Short- and Long-term Health Effects of a Residential Stay in a Danish Christmas Seal Home.

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PROTOCOL

Title: EVIDENSE of the effort on the Danish Christmas Seal Houses: Short and long-term effects on health status, physical fitness, physical activity level, learning, sleep and well-being for children on Danish Christmas Seal Houses – with and without a high intensity activity/health education program.

The study is collaboration between Institute of Sports and Biomechanics, Faculty of Health Science, University of Southern Denmark, Institute of Nutrition, Exercise and Sport, University of Copenhagen and the Danish Christmas Seal Houses (Julemærkefonden).

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Aim

The aim of the project is to document the short-term effects on health, physical fitness, physical activity level, learning, sleep and well-being from a 10 weeks residential stay on one of the Danish Christmas Seal Houses. Furthermore, to document the long-term effects 3 and 12 months after the stay. In addition, the project examines if a special effort with a high intensity activity/health education program (HIHE) increases the effects on physical fitness and health knowledge, learning capabilities, sleep patterns, well-being and adherence to a physical active lifestyle compared to the standard program.

Theoretical background

Physical activity and health

Physical inactivity and childhood obesity is connected to risk factors for cardiovascular disease (Tremblay et al. 2011, Han et al. 2010, Nadeau et al. 2011, Andersen et al. 2006). Because low aerobic fitness and obesity in childhood most likely extends into the adult life, this is a worldwide concern (Trudeau et al. 2003, Reilly 2006). Habits and attitudes about physical activity are shaped during childhood (Malina 1996, Kristensen et al. 2008), and the Body Mass Index (BMI) of childhood is directly correlated with the risk of cardio vascular (CV) disease later in life (Baker et al. 2007).

In Denmark, 21% of the girls and 15% of the boys are overweight because of lifestyle and lack of physical activity (Pearson et al. 2005). Research has shown that the overall health and physical fitness in Danish school children has worsened over the resent years (Wedderkopp et al. 2004, Ekeland et al. 1999, Rasmussen, Due & Holstein 2000). From 1998-2007 the proportion of children in school age, who regularly do sports or exercise, dropped from 89% to 84%, including a drop from 93% to 88% among the 10-12 years old children (Pilgaard 2008). Furthermore, there were a reduction in 2006-2010 in the amount of highly active children (Rasmussen & Due 2010), and the level of daily physical activity has become more uneven distributed over the last 20 years. With an increasing amount of children who are insufficiently active, as the result (Wedderkopp et al. 2004, Wedderkopp et al. 2001, Ekeland et al. 1999).

A Danish study has shown that the total physical activity volume of Danish girls is lower than that of Danish boys, due to a lower activity level in after school programs, where they are less included in physical activity such as team sports and ball-games. This results in more girls (30%) than boys (17%) who do not reach the recommended level of daily physical activity (Nielsen, Pfister & Andersen 2011). The daily physical activity level drops with increasing age (Pearson et al. 2005, Sundhedsstyrelsen 2006, Sundhedsstyrelsen 2010, With-Nielsen & Pfister 2011), and an increasing number of Danish schoolchildren are inadequate physical active – especially after 10-11 years of age. The age dependent drop applies for both organised sport and unorganised physical activity, because fewer 13-15 year-old children participate in both organised sport and unorganised physical activity after school in comparison to 10-12 year-old children (Pilgaard 2012). Therefore, there are a need for initiatives that can increase and maintain the physical activity level of children and young people.

There have been an extensive number of studies, studying the fitness and health profiles of European and Danish children (Andersen et al. 2006, Andersen et al. 2008, Bencke et al. 2002, Seabra et al. 2012), but most studies have used a cross-sectional design. For instance, a large cross-sectional study showed that risk factors of cardio vascular disease accumulated in 15% of Danish children (9-10 year) and young people (14-15 year). Accumulation of 4-5 risk factors was positive related to BMI and negatively related to fitness level for both genders in these age groups (Andersen et al. 2003, Wedderkopp et al. 2003).

