BMJ Open

Active Play in After School Programs -development of an intervention and study protocol for a matched-pair cluster-randomized trial assessing physical activity play in after school programs

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-016585
Article Type:	Protocol
Date Submitted by the Author:	24-Feb-2017
Complete List of Authors:	Riiser, Kirsti; Oslo and Akershus University College of Applied Siences Helseth, Sølvi; Oslo and Akershus University College of Applied Siences Ellingsen, Hanna; Sandefjord Municipality Fallang, Bjørg; Oslo and Akershus University College of Applied Siences Løndal, Knut; Oslo and Akershus University College of Applied Siences
Primary Subject Heading:	Public health
Secondary Subject Heading:	Paediatrics
Keywords:	Children, Physical activity, Play, After school programs, Intervention

Active Play in After School Programs -development of an intervention and study protocol for a matched-pair cluster-randomized trial assessing physical activity play in after school programs

Kirsti Riiser
Department of Physiotherapy, Faculty of Health, Oslo and Akershus University College of Applied Sciences, Oslo, Norway

Sølvi Helseth
Department of Nursing and Health Promotion, Faculty of Health, Oslo and Akershus University College of Applied Sciences, Oslo, Norway

Hanna Ellingsen
Department of Family Health Services, Municipality of Sandefjord, Norway

Bjørg Fallang
Department of Physiotherapy, Faculty of Health, Oslo and Akershus University College of Applied Sciences, Oslo, Norway

Knut Løndal
Department of Primary and Secondary Teacher Education, Faculty of Education and International Studies, Oslo and Akershus University College of Applied Sciences, Oslo, Norway

Corresponding author
Kirsti Riiser
Department of Physiotherapy, Faculty of Health
Oslo and Akershus University College of Applied Sciences
PO Box 4 St. Olavsplass
N-0130 Oslo
Norway
Email: kirsti.riiser@hioa.no
Tel.: +4767236173

Word count: 4182

ABSTRACT

Introduction: Interventions delivered in after-school programs (ASP) have the potential to become a means of ensuring physical activity among young schoolchildren. This requires a motivational climate, allowing for self-determination, based on the activity's character of play. If trained, ASP staff may represent a valuable resource for supporting physical activity play and physical activities in everyday life for all children. Increasing knowledge and supportive skills among ASP staff may also potentially increase their motivation for work. The purpose of this article is to describe the development of the "Active play in ASP" intervention, which aims to promote physical activity among first graders attending ASP, and to present a protocol for a matched-pair cluster-randomized trial (RCT) to evaluate the intervention.

Methods and analysis: Informed by experiences from practice, evidence-based knowledge and theory, the intervention was developed in a stepwise process including focus group meetings and a small-scale pilot test. The Active play in ASP intervention contains a course program for ASP staff to increase their awareness and skills in how to support physical activity through play. In a cluster RCT, the ASPs will be matched and randomly allocated to receive the 7 months intervention or to a control group. Outcomes will be assessed at baseline, after 7 months and 19 months. Physical activity as measured by accelerometer is the primary outcome. The study uses a mixed methods approach to provide rich descriptions of the concept of children's physical activity in ASP. Moreover, the trial will assess whether the ASP staff may benefit from participation in the intervention in terms of increased work motivation. Lastly, we will perform a process evaluation of the intervention.

Ethics and dissemination: The study is reviewed and approved by The Data Protection Official for Research. Results will be presented in conferences and peer-reviewed journals.

Trial registration number: NCT02954614

Strengths and limitations of this study

- *The Active play in ASP is the first randomized controlled physical activity study with a relatively large sample that is performed in an ASP setting in Scandinavia.*
- *The study will apply a mixed methods approach to assess physical activity, providing an extensive insight into children's physical activity in ASP.*
- *A weakness may be that the intervention follow-up throughout the school year is limited to one meeting per month. The decision is made pragmatically due to a consideration of what is realistic should the intervention be translated into routine practice.*
- *Using local school physiotherapists to deliver parts of the intervention strengthens the external validity of the study, but may also increase variation in the results.*

BACKGROUND

Over the last years, increased attention has been centred on relationships between physical activity and children's health and well-being. Physical activity may positively influence a number of health factors (1, 2). Research has also begun to emphasize the role played by children's physical-motor functioning and activity levels in academic performance (3, 4), as well as its effect as a preventive mechanism against antisocial behaviour (5). Another important reason for focusing on children's physical activity levels is the preventive effect physical activity may have on overweight and obesity (6). Perhaps most importantly, physical activity may be a positive source for the development of children's well-being (5). However, as shown in research from the field of sports and physical education, an autonomy supportive and mastery oriented motivational climate is required, allowing for the child's self-determination and the intrinsic values of the activity and the activity's character of play (5). In the present context, the term "physical activity play" refers to such play, incorporating subjective and experienced aspects of movements and self-driven and autotelically oriented activities (7, 8). Physical activity play includes vigorous locomotory movements, stabilizing postures and/or manipulative movements (8, 9). Physical activity, which is commonly described as any bodily movement produced by skeletal muscles that result in energy expenditure, (10) can take place in the household or domestic domain, the occupational domain, the transportation domain and the leisure time domain (11). Physical activity is thus considered a collective term including physical activity play as well as e.g. hiking or more organized forms of sports activities.

There is some evidence that physical activity interventions in school can be effective in increasing the proportion of children engaging in moderate and vigorous physical activity during school time as well as the duration of time spent on these activities (12). However, physical activity in school is often limited to physical education or recesses. Consequently, during school hours, the children are not provided with opportunities to be as physically active as recommended, that is at least one hour of moderate to vigorous physical activity a day (13). Interventions directed at *after-school programs* (ASPs) have the potential to become a means of increasing physical activity among young children (14). No national educational objectives are associated with Norwegian ASPs. In contrast with the sports-dominated extracurricular physical education in several other European countries (15), Norwegian ASPs are expected to stimulate self-managed activities in the children's leisure time (16). Thus, the stage is set to provide various content appropriate to the interests of the children, for example various types of physical activity. As 62% of first to fourth graders and as many as 81% of first graders attend ASP, a large proportion of children in the relevant age group can be reached. Results from previous research in Norway show that children's physical activity during their stay in the ASP is extensive when they have time devoted to child-managed play outdoors (16, 17). Nevertheless, some children fall by the wayside, and this may hamper their activity level and their well-being (18). It also seems to be a trend that activities in ASPs are more organized than earlier (19). The staff are more engaged in arranging and managing various activities for groups of children, and their opportunities to attend to child-managed activities have diminished. This has weakened their possibility to initiate child-managed movement play among the least active children (19). It seems to be particularly important for the ASP staff to develop pedagogic skills in order to provide adapted frameworks for *all* children's physical activity, in addition to provide child-managed physical activity play (20, 21). Thus, it is essential to know how to support such play. If trained, ASP staff members may represent a valuable resource for supporting physical activity play and other forms of physical activities in everyday life for all children. Another potential benefit of an intervention addressing increased knowledge and skills among ASP staff is that the staff may experience a boost in their work motivation. This has previously been shown to be the case among physical education teachers (22). Physiotherapists have an essential role in the delivery of primary health care to

children and adolescents in Norway (23). Within a school health context the physiotherapist initiates and participates in tasks focusing on health promotion, disease prevention and interventions that improve or maintain fitness, health and well-being. Their role includes provision of education and consultation with other professionals in the child's environment, making physiotherapists important contributors to an ASP based physical activity intervention. Few, if any, studies have evaluated efforts concerning the use of physical activity play as a health promoting strategy involving school physiotherapists.

AIM

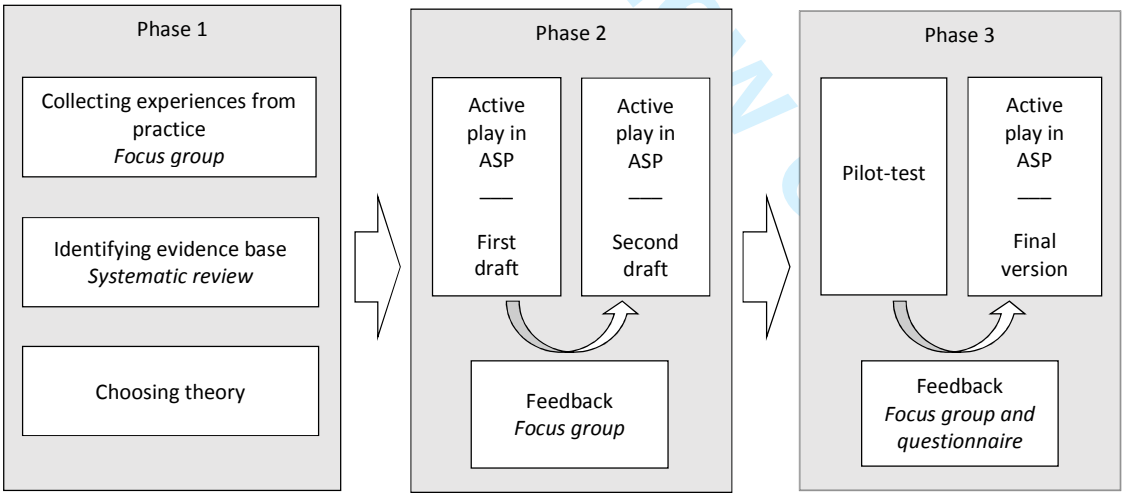
The purpose of this article is to describe the development of the Active play in ASP intervention and to present a protocol for a matched-pair cluster-randomized trial. The Active play in ASP intervention comprises a course program for increasing knowledge and supportive skills among ASP staff. The aim of the planned trial is to assess the immediate and long-term (one-year) efficacy of the intervention on first graders' physical activity in the ASP and their well-being, conceptualized here as quality of life. Moreover, we aim to investigate the characteristics of first graders' physical activity in ASP and the qualitative aspects of their understanding and experience of the activity. In addition, the trial will explore if the ASP staff can benefit from participation in the intervention in terms of increased motivation and work satisfaction. Lastly, we will perform a process evaluation of the intervention.

