The Effect of Increased Physical Activity on Adolescent's health and Academic Performance:

The School in motion "ScIM"

Study protocol

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1.0 INTRODUCTION

As part of creating a better knowledge base for future work on physical activity among adolescents, the "Folkehelsemeldingen - Mestring og muligheter" has defined a trial with a selection of secondary schools where students will receive about four hours of physical activity and physical education during the week.[1] The experiment should be organized so as to best study the effects of increased physical activity (PA) and/or physical education (PE) on the participants physical and mental health, learning and learning environment and, if possible, how it affects the development of PE as a subject.

The main aim of this project is thus defined to find models of PA/PE that can be used in Norwegian lower secondary schools. These models are intended to have an impact on the adolescents' physical health, mental health, learning and learning environment. The fact that the intervention models should affect four different outcomes will make this project very challenging. However, as we face a global trend with increased prevalence and premature deaths caused by non-communicable diseases such as cardiovascular disease, type 2 diabetes, chronic lung disease and cancer this project is timely. Worldwide, these diseases cause two thirds of all deaths and one of four deaths among those below 60 years of age. Non-communicable diseases are partly due to increased sedentary lifestyle,[2] and physical inactivity is defined as a significant public health problem for people of all ages.[3] Globally, physical inactivity is referred to as one of the four leading causes of mortality.[2] According to the World health organization, 10% of all deaths in Europe are related to inactivity.[4] In May 2012, the World Health Assembly (WHA) adopted the target of reducing premature death of non-communicable diseases by 25% by 2025. WHO has identified four overall indicators and targets to reach this target. One of the goals is that the proportion that is physically inactive should be reduced by ten percent.

Among adults, the literature shows a strong association between physical activity and the risk of non-communicable diseases,[5,6] however, this relationship is not as clear among children and adolescents.[7] This might be due to the fact that these diseases usually manifest in adulthood. At the same time, pathological processes are known to start already in early childhood,[8] and cross-sectional studies show that physical activity is related to risk factors for non-communicable diseases already at a young age.[9-11] Furthermore, a review has shown that physical activity interventions carried out in the primary school affects some components of physical health.[12] However, it is important to emphasize that this knowledge is inadequate among adolescents in upper secondary school. Early adolescence is characterized by major biological, psychological and social challenges. Results from the "ungdata" report show that the proportion reporting mental disorders in adolescence is high and that the extent of mental disorders increases through adolescence.[13]

The main aim of this study is to investigate whether participation in this project leads to increases in objectively measured physical activity level in 14-year-old boys and girls after a one-year school-based physical activity intervention compared to the control group.

In addition, secondary aims are to investigate whether participation in a one-year school-based physical activity intervention results in changes to the following outcomes when comparing the adolescents in the intervention groups with the adolescents in the control group:

1. Higher objectively measured moderate-to-vigorous physical activity (MVPA)
2. An increase in the proportion adolescents meeting physical activity guidelines (measured objectively)
3. Reductions in time spent sedentary (measured objectively and self-reported).
4. Improvements in muscle strength and cardiorespiratory fitness
5. Improvements in mental health variables including overall psychosocial problems and strengths, quality of life, self-evaluation of competence or adequacy and symptoms of anxiety and depression.
6. Improvements in academic performance in reading and numeracy.
7. Improved learning environmen

2.0 METHODS

School in motion (ScIM) is a school-based cluster-randomized controlled trial (RCT) with three arms. The study last two years, where the first year is used to pilot the models, and the RCT will be completed in the school year 2017-18.

The study is initiated by the Norwegian Directorate for Education and Training.

2.1 Design

Adolescents in 9th grade will be invited to participate in the study. This is a multi-center study and four universities and colleges in Norway are included (Norwegian School of Sport Sciences, Sogn and Fjordane University College, University of Agder and University of Stavanger). The Norwegian School of Sport Sciences is the coordinating unit.
Schools located in municipalities in the geographical area around the four universities will be invited to participate. This will be a cluster sample with schools as the primary unit. When a school agree to participate, all adolescents in 9th grade will be invited to participate in the study. After inclusion, schools will be randomly allocated to either one of the intervention arms or the control arm. The randomization will be conducted by a neutral third part not affiliated with the project team.