It is well known that regularly physical activity is connected with significant positive physical and mental effects. Physical activity plays an essential role in the prevention of a number of diseases, which challenges the modern society (Ebbeling et al. 2002). Studies show, that those children, who are regularly involved in activities in sports clubs, have better heart and bone health than children, who are not members in the local sports club (Seabra et al. 2012). Studies, that examined measurements of aerobic endurance, have found favourable connections between aerobic fitness and systolic- and diastolic blood pressure (Ondrak et al. 2007) and arterial stiffness (Boreham et al. 2004). Likewise, a study has shown that children, 9-10 years of age, who played recreational football 3x40 minutes a week for 10 weeks, enhanced the structural and functional functions of the heart (Krustrup et al. 2014).

Most physical activity recommendations regarding childhood, including school based activities, focus on training duration, e.g. 60 minutes a day (Strong et al. 2005, WHO 2003, UK CMOs report 2011, Sundhedsstyrelsen 2005). But newer studies have shown that intense training is more effective for adults and young people in relation to improvements of aerobic and anaerobic fitness, compared to moderate intensity training (Krustrup et al. 2010a+b, Ingul et al. 2010, Sperlich et al. 2010). Newer studies on children, have shown high intensity during recreational football, basketball and unihockey (Bendiksen et al. 2012, Randers et al. 2010a), and that recreational football can improve submaxim and max physical capacity, motor skills and self-worth in overweight children (Faude et al. 2010). Furthermore, studies have shown, that football training improves body perception, self-worth and inclination to participate in physical activity (Seabra et al. 2014), and also structural and functional effects on the cardio vascular system in overweight children (Hansen et al. 2013).

Scientific reviews concludes, that school interventions with physical activity can be effective in improving health status, since these interventions has potential to reach all children, including the ones with low fitness, overweight or low bone mineral density, e.g. girls with limited physical activity during and after school together with low Ca^{2+} intake (Van Sluijs et al. 2007, Dobbins et al. 2009). There are surprisingly few intervention studies targeting assessments of physical training for children, and they have, in general, not shown long term adherence. This complicates interventions and public health campaign recommendations (Wilfley et al. 2007, Harris et al. 2009).

A pilot study with”FIFA 11 for Health” in Denmark, was initiated in the 2015/16 school year, with 546 participating 10-11 year old pupils. The study showed that the”FIFA 11 for Health” program had a positive effect on systolic and diastolic blood pressure, BMI and fat percentage in the children (Ørntoft et al. 2016). This could indicate a lowered risk for cardio vascular diseases in the adult life (Baker et al. 2007, Andersen et al. 2003, 2006 and 2011). Furthermore, the pilot study examined the well-being of the pupils. The results showed a significant positive effect in regard of social well-being, among those pupils that completed the ”FIFA 11 for Health” program, but no change among the pupils who participated in the regular school program (Fuller et al. 2016). Additionally, the study showed an 11.9% improvement in health knowledge, and 72.4% of the participating children had a positive experience with the program, and only 4.8% had a negative experience (Fuller et al. 2016).

Cognitive functions

The connection between physical activity and cognitive functions has been examined by several studies. The focus has mainly been on the executive functions, which cover the cognitive processes that are responsible for problem solving and goal orientated action (Diamond 2006, Hillman et al. 2008). Especially the coupling between the fitness level and cognitive functions in children have been examined, and several cross-sectional studies on school children have found positive associations between the children's physical fitness and cognitive (Chaddock et al. 2012) and academic performance (Hillman et al. 2008). Recently, similar findings have been found with Danish children, and on top of that, it has been shown that children who participate in sports club activities perform better in cognitive tests and reading (Geertsen et al. 2016). Other cross-sectional studies have related these associations to structural differences in the nerve system, where children with high fitness levels have a larger volume in some of the central brain structures, i.e. memory, than children with low fitness levels (Chaddock et al. 2011, 2010, Pontifex et al. 2011). Although these correlations does not explain causality, the positive connections are confirmed by several intervention studies with physical activity, which have shown positive effects on i.e. cognitive functions (Chaddock-Heyman et al. 2013, Davis et al. 2007, Hillman et al. 2014). It seems like the type of physical activity is of importance for the effect on cognition. Among others, Pontifex and colleagues (2009) found, that the effect on cognition was specific for aerobic training rather than strengths training (Pontifex et al. 2009). In addition, a new study has shown that the intensity of the physical activity is significant for cognitive functions such as motor skill processing (Thomas et al. 2016). Moreover, studies have shown that fine and gross motor skills were positively associated with cognitive functions in children (Geertsen et al. 2016). In relation to this, it will be interesting to measure if ball games (such as football), which consist of a high amount of coordinating complex physical movements, strategy and goal oriented actions (Pesce et al. 2009), can develop the cognitive functions in children, in particular the development in executive functions (Best 2010). Simultaneously, it is an area with great political attention in relation to the new Danish reform for the primary and lower secondary school, where children 6-16 years of age is active 45 minutes a day during school hours. In spite of many earlier studies, there is a lack of knowledge about whether or not programs like " FIFA 11 for Health" is capable of implementation, and if the characteristics of the programs can influence not only health and social factors, but also cognitive functions, including brain activity, in children.