METHODS AND ANALYSIS

Development of the intervention

In the *first phase* of the Active play in ASP intervention development, we gathered information from the field, identified the evidence base and chose appropriate theory (Figure 1).

Figure 1 Process of development of Active play in ASP



As emphasized by Craig et al (24), a key question in the development and evaluation of complex interventions is whether the intervention will work in everyday practice. In the present study, we draw on experiences from "Health Promoting ASP", a project previously run in five ASPs in a

municipality in Norway. The project emphasizes healthy food, physical activity and well-being among the children during ASP time. It was initiated by local school physiotherapists in cooperation with school head masters and implemented throughout a school year. The project has been well received by the ASP staff and the school administrations. However, insufficient evaluation makes it difficult to determine the impact on the children's behaviour. In the present trial, we decided to limit the scope of the intervention and focus solely on how to support physical activity. A school physiotherapist from "Health Promoting ASP" and three employees representing three different ASPs participated in a semi-structured focus group meeting to share their experiences and to pinpoint possible barriers to and facilitators for implementation and potential successful outcomes. The focus group meeting was moderated by one of the researchers. Main features of the Active play in ASP intervention, both content and structure, were outlined based on the summary of the focus group meeting.

Parallel to this process, previous research on physical activity interventions in ASPs was systematically reviewed and published in a master thesis (25). The review, which included 17 articles, indicated that ASP interventions emphasizing competence building among the staff can lead to increased levels of physical activity for the children (25). Positive effects on the children's activity level were found only in interventions that incorporated flexible programs that were adaptable to each single ASP. Efficient programs emphasized positive feedback and encouragement regarding physical activity, goal setting and evaluation of measures, development of schedules for physical activity, structuring and administration of the environment and arrangements for physical activity for the children. Highly structured programs (i.e. standardized activity programs) were reported to be more difficult to implement, which may explain their limited effect on children's physical activity. The results of the review echoed the feedback given by the focus group, which also emphasized the value of an adaptable intervention. The focus group members stressed that it is essential to develop an understanding of how each ASP is organized. Contextual factors and professional experiences need to be acknowledged and included in the implementation process.

In this first phase, we also decided on a theoretical framework. *Self-determination theory* (SDT) is frequently utilized in health behaviour research as well as in educational research and was considered appropriate in the context of children's activity play. The theory has relevance for understanding motivated physical activity engagement. It emphasizes that being motivated by self-determined reasons leads to greater engagement and well-being than being motivated by controlled reasons (26). Self-determined motivation is associated with positive outcomes in children such as exercise behaviour, quality of life and a positive self-concept (27). According to SDT, social environments that support the individual's basic psychological needs (autonomy, competence and relatedness) will foster more self-determined motivation (28). Autonomy reflects the need to engage in activities with a sense of choice, competence represents the feeling that one will be able to accomplish tasks, while relatedness refers to the sense of being understood and respected by significant others (29). Autonomy support, structure and interpersonal involvement can support the basic psychological needs and thus facilitate adoption and maintenance of physical activity (30). Facilitating the children's choices and supporting their free expression are central to basic need support in play. In an ASP context, application of these principles implies that the staff should not intervene in play situations in a commanding or controlling manner, but rather support and gently encourage activities. Simultaneously, the self-chosen and child-managed character of play should be retained (31). In addition to informing the content of the present intervention, e.g. application of theoretically anchored principles for activity support, the self-determination theory has contributed to the modelling of the likely processes of change (32).

In the *second phase* of development, we drafted a course program that subsequently was presented to the same ASP focus group that participated in the initial phase. The group was encouraged to respond to questions regarding the feasibility and usefulness of the intervention. A second draft was prepared building on their feedback. In the *third phase*, the intervention was tested in a small-scale pilot study including two ASPs over a period of 4 months. Along with the piloting of the intervention, we tested all outcome measures and measurement procedures at baseline and post intervention. The staff from the two pilot ASPs provided feedback by answering a short questionnaire with semi-structured questions related to their experience of the intervention. In addition, a strategic sample of three employees from each of the two ASPs participated in two focus group interviews moderated by one of the researchers. The focus group interview allowed the employees to speak more freely about their experiences with the intervention. Only minor changes had to be made to complete the final version.

Intervention content

Active play in ASP is a course program aimed at ASP staff with the intention of increasing their knowledge and skills regarding how to support children's physical activity play. However, providing *activity support* is not merely the responsibility of the employee in interaction with one child or group of children. The program also emphasizes the potentials of *institutional activity support*, reflected in how the ASP is organized concerning time structure (time spent indoors/outdoors), routines and rules, and the ASP's access to and utilization of activity places and equipment. The intervention has the potential to reach all children in the ASP. However, as described later, only first graders are included in the measurements of the trial.

The ASP staff in each intervention ASP will participate in the course program as described below (Table 1). The initial part of the program is led by the researchers. The local school physiotherapist attends and contributes during the initial part (the intro-sessions, mapping and planning) and is responsible for monthly follow-up after the first sessions. Thus, prior to the ASP course program, the physiotherapists are provided with an 8-hour introduction course presenting the intervention and how it is organized, emphasizing their role. To increase fidelity and adherence to the intervention, the physiotherapists receive a detailed workbook outlining the interventions' rationale, content and assignments for the ASP staff.

The ASP course program starts in October with two 3-hour sessions arranged locally at each participating ASP. The sessions focus on children's physical activity in play, friends, activity place, ASP staff's interaction styles, motivation and activity support. The sessions include lectures, theme based discussions and group tasks. The staff are encouraged to give examples from their own practical experience. Moreover, the ASP is mapped to document activity equipment and indoor and outdoor facilities. This information is used as a supplement in the following meetings. Subsequently the staff, supervised by the local school physiotherapist and a research group member, outline how the ASP will include new knowledge and previous experiences in strategies for supporting children's activity play during their time in the ASP. The program continues during the school year with monthly meetings for the staff and the local school physiotherapist where they work on predefined tasks related to physical activity play. See Table 1.

	Component	Content
Introductory course for school physiotherapists	1-day course	Information on the intervention and the physiotherapists' role and responsibilities. Presentation of intervention workbook.
Course program ASP staff	3-hour session	Introduce research-based knowledge about children's physical activity in play. Increase the staff's awareness of how such play can be influenced and supported in ASP.
	3-hour session	Basic theoretical principles of SDT applied to physical activity and physical activity play among children; how to be activity supportive.
	Mapping	Thorough mapping of the ASP equipment and facilities.
	Planning (1-2 hour meeting)	Summary of intro-sessions; how to make use of new knowledge.
	5 meetings (monthly 1-2 hours) led by the local school physiotherapist	Discussions and practical tasks focusing - Motor learning in children - Equipment and environment - Mapping of staff competencies - Inclusion/exclusion in play - How to lead and support activity in groups