Some schools already arrange for extended time for physical activity during the school day. Schools that already are working systematically with PA or extended PE as an integrated part of their curriculum will be excluded from participation in the study. However, this does not apply to schools that have organized specific events e.g. activity days, school tournaments and mountain hikes.

The project was reviewed by the Regional Committee for Medical and Health Research Ethics (REK) in Norway, who according to the Act on medical and health research (the Health Research Act 2008) concluded that the study did not require full review by REK. We will therefore apply for approval from The Norwegian Social Science Data Services (NSD) for permission to collect personal data. From an ethical point of view, upper secondary school pupils are not able to give valid consent to participation in surveys. We will therefore obtain written consent from the pupils' parents/caregivers before inclusion in the study. Both parents/caregivers and the adolescents will receive information about the goals of the study, any disadvantages or discomfort that may arise, that participation is voluntary and that they may withdraw from the study at any time and without justification.

2.2 Intervention models

The planned intervention will be implemented during one school year. The schools in the two intervention arms will provide one extra hour each week to do physical activity. In addition, these schools will also redistribute 5% of the remaining hours of the school week to one extra PE-lesson each week.

The schools randomized to the intervention arms are allocated to one of two models.

The first model is called **"Physical Active Learning"** and consists of the components:

- *Additional physical education*: All activity will be conducted in accordance with the current curriculum. The school's physical education teacher will lead this activity.
- *Physical active learning*: The curriculum of the subjects (i.e. maths, English, Norwegian) will be taught in a physically active manner. The term "Physical active learning" should be stated on the pupils' schedule as 30 minutes per week, preferably not on the same day as the PE-lessons. This activity should be led by the teacher of the current subject.
- *Physical activity*: Without a connection to any specific subject "Physical activity" should be performed 30 minutes a week, preferably on days without PE-lessons and physical active learning. A teacher in collaboration with the pupils should lead the activities, and pupil involvement should be emphasized. The activities should be joyful, and the pupils' well-being should be in focus.

The second model is called **"Don't worry-Be happy"**, and is also based on two extra lessons of PA and PE each week. The lessons must have their own names not associated with PE or PA. Examples of such terms are "don't worry" (PE) and "be happy" (PA).

The Be Happy lessons are self-organized activity groups of at least three pupils, developed according to activity preferences. In the initial phase of the model, the pupils should, in collaboration with the teachers, discover different activity contexts for the "be happy" lesson. The main aim of this phase is that all pupils should be able to find a desirable activity context. Examples of activity contexts are dance/choreography, traditional sports, outdoor activities, drama, yoga and hiking groups. An activity context should be defined as a group of young people who will develop and exchange interests and values with peers through a clear form of activity during school hours (and possibly beyond school hours). They will develop goals for the activity, as well as both annual and period plans for the activity. The social dimension of friendship in motion should be central in all groups. The "don't worry" lesson should take place within the class (like other PE lessons), but this lesson should be related to the "be happy" activities. The adolescents work individually or in smaller groups with the teacher as support.

2.3 Outcome measures

All participants will be tested at baseline and at the end of the intervention period. The variables are described below.

In this project, **physical health** is defined as good bodily health achieved through a balance of regular physical activity, ability to perform daily activities with excess and the presence of physiological features and qualities associated with low risk of developing lifestyle diseases and disorders.

- **Physical activity**

Physical activity is the main outcome variable. The participants physical activity level will be assessed by ActiGraph accelerometers (model GT3X+) (ActiGraph, LLC, Pensacola, Florida, USA). The GT3X measures acceleration in three individual plans of motion. ActiGraph accelerometer is widely accepted as a valid and reliable too for measuring physical activity in adolescents.[14-16]. Participants will be asked to wear the accelerometer at the right hip for seven consecutive days. Outcomes for physical activity levels are mean physical activity level (counts/min) and time spent in different PA intensities using established cut-offs (sedentary time, light physical activity, moderate physical activity, moderate-to-vigorous physical activity and vigorous physical activity). Further, a questionnaire will be developed to gain information on type of activity that is performed as well as information regarding the activity context.