Hypothesis

This project incorporates recreational football and health-knowledge. A pilot study has shown positive effects on blood pressure, BMI and fat percentage in children (Ørntoft et al. 2016), and there are comprehensive evidence about the positive cardio vascular (Krustrup et al. 2009, 2013), metabolic (De Sousa et al. 2014) and muscular-skeletal effects (Krustrup et al. 2010c, Helge et al. 2010, Oja et al. 2015) of football for adults. Furthermore, the pilot study showed increased health-knowledge and school related well-being among the participating pupils.

Thus, the hypothesis is that a 10-week residential stay at the Danish Christmas Seal Houses (DCSH) has positive effects on general health, physical fitness, learning, sleep patterns and well-being. Furthermore, the HIHE program ("FIFA 11 for Health program – health-knowledge on the football pitch") will result in larger improvements on health, physical fitness sleep patterns, well-being and adherence to a physical active lifestyle than the standard program in DCSH.

Participants, inclusions- and exclusions criteria

There are 24-48 children on each of the DCSH. They have a continuously admission of children in the age range 7-14 years, and every child is offered a 10 weeks residential stay. From september 2018 about 600 children (boys and girls) will be recruited from two DCSH.

Inclusions criteria:

- Boys and girls in a 10-week residential stay at the DCSH in the age of 7-14 year.
- Informed consent from parents/legal guardian.
- Willingness to participate in training and tests.

Exclusions criteria:

- Participants, of which the scientists do not find, suited to follow the procedures of the protocol and the program for training and testing.

Participants can at all times choose to with-draw from tests, if this is desired or necessary due to illness or injury. All children at the DCSH participate in the training as part of the scheduled program.

The specific reasons to include individuals, who cannot give informed consent, are group C, cf. Comity law §19: "That the project can only be completed by including individuals, whom are in the specific age

group, illness or condition, and that the project have a direct possibility to transfer large positive advantages to the patient population that consist of the same age group, illness or condition as the participant, and that the project involve minimal risk and inconvenience for the child or the young participant". The project can give valuable information on health-related training effects and form the foundation for physical activity recommendations for overweight children in Denmark. The project is also useful for any specific participant, as participants and parents, besides for the training, achieve knowledge about physical capacity and health. Furthermore, there are minimal risks for the participant in relation to the tests, measurements and training.

Statistic and power calculation

The primary outcome of the project is fat percentage, and among the most important secondary outcomes are aerobic fitness, health-knowledge and well-being. The power calculation is based on the result of the pilot project (Ørntoft et al. 2016). The power calculation is measured with t-test. Some variables are expressed in table below and are based on the development on variables from the pilot study and a study with children from the same age group as on the DCSH (Bendiksen et al. 2014). The calculations are based on a power of 0.80 and p-value of 0.05.

Calculation of number of participants (N) in relation to the evaluation on the DCSH standard program and the assessment of activity and health-program (HIHE).