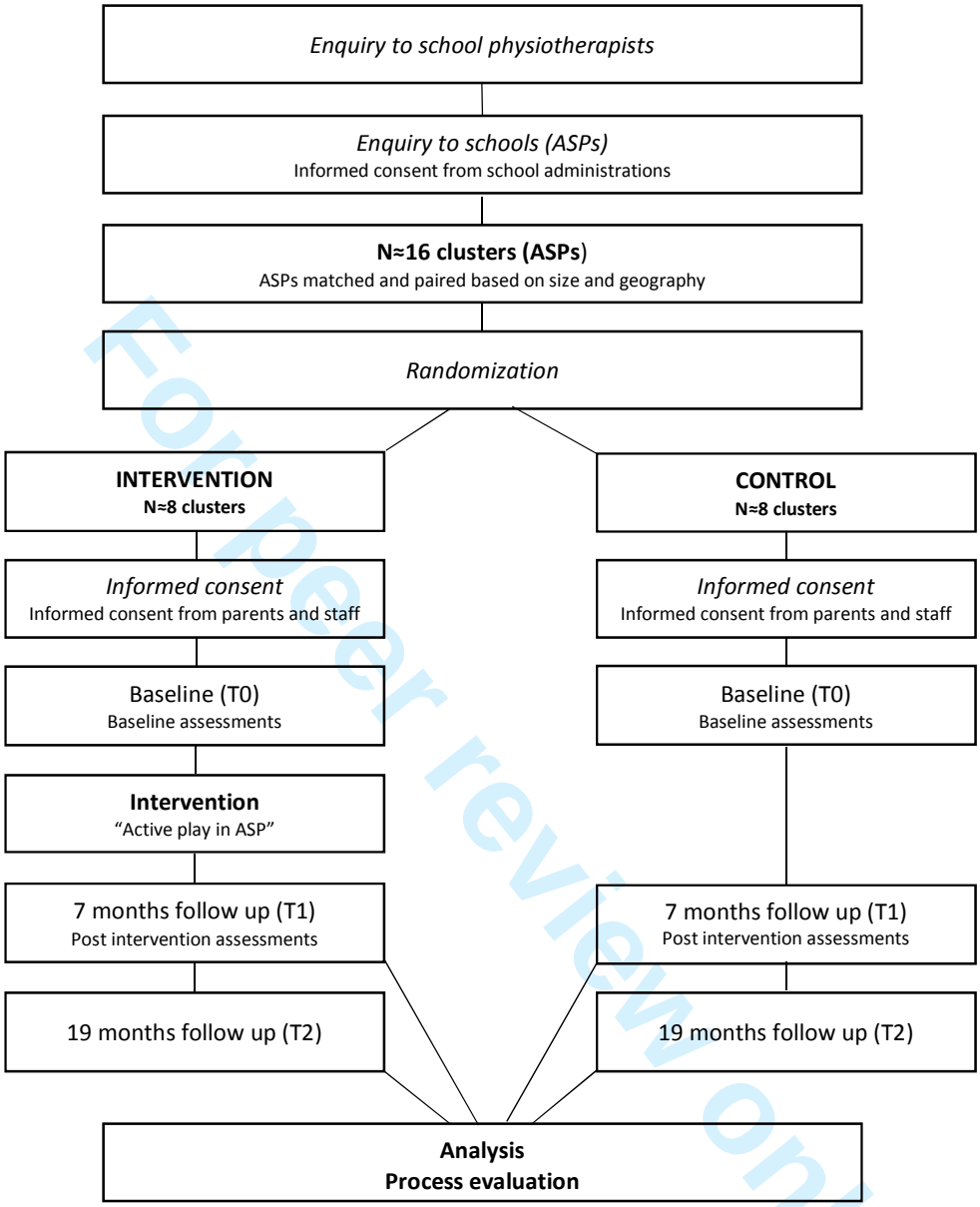
Table 1 Intervention components and course program content

In line with the basic principles of SDT, we also aim to create a supportive context for the staff during the course program. By providing a meaningful rationale for the intervention, acknowledge the staff's feelings, and give opportunities for choice and contribution, their autonomy is supported. Structure is provided through informative feedback, clear expectations and optimal challenges while interpersonal involvement will be ensured by devoting time, energy and affection to the staff before, during and after the course sessions (33, 34). An overview of the trial procedure is outlined in Figure 2.

Study design

The study is designed as a matched-pair cluster-randomized trial utilizing a mixed methods approach. The Active play in ASP intervention is compared to control ASPs, which receive no follow-up in addition to the usual afterschool program. A process evaluation is embedded in the trial (Figure 2).

Figure 2 Flow chart of the study design



Recruitment

The intervention follow-up and the trial rely on assistance from local school physiotherapists. Even though municipalities in Norway are strongly advised to ensure physiotherapy resources for health promotion activities in schools through the school health services, such resources are generally scarce. Thus, as a first step in the recruitment process, school health services in centrally located municipalities (maximum 90 minutes' drive from the study office) in three counties in the eastern part of Norway will be approached and invited to participate. As school physiotherapists are located and have signed up, they are asked to assist in the further recruitment of ASPs in schools within their area of responsibility. School administrators are required to provide written consent to participation.

The consent is obtained before randomization and is considered binding. After randomization, the parents of all first grade pupils attending the participating ASPs are informed about the study and asked for a written consent on behalf of their child. In addition, all ASP staff and physiotherapists will be asked for a written consent to participation in the trial. The control ASPs will be offered the intervention after the study is completed.

Randomization

The clusters, that is the ASPs in the schools, will be paired based on available background information on size and geography. The categories “small”, “medium” or “large” and “urban” or “rural” are chosen based on the assumption that the size of the school with regard to number of pupils as well as space and access to nature areas may have an impact on the children’s activity level. Following matching, tags with the names of the ASPs are put in envelopes and sealed, and then randomly allocated to receive the intervention or to control. While the recruitment, enrolment of participants and the matching of clusters are done by the research team, the person revealing the allocation is not involved in the study. Due to the design of the study, a blinding of trial participants (ASP staff) and outcome assessors is not feasible.

Measures

Measures are obtained at three time points: at baseline (T0), immediately after the 7 months intervention (T1) and one-year post intervention (T2).

The primary outcome of the study will be child physical activity. Because no measure is suitable for assessing both type, amount, intensity, variability, quality and experience of physical activity, several instruments and methods, quantitative as well as qualitative, will be used to capture as much information as possible. Physical activity intensity will be assessed objectively by ActiGraph© accelerometer during the time spent in ASP over a period of one week. The schedule of the day, common activities (duration of different types of activities) and factors that may affect physical activity indoors and outdoors (number of staff, weather, special events) will be logged daily by ASP staff during the week of accelerometer measurements. Moreover, a sub sample in each ASP will be directly observed. Registrations of both quantified physical activity (type, intensity, duration and frequency) and rich descriptions of physical activity during a day in ASP will be performed. Self-reported leisure time physical activity will be measured by the UngKan2 questionnaire. The questionnaire will be completed electronically by the child in cooperation with parents (35). Finally, qualitative interviews will be performed post intervention with a subsample from each cluster in the intervention group. The interview will focus on the children’s experiences with physical activity in the ASP.

Secondary outcomes include the child’s experience of being in the ASP. Items are adjusted from a questionnaire from the Norwegian part of the Health Behaviour in School-aged Children (HBSC) study (36). The items are chosen based on how they correspond with key concepts of SDT. The questions are answered electronically by the child in cooperation with the parents. Furthermore, child well-being, in this study conceptualized as health-related quality of life, is assessed by the Kidscreen-27 proxy version and obtained electronically (37). Additionally, the children’s height and weight will be measured and body mass index (BMI) calculated (38).

For evaluation of if and how the intervention may benefit the ASP staff, self-report instruments will be used for assessing their work-related basic needs satisfaction (39), motivation for work (40), job satisfaction (41) and subjective well-being (42). At baseline, the staff will also be asked to report age, sex and duration of employment in the current ASP.

A process evaluation will be performed at the end of the intervention in order to evaluate how the ASP staff in the intervention group and the physiotherapists experienced participation. All ASP staff from the intervention ASPs will be asked to complete a short questionnaire including questions on the experience of participation, potential obstacles, gains and improvements. 3-5 staff members from each cluster will be asked to participate in semi-structured focus group interviews exploring views on impact of the intervention on the children, the ASP in general and on the staff. They are also asked questions regarding potential improvements. All physiotherapists will be invited to participate in a similar focus group.

Sampling

A rough estimate of the required sample size is based on the primary outcome physical activity as measured by ActiGraph© accelerometer. Due to the exploratory nature of our study, we keep the significance level alpha at 1% and power at 90% to correct for multiple testing. All tests will be two-sided. Based on the results of our pilot test and previous studies (14, 43), we consider 6 minutes increase in moderate and vigorous physical activity (MVPA) to be of clinical importance, which represents 10% of the one hour of MVPA recommended by the guidelines. Based on the above, we estimate N to be 121 in each group without accounting for cluster effects. We plan to enrol 200 children in each group to secure sufficient power for additional analyses on cluster level. With an estimation of a minimum of 25 first graders in each ASP, we will have to include a maximum of 16 ASPs.

For the observations, a sample of three children from each cluster will be drawn. Initially, the children are stratified based on gender to ensure equal distribution of boys and girls.

The children eligible for selection for the qualitative interviews will be in the intervention group. A roughly estimated sample size would be 16-20 children with 2-3 children from each ASP. A strategic sampling aimed at maximum variation according to gender and ethnicity is an appropriate sampling procedure.

The expected number of participating ASP staff depends on the size of the ASPs that accept the request for participation. A rough estimate is 8-10 employees per ASP, yielding a sample of approximately 150.

Analysis

The differences between the intervention group and the control group will be assessed by repeated measure analyses using linear mixed models for repeated measures as implemented in SPSS. This approach is flexible and it is possible to model the dependence between observations from the same individual. A possible cluster effect will be accounted for in the model as a random effect.

The observations will be analysed and presented with descriptive statistics in addition to text summaries. Qualitative interviews and field notes from the observations will be analysed by systematic text condensation, implying a hermeneutic approach to data collection and analysis (44, 45). The NVivo 10 software for qualitative analysis will be used.

Ethics

The study is reviewed and approved by The Data Protection Official for Research (NSD). Informed consent to participate in the study is requested from the parents on behalf of the children. In addition, age adjusted oral information will be given to the young children. Participants are guaranteed full confidentiality. Consent to participate in the trial will also be obtained from the ASP staff and the physiotherapists.

Information about participant identities will be stored separately from the study results. Data are anonymized in all publications and reports of the study. Participant data are protected in accordance with NSD's guidelines.

Dissemination

Results from the study will be published in scientific peer-reviewed journals and master thesis. Reports written in lay language will be provided to all participating ASPs and school administrations when the study is completed. Any changes or additions to the protocol will be reported to The Norwegian Centre for Research Data and registered in clinicaltrials.gov. Authorship is granted to project group members and others that fulfil the authorship criteria recommended by the International Committee of Medical Journal Editors.

