accordingly, the fact that girls

tend to express fears more freely and truthfully than boys on self-report measures should also be taken into account (108).

Thus, the underlying reasons for age and sex differences and therefore the different prevalence results should be kept in mind when interpreting the results. From the clinical perspective, the risk of overlooking the need of some patients for extra attention should be considered in particular.

4.3 Overlap between intra-oral injection fear and dental fear

The strong overlap between those highly fearful of intra-oral injections and those highly fearful of dental treatment indicated an association between intra-oral injection fear and dental fear among children and adolescents. This was further supported by the finding that pupils with a high level of intra-oral injection fear reported significantly higher mean scores on the CFSS-DS scale compared to those with a low level of intra-oral injection fear (Paper 2, Table 3). As the correlation between the scales assessing intra-oral injection fear (IOIF-s) and dental fear (CFSS-DS) was as strong as the correlation between the scale assessing intra-oral injection fear (IOIF-s) and injection fear (IS-c) (the latter two assessing similar constructs), this adds further support indicating a relationship between intra-oral injection fear and dental fear. The coincident high dental fear and BII fear levels indicate that the entities are linked (40, 52-54). Previous findings in other age groups revealed similar results in the overlap between BII fear and dental fear (38, 58).

As Study I is cross-sectional, it cannot determine causal relations. However, it is reasonable to believe that patients avoiding intra-oral injections are at greater risk of undergoing painful dental procedures. Pain and negative dental experiences are known to be risk factors for developing high dental fear (2, 37, 92). A higher proportion of those with high dental fear also had high intra-oral injection fear, compared to the proportion of those with high intra-oral injection fear who also have high dental fear. This adds support to the idea that BII fear could precede dental fear.

Additionally, dental phobia has been found to have an onset prior to 12 years of age which is later than the other BII phobia subtypes (5). A possible clinical implication of these findings suggests that intra-oral injection fear should be addressed before treatment of dental fear.

4.4 Consequences of high fear of intra-oral injections

To evaluate the possible consequences of high fear of intra-oral injections in terms of avoidance of dental care, multiple logistic regression analyses were conducted. Intra-oral injection fear was found to be the main predictor of avoidance of dental treatment when an intra-oral injection was needed. This finding adds further support to the suggestion of addressing intra-oral injection fear prior to treatment of dental fear. Additionally, dental fear and prior experience with intra-oral injections were associated with avoidance. A limitation of the analyses was that the variables representing intra-oral injection fear and dental fear were highly correlated. Nonetheless, as the correlation coefficient was considered not too strong, and because both variables were considered important to the analysis, both variables were included. The fact that no prior experience with intra-oral injections was found to predict avoidance may reflect on the finding that this group probably also contains avoiders. Additionally, younger children, found to have a higher level of intra-oral injection fear, may not have as much dental experience as older children due to a not yet developed need for treatment.

In total, approximately ten percent of the participants in Sample I were characterized as "Avoiders", yielding a figure higher than a previous similar study revealing 3.3% "Avoiders" among 18-year-olds (58). As avoidance is strongly associated with intra-oral injection phobia (1), it could be speculated on whether the proportion may reflect the prevalence of intra-oral injection phobia. The figure is in line with previous studies among 10-11-year-olds (40). However, the limitations of the validity of the "Avoidance" variable should be kept in mind.

4.5 Treatment of intra-oral injection phobia

Although CBT has been shown to be effective in treating adults suffering from intra-oral injection phobia (67), no previous study has been published with focus on children and adolescents. The effectiveness of CBT on children and adolescents diagnosed with I-OIP performed by specially trained dentists was explored in Study II in terms of both self-reported fear and behaviour. The main findings were that CBT conducted in only 5 hours was effective for patients diagnosed with I-OIP. This outcome was indicated as the results revealed lowered scores both in the self-report scales assessing BII fear and dental fear, and altered behaviour assessed by the BAT, at post-treatment and at 1-year follow-up. Additionally, the children's ability to receive injections both during CBT treatment and at their local PDS clinic during a 1-year follow-up period indicated behavioural change and successful treatment of the I-OIP.

The fear levels on all four psychometric scales were significantly reduced. However, the largest reduction in effect size was found on the IOIF-s. The fear level of the IOIF-s was reduced from above the cut-off, to a level substantially lower than the cut-off post-treatment. The frequencies of negative thoughts during the BAT were also largely reduced, which may be interpreted as the result of patients experiencing increased control in the situation as well as partly due to a reduction of catastrophic thoughts as a consequence of exposure and psychoeducation during CBT. Another important finding was that the patients demonstrated improvements on the BAT, from being unable to receive an intra-oral injection pre-treatment, to having a "successful injection" post-treatment. Even though the patients did not undergo a full diagnostic interview post-treatment and at 1-year follow up, it could be speculated on whether these improvements in both behaviour and on the self-report scales may imply that the patients no longer fulfilled the criteria for a diagnosis of I-OIP.

Previous studies have reported that motivation and credibility of CBT is essential for the treatment outcome (63, 111). However, due to the level of cognitive maturation, children may be less able to understand the treatment rationale. Additionally, they are more dependent on parent/guardian motivations and decisions for treatment (112). As cognitive maturation and development may cause the cognitive appraisal of motivation and treatment credibility to be different for children than among adults, these issues were not considered to be inclusion/exclusion criteria in this study. Neither were patients diagnosed with ADHD or Asperger syndrome excluded from the study. An association has been found between ADHD and BII phobia (113). Furthermore, within the targeted age group, not all children have been diagnosed despite their condition, leaving no certainty of actually excluding those with ADHD and Asperger syndrome. This was reflected in Study II as 1 patient was diagnosed with Asperger syndrome within the 1-year follow-up assessment, whereas 2 patients were under further consideration by psychologists due to attention, concentration and behaviour problems. By exerting stricter inclusion and exclusion criteria in terms of motivation, ADHD and Asperger syndrome, attrition could have been limited and treatment outcomes possibly improved. Regardless, however, stricter inclusion/exclusion criteria would leave some children and adolescents suffering from intra-oral injection phobia with limited treatment options. Additionally, this approach yields a treatment tested in a sample reflecting the spectrum of patients actually being referred and in need for help.

A previous study has found BII phobia to yield a less favourable treatment response compared to other specific phobias (61). However, the findings in Study I (Paper 3) are in line with previous studies of similar treatments for other specific phobias in children that showed 50%-60% of adolescents are diagnosis-free at follow-up (59, 60, 66). One of the most important characteristics of this study compared to other studies of the BII phobia was collaboration between health professionals. The fact that the main therapist was the dentist and not the psychologist facilitated exposure therapy *in vivo*. Hence, it is likely to believe that post-graduate courses in elements of CBT would enable paediatric dentists to treat children and

adolescents with moderate and severe levels of intra-oral injection fear (114). This is further facilitated by the short duration of treatment.

Specific phobias such as I-OIP are influenced by a number of different elements such as vulnerability, psychological preparedness and cognitive maturation (20, 22, 40). Additionally, as BII phobia has a heterogeneous presentation in children and adolescents, a more individualized number of treatment sessions for children rather than the limit of 5 sessions of CBT presented in Study II might have further improved the results. Based on the results of this study, CBT performed by a specially trained dentist represents an effective treatment of intra-oral injection phobia. The author suggests that with an individualized number of treatment sessions, CBT is a recommended treatment and should be offered to children and adolescents suffering from intra-oral injection phobia.

4.6 Future research

CBT was found to be efficient for the treatment of I-OIP in children and adolescents (Paper 3). However, there is a lack of knowledge on which elements of the therapy that are most efficient. As pre- and post-treatment assessments restrict the evaluation of therapy to when treatment is over, it is important to know what changes during treatment, to detect what causes these changes and how the patient functions during treatment. As these elements of change are not known, it can only be speculated what the key elements of the alterations are in terms of behaviour, cognitions, anxiety symptoms, trust, sense of control and coping. It would be interesting to explore the process involved in these alterations to identify ways to optimize the delivery of treatment. Furthermore, as the prevalence of intra-oral injection fear among girls was reported to be significantly higher than among boys, it is reasonable to expect that in general, more girls will be referred to or will seek treatment for I-OIP. As girls tend to display emotions differently compared to boys, exploring gender differences in treatment outcomes would be of further clinical value.

A high level of dental fear was found to be prevalent among children and adolescents and was found to be one of the main reasons for avoidance of dental care (Paper 2). A consequence may be reduced dental health (115). As CBT is found to be efficient in treating children with I-OIP (Paper 3), future research should explore the effectiveness of an adjusted CBT version for children with dental phobia.

Furthermore, the association between intra-oral injection fear, pain, unpleasantness, disgust and fainting should be explored in children and adolescents. As these are some of the typical and unique elements of I-OIP (19, 30), the prevalence and whether these elements contribute to avoidance of necessary treatment should be further investigated.

5.0 CONCLUSIONS

- The novel IOIF-s revealed applicability and satisfying psychometric properties in terms of reliability and validity, to assess the level of fear of intra-oral injections among children and adolescents. .

- High intra-oral injection fear was found to be prevalent among 10-16-year-olds and associated with avoidance of necessary dental treatment. Accordingly, high fear of intra-oral injections should be addressed before treatment of dental fear.

- An association between the diagnose BII phobia and dental phobia was implied due to the strong observed overlap between high fear of intra-oral injection and high dental fear.

- CBT performed by specially trained dentist, modified for children and adolescents with intra-oral injection phobia is effective and may prevent future avoidance of dental treatment. CBT represent a recommended treatment and should be offered for patients suffering from intra-oral injection phobia, within the age-range of 10-16 years.

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PAPER 1

I

REVIEW

Reliability, validity and cutoff score of the Intra-Oral Injection Fear scale

KARIN G. BERGE[1,2], MARGRETHE VIKA[1,2], MAREN LILLEHAUG AGDAL[1,2], STEIN ATLE LIE[1] & MARIT SLÅTTELID SKEIE[1]

[1]Department of Clinical Dentistry, Faculty of Medicine and Dentistry, University of Bergen, Bergen, and [2]Oral Health Centre of Expertise in Western Norway – Hordaland, Bergen, Norway

International Journal of Paediatric Dentistry 2016

Background. A proper assessment tool is needed to gain more knowledge about fear of intraoral injections in children.
Aim. The aims of this study were to evaluate the reliability and validity of the novel Intra-Oral Injection Fear scale (IOIF-s) and to establish a cut-off score for a high level of such fear.
Methods. Data were obtained from two samples of 10- to 16-year-olds in Hordaland, Norway. Sample I, 1460 pupils attending elementary and high schools, provided questionnaire-based data. The survey instruments used were IOIF-s, Children's Fear Survey Schedule-Dental Subscale (CFSS-DS), Mutilation Questionnaire for Children (MQ-c) and Injection phobia Scale for Children (IS-c). Sample II was 67 patients, diagnosed with intraoral injection phobia at the Center for Odontophobia, Oral Health Center of Expertise in Western Norway-Hordaland, who provided IOIF-s data.
Results. Cronbach's alpha was 0.95. The IOIF-s discriminated between subjects with and without intraoral injection phobia and was associated with the other survey instruments of similar construct. Principal component analysis revealed a two-component solution, characterized as 'Contact Fear' and 'Distal Fear'. Receiver-operating characteristic (ROC) curve indicated that a cutoff score of 38 was appropriate.
Conclusion. The IOIF-s showed satisfying psychometric properties in terms of reliability and validity.