Power calculation	Intervention group (HIHE)	Standard group	IG vs SG	Delta IG SG Sample size
Fat percentage, intervention period	-9.6 (4.2)	-8.9 (3.7)	-0.6 (2.3)	232
Fat percentage, follow-up period	5.0 (13.4)	8.4 (12.9)	-3.3 (11.2)	182
Aerobic fitness	148 (63)	-106 (83)	254 (85)	4
Health-knowledge	11.9 (23.5)	2.6 (23.7)	9.4 (23.5)	100
Muscle mass	0.6 (0.7)	0.5 (0.9)	0.6 (0.8)	29

Number of participants, 1:1 randomisation	Number of participants with 75% at post-tests
464	580
364	455
8	10
200	250
58	73

The calculations are based upon a randomisation of 1:1, 50% of the participants participate in the standard program. Based on the power calculation, the total number of participants is estimated to be approx. 600 children. This is under the consideration of a completion rate of 75%.

All outcomes will be analyzed by means of linear mixed models including two-way interaction between intervention (standard and intervention) and time (before and after) as fixed effect and child and site as random effects (to account for differences between children and between sites, respectively). Adjustment for age, sex, and possibly other covariates/confounders will also be included as fixed effects in the models.

Method

Design

Approximately 600 boys and girls in the age 7-14 years are recruited from two DCSH. The design is a cross-over design at DCSH level over a two-year period with two intervention groups: A standard group (with the standard program (SG)) and a standard + HIHE (SG+). In SG+ the children will, in addition to the standard program, play recreational football 2x45 min. a week. In SG the children will perform the planned activities according to the schedule. The training in SG+ will be performed indoor or outdoor on grass (depending on the facilities on the specific DCSH) with different football exercises (dribbling, ball control, passes etc.) and small-sided games with high intensity (3v3 to 5v5) on two goals. All training sessions take place on the DCSH or in the immediate vicinity of the DCSH. Every week, a specific football skill is connected with a health message. E.g., the skill of passing the ball to each other is related to respect of each other and avoid bullying.

Training protocol

Recreational football

In keeping with studies on as well untrained men as on children (Krustrup et al. 2010a, Andersen et al. 2010; Bendiksen et al. 2012, Ørntoft et al. 2016), the training consists of different football exercises such as passes, shots, dribbling etc., and as small-sided games. The small-sided games are performed as ex. 3v3 on small goals (2x5 m goals).

The risk of injury is markedly higher in football matches (5 times higher) than during football training for young players (Brito et al. 2012). Nevertheless, it is emphasized, that muscle strains and twist injuries in joints also can occur during training on small goals. But the injury frequency for 10 year-old children in football training is approx. 5 per 1000 training sessions, and therefor low (Malina et al. 2006). Furthermore, the FIFA 11 for Health pilot study, including Danish 10-11 year-old school children, did not report any injuries during the training (Ørntoft et al. 2016).

Tests and measurements

The participants will be tested in the start and end of their 10-week residential stay at the DCSH.

Furthermore, there are follow-up tests 3 and 12 months after their stay. The, in total, four tests days include measurements of physical fitness, physical performance, cognitive functions and questionnaires about health-knowledge, well-being and sleep patterns. For further descriptions, see below. Each test day is of approx. 4-5 hours duration.

Measurements

Each test day is planned in collaboration with DCSH staff or parents (the fourth test day) and are performed by a member of the scientific group (Human physiologists).

Anthropometric measurements: Body weight and standing and sitting height are measured with a portable weight (Inbody 720) and altimeter, respectively. Moreover, the Inbody 720 will make an estimate of muscle mass and fat percentage. After a minimum of 10 min. of rest in the supine position in a quiet room, measurements of resting heart rate and blood pressure are performed.

Balance and muscle strengths/horizontal jumping length: Balance performance is measured by the Stork test (Panta et al. 2015). It is measured on both legs, and best out of three trials counts as the result. The children stand barefooted or in one´s stocking feet on the floor. With eyes open and their weight on the entire sole of the supporting foot, arms on the hips, and the not weight-bearing foot are placed on the inside of the opposite knee. When the child has found his/her balance, the heel of the supporting foot is lifted, and the timer starts. Time stops for following reasons:

- Hands/arms leave the hips.
- The supporting foot moves.
- The heel touches the floor.
- The foot, which rests on the knee, is removed from the knee.