DISCUSSION

The apparent need for systematically developed physical activity interventions adaptable to Norwegian ASPs makes a strong case for the trial described. The article describes how a complex intervention to ensure physical activity play during ASP time is carefully developed in close cooperation with school physiotherapists and representatives from ASPs. That the intervention originates from practice, and that the practice experiences are combined with previous research within a theoretical framework, are among the advantages of this study. Involvement of appropriate users in the different stages of an intervention study is likely to result in a higher chance of producing implementable data (24).

The present article also describes how the intervention will be explored in a matched-pair cluster-randomized trial. A strength of the planned trial is its combination of measures of physical activity. Interventions, whether they include physical activity as a primary or secondary outcome, tend to focus on the *quantity* of physical activity (duration, intensity and frequency), and not the *quality*. This study aims to mix objectively measured physical activity, logs and direct observations to be better able to give rich descriptions of the concept of children's physical activity in ASP. By including qualitative methods in the investigation, we gain information about the type of physical activity the children actually perform, where they perform the activity, with whom they spend time, and whether the activity is initiated and managed by the children themselves or by adults. Mixing methods in the same study may thus increase the possibility of evaluating the effect in addition to gaining an understanding of the mechanisms involved in the outcome of the intervention (46).

Trial Status

The intervention is ongoing with baseline data collection completed in October 2016. Short-term intervention (T1) data collection is due to be completed in June 2017 and long-term data in June 2018.

Acknowledgments

We thank the ASP staff that have been involved in the development and piloting of the intervention and the trial. Their enthusiastic participation was decisive in the development of Active play in ASP.

FOOTNOTES

Contributors

All the authors contributed to the study's conception, planning and design. KR and HE were responsible for drafting the intervention and managing the pilot trial. KR had primary responsibility for writing the paper in close collaboration with KL. HE, BF and SH participated in revising the article by providing comments and revisions. All authors approved the final version for publication.

Funding

This project is funded by the Norwegian Fund for Postgraduate Training in Physiotherapy and Oslo and Akershus University College of Applied Sciences.

Competing interests

None declared.

Ethics approval

The study was first reviewed by The Regional Committee for Medical and Health Research Ethics. The Committee concluded that the study is not covered by the Health Research Act. Consequently, the study protocol was submitted and reviewed by The Data Protection Official for Research (NSD) to ensure that that the project is in accordance with the Personal Data Act and the Personal Health Data Filing System Act (reference number 46008).

References:

1. Janssen I, Leblanc AG. Systematic review of the health benefits of physical activity and fitness in school-aged children and youth. The international journal of behavioral nutrition and physical activity. 2010;7:40.
2. Biddle SJ, Gorely T, Stensel DJ. Health-enhancing physical activity and sedentary behaviour in children and adolescents. J Sports Sci. 2004;22(8):679-701.
3. Biddle SJ, Asare M. Physical activity and mental health in children and adolescents: a review of reviews. British journal of sports medicine. 2011;45(11):886-95.
4. Fedewa AL, Ahn S. The effects of physical activity and physical fitness on children's achievement and cognitive outcomes: a meta-analysis. Research quarterly for exercise and sport. 2011;82(3):521-35.
5. Ommundsen Y, Løndal K, Loland S. Sport, children and well-being. In: Ben-Arieh A, Casas F, Frønes I, Korbin JE, editors. Handbook of child well-being. Dordrecht: Springer Reference; 2014.
6. Waters E, de Silva-Sanigorski A, Hall BJ, Brown T, Campbell KJ, Gao Y, et al. Interventions for preventing obesity in children. Cochrane database of systematic reviews. 2011(12):CD001871.
7. Gadamer H. Truth and method. London: Sheed and Ward; 1989.
8. Pellegrini AD, Smith PK. Physical activity play: the nature and function of a neglected aspect of playing. Child development. 1998;69(3):577-98.
9. Gallahue DL, Ozmun JC. Understanding motor development : infants, children, adolescents, adults. 6th ed. Boston ; London: McGraw Hill; 2006. xix, 524 p. p.
10. Caspersen CJ, Powell KE, Christenson GM. Physical activity, exercise, and physical fitness: definitions and distinctions for health-related research. Public Health Rep. 1985;100(2):126-31.
11. Warren JM, Ekelund U, Besson H, Mezzani A, Geladas N, Vanhees L, et al. Assessment of physical activity - a review of methodologies with reference to epidemiological research: a report of the exercise physiology section of the European Association of Cardiovascular Prevention and Rehabilitation. Eur J Cardiov Prev R. 2010;17(2):127-39.
12. Dobbins M, Husson H, DeCorby K, LaRocca RL. School-based physical activity programs for promoting physical activity and fitness in children and adolescents aged 6 to 18. Cochrane database of systematic reviews. 2013;2:CD007651.
13. The Norwegian Directorate of Health. [Norwegian guidelines on diet, nutrition and physical activity]. Oslo: The Norwegian Directorate of Health; 2014.
14. Beets MW, Beighle A, Erwin HE, Huberty JL. After-school program impact on physical activity and fitness: a meta-analysis. American journal of preventive medicine. 2009;36(6):527-37.
15. Green K. Understanding physical education. London: Sage; 2008. vii, 280 p. p.
16. Løndal K. Revelations in bodily play. A study among children in an after-school programme. Phd Dissertation. Oslo2010.
17. Løndal K, Bergsjø C. [Physical activity in after-school programmes. A study of four after-school programmes in Oslo]. Oslo: Oslo Univeristy College; 2005.
18. Løndal K. Children's lived experience and their sense of coherence: Bodily play in a Norwegian after-school programme. Child Care in Practice. 2010;16(4):391-407.
19. Løndal K, Lund S, Bergsjø CH. [Facilitating physical activity in after-school programmes in Oslo]. Tidsskriftet FoU i praksis. 2016;10(2):43-61.
20. Dowda M, Pate RR, Trost SG, Almeida MJ, Sirard JR. Influences of preschool policies and practices on children's physical activity. J Community Health. 2004;29(3):183-96.
21. Constantinides P, Montalvo R, Silverman S. Teaching processes in elementary physical education classes taught by specialists and nonspecialists. Teach Teach Educ. 2013;36:68-76.
22. Cheon SH, Reeve J, Yu TH, Jang HR. The teacher benefits from giving autonomy support during physical education instruction. Journal of sport & exercise psychology. 2014;36(4):331-46.
23. The Norwegian Directorate of Health. [Strategy for the public health center- and the school health service]. Rapport IS-1798. Oslo: The Norwegian Directorate of Health; 2010.
24. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337:a1655.

25. Øygardslia H. [Interventions to increase physical activity in after-schhool programmes; a systematic review] [Master thesis]. ODA Open Digital Archive: Oslo and Akershus University College of Applied Sciences; 2016.
26. Ryan RM, Deci EL. Active human nature. In: Hagger MS, Chatzisarantis NL, editors. Intrinsic motivation and self-determination in exercise and sport. Champaign: Human Kinetics; 2007. p. 1-21.
27. Standage M, Gillison F, Treasure D. Self-determination and motivation in physical education. In: Hagger MS, Chatzisarantis NLD, editors. Intrinsic motivation and self-determination in exercise and sports. Champaign; IL: Human Kinetics; 2007. p. 71-87.
28. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. American Psychologist. 2000;55(1):68-78.
29. Ryan RM, Patrick H, Deci EL, Williams GC. Facilitating health behaviour change and its maintenance: Interventions based on Self-Determination Theory. The European Helath Psychologist. 2008;10:2-5.
30. Edmunds J, Ntoumanis N, Duda JL. Testing a self-determination theory-based teaching style intervention in the exercise domain. Eur J Soc Psychol. 2008;38(2):375-88.
31. Broström s. SFO som arena for læring. In: Ankerstjerne IT, editor. SO- og fritidspedagogik -før, nu og i fremtiden. Fredrikshavn: Dafolo; 2010.
32. Fortier MS, Duda JL, Guerin E, Teixeira PJ. Promoting physical activity: development and testing of self-determination theory-based interventions. Int J Behav Nutr Phy. 2012;9.
33. Edmunds JK, Ntoumanis N. Perceived autonomy support and psychological need satisfaction in exercise. In: Hagger MS, Chatzisarantis NLD, editors. Intrisic motivation and self-determination in exercise and sport. Champaign, IL: Human Kinetics; 2007.
34. Reeve J. Self-determination theory applied to educational settings. In: Deci EL, Ryan RM, editors. Handbook of self-determination research. Rochester, NY: University of Rochester Press; 2002.
35. Kolle E, Stokke J, Hansen B, Andersen S. [Physical activity among 6-,9,- and 15 year olds in Norway 2011.]. Oslo; 2012.
36. Samdal O, Leversen I, Torsheim T, Manger MS, Brunborg GS, Wold B. [Trends in health and lifestyle among children and adolescents 1985-2005. Norwegian results from the study "Health behavior among school children. A WHO study in several countries]. Bergen: HEMIL-senteret, University of Bergen; 2009.
37. The KIDSCREEN Group Europe. The KIDSCREEN questionnaires. Quality of life questionnaires for children and adolescents Lengerich, Germany: Pabst Science Publishers; 2006.
38. Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child overweight and obesity worldwide: international survey. BMJ. 2000;320(7244):1240-3.
39. Van den Broeck A, Vansteenkiste M, De Witte H, Soenens B, Lens W. Capturing autonomy, competence, and relatedness at work: Construction and initial validation of the Work-related Basic Need Satisfaction scale. Journal of Occupational and Organizational Psychology. 2010;83(4):981-1002.
40. Gagné M, Forest J, Vansteenkiste M, Crevier-Braud L, Van den Broeck A, Aspeli AK, et al. The Multidimensional Work Motivation Scale: Validation evidence in seven languages and nine countries. European Journal of Work and Organizational Psychology. 2015;24(2):178-96.
41. Andersen IA, Andersen JR. [Validation of an instrument to measure job satisfaction]. Sykepleien Forskning. 2012;7:334-40.
42. Pavot W, Diener E. Review of the satisfaction with life scale. Psychological assessment. 1993;5(2):164.
43. Cradock AL, Barrett JL, Giles CM, Lee RM, Kenney EL, deBlois ME, et al. Promoting physical activity with the out of school nutrition and physical activity (OSNAP) initiative: A cluster-randomized controlled trial. JAMA Pediatr. 2016;170(2):155-62.
44. Kvale S, Rygge J, Brinkmann S, Anderssen TM. Det kvalitative forskningsintervju. 2. utg. ed. Oslo: Gyldendal akademisk; 2009.