Introduction

Blood-injury-injection (BII) phobia is one of the five different types of specific phobias classified in the Diagnostic and Statistical Manual of Mental Disorders 5 (DSM-5)[1]. Individuals with BII-phobia are characterized by extreme anxiety and avoidance in relation to seeing blood or injuries, undergoing invasive medical procedures or receiving injections[1]. Nausea, aversion and the feeling of disgust are strongly associated with exposure to the BII-phobic stimuli[2–5]. Unique for the BII-phobia is the high frequency of a vasovagal response associated with fainting when exposed to the phobic stimuli[6]. Fear and anxiety provoking situations or those in which phobic stimuli may be encountered, are avoided or endured with intense anxiety[1,7].

There are two main subgroups of the BII-phobia: blood-injury phobia (BIP) and injection phobia (IP). IP is further divided into two separate, sometimes overlapping conditions, extra-oral IP (E-OIP) and intraoral IP (I-OIP)[6,8]. Extra-oral injections concern a variety of injections, most often vaccinations, taking blood samples or intravenous cannulations (e.g., venflons). Intraoral injections are mainly used for local anesthesia to prevent procedural pain during dental treatment.

The onset of the BII-phobia has been reported to be 5.5–10 years of age[6,9–11]. In children, poor pain control during dental treatment, for example due to avoidance of intraoral injections, may contribute to the development of dental fear and anxiety[12–15]. The early onset of the BII-phobia combined

Correspondence to:
K.G. Berge, Center for Odontophobia, Oral Health Centre of Expertise in Western Norway – Hordaland, Pb. 2354 Hansaparken, 5867 Bergen, Norway.
E-mail: Karin.berge@hfk.no

with the consequences associated with the disorder highlights the need for early and correct identification. With respect to the I-OIP subtype of IP, detection at an early age is essential to providing proper treatment and thus, hopefully, to preventing painful dental experiences[16].

Intraoral IP is a clinical diagnosis which can only be diagnosed by trained professionals, usually psychologists or psychiatrists[1]. They are capable of distinguishing a high level of intraoral injection fear from phobia. Nevertheless, tools such as self-reporting questionnaires and psychometric scales are used to assess the level of fear in clinical dental settings, to estimate its prevalence in a population and to register differences between experimental and control groups[8,17]. To establish a proper fear cutoff score on psychometric scales is essential as it allows us to distinguish highly fearful individuals from non-fearful individuals, both in larger populations and in clinical dental settings. In the clinical setting, an established cutoff score may additionally be used to indicate the need for referral to qualified specialists[8,17,18].

Hitherto, there are no articles published presenting psychometric scales which distinguish between extra- and intraoral injection fear in children. Currently, if at all reported, fear of intraoral injections is embedded in a broader fear assessment, or based on single questions. The widely used Children's Fear Survey Schedule-Dental Subscale (CFSS-DS) assessing dental fear only have one single item covering fear of intraoral injections[19]. Similarly, in the Injection Phobia Scale for children (IS-c) assessing injection fear in general, all but one single item concerning intraoral injections cover situations regarding extra-oral injections such as vaccines and blood samples[20], which limits the use in a dental setting. Also single questions such as the Visual Analogue Scale (VAS) may be used for assessing fear of intraoral injections, but can only cover one aspect of the fear response[17]. Although responses to single questions indicate that fear of intraoral injections is one of the most common fears related to dental treatment[21,22], it cannot assess the different aspects and dimensions of the more complex fear response, which is covered more broadly in a psychometric scale[1,17].

This lack of a scale for measuring intraoral injection fear in children and adolescents led a research group at the University of Bergen, Norway, to develop the Intra-Oral Injection Fear scale (IOIF-scale) for children and adolescents. In its development, both psychologists and dentists with expertise in dental phobia and cognitive behavioral therapy took part.

The primary aim of this study was to evaluate the reliability and validity of this IOIF-scale. The secondary aim was to establish a cutoff score for a high level of intraoral injection fear.

Materials and methods

Study sample and design

The collected data in this study originated from two studies administered from the Center for Odontophobia, Oral Health Centre of Expertise in Western Norway, Hordaland, Norway. One study took place at elementary schools in Hordaland County (Sample I) and the other (Sample II) at the Centre for Odontophobia. Data collection was undertaken from February 2013 to April 2015.

Sample I (non-clinical sample) comprised collected questionnaire data from 1460 pupils (10- to 16-year-olds) attending elementary schools. The schools were cluster-sampled. The questionnaires, distributed in classrooms, were completed within 45 min. A short standard introduction outlining the anonymity and purpose of the study was given prior to completing the questionnaires. The IOIF-scale included in this paper-and-pencil questionnaire had previously been pilot tested on 154 pupils, 11- to 15-year-olds. In the pilot study, no problems regarding the understanding of the content of the IOIF-scale were reported; hence, no adjustments to the scale were made.

Additionally, the questionnaire data consisted of Mutilation Questionnaire for Children (MQ-c)[20], IS-c[20], CFSS-DS[19,23] and two single questions regarding avoidance of

intraoral injections and self-perceived fear of intraoral injections.

Sample II (clinical sample) consisted of collected data from 67 patients diagnosed with intraoral injection phobia (10–16 years), enrolled at the Center for Odontophobia. The patients had all refused intraoral injections due to fear prior to enrollment and were therefore recruited by referral from the Public Dental Service (PDS). The patients had been going through a semi-structured diagnostic interview, carried out by a psychologist, as part of an ongoing randomized controlled treatment study. The interview was based on a modified version of the Anxiety Disorders Interview Schedule-IV (ADIS-IV)[24]. In addition to the interview, the patients had completed the IOIF-scale. A random subsample of 26 patients also completed the IOIF-scale a second time with a 5-week interval.

Measuring tools

The IOIF-scale is a 12-item questionnaire in Norwegian, which assesses fear of intraoral injections. Each pre-coded response ranged from 1 to 5 [(1 = not afraid at all, 2 = a little afraid, 3 = a fair amount, 4 = pretty much afraid and 5 = very afraid), sum score range: 12–60]. The aim of this scale was to cover different potential fear provoking situations or objects associated with intraoral injections. The underlying rationale for obtaining the measures was to estimate the feeling of fear evoked in response to exposure to the respective triggers of fear. The following scales were all in Norwegian. The Norwegian versions were based on the Swedish version, as these two Scandinavian languages are closely related to each other. For measuring injection fear, IS-c was applied[20]. The IS-c, an 18-item scale, ranged from 0 to 4 [(0 = not afraid at all, 1 = a little afraid, 2 = a fair amount, 3 = pretty much afraid, 4 = very afraid), sum score range: 0–72]. The MQ-c was used to assess blood-injury fear[20], which was a 15-item scale with five response alternatives [(0 = not afraid at all, 1 = a little afraid, 2 = a fair amount, 3 = pretty much afraid, 4 = very afraid), sum score range: 0–60]. Also the CFSS-DS, a scale consisting of 15-items

measuring dental fear in children was applied[19,23]. The five response options were graded from 1 to 5 [(1 = not afraid at all, 2 = a little afraid, 3 = a fair amount, 4 = pretty much afraid, 5 = very afraid), sum score range: 5–75]. The respondents of the questionnaires were further asked to estimate the probability of proceeding with dental treatment when an intraoral injection was needed. The options were 'definitely', 'probably', 'probably not' and 'certainly not'. Avoiders were defined as those responding 'certainly not', and non-avoiders were defined as those responding 'definitely'. Furthermore, self-perceived fear of intraoral injections was evaluated using VAS (0 = no fear at all; 10 = terrified).

Statistical analysis

Internal consistency reliability of the IOIF-scale was assessed by Cronbach's alpha, alpha if item deleted, inter-item correlation coefficients and the corrected item–total correlation. Test–retest was assessed by the intraclass correlation coefficient.

To assess concurrent validity, the IOIF-scale sum scores data from Sample I and Sample II were compared by an independent sample *t*-test. Leven's test for equality of variances was conducted for the *t*-tests. When the assumption of equal variances was violated, *t*-statistics not assuming homogeneity of variances were computed. Construct validity, both convergent and divergent, was also evaluated in the following analyses (Sample I); the IOIF-scale scores of the non-avoiders and the avoiders were compared, using an independent sample *t*-test. Spearman's correlations were also calculated between the sum score of IOIF-scale and the single question rating self-perceived fear of intraoral injections. Furthermore, Spearman's correlations between the IOIF-scale and the MQ-c, IS-c and CFSS-DS sum scores were performed.

Principal component analysis (PCA) with oblimin rotation was conducted to identify the underlying structure (Sample I). Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy) and Bartlett's test of sphericity were checked before interpreting the rotated

component loadings. Factorability of the correlation matrix was further assured by checking for at least some correlations of $r = 0.3$ or greater. Component loadings above 0.4 were considered as substantial loading on a particular subset of items. The number of components to be retained was guided by three decision rules: (1) by Kaiser's criterion (eigenvalues above 1), (2) by inspection of the screeplot (components above the change in the shape of the plot were retained) and (3) by use of parallel analysis[25]. In the parallel analysis, the sizes of the eigenvalues obtained from PCA were compared with those obtained from a randomly generated data set of the same size. Components with eigenvalues exceeding the values obtained from the corresponding random data set were considered separate components.

The receiver-operating characteristic (ROC) curve was used to determine the most discriminant IOIF-scale cutoff score, in order to separate those with I-OIP from all others, with the best balance between sensitivity and specificity[17]. The ROC was illustrated graphically, and the area under the curve (AUC) was calculated both for the continuous IOIF-scale and for the IOIF-scale dichotomized by the cutoff value chosen, against the patients diagnosed with I-OIP (Sample II) as a reference standard.

Sum scores on the scales were calculated using the mean of the items multiplied with the number of items. Mean values were calculated if 20% or fewer of the items had missing information for each individual. The sum score for individuals with missing information on 20% or fewer was hence imputed and replaced the missing values, using the mean of the other items. Due to item nonresponse, N differed slightly between analyses. Data were analyzed using SPSS version 22.0 (IBM, Armonk, NY, USA). Parallel analysis was conducted using the software developed by Watkins[25].

Ethical approval

Approval by the Regional Committees for Medical and Health Research Ethics in Norway, 2010/63-3, was obtained. Permission to conduct the questionnaire study at schools was obtained from the educational authorities and school administrations in each municipality. Informed passive consent was obtained both from the pupils and their guardians. In the study in which patients were included, written informed consent was obtained from patients and their guardians.

Results

In the 31 schools which accepted the invitation to participate in the study (Sample I), only 19 pupils declined to participate, yielding a response rate of 98.7%. The mean age of the participants ($N = 1441$) was 12.7 years (SD = 1.9), and 50.9% were girls. Age distribution is shown in Table 1. In Sample II, the mean age of the participants ($N = 67$) was 12.2 years (SD = 2.0), and 58.2% were girls.

Internal consistency reliability and reproducibility

The internal consistency reliability of the items in the IOIF-scale (Sample I) yielded a Cronbach's alpha value of 0.95. As shown in Table 2, the corrected item–total correlation coefficient ranged from 0.59 (Item 6, *hear somebody talk about having an intraoral injection*) to 0.88 (Item 8, *sitting in a dental chair, waiting for the intraoral injection*). The correlation matrix showed no negative correlations. The interitem correlations ranged from 0.38 (item 6 and item 10; *hear somebody talk about having an intraoral injection* and *the anesthesia not working*) to 0.86 (item 8 and item 1; *sitting in a dental chair, waiting for the intraoral injection* and *when the dentist says you need an intraoral injection*) (Table 3).

Table 1. Distribution of participants according to sex and age (Sample I).

Age (year)	Girls	Boys	Sex not reported	Total
10	89	84	–	173
11	170	147	4	321
12	112	134	4	250
13	107	92	–	199
14	85	75	1	161
15	88	72	2	162
16	76	97	2	175
Total	727	701	13	1441

Table 2. Intra-Oral Injection Fear scale (IOIF-s): mean (SD), corrected item with total correlation, alpha if item deleted (Sample I).

