The child with tension-type headache

Physical factors and interactive interventions

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The child with tension-type headache

Physical factors and interactive interventions

by

Birte Tornøe

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The child with tension-type headache. Physical factors and interactive interventions

Abstract

Tension-type headache (TTH) in children and especially girls is a prevalent problem worldwide, and means there is a risk of school absenteeism, medication overuse and persistent headache. Knowledge about the associated physical factors is limited, as is knowledge on evidence based interventions.

Aim: The overall aim of this thesis was to examine the associations of physical factors with frequent or chronic TTH in children. Furthermore to examine aspects of interactive interventions as empowering patient education studying where and how to direct interdisciplinary headache services for the child and parents from the perspective of a physiotherapist..

The first study piloted computer-animated relaxation therapy with children 7-13 years of age and investigated how so young the children experienced the therapy. Furthermore it piloted enrolment procedures, the compliance of the child and parents and to gauge whether a large-scale controlled trial was warranted. The second study aimed at determining the test-retest repeatability of neck-shoulder muscle strength in healthy children 9-18 years of age. The second study also determined the test-retest repeatability of the Total Tenderness Score (TTS) and of a sub-maximal cycle ergometer test predicting maximal oxygen uptake. The third study was a case-control study aiming at examining the combined measurements of muscle strength in the neck-shoulder region, aerobic power, and pericranial tenderness in girls 9 to 18 years of age, and the measurements associations with frequent episodic or chronic TTH compared to healthy controls. The fourth study based on a randomized controlled trial examined the outcomes of specific strength training of shoulder muscles compared with counselling with nurse and physiotherapist in short defined patient education programmes for girls 9-18 years with TTH.

Results: Results from study I indicated that a nine session course in computer-animated relaxation therapy seemed a significantly effective learning strategy presenting a mean improvement percent of 45% of headache frequency. The children expressed a growing understanding of body reactions and an acquired ability to deactivate and regulate these reactions. The study also elucidated the enrolment procedures and capacity of the clinic for the planning of the larger study. The results from study II found acceptable test-retest repeatability, providing a stable basis for the research in study III and IV. The main findings in study III were that girls with TTH had significantly higher pericranial tenderness than controls in correlation with headache frequency ($r=0.66$, $p<0.001$). Results indicated a significant association between reduced shoulder and neck strength and headache. There was likewise a significant association between reduced predicted VO_2max and headache. From study IV the girls self-reported health related quality of life indicated experienced difficulties in physical health, emotional health and school functioning. The results showed a significant effect on headache frequency and duration from both strength training and counselling with no significant between group differences. During 22 weeks 33% of the girls had a headache reduction ≥ 30% and 26% reached a reduction of ≥ 50%. Both groups also seemed to benefit from exercising or body awareness with a significant reduction in neck extension/flexion ratio. Strength training showed a potential to increase strength and oxygen uptake. Perceived lack of time and/ or motivation constrained inclusion and caused dropouts.

Conclusion: As a conclusion the results highlight that physiotherapy plays a central role in headache services in educating the children in strategies to enhance health-related physical factors and body-awareness, reduce headache and thus improve their quality of life. Strength training or relaxation therapy in combination with interdisciplinary counselling will provide positive outcomes. As both relaxation therapy and strength training presented significant outcomes the use of these interventions should be decided by the physiotherapist, the child and parents after an evaluation of the child's individual needs. Interpreting the results within an empowering patient education we can summarize that the interventions and materials used in the studies were relevant and suitable for children 7-18 years of age. It is recommended to consider the relationship between weekly exercise intensity and exercise variation in order to keep a stable weekly exercise volume. Motivation for change and the barriers the contemporary family, children and parents may experience in order to integrate learning and change habitual physical behaviours need to be examined. The organization of patient education is recommended to be considered innovatively in order to further reach the needs of the contemporary family. This thesis presents the dimensions of empowerment that are essential in relation to the child with TTH and their parents.

Key words: Empowering patient education, headache, child, health, neck and shoulder muscles, muscular fitness, cardiovascular fitness and physiotherapy

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To my children Trine and Toke

“Above all, do not lose your desire to walk. Every day, I walk myself into a state of well-being and walk away from every illness. I have walked myself into my best thoughts, and I know of no thought so burdensome that one cannot walk away from it. But by sitting still, and the more one sits still, the closer one comes to feeling ill. Thus if one just keeps on walking, everything will be all right”

Danish philosopher Søren Kierkegaard, 1813-1855

Contents

Abstract

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headache. There was likewise a significant association between reduced predicted VO_2max and headache. From study IV the girls self-reported health related quality of life indicated experienced difficulties in physical health, emotional health and school functioning. The results showed a significant effect on headache frequency and duration from both strength training and counselling with no significant between group differences. During 22 weeks 33% of the girls had a headache reduction ≥ 30% and 26% reached a reduction of ≥ 50%. Both groups also seemed to benefit from exercising or body awareness with a significant reduction in neck extension/flexion ratio. Strength training showed a potential to increase strength and oxygen uptake. Perceived lack of time and/ or motivation constrained inclusion and caused dropouts.

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Motivation for change and the barriers the contemporary family, children and parents may experience in order to integrate learning and change habitual physical behaviours need to be examined. The organization of patient education is recommended to be considered innovatively in order to further reach the needs of the contemporary family. This thesis presents the dimensions of empowerment that are essential in relation to the child with TTH and their parents.

Abbreviations

Body awareness therapy	BAT
Coefficient of variation in %	CV%
Confidence Interval	CI
Empowering Patient Education	EPE
Force steadiness	FS
Health Related Quality Of Life	HRQOL
International Classification of Headache Disorders	ICHD
Maximal voluntary contraction	MVC
Metabolic equivalent of task	MET
Method error	ME
Mean median frequency	MDF
Odds ratio	OR
Per protocol	PP
Predicted maximal oxygen uptake	VO_2max
Rate of force development	RFD
Repetition maximum	RM
Root mean square	RMS
Surface electromyography	SEMG
Tension-type headache	TTH
Total Tenderness Score	TTS
World Health Organization	WHO
World Confederation for Physical Therapy	WCPT

List of papers

This thesis for the doctoral degree is based on the following papers referred to in the text by their Roman numerals:

I Tornoe B. & Skov L. Computer Animated Relaxation Therapy in Children between 7 and 13 Years with Tension-Type Headache: A Pilot Study. Appl Psychophysiol Biofeedback 2012; 37:35-44

II Tornoe B., Andersen L.L., Skotte J.H., Jensen R., Gard G., Skov L., Hallström I. Test-retest repeatability of strength capacity, aerobic power and pericranial tenderness of neck and shoulder muscles in children-relevant for tension-type headache. Journal of Pain Research 2013; 6:1-9

III Tornoe B., Andersen L.L., Skotte J.H., Jensen R., Gard G., Skov L., Hallström I. Reduced neck-shoulder muscle strength and aerobic power together with increased pericranial tenderness are associated with tension-type headache in girls: A case-control study. Cephalalgia 2013; 34(7): 540-547

IV Tornoe B., Andersen L.L., Skotte J., Jensen C., Madsen B.K., Jensen R., Gard G., Skov L., Hallström I. Specific strength training compared with interdisciplinary counselling for girls with tension-type headache- A randomized controlled trial. Submitted.

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Thesis at a glance

Study/ paper	Objectives	Methods	Results	Conclusions
I	To evaluate the effect of computer-animated relaxation therapy in children aged 7-13 and to examine how the children experienced the therapy. To gauge the enrolment procedures, clinic capacity and the compliance of the child and parents.	N=9 children with tension-type headache (TTH), (8 girls, 1 boy) 7-13 years Pilot study-descriptive and before-after intervention	The results showed a mean improvement of 45% for headache frequency at 3 months follow up versus base-line. The children expressed a growing understanding of body reactions and an ability to regulate these.	Computer animated surface electromyography (SEMG) seems an applicable learning strategy for young headache sufferers. Dialogue and guidance from a participant observer is necessary to achieve body awareness.
II	To determine the test-retest repeatability of isometric maximal voluntary contraction (MVC) and force steadiness (FS) of neck flexion and extension. MVC and rate of force development (RFD) of shoulder abduction. Total Tenderness Score (TTS) and sub maximal cycle ergometer test predicting VO_2 max	N=25 healthy children (15 girls, 10 boys) 9-18 years Blinded repeatability study.	Isometric MVC showed acceptable repeatability (ICC 0.90−0.97). The force steadiness revealed a trend of systematic changes and need further examination. RFD, TTS, and prediction of VO_2 max showed repeatability, with ICC 0.80−0.87.	The measurement of strength capacity, aerobic power, and tenderness provide acceptable repeatability suitable for research in children
III	To examine the combined measurements of muscle strength in the neck-shoulder region, aerobic power, and pericranial tenderness (TTS) in girls from 9 to 18 years of age, and their associations with frequent episodic or chronic TTH compared to healthy controls	N=82, 41 girls with TTH and 41 healthy girls 9-18 years Blinded case-control study	Girls with TTH had significantly higher TTS than controls. The odds ratio (OR) of girls having headache is 7.6 for weak to strong shoulder muscles; OR 3.1 for weak to average neck-shoulder strength; OR 1.3 for neck flexion strength; and OR 5.2 for each unit of decrease in VO_2 max.	Reduced neck-shoulder strength and aerobic power together with increased pericranial tenderness are associated with TTH in girls. Future interventions should be directed towards health promoting patient educational programs on enhanced physical exercising.
IV	To examine the effects of specific strength training compared with counselling by nurse and physiotherapist in short, defined patient education programmes.	N=49 girls with TTH 9-18 years Randomized controlled trial	Headache frequency decreased significantly p=0.001 and duration p=0.022. The odds of having headache a random day decreased during 22 weeks by 0.65 (0.50-0.84) (OR (95%CI)). Neck extension/flexion ratio decreases to 1.7, indica-ting a change in muscle balance over the neck.	Both strength training and counselling lead to headache reduction. Adjusting muscle-balance seems to precede strength gains. Strength training might lead to important changes in the child's physical capability and health. Restructuring patient education and examining dose-response of exercising is recommended.

Preface

My interest in interdisciplinary pain management began in 2000-2003 while doing my master's degree in physiotherapy at Queen Margaret University in Edinburgh, Scotland. At that time professionals and evidence-based governmental guidelines in the UK focused on a biopsychosocial approach, with emphasis on educating pain sufferers about pain mechanisms and how to cope. What I encountered as an experienced paediatric physiotherapist inspired my subsequent work with children with headache in a tertiary headache clinic, where the present studies took place.

Children with frequent or chronic tension-type headache spend years of their childhood with this illness and I am pleased to be able to add to the knowledge on what patient education in headache service might be directed at and how. Furthermore it is my interest to provide evidence for practice in the clinic.

One of the challenges of empowering patient education is that it requires health care professionals to have both competences in learning strategies and knowledge about psychophysiological and neurological functions. Challenges likewise exist at the organizational level.

My hope is that this thesis has succeeded in contributing to the research that reflects these complex areas from a perspective of physiotherapy.

General definitions

Aerobic power	Maximal aerobic power equals maximal oxygen uptake and is a single measure of a) the maximal energy output by aerobic processes, and b) the functional capacity of circulation measured in L x min^{-1} (1). Physical performance is linked to maximal oxygen uptake. Oxygen uptake is dependent on cardiac output, the pulmonale system, oxygen carrying systems, and muscle capacity. Oxygen uptake is affected by heredity, sex, age, state of training, and changes in altitude. Maximal oxygen uptake can be either measured or estimated. The maximal oxygen uptake of children is not as high as expected for their size compared to adults, which means the child has a lower efficacy (1).
Case-control study	A case-control study studies a group with a disease compared to a group without the disease in order to examine associated factors (2).
Family and parents	Family is defined by the American Academy of Pediatrics, Task Force on the family, by a functional definition. A family may comprise a child/children living with a single parent, 2 parents, an adoptive family, foster family or separated family. Parents may be of opposite sex or same sex. Families are diverse in relation to culture, ethnicity, sexual orientation and religion. Family structure affects child development (3).
Health	Health, as defined by the World Health Organization (WHO), is "*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*". When these conditions are not fulfilled, individuals can then be considered to have an *illness* or *to be ill* (4).

Interdisciplinary	Interdisciplinary is a widely used term parallel to multidisciplinary or interprofessional, meaning that two or more professions act together in a team structure in order to conduct a goal directed counselling with a specific client and the ability to add other specialist areas if needed (5).
Intervention	Intervention, by encyclopaedia, comes from the Latin word 'interventio' = intervene and in health care service it means influencing another person or group through dialogue and educational programmes.
Logistic regression analysis	Logistic regression analysis is a technique used to assess the association or impact between a dichotomous outcome variable and several predictor variables calculated to odds ratios. The odds ratio (OR) represents the change in odds of being in one of the categories of outcome when the value of a predictor variable changes (increases or decreases) by one unit for continuous variables (6). In a case-control study the relative risk is approximated by the OR (2).
Measurement of health-related quality of life, HRQOL	Patient self-reporting on his or her perception of health-related quality of life. "It is a multidimensional construct that reflects the interplay between disease and patient's subjective evaluation of his or her physical, social, and emotional functioning" (7).
Physical activity	The WHO defines physical activity as any bodily movement produced by skeletal muscles that requires energy expenditure (8). In 2004-2011, the WHO published a strategy on diet, physical activity, and health (9). Physical activity was listed as a key determinant of energy expenditure and thus fundamental to energy balance and health. Physical activity levels were for adults presented in METs (metabolic equivalent task) per week. One MET is defined as 1kcal/kg/h. One MET is equivalent to the energy/oxygen cost of sitting quietly. Physical activities and levels of intensity can be expressed in METs per hour per week. Physical activity levels for children were expressed in time.

Physical exercise/training	Exercise is a subcategory of physical activity. Exercise is physical activity that is planned, structured, repetitive, and purposive in the sense that improvement or maintenance of one or more components of physical fitness is an objective (10).
Physiotherapy/physical therapy	The World Confederation for Physical Therapy (WCPT) defines physical therapy as providing services to individuals and populations to develop maintain and restore maximum movement and functional ability throughout the lifespan. Physical therapy is concerned with identifying and maximizing quality of life and movement potential within the spheres of promotion, prevention, treatment/ intervention, habilitation and rehabilitation; encompasses physical, psychological, emotional and social well-being. Functional movement is seen as central to what it means to be healthy. (11).
RCT	In a randomized controlled trial study participants are after assessment of eligibility randomly allocated to receive either a new treatment or a control treatment (12).

Introduction

Children with headache exhibit an increasing health problem worldwide (13). A condition of frequent episodic or chronic tension type headache (TTH) is debilitating for a child, and might lead to absence from school, an undesirable use of medication (14) and an imprint on the child's developmental history.

Research in order to examine underlying pathophysiology of headache and the best practice of interventions is limited in children. Intriguing research conducted in the last 10-15 years in adults and adolescents with tension-type headache are substantial (15, 16) and could be a start point in the research with children suffering from headache. From this research we have attained an increased knowledge of the pathophysiological mechanisms concerning the sensitization of the peripheral and central nociceptive systems, a beginning understanding of chronic pain mechanism (17) and knowledge of the importance of preventing a frequent pain situation before it converges to a chronic stage. This is a highly important matter concerning children, but a likewise research is yet in its early stages.

Research concerning physical and muscular functions and pain in general as well as in headache is overall poorly understood for all age groups. In order to be able to plan the most relevant non-pharmacological prevention and service programs for both children and adults with TTH, research in these areas is important.

The main interest of the present thesis is to contribute to research knowledge of underlying physical factors and their possible association with a severe and chronic headache condition in children; and furthermore to examine aspects of interactive interventions leading to self-care.

Background

The main perspective of this thesis is the child with TTH and aspects of developmental and ethical rights and needs are addressed. Then follow the descriptions of factual knowledge about headache and empowering patient education (EPE) aiming towards the specific objectives of the thesis.

Main concepts

In order to present a clear and thorough description of the use of concepts as proposed by Persson & Sahlin (18) chapter 1, the background is introduced with expanded definitions and conceptions of main themes and frames.

The child

In research concerning children we have to address the question ‘what is a child?’ and ‘what defines the child at different ages?’ and how are children’s understanding and explanations of illness? What are the legal rights of the child? The UN Convention on the Rights of the Child defines *a* 'child' as *“a person below the age of 18, unless the laws of a particular country set the legal age for adulthood younger”*(19). Bibace and Walsh and later Koopman (20, 21) described that the child’s perception of illness follows the Piagets’ categories of a child’s cognitive development, and is here presented in a short version.

1 Prelogical explanations (2-6 years): This period is characterized by inability to distance themselves from their environment and explanations being dominated by their immediate spatial or temporal experiences and unable to explain cause and effect. The cause of illness is located in objects or people approximate but not touching the child.

2 Concrete logical explanations (7-11 years). The child now distinguishes between the cause and effect of illness, the cause being external and ‘harmful’. Later the illness is located inside the body and cause may be outside. The body is described in vague and nonspecific terms.

3 Formal-logical explanations (>11 years). The child now understands and gives physiological explanations. A period of the greatest differentiation between self and others. The source and nature of illness lies in the physiological structures and functions. The child might now add a psychological dimension to the explanation of illness. The child is now aware that a person's thoughts and feelings can affect the body.

Decision making in child health care service

Children are vulnerable participants in health care and research, and the child's ability to participate is dependent on age, cognitive resources and influenced by the social/family environmental context. The child is protected by the UN Convention on the Rights of the Child (19), where the child's right to grow and reach their potential is stressed. When making decisions that affect the child, the child has the right to be heard and to have his/her opinion taking into account. They have the right to share information by talking, drawing and writing. This means that even young children have the right to be informed and take part in decision-making giving assent as an interactive process (22) and it is up to the health care professionals to provide the information and communicate in a way that correspond with the child's developmental abilities.

Participation in decision making is determined by age levels and at 12 years of age the child is considered to be able to understand the procedures of informed consent. Children over 16 years are in the UK seen as 'Gillick competent' and can give consent to treatments if the person understands the information (Gillick v West Norfolk, 1985). In important matters the child's competences might be examined in order to determine the child's ability to understand. Competences are influenced by the cognitive developmental level and achieved learning (22). At the age of 18 the child has in most countries the legally right to informed consent and individually making decisions.

When a professional addresses a child in a health care program or research setting, both the child's developmental capacity and ethical needs must be taken into account in order to secure that the child understand the situation. The child's cognitive development influences the child's ability to understand the disease and receive education (20, 23). It is challenging for the child to manage self-care, which requires a combination of knowledge and skills and is related to age. The children therefore need support from the parents, family and other environments. The American Academy of Pediatrics Task Force on the family stated that a child's physical and emotional health and their cognitive and social functioning are strongly influenced by how well their families function (3). Figure 1 provides a figure of actors in the service to the child with TTH in the health care system.

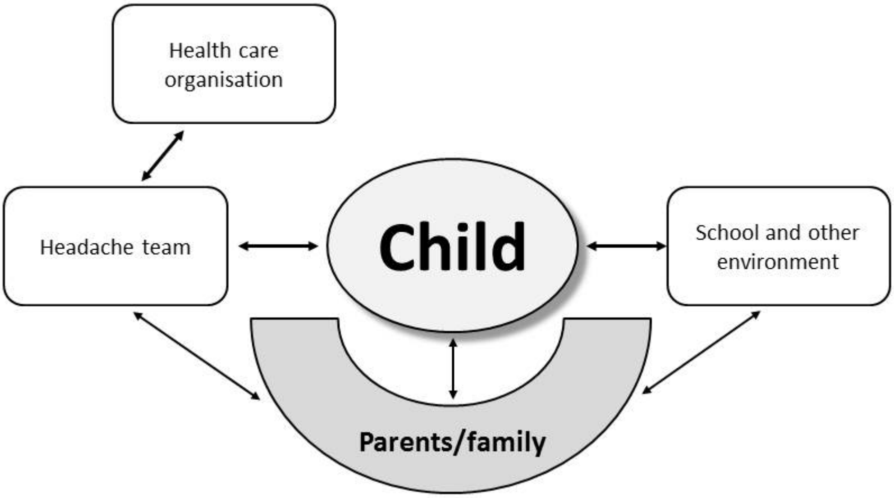

Figure 1. Actors in the headache service to a child with TTH

Pain and health care service

Frequent or chronic TTH is a pain condition. Pain is defined by the International Association for the Study of Pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (24). Frequent and chronic TTH is defined by the International Classification of Headache Disorders (ICHD) (25, 26). Pain and health care service are described in terms of the 1) organization and 2) service modalities.

Interactive interventions, counselling and empowering patient education (EPE) are concepts describing the relationship between the patient and the health provider. Interactive intervention means by encyclopaedia interventions based on human to human communication and/or human to computer communication. It comprises elements that empower an active learning situation. Counselling is widely used both in interdisciplinary and psychological interventions. *Counselling is aimed at producing constructive behavioural and/or personality change (27)*. Effective counselling includes that the counsellor employs interpersonal skills. Empathy, warmth and genuineness are central attributes of an effective counsellor. Warmth is related to both objectivity and involvement. The counsellor attitudes should be positive and tolerant rather than using advice and persuasion (27).

Patient education was defined at a common European meeting in Paris 1999 on the evolution and developments of patient education in the health care systems and stated as the following:*”Patient education concerns all educational activities directed to patients, including aspects of therapeutic education, health education* *and clinical health promotion"*(28). Standards or guidelines are not yet established and clinical practice guidelines are to be found within the literature for each separate disease such as for headache the British Association for the Study of Headache (29). Paediatric patient education has as defined by Feudtner (30) the purpose of increasing knowledge and skills leading to self-care. Learning results can be symptom reduction, reduction of psychosocial stress, enhanced decision making, satisfaction and quality of life.

Empowering patient education as a theoretical frame

Empowerment in the clinical setting with children is closely linked to the rights of the child and the process of decision making. The concept of empowerment takes its out-spring in strategies for policy and social research in the 1960s and 1970s developing further in the 1980s (31). In the 1990s the concept of empowerment was examined as a strategy in health providing and nursing research (32).

Empowerment is a dynamic concept where power is both given, taken and shared (31, 32). Empowerment is a concept, fundamentally positive and defines either a process or an outcome. Certain assumptions are related to the use of empowerment in health care service: Health belongs to the individual and the individual has the prime responsibility for his/her health. The individual's capacity for growth and self-determination needs to be respected. Individuals have the ability to make decisions and act on their behalf if proper informed (32). In treatment settings it refers to equalizing the relationship between the patient and the health provider promoting shared decision making and equal power in the treatment situation as a collaborative process (32). This is strengthened through the dialogue, where the patient has the opportunity to recognize and gain knowledge of his own situation and disease (33), leading to greater self-efficacy, control and skills-development in order to be able to practice self-care (34).

Knowledge and power is closely related. Rappaport (35) defines empowerment as a process where people gain mastery over their own situation- a process of many forms. "Empowerment implies that many competencies are already present" and that we in the process of the clinical setting or social and community settings are seeking that "new competencies are learned in a context of living life, rather than being told what to do by experts".

According to research by Leino-Kilpi et al. (36) empowering patient education, EPE, can be used as a model to examine and evaluate patient education by seven dimensions visualized in a figure reflecting the patient/client's *needs and knowledge fields.* The seventh cognitive dimension was removed from the model in 2012, as to all learning is cognitively related. Considering the child is in a cognitive developmental process defined by steps, it was for this thesis found relevant to keep this dimension.

Physiotherapists as well as other professionals engaged in health care service require educational knowledge implying both competences in how to empower a learning process and how to facilitate an empowering learning outcome (37). The concept of EPE is useful as a guide to content, methodology, ethical considerations and how to evaluate patient education.

Child health care service from an empowerment perspective has to consider that different actors such as the child, the parents, the health providers and the organization are in play. Children and parents may have different needs and knowledge, which has to be incorporated in the interventions. Likewise health providers and the organization may have different needs and knowledge. Barriers might be clarified by the dimensions of EPE. Outcomes are evaluated on accomplished knowledge and skills. The seven dimensions of EPE by Leino-Kilpi et al. (36) are presented in Figure 2. Further descriptions are provided in the section of result discussion Table 8.

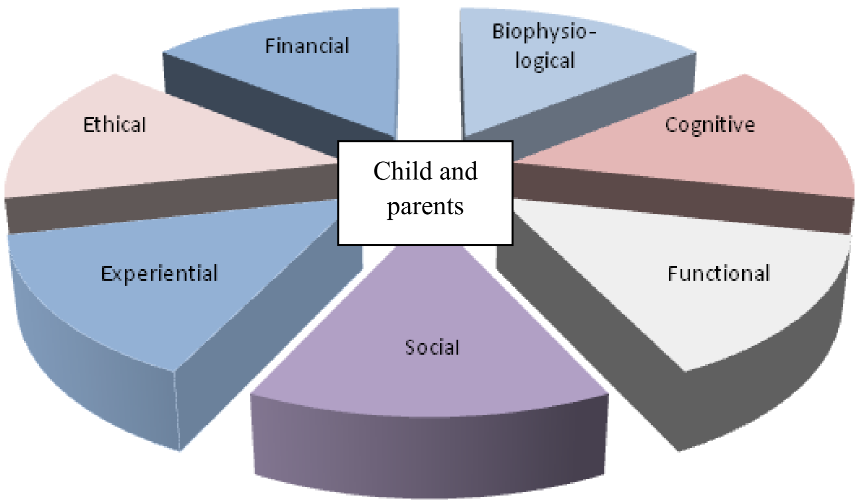

Figure 2. Seven dimensions of empowerment according to Leino-Kilpi et al. (36)

Knowledge about headache and interventions

The following describes the diagnostic criteria, prevalence and etiology relevant for children with a frequent or chronic TTH. Finally interventions and health related physical factors are highlighted.

Diagnosis and prevalence

Bille was the first to report paediatric migraine epidemiology in 1962 (38). Repschlaeger & McPherson reports in 1984 about both migraine and TTH in adults (39). Carlsson examined as one of the first the prevalence of recurrent headache in schoolchildren 7-16 years of age in the Göteborg population 1993 and reported of 26% of the 1144 children having monthly headaches and 6% having frequent weekly headaches (40).

In the last decade 6-12 months prevalence of frequent episodic TTH (FETTH) and chronic TTH (CTTH) as primary headaches in children differs from 2-23% depending on age, sex and headache frequencies (Table 2, in the back of the thesis). TTH seems to develop around the age of 7 (13, 41), though it might be present under the age of 7 in both frequent episodic and chronic forms (42). The prevalence of TTH is found to be higher in girls worldwide (13, 43, 44) and increases with age (45, 46). Prevalence of headache in urban regions is found significantly higher than suburban or rural areas (44). Recurrent headache as a whole seems to have increased over time period from 1974 exemplified in Finnish or Turkish school children (47, 48).

The criteria for diagnosing TTH in children follow the adult criteria defined by the International Headache Society (IHS) updated in 2004 in ICHD-II (25) and in ICHD-III beta version 2013 (26). The criteria are listed in Table 1.

Table 1. Diagnostic criteria for primary frequent episodic and chronic TTH according to ICHD-III (25, 26).

Diagnose criteria	Frequent episodic TTH 2.2 Associated with or without pericranial tenderness	Chronic TTH 2.3 Associated with or without pericranial tenderness
Criteria A	At least 10 episodes of headache occurring ≥1 but <15 days per month for >3 months and fulfilling B-D	Headache occurring on ≥15 days per month on average for >3 months fulfilling criteria B-D
Criteria B	Lasting from 30 min to 7 days	Lasting hours to days, or unremitting
Criteria C	At least 2 of the following four characteristics: • bilateral location • pressing or tightening (non pulsating) quality • mild or moderate intensity • not aggravated by routine physical activity such as walking or climbing stairs	At least 2 of the following four characteristics: • bilateral location • pressing or tightening (non pulsating) quality • mild or moderate intensity • not aggravated by routine physical activity such as walking or climbing stairs
Criteria D	Both of the following: • no nausea • no more than one of photophobia or phonophobia	Both of the following: • no more than one of photophobia, phonophobia or mild nausea • neither moderate or severe nausea nor vomiting
Criteria E	Not better accounted for by another ICHD-3 diagnosis	Not better accounted for by another ICHD-3 diagnosis

A review (49) of studies examining the 6-12 months prevalence of episodic (ETTH) and chronic TTH (CTTH) in children worldwide from the Years 2002-2013 is provided in Table 2 in the back of the thesis. Reporting and comparing prevalence estimations is however challenged because the use of the criteria episodic TTH (infrequent or frequent) differs between the studies. The presentation is therefore modified referring to the following studies (13, 14, 41, 44-47, 50-53).

The children suffer from headache 1/2-24 hours a day and in the chronic form often from morning until they go the sleep. Unlike migraine the children suffering from TTH can continue activities in the daytime, but these children report of tiredness and withdrawal from social activities and perhaps avoidance of excessive physical activity. The children present impairments compromising concentration, school learning and attendance and leisure activities (14, 54, 55). Anxiety and depression symptoms are found to be co-existing with TTH (13, 54, 56) and need to be specially addressed and diagnosed.

Soee et al. (57) examined the distribution of diagnoses administrated in a tertiary children's headache clinic in one year 2009-2010 and found that of 169 new-diagnosed children 20% suffered from migraine, mixed headache 27%, chronic TTH 20%, frequent episodic TTH 14%, medication overuse headache (MOH) 4% and other headaches (primary or secondary) 15%.

Etiology and pain mechanisms

The etiology behind TTH is not yet clarified. There is a consensus that the etiology is multi-factorial and that psychosocial stressors and/or mechanical stressors are of importance (16, 58, 59). Factors associated with TTH are seen to be related to school and family (14, 54). The frequent uses of computers have been found related with TTH in adolescents (60). A history of frequent headache has been hypothesized to lead to persistent headache (16, 26) and a risk of medication overuse and medication overuse headache MOH (59). The etiology of TTH is linked to pathophysiological theories about nociception and the role the pericranial muscles might play.

Pathophysiological theories

In 1965 Melzack and Wall (61) presented a contemporary model of pain -the gate control theory. This model was abandoned /updated in 1989 -2004 with Melzacks neuromatrix model (62). This model is still under change due to contemporary neuroscience, but the main aspect, Melzack suggested after substantial phantom pain research, was that chronic pain emerges in the brain within a largely distributed neural network and modified by sensory experiences. The initial stimuli may be either psychological or physical stress understood as any threat to the biological homeostasis.

Theories related to frequent and chronic TTH see periphery and central sensitization as the possible mechanism responsible for the maintenance of TTH in both children and adults. One consequence is the accompanied enhanced pericranial tenderness by palpation and altered pain perception (17, 63-65). The descending part of trapezius together with its insertion is found to be the most tender site (13, 17, 65, 66). Bendtsen and Fernandez-de-las-Penas discussed the role, pericranial muscles might play (67). They concluded that muscle pain in TTH is not caused by generalised muscle contraction, which is supported by EMG studies. Though increased local muscle tension secondary to mechanical or mental stress and/or a decrease in micro blood flow to the muscle fibres may contribute to microtraumas. Studies suggest that also active myofascial triggerpoints play a role in prolonged inputs (67).

Nociception, hyperalgesia and sensitization

The nociceptive system comprises of multiple small, unmyelinized slow polymodale C-fibers, and larger, myelinized and fast A-fibers. The Aδ mechanical nociceptor and polymodal C receptors respond to thermal, chemical and mechanical stimuli that pose a potential noxious risk to the skin and body. The C-afferents synapse in the dorsal horn, predominantly lamina I and II with polysynaptic interneurons. Sensory impulses via C axons continue by mostly sub thalamic tracts with connections to the autonomic nervous system in the dorsal horn or at higher levels for blood pressure, breath, sweat and respiration control. (68, 69). The trigeminal ganglion is analogous to the dorsal root ganglion of the spinal cord and processes painful sensations in the face and motor supply to chewing muscles via the Trigeminal nerve.

Myogeneous pain is likewise nociceptive and originates within the muscle-tendon complex. It is supplied by free nerve endings from sensory afferents (group III+IV) synapsing in lamina II responding on mechanical and chemical stimuli (70) (II/chap.3).

From the dorsal horn there are connections to the lateral and anterior horn for correspondence with low motor neurons. These connections may affect muscle tone and increase/decrease movement ability. The system is a potential 'fight or flight system' related to defence mechanisms (71).

The Aβ and Aδ-fibres synapse in superficial and deeper layers of the dorsal horns and send sensory impulses via the spinothalamic tract directly via thalamus to the postcentral gyros for quick pain sensations and mechanical sensations also with connections to the autonomous system and to the limbic system (69, 71, 72).

Prolonged mechanical stimuli may result in awakening of nociceptors, which are defined as mechanically insensitive afferents or silent nociceptors having high mechanical thresholds and therefore respond only to prolonged stimuli. These silent nociceptors are seen as partly responsible for a sensitization characterized by a decrease in thresholds, augmented response to stimuli and ongoing spontaneously activity (73). The activity also affects Aβ-afferents, normally involved in innocuous tactile sensations (72).

Clinical pain as allodynia is so produced by stimuli that normally not evoke noxious sensations (72). Hyperalgesia is defined as a leftward shift of the stimuli-response curve (64, 68, 72, 73) meaning increased pain response to stimuli in the affected body-area (primary hyperalgesia) and increased response in the unaffected body-area (secondary hyperalgesia) processes by hyper responsive Aδ/C-afferents. Central sensitization might occur after prolonged tissue-damaging stimuli or inflammation processed via C-afferents or free nerve endings (68, 72, 73). Connections to thalamus and limbic systems are believed to promote complex behavioural, motivational and affective responses (69, 71).

There are descending modulatory pathways known as 'descending analgesia systems' utilizing endogenous opioids and other neurotransmitters to affect spinal transmission (68, 69, 73). The production of pain is usually inhibited in the CNS but the inhibition might be suppressed.

Standard headache service

Headache service for children with recurrent headache is in most western countries organized in a 3 level-system comprised by primary community care, secondary care by specialized clinics and academic headache centers as tertiary care (74). In the tertiary centre the headache health care service is organized in an interdisciplinary team-setting with neuropaediatric physicians, specialist headache nurses, specialist physiotherapists and specialist psychologists (57, 74). Furthermore a variety of other consultants from relevant specialists areas are available for expanded examinations (74). There is both guidelines for and consensus about the interdisciplinary approach, but evaluations of the effect are sparse (74, 75). The main aim is to provide a flexible team service to the patient, where the treatment goals are shared between team members and the patient and verified in the team procedures (5, 74).

As headache is a common symptom in many diseases the parents' first concern is the speculations about a possible serious condition (58). Clarifying a diagnosis and excluding a serious intracranial course is important to the child and parents and the earliest responsibility for the neuropaediatric physicians. Parents and children are often relieved after the diagnosis has been clarified. Monitoring a full clinical history of the child's situation and a thorough neuropaediatric examination of the child is the first step of an intervention program (58, 76).

The use of a pain calendar for monitoring headache frequency and intensity by Visual Analogue Score (VAS)/numeric scale has been found feasible and valid in children (77, 78) and is a valuable tool in monitoring the child's disease. Children younger than 12 years of age need the help from parents to fulfil the diary precisely. The most used diary is a paper diary, but the risk of inaccuracy and limited reliability and compliance is experienced in research (79). A discrepancy between the child's monitoring and the parent's reports was found in a survey in Norway (80) with a tendency of parents underestimating the child's condition. An RCT study of 60 children with recurrent headache in USA (79) comparing the use of electronic diaries and paper diaries found significantly greater compliance and accuracy with the use of an e-diary, which would be preferable.

The role of the nurse

The headache nurse has a central role as a contact nurse for the child and family and is the professional, who helps monitor and control the planned course. The specialist nurses help and educate in filling in headache diaries, as well as support and give advice about the use of medication (57, 74). Another important work area is to guide and help families through a detoxification period.

As parents to a child with TTH and professionals are reluctant to choose preventive medication to the child as a first choice, patient education is important in paediatric headache team service. The focus is on helping the family to change specific behaviours in lifestyle at home and in school, as a way to prevent development or triggering the headache (75). The most basic lifestyle factors that are enabled through dialogue are sleep, liquids, food (81), physical activity (82) and the handling of psychosocial stressors (14, 81).

The role of the psychologist

The role of the psychologist is that of examining and supporting motivation to change behaviours and promoting pain coping strategies (74). Further the psychologist is involved in patients presenting psychopathological symptoms such as anxiety, depression or other mood symptoms.

The role of the physiotherapist

Physiotherapy is conducted following international guidelines such as the International Guidelines for the Management of Headache (29). The clinical reasoning follows the main concept of the International Classification of Functioning, Disability and Health, ICF (ICF-CY) (83). The role of the physiotherapist is that of conducting body examinations on the basis of which treatment suggestions are planned. The evidence of physiotherapy and spinal manipulation compared to other treatments for headache in adults was found insufficient in a systematic review by Lessinck et al. (84).

Body awareness, body knowledge and body functions are central in physiotherapy. Physiotherapy has until now not been described as a science in itself, but relates to sciences in neurophysiology and movement sciences. The scientific theoretical approaches might represent a spectrum from hypotheses-deductive methodology to phenomenology. The latter originates from the philosopher Merleau-Ponty's Phénoménologie de la Perception 1945, part one- le Corps (85). Merleau-Ponty described the perceived body and its existence in the world. He increased the focus on the subjective body as the key to understanding and learning. He changed the concept of intentionality (the awareness is always directed towards something) and connected it with a body scheme, where the meaning is given in the centre of the body. He underscored that the body is our anchoring in a world.

More recently Body Awareness Therapy (BAT) (86) was developed by the Swedish physiotherapist Gertrud Roxendal, who based her BAT upon the ideas and exercises of Jacques Dropsy (87) a French psychoanalyst and dramaturge. He was inspired by both Western and Eastern philosophers, which can be recognized in his choice of exercises. The exercises aim to increase awareness of body functions such as 1) anchoring 2) midline 3) centre 4) breathing and 5) flow (86) leading to awareness and control of body reactions and stress. These elements are incorporated in the relaxation techniques used in interventions.

Evidence of interventions

Progressive relaxation therapy has been the most evidenced intervention in management of adult and adolescent with chronic TTH latest by Söderberg (88, 89). The progressive relaxation therapy was developed by the physiologist E. Jacobson in 1938 as a method of “approaching patients, who had fatigue, debility and lowered resistance”, patients with tension and anxiety, who needed having their “energy output in muscular terms be economized in interest of their health” (90)

The method of relaxation was later refined by Bernstein and Borkovec (91) and they named tension headaches as a specific target of the therapy. The main elements of the technique are according to the authors : 1) understanding tension as a part of a problem 2) training sequentially tense and relax of various muscle groups and directing the attention, 3) the order goes hands-arms-face-neck-chest-shoulder-abdomen and legs. The training might proceed until the person manages quick relaxation.

Evidence for non-pharmacological interventions involving children is sparse. Table 3 presents a review (49) of original studies for children with TTH from 1995-2013.

Table 3. Studies after 1995 involving non-pharmacological interventions for children with TTH

Studies	**Participants**	**Intervention**	**Outcome measure**	**Conclusion**
Andrasik et al. 2007 (92) Controlled trial	N=80 Range 7-17 years FETTH	A. 4 group sessions of relaxation /8weeks B. Amitriptyline 10mg daily/3 mths	Headache activity MIDAS questionaire Follow ups 3,6,12,24 mths	Headache frequency and disability significantly reduced in both groups at 1 and 2 years follow-up. Most drop-outs in medical group
Bussone et al. 1998 (93) RCT biofeedback assisted relaxation training for young adolescents	N=35 Mean age 11.1(2.6) FETTH	A. EMG biofeedback-assisted relaxation. Bifrontal auditory B. Relax-placebo/ control 10 sessions/2/week	Headache activity STAIC (anxiety inventory) After intervention and 3,6, 12 mths follow up	Significant between group differences with improved headache frequency enhancing 6-12 mths
Gottschling et al. 2008 (94) RCT of Laser acupuncture in children with headache	N=43 22 migraine 21 FETTH Mean age 12.3(2.6)	A. Acupunctural active laser B. Placebo laser 4 sessions/4 weeks	Headache activity at follow-ups up at 4,8,12 and 16 weeks	Significant between group differences with effect of active laser on headache frequency, intensity and duration.
Grazzi et al. 2001 (95) Clinical outcome of EMG biofeedback-assisted relaxation training in juvenile TTH	N=54 Mean age 12.1 FETTH	EMG biofeedback-assisted relaxation Bifrontal-auditory. 10 sessions/2/week	Headache activity EMG values Follow up 1,3,6,9,12,36 mths	Significantly improved headache frequency enhancing up to 3 years follow up
Larsson & Carlsson 1996 (89) RCT of nurse-administered relaxation training for children with CTTH	N=26 10-15 years CTTH	School-based progressive relaxation B. No treatment 10 sessions/2/week	Headache activity After intervention and 6 mths follow up	Significant between group differences with improved headache frequency after treatment and at 6 months follow-up
Trautmann & Kröner–Herwig 2010 (96) RCT of Internet-based self help training for recurrent headache in childhood and adolescents	N= 65 Mean age 12.7 n=24, n=22, n=19 Migraine, TTH or mixed>2/mth	RCT: 3 active treatment conditions: 1. Cognitive Behavioural Therapy, via 6 weeks internet modules and CD. 2. AR Applied Relaxation by one self help module and CD. 3. Education by one self help module. All had email contact.	Headache diary Pain Catastrophizing Scale. Children's Depression Inventory. HRQOL. Learning outcomes were documented via email contact. Baseline, after intervention and 6 mths follow up.	All 3 conditions resulted in reduction in headache frequency and duration. CBT internet education highest within-effect size. Internet contact does not affect patient-provider relationship negatively.
Von Stülpnagel et al. 2009 (97) Myofascial trigger points in children with TTH. A pilot study	N= 9 girls Mean age 13.1 FETTH	Trigger-point specific physiotherapy 8 sessions/2/week	Headache activity after intervention	Reduction in headache frequency and intensity.

Physical activity, aerobic power and muscular fitness as health indicators

Physical activity and aerobic power

For children and youth, the WHO's Global Recommendations on Physical Activity for Health 2011 (8) states that physical activity includes play, sports, transportation, chores, recreation, physical education or planned exercise in the context of family, school, and community activities. A WHO outcome indicator of the strategy is percentage of children in a community participating in least 60 minutes of physical activity per day (9). Children aged 5-17 should accumulate at least 60 minutes of moderate to vigorous-intensity aerobic physical activity daily. Greater amounts are recommended to provide additional health benefits. The activities should comprise vigorous-intensity activities at least three times a week and include ones that strengthen muscle and bone. Aerobic power as either measured or estimated VO_2 max is by WHO considered to be the best indicator of cardio respiratory fitness (8). Some research suggests a connection between physical activity levels and the prevalence of headache both in adults (82) and children (60).

Muscular fitness in relation to TTH and children

Muscular fitness is defined as the capacity to carry out work against resistance. The main health related muscular fitness components are maximal isometric or dynamic strength, explosive strength and endurance strength (98). Oksanen et al. (99, 100) found lower upper extremity endurance and lower neck flexion strength in 17 year old girls with TTH. A relationship between muscular force and pain was found by Andersen et al. (101) in female workers with a reduced ability to rapidly activate painful trapezius muscles measured by the rate of force development (RFD).

Latest research in adults with TTH has shown that physical training has a long lasting effect in reducing headache frequency and intensity (88). Physical training was here described as a combination of strength exercise training and cardiovascular warm-up. Research targeting office workers with neck-shoulder pain and frequent headaches found significant pain reductions from brief daily resistance training for upper extremities (102).

Strength training for children is recommended to follow specific guidelines (103-105). Strength training beyond the goal of reducing headache may have an impact on strengthening the musculoskeletal tissue and increase aerobic power (106) (chap 7, 15). Exercising also decreases the risk of sport injuries and provides fundamental health benefits (8). Furthermore it might have a behavioural impact on teaching the child healthy lifestyles (9).Traditional concerns in strength training in children are the risk of injury to the growth plates, though there are few reports of this. Children above the age of seven may participate. The training should be adjusted individually to the child's maturity of the musculoskeletal system. The general paediatric guidelines for progressive resistance exercise are 1) warm up 2) a focus on technique, quality and learning of exercises 3) 1-3 sets of 6-15 repetitions 4) training 2-3 times a week on non-consecutive days 5) keep the program fresh and challenging by systematically varying the program. Free resistances as free weights or elastic bands are preferred. The technical performance of exercise should be a priority to the progression.

The role of muscular fitness and aerobic power to prevent diseases is increasingly recognized (98, 105). Likewise is there evidence that suggests that physical activity, aerobic power and muscular fitness promotes mental health and cognition in children (98, 105).

Concluding limitations in research

Research concerning children with TTH is sparse both when it comes to associated physical factors and relevant non-pharmacological interventions. Physical factors associated with TTH in children such as muscle strength and aerobic power has not yet been examined. Pericranial tenderness has been examined in children with TTH (65) but not in connection with interventions.

Relaxations therapy as a coping strategy has shown to be effective for adults and adolescents, but there are few studies involving children younger than 15. Physical exercise or strength training as a way of preventing or reducing headache symptoms and enhancing health status in children with TTH has not yet been researched. Likewise is knowledge about patient education, headache and children sparse.

Aims and objectives

The overall aim of this thesis was to examine the association of selected physical factors with a frequent or chronic headache condition in children. Furthermore this thesis aims to examine aspects of interactive interventions, and interpreting the results within a frame of empowering patient education. The objectives are:

- To evaluate the effect of computer-animated relaxation therapy in children between 7-13 years with TTH and to examine the children's experiences with the therapy. Furthermore to gauge the enrolment procedures and clinic capacity and the compliance of the child and parents (Paper I).
- To determine the test-retest repeatability of isometric maximal voluntary contraction (MVC) and force steadiness (FS) of neck flexion and extension, and of isometric MVC and RFD of dominant unilateral shoulder abduction in healthy children 9-18 years of age. Furthermore to determine the test-retest repeatability of the TTS and a sub maximal cycle ergometer test predicting maximal oxygen uptake (Paper II).
- To examine the combined measurements of muscle strength in the neck-shoulder region, aerobic power and pericranial tenderness in girls 9 up to 18 years of age, and their associations with frequent episodic or chronic TTH compared to healthy controls (Paper III).
- To examine the outcomes of specific strength training compared with counselling by nurse and physiotherapist in short, defined patient education programmes for girls with TTH 9-18 years (Paper IV).

Methods

The following presents the setting, design and participants. Furthermore the data collection, methodology of interventions and statistical analyses are described.

Setting

The four studies took place at the Children's Headache Clinic, Glostrup and Herlev Hospitals, University of Copenhagen, from October 2008 to September 2013. The testing was conducted at the Danish Headache Centre, Glostrup Hospital, University of Copenhagen. Test instruments were provided and supervised from the National Research Centre for the Working Environment, Copenhagen.

All children with TTH, diagnosed at the headache clinic exclusively with a diagnosis of frequent episodic or chronic TTH, according to the ICHD 2004/2013 (25, 26) were invited to participate.

Exclusion criteria were migraine headache more than once per month for a period of six months, a history of trauma, arterial hypertension or intracranial hypertension; headache secondary to a cervical or other morbidity; and headache associated with a psychiatric comorbidity. Another exclusion criterion was headache associated with a significant learning disability or complicated social situation that required special education and/or community involvement. Participants with TTH were at the first diagnostic visit informed by the contact physician and nurse about the child's basic needs for adequate food, liquids, sleep and activity.

Design

The methodology of the studies is mainly described as a hypothetico-deductive methodology. Hypotheses are provided in Appendix A. A brief overview of the methodology is provided in Table 4.

Table 4. Methodology of the studies

Study/paper	**I**	**II**	**III**	**IV**
Design	Pilot study. Descriptive/explorative and before-after intervention	Blinded repeatability study	Blinded case-control study	Test-blinded randomised and controlled trial
Participants	N=9 children (8 girls, 1 boy) with TTH, 7-13 years	N=25 healthy children, (15 girls, 10 boys) 9-18 years	N=82, 41 girls with TTH and 41 healthy girls, 9-18 years	N=49 girls with TTH, 9-18 years
Data collection	Study group characteristics Self-reported headache frequency and intensity Total Tenderness Score Surface EMG data Children's evaluations. All measures baseline, after 6 weeks intervention and 3-month follow up/home practice	Study group characteristics Beighton Score Total Tenderness Score Muscle strength and stability (MVC, FS, RFD) Predicted Max Oxygen Uptake	Study group characteristics Self-reported headache frequency, intensity and duration Beighton Score Total Tenderness Score Muscle strength (MVC, RFD) Predicted Max Oxygen Uptake	Study group characteristics Outcome measures as in study III -baseline, after 10-weeks intervention and after 12 weeks of follow-up/home practice. PedsQl^{TM} and PedMIDAS self-reports baseline and at two-year follow up
Analyses	Descriptive statistics Paired-samples t-test	Descriptive statistics One-way ANOVA Bland-Altman plots and by quantifying the variability	Descriptive statistics Binary logistic regression Mann-Whitney U test	Statistician blinded. Descriptive statistics GLIMMIX proc; MIXED proc. Two samples t-test

In study I mixed methods were used with an applied ethnographic approach (107). The researcher acted as a participant observer using observations and dialogue to gain insight into the child's daily life and challenges. The aim was to explore and guide the child through a process of identifying where and when to practice self-regulating techniques. Another aim was to guide the child to body awareness with the support of computer-animated biofeedback. Field notes were taken and the child's reflections and exercising of self-control were supported.

Methodology and design of the studies III and IV followed the STROBE (108) and CONSORT recommendations (109). Furthermore, international recommendations and guidelines for trials of recurrent headache (74, 110) and methodological considerations in research with children were taken into account (23). Guidelines for complex interventions were likewise consulted (111).

Participants

Study I

Nine consecutive children (8 girls and 1 boy) 7-13 years of age with TTH participated in the study. The children were newly diagnosed and recruited from 1/10 2008-1/5 2009. Three boys did not start because their parents were too busy to attend the nine sessions scheduled. No children dropped out after the start and all nine children attended the three-month follow up. Seven children completed eight sessions, and five of them completed the ninth and final session. Two children completed seven consecutive sessions. Enrolment is provided in Figure 3.

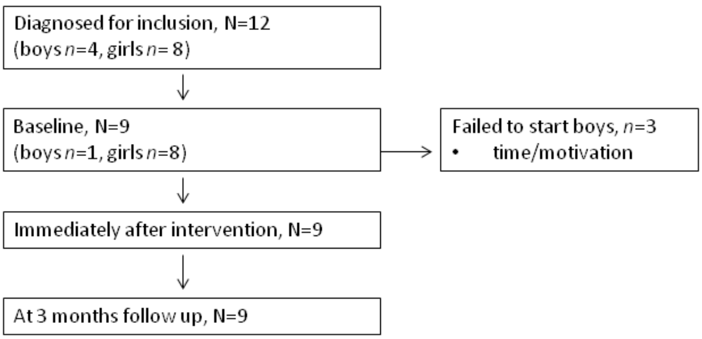

Figure 3. Flow diagram of study I

Study II

A convenience sample of 28 healthy children 9-18 years of age agreed to participate in two rounds of testing. The children were recruited from local schools in the suburban area of Copenhagen and were not suffering from frequent episodic or chronic TTH, migraine or any other diseases

Two girls failed to follow the plan and one boy did not show up for the second test date. Thus, 25 of the children (10 boys and 15 girls) participated in the test-retest design with a one-week interval.

Study III

Participants in study III comprised 44 consecutive girls 9-18 years of age, diagnosed with TTH after the 1 May 2010 to July 2012 and agreed to participate in the study. Boys were initially included in the study, but the inclusion was cancelled the 1st of October 2011 because there were only three boys enrolled of which two dropped out. Forty-three age and geographically matched healthy girls with no more than one episode of headache per month and no other illnesses participated as healthy controls recruited from local schools in the suburban area of Copenhagen. Two of the healthy girls and three of the girls with TTH failed to start. Flowchart is provided in paper III.

Study IV

Participants in study IV were 53 consecutive girls 9-18 years of age diagnosed with TTH after the 1 May 2010 to 1 September 2013. Fifty-three girls were randomised into intervention A or B. Four girls failed to start. Twenty-four girls followed group A and 25 group B. Four girls failed to attend the last test round in group A, and five girls in group B. A flow diagram of enrolment, allocation and analysis for study IV is provided in Figure 4.

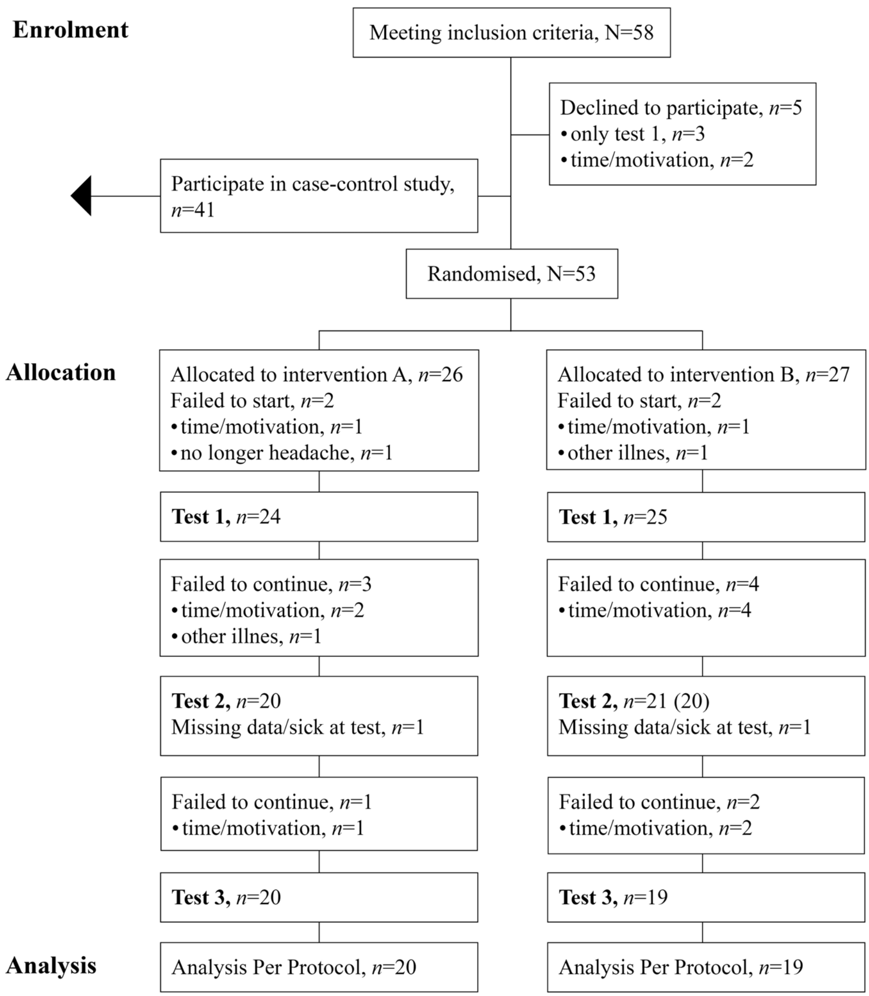

Figure 4. Flow diagram of study III and IV.

Data collection and procedures

Self-reports

Self-reports and measurements used in the studies is provided in Table 5. The following is a list that describes the self-reports, measurements and their procedures.

1 Study I, III and IV: At least 1-6 months before physicians' examination the family completed a detailed headache diary with pain frequency, intensity and duration. The diary was similar to the one recommended by Jensen et al. (76). After the first diagnostic examination the child and family filled in a headache calendar every evening with the most dominant, but not the highest, pain for the day measured on a 10 cm VAS/numeric scale (77). The total duration for the day was noted. The children were not allowed to take regular medication, but if any medication was taken, it was noted. In study I and IV, the child and parents reported the pain from one month before baseline and till the 3-month follow up; In study I there were 6 weeks of intervention and a 3-month follow up period/ home practice. In study IV, there were 10 weeks of intervention and a 3-month follow up/home practice.

2 Study IV: HRQOL reports were administered baseline by secretaries and nurses and repeated 24 months later by mail. At the initial diagnostic physician's examination the child and family filled in the PedsQL^{TM} 4.0 Generic Core Scales for age appropriate child and parental quality of life reports, validated and validated in translation (112-114). The questionnaire consisted of 23 items comprising four dimensions: physical functioning (8 items), emotional functioning (5 items), social functioning (5 items) and school functioning (5 items), which were scored on a five-point Likert scale (0-4/ never – almost always). Parental and child reports were collected for 8-12 and 13-18 year olds. For data analysis raw scores 0-4 were transformed reversely to 0-100 scale scores following the scoring instructions (115).

3 Study IV: The PedMIDAS report was conducted on disability at school, home and social/sports activities (116), validated in children with migraine (117, 118) and in children with TTH (119).

4 Study I: The children filled in a brief written evaluation questionnaire immediately after six weeks of intervention with the support of a parent.

Table 5. Self-reports and measurements in the studies

Measurement	Study I	Study II	Study III	Study IV
Self-reports of headache	X		X	X
Self reports of HRQOL				X
Self-reported evaluation	X			
Height and weight		X	X	X
Calculated BMI v/h^2		X	X	X
Beighton Score		X	X	X
Total Tenderness Score	X	X	X	X
SEMG	X			
Maximal voluntary contraction		X	X	X
Rate of force development		X	X	X
Force steadiness		X	X Not analysed	X Not analysed
Predicted VO_2max		X	X	X

Measurements

Extensive pilot experiments were conducted for the measurements of tenderness, muscle strength and SEMG, including adults initially, then children, who willingly participated. Pilot testing of repeatability was likewise conducted for muscle testing in a group of children.

In study I, measurements were conducted baseline, after six weeks of intervention and after 12 weeks of follow-up/home practice. SEMG data were extracted for the first 120 seconds of baseline (relax 1), 120 seconds of self-control (relax 2), and for the interactive in-between period. In study IV, measurements were conducted baseline, after 10 weeks of intervention and after 12 weeks of follow-up/home practice.

Description of measurements

1 Study group characteristics such as age, height and weight were measured. BMI was calculated.

2 In order to assess hypermobility as a potential confounder associated with headache, general joint mobility was screened using the revised Beighton Score (120), which is a bilateral examination in a standing position of five joint movements that includes the fifth metacarpophalangeal joint, the thumb, elbow, knee, and hands flat on the floor with stretched knees. The maximum score is nine points. The cut-off level for hypermobility was

5/9 (120). A goniometer (Smith & Nephew Rolyan Inc, London, UK, A 441-1) was used to measure the passive bilateral dorsiflexion of the fifth metacarpophalangeal joint and the passive bilateral hyperextension of the elbow and knee.

3 Tenderness of pericranial muscles was examined in a supine or sitting position in a chair with adjustable neck and leg support. The TTS system was first presented by Langemark and Olesen in 1987 (121) and later validated by Bendtsen et al. (122, 123). A summed score was calculated from individual scores of seven bilateral sites (masseter, frontalis, temporalis, processus mastoideus, occipital insertion, trapezius and sternocleidomastoideus). In study I the medial corner above the eye, the origin of the orbicularis oculi muscle, was the seventh site according to Carlsson (66). The four-point scale score was as follows: 0=denial of tenderness, no visible reaction; 1=verbal report of discomfort or mild pain, no visible reaction; 2=verbal report of moderate pain, with or without visible reaction; and 3=verbal report of marked pain and visible expression of discomfort. The palpation was conducted with small rotational movements, and pressure was maintained for 4 to 5 seconds. The palpation pressure was initially controlled by a palpometer (122) on an arbitrary scale, 80−200 arbitrary units (AU), reaching a standardised pressure of 120 AU (123) The palpometer was an original instrument made at the Danish Headache Centre. The maximum possible total score was 42 points. Figure 5 illustrates the sites from study I and IV.

4 SEMG data were raw signals collected using a ten channel Nexus-10 apparatus for physiological monitoring and feedback with wireless communication technology; certified class IIa (EU), fast inputs 2,048 samples/s, 24 bit AD converter. Cables were low noise carbon coated, for bipolar placement. Software was the Biotrace+ 2008, which is capable of designing and monitoring sessions and workshops (Mindmedia, Netherlands). The band-pass filtering was 10–500 Hz and epoch duration for root mean square (RMS) and average rectified value was 1/16 s., and mean median frequency (MDF) 1 s. All raw session data were preserved and stored in output files. Sensors were 32x22 mm rectangular Ag/AgCl pre-gelled EMG/ECG electrodes. Hypoallergenic hydro gel was applied and the electrodes were affixed by standard snap connector (MBS manufacturer/item no. 3SG3-N). The child sat in a comfortable adjustable chair, with arms and feet supported, in front of a table with the computer. After proper skin preparation (isopropyl/alcohol 70%) electrodes were placed according to SENIAM recommendations (124). Right and left sides were recorded simultaneously. RMSs and MDFs were extracted for the 120 seconds of baseline (relax 1), 120 seconds of self-control (relax 2), and for the interactive period, when the child was working with the screens.

5 Isometric muscular testing was conducted using a computerised force transducer, model Vishay Nobel, type KIS-2, max. 2kN (Vishay Precision Group, Malvern, PA, USA) wall-mounted on a custom-built adjustable stand. The child was positioned on a chair with the upper and lower trunk fixed with belts. For neck flexion measurements the lower edge of the padded force transducer corresponded with the line between the eyebrows, while for neck extension measurements the pad was positioned with the lower edge corresponding with the protuberantia occipitalis. The testing included isometric MVC in neck flexion and extension from a neutral upright position. The child was instructed to slowly build up the force to maximum within two seconds and then exert maximal pressure for about three seconds and thereafter slowly relax again. FS in both neck flexion and extension were removed from analyses after results from study II showed a tendency of systematic changes between test and retest.

For shoulder MVC and RFD the child was asked to lie on a mattress in a supine position. The dominant shoulder was then positioned in external rotation and abduction, while the elbow was stretched to position the back of the wrist on the pad. The child was instructed to press as fast and as forcefully possibly in the direction of abduction.

6 Aerobic power was determined by a Monark Ergomedic 939E PC bike (Monark Exercise AB, Stockholm, Sweden) using a sub maximal Åstrand test procedure and nomogram/accompanying tables for predicting VO_2 max (1). Heart rate was monitored using an adjustable Polar pulse belt (ProTerapi A/S, Brøndby, Denmark) and recorded continuously on a computer.

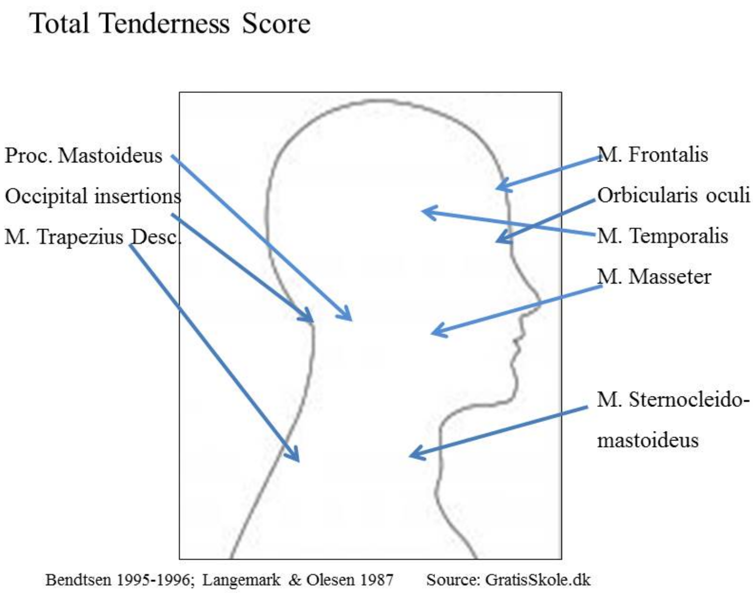

Figure 5. Bilateral palpation sites of TTS

Interventions

Study I

In study I, a course of nine sessions of modified relaxation therapy and biofeedback was scheduled for each child. Parents participated in the first and last session to be introduced to and to evaluate the therapy. The individual sessions were 2-8. Sessions were scheduled as two sessions a week the first three weeks and then once a week. The time, 9 am, and days for meeting were constant throughout sessions. The child and parents were introduced to a modified progressive relaxation therapy adapted from Bernstein and Borkovec (91).

The children received a written folder that consisted of age-appropriate text and pictograms of tension and relaxation exercises for seven muscle groups (fist, elbow, shoulder-shrug, forehead, jaw, abdomen and legs as a whole).The child was encouraged to exercise at home once a day and additionally practice body awareness and relaxation in daily life. Each session started with a dialogue about home practice and experiences, and a short relaxation procedure. The focus of this was on relaxed up-right sitting posture, awareness of self and body, abdominal breathing and tension versus relaxation of the seven muscle groups. After a short dialogue and practice, the child was connected to the biofeedback system and the child worked for at most 20 minutes with the screens.

The interactive feedback screens were set up in such a way that the child was able to click to and fro between different screens using the mouse. The child was encouraged to stay at one screen for a minimum of two minutes. Each session comprised four to five screens of visual feedback consisting of brief moving videos or animations, bar graphs or digital windows visualising the tension level, and with underlying auditory musical feedback. All feedback was inhibited when tension went above the specified threshold level. The threshold was adjusted manually by the therapist to encourage the child to respond to feedback and to reduce the tension level. The therapist's role was that of a participant observer guiding the child to be aware of the body when receiving feedback and exploring when and how to use self-regulating techniques. Every week there was a new set up of screens to keep the child motivated. Screen set-ups were identical for all children. The total session time was 45 minutes.

Study IV

In study 4 the participants were randomised by a secretary, blinded to the study, using computer-generated allocation of blocks of 10 into two intervention groups, A and B. Interventions were short, defined patient education programmes of 10 weeks of home training with approximately 140 minutes of supervised training or counselling, followed by 12 weeks continued home practice without supervision.

Group A was taught and supervised by the physiotherapist in progressive specific strength training with resistive tubing elastics (Thera-Band, Hygenic Corporation, Ohio, USA) and keeping a diary. Training comprised four alternating exercises, two by two, and involved progression from one set with 10 repetitions moving to three sets with 10 repetitions. The elastics were red, green and blue for progressive resistance. To determine the level of resistance a 15 repetition maximum was used for estimating an exercise resistance equivalent 75-80% of one repetition maximum (125). The children were taught to warm up their arms and to be aware of exercise quality and breathing. The task was to conduct home exercise three times weekly, monitored in the diary and supported by the parents. The progressive strength training was based on research and recommendations by the American Academy of Pediatrics, Committee on Sports Medicine and Fitness, policy statement for paediatric training (103), Faigenbaum et al. (105, 126) and Andersen et al. (127). Paper IV contains a figure illustrating the exercises. Group A was not provided any counselling during the 10 weeks of intervention. After the 10 weeks of intervention, the child and family were provided one counselling session with the nurse in order not to withhold any help for the family.

Group B was provided with need-based counselling based on international guidelines (110). Group B was considered the control group being an 'established intervention' proven to be effective in the treatment of children in the same tertiary clinic (57). The intervention comprised one session with the nurse and two sessions with the physiotherapist. The focus was on a motivational dialogue based on topics on a checklist promoting lifestyle changes and self-care with the purpose of enhancing the child's health and well-being at home and at school. The child was encouraged to practice the agreed life-style changes at home. Paper IV has a table with a list of the counselling topics the nurse and physiotherapist used.

Both interventions were followed by a twelve-week period in which home practice was advised to be continued without supervision. During this period, families could call for psychology counselling if needed. The addition of psychological counselling and/or vitamin D supply in the project period was noted as additional explanatory variables following international guidelines for trials (110). A timeline for study IV is provided in paper IV.

Statistical analyses

The statistical analyses were conducted using SPSS 17-20 and SAS 9.3. A *p*-value of 0.05 was chosen as the level of significance.

Study I

The effect of computer animated relaxation therapy was evaluated by the primary outcome variables headache frequency and intensity over 30 days. Secondary outcome variables were TTS and SEMG data. Paired samples t-test was used to examine the before-after effect. SEMG data were presented in box plots. Other data were presented by descriptive statistics. Furthermore, qualitative data from children's written evaluations were reported in a condensed form.

Study II

The test-retest repeatability was examined of isometric MVC and FS of neck flexion and extension; isometric MVC and RFD of dominant shoulder and pericranial tenderness recorded by means of TTS and a sub maximal cycle ergometer test predicting VO_2 max. The analyses comprised a four-step analysis involving a intraclass correlation coefficient, changes in the mean between the two test occasions, the levels of agreement visualised in Bland-Altman Plots and by quantifying the variability (128).

Study III

The power analysis was based on preliminary data onf the RFD variable showing that 45 girls were required in each study group to be able to detect a significant difference between the groups with a power of 80%. A logistic regression analysis was used to examine the associations between the independent test variables and the dichotomised dependent variable headache or not (no more than once per month). The associations were presented as OR and 95% confidence intervals. The results were adjusted for age and BMI as the confounders for growth. Furthermore, data were presented by descriptive statistics. Differences between study groups were analysed using Mann-Whitney U test. Correlations were analysed using Spearmans test.

Study IV

The power analysis for study IV was based on preliminary data from study III. With a mean headache frequency of 20 days (SD 9.6), significance of 5%, a power (1-β) at 80% and with an expected difference at 40%, 23 participants in two groups were required.

Statistics were analysed by a statistician, who was blinded to the study. Descriptive statistics were presented for all group characteristics. The primary outcome variable headache frequency out of 28 days was calculated. Mean headache intensity and durations over 28 days were calculated. As secondary variables the mean peak MVC and RFD data were calculated, as well as mean TTS and predicted VO_2 max. Psychological counselling and/or vitamin D supply in the project period were incorporated in the analysis as additional explanatory variables (110). Results were adjusted for age and BMI.

At baseline differences in headache intensity, peak data, TTS and oxygen uptake were analysed using two-sample t-test. Headache frequency and headache duration were analysed as binomial counts (count parameter equalled 28 days and 24 hours) using generalised linear models. Headache frequency, headache duration and headache at test were analysed using the repeated measurement analysis Proc Glimmix. The model included time and the interaction between time and intervention. The rest of the variables were analysed by linear mixed models for repeated measurements with the MIXED procedure. Per protocol, analysis was conducted for all completers of the study. An intention to treat analysis was calculated as modified to a final observation carried forward technique (129). All analyses were conducted in SAS.

Clinically important differences of measurements were considered when the results were interpreted, using the results from article II and from Powell et al. (78). For headache frequency, the minimum clinically important reduction was that of one day and for intensity, it was 10 mm VAS. For the secondary variables see the coefficients of variation in article II.

Ethical considerations

The studies followed the ethical principles of the World Medical Association Declaration of Helsinki 2008 and 2013 (130), first adopted in 1964, and the UN Convention on the Rights of the Child 1989 (19). The specific rights of the child related to decision making and the child's developmental capacity are described in the background section of this thesis.

Medical professionals and researchers are obliged to respect and protect the life, health, dignity, integrity and right to self-determination of participants in clinic and research. Furthermore, they must respect the right to privacy of research participants and their right to confidentiality of personal information. Research should be conducted with a careful assessment of minimised risks and burdens. Research should promote benefits, justice and equality.

Life, health, dignity, integrity and equality

In general, the studies were planned and conducted in such a way that participation in examinations and treatments would prioritise the best interest and well-being of the child. Another priority was to provide the child and parents with information on health and related body functions. The child and the parents' statements were considered with equal weight with respect to the views of the child.

Risks and burdens

Because children are vulnerable people the planning and piloting of procedures required careful risk assessment of any type of harm to or pressure on the child. This consideration formed the basis for specifically choosing a sub maximal cycle ergometer test and when piloting the neck tests. The parents were invited to be present during procedures as a precaution.

ClinicalTrials.gov and the National Committee on Health Research Ethics for Hospitals in the Capital Region of Denmark (ID: H-3-2009-081) approved the study's detailed research protocol and information sheets for participants in study II, III and IV. The Danish Data Protection Agency also approved the studies. Any new steps in the research process have also been approved by the committee after submission of additional protocols.

The Department of Development at Glostrup Hospital, University of Copenhagen approved study I, which was a developmental study that did not require acceptance by the regional committee.

Confidentiality, self-determination and justice

The individual has the right to self-determination and to voluntarily give an informed decision. Participants were informed about the research in detail, both orally and in writing. Justice was sought as to inform about both the burdens and the benefits or non-benefits of participation in the research.

Careful attention was paid to how and when the information was given. The child and parents were given at least 24 hours to reflect before making a decision. The child and parents were informed of their general rights in participating in a medical study. They were informed about the confidentiality of personal information and the right to withdraw from the study without any consequences regarding the child's future treatment. The parents gave written informed consent and the children gave oral informed assent. Children older than 15 years of age were given age-appropriate written information.

Healthy children received written material in a sealed envelope from the school after permission from the school board and head. After reading the material, parents with healthy children had to actively respond to the researcher by mail or phone in order to avoid influencing their decision. This procedure was recommended by the Health Research Ethics Committee.

Results

The results presented are based on the participants characteristics, test-retest repeatability and the associations between physical factors and headache in girls. Outcomes from interactive interventions in study I and IV are presented together. The corresponding hypotheses are available in Appendix A.

Characteristics of participants

The characteristics of the participants in the four studies are provided in Table 6 with data of baseline age, anthropometric measures, headache characteristics, pericranial tenderness and disability reports.

Participants in study IV also reported baseline deficits in the areas of physical, emotional and school functioning as results from HRQOL questionnaires. These results are presented in paper IV with the results from child and parental reports.

Table 6. Baseline characteristics of study participants

Study/ characteristics	Study I, N=9		Study II, N=25	Study III, N=82, 41/41		Study IV, N=49	
Age in years Mean (SD)	Boys Girls	13.0 10.6 (1.6)	13.7 (1.8)	TTH Healthy	12.7 (2.0) 12.3 (2.8)	Group A Group B	13.4 (2.0) 13.3 (1.7)
BMI w/h^2 Mean (SD)			18.8 (2.0)	TTH Healthy	19.9 (3.2) 20.1 (3.0)	Group A Group B	19.7 (3.1) 19.5 (2.9)
Total Tenderness Score (0-42) Median (quartiles)	Boys Girls	23.0 24.8 (7.0) Mean (SD)	11.5 (8.3)	TTH Healthy	23.0 (16.0-26.5) 7.0 (4.0-12.0)	Group A Group B	19.6 (7.7) 21.6 (8.8)
Headache frequency, days/28d Median (quartiles)	Boys Girls	12.0 20.0 (9.4) 5-30 Mean (SD) range/30d	-	TTH Healthy	24.0 (11.0-28.0) -	Group A Group B	22.0 (13.5-28) 24.0 (11.0-28)
Headache duration hours/28 d Median (quartiles)			-	TTH Healthy	10.0 (4.5-24.0) -	Group A Group B	8.0 (4.1-13.8) 9.3 (3.7-24.0)
VAS Score /28d Median (quartiles)	Boys Girls	1.0 5.3 (1.7) 3-7.7 Mean (SD) range/30d	-	TTH Healthy	4.6 (3.6-6.0) -	Group A Group B	4.7 (3.2-5.5) 4.3 (3.4-5.6)
VAS Score at test Median (quartiles)			-	TTH Healthy	1.5 (0.0-4.0) -	Group A Group B	0.5 (0.0-3.1) 2.0 (0.0-3.5)
Disability/PedMIDAS			-		-	N=36:	Grade I=3 Grade II=15 Grade III=7 Grade IV=11

Repeatability *(study II)*

The results from study II indicated acceptable test-retest repeatability, providing a stable basis for the research in study III and IV. Repeatability was examined by a four-step analysis and the FS revealed trends of systematic changes between the two test occasions. The test was therefore removed from future analyses. Intraclass correlation coefficients are provided in Table 7.

Table 7. Intraclass correlation coefficients with 95% confidence intervals

Variables/ICC	ICC (95% CI)
Peak shoulder MVC (N × 10^{-1})	0.97 (0.92-0.98)
Peak shoulder RFD (N × 10^{-1} x^{-s})	0.79 (0.58-0.90)
Peak neck extension MVC (N x 10^{-1})	0.91 (0.81-0.96)
Peak neck flexion MVC (N x 10^{-1})	0.91 (0.82-0.96)
Peak neck extension FS (N x 10^{-1})	0.76 (0.53-0.89)
Peak neck flexion FS (N ×x 10^{-1})	0.67 (0.39-0.84)
Mean TTS (0–42)	0.87 (0.74-0.94)
MeanVO_2 max (l · min^{-1})	0.80 (0.60-0.91)

From the four-step analysis the TTS revealed a method error at 2.69 and corresponding coefficient of variation at 25.05%. The shoulder RFD revealed a method error at 7.86 and CV% at 32.13. This variability between two test occasions was interpreted in the results of interventions.

Associations with headache *(study III)*

Results from study III demonstrated that girls with TTH had significantly higher pericranial tenderness than controls in correlation with headache frequency ($r=0.66$, $p<0.001$). Results indicated an association between shoulder and neck strength and headache with the following OR for girls having headache: 7.6 (95% CI 1.4–40.9) for weak to strong shoulder muscles; OR 3.1 (95% CI 1.2–8.1) for weak to average neck-shoulder strength; and OR 1.3 (95% CI 1.0–1.6) for neck flexion strength. There was likewise an association between predicted VO_2max and headache showing OR 5.2 (95% CI: 1.4–19.6) for headache for each unit of decrease in predicted VO_2 max.

It was concluded that reduced neck-shoulder strength and aerobic power, together with increased pericranial tenderness, are associated with TTH in girls.

Primary outcomes *(study I+IV)*

Results from study I indicated that a nine-session course in relaxation therapy supported by pictogrammes and SEMG computer animated biofeedback is a feasible and well-received intervention for children 7-13 years of age and provides a mean headache improvement of 45% for headache frequency at baseline versus three-month follow up.

Results from study IV showed that both specific strength training and counselling by a nurse and a physiotherapist resulted in a significantly decreased headache frequency, p=0.001 and decreased headache duration p=0.022, with no significant between-group differences. The odds of having headache a random day decreased during 22 weeks by 0.65 (0.50-0.84) (OR (95% CI)) for both groups. During 22 weeks 33% of the girls had a headache reduction ≥30%, group A 6/20 girls, group B 7/19. Twenty-six percent had a headache reduction ≥50%, group A 4/20 girls and B 6/19. Paper IV presents all results.

At the baseline test, the girls in groups A and B, 42% and 44% respectively, had no headache. The mean VAS score at the baseline test was 1.6 (SD 2.0) for group A and 2.2 (SD 2.6) for group B. No significant differences were identified over time and between interventions.

Secondary outcomes *(study I+IV)*

In study I, the TTSs seemed to decrease significantly in children with a frequent headache. SEMG data showed that the children had managed to work with tension regulation. The children evaluated that they had experienced efficacy in tension and pain control through enhanced body awareness. Four learning phases are presented in the article on how to practice attention and body awareness. The results also showed that children younger than 13 years of age need both dialogue and guidance by a participant observer to be able to achieve body awareness and to be able to verbalise reflections. All children revealed through dialogue an inner knowledge of relationships between psychosocial elements and the occurrence of headache. The study also revealed that the capacity of the clinic did not allow a large scale three-group study, on the basis of which study IV was planned.

In study IV, TTS increased significantly (p=0.001) for both groups. Both interventions resulted in an unanticipated significant decrease in neck extension strength with a decrease in cervicothoracic ratio from 1.9 to 1.7, indicating a change in muscle balance. During 22 weeks peak shoulder MVC increased ≥10% in 5/20 girls for group A and 2/19 girls for group B. In group A, 4/20 increased shoulder MVC ≥20% and none in group B. Predicted VO_2max increased ≥5% in 8/20 girls and ≥10% in 5/20 girls in group A. In group B, 6/19 girls increased VO_2max ≥5% and 3/19 girls ≥10%. In group A, 4/20 increased oxygen uptake ≥15% and 1/19 in group B. In the A group 50% of those girls with a headache reduction of ≥ 30% had an increase in VO_2max >5%. For the B group this was the case for 29%.

Discussion

Methodological considerations

Careful attention has been paid to describing concepts clearly and in an expanded manner to establish scientific robustness as proposed by Persson and Sahlin (18). Attention to three main areas were proposed (18): 1) conceptual importance and correctness; 2) knowledge base and stability: what do we know or not know? and 3) incorrectness. The background section of this thesis tries to address parts of these aspects in combination with the following discussion of methodology.

Hypothetico-deductive methodology

The main methodology used in the studies was hypothetico-deductive, allowing us to hypothesise about a certain phenomenon in a way that addressed the underlying who, what, where, why and how (18) (chap. 2 & 3). Hence, these aspects are defined in the thesis as follows. Who: the child 7-18 years of age; what: frequent and chronic TTH; where: a specialised headache clinic in Copenhagen. But the intriguing questions of why and how remain. Why do these children suffer from headache at around the time they start school or even earlier? How should we direct interventions? Finally, are there questions we have failed to ask?

Our goal was to identify associations, predictors and eventually causality to answer the how and why these children develop headache. Popper discusses the concept of scientific objectivity, stating that the objectivity of a hypothesis or scientific statement lies in the fact that it is testable and that the experimental procedures can be reproduced by anyone in repeated experiments following the same procedures (131) (part I, section 8).

The aim of auxiliary hypotheses is to avoid taking any underlying factors for granted by specifying conditions and additional important premises. If the test results are false, either the hypothesis or one of the auxiliary hypotheses is false (18, 132) (Persson & Sahlin p 52; Hempel p. 28). For example, if our test system implies systematic errors, the results will be unreliable and interfere with the ability to accept or reject the hypothesis, or we might accept the hypothesis on a false premise. Appendix A lists hypotheses and auxiliary hypotheses.

Based on a theoretical framework and a test-retest analysis, the case-control study provides solid documentation. Furthermore the logistic regression is according to Popper neither falsifiable nor verifiable as it is a relative frequency (131) (part 8, section 66). This is evaluated as strength.

Validity

Validity refers to the ability of an instrument to measure the attributes of the construct under study (133).

Instruments

In spring 2013, an updated version of the ICHD-III beta was published. The classification of TTH remained the same as in version II, which is the version used in our studies. Based on the classification, the diagnostic procedures for the children were standardised for all inclusion/exclusion procedures.

The various instruments used in the study were selected based on evidence of their validity. Devices used for measurements were calibrated before and during use.

Pediatric Quality of Life Inventory, PedsQL^{TM}4.0, was from varies studies reported valid in translation, valid and reliable in relation to feasibility, internal consistency estimates of reliability and construct validity, ensuring that the instrument is useful to the group of participants, capable of comparing patient groups, and able to measure the construct intended (112-114). Additionally Connelly et al. 2014 (134) examined PedsQL^{TM} in a group of children with recurrent headache for internal consistency of reliability, criterion-related validity, construct validity and responsiveness. The results were found valid and reliable for this group.

Validity in trials

Validity in clinical trials refers to internal and external validity and to errors in hypothesis testing, which is described in the following.

Internal validity

Internal validity in clinical trials refers to the ability of the researcher to attribute differences in the groups or participants to the independent variable. Threats to the internal validity are sources of alternative explanations for the outcome of the investigation (135). Possible threats to the internal validity are maturation, history, testing/ instrumentation, regression to the mean, selection bias and dropouts (135).

In studies with children, *maturation* is a possible threat as children grow and develop throughout the research period. This uncontrollable factor was dealt with using statistical methods that adjust for age and BMI. Natural improvement of the headache condition may also account for some of the effects (135). As a result, the influence of time was analysed with regard to results.

History refers to natural changes over time in every day habits that families might have develop during the research period that can affect the outcome of the study (135). Although this threat can partly be dealt with via information, it is inherently uncontrollable.

Threats to validity may also be changes in the interventions over time in the organisation or undesired diffusion between interventions (111). In the present studies, great effort was made to counteract changes over time using controlling instruments, such as electronic journals and booking systems, and by continuously providing all involved personnel with continuous oral and written information.

Threats from *testing and instrumentation* were opposed based on thorough pilot experiments, test-retest examinations and calibrations. *Regression to the mean* refers to the phenomenon in which participants are selected for treatment for their high/low value of a certain variable. When the measure is repeated some time later, the average value of the subgroup at second reading is less/higher (12). In the present studies, both treatment group and controls have high values of headache and the headache was continuously monitored daily. Regression to the mean is therefore less relevant for the primary outcome variable, but might be considered for the secondary variables, such as muscle strength and aerobic power testing. It was countered by standardised procedures.

Selections bias occurs when study participants are not representative of the population the study refers to (12). Furthermore, the participants involved might differ from those who did not want to participate, or those who are lost to follow up might differ from those who are not.

Inclusion of healthy controls for study II and III followed health ethics committee guidelines in order not to put any pressure on the families. After being provided with written information, families had to independently actively respond to the researcher. One weakness to this approach is that socioeconomically advantaged families were perhaps more likely to respond.

Soee et al. (57), who divided families with a child with headache into five categories based on education and work status, found that 46.8% of them land in the two highest categories and 14.2% land in the middle. Participants in the present studies were drawn from the same clinic and area of Copenhagen, so the match of healthy controls was considered acceptable.

Dropout or lost to follow up are reported in detail, and a modified intention to treat analysis is reported to counteract possible influences.

The use of *a control group* helped ensure internal validity in study IV. According to the Declaration of Helsinki (130) placebo control groups are only recommended if no proven treatment can be controlled against. Group B in study IV was considered the control group and an 'established intervention' proven to be effective in the treatment of children in the same tertiary clinic (57). In accordance with the UN Convention on the Rights of the Child (19), prioritising the safety and well-being of the child excludes the use of a wait-list control group. Due to the seriousness of the ethical issues concerned, our interventions involve a complex combination of various health care professionals at different organisational levels. Because our studies also targeted families with a variety of behavioural cultures and expectations; hence, the possibility that some of them might receive diverging information from the staff or that a diffusion between intervention groups might occur. Controlling for these human factors was essential and was supported by continuous verbal and written information materials, by checking electronic booking systems and by writing in the electronic journals.

Thus, the complexity of the interventions posed a challenge with regard to the hypothetico-deductive methodology due to the difficulty involved in isolating the 'active ingredients'. Therefore focusing on who accomplished what, from which intervention may be useful. After consulting guidelines for complex interventions (111), we examined and piloted the feasibility of testing and interventions and assessed their effectiveness. For future research, examining the process of change and the cost-effectiveness of interventions is recommended. With the exception of study I we did not examine how information was received and perceived by child and parents in study IV and therefore have no data on what knowledge they gained from patient education.

External validity

External validity refers to the degree to which the results from the study are generalisable to the population of interest (12). International guidelines from the American Headache Society, (110), STROBE and CONSORT statements (108, 109) and guidelines for complex interventions (111) were closely adhered to in order to improve the quality of trials to secure both internal and external validity and repeatability .

Repeatability

Repeatability of a measurement refers to the variation in repeat measurements with the same participant under identical conditions. Reproducibility refers to the variation in measurement with a participant under changing conditions (136). Study II, which is a repeatability study, confirms the foundation of study III and IV and relates to the auxiliary hypotheses.

Errors in hypothesis testing

As decisions are based on a sample, errors might occur. The maximum possibility of type I error is set by the level of significance of 0.05 in the present studies, which means that we reject the null hypothesis if the p-value of results are ≤0.05. The type I error (α) represents the possibility of falsely rejecting a true H_0 equivalent, the rate of false positive (12).

The chance of type II (β) errors is related to the rate of false negatives. Power (1-β) is the probability of correctly rejecting a false H_0 and thereby correctly finding a real significant difference in treatment effects (12).

Factors affecting power

The *sample size* affects the power in the way that the power increases with increasing size. As a result, the power calculations were essential when preparing the studies, even though they were preliminary as only preliminary data were available for calculation. The *variability* of repeated testing, as examined and reported in study II, affected the power and is responsible for the uncertainty in the power analysis.

The *size of effect* affects the power in such a way that the larger effect, the greater power. The chance of detecting a large difference is greater than detecting a small difference (12).

The *significance level* affects the power. The larger the level, the greater the power. For example, a decrease in significance level requires a larger sample.

The power analysis in the present studies was based on a p-value of ≤0.05 and power (1-β) at 80% with an expected difference at 40%. Multiple testing or subgroup analyses were deselected in the studies in order not to affect power by devaluating the p-value (12). As a result, no adjustments for multiple testing were applied.

General discussion of results

This section discusses the results and interprets them within the frame of Empowering Patient Education (EPE).

Primary characteristics and outcomes

Results from this thesis indicate that girls with frequent episodic or chronic TTH present measurable deficits in physical health associated with headache. Our study is the first to measure a girl's physical status, such as muscle strength and aerobic power, in combination with HRQOL self-reports. These reports indicate the difficulties experienced with physical health, emotional health and school functioning, which supports the studies' measured outcomes. Our findings correspond with Kaczynski et al.'s study (54), which reported school difficulties in children with TTH, and with Strine et al.'s (14), which reported attention difficulties in school. These self-reports highlight an area that needs to be further explored. The 24 months follow-up in HRQOL self-reports is not included in this thesis as data collection is still ongoing. According to Kaczynski et al. (54) children with TTH tend to choose passive coping strategies, and their parents more protective patterns. Consequently, patient education should empower the child and parents to practice active coping strategies to enhance the child's health status.

Studying the outcomes from interactive interventions the results from study I indicated that computer animated relaxation therapy with nine individual sessions seemed a significantly effective learning strategy. Results from study IV showed that both strength training and interdisciplinary counselling had a significant outcome in reduced headache frequency and duration. As both relaxation therapy and strength training present a reduction in headache as well as enhanced body awareness, the use of these interventions should be determined by the physiotherapist, the child and the parents after an evaluation of the child's individual needs. These results correspond with Söderberg et al.'s (88) findings for adults with TTH. Combining these approaches with counselling by nurse will provide positive outcomes.

Study IV showed that headache in the girls was either absent or very low in intensity when the testing took place. We did not examine day variation, but we know that most of the tests were conducted before noon or early pm. These observations indicate that headache increases in daytime, with the highest intensity later in the day, which might be related to day stressors or tiredness, as reported by Connelly (81).

Secondary outcomes

In study I the TTS decreased significantly in the children with frequent TTH together with a decrease in headache frequency. The group, however, was small and not controlled. As a result, these results need to be supported by more studies. In study IV the pericranial tenderness significantly increased as measured by the TTS. Increased tenderness is believed to arise from persistent headache and increased sensitivity (67). Consequently, we anticipated that tenderness would decease with a reduction in headache. The present result was interpreted as being due to measurement variation, which is why the TTS must be examined further, possibly with the use of a modern palpometer. The lack of reduction in tenderness might underscore that recovery from a chronic headache situation has a prolonged perspective.

There was an indication of a change in the muscle balance over neck and shoulder from both interventions, possibly because of changes in posture due to strength training and body awareness exercises. Strength training also showed the potential to increase strength and oxygen uptake, but the results might indicate that change in muscle balance precedes gain in strength for the girls with TTH. Faigenbaum et al. point out that if the children's prerequisite motor skills have developmental deficits, it might interfere with the results from strength training (137). The exercise intensity versus exercise variation should be considered in order to keep a stable weekly volume.

The counselling empowered the individual family to practice self-care but the outcomes in muscle strength and aerobic strength were minor, in spite of the fact that the families in counselling had made shared suggestions about how the child could be more physically active. We know that the families were working with a variety of lifestyle topics and that change in habitual physical activity may be challenging. Biddle and Mutrie (138) list the determinants for change in being physically active as knowledge, motivation, self-efficacy and attitudes, which are also the areas the patient education in our studies targeted. Aujoulat et al. (34) conclude that empowerment in patient education may be viewed from both a patient-provider interactive process and an intra-personal process. Based on the present studies, we can add the interactive process between parents and child. These perspectives need further study and should be incorporated when considering innovative approaches to patient education.

Results and empowering patient education, EPE

This thesis emphasises the need to examine the factors that support or limit the outcome of patient education. Based on work by Leino-Kilpi (36), Tables 8a-8b, below, lists the EPE dimensions, in addition to highlighting its outcomes, possible barriers and future needs as modified for children. A child's motor skill competencies and physical activity habits are learned behaviours developed in the context of the family, school and other environments (137). The practice of self-care are to be incorporated into the family's every day life. The parents and family therefor play an important role to fulfil the child's needs as well as their own.

Table 8a. EPE dimensions for the child

Dimension	Meaning
Bio-physiological	The child is empowered when they know about headache and bodily needs and can act on them; able to act in the manner they wish to control the problem
Cognitive	The child is empowered when they interact in the learning situation and understand the knowledge provided
Functional	The child is empowered when they know their functional ability and can act on it; able to act in the manner they wish to control the problem.
Social	The child is empowered by being able to keep or have a social network
Experiential	The child is empowered if earlier experience to manage can be used
Ethical	The child is empowered when they can act based on their own values and are respected by others due to the right to autonomy
Financial	The family is empowered when it can manage the situation financially or in time

Table 8b. EPE dimensions, outcomes, possible barriers and future needs

Dimension	**Outcome**	**Possible barriers**	**Future needs**
Bio-physio-logical	Age-specific material was well received; The child learned to manage a concrete exercise program supported by visual material. The child managed to reduce headache.	The child does not understand; intensity of exercises is too small or variation decreases volume; parents lack knowledge or are too busy to give support; family or school environment does not support the child's possible control.	Dose-response relationship to exercising with children with TTH needs to be examined; Accomplished knowledge should be examined; more information should be digital and easily accessible that addresses both child and parents.
Cognitive	Self-reports revealed emotional and school functioning difficulties; children learned to exercise or use relaxation techniques with age-specific interactive methods.	Knowledge, expectations and social culture in the family have influence; material or environment does not call for the interest of the child; the child does not understand.	The child's cognitive level and competences should be considered; incorporating electronic devices in learning; consider environmental issues; school difficulties need to be examined.
Functional	Girls with TTH had deficits in both measured and experienced physical functioning; The girls managed to reduce headache and enhance physical skills. Over nine sessions of relaxation therapy the child managed body awareness and a sense of control.	The child and parents do not know or do not recognise the child's functional level; there is limited physical social behaviour in the family or school; There is a limited culture for stress regulation in the family or school.	The child and parents need more knowledge about active coping strategies; families need to learn to play/be physically active *together*; and to know why this is important. Electronic devices can be used outdoors.
Social	Drop-outs were explained by perceived lack of time and or motivation.	Knowledge, expectations and social culture in relation to child, parents and family influence.	Support play/physical social behaviours within the child's network; both child and parents' motivation and barriers for change need to be examined.
Experiential	Earlier exercise or body experiences were used.	Earlier experiences related to more passive coping strategies.	More knowledge about active strategies should be available digitally or online.
Ethical	The child interacted in a learning situation when addressed age appropriately.	The parents or professional act on behalf of the child.	Sessions without the parents might promote the child's ability for self efficacy.
Financial	Time in the organisation and the parents were limited.	Time limits are too narrow to support participation, learning and outcomes.	More online or digital material; additional socially informative events for children and parents.

Interpreting the results within the frame of EPE shows that the interventions and materials used in the studies were relevant and suitable for for the participating children 7-18 years. The children managed to participate and learned to use the active techniques and strategies. The children's compliance was good, and even young children below the age of 13 took responsibility for their situation and were empowered, if allowed.

Barriers for outcomes were hypothesised to be related to the knowledge the participating children and parents imply about headache and associated factors. Barriers likewise seemed to relate to the ability to maintain or progress with physical activities in daily life, where limited time was frequently perceived as a barrier. Barriers may therefore be present in the contemporary family behavioural culture and structure. Likewise, the organisation of patient education may be a barrier that needs to be developed and adapted to suit contemporary families.

Empowering dimensions for the child with TTH are provided in Figure 6. The figure illustrates those dimensions that include the results and appeared essential for the child's knowledge and skills. Figure 7 provides dimensions of parents' possible future needs.

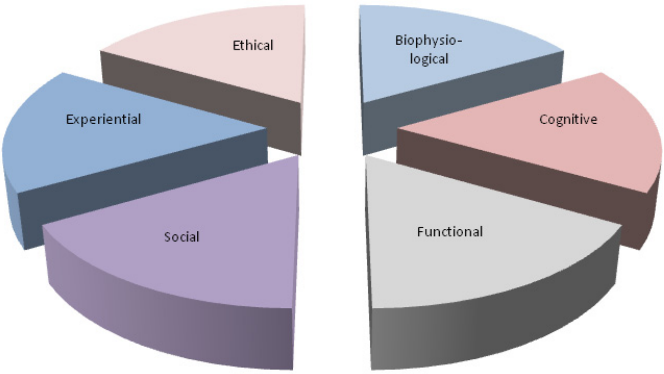

Figure 6. Empowering dimensions for the child with TTH

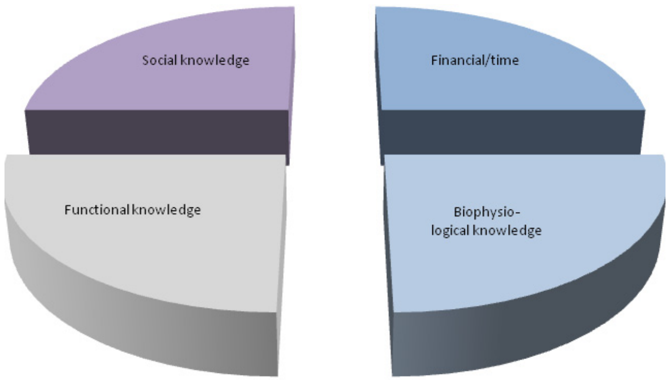

Figure 7. Empowering dimensions for parents' possible future needs

General conclusions

In this thesis, the physical factors associated with frequent and chronic TTH in girls are presented. The results highlight that physiotherapy plays a central role in headache services, providing evidence of interactive interventions with a potential to reduce headache significantly and to teach children strategies to enhance health-related physical factors and awareness and thus their quality of life. Physiotherapy is seen as working in combination with interdisciplinary counselling.

The main conclusions are that:

- Reduced neck-shoulder strength and aerobic power combined with increased pericranial tenderness are associated with TTH in girls.
- Specific strength training has the potential to reduce headache and increase measured physical outcomes, such as strength and VO_2max. The results indicate that it is important to consider the weekly volume when exercises are varied. The dose response of exercising with girls with TTH needs to be researched further.
- Relaxation techniques supported by age-relevant pictogrammes and computer animations with a physiotherapist as a participant observer resulted in significant headache reductions and learned headache control. The intervention is time consuming but superior. More knowledge is needed about psychosocial stressors in children and their ability to cope.
- Counselling provided by a nurse and a physiotherapist resulted in significant headache reduction. It also led to a limited change in measured physical outcomes, such as strength and VO_2max. Motivation for change and the barriers the contemporary family might experience in order to integrate learning and change habitual physical behaviours by counselling need to be examined for both children and parents.
- Results from strength training and counselling for girls with TTH showed a change in muscle balance over the neck. Muscle balance may precede strength gains in children with TTH. Prerequisite motor skills need to be considered in physiotherapy with children with TTH.

- Perceived lack of time and/ or motivation constrained inclusion and caused dropouts. Looking at the organisation of patient education in an innovative manner is recommended to further reach the contemporary family. Patient education about headache and active strategies targeting both boys and girls in different age groups and their parents could be available digitally or online. Informative social events for parents and children could likewise be a possible option to enhance knowledge and reduce the use of time and costs.

Recommendations and future perspectives

Physiotherapy plays a central and relevant position in headache services with a core aspect of patient education in relaxation techniques, strength training and aerobic fitness.

Modified relaxation therapy supported by easily accessible material with exercise using text or pictograms can be recommended. Computer animated bio-feedback is time consuming but superior, if the child has a habitually active daily life.

Recommendations for future strength training involving children with TTH need to be supported by further research. Results from this thesis support that guidelines for strength training and children should be followed. A variety of three to four exercises at a time seems appropriate for children to be able to self-manage. Alternating the exercise between trainings sessions should be considered because too much variation seems to decrease the weekly volume. Keeping the training intensity as high as possible without compromising exercise quality appears to be important in order to achieve physically measurable effects. A physiotherapist must adjust training to the child and incorporate an evaluation of possible developmental exercise deficits. Physiotherapists can work to find new ways of improving the motivation of children to engage in active coping strategies with and not despite electronic devices in order to counteract a sedentary lifestyle.

This thesis suggests that a combined interdisciplinary approach that includes relaxation therapy or strength training with physiotherapist will result in positive outcomes. When a lack of time is a hindrance for both the health care staff and families, supplementary digital learning could be a solution to allow families to receive the needed information about headache, pain mechanisms and active coping strategies when it suits their daily schedules. Additional socially informative events for child and family on how to empower socially physical health behaviours are a possible option for limiting the amount of sessions necessary while simultaneously supporting interactive learning.

It will be necessary to examine the needs of contemporary families, children and parents, the knowledge gained and the barriers they face in order to reinvent social or interactive physical behaviours for the benefit of the child’s health and well-being.

Summary in Danish

Børn og især piger med spændingshovedpine (på engelsk tension-type headache, TTH) har en høj forekomst på verdensplan og betyder for børnene en risiko for skolefravær, medicin over forbrug og vedvarende hovedpine. Den viden, der findes om fysiske faktorers sammenhæng med hovedpine, er begrænset, ligesom viden og dokumentation for interventioner er det.

Det overordnede mål med denne tese var at undersøge de fysiske faktorer, som har en sammenhæng med hyppig eller kronisk spændingshovedpine hos børn. Endvidere at undersøge aspekter af interaktive interventioner som empowerment i patient uddannelse, for at undersøge hvad og hvordan vi bør planlægge den interdisciplinære hovedpine service for barnet og forældrene set fra et fysioterapeutisk perspektiv.

Det første studie undersøgte i et pilotstudie computeranimeret afspændingsterapi med børn 7-13 år og hvordan så unge børn oplevede terapien. Endvidere undersøgte det inklusions procedurer, barnet and forældrenes compliance samt estimerede om et større controlleret studie kunne lade sig gøre. Det andet studie havde til formål at bestemme test-retest repeterbarheden af muskel styrke variabler for nakke og skulder hos raske børn 9-18 år. Endvidere at bestemme test-retest repeterbarheden af Total Tenderness Score (TTS) og af en sub maksimal cykel ergometer test som estimerede maksimal oxygen optag. Det tredje studie var et case-control studie, som havde til formål at undersøge kombinerede målinger af muskelstyrke i nakke-skulder region, aerobic power, and perikraniel ømhed hos piger 9 til 18 år og sammenhængen med hyppig eller kronisk spændingshovedpine sammenlignet med raske kontroller. Det fjerde studie var et RCT studie som undersøgte resultaterne af specifik styrketræning af skulderens muskler til sammenligning med samtaler og vejledning med fysioterapeut og sygeplejerske i korte definerede patient uddannelses forløb for piger 9-18 år med TTH.

Resultaterne fra studie I viste at et 9 sessioners kursus i computer-animeret afspændingsterapi er en signifikant effektfuld lærings strategi som viste en middel forbedringsprocent på 45% på hovedpinehyppighed og øget krops opmærksomhed. Børnene udtrykte en begyndende forståelse for kroppens mulige reaktioner og lærte sig at deaktivere og regulere disse reaktioner Studiet klargjorde også inklusions procedurer and klinikkens kapacitet med henblik på planlægning af det større studie. Resultaterne fra studie II viste acceptable analyser for repeterbarhed og var dermed et stabilt grundlag for studierne III og IV. De vigtigste fund i studie III var, at piger med TTH er signifikant mere ømme end raske kontroller og

ømheden er korreleret med hovedpine frekvensen ($r=0.66$, $p<0.001$). Resultaterne viste også en signifikant association mellem reduceret nakke-skulder styrke og hovedpine. Endvidere sås en significant association mellem reduceret estimeret VO2max og hovedpine. I studie IV viste pigernes selv-rapporterede sundheds-relaterede livskvalitet, at de oplevede vanskeligheder i fysisk sundhed, følelses-mæssig sundhed og skolefunktion. Resultaterne viste en signifikant reduktion af hovedpinefrekvens og varighed af både styrketræning og vejledning uden signifikante forskelle på de to interventioner. I løbet af 22 uger fik 33% af pigerne en hovedpine reduktion på ≥30% and 26% på ≥50%. Begge grupper opnåede efter øvelser og kropsbevidsthed en signifikant reduktion i nakke ekstensions/fleksions ratio. Styrke træningen viste potentiale til at øge både muskelstyrke og oxygen optag. En oplevelse af tidspres og manglende motivation begrænsede patient indtaget og var årsag til frafald.

Som konklusion peger resultaterne på, at fysioterapi har en central rolle i hovedpine service i at undervise børnene i strategier, der kan bedre sundheds-relaterede fysiske faktorer og opmærksomhed på kroppen, reducere hovedpine og dermed også højne livskvalitet. Styrketræning eller afspændings terapi i kombina-tion med interdisciplinær samtale og vejledning vil føre til positive resultater. Da både afspændingsterapi og styrketræning viste signifikante resultater bør brugen af disse interventioner afvejes i et samarbejde mellem fysioterapeut, barn og forældre og vurderes på basis af barnets individuelle behov. Når vi evaluerer resultaterne i forhold til en 'empowering patient education' teorimodel kan vi konkludere, at de interventioner og materialer, som blev anvendt, var relevante og tilpassede børn 7-18 år. Det anbefales at overveje forholdet mellem ugentlig øvelses intensitet og øvelses variation for at holde et stabilt ugentligt træningsvolumen. Motivation for forandring og de barrierer, som den nutidige familie måtte opleve i forhold til at integrere det lærte og ændre vaner for fysisk aktivitet i hverdagen bør undersøges nærmere. Det foreslås, at man med et innovativt sigte reviderer patient uddannelsen og dens organisering, således at den i højere grad er tilpasset den nutidige familie. Denne tese præsenterer de dimensioner af empowerment som er væsentlige i forhold til børn med TTH og deres forældre.

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Table 2. Studies examining 6*-12-month prevalence in children with TTH worldwide from 2002-2013 using IHS/ICHD-II

Studies	Partici-pants Age	Country	Design	Prevalence ETTH+FETTH/ CTTH in %	Mean onset of headache	Accompanying, independent symptoms/other observations
Anttila et al. 2002	1409 12 years	Finland	Population-based study*	12.2/ 0-1.6% Both sexes	7.4 years	Photo/phonophobia, abdominal pain, neck-shoulder symptoms, depression, oromandibular dysfunction
Arruda et al. 2010	1994 5-12 years	Brazil	Population-based study	Pooled ETTH, FETTH and probably TTH Both sexes 17.4/0.05%	No report	High prevalence in pre-adolescent children
Gassmann et al. 2008	3984 8-15 years	Germany	Population-based study* Second wave	Overall TTH 27.1/ ? Both sexes	No report	Increased prevalence with age and gender; 4% changed from TTH to Migraine. 8% from M to TTH
Kröner-Herwig et al. 2007	5586 7-14 years	Germany	Population-based study*	18.5% Both sexes	7.5 years	Associated with parental history of headache
Laurell et al. 2004	1850 7-15	Sweden	Population-based study	Overall TTH 9.8/0.1%		Related to gender >13 years
Ozge et al. 2010	1155 Mean 15.2 (1.1) years	Turkey	Population-based follow-up study	2003: 22.6/5.9% 2007: 57.5/11.1% Both sexes	No report	Phonophobia; history of parental headache: PedMidas >17 days affect MOH
Rho et al. 2011	5039 6-18 years	South Korea	Population-based study	Female: 16.3/? Male: 10.7/? Overall: 13.7/ ?	Boys 10.4/girls 11.6 years	Prevalence higher in urban areas compared to suburban ; related to age and gender
Silva et al. 2012	1605 10-93 years	Brazil	Population-based study	Overall TTH 22.9% both sexes	No report	Impact mostly on pain and energy levels
Strine et al. 2006	9264 4-17 years	USA	Population-based study	FSH 6.7% both sexes	No report	Emotional , cognitive and social difficulties
Unalp et al. 2007	2384 14-18 years	Turkey	Population-based study	5.7% both sexes	No report	Associated with a family history of headache, fatigue, sleeplessness and anxiety
Zwart et al. 2004	8255 13-18 years	Norway	Population-based study	Female: 23.2%/0.5 –7.6% Male: 12.5/0.5–7.6% Overall 18%	No report	Related to gender