45. Malterud K. Systematic text condensation: A strategy for qualitative analysis. Scand J Public Healt. 2012;40(8):795-805.
46. Hallberg IR. Knowledge for health care practice. In: Richards DA, Hallberg IR, editors. Complex interventions in health: An overview of research methods. New York: Routhledge; 2015.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	_1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_2_____
	2b	All items from the World Health Organization Trial Registration Data Set	_____
Protocol version	3	Date and version identifier	_____
Funding	4	Sources and types of financial, material, and other support	_12_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_1,11_____
	5b	Name and contact information for the trial sponsor	_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_____

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	_2,3_____
	6b	Explanation for choice of comparators	_____
Objectives	7	Specific objectives or hypotheses	__3_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	__6,7_____

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	__7_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	__7,8_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	__5,6_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	___8,9_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	___7_____

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7,9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7,8
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8,9
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	___9,10_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	___9_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	__9,11_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	__10_____

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	__9_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	__10_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	__11_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	__10_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_____
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

2015

ACTIVE PLAY

-an after school program intervention to promote physical activity and health-related quality of life in young children

PROJECT OUTLINE

HØGSKOLEN I OSLO OG AKERSHUS

FAKULTET FOR HELSEFAG

Abstract

Background: Physical activity (PA) is a key component in health promotion and prevention of overweight. Interventions delivered in after-school programs (ASP) have the potential to become a means of ensuring PA among young schoolchildren. This requires a motivational climate, allowing for self-determination and the intrinsic values of the activity, on the activity's character of play. ASP staff could be trained in stimulating all children in physical activities in their everyday life. Physiotherapists in primary care possess knowledge of motor development and learning, and are important contributors to an ASP-based physical activity intervention.

Aim: To develop a complex intervention that emphasizes physical activity play, and to examine the extent to which it promotes PA and health-related quality of life and prevents overweight in a population of young children. We aim to increase the knowledge and autonomy supportive skills among ASP staff members, enabling them to promote physical activity through play among all first graders in ASP.

Moreover, in addition to investigate if the children benefit from receiving autonomy support, we aim to study whether the ASP staff themselves benefit from giving autonomy support in terms of increased need satisfaction and autonomous motivation for work.

The intervention: Includes training of ASP-staff members in the fundamental principles of self-determination theory and practical applications for motivating young children in PA through play. Information will be given on the benefits of a physically active lifestyle and the staff will be encouraged to map opportunities for PA in their local ASP and to incorporate strategies to increase PA through play among the children throughout the day.

Methods/design: A complex intervention using a mixed methods approach will be developed and evaluated. A pilot trial will assess the potential of this innovative approach and provide information necessary to perform a cluster randomized controlled trial (RCT). A cluster-randomized controlled trial (RCT) will together with qualitative interviews and observations, evaluate the effectiveness of the intervention.

Active play -an after school program intervention to promote physical activity and health-related quality of life in young children

Background

The promotion of physical activity is an essential public health strategy to improve the health of individuals and populations [1]. Over the last years, there has been an increased attention to relationships between physical activity (PA) and children's health and well-being. Research has begun to emphasize the role played by children's physical-motor functioning and activity levels for functioning and academic performance in school [2, 3] as well as a preventive mechanism against antisocial behavior [4]. Another important reason for the focus on children's PA levels, is the increased prevalence of overweight and obesity. There is evidence that the obesity epidemic poses a threat to children's overall physical and psychosocial functioning [5]. PA is associated with prevention of weight gain over the life span and is considered a key component in both prevention and treatment of overweight and obesity [6, 7]. In addition to having a potentially preventive effect on overweight, PA may also positively influence on a number of physical and psychosocial health factors [8, 9].

Interventions carried out in a school setting can target simultaneously children both at risk and not at risk for future diseases, and can increase both knowledge and behavior conductive to healthier lifestyles. Additionally, primary preventive interventions have a potential to reduce the associated gap in health inequalities, ensuring that the interventions reach not only those with a more socioeconomically advantaged position. A recently updated Cochrane review [10] found some evidence that interventions aimed at increased PA specifically were effective in increasing the proportion of children engaging moderate to vigorous PA during school time as well as the duration of time spent in these activities. However, the magnitude of effect was generally small and research on the long-term impact of interventions is needed [10]. Interventions, whether they include PA as a primary or secondary outcome, tend to focus on the *quantity* of PA (duration, intensity and frequency), and not the *quality*. Quality physical activity experiences are those that prompt commitment and adherence to active living, as well as facilitating outcomes such as moral and social development, motor competence, positive self-perceptions and attitudes [11]. Physical activity may be an important positive source for the development of children's wellbeing. However, and as shown in research from the field of sports and physical education, an autonomy supportive and mastery oriented motivational climate is required, allowing for the child's self-determination and the intrinsic values of the activity and its character of play [4]. In the present context, the term "physical activity play" refers to such a character of play, incorporating subjective and experienced aspects of movements [12] and self-driven and autotelic-oriented activities [13]. Physical activity play also includes movements with a dimension of physical vigor expressed through locomotory movements, stabilizing postures and/or manipulative movements [14, 15]. "Physical activity" refers to any bodily movement produced by skeletal muscles that results in energy expenditure [16] and can be described by type, intensity, frequency and duration [17].

Physical activity during the school curriculum is often limited to hours of physical education or recesses. As a result, the school curriculum struggle to provide enough opportunities for children to be physically active, which again limits the children's possibilities to meet the recommendations of at least one hour of moderate to vigorous PA a day [18]. Interventions delivered in after-school programs (ASP) have the potential to become a means of increasing PA among young schoolchildren. All municipalities in Norway are legally obligated to offer ASP from the first to the fourth grade meaning that children can stay in school before and after ordinary school-time. 63,4 % of first to four graders attend the ASP [19]. Despite a close organizational connection with the school, no formal educational objectives are associated with ASPs. Instead it is required that programs provides facilities for play and participation in activities appropriate for the age, level of physical ability and

interest of the children [20]. In contrast with the sports-dominated extracurricular PE in several other European countries [21], Norwegian ASP staff members are expected to stimulate self-managed activities in the children's leisure time [22].

Results from previous research in Norway show that children's physical activity during their stay in the ASP is extensive when they have time devoted to child-managed play outdoors [22, 23]. Nevertheless, some children fall by the wayside, and this may have a restrictive effect on their activity level and their well-being [24]. It seems to be particularly important for the ASP staff to develop pedagogic skills in order to provide adapted frameworks for *all* children's activity, in addition to provide child-managed physical activity play. Thus, it is essential to know how to influence physical activity play in these settings. There are no governmental requirements for formal pedagogical education for the staff [25]. However, ASP employees themselves, parents and collaborators requests increased competence among the staff, primarily to ensure that all children, both children with typical development and children with disabilities and special needs, are included in activities [25]. We claim that ASP-staff members may represent a valuable resource, which can be trained in how to provide physical activity play and other forms of physical activities in everyday life for all children.

Physiotherapists have an essential role in the delivery of primary health care to children and adolescents in Norway [26]. Within a school health context the physiotherapist initiate and participate in tasks focusing on health promotion, disease prevention and interventions that improve or maintain fitness, health and wellbeing. Physiotherapists' knowledge about motor development and motor learning is valuable in the promotion of PA among children. Physiotherapists possess expertise in how to initiate and guide others in processes of mastering and behavioral change. Their competence is provided through theoretical knowledge about communication, cooperation, motivation, learning and behavioral change. Moreover, their role includes provision of education and consultation with other professionals in the child's environment, all of which makes the physiotherapist an important contributor to an ASP-based PA intervention. While a growing body of research supports the effectiveness of PA interventions delivered in the school setting, few, if any, studies have evaluated efforts concerning the use of physical activity as a health promoting and obesity preventive strategy involving physiotherapists.

The purpose of this project is to develop and examine the extent to which a primary preventive intervention that emphasizes physical activity play promotes physical activity, increases HRQoL and prevents overweight and obesity in a population of young schoolchildren attending the after-school-program (ASP). The target group is children in first grade (aged 5-6) participating in the ASP.