IOIF-s item Do you feel frightened	Mean (SD)	Corrected item–total correlation	Alpha if item deleted
IOIF-s 1: when the dentist tells you that you will need an anaesthetic injection	2.25 (1.25)	0.86	0.94
IOIF-s 2: when you feel the sting from the syringe	2.39 (1.32)	0.85	0.94
IOIF-s 3: when the dentist applies anesthetic ointment to your gums	1.72 (1.06)	0.77	0.94
IOIF-s 4: for the anesthetic liquid itself	1.76 (1.08)	0.75	0.94
IOIF-s 5: when you see a picture of a person being anesthetized at the dentist	1.44 (0.85)	0.68	0.95
IOIF-s 6: when someone tells you that they have had an anesthetic injection at the dentist	1.32 (0.74)	0.59	0.95
IOIF-s 7: that the sting from the syringe will be painful	2.40 (1.31)	0.83	0.94
IOIF-s 8: when you are sitting in the dentist's chair preparing to have an anesthetic injection	2.38 (1.37)	0.88	0.94
IOIF-s 9: when you can feel the anesthetic starting to work (numbness)	1.77 (1.09)	0.74	0.94
IOIF-s 10: that the anesthetic will not work	2.31 (1.37)	0.69	0.95
IOIF-s 11: when you see the needle of a syringe	2.34 (1.41)	0.82	0.94
IOIF-s 12: when you see a picture of a dentist's syringe	1.56 (1.04)	0.66	0.95

In Sample II, analysis performed on the 26 duplicate recordings on the IOIF-scale gave an intra class correlation of 0.79 (95% CI: 0.53–0.90).

Validity

The mean sum score of the IOIF-scale discriminated significantly between participants in Sample I (mean = 23.67, SD = 11.23) and Sample II (mean = 40.22, SD = 8.9), $P < 0.001$. The IOIF-scale total score discriminated significantly between non-avoiders of intraoral injections and the avoiders of intraoral injections (respectively, mean = 17.93, SD = 7.68, *vs* mean = 38.76, SD = 13.21, $P < 0.001$) with a mean difference of 20.83 [(95% CI: 24.55–17.11), $\eta^2 = 0.15$]. There was a significant correlation between the sum score for the IOIF-scale and the participants' single question rating self-perceived fear of intraoral injections, $\rho = 0.78$, $P < 0.001$.

Additionally, a significant correlation between the sum scores of the IOIF-scale and IS-c was found ($\rho = 0.83$, $P < 0.001$), and also between the sum scores of the IOIF-scale and MQ-c ($\rho = 0.65$, $P < 0.001$). The correlation between the IOIF-scale and IS-c showed significantly higher values than the correlation between the IOIF-scale and MQ-c ($Z = 10.94$, $P < 0.001$). There was also a significant correlation between the IOIF-scale and the measure of CFSS-DS ($\rho = 0.83$, $P < 0.001$).

As for the suitability for PCA, the Bartlett's Test of Sphericity showed high significance ($P < 0.001$), whereas the KMO measure of sampling adequacy showed a value of 0.95, supporting the factorability of the matrix. Inspection of the correlation matrix also revealed the presence of several coefficients above 0.3.

Principal component analysis and oblimin rotation revealed the presence of two components with eigenvalues exceeding 1, values showing 7.7 and 1.02 (Table 4). On the basis of 0.4 as salient loading, inspection of the pattern matrix revealed that there were no items with loadings on multiple components, and both components had items with salient loadings. The two components accounted for 72.7% of the total scale variance. The first component explained 64.2% of the variance, whereas the second component accounted for 8.5%. Pearson's correlation between the two components was $r = 0.65$. An inspection of the screeplot indicated a break after the second component. The parallel analysis showed one component with eigenvalue exceeding the corresponding criterion value for a randomly generated data matrix of the same size (12 variables × 1441 respondents). The first random eigenvalue generated by the parallel analysis was 1.15. The second random eigenvalue was 1.11 and exceeded the second

Table 3. Inter-item correlation matrix for Intra-Oral Injection Fear scale (IOIF-s) scores (Sample I).

	1	2	3	4	5	6	7	8	9	10	11	12
IOIF 1	1.00											
IOIF 2	0.85	1.00										
IOIF 3	0.67	0.68	1.00									
IOIF 4	0.64	0.65	0.70	1.00								
IOIF 5	0.56	0.54	0.61	0.60	1.00							
IOIF 6	0.50	0.44	0.49	0.48	0.63	1.00						
IOIF 7	0.79	0.79	0.61	0.61	0.54	0.46	1.00					
IOIF 8	0.86	0.84	0.69	0.64	0.56	0.50	0.81	1.00				
IOIF 9	0.65	0.65	0.65	0.68	0.56	0.50	0.61	0.66	1.00			
IOIF 10	0.60	0.62	0.56	0.55	0.43	0.38	0.64	0.63	0.56	1.00		
IOIF 11	0.75	0.76	0.62	0.58	0.54	0.45	0.76	0.78	0.60	0.63	1.00	
IOIF 12	0.53	0.53	0.54	0.50	0.66	0.57	0.52	0.56	0.47	0.45	0.63	1.00

eigenvalue generated by the PCA slightly, being 1.02.

Receiver-operating characteristic curve

Identification of I-OIP by the continuous scale showed an AUC of 0.87 (95% CI: 0.84; 0.90 $P < 0.001$). The ROC curve showed that by dichotomizing the IOIF-scale at a cutoff score of 38, I-OIP was detected with a sensitivity of 0.61 and a specificity of 0.85, AUC = 0.73 (95% CI: 0.66; 0.80 $P < 0.001$). The cutoff score of 38 was set, as a lower cutoff score increased the sensitivity but decreased the specificity (Fig. 1).

Table 4. Oblimin rotated pattern matrix and communalities for the Intra-Oral Injection Fear scale (IOIF-s). Rotation converged in five iterations (Sample I).

	Pattern coefficients		
	Comp 1	Comp 2	
Eigenvalue % Total variance	7.7 64.2	1.02 8.5	Communalities
Item			
IOIF item 2	**0.961**	−0.072	0.839
IOIF item 8	**0.932**	−0.013	0.852
IOIF item 1	**0.916**	−0.014	0.823
IOIF item 7	**0.911**	−0.039	0.785
IOIF item 11	**0.823**	0.058	0.743
IOIF item 10	**0.818**	−0.080	0.590
IOIF item 9	**0.614**	0.233	0.617
IOIF item 3	**0.558**	0.324	0.651
IOIF item 4	**0.542**	0.329	0.634
IOIF item 6	−0.071	**0.895**	0.724
IOIF item 5	0.055	**0.846**	0.778
IOIF item 12	0.111	**0.748**	0.680

Major loadings on each item are bolded.

Discussion

To our knowledge, the IOIF-scale presented in this article is the first scale developed to assess fear of intraoral injections in children and adolescents. Overall, the psychometric properties of the scale demonstrated satisfying reliability and validity and provided further support for wider applicability of the IOIF-scale within this age group in the county of Hordaland, Norway.

As for assessing dental fear and anxiety in children, several scales have previously been developed[26,27]. It is known from the literature that intraoral injections constitute one of the most anxiety provoking stimuli for children and adolescents related to the dental setting[15]. The need for the development of an appropriate psychometric instrument assessing this specific fear in children should therefore be obvious, and the aspect of identifying the anxiety provoking stimuli in the dental clinic due to such an instrument would be highly valued. A scale which could assess the level of fear would also be of great importance for research purposes, enabling the prevalence of fear of intraoral injections to be estimated and the need for resources in terms of treatment to be assessed.

A strength of the study was the relatively high amount of collected data behind the study results and the high response rate among the pupils in Sample I. Nevertheless, one should bear in mind that those few who did not participate might have differed from the rest of the sample, as high fear may cause
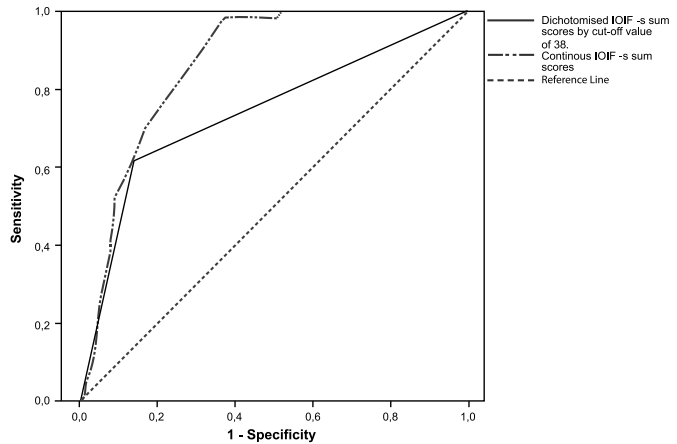
Fig. 1. Receiver operating characteristics curve for Intra-Oral Injection Fear scale (IOIF-s) dichotomized by a cutoff score of 38, and for the continous IOIF-s sum scores.

avoidance or reluctance in answering questions about intraoral injections[1].

The reliability of the scale was demonstrated by the fact that the internal consistency of the IOIF-s was shown to be excellent, indicating homogeneity of the scale[17]. This was further supported by examining the impact of removing each item from the scale, revealing no items with a value higher than the final alpha value obtained, which confirmed the use of the 12 items comprising the scale. The interitem correlations were all positive, indicating that the items of the scale were correlated with each other. Nonetheless, the correlations were not considered high enough for any item to be excessive[17].

The test–retest reliability obtained indicates that the sum score of the IOIF-scale generated at a single assessment could be representative for the level of intraoral injection fear at another point in time. The scale was completed at the Center for Odontophobia at both time points. At the first assessment, the patients underwent semistructured diagnostic interview by the psychologist, which may have influenced their ratings at the following session. It could therefore be expected that the Intra Class Correlation obtained might be conservative.

The IOIF-scale demonstrated concurrent validity in discriminating strongly between the respondents with and without a known diagnosis of intraoral injection phobia. This

emphasizes the ability of the IOIF-scale to differentiate highly fearful children from a larger reference population, an essential feature for usefulness not only as a screening tool, but also in a clinical context[17,28].

Construct validity was shown in that the IOIF-scale discriminated strongly in the expected direction between the respondents characterized as avoiders and those characterized as non-avoiders of intraoral injections. This could be anticipated as avoidance is associated with the specific phobia[1], and was also supported by the large effect size, indicating that the scale was able to detect differences between the groups. The strong correlation between the IOIF-scale sum score and the patients' self-perceived fear of intraoral injections based on ratings on a single question added support to the convergent validity.

The IOIF-scale further illustrated construct validity, as the test scores were associated with the dental fear scale (CFSS-DS). Additionally, it showed stronger associations with the injection fear scale (IS-c) than the blood-injury fear scale (MQ-c), both currently used assessing BII-fear related to dental settings. This difference in strength of correlations with IS-c and MQ-c might also be seen as support for the divergent validity for the IOIF as the theoretical fundament of fear of intraoral injections is closer to fear of injections than the construct measured by MQ-c[6].

Although the correlation with IS-c, MQ-c and CFSS-DS was considered high, it was not overly high, suggesting that the IOIF-scale covered components of this trait not tapped by the existing scales[17].

The PCA revealed that the Kaiser's criterion, based on the eigenvalues extracted, and the screeplot, both were supportive of a two-component structure of the IOIF-scale. The parallel analysis, on the other hand, indicated that a one component structure also had to be taken into consideration; however, the indistinct demarcations of the components revealed by the PCA, combined with the theoretical coherence, favor a two-component structure classified as 'Contact Fear' and 'Distal Fear'. The 'Contact Fear' component, which accounted for the strongest part of the intraoral injection fear, included nine of the items which were related to the respondents' fear of actual contact with the intraoral injection procedure. The component classified as 'Distal Fear' was found to explain part of the construct, but accounted for a far less prominent part of the variance. This component included three of the items, all relating to indirectly or remotely contact with intraoral injections. The PCA thus indicated that the IOIF-scale measured the relevant construct explained by the components 'Contact Fear' and 'Distal Fear' and that the component structure was theoretically adequate, supporting the construct validity of the IOIF-scale.