Explosive leg strength is measured by standing longitudinal jumping, performed at two-legged offset and landing with arms placed on the hip in the starting position. The start position is behind a line on the floor and landing on a thin mat where the participants are instructed to land on their legs. Distances from the two-legged offset to the point where the rear heel affects the mat, is noted - best

out of 2 trials (Ortega et al. 2008, Reiman & Manske 2009). Standing longitudinal jump is correlated with both upper and lower body strength tests for children and adolescents and can therefore be considered as a general index for muscular fitness (Castro-Pinero et al., 2010).

Aerobic fitness and intermittent performance: The original Andersen interval run test is used for indirect estimation of maximal oxygen uptake (Andersen et al., 2008). The participants run back and forth between cones on a 20m lane and touch the line between the cones at each end. After 15 sec. the participants stops as soon as possible (about two steps) and rests for 15 seconds. This procedure is followed for a total of 10 minutes. The 15 sec. periods are indicated by music that stops during rest periods. All participants start and stop the test at the same time. The distance traveled is recorded as test result. This test has previously been performed in 6-13 year olds, and no risks or adverse effects have been observed relating to the testing performed. The test is also validated for children in the age group 6-13 years (Andersen et al., 2008, Ahler et al., 2012).

Cognitive functions: During the four test rounds, the participants are tested in a computer-based objective cognitive test battery that has been validated and verified in the age group 10-18 years to address children's cognitive functions (Cromer et al., 2015). The battery consists of four tests, which tests reaction time, attention, visual learning and long-term memory, work memory and executive functions (Cromer et al., 2015) - see further description below.

The reaction time is addressed by a 'Detection Test' (Houx and Jolles, 1993). The participant sits with the dominant hand's index finger resting on a yes button on the keyboard. On the screen there is a set of playing cards in a pile facing upside down. When the test starts, the first card turns so that the image page appears. As soon as this happens, the participant must press the yes button. Then the card disappears into the deck and a new card is turned, to which the participant must press the yes button again. The participant will be encouraged to work as fast and as accurately as possible. Response time for correct answers in milliseconds (lower response time = better performance) is the primary outcome that is stored and used in the following analysis.

The participants attention is measured using an ‘Identification Test'. The participant has the right and left index fingers respectively resting on one yes and one no button. On the screen there is a set of

playing cards in a pile facing upside down. The test is initiated and a playing card is turned and is either red or black. The participant must now answer whether the card is red or not by pressing either yes or no button in accordance with the required response. Then the card disappears into the deck and a new card is turned. Response time for correct answers and number of errors are the primary outcome.

Participants 'visual learning are evaluated through a 'One Card Learning Test'. At 'One Card Learning Test ', the participant is sitting with the right and left index fingers respectively resting on one yes and one no button. On the screen there is a set of playing cards in a pile facing upside down. The test is initiated by turning the first card face up. The participant must now indicate whether the card has been shown before in the test by either pressing the yes or no button. Then the card disappears into the deck and a new card is turned. The participant must try to remember all cards shown in the test. The proportion of correct answers and response time are the primary outcome.

The participants 'working memory is addressed through a 'One Back Test'. The participant has the right and left index fingers respectively resting on one yes and one no button. On the screen there is a set of playing cards in a pile facing upside down. The test is initiated by turning the first card face up. The participant must decide whether the card is identical to the previously displayed card by pressing either the yes or no button. Then the card disappears into the deck and a new card is turned. Response time for correct response and the number of errors are the primary outcome.

The testing is done individually in a room by a laptop or desktop computer with internet access. Data collection takes place by participants having a unique username and login, which is entered using a sent link from the investigators. The tests last a maximum of 45 minutes in total.

Metabolic markers: Saliva Tissues collected by a Salivette tube are used to indicate the level of hormone insulin. The insulin level may indicate an increased risk of insulin resistance and type 2 diabetes (Goodson et al., 2014). Spit samples are kept as cold as possible until they can be centrifuged. Samples are centrifuged, supernatant stripped into cryo tubes, stored at -20 degrees, later -80 degrees. Hair samples for the determination of long-term exposure to the biomarker Cortisol, consisting of approx. 100 hairs cut as close to the scalp as possible. It is kept in an envelope until analysis (Suavé et al., 2007).