- **Health-related physical fitness**

Health-related physical fitness is defined as physiological features and qualities that are associated with low risk of development of lifestyle diseases and disorders and include components such as cardiovascular fitness, muscular endurance, muscular strength and body composition.

Cardiorespiratory fitness

Cardiorespiratory fitness is one of the most important components of the term health-related physical fitness and studies clearly shows that individuals with good cardiorespiratory fitness have better physical health compared to those with poorer cardiorespiratory fitnes.[17-19] Cardiorespiratory fitness will be measured with an intermittent practicable running field test (the Andersen-test).[20,21] The Andersen-test is a practical field test that requires minimal equipment and is of low cost. It is particularly practical in a school setting because it is easy to administer and a relatively large number of participants can be tested at the same time. The use of endurance tests to exhaustion has previously been used in large population studies in Norway[22-24] and experience indicates that there is a low dropout from such tests. The participants will run from one end line to another (16 m apart) in an intermittent to-and-from movement, with 15-seconds running and 15-seconds breaks (standing still) for a total of 10 minutes. The distance covered (in meter) will be recorded as the outcome for analysis.

Muscle strength

Muscle strength is required to move the body, and the level of muscle strength can affect both the activities of daily living as well as the inclination to participate in various types of activities. Recently, research has also shown that muscle strength is an important factor in prevention of development of chronic diseases among adults[25], and muscle strength have also been associated with risk factors for non-communicable diseases among children and adolescents.[26] Therefore, muscle strength is an important part of an individual's health-related physical fitness and the participant's (sustained, isometric and explosive) muscle strength will

be measured using reliable and validated tests from the EUROFIT test battery: i) Abdominal strength and endurance: sit-ups, ii) Upper body isometric strength: handgrip strength, and iii) Lower body explosive strength: standing long jump.

*Anthropometr*y
Overweight and obesity is a strong predictor of chronic diseases such as high blood pressure, poor lipid profile and type 2 diabetes. Furthermore, we know that placement of adipose tissue is of major importance for disease development. Abdominal obesity is considered as a better measure of risk of developing chronic disease than body mass index.[27] The following anthropometric measurements will therefore be included: participants' height, body weight and waist circumference. From each individuals height and body weight, their body mass index will be calculated.

MENTAL HEALTH concerns whether a person manages to use his cognitive and emotional skills to function in society and meet everyday demands. In research literature, mental health is often related to the chosen goals of mental health. In this study, the aim is to measure mental health by both symptoms of various mental disorders and quality of life that deals with physical and emotional well-being, self-esteem and relationships with family, friends and school. When selecting instruments for measuring mental health, the best instruments for this age group with official Norwegian translations have been chosen.

- **Strength and Difficulties Questionnaire (SDQ)**

The Strength and Difficulties Questionnaire (SDQ) will be used. This is a short screening tool for assessing young people's mental health.[28] The instrument has 25 questions and covers five scales (emotional, conduct, hyperactivity, peer problems and prosocial behavior). SDQ has previously been used in both population-based and clinical studies in several countries (Youthinmind) including Norway.[29,30]

- **Hopkins symptom check list (HSCL)**

Hopkins symptom check list (HSCL) will also be included in the questionnaire. HSCL is considered as a good tool for mental health surveying, and the short version consisting of 10 questions is included (HSCL-10). Each question is answered on a four-part scale: "not bothered", "a little bothered", "quite bothered" and "very bothered". Not bothered gives 1 point, while very bothered gives 4 points, and when the points are summed, a score between 10 and 40 is gained where 40 means very bothered.