The two components were comparable to the two factors extracted by factor analysis of the IS-c, and the two components extracted by the PCA of the Injection Phobia Scale-Anxiety (IPS-Anx) (assessing injection fear in adults), where the labeling 'Contact Fear' and 'Distal Fear' also were suggested[20,28]. There were no items in the IOIF-scale with loadings on more than one factor. In comparison, the IS-c has one item loading on both factors, based on the criterion of 0.40 as salient loading, whereas the IPS-Anx equivalently has two items loading on both components[28].

One of the main properties of a scale is its ability to interpret the scores, allowing both appropriate referrals, and statistical comparison of tests. The appropriate cutoff value for the IOIF-scale set to separate persons with high intraoral injection fear from persons with low and moderate intraoral injection fear was 38 (sum score 12–60). This cutoff value demonstrated moderate discriminative properties[18]. By choosing a lower cutoff value, the sensitivity would increase. From a clinical and research perspective, it can be argued that specificity in this case is more important than sensitivity. Fear, anxiety and phobia in children emanate from a continuum[1], and therefore, it could be regarded as more valuable in this case, ensuring that those who are classified as not having a high level of fear of intraoral injections are correctly identified. As the diagnosis intraoral injection phobia cannot be determined solely by a scale, but must be set by a psychologist, the cutoff value set was reasonable for the target population, separating clinical from subclinical respondents. Still, a limit to the cutoff value set is that the sensitivity obtained was relatively low in favor of gaining higher specificity. Consequently, the cutoff value has to be interpreted with caution.

The scale was developed for children as a self-report measure, and not completed as a proxy measure provided by guardians. This strengthened the reliability and validity of the scale, as studies show moderate agreement between child and parental ratings on self-reports[29]. Content validity was supported by the fact that children participated in the pilot study, securing that the language and terminology were comprehensible for the target group.

As the onset of BII-phobia is varying from 5.5 to 10 years of age[6,9–11], this scale was designed to capture children from the age of 10–16 years. The lower limit was both to ensure that the phobia in most of the children was fully developed, but also to secure that the children were able to complete the questionnaire by themselves. Below the age of 10, the wording of the scale would probably have to be somewhat modified, and perhaps assisted by symbols, due to the children's cognitive maturation[30]. Additionally, a scale completed as a proxy measure would have to be considered.

A limitation of the scale was that it did not assess physical reactions, thoughts or

behavior, which also are elements influencing fear and anxiety of intraoral injections[27]. Nor did the scale assess whether the anxiety influenced daily living, which is required to meet the criteria for diagnosis of a specific phobia. On the other hand, this allowed the scale to be brief and let the children complete the scale by themselves, making it relevant and easy to use for the dental team.

Cross-validation in different cultural settings is needed for further generalization of the validity of the scale. In future research, further clinical evaluation of the scale should be assessed, as it is important to demonstrate that the scale is sensitive to change during treatment of intraoral injection phobia. Age and sex differences should be described and further explored.

In conclusion, the IOIF-scale showed satisfying psychometric properties in terms of reliability and validity in children and adolescents in Hordaland. The cutoff score of 38 on the IOIF-scale was found to be appropriate for detecting a high level of intraoral injection fear in this sample. The IOIF-scale should therefore be seen upon as useful in the dental clinic for the evaluation of the child's intraoral injection fear and as an appropriate research tool for prevalence studies of high intraoral injection fear in children and adolescents. It represents a useful supplement to the psychologist's clinical judgement.

Why this paper is important to paediatric dentists
- As intraoral injection is known to be one of the most anxiety provoking stimuli for children in a dental setting, the development of an appropriate psychometric instrument assessing this specific fear should be of great value for the pediatric dentist.
- Identification of high fear of intraoral injections at an early age is important for the provision of appropriate treatment for the patient, to prevent painful dental experiences and to allow the prevalence of fear of intraoral injections in a population to be assessed.
- An established cutoff score on the IOIF-s is essential to distinguish highly fearful individuals from non-fearful individuals, both in a larger population and in a clinical dental setting. Additionally, in a clinical dental setting, the cutoff score on the IOIF-s may be used to indicate the need for further referral to qualified specialists.

Conflict of interest

The authors declare no conflict of interest.

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PAPER 2

II

High fear of intra-oral injections: prevalence and relationship to dental fear and dental avoidance among 10-16-year-old children

Karin G. Berge [1,2], Maren Lillehaug Agdal [1], Margrethe Vika [1], Marit Slåttelid Skeie [2]

[1] Oral Health Centre of Expertise in Western Norway, Hordaland, Bergen, Norway

[2] Department of Clinical Dentistry, Faculty of Medicine and Dentistry, University of Bergen, Bergen, Norway

Running title: Intra-oral injection fear

Corresponding author:

Karin G. Berge, Oral Health Centre of Expertise in Western Norway, Hordaland, PO Box. 2354 Hansaparken 5867 Bergen, Norway.

Telephone: +47 55 58 53 21

E-mail: karin.berge@hfk.no

Abstract:

The present study aimed to *(i)* estimate the prevalence of self-reported high fear of intra-oral injections, high blood-injury fear and injection fear, *(ii)* explore the overlap between high fear of intra-oral injections and high fear of dental treatment, and *(iii)* evaluate the possible consequence of high fear of intra-oral injections in terms of avoidance of dental care. The sample included 1441 10-16-year-olds attending elementary schools in a county of Norway. Data were collected by use of questionnaires completed in classrooms. The survey instruments used were Intra-Oral Injection Fear-scale, Children's Fear Survey Schedule-Dental Subscale, Injection Phobia scale for children, and Mutilation Questionnaire for children. In total, 13.9% of the children reported high intra-oral injection fear. A strong association was found between fear of intra-oral injections and dental fear. When an intra-oral injection was needed, 10.6% would avoid dental treatment. In multiple regression analysis, high intra-oral injection fear was found to be associated with avoidance of dental treatment (OR=6.52; 95% CI 3.99-10.67). It was concluded that high fear of intra-oral injections was prevalent, and might lead to avoidance of necessary dental treatment. Hence, intra-oral injection fear should be addressed before treatment of dental fear.

Karin G. Berge, Oral Health Centre of Expertise in Western Norway, Hordaland, PO Box. 2354 Hansaparken, 5867 Bergen, Norway.

E-mail: karin.berge@hfk.no

Introduction

Blood-Injury-Injection (BII) phobia constitutes one of five different types of specific phobias, and consists of two subgroups, blood-injury phobia (BIP) and injection phobia (IP) (1, 2). BII phobia has usually its onset prior to 10 years of age (3-5), and is in contrast to other phobias associated with a vaso-vagal response (6, 7). Experiences of both high fear and fainting according to BII stimuli, are reported to be linked to avoidance or denial of necessary dental and medical treatment (8-10). IP can be further divided into two separate conditions; extra-oral and intra-oral injection phobia, respectively (11, 12).

Intra-oral injections have been shown to be among the most fear-provoking stimuli in the dental setting (13-16), but the prevalence figures for this fear are inconsistent. A study among Dutch children aged 4-11 years showed that high fear of needles related to dental treatment was higher among the younger children than the older (17). The reported prevalence was 11% among 10-11-year-olds, but 19% among 4-6-year-olds. In a sample of Norwegian 18-year-old adolescents, 17% had experienced high fear during their last intra-oral injection (18). The prevalence was higher among girls than boys, and higher for intra-oral injections than extra-oral injections. Also, 3.3% reported that they would avoid dental treatment if they knew that an intra-oral injection was needed. Likewise, 4.6% of students and staff at the University of Washington were found to have avoided intra-oral injections due to fear (10). To our knowledge, there are no published studies about avoidance of treatment due to intra-oral injection fear among children.

Although intra-oral injection phobia and dental phobia are considered separate conditions according to the Diagnostic and Statistical Manual of Mental Disorders-V (DSM-V) (1), a substantial overlap has been documented between dental fear and BII fear (13, 19, 20), and between dental fear and the BII subgroup intra-oral injection fear (11). However, these findings of overlap are only reported among 18-year-olds and adults, whereas similar assessment among children is lacking in the literature. Patients avoiding dental injections due to high fear or phobia of intra-oral injections are more likely to experience painful dental procedures. Painful dental experiences, anticipated fear of

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such pain and negative dental experiences are documented to be predictors for developing dental fear and anxiety (21-23). All this corroborates that the prevention of negative experiences connected with intra-oral injections is of vital importance. Early assessment of high intra-oral injection fear is therefore essential in order to offer the affected patients appropriate treatment, such as cognitive behavioural therapy (24-26) and/or applied tension (27). The reasons for a lack of knowledge of intra-oral injection fear and variations in prevalence estimates might be that adequate assessment methods have been lacking and that different criteria have been used for assessing the fear. The prevalence estimates for intra-oral injection fear which have hitherto been published are based on single questions (17, 18). The newly published Intra-Oral Injection Fear-scale (IOIF-s) (28) should in this respect represent an improvement because it was found to be a reliable and valid assessment tool.

The aims of the study were *(i)* to estimate the prevalence of self-perceived high fear of intra-oral injections, blood-injury fear and injection fear among 10-16 year-olds, *(ii)* to explore the overlap between high fear of intra-oral injections and high fear of dental treatment, and *(iii)* to evaluate the possible consequence of high fear of intra-oral injections in terms of avoidance of dental care.

Material and methods

The study was approved by the Regional Committees for Medical and Health Research Ethics in Norway (REC number 2010/63-3). Permission to conduct the study was obtained from the educational authorities and school administrations in each municipality.

This cross sectional questionnaire study included 10-16-year-old pupils, attending public elementary schools in Hordaland County, Norway. The data collection was carried out between January 2014 and March 2015. Since classical conditioning is one of the main etiological factors in BII phobia (9), sampling based on public dental clinics was conducted in order to minimize the effect of single dentists treating all pupils in the area. Public dental clinics in Hordaland County ranged from large to small (n=46). The schools belonging to the catchment areas of the largest public dental clinic, according to the list, were first invited to participate in the study. Subsequently, the schools in the catchment areas of the consecutive public dental clinics of the list were invited. The selection of

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schools stopped when the required sample size was reached. According to Statistics Norway (29) , the total population of 10-16-year-olds in Hordaland County was approximately 44,000 children. The sample size calculation was based on results from a pilot study which found a prevalence of high intra-oral injection fear of 6%. This value for prevalence, and an absolute precision of 2% with a 95% confidence interval, gave a sample size of 550 pupils. To ensure detecting differences in prevalence between age groups (10-12 year-olds *vs* 13-16 year-olds) and sex, the sample size needed was 1100. The dichotomization of age groups was chosen in order to detect age effects due to cognitive maturation and further development of executive functions (30). Additionally, the dichotomization refers to pupils respectively attending primary and secondary school. Assuming an anticipated drop-out of 25%, the final sample size was set to 1400.

An information sheet about the study was distributed to parents/guardians in advance by the teacher to the pupils, and also sent to the guardians by e-mail. It outlined the purpose and anonymity of the study and that participation was optional, and it underlined the opportunity to opt out. Contact information for the first author was provided. The information sheet was in Norwegian, and the reading level basic and easy readable, because some parents/guardians were possibly not fluent in Norwegian (the immigrant population of Hordaland County was estimated to be approximately 10% (31)). Informed passive consent was obtained from both the children and their guardians. Passive consent was approved because the questionnaire was considered of such a character that this limitation was found acceptable. On the day of the investigation, the pupils also received a short standard introduction from the first author. The purpose of the study and the content of the questionnaire were shortly explained. The voluntariness and anonymity was outlined, and the pupils were told that they could disrupt the completion at any time. Further, the pupils were told to answer the questionnaire by themselves; however, the first author could answer questions about the content during the completion. Pupils already having extra assistance at school (e.g. due to learning disabilities or language difficulties) were allowed to have extra assistance also during the completion. Completion of the questionnaires was performed in a classroom (45 min), supervised by the first author, and with a teacher present. A copy of the questionnaire may be obtained from the corresponding author.