Health-knowledge and general- and sport-psychological measurements

By means of questionnaires we will, at baseline, at the end of the stay at DCSH and also 3 and 12 months after end of stay, examine the participants' health, well-being / mental health, ego and task orientation, cohesion of participants, stress levels and sleep habits. During the completion of the questionnaires, there will be a test-responsible present to assist in the possible challenges of reading and understanding the questionnaires. Participants' health-knowledge is measured through a questionnaire (Appendix 2) that examines the participants' learning and understanding of the 11 health messages (Fuller et al. 2010, 2011, 2015, 2016). There is a total of 38 questions. The purpose of the questionnaire is to investigate how much participants have learned in each of the 11 health messages in the program.

Participants' well-being / mental health are measured via PedsQL questionnaire (Varni et al., 1999, Appendix 3), as well as using a Kids Screen questionnaire (Ravens-Sieberer et al., 2001, Appendix 4). The questionnaires aim to measure the well-being of the participants. The scale intends to cover a wide range of dimensions in well-being and contains a total of, respectively, 22 and 25 questions. A previous survey has tested the validity of the questions (Nunnally 1978).

Participants' Ego- and task-orientation is measured through the Task and Ego Orientation Questionnaire (TEOSQ; Duda & Nicholls, 1992). The questionnaire contains 13 questions (7 for assignment and 6 for ego orientation), which can be answered on a Likert scale from 1 to 5, where 1 is "Highly Disagreeable" and 5 is "Fully Agree" (Appendix 5). Task-oriented participants emphasize doing their best, experiencing progress and / or improving skills while ego-oriented participants are measuring themselves against the others and emphasizing to be successful and better than others. The questionnaire is validated and translated into Danish. TEOSQ has been used in studies in Danish studies (Thomas et al., 2016).

Participants' cohesion is measured via the Youth Sport Environment Questionnaire (YSEQ, Eys et al., 2009, Appendix 6). The questionnaire contains 12 questions that can be answered on a Likert scale from 1 to 5, where 1 is "Does not fit" and 5 is "Fits completely". Cohesion describes how the participant perceives the class's solidarity to social aspects and the ability to solve tasks in unity (Carron et al., 2002). The questionnaire is validated in English (Eys et al. 2009) and the Danish version has been used in similar studies (Elbe et al., 2016).

The Children's Sleep Habits Questionnaire (CSHQ) is used in the assessment of the participants' sleep habits. The questionnaire is available in several versions (Appendix 7-8), containing 33 or 26 questions for completing by the parents and the child itself, respectively. The questions are answered "Commonly" (5-7 t. Weekly), "Sometimes" (2-4 t. Weekly) or "Rare" (0-1 t. Weekly). The questionnaires clarify sleep habits, sleep disorders and consequences of disturbed sleep (Owens et al., 2000a). The questionnaires are validated in English (Owens et al., 2000b), and CSHQ - parent version has been used in studies in Danish (Hjort et al., 2014). The children's version will be used at baseline, after the 10week residential stay, as well as both 10 weeks and 12 months after the stay at DCSH, while the parent version will be used at baseline and 10 weeks and 12 months after the stay. The children's version (Appendix 8) is attached in English. Before the start of the project, the version will review a translation process into Danish, back-translation into English, as well as pre-testing with 5-10 children, and can thus be used as a self-reporting version.

Participants' stress levels are measured via the Strengths and Difficulties Questionnaire (SDQ). The self-completion version for the children is validated in English (Goodman et al. 1998). The questionnaire contains 30 questions answered with "fails", "fits partially" or "fits well" within the last 6 months (baseline - afterwards it is within the last month). The student version (Appendix 9a + b) will be used at baseline after the stay, as well as both 10 weeks and 12 months after the stay at DCSH (Obel et al., 2004). The questionnaire reveals symptoms in emotional, behavioral, hyperactivity / concentration and social challenges. The questionnaire for parent completion (Appendix 10a + b) was previously used in studies with Danish youth (5-12 years) (Kristensen et al., 2014, Niclasen et al., 2012). The parent version will be used at baseline and 10 weeks and 12 months after the stay.