- **Quality of life**

KIDSCREEN is a questionnaire that measures health-related quality of life in children and adolescents aged 8-18 years. In this study KIDSCREEN-27 is used that includes five Rasch scaled dimensions: physical well-being, psychological well-being, autonomy & parents, peers & social support and School Environment. The questions are answered on a five-point Likert scale that indicates either the frequency or intensity of a behavior or feeling.[31] This instrument has also been used in the Active Smarter Kids (ASK) study.[23]

- **Self-evaluation of competence or adequacy**

The Norwegian revised edition of Harter's Self-Perception Profile for Adolescents (SPPA) will be used.[32] The instrument contains 35 questions, and the questions are related to scholastic competence, social acceptance, athletic competence, physical appearance, romantic appeal, close friendship and global self-worth. Each question is answered on a 4-point scale indicating whether the statement is really true, sort of true, sort of un true or really untrue for the participant.

LEARNING is often defined as a relatively lasting change in experience and action as a result of past experience, and it is often distinguished between learning as a process and as a product. Research on how children and young learn are many and varies depending on the theoretical starting point for understanding learning, eg. whether it is behaviorist, humanistic, cognitive, or socio-cultural learning theories. In today's school, in-depth learning, metacognition and that the pupils themselves contribute to their own learning are central concepts.

- **The Pupil Survey**

The pupil survey is part of the national quality assessment system, and it contains questions related to learning and well-being at the school. The survey is compulsory for pupils in 7th grade, 10th grade and at upper secondary level 1 and optional for the rest. The Directorate of Education and Training is responsible for carrying out the survey. In the pupil survey, it is possible to identify the pupils personally, and we will apply to receive data from the national educational base. The questions of interest are, among other, those that concern the well-being of the pupils at the school, motivation, working and learning condition, support from teachers, pupil participation and school environment.

- **Academic performance – national tests**

Academic performance in reading and numeracy will be measured using specific standardized Norwegian National tests designed and administrated by The Norwegian Directorate for Education and Training. The tests are carried out during the fall semester for pupils in the 8th and 9th grade. The Norwegian Directorate for Education and Training will assist in designing an appropriate test that can be used post intervention.

- **Marks**

The use of marks in lower secondary school is authorized in the Regulations for the Education Act, and the pupils receive in numerical grades from 1-6 in the various subjects. The mark shall be determined on the basis of an assessment of the pupil's competence based on the competence goals set in the curriculum for the individual subjects. In the questionnaire we will ask students about grades in central subjects.

LEARNING ENVIRIONMENT can be defined as the total cultural, relational and physical conditions in the school that are important for the pupils' learning, health and well-being.[33]

The Classroom Climate Scale instrument will be used to investigate learning environment. This is a form consisting of 22 questions answered on a 4-point scale. The questions are

related to intrinsic and extrinsic motivation, anticipation and teacher-student relations.[34] Teachers will also answer a teacher's version of this form, which consists of 14 different questions.

2.4 Data collection

Data will be collected both objectively and through a self-reported questionnaire. The questionnaire will include questions about background factors, type of activity, transport to and from school, as well as sedentary behaviour (sedentary activities, PC and TV habits). There will also be questions related to sleep and health habits such as smoking and alcohol use.

The data collection will be school-based and the various tests will be carried out during school hours. A team of experienced testers will visit the participating schools to carry out the tests. The computer based questionnaire will also be answered during school hours. All pupils participating in the study will be tested before the intervention starts and at the end of the intervention period.

2.5 Power calculations and statistical analysis

Power calculations are done to examine how many participants it should be in each group, if a given difference between groups should be significant at a given level (for example, $p < 0.05$) and with a given power (for example, 90% probability of rejecting a false null hypothesis). The required size of the sample depends on how small differences one can detect over time, as well as how large the variation of the current variable is in the population.

In this project, the power calculations are based on the main outcome variable (mean physical activity level [counts/min]). As can be seen in table 1, the number of participants required to detect a specific difference between the groups increases significantly the smaller the difference. Data for SD and mean value of the physical activity variable is based on previous studies conducted in the Norwegian adolescent population.[35] The power calculation is performed as a two-sided calculation with an $\alpha = 0.05$ and $1-\beta = 0.9$. Since this is a cluster sample, the sample size is adjusted for an inflation factor that will be determined by the number of members in the cluster and the intra-class correlation. The correlation is assumed to be small as the cluster is school, therefore the inflation factor is set to 1.1.