The expected outcome of the study is an approach that will provide ASPs and school health care with a strategy for physical activity promotion and prevention of childhood overweight to be implemented in everyday practice.

Theoretical framework

There is an increased recognition that interventions aimed at changing health behavior should draw on theories of behavior and behavior change [27]. Self-determination theory (SDT) is increasingly utilized in the development of health behavior interventions. SDT may also be particularly appropriate for understanding children's PA levels and are used to promote the adoption and maintenance of a physically active lifestyle. In addition to important aspects related to perceptions of competence, SDT emphasizes the individuals' interest or desire to perform the behavior, and how characteristics of the social environment can facilitate optimal motivation and support [28]. Self-determination theory contends that being motivated for autonomous or intrinsic reasons (that is, because PA is fun or provides valued benefits, such as feelings of competence or spending time with friends) leads to more positive cognitive, affective and behavioral outcomes than does being

motivated by externally controlled reasons. An autonomy supportive context acknowledges the child's perspective and minimizes control and pressure [29, 30]. Evidence from the physical education and psychology literature indicates that autonomous motivation is associated with positive outcomes in children such as exercise behavior, quality of life and positive self-concept [31]. Scandinavian leisure pedagogy specifically focus on *situation* in the ASP, and emphasizes that professional practice in such institutions should take on the child's perspective [32, 33]. This presupposes that activities are autonomously motivated.

Additionally, it is demonstrated that in a school setting, providing autonomy support to students may benefit the teachers themselves. Research showed that workshops designed to help teachers learn how to become more autonomy supportive not only lead to greater autonomy-supportive teaching, but also resulted in increased need satisfaction for teaching, higher job satisfaction and less exhaustion after teaching [34]. Similar studies have not been carried out in the context of ASP. The present study aim to investigate whether the ASP staff themselves may benefit from giving autonomy support in terms of increased need satisfaction and autonomous work motivation.

Aims

The overall aim of the study is to develop a complex intervention that emphasizes physical activity play, and to examine the extent to which the intervention promotes PA and HRQoL and prevents overweight in a population of young children. In order to do so, we aim to increase the knowledge and autonomy supportive skills among ASP staff members, enabling them to promote physical activity through play among all first graders in ASP.

Additionally, the present study aims to investigate whether the ASP staff themselves may benefit from giving autonomy support in terms of increased need satisfaction and autonomous work motivation.

Phase 1: Development

-to perform a review of literature on PA interventions in an ASP-setting
-based on the review, experiences from previous projects in ASPs in a municipality in Norway and in cooperation with physiotherapist and ASP-staff; to develop an intervention inspired by self-determination theory to promote physical activity through play among first graders in the ASP

Phase 2: Feasibility testing and piloting

-to assess test procedures and investigate the feasibility and implementation of the intervention in a pilot trial
-to gain knowledge about young children's preferences and experiences related to PA
-to explore and describe children's, ASP-staffs' and physiotherapists' experiences of taking part in the intervention
-to explore barriers and facilitators to take part in the intervention; children's, ASP-staffs', and physiotherapists' perspectives

Phase 3: Evaluation

-to evaluate the effect of the intervention in a cluster-randomized trial on measures of PA, HRQoL and BMI
-to evaluate the effect of participation on the staff's need satisfaction and motivation for work
-to explore and describe ASP-staffs' and health professionals' experiences of taking part in the intervention

Tentative research questions

Baseline (T0)

1. On average, how physically active are first graders during the time they spend in ASP?
2. What characterizes the children's physical activity in the ASP?
3. How do the parents report their children's HRQoL?
4. Is there a relationship between PA, HRQoL and BMI among first graders in ASP?
5. How do the ASP-staff report their need satisfaction, perceived competence and motivation for work and is there a relationship between these variables?

Post intervention (T1)

6. Is the intervention effective in terms of increased PA during ASP time and in general?
7. Is the interventions effective in terms of sustained or increased HRQoL?
8. Do the intervention prevent that the proportion of children with age- and gender adjusted BMI > 25 increases?
9. How do the children understand and experience physical activity in the ASP?
10. Is the intervention effective in increasing basic need satisfaction, perceived competence and autonomous motivation for work among ASP-staff?

Long term (T2)

11. If any effects, do they hold over time?
12. All the above considered, is "Active play" an appropriate tool for use in an ASP?

The intervention

The study will be informed by the framework given by Medical Research Council [35] using a mixed methods approach (Table 1). A preliminary outline of the intervention includes information to the parents from the school nurse and the local physiotherapist in a parent's group meeting. measurement of height and weight, delivered by the school nurse and in accordance with the regular program and guidelines in the school health care [36].

Members of the research group will be responsible for the training of the ASP staff members in cooperation with the local physiotherapist. Before intervention start, ASP staff members will attend a training program including sessions in which the staff members are taught the fundamental principles of self-determination theory and practical applications for motivating young children in physical activity through play. They will be trained in using an autonomy-supportive style that acknowledges feelings and preferences. The sessions will include opportunities to practice autonomy-supportive feedback and group management and will also focus on increasing health behavior knowledge in general. The staff will be encouraged to map the opportunities for PA in their local ASP and to incorporate strategies to increase PA through play among the children during the day.

All children will participate in indoors and outdoors activities depending on the facilities of the ASP and in accordance with the plans made by the ASP staff members and the local physiotherapist. The children will be included in decisions on PA. Most importantly, they will be given time and space to engage in self-initiated and self-managed active play and PA during the ASP time.

The detailed intervention (structure and content of the ASP-staff training program, features and content) will be developed systematically in close collaboration with ASP staff and physiotherapists using the best available evidence based on prior research and experiences from field.

A complex intervention to promote physical activity among young children in ASP (2015-2018)			
2015			
PHASE 1	Development (June-Jan)	*Based on workshops, meetings, interviews:* - Training program (research group with representatives from school physiotherapists, ASP staff members, ASP leader,) - Information brochure (research group with representatives from school physiotherapists, school nurse, ASP staff members,) - Framework for mapping of PA opportunities in the ASP (research group, school physiotherapist, ASP staff members) *Based on a systematic review* - Master student (Master of physiotherapy) *Procedure for recruitment* - Research group	
2016		**Intervention ASP (N=2 ASPs/70)**	
PHASE 2	Baseline T0 (pilot)	Measures of all children: PA intensity (one week accelerometer), UngKan2, HRQoL, BMI, sociodemographic variables Measures of subsample (N=6)direct observation Measures of staff: Basic needs, motivation for work, subjective well-being	
	4 months pilot intervention (Jan-May)	**Intervention** Information to ASP-staff and parents at staff-meeting and parents meeting, information on the project. Training program in sessions for ASP-staff in cooperation with local physiotherapist. Mapping of opportunities for PA in the ASP/school environment and planning of weekly activities. Daily activities for the children, autonomy support provided by staff in play and PA throughout the day.	
	T1 (pilot)	Measures of all children: PA intensity (one week accelerometer), UngKan2, HRQoL, BMI Measures of subsample (N=6): direct observation Measures of staff: Basic needs, motivation for work, subjective well-being Qualitative interviews: children (N=4), all staff members (focus groups), physiotherapist.	
	Evaluation of feasibility	Adjustments based on the evaluation of phase 1 and 2.	
2016-2018		**Intervention ASP (N=8 ASPs/ 200)**	**Control ASP (N=8 ASPs/200)**
PHASE 3	Baseline T0	Measures of all children: PA intensity (one week accelerometer) UngKan2, HRQoL, BMI, sociodemographic variables Measures of subsample (N=24 (12+12)): direct observation Measures of staff: Basic needs, motivation for work, subjective well-being	
	9 months Intervention (Sept-May)	**Intervention** As described above, adjusted based on evaluation of phase 1 and 2 (pilot).	**No intervention**
	T1 9 months follow-up	Measures of all children: PA intensity (one week HR monitoring), UngKan2, HRQoL, BMI Measures of subsample (N=24 (12+12)): direct observation Measures of staff: Basic needs, motivation for work, engagement in work, subjective well-being Qualitative interviews (intervention group): children (N=16), all staff members (focus groups), physiotherapists (1-2 focus groups)	
	T2 21 months follow-up	Measures of all children: PA intensity (one week accelerometer), UngKan2, HRQoL, BMI Measures of staff: Basic needs, motivation for work Qualitative interviews (intervention group): all staff members (focus groups), physiotherapists (1-2 focus groups)	

Table 1. Project outline.

The study will combine qualitative and quantitative methods, as mixed methods will enable us to answer simultaneously a combination of exploratory and confirmatory questions [37]. We assume to gain sufficient information about testing procedures and the intervention content and outline during a 4-month pilot trial including approximately 70 children from 2 ASPs in each of the two groups. The RCT intervention period will follow the school year with the intervention starting in the beginning of September (T0) and ending in May (T1). Follow-up assessments (T2) will be carried out in May, one year after T1 (Table 2).