The first section of the questionnaire consisted of demographic items such as year of birth and sex. The second section included single questions concerning intra-oral injections. A) *Time since last intra-oral injection:* (< 1 yr ago, ≥1 yr ago, never received or can't remember having received one). B) *Avoidance of intra-oral injections*: The pupils were asked to estimate how sure they were of being able to cope with dental treatment, knowing that an intra-oral injection was required ("definitely", "probably", "probably not", "certainly not"). The third section included psychometric instruments assessing BII fears. A) Intra Oral Injection Fear Scale (IOIF-s), a 12-item self-report instrument validated in 10-16-year-olds, was applied (28). Each response was scored from 1 to 5 (1 = not afraid at all, 5 = very afraid) with a sum score range from 12 to 60. A cut-off score of 38 was used to indicate high fear of intra-oral injections (28). B) *Fear of Dental treatment*: By use of Children's Fear Survey Schedule–Dental subscale (CFSS-DS) which consisted of 15-items measuring dental fear in children (32, 33). The five response options were graded from 1 (not afraid at all) to 5 (very afraid), with a sum score range from 15 to75. The scale is validated in 4-15-year-olds and a cut-off score of 38 was used to indicate high dental fear (33-36) . C) *Fear of injections*: By use of Injection Phobia Scale for children (IS-c) , an 18-item questionnaire assessing fear of injections validated in 8-17-year-olds, each response option ranged from 0 to 4 (0 = not afraid at all, 4 = very afraid) (37). Sum score varied from 0 to 72. There is no validated cut-off score. D) *Blood-injury (BI) fear*: Mutilation Questionnaire for children (MQ-c), validated in 8-17-year-olds, was a 15-item instrument with five response alternatives in each item ranging from 0 to 4 (0 = not afraid at all, 4 = very afraid) (37). Sum score varied from 0 to 60. There is no validated cut-off score. The last three self-report instruments were in Norwegian, based on the validated Swedish versions, as these two Scandinavian languages are closely related.

Variables were constructed for logistic regression analysis. The dependent variable was "Avoiders"/"Non-avoiders" where Avoiders (1), were those responding "certainly not" or "probably not", while Non-avoiders (0) were those responding "definitely" or "probably" when asked how sure they were of being able to cope with dental treatment, knowing that an intra-oral injection was required. Independent variables also underwent dichotomization. The dichotomization of the variable "High/Not high fear of intra-oral injections", was based on the sum score achieved on the IOIF-s,

(High fear (> sum score 38 (1), Low fear (≤sum score 38 (0)). The variable "High/Not high dental fear", was similarly based on the sum score achieved on the CFSS-DS (High dental fear (>sum score 38 (1), Low dental fear (≤sum score 38 (0)). The variable "Sex" was "Girls" (1) and "Boys"(0), and the variable "Age" was divided into "Youngest" (10-12 yr (0)) and "Oldest" (13-16 yr (1)). The variable "Experience with intra-oral injections" was dichotomized "Yes (1) /No" (0). Participants who responded having received intra-oral injections " <1 yr ago" or " ≥1 yr ago" were coded as "Yes". The participants responding "never received or can't remember having received intra-oral injections" were coded as "No".

Statistical analyses were performed using SPSS, version 22.0 (IBM, Armonk, NY, USA). Group differences were analyzed with one-way analysis of variance. Leven's test for equality of variances was conducted for the analysis of variances. When the assumption of equal variances was violated, the Welch test, not assuming homogeneity of variances was conducted. Effect size (eta-squared) was calculated for differences in mean sum scores between groups, and the results based on the following guidelines: 0.01=small effect, 0.06= medium effect, 0.14=large effect (38). Chi-square tests with Yates Continuity Correction were employed to assess associations and differences between groups of participants with a high level of fear of intra-oral injections, and those with a high level of dental fear.

Logistic regression models were used to investigate associations between independent variables and the dependent variable. Both bivariate and multiple (standard) analyses were carried out, and provided Odds Ratios (ORs) with 95% Confidence Intervals (CIs). Multicollinearity between the independent variables was assessed by Pearson's correlation coefficient.

Sum scores on the scales were calculated using the mean of the items multiplied by the number of items. Mean values were calculated if 20% or fewer of the items had missing information for each individual. The sum score for individuals with missing information on 20% or fewer was hence imputed and the missing values replaced using the mean of the other values.

Results

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Owing to a strike at a national level among teachers during the period of the study and a busy schedule for other teachers, 61 schools of those invited refused to participate in the study. New schools were invited until the sample size was reached. In total, 31 schools participated in the study (33.7% of the invited schools). In total, 1460 10-16-year-olds were invited to participate in the study. Since only a few pupils (n=19) for unknown reasons did not participate in the study, the final sample consisted of 1441 participants, yielding a response rate of 98.7%. Of the participants reporting sex (n=1428), 50.9% were girls (Table 1). The majority of the children (59.4%) responded that they could remember having had an intra-oral injection, with 31.1% having had one in the past year.

The mean scores for the scales IOIF-s, CFSS-DS, MQ-c and IS-c are shown in Table 2. The mean scores in all four scales were significantly higher in girls ($p<0.001$). The mean IOIF-s sum score differed by age, showing significantly higher values for the youngest age group than the oldest (M=24.7, SD= 11.2 vs M= 22.5, SD=11.1, $p<0.001$, F (1, 1416) = 13.6, eta squared = 0.01).

A Chi-square test indicated a significant association between those with a score above cut-off of the IOIF-s and sex, χ^2 (1,n=196) = 62.03; $p<0.001$. In total, 13.9% (21.1% of girls, 6.4% of boys) scored above the cut-off for the IOIF-s. Furthermore, there was a significant association between those with a score above cut-off of the CFSS-DS and sex, χ^2 (1,n=166)=39.38; $p<0.001$. In total, 11.7% (17.1% of girls and 6.2% of boys) scored above the cut-off on the CFSS-DS.

A significant association was found between fear of intra-oral injections and dental fear, χ^2 = 440.8 (1,n=1409)=440.8, $p<0.001$. Among all of the children, 7.9% (n=112) had both high fear of intra-oral injections and high dental fear. Of the pupils reporting high fear of intra-oral injections, 57.7% (n=112/194) also reported high dental fear, while 66.3% (n=112/169) of those reporting high dental fear also reported high fear of intra-oral injections.

As shown in Table 3, pupils with a high IOIF-s sum score had significantly higher mean sum scores on the CFSS-DS, MQ-c and IS-c scales than pupils with low IOIF-s sum score ($p<0.001$). Among pupils belonging to the high IOIF-s group, there were no significant sex differences.

The IOIF-s mean sum score was significantly lower among those who had previously experienced intra-oral injections, than those with no prior experience of intra-oral injections or no recollection of such (M=22.2, SD=10.6 vs M=25.9, SD=11.9, p<0.001, F (1,1115)=37.1, eta squared=0.03).

Cross-tabulation showed that a total of 10.6% of the children, 12.3% of the girls and 8.8% of boys, were characterized as avoiders. In the group of avoiders, 59.1 % were girls. The mean and total sum scores (IOIF-s, CFSS-DS, MQ-c and IS-c) of the Avoiders, and the Non-avoiders are compared in Table 4, and show significantly higher sum scores on all four scales among Avoiders. The effect size was largest with the IOIF-s (eta squared =0.188).

Table 5 presents associations between the independent variables ("High/Not high fear of intra-oral injections", "High/Not high dental fear", "Girls"/"Boys", "Oldest"/"Youngest", "Experience/No experience with intra-oral injections") and the dependent variable ("Avoiders/Non-avoiders"). The Table illustrates that all of the independent variables were significantly associated with Avoiders. The peak OR values were found for IOIF-s (OR=12.7) and CFSS-DS (OR=10.5).

Multiple logistic regression analysis with the same dependent variable ("Avoiders/Non-avoiders") is shown in Table 6. IOIF-s, CFSS-DS and previous experience with intra-oral injections were significantly associated with the dependent variable.

Discussion

In the present study, we found that high BII fear, and the subtype high fear of intra-oral injections, was prevalent among 10-16-year-olds. Furthermore, a strong association between high intra-oral injection fear and high dental fear was indicated within the same age group. High fear of intra-oral injections, high dental fear and no previous experience with intra-oral injections were found to be predictors of avoidance.

The study is based on a large sample of pupils from Hordaland County, Norway. The teacher strike leading many of the schools to decline participation was at a national level, afflicting public

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elementary schools regardless of area and demographic characteristics. Thus, the impact on the outcome measures of the study is probably limited. The response rate among the pupils was found to be excellent. Nevertheless, the sample was limited to only one Norwegian county and was not representative of all Norwegian pupils within this age range. The structure of the public dental service (PDS) and the public school system in the county is based on national guidelines. The PDS in Norway is free of charge for all children within this age range, and approximately 97.5% (29) of all children attend public elementary schools. It is therefore reasonable to believe that the findings reflect the situation for the chosen age group in Norway.

The sex differences on all four scales were shown to be statistically significant, which is in line with previous studies (11, 34). Whether this is a result of girls expressing their fears more freely on self-report scales cannot be determined by this study, but should be kept in mind when interpreting the results (39). Among the high IOIF-group, there was no significant sex difference in any of the scales. Also, there was a statistically significant age gradient in fear of intra-oral injections. However, the effect size statistics showed that the magnitude of the differences between the groups was small, indicating no strong age influence. A larger sample size allowing us to look at differences between separate age groups might possibly have provided different findings. Previous studies have reported inconsistent findings on age differences among children regarding BII fear/phobia and dental fear/phobia. Several studies have reported that dental fear is less common in older individuals (16, 34), but, like our study, these associations were not very strong. This may to some extent be due to developmental changes and maturation of cognitive abilities in children, and may therefore differ due to the age range from which the study samples are taken. These changes may perhaps not be linear over time (39). One should also take into account that differences in health care systems may influence the inconsistent age effect in studies across different countries. A less or differently developed/accessible dental health care system, or not affordable to certain segments of the population, may influence dental habits. In the study by MAJSTOROVIC et al. (17) the authors assumed that children who were extremely anxious at age 11 years might develop into "hardcore needle phobics" later on, which highlights the importance of early detection of high intra-oral injection fear.

By providing this particular group of children with extra attention and proper treatment, the development of intra-oral injection phobia may be preventable.

Both the strong overlap between the IOIF-s and CFSS-DS, and the fact that the pupils with high fear of intra-oral injections had higher mean scores on the CFSS-DS scale, indicated a relationship between dental fear and intra-oral injection fear within this age group. This is in concordance with previous findings in other age groups (11,13, 40). Even though this cross-sectional survey cannot determine causality, it may be hypothesized that a child who avoids intra-oral injections will be at risk of being exposed to more painful dental treatment, and consequently more prone to developing high dental fear (21, 41).

The higher intra-oral injection fear level among those with no prior experience with intra-oral injections than in those who previously had received injections at the dentist, may reflect the fact that the first group probably also includes avoiders. By comparing the ''Avoiders'' and those labelled ''Non-avoiders'', significantly higher sum scores on all four scales (CFSS-DS, IOIF-s, MQ-c and IS-c) among the "Avoiders" were documented. The effect sizes though, indicating the magnitude of the associations, were large for the IOIF-s, CFSS-DS and IS-s, but considered very small for the MQ-c. This could also be an indication of an association with dental fear, and may be seen as support for the division of BII-fear in the distinct subtype blood-injury and subtype injection, as described by Ost (2).