Other measurements

In addition to the above test days, the following measurements are performed during the high intensity training in the SG+:

Continuous intensity measurements during training

Frequently during the training intervention, activity registrations will be made. There will be measured up to 4 times at approx. 50 participants from both DCSH. Activity registrations include pulse rate measurements (Polar Team 2), GPS measurements and accelerometer measurements to determine

intensity and motion pattern analysis. At the trainings where activity registrations are made, short questionnaires are also provided for measurements of perceived exertion and flow in relation to the training (Elbe et al., 2010, Appendix 11). In relation to accelerometer measurements, there will also be a record of participants' daily activity level and sleep patterns, up to 25% of participants, during the intervention period.

The questionnaires, within the various measurement areas, are based on already tested reliability questionnaires relative to the participant population, cf. the above references. The questionnaires are introduced by a qualified person with relevant professional education, which is also present during the completion of the forms. The answers to the questionnaires are treated confidentially as all other individual results. The participant will not be asked to give up his name and the questionnaires will be coded.

Additional information

Via a parent-filled questionnaire (Appendix 12) knowledge about socioeconomic data, ethnicity, background information and health surveys are obtained. Absence lists, as well as results from school-related tests, are also obtained through the DCSH in order to utilize the large number of participants in various subgroup analyses.

Side effects, risks and disadvantages of the participants

Tests and measurements

Overall, tests and measurements in the study are non-invasive. In relation to the training intervention, football represents an activity that children already do to a large extent in daily life: Children play soccer, running and jumping, etc. Therefore, there are no particular risks considered for these activities. There may, however, be injuries in football training, but the injury rates are low, see section on training protocol.

Biobank

Hair samples and salivary samples are anonymized and stored for total analysis after completion of the test period. All samples are destroyed after analysis. Hair samples are stored at room temperature, and saliva samples on freezer (initially -20 degrees, then -80 degrees).

Scientific ethical statement: Advantages and risks

Football training for 10 weeks is considered to be a training improvement and generally health-enhancing for recruited participants. More generally, it is a declared goal of the study to contribute with information that can form the basis for recommendations regarding health effects of football training for overweight children at DCSH. In relation to paediatric research, the project will be able to contribute with new knowledge about the effects of a health-enhancing model and this society benefit is estimated to exceed the risks for the children in both the training and the various tests.

All training and tests are carried out by staff with the right professional qualifications. The well-being and safety of the participants will be of highest priority. There will therefore be great attention to the well-being of any specific child in carrying out the protocol's procedures, and the child will be excluded from the study if it is considered to be the best for the child, and subsequently the child and his/her parents will be informed of the basis for the decision. As a participant / parent, knowledge of the state of health in the form of blood pressure and the child's physical ability is given in addition to knowledge of intermittent exercise capacity, balance and spring strength. Compared to all these measurements, participants / parents will be able to see how he or she is relative to the average, so that it can be evaluated whether the child is over, below or in line with the standard. Only participants / parents receive the results of the individual measurements. As for the participants in the DCSH with the standard program, they must follow the standard program, and are, through participation, given test results and other information of personal interest.

Personal information

The study is reported to the Data Inspectorate as a public research project under the Institute's Joint Review System, by journal number 2015-57-0008. Information regarding the participants is protected under the Personal Data Processing Act - Personal Data Act and Health Act. All data will be encoded so that participants' results can only be identified by relevant persons. After the intervention period, each participant will have the opportunity to access own data and average data for the entire group. In the consent statement, parents respond to whether the participants/parents want access to their own data within four months after the end of the project. Information that appears in connection with the research project is subject to confidentiality. By publication in a scientific journal, all data will appear in anonymous form. Both positive, negative and inconclusive results will be published.

Authorities, controlling health science research projects have the right to access data; these authorities will also be subject to professional secrecy. All data will be fully anonymized after the end of the project.

The study is conducted in full compliance with the Helsinki Declaration.

Financial aspects

The project is initiated by Peter Krustrup, Professor of Sport and Health, at the Department of Sport and Biomechanics at the University of Southern Denmark and Honorary Visiting Professor at the University of Exeter, England. The project is funded in collaboration between the University of Southern Denmark and the University of Copenhagen. There are rcieved funds from TrygFonden, Helsefonden and Augustinusfonden for manpower and measuring equipment. All external co-financing will be deposited on a SDU research account subject to public audit. If further support is granted to the project in connection with other applications, the Regional Scientific Ethics Committee will be informed of this and the participant information will be updated with the name of the grantor and the amount of support. The updated participant information will be provided to the participants. There is no one in the project group that is affiliated with private companies or funds with interests in the research project.