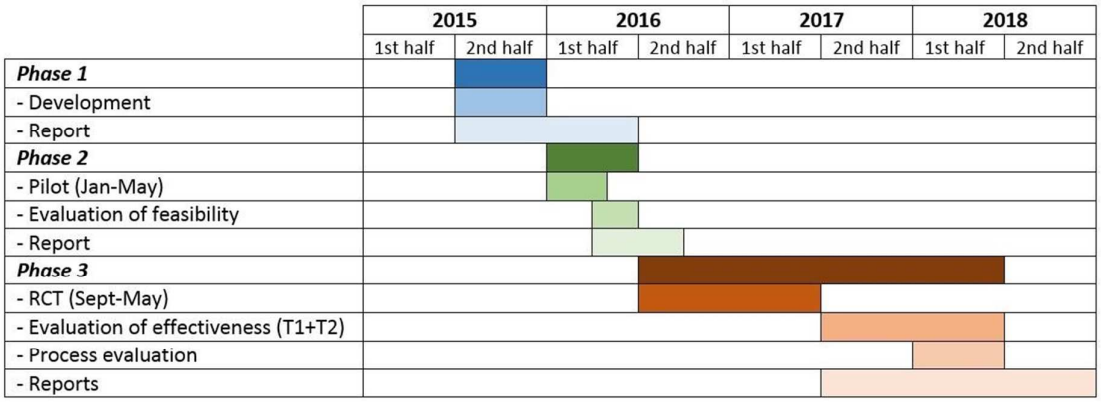


Table 2. Tentative process plan.

Measures

The primary outcome of the study will be child PA. Because no measure is suitable for assessing both type, amount, intensity, variability, quality and experience of PA, several instruments and methods will be used to capture as much information as possible. Secondary outcomes include HRQoL and BMI. Moreover, self-report instruments are used for assessing needs satisfaction, motivation for work and subjective well-being among ASP-staff. Process outcomes includes qualitative assessments of how ASP staff members and health-care professionals (physiotherapists) experienced the intervention.

All children: Measures of PA intensity will be assessed by ActiGraph © accelerometer during the time spent in ASP over a period of one week. Self-reported physical activity will be assessed by the UngKan2 questionnaire. The questionnaire will be completed by the child in cooperation with parents [38]. Child health-related quality of life (HRQOL) will be measured with the Norwegian proxy-version of Kidscreen-27 [39]. The questionnaires will be answered electronically. Weight and height will be measured and BMI calculated according to the age and gender specific cut-offs [40]. Age and gender are collected.

All parents: Socio-demographic data (age, gender, level of education, ethnicity, parent marital status, number of children).

All ASP-staff: Basic needs satisfaction at work [41] and The multidimensional work motivation scale [42].

Subsample of children (intervention and control groups): Direct observation including registration of both quantified PA (type, intensity, duration and frequency) and rich descriptions of PA will be performed [23].

Subsample of children (intervention group): Qualitative interviews will be performed post intervention with a subsample of approximately 16 children in the intervention group about their experiences with PA in the ASP.

Professional outcomes: Semi-structured focus group interviews with ASP staff members and physiotherapists will be performed to evaluate experiences as well as organizational and professional barriers and facilitators to the intervention.

Sample, setting and power calculation

The target group is children starting primary school in Norway, aged 5-6 years. The context is school health care and ASP in primary schools in selected parts of eastern and southern Norway. In the development of the current study application, cooperation is established with the school health service in Sandefjord (Vestfold). Based on their experiences from a similar ongoing project, local authorities have expressed interest in participating in the development and piloting of the intervention. Informal cooperation is established with local authorities on child health in municipalities in eastern and southern parts of Norway. These communities vary in sociodemographic properties, especially in cultural diversity. For the RCT, schools will be stratified on site, cultural diversity and school size, and randomly selected to intervention and control groups.

The sample size (N) is dependent upon the planned statistical analysis. The study comprises several analysis and a proper power-analysis where all the necessary factors are taken into consideration, before deciding on the final sample-size are required. No single instrument is available for assessment of all dimensions of PA. Thus, at this point, a rough estimate of the needed sample is based on the secondary outcome HRQoL as measured by the Kidscreen questionnaire [43]. Given a significance level at 0.05, power at 0.80 and a two-tailed significance test we estimate N to be 160 in each group. We plan to enroll 200 children in each group to secure sufficient power for some analysis on cluster level. With an estimation of a minimum of 25 first graders in each ASP, we will have to include maximum 16 ASPs all together.

The children eligible for selection to the qualitative interviews will be in the intervention group. A roughly estimated sample size would be 16-20 children with 2 children from each ASP. A strategic sampling aimed at maximum variation according to gender and ethnicity is an appropriate sampling procedure.

Data analysis

The differences between the intervention and control group will be assessed using repeated measure analyses for each of the dependent variables (main outcomes) in a mixed effect model using SPSS. This approach is flexible and it is possible to model the dependence between observations from the same individual. There may also be class and school effects which can be accounted for. Growth curve analyses will be considered given the three different points of measurement. The observations will be analyzed and presented with descriptive statistics in addition to text summaries. The qualitative interviews will be analyzed according to Kvale and Brinkmann [44], implying a hermeneutic approach to data collection and analysis. Hermeneutics is the study of the interpretation of texts and the purpose is to obtain valid understanding and meaning of the texts. The NVivo 10 software for qualitative analysis will be used.

Ethical aspects

The study will apply for approval from The Regional Ethics Committee. The researchers will carefully design the intervention to have concern for the target group. With a focus on primary prevention for all children, stigmatization of overweight children might be avoided. Informed consent to participate in the study are required from parents, on behalf of the children. In addition, information will be given to the young children. Participants are guaranteed full confidentiality. Consent to participate will also be obtained from the Asp staff and the representatives from the school health service.

Communication and dissemination

Results of the study will be presented on scientific meetings and congresses, and published in both national and international peer reviewed journals, as well as in popular scientific journals and media.

We plan at least 4 publications in peer-reviewed, international journals. The project has the potential to include at least one master thesis at HiOA (Master in Physiotherapy). The acquired knowledge and competence from the study will benefit students at Master levels. Popular scientific communication of results to the user groups specifically will be prioritized. In addition, workshops for researchers on methodological challenges and experiences related to performing interventions related to overweight and obesity will be arranged. Workshops will be offered to health care professionals (physiotherapists and school nurses) and ASP-leaders, staff, school leaders and teachers.

Project management

The owner of the project will be Oslo and Akershus University College of Applied Sciences, Faculty of Health, Institute of Physiotherapy. The project group members will contribute to the research with their expertise within relevant fields of research (curriculum vitae attached). Professor Sølvi Helseth (Institute of Nursing) has clinical and research experience within the field of public health nursing, leader of the research group *Livskvalitet og smerteforskning*. She has developed and is responsible for the study (SCIPO) on which the postdoc study originate from, her collaboration and supervison is mandatory. Associate Professor Bjørg Fallang (Institute of Physiotherapy) has clinical and research experience within habilitation and children's activities in everyday life, and is a member of the research groups *(Re)habilitering - individ tjenester og samfunn* and *The Lives of Children and Professional Practice*. Her competence will provide the link to develop this research field in relation to the Master in physiotherapy. Professor Knut Løndal (Faculty of Education and International Studies Department of Primary and Secondary Teacher Education) has special competence within the field of physical education and children's physical activity with a particular focus on research on ASP, member of the research group *Kropp, læring, mangfold.* The postdoctoral candidate will together with the project group, be responsible for the development and evaluation of the intervention and will be the lead writer of the articles. Assistant Professor and public health nurse Nina Misvær will assist during data collection with main responsibility of measuring weight and height of the participants at all test points.

Possible expansion of the study

In addition to the outlined study, we have drafted a step 2 including a secondary preventive strategy to target children with age- and gender adjusted BMI >25 and their families. The aim is to provide reinforced follow-up by the school nurse/physiotherapist tailored to each family. In the future, dependent of additional funding, it is highly relevant to supplement the present intervention in a combined primary/secondary preventive strategy with the potential effect of reducing BMI among overweight/obese children in addition to promoting PA and subsequently HRQoL.

References:

1. World Helath Organization, *Global strategy on diet, physical activity and health*, W.H. Organization, Editor. 2004: Geneva.
2. Biddle, S.J. and M. Asare, *Physical activity and mental health in children and adolescents: a review of reviews.* Br J Sports Med, 2011. **45**(11): p. 886-95.
3. Fedewa, A.L. and S. Ahn, *The effects of physical activity and physical fitness on children's achievement and cognitive outcomes: a meta-analysis.* Res Q Exerc Sport, 2011. **82**(3): p. 521-35.
4. Ommundsen, Y., K. Løndal, and S. Loland, *Sport, children and well-being*, in *Handbook of child well-being*, A. Ben-Arieh, et al., Editors. 2014, Springer Reference: Dordrecht.
5. Rocchini, A.P., *Childhood obesity and a diabetes epidemic.* N Engl J Med, 2002. **346**(11): p. 854-5.
6. Waters, E., et al., *Interventions for preventing obesity in children.* Cochrane Database Syst Rev, 2011(12): p. CD001871.
7. Oude Luttikhuis, H., et al., *Interventions for treating obesity in children.* Cochrane Database Syst Rev, 2009(1): p. CD001872.
8. Janssen, I. and A.G. Leblanc, *Systematic review of the health benefits of physical activity and fitness in school-aged children and youth.* Int J Behav Nutr Phys Act, 2010. **7**: p. 40.
9. Biddle, S.J., T. Gorely, and D.J. Stensel, *Health-enhancing physical activity and sedentary behaviour in children and adolescents.* J Sports Sci, 2004. **22**(8): p. 679-701.
10. Dobbins, M., et al., *School-based physical activity programs for promoting physical activity and fitness in children and adolescents aged 6 to 18.* Cochrane Database Syst Rev, 2013. **2**: p. CD007651.
11. Smith, A.L., *Peer relationships in physical activity contexts: A road less traveled in youth sport and exercise psychology research.* Psychology of sport and Exercise, 2003. **4**(1): p. 25-39.
12. Morris, D., *The sense of space*. 2004, Albany: State University of New York Press. xi, 220 p.
13. Gadamer, H., *Truth and method*. 1989, London: Sheed and Ward.
14. Gallahue, D.L. and J.C. Ozmun, *Understanding motor development : infants, children, adolescents, adults*. 6th ed. 2006, Boston ; London: McGraw Hill. xix, 524 p.
15. Pellegrini, A.D. and P.K. Smith, *Physical activity play: the nature and function of a neglected aspect of playing.* Child Dev, 1998. **69**(3): p. 577-98.
16. Caspersen, C.J., K.E. Powell, and G.M. Christenson, *Physical activity, exercise, and physical fitness: definitions and distinctions for health-related research.* Public Health Rep, 1985. **100**(2): p. 126-31.
17. Corder, K., et al., *Assessment of physical activity in youth.* Journal of Applied Physiology, 2008. **105**(3): p. 977-987.
18. The Norwegian Directorate of Health, *Anbefalinger om kosthold, ernæring og fysisk aktivitet*, Helsedirektoratet, Editor. 2014.
19. The Norwegian Directorate for Education and Training, *GSI-tall 2013/2014*.
20. Ministry of Church and Education, *Education Act*. 2009.
21. Green, K., *Understanding physical education*. 2008, London: Sage. vii, 280 p.
22. Løndal, K., *Revelations in bodily play. A study among children in an after-school programme. Phd Dissertation*, in *The Norwegian School of Sport Sciences*. 2010a: Oslo.
23. Løndal, K. and C. Bergsjø, *Fysisk aktivitet i skolefritidsordningen. En undersøkelse i fire skolefritidsordninger i Oslo. HiO-rapport 2005.* 2005, Høgskolen i Oslo: Oslo.
24. Løndal, K., *Children's Lived Experience and their Sense of Coherence: Bodily Play in a Norwegian After-school Programme.* Child Care in Practice, 2010b. **16**(4): p. 391-407.
25. Kvello, Ø. and C. Wendelborg, *Nasjonal evalureing av skolefritidsordningen*, in *NTF-rapport 2002-4*. 2002: Steinkjær.

26. The Norwegian Directorate of Health, *Utviklingsstrategi for helsestasjons- og skolehelsetjenesten*, in *Rapport IS-1798*. 2010.
27. Michie, S., et al., *From Theory to Intervention: Mapping Theoretically Derived Behavioural Determinants to Behaviour Change Techniques.* Applied Psychology, 2008. **57**(4): p. 660-680.
28. Ryan, R.M. and E.L. Deci, *Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being.* American Psychologist, 2000. **55**(1): p. 68-78.
29. Markland, D., et al., *Motivational interviewing and self-determination theory.* Journal of Social and Clinical Psychology, 2005. **24**(6): p. 811-831.
30. Edmunds, J., N. Ntoumanis, and J.L. Duda, *Helping Your Clients and Patients Take Ownership over Their Exercise: Fostering Exercise Adoption, Adherence, and Associated Well-Being.* Acsms Health & Fitness Journal, 2009. **13**(3): p. 20-25.
31. Standage, M., F. Gillison, and D. Treasure, *Self-determination and motivation in physical education*, in *Intrinsic motivation ans self-determination in exercise and sports*. 2007, Human Kinetics: Champaign; IL. p. 71-87.
32. Orwehag, M.H., *Fritidspedagogisk didaktik -att vara lärare i fritidshem*, in *Fritidshemmets didaktik*, A.S. Pihlgren, Editor. 2013, Studentlitteratur: Lund.
33. Broström, s., *SFO som arena for læring*, in *SO- og fritidspedagogik -før, nu og i fremtiden*, I.T. Ankerstjerne, Editor. 2010, Dafolo: Fredrikshavn.
34. Cheon, S.H., et al., *The teacher benefits from giving autonomy support during physical education instruction.* J Sport Exerc Psychol, 2014. **36**(4): p. 331-46.
35. Craig, P., et al., *Developing and evaluating complex interventions: the new Medical Research Council guidance.* BMJ, 2008. **337**: p. a1655.
36. The Norwegian Directorate of Health, *[National guideline for weighing and measuring at health clinics and in the school health service]*. 2010.
37. Lund, T., *Combining Qualitative and Quantitative Approaches: Some Arguments for Mixed Methods Research.* Scandinavian Journal of Educational Research, 2012. **56**(2): p. 155-165.
38. Kolle, E., et al., *Fysisk aktivitet blant 6-,9- og 15 åringer i Norge. Resultater fra en kartlegging i 2011*, Helsedirektoratet, Editor. 2012: Oslo.
39. Haraldstad, K., et al., *Health related quality of life in children and adolescents: reliability and validity of the Norwegian version of KIDSCREEN-52 questionnaire, a cross sectional study.* Int J Nurs Stud, 2011. **48**(5): p. 573-81.
40. Cole, T.J., et al., *Establishing a standard definition for child overweight and obesity worldwide: international survey.* BMJ, 2000. **320**(7244): p. 1240-3.
41. Van den Broeck, A., et al., *Capturing autonomy, competence, and relatedness at work: Construction and initial validation of the Work-related Basic Need Satisfaction scale.* Journal of Occupational and Organizational Psychology, 2010. **83**(4): p. 981-1002.
42. Gagné, M., et al., *The Multidimensional Work Motivation Scale: Validation evidence in seven languages and nine countries.* European Journal of Work and Organizational Psychology, 2015. **24**(2): p. 178-196.
43. The KIDSCREEN Group Europe, *The KIDSCREEN questionnaires. Quality of life questionnaires for children and adolescents* 2006, Lengerich, Germany: Pabst Science Publishers.
44. Kvale, S., et al., *Det kvalitative forskningsintervju*. 2. utg. ed. 2009, Oslo: Gyldendal akademisk. 344 s.

1. World Helath Organization, *Global strategy on diet, physical activity and health*, W.H. Organization, Editor. 2004: Geneva.
2. Biddle, S.J. and M. Asare, *Physical activity and mental health in children and adolescents: a review of reviews.* Br J Sports Med, 2011. **45**(11): p. 886-95.
3. Fedewa, A.L. and S. Ahn, *The effects of physical activity and physical fitness on children's achievement and cognitive outcomes: a meta-analysis.* Res Q Exerc Sport, 2011. **82**(3): p. 521-35.
4. Ommundsen, Y., K. Løndal, and S. Loland, *Sport, children and well-being*, in *Handbook of child well-being*, A. Ben-Arieh, et al., Editors. 2014, Springer Reference: Dordrecht.

5. Rocchini, A.P., *Childhood obesity and a diabetes epidemic.* N Engl J Med, 2002. **346**(11): p. 854-5.
6. Waters, E., et al., *Interventions for preventing obesity in children.* Cochrane Database Syst Rev, 2011(12): p. CD001871.
7. Oude Luttikhuis, H., et al., *Interventions for treating obesity in children.* Cochrane Database Syst Rev, 2009(1): p. CD001872.
8. Janssen, I. and A.G. Leblanc, *Systematic review of the health benefits of physical activity and fitness in school-aged children and youth.* Int J Behav Nutr Phys Act, 2010. **7**: p. 40.
9. Biddle, S.J., T. Gorely, and D.J. Stensel, *Health-enhancing physical activity and sedentary behaviour in children and adolescents.* J Sports Sci, 2004. **22**(8): p. 679-701.
10. Dobbins, M., et al., *School-based physical activity programs for promoting physical activity and fitness in children and adolescents aged 6 to 18.* Cochrane Database Syst Rev, 2013. **2**: p. CD007651.
11. Summerbell, C.D., et al., *Interventions for preventing obesity in children.* Cochrane Database Syst Rev, 2005(3): p. CD001871.
12. van Wijnen, L.G., et al., *The impact of school-based prevention of overweight on psychosocial well-being of children.* Obes Rev, 2009. **10**(3): p. 298-312.
13. Smith, A.L., *Peer relationships in physical activity contexts: A road less traveled in youth sport and exercise psychology research.* Psychology of sport and Exercise, 2003. **4**(1): p. 25-39.
14. Morris, D., *The sense of space*. 2004, Albany: State University of New York Press. xi, 220 p.
15. Gadamer, H., *Truth and method*. 1989, London: Sheed and Ward.
16. Gallahue, D.L. and J.C. Ozmun, *Understanding motor development : infants, children, adolescents, adults*. 6th ed. 2006, Boston ; London: McGraw Hill. xix, 524 p.
17. Pellegrini, A.D. and P.K. Smith, *Physical activity play: the nature and function of a neglected aspect of playing.* Child Dev, 1998. **69**(3): p. 577-98.
18. Caspersen, C.J., K.E. Powell, and G.M. Christenson, *Physical activity