In this sample, 10.6% of participants were characterized as "Avoiders", a figure higher than previously reported in Hordaland County among 18-year-olds (3.3%) (11). Nevertheless, self-reports on dental avoidance behavior should be interpreted with caution. The youngest children are often attending dental appointments in the presence of their parents or guardians. This may influence the child's behavior, and attendance and treatment may not be perceived as entirely optional, possibly influencing their response to this particular question. Hence, the wording of the "avoidance" variable was targeting the treatment situation involving the intra-oral injection, in which the child is more in position to avoid, rather than by targeting attendance to the treatment session. However, even though this is probably one of the closest approaches as to assess self-reported avoidance behaviour in young

children, this indirect approximation introduces some biases, such as possibly including some children afraid of other dental procedures (*e.g* drilling). Another factor with possible impact is the fact that the pupils were sitting in a classroom while completing the questionnaire, and were not exposed to the syringe or an actual dental situation. Since *in vivo* exposure to the specific anxiety provoking stimulus is known to generate an immediate and extreme anxiety response (1), true avoidance behavior is hard to predict accurately by self-reports.

In general, avoidance is strongly associated with specific phobias and also is one of the criteria for a specific phobia diagnosis (1). One may speculate that the proportion of "Avoiders" may be seen as an indication of the prevalence of intra-oral injection phobia in children. This estimate is somewhat in line with the previous study on prevalence in 10-11-year-olds, by MAJSTOROVIC *et al.* (17). The bivariate analysis revealed significant associations related to avoidance with all the variables, even though the sex and age factors were not as strongly related. In the multivariate analysis, the significant factors in the model for being predictors of avoidance were fear of intra-oral injections, dental fear and previous experience with intra-oral injections (Table 6). A limitation of the model was the correlation coefficient of 0.83 found when assessing multicollinearity between intra-oral injection fear and dental fear. Both variables were considered important to the analysis, and the correlation coefficient regarded not too strong for them to be included in the multivariate analysis.

A limitation of the study is that the accuracy of self-reports in children on the not validated variables dental attendance and avoidance may be recall biased. Additionally, they may have had difficulties in understanding some of the questionnaire items. Nevertheless, the pilot study revealed no difficulties with the wording or understanding of the questions. Also, the first author giving the instructions and being present at the time of completion secured standardized information on questions related to the content of the questionnaire during the completion. Additionally, the children, especially the fearful ones, might have completed the questionnaire according to what they believe to be 'preferable', introducing a degree of social desirability bias. This may have caused children to over-report dental attendance and under-report avoidance and fearfulness. In an attempt to limit this effect, anonymity of the study was outlined, both in a written form prior to the study, and was repeated at the

day of completion. Another limitation is the fact that some parents/guardians (*e.g* immigrant parents) may have trouble reading Norwegian and thereby did not understand the content of the information sheet, yielding possible false positive consent to participation in the study. Norwegian is the language in which official written information from the schools is given. Parents/guardians not fluent in Norwegian are generally expected to seek external assistance. Additionally, even though the CFSS-DS had been validated only up to the age of 15, we chose to use this scale also in 16-year-olds, enabling comparisons across age groups. This should represent only minor problems in terms of cognitive development, and, additionally, the CFSS-DS is derived from a validated adult version.

This study has documented that high fear of BII and the subtype fear of intra-oral injections were prevalent among 10-16-year-olds. The strong overlap between high fear of intra-oral injection and high dental fear may also indicate an association between the diagnosis BII phobia and dental phobia according to the DSM-V criteria. High fear of intra-oral injections was also found to be associated with avoidance of necessary dental treatment when local anesthesia is needed. For this reason, intra-oral injection fear should be addressed before treatment of dental fear.

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Table 1

Distribution of 10-16- year-old pupils attending public elementary schools, according to age and sex

Age	Girls, n (%)	Boys, n (%)	Total, N (%)
10	89 (6.2)	84 (5.9)	173 (12.1)
11	170 (11.9)	147 (10.3)	317 (22.2)
12	112 (7.8)	134 (9.4)	246 (17.2)
13	107 (7.5)	92 (6.4)	199 (13.9)
14	85 (6.0)	75 (5.3)	160 (11.2)
15	88 (6.2)	72 (5.0)	160 (11.2)
16	76 (5.3)	97 (6.8)	173 (12.1)
Total	**727 (50.9)**	**701 (49.1)**	**1428 (100)**

Table 2

One-way analysis of variance evaluating the impact of sex on levels of the Intra-oral injection fear scale (IOIF-s), Children's Fear Survey Schedule-Dental Subscale (CFSS-DS), Mutilation Questionnaire for children (MQ-c), and Injection phobia scale for children (IS-c)

	Girls Mean (SD***)	Boys Mean (SD***)	Total Mean (SD***)	N	Statistics
IOIF-s*	27.5 (11.8)	19.7 (9.1)	23.7 (11.2)	1406	$F_{(1, 1344.5)}=193.8$; $p<0.001$
CFSS-DS**	28.3 (10.3)	22.3 (8.1)	25.4 (9.8)	1416	$F_{(1, 1366)}=150.2$; $p<0.001$
MQ-c	17.3 (11.1)	10.2 (9.8)	13.8 (11.1)	1417	$F_{(1, 1406.2)}=159.2$; $p<0.001$
IS-c	18.4 (15.9)	9.7 (12.0)	14.1 (14.8)	1406	$F_{(1, 1329.3)}=133.1$; $p<0.001$

*Cut-off score IOIF-s > 38
**Cut-off score CFSS-DS > 38
***SD, standard deviation

Table 3

One-way anaysis of variance evaluating the impact of respectively high and low scores on the Intra-Oral Injection Fear (IOIF) scale, of the Children's Fear Survey Schedule-Dental Subscale (CFSS-DS), the Mutilation Questionnaire for children (MQ-c), and the Injection phobia scale for children (IS-c).

		IOIF-high* Mean (SD**)	n	**IOIF-low*** Mean (SD**)	n	**Statistics**
CFSS-DS***	Girls	41.5 (10.4)	150	24.9 (6.9)	565	F (1, 185.0) = 343.1; p<0.001, eta sq:0.43
	Boys	39.1 (12.8)	43	21.2 (6.4)	639	F (1, 43.4) = 82.1; p<0.001, eta sq:0.28
	Total	41.0 (11.0)	194	23.0 (6.9)	1215	F (1, 218.0)= 493.3; p<0.001, eta sq:0.40
MQ-c	Girls	25.4 (11.7)	151	15.2 (9.9)	567	F (1, 210.5) = 96.9; p<0.001, eta sq:0.14
	Boys	21.7 (14.4)	44	9.4 (8.7)	636	F (1, 45.2) = 31.1; p<0.001, eta sq:0.10
	Total	24.7 (12.6)	196	12.1 (9.7)	1214	F (1, 234.1) = 179.7; p<0.001, eta sq:0.16
IS-c	Girls	38.2 (15.0)	152	13.0 (11.3)	562	F (1, 200.3) = 371.8; p<0.001, eta sq:0.42
	Boys	36.3 (15.7)	44	7.9 (9.3)	637	F (1, 45.1) = 140.0; p<0.001, eta sq:0.34
	Total	37.8 (15.1)	197	10.3 (10.6)	1210	F (1, 228.6) = 604.9; p<0.001, eta sq:0.42

* IOIF-high; sum score IOIF-s > 38, IOIF-low; sum score IOIF-s ≤ 38

**SD, standard deviation

*** Cut-off score CFSS-DS > 38

Table 4

One-way analysis of variance evaluating the impact of dental Avoiders* and Non-avoiders* on the Intra-oral injection fear scale (IOIF-s), Children's Fear Survey Schedule-Dental Subscale (CFSS-DS), Mutilation Questionnaire for children (MQ-c) and Injection phobia scale for children (IS-c).

	Avoiders* Mean (SD**)	n	Non-avoiders* Mean (SD**)	n	Statistics	
IOIF-s	37.6 (11.6)	149	21.9 (9.8)	1255	$F(1, 174.0)=249.6; p<0.001$	eta sq=0.188
CFSS-DS	36.8 (12.5)	149	24.0 (8.4)	1262	$F(1, 164.3)=150.8; p<0.001$	eta sq=0.164
MQ-c	21.0 (12.9)	150	13.0 (10.5)	1262	$F(1, 173.5)=53.6; p<0.001$	eta sq=0.05
IS-c	29.8 (17.7)	148	12.1 (13.1)	1256	$F(1, 166.6)=139.2; p<0.001$	eta sq=0.137

*Avoiders were defined as those responding "certainly not" or "probably not", whereas Non-avoiders were those responding "Definitely" or "Probably" when asked if they were able to cope with dental treatment knowing that an intra-oral injection was required.
**SD, standard deviation.

Table 5

Bivariate logistic regression analyses of factors related to being included in the Avoider* group

Variable	n	B	Odds ratio	95% CI**	p
IOIF-s*					
IF (score 1)	192	2.545	12.74	8.73-18.58	<0.001
Non-IF (score 0)	1212				
CFSS-DS†					
DF (score 1)	165	2.349	10.48	7.14-15.37	<0.001
Non-DF (score 0)	1246				
Sex					
Girls (score 1)	716	-0.374	0.69	0.49-0.97	0.033
Boys (score 0)	694				
Age‡					
Old (score 1)	691	-0.559	0.57	0.40-0.81	0.002
Young (score 0)	731				
Experience with io-i§					
Yes (score 1)	568	-0.830	0.44	0.31-0.62	<0.001
No (score 0)	824				

* Avoiders were defined as those responding "certainly not" or "probably not", when asked if they were able to cope with dental treatment knowing that an intra-oral injection was required.
** CI: Confidence Interval
*** IOIF-s, Intra-oral injection fear scale; IF, high intra-oral injection fear (IOIF-s> 38)
† CFSS-DS, Children's Fear survey Schedule-Dental Subscale; DF, dental fear (CFSS-DS> 38)
‡ Old, (13-16 year); Young, (10-12 year)
§ Experience with io-i, experience with intra-oral injections

Table 6

Multiple logistic regression analyses of factors related to being included in the Avoider* group

Variable	n	B	Odds ratio	95% CI**	p
IOIF-s*					
IF (score 1)	192	1.875	6.52	3.99-10.67	<0.001
Non-IF (score 0)	1212				
CFSS-DS†					
DF (score 1)	165	1.292	3.64	2.20-6.04	<0.001
Non-DF (score0)	1246				
Sex					
Girls (score 1)	716	0.243	1.28	0.83-1.95	0.261
Boys (score 0)	694				
Age‡					
Old (score 1)	691	-0.368	0.69	0.46-1.04	0.077
Young (score0)	731				
Experience with io-i§		-0.650	0.52	0.35-0.78	0.001
Yes (score 1)	568				
No (score 0)	824				

-2LL: 714, 89.8% correctly predicted; Nagelkerke's R^2=0.289

* Avoiders were defined as those responding "certainly not" or "probably not", when asked if they were able to cope with dental treatment knowing that an intra-oral injection was required.
** CI: Confidence Interval
*** IOIF-s, Intra-oral injection fear scale; IF, high intra-oral injection fear (IOIF-s> 38)
†CFSS-DS, Children's Fear survey Schedule-Dental Subscale; DF, dental fear (CFSS-DS> 38)
‡ Old, (13-16 year); Young, (10-12 year)
§Experience with io-i, experience with intra-oral injections

APPENDIX I

UNIVERSITETET I BERGEN
Det medisinsk-odontologiske fakultet

Tannhelsetjenestens
kompetansesenter
Vest / Hordaland

SPØRREUNDERSØKELSE OM BARN OG UNGES FORHOLD TIL TANNLEGEBEHANDLING OG BEDØVELSE

Undersøkelsen er ANONYM, det skal ikke skrives navn på skjemaene, og ingen på skolen skal se hva du har svart.