Remuneration or other benefits

Compensation for transport costs or loss of earnings for the parents is not compensated because all testing and training takes place at the DCSH or in the participants own home.

Recruitment of participants

The participants are recruited from two DCSH. In the project's cooperation agreement, it is specified that two of the DCSH change practice for one year. In this manner, all the children at the two DCSH are participating in the HIHE intervention, regardless of their participation in tests. To investigate the standard program, all tests will be carried out at both of the DCSH for one year. After the first year the two participating DCSH change intervention group. Alongside the general information about the stay at the DCSH, written information about the study will be provided and subsequently an oral information meeting / parent meeting cf. the description below.

Publication of study results

The intention is to publish scientific articles on the results of the project during 2021-2022, including both the short and long-term effect of the DCSH standard program and the effect of the HIHE program. If it is not possible to publish the results in a journal, the results will be published otherwise. The primary test results will also be published in Danish in 2021, partly as a research report in Danish and partly in short format for use in DCSH setting, both in printed and electronic versions. In addition, the plan is to organize at least two seminars on the DCSH efforts and the local follow-up to the DCSH efforts by 2021. Both positive, negative and inconclusive results will be published. The project is registered at www.clinicaltrials.gov

Insurance

The trial participants will be covered by the "Law on Complaints and Compensation Access in the Health Care" Act (see Act No. 1113 07/11/2011 www.retsinformation.dk/Forms/R0710.aspx?id=138893).

Providing oral information and obtaining consent

The potential participants are not yet of legal age, and therefore cannot give their consent for participation in the study without parental consent. Parents of the potential participants will receive written information about the project at a meeting at the DCSH eight weeks before start-up (participant information and the booklet entitled "Experimental Rights in a Health Science Research Project" published by the Scientific Ethics Committee Aug. 2014). Thereafter, an information meeting (8-24 families) will be held at the specific DCSH, with potential participants and their parents, where qualified project staff who have been assigned this task delegated by the project manager provide oral information on the background of the study, purpose, study protocol, methods used and any risks and side effects as well as review the leaflet "Before You Decide" published by DNVK Aug. 2014. These meetings are held every 2 to 3. week at each DCSH. The child will also receive the oral information at a level that fits its age and understanding frame by a project employee with experience in communicating to children, and the child is involved in the conversations with the parents about the study to the extent that the child can understand. The child's opinions will, to the extent that they are relevant, be given importance. It is emphasized that the content of the oral information is disseminated to suit the target group, 7-14-year-old children.

The parents are informed in advance of the oral information meeting that they may bring an observer to this meeting. After submitting the oral information, we offer 1 day's reflection time in relation to the final commitment and signature of the consent statement, but it will also be possible to give consent immediately after the oral information is provided. Deputy consent will be obtained from both custody holders; however, one custodian may give the other proxy to sign on behalf of both. By proxy, it should be clearly stated what the purpose is (participation in the HIHE program at DCSH) and for the duration of the proxy (12 months after the end of the stay at the DCSH). It is emphasized that they can at any time withdraw from the study. The submission of consent to participation in the project is adapted to the other information and consent of the DCSH.

Throughout the process, we will endeavour to have a high level of information to ensure that all parties feel well informed and safe in attending and completing the study. Thus, an electronic video version of the oral information will also be prepared for parents who will see it again at home. Emphasis will be placed on the fact that the children understand that they voluntarily participate, and their parents are giving their consent to their participation, that they can stop their participation at all times without giving reasons and that this will have no consequence for them. We are aware that there may be pressure on a participant, for example, if he/she is the only one at the DCSH that does not want to participate in the study. From the project team, we will do what is possible to ensure that no one feels pressured to participate. This aspect will also be addressed in the oral information.

No project-related procedures are performed until there is proper consent signed by the parent / authority owner, project manager or project officer who has been delegated the task by the project manager. The test participant / parents are offered a copy of the consent statement.

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