Table 1. Power calculations based on the main outcome variable (physical activity expressed as mean counts/min). The column "minimum difference" refers to the level of difference that can be detected between groups.

Variable	Minimum Difference	Variation (SD)	N
Physical activity level (accelerometer)	10 % (70 counts/min)	150 counts/min	246
Physical activity level (accelerometer)	7 % (49 counts/min)	150 counts/min	492
Physical activity level (accelerometer)	5 % (35 counts/min)	150 counts/min	984
Physical activity level (accelerometer)	3 % (21 counts/min)	150 counts/min	2706

In this project, it was considered important to be able to detect (or reject) 7% differences in the mean physical activity level between the intervention and control groups. This meant it was necessary to examine 492 pupils in each group. Further, during the trial a drop-out rate of 20% at the individual level should be expected, consequently 590 individuals in each group should be included. However, there should be at least 10 schools per intervention arm (ie per model to be tested) in order for the randomization to have effect. The strategy is then to include schools up to at least 10 schools per intervention arm, and a minimum of 590 individuals will be included in each arm.

Data will be described with suitable measures of central tendency and variability, along with confidence intervals. Mixed models with school as random effect, adjusted for class, individual and baseline values, will be used to investigate the difference in the different variables when comparing the pupils in the two intervention groups with the pupils in the control group. By building up a mixed model, all participants who have data at baseline and everyone who has data at the post- test is included, and thus all data in the project are utilized. Further, per protocol analysis will also be conducted. In these analysis, participants in schools that completed at least 80 % of the intervention program will be compared with the pupils in the control group. A two-sided p-value < 0.05 is considered statistically significant.

3.0 PILOT STUDY

During the school year 2016-17, this project will be pilot tested. One of the main goals is to pilot the implementation of the two intervention models, in addition it will include piloting the measuring instruments and the various tests/examinations. It will also be a test of the logistics with regards to inclusion of participants, collection of data and processing of data, so that when the RCT is rolled out during fall 2017, the actual intervention will have been thoroughly tested. Implementation research suggests that successful implementation of a school-based intervention requires that the researchers include partners at an early stage, and stakeholders (school leaders, teachers, pupils and parents) should be active participants in the development of design, implementation and dissemination of the intervention model.[36] Interventions are more likely to be successful when most or all individuals in the setting are committed to the intervention and feel ownership for it. In particular, experience from previous studies shows

better implementation of school-based interventions if the school is committed to the intervention through national, regional and local school policies. Therefore, the pre-planning phase as well as the implementation of the intervention models are an important part of the pilot study.

Six schools in the Oslo area will be included in the pilot study. There is assumingly around 100 pupils in 9th grade at these schools, which means that approximately 600 pupils will be invited to participate. The sample in the pilot study will be a convenience sample. In the pilot study, each intervention model will be tested in two schools (a total of four schools) and two schools will be included as control schools. The two intervention models are planned to be implemented over 16 weeks, and the pupils will be tested both pre- and post-intervention.

4.0 IMPLEMENTATION

According to implementation research, four essential phases are important to achieve a successful implementation of extended physical activity at the lower secondary level.[36]

1) **Pre-planning**
   This project is initiated and has support from key stakeholders including the Ministry of Education and Research and the Ministry of Health and Care Services. Close cooperation with the aforementioned authorities can give the project group valuable access to established meeting places for dialogue with national, regional and local school policy bodies, the school health service, the parent committee for primary education and school leaders at the selected schools. In addition, the school management must feel committed to participation in the study as they play a crucial role in the successful implementation of health promotion measures both as initiator, and as responsible organizational facilitator.[37] The teachers also play a key role in the pre-planning phase.

2) **Planning of the program and activities**
   There will be arranged focus groups with pupils where the aim is to develop an understanding of what preferences they have when it comes to both type of activity and the context where the physical activity should take place. This will ensure pupil participation, and consequently the target group prefers the content of the program. Through information meetings and training of teachers, the aim is to improve adherence to the program from key personnel (principals and teachers).