DELTAGELSE ER FRIVILLIG.

- Utfyllingen skal skje her i dette klasserommet
- Det skal være ro i rommet, og ingen snakker med hverandre
- Legg skjemaet i kartongen med fremsiden ned når du er ferdig

PÅ FORHÅND TAKK FOR HJELPEN!

Vennlig hilsen

Karin G. Berge
Tannlege, stipendiat

Veiledere

Marit Slåttelid Skeie	Margrethe Elin Vika	Maren Gry Lillehaug Agdal
Førsteamanuensis	Psykolog, PhD	Tannlege, PhD

Opplevelse av tannbehandling blant barn og unge

Spørreskjema til barn og ungdom fra 10 til 16 år

Fødselsår: _____

Kjønn:

(sett et kryss)

☐ Jente
☐ Gutt

Når fikk du bedøvelse hos tannlegen sist?

(sett et kryss)

☐ Mindre enn et år siden
☐ Mer enn 1 år siden
☐ Har aldri fått bedøvelse hos tannlegen, eller kan ikke huske å ha fått det

Hvor redd er du for å få sprøyte i munnen?
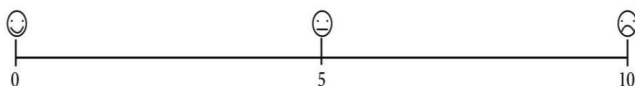
Ikke redd i det hele tatt   Så redd det går an å bli

Når fikk du vaksine eller tok blodprøve sist?

(sett et kryss)

☐ Mindre enn et år siden
☐ Mer enn 1 år siden
☐ Har aldri fått vaksine eller blodprøve, eller kan ikke huske å ha fått det

Hvor redd er du for å få sprøyte på kroppen (vaksine, blodprøve)?
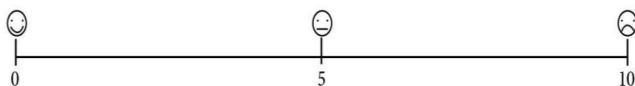
Ikke redd i det hele tatt   Så redd det går an å bli

Har du en eller flere ganger besvimt i følgende situasjoner?

(kryss av for ja eller nei)

Når jeg har fått bedøvelse hos tannlegen..☐ Ja   ☐ Nei
Når jeg er blitt vaksinert eller har tatt blodprøve hos lege/helsesøster.................☐ Ja   ☐ Nei
Når jeg har sett et menneske eller et dyr som er blitt skadet...............................☐ Ja   ☐ Nei
Når jeg selv er blitt skadet eller begynt å blø...☐ Ja   ☐ Nei
Antall ganger besvimt (omtrent): _____

Dersom du skal til tannlegen og vet at du trenger bedøvelsessprøyte for å ordne en tann, hvor sikker er du på at du vil komme til å møte til timen?
(sett et kryss)
☐ Helt sikker på at jeg møter
☐ Sannsynligvis møter jeg
☐ Sannsynligvis møter jeg ikke
☐ Helt sikker på at jeg ikke møter

Dersom du skal til tannlege og vet at du trenger bedøvelsessprøyte for å ordne en tann, hvor sikker er du på at du vil komme til å mestre behandlingen?
(sett et kryss)
☐ Helt sikker på at jeg mestrer behandling
☐ Sannsynligvis mestrer jeg behandling
☐ Sannsynligvis mestrer jeg ikke behandling
☐ Helt sikker på at jeg ikke mestrer behandling

Dersom du har tatt bedøvelse, hvor ubehagelig var den siste bedøvelsen hos tannlegen?
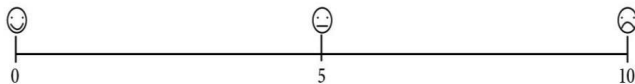
Ikke ubehagelig i
det hele tatt

Det mest ubehagelige
jeg kan forestille meg

Dersom du har tatt bedøvelse, hvor smertefull var den siste bedøvelsen hos tannlegen?
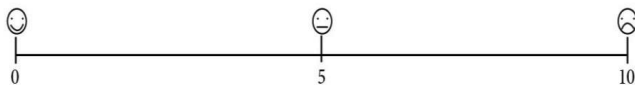
Ikke smertefull i
det hele tatt

Det mest smertefulle jeg
kan forestille meg

IOIF-s *

Tenk deg at du er i situasjoner som beskrevet nedenfor. Marker med å sette et kryss i ruten for det svaret som passer best for deg. Sett bare et kryss for hvert punkt.

Hvor redd er du...

	Ikke redd i det hele tatt	Bare litt redd	Ganske redd	Svært redd	Livredd
1. når tannlegen sier at du trenger en bedøvelsessprøyte	☐	☐	☐	☐	☐
2. når du kjenner stikket av bedøvelsessprøyten i munnen	☐	☐	☐	☐	☐
3. når tannlegen smører bedøvelsessalve på tannkjøttet	☐	☐	☐	☐	☐
4. for selve bedøvelsesvæsken (bedøvelsesmiddelet)	☐	☐	☐	☐	☐
5. når du ser bilde av en person som får bedøvelse hos tannlegen	☐	☐	☐	☐	☐
6. når du hører noen fortelle at de har fått bedøvelse hos tannlegen	☐	☐	☐	☐	☐
7. for at stikket skal være veldig smertefullt	☐	☐	☐	☐	☐
8. når du sitter i tannlegestolen og snart skal få en bedøvelsessprøyte	☐	☐	☐	☐	☐
9. når du kjenner at du blir nummen (bedøvet)	☐	☐	☐	☐	☐
10. for at bedøvelsen ikke skal virke	☐	☐	☐	☐	☐
11. når du ser nålen på en bedøvelsessprøyte	☐	☐	☐	☐	☐
12. når du ser bilde av en tannlegesprøyte	☐	☐	☐	☐	☐

* The abbreviated heading was not present in the original questionnaire

CFSS-DS*

Marker med å sette kryss i ruten for det svaret som passer best. Sett bare et kryss for hvert punkt.

Hvor redd er du...

	Ikke redd i det hele tatt	Bare litt redd	Ganske redd	Svært redd	Livredd
1. for tannlegen	☐	☐	☐	☐	☐
2. for doktoren	☐	☐	☐	☐	☐
3. for å få sprøyte eller bedøvelse	☐	☐	☐	☐	☐
4. når noen undersøker munnen og tennene dine	☐	☐	☐	☐	☐
5. når du gaper hos tannlegen	☐	☐	☐	☐	☐
6. når noen du ikke kjenner berører deg	☐	☐	☐	☐	☐
7. når noen du ikke kjenner ser på deg	☐	☐	☐	☐	☐
8. når tannlegen borer i tennene dine	☐	☐	☐	☐	☐
9. når du ser tannlegen bore i tennene hos en annen	☐	☐	☐	☐	☐
10. når du hører tannlegeboret	☐	☐	☐	☐	☐
11. når noen holder et instrument inni munnen din	☐	☐	☐	☐	☐
12. for å kveles eller sette noe i halsen	☐	☐	☐	☐	☐
13. for å måtte innlegges på sykehus	☐	☐	☐	☐	☐
14. for personer med hvite lege- eller tannlegeklær	☐	☐	☐	☐	☐
15. når tannlege eller tannpleier pusser tennene dine	☐	☐	☐	☐	☐

* The abbreviated heading was not present in the original questionnaire

IS-c*

Her beskrives ulike situasjoner som personer som er redde for sprøyter kan synes er ubehagelige. **Kryss av for hvor redd du hadde vært om du befant deg i situasjonen.** Husk på at det ikke finnes noe rett eller galt svar.

Hvor redd er du...

	Ikke i det hele tatt	Litt	Ganske mye	Mye	Veldig mye
1. Ta blodprøve ved stikk i fingeren	☐	☐	☐	☐	☐
2. Få en sprøyte i overarmen	☐	☐	☐	☐	☐
3. Se et bilde av en sprøyte	☐	☐	☐	☐	☐
4. Kjenne sykehuslukt	☐	☐	☐	☐	☐
5. Få en bedøvelsessprøyte av tannlegen	☐	☐	☐	☐	☐
6. Ta en blodprøve	☐	☐	☐	☐	☐
7. Se en person ta en blodprøve i virkeligheten	☐	☐	☐	☐	☐
8. Få en sprøyte i baken	☐	☐	☐	☐	☐
9. Se bilde av en person som får sprøyte	☐	☐	☐	☐	☐
10. Høre noen fortelle om å få sprøyte	☐	☐	☐	☐	☐
11. Se på og ta på blodårer på armens innerside	☐	☐	☐	☐	☐
12. Se film om en person som får en sprøyte	☐	☐	☐	☐	☐
13. Se en annen person få en sprøyte i virkeligheten	☐	☐	☐	☐	☐
14. Se en person i sykepleieruniform	☐	☐	☐	☐	☐
15. Ta hull i ørene	☐	☐	☐	☐	☐
16. Få en vaksinasjon	☐	☐	☐	☐	☐
17. Få en sprøyte som går inn i en blodåre	☐	☐	☐	☐	☐
18. Se på at en annen person tar blodprøve ved stikk i fingeren	☐	☐	☐	☐	☐

* The abbreviated heading was not present in the original questionnaire

MQ-c*

Her beskrives ulike situasjoner som personer som er redde for blod kan synes er ubehagelige. **Kryss av for hvor redd du hadde vært om du befant deg i situasjonen.** Husk på at det ikke finnes noe rett eller galt svar.

Hvor redd er du...

	Ikke i det hele tatt	Litt	Ganske mye	Mye	Veldig mye
1. Se en hardt skadet person på tv	☐	☐	☐	☐	☐
2. Gå til sykehuset og besøke en syk eller skadet person	☐	☐	☐	☐	☐
3. Se en slakter jobbe	☐	☐	☐	☐	☐
4. Tenke på å jobbe som lege eller sykepleier	☐	☐	☐	☐	☐
5. Se noen som er skadet i øyet	☐	☐	☐	☐	☐
6. Se en person som blør	☐	☐	☐	☐	☐
7. Se skader eller ulykker i virkeligheten	☐	☐	☐	☐	☐
8. Se en operasjon på TV	☐	☐	☐	☐	☐
9. Hjelpe noen som er blitt skadet eller blør	☐	☐	☐	☐	☐
10. Bruke skarpe kniver	☐	☐	☐	☐	☐
11. Tenke på å måtte opereres	☐	☐	☐	☐	☐
12. Å skjære meg ved et uhell	☐	☐	☐	☐	☐
13. Se en blodflekk	☐	☐	☐	☐	☐
14. Se et åpent sår	☐	☐	☐	☐	☐
15. Rengjøre et sår	☐	☐	☐	☐	☐

* The abbreviated heading was not present in the original questionnaire

APPENDIX II

Tannhelsetjenestens
kompetansesenter
Vest / Hordaland

Til foresatte til elev i   klasse

Informasjon om spørreundersøkelse angående barn og ungdoms forhold til tannbehandling og bedøvelse.

Universitetet i Bergen og Tannhelsetjenestens kompetansesenter vest-Hordaland skal gjennomføre et forskningsprosjekt som skal kartlegge hvordan barn og ungdom synes det er å gå til tannlegen, og spesielt om de er redde for blod, skader, få bedøvelse og andre injeksjoner. Undersøkelsen er et ledd i vårt arbeid med å kunne forebygge at barn og voksne får problemer med å mestre tannbehandling.