3) **Program delivery**
   In this phase, the planned program is implemented. It is important to make sure the program is included in the school's curriculum. Teachers are an important factor for program delivery, and training of teachers will be performed. Further, parents are important and they will be invited to information meetings at the school. At these meetings written and oral information about the project will be provided, and they will also be informed of potential risks or discomfort when participating in the study.

4) **Monitoring and evaluation of the implemented program**

In this phase, the program will continuously be evaluated to assess whether the program work as planned. School leaders and teachers will through logbooks, questionnaires and interviews provide data related to; 1) the extent to which the program and its elements is implemented as planned (fidelity); 2) how much of the program is delivered (dose delivered); 3) how well different program components are delivered (quality); 4) how responsive participants were to the program (responsiveness); and 5) changes made to the program during implementation that enhance its fit with the context (adaptation). Furthermore, parents and pupils will be asked general questions about the school's communication on physical activity and in addition there will be specific questions for participants in the intervention groups about the dosage of the program and the utility value of the various components.

All of these sub-elements will create a common understanding of the premises of the project and thus create a mutual commitment to the implementation of the program. This approach allows a certain degree of local adaptation of the program to ensure implementation, while at the same time there is a need to limit local variation from a research perspective. Good dialogue enables both conditions.

5.0 PROJECT MANANGEMENT, ORGANIZATION AND COLLABORATION

The subject group includes persons from five national research institutions:

- Norwegian school of sport sciences (NSSS)
- Sogn og Fjordane University College (HiSF)
- University of Agder (UiA)
- University of Stavanger (UiS)
- Centre for Child and Adolescent Mental Health, Eastern and Southern Norway (RBUP)

Researchers from the Department of Sports Medicine, NSSS, will coordinate the study. There will be a working group consisting of the most central researchers:
Elin Kolle (primary investigator, NSSS), Sigmund Anderssen (NSSS), Reidar Säfvenbom (NSSS), Ulf Ekelund (NSSS), Jostein Steene-Johannessen (NSSS), May Grydeland (NSSS), Geir Kåre Resaland (HiSF), Sveinung Berntsen (UiA), Sindre Dyrstad (UiS) and Åse Sagatun (RBUP). This group will meet regularly during the study period.

All contributors will be included to a greater or lesser extent in different phases of the project. For example, some will only be involved in the planning phase and selection of measurement methods for the different outcome variables, while others will mainly participate in the implementation of the programs.

Employees at the National Center for Food, Health and Physical Activity will also be a part of the project group. The project will be completed in close collaboration with the working group at the Norwegian Directorate for Education and Training.

6.0 QUALITY ASSURANCE

The researchers involved in this project have extensive experience in carrying out major research projects. This in itself contributes as a basis for good routines for quality assurance of the various phases of the project. Valid and reliable assessment instruments will be used, and all involved personnel will conduct extensive training. To reduce measurement errors, a multi-level quality control is added:

a) All assessment instruments will be calibrated according to specific procedures.
b) A detailed manual for the data collection procedures is prepared. When using an accelerometer to measure physical activity, a template is prepared for programming and downloading data. If some employees in the project group team quit their job during the project period, they will be replaced as soon as possible. The project group as a whole has broad experience and somewhat coherent knowledge; this means that if a leading person in the project quit the job, others can take over this role.
c) In order to control systematic measurement errors, either due to different test personnel or different test instruments, systematic inter- and intratester tests will be performed
d) The use of electronic questionnaires reduces the risk of data entry errors.

All sensitive data (digital and non-digital) generated through the trial are confidential and will be processed in accordance with standards set by the Data Inspectorate and in accordance with the Act on Health Research and the Personal Data Act. Appropriate data protection measures will be applied to ensure total confidentiality of computer files. The project group have extensive experience and professional expertise in protection of data using database structures. In this project there is a strive for a population-based approach that focuses on and treats, all pupils equally and thoughtfully, regardless of race, gender, size or form.

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