Som del av dette prosjektet planlegges det en spørreskjemaundersøkelse blant elevene i **….. klasse ved …… skole.**

Spørreskjemaene består av følgende deler:
1. Generell del: Fødselsår, kjønn, erfaringer med sprøyte, blod og skader
2. Skjema som måler redsel for tannbehandling
3. Skjema som måler redsel for injeksjoner/sprøyter/vaksinasjoner
4. Skjema som måler redsel for bedøvelse hos tannlege

Spørreskjemaene vil bli utdelt i klasserommet og skal fylles ut der. Karin G. Berge, stipendiat ved UiB/TkV-H, vil først veilede elevene om fremgangsmåten. Berge vil også være tilstede under utfyllingen. Det er avsatt ca. 1 skoletime til dette.

Undersøkelsen er fullstendig anonym ved at det ikke skal skrives hverken navn eller klasse på skjemaet. Deltagelse er frivillig for den enkelte elev. Dersom du/dere ikke ønsker at deres barn skal delta, ber vi om at svarslippen nedenfor fylles ut og tas med tilbake til skolen, eller at det sendes en e-post til klassens kontaktlærer eller undertegnede. Denne forespørselen sendes både med eleven via ranselpost, og pr. e-post til foresatte.

Dersom det ønskes flere opplysninger om prosjektet, eller det ønskes hjelp i forbindelse med at barnet har problemer med tannbehandling eller bedøvelse kan dere kontakte undertegnede på telefon 55 58 53 21 eller e-post: karin.berge@hfk.no

Vennlig hilsen

Karin G. Berge
Tannlege, stipendiat
UiB, TKV-H

Klipp og returner………………………………………………………………………………

Jeg <u>ønsker ikke</u> at mitt barn ………………………………i klasse………skal delta i spørreundersøkelsen om barn og ungdoms forhold til tannbehandling og bedøvelse.

Sted………………..Dato………..….Signatur…………………………………..

Til rektor

Forespørsel om deltagelse i spørreundersøkelse om barn og unges forhold til tannlegesprøyte.

Vi ber om tillatelse til å gjennomføre en spørreundersøkelse om 10-16 åringers forhold til tannlegebe-handling, og da spesielt erfaringer forbundet med det å få satt sprøyter. I alt 1400 barn og unge er trukket ut på en slik måte at de representerer 10-16 åringer i Hordaland**.** Det er derfor av stor betyd-ning at de uttrukne skolene sier seg villig til deltagelse. Elever i **..** klasse ved **…..skole** er blant dem som er plukket ut for deltagelse.

Undersøkelsen gjennomføres i løpet av 2014/2015. Deltakerne i studien og deres foresatte blir infor-mert om at deltakelse er frivillig, og at opplysningene er anonymisert. Foresatte må samtykke til at deres barn kan delta i undersøkelsen.

Helsedirektoratet finansierer undersøkelsen, som gjennomføres i regi av Senter for odontofobi, Tannhelsetjenestens kompetansesenter Vest – Hordaland og Universitetet i Bergen. Prosjektet er godkjent av Regional komité for medisinsk forskningsetikk. Det aktuelle spørreskjemaet er blitt prøvd ut på en skole i Bergen med positive tilbakemeldinger.

Undersøkelsen vil bidra til økt innsikt i ungdommers forhold til sprøyter. Slik kunnskap er viktig for å kunne forebygge at barn og unge utvikler problemer i forbindelse med det å få satt sprøyter, og for å kunne gi dem som *har* slike problemer best mulig behandling.

Elevene skal fylle ut spørreskjemaet i klasseromssituasjonen, og hver klasse som skal delta må påreg-ne at det går med én skoletime. Stipendiat Karin G. Berge vil foreta den praktiske gjennomføringen. Hun vil i løpet av de neste ukene ta direkte kontakt med skolen, slik at nærmere avtale kan gjøres.

……… kommune har gitt tillatelse til å gjennomføre spørreundersøkelsen.

Vennlig hilsen

Karin G. Berge
Tannlege, stipendiat

Veiledere

Marit Slåttelid Skeie	Margrethe Elin Vika	Maren Lillehaug Agdal
Førsteamanuensis	Psykolog, PhD	Tannlege, PhD

Til skolesjefer i grunnskolen i Hordaland

Bergen …..

Forespørsel om tillatelse til å gjennomføre spørreundersøkelse i grunnskolen.

Vi ønsker med denne henvendelsen å be om tillatelse til å kontakte ulike grunnskoler i utvalgte kommuner for å gjennomføre en spørreundersøkelse. Denne spørreundersøkelsen omhandler barn og unges forhold til tannlegebehandling, og spesielt da erfaringer forbundet med det å få bedøvelsessprøyte. Vi ser på undersøkelsen som viktig, både for å forebygge at barn og unge utvikler problemer i forbindelse med injeksjoner, men også for å kunne gi de som allerede *har* problemer med dette, den best mulige behandling.

Spørreskjemaene som skal benyttes, har tidligere vært brukt på 154 elever i Bergen kommune med positive tilbakemeldinger. Denne gangen håper vi på å nå i alt 1400 elever i grunnskolen i Hordaland fylke i alderen 10-16 år. Elevene trekkes ut skolevis på en slik måte at de vil representere aldersgruppen i fylket. Planen er at elevene fyller ut spørreskjemaet i et klasserom. Hver klasse som er trukket ut til å delta, må regne med at det går med ca én skoletime. Den praktiske gjennomføringen vil foretas av stipendiat Karin Berge.

Helsedirektoratet finansierer undersøkelsen, som gjennomføres i regi av Senter for odontofobi, Tannhelsetjenestens kompetansesenter Vest - Hordaland og Universitetet i Bergen. Prosjektet er godkjent av Regional komité for medisinsk forskningsetikk. Det innebærer at deltakerne i studien blir informert om at deltakelse er frivillig, og at opplysningene blir anonymisert. Alle foresatte av berørte elever mottar informasjonsskriv og må samtykke til at deres barn kan delta i undersøkelsen.

Dersom du har spørsmål som du ønsker svar på, kan du sende e-post til stipendiat Karin Goplerud Berge (karin.berge@hfk.no), ringe Senter for odontofobi 55 58 64 62/55 58 37 93, eller ta kontakt med oss ved Kompetansesenter Vest- Hordaland (SFO), Årstadveien 19, 5009 Bergen.

Vennlig hilsen

Karin Goplerud Berge
Tannlege, stipendiat

Veiledere

Marit Slåttelid Skeie	Margrethe Elin Vika	Maren Gry Lillehaug Agdal
Førsteamanuensis	Psykolog, PhD	Tannlege, PhD

APPENDIX III

Tannhelsetjenestens
kompetansesenter
Vest / Hordaland

Forespørsel om deltagelse i forskningsprosjektet

«Behandling av barn med angst for bedøvelse hos tannlegen»

Bakgrunn og hensikt

Vi ber foresatt(e) for

………………………………………………………….(barnets navn)

om tillatelse til at barnet deltar i en behandlingsstudie for å undersøke effekten av en behandling for å mestre bedøvelse (sprøyte) hos tannlege.

Hva innebærer studien?

Formålet med studien er å undersøke effekten av en behandlingsmetode for barn med angst for bedøvelse hos tannlegen. Metoden er kunnskapsbasert, og er den anbefalte behandlingsmetoden nasjonalt i forhold til en slik angst.

Prosedyre:

1.time: Barnet vil først bli bedt om å fylle ut noen spørreskjema. Deretter får barnet en samtale med psykolog for å diagnostisere barnets angstproblemer, samt en test for å undersøke hvorvidt det mestrer sprøyten eller ikke. Etter dette avtales med barn og foresatte om man ønsker deltagelse i studien eller ikke.

Dersom barnet inkluderes i studien, blir det enten tilbudt time til behandling den påfølgende uken, eller hun/han blir satt på venteliste i 5 uker og deretter tilbudt behandling.

<u>2.-6. time:</u> Behandlingen gjennomføres av tannlege over inntil 5 seanser der de viktigste prinsippene er følgende: informasjon, kontroll, gradvis eksponering og samarbeid. Barnet bestemmer selv tempoet og kan når som helst avbryte. Når barnet mestrer sprøyten avsluttes behandlingen.

<u>Video:</u> Det vil bli tatt video av alle behandlingssekvensene for å kvalitetssikre behandlingen. Opptakene oppbevares nedlåst, og kun medlemmer av forskergruppen vil få adgang til å se dem. Når barnets kontakt med senteret avsluttes, vil de bli slettet. De vil ikke bli brukt i undervisningssammenheng med mindre dere er blitt forespurt og har gitt skriftlig tillatelse til dette på forhånd.

<u>Oppfølging 1 uke etter:</u> Barnet får time ca. en uke etter behandlingen avsluttes for å evaluere resultatet av behandlingen. Det innebærer ny utfylling av spørreskjema og en test på om barnet mestrer tannlegesprøyte. Deretter vil hun/han bli henvist tilbake til sin vanlige tannlege.

<u>Oppfølging 1 år etter:</u> Barnet vil bli innkalt for ny evaluering av resultatet av behandlingen. Dette innebærer utfylling av spørreskjema, intervju med psykolog og test om barnet mestrer tannlegesprøyte.

Mulige fordeler og ulemper

Mange typer tannbehandling er smertefull uten bedøvelse, og den mulige gevinsten for barnet er å bli kvitt en type angst som hindrer nødvendig behandling, både nå og i fremtiden. Deltagelse i studien krever en ekstra oppfølgingsseanse etter endt behandling, og en kontrollseanse ett år etter ferdig behandling. Halvparten av deltagerne i studien vil også, etter loddtrekning, stå på venteliste i 5 uker før behandling. Utover dette er behandlingen tilnærmet lik ordinær behandling ved Senter for odontofobi.

Hva skjer med informasjonen om barnet?

Spørreskjema og notater gjort av psykolog og tannlege lagres i Senter for odontofobi i hht. Forskrift om journalføring. Forskningsdata skal lagres i en datafil på Universitetet i Bergen uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter barnet til denne datafilen gjennom en navneliste som oppbevares atskilt fra datafilen.

Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til barnet. Det vil heller ikke være mulig å identifisere barnet i publikasjoner av studien.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til at barnet deltar i studien. Dette vil ikke få konsekvenser for barnets tilbud om gratis behandling hos Senter for odontofobi og i Den offentlige tannhelsetjenesten.

Rett til innsyn og sletting av opplysninger om barnet
Hvis du sier ja til at barnet deltar i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om barnet. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker barnet fra studien, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi og forskning
Behandlingen er gratis, men reiseutgiftene dekkes ikke av prosjektet. Barnet er forsikret etter vanlige regler for pasienter som behandles i Den offentlige tannhelsetjenesten og i Odontologisk klinikk på Universitetet i Bergen.

Dersom du ønsker at barnet skal delta, undertegner du samtykkeerklæringen på neste side. Dersom du har spørsmål til studien, kan følgende kontaktes:

Karin G. Berge
Tannlege, stipendiat
Tlf: 55 58 53 21

Marit Slåttelid Skeie	Margrethe Elin Vika	Maren Lillehaug Agdal
Førsteamanuensis	Psykolog, PhD	Tannlege, PhD

Samtykke til deltakelse i studien

«Behandling av angst for bedøvelse hos tannlegen»

.…………………
Sted, dato

Jeg/vi gir samtykke til at barnet mitt

…………………………………………..

deltar i studien slik den er beskrevet i informasjonen. Jeg/vi samtykker også til at det blir tatt video av alle behandlingssekvensene, men da under den forutsetning at opptakene oppbevares nedlåst og at kun medlemmer av forskergruppen har adgang til opptakene. Opptakene kan ikke brukes i undervisningssammenheng uten at jeg/vi er blitt forespurt og gitt skriftlig tillatelse på forhånd.

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Foresattes underskrift (en eller flere)

………………………………………….
Barnets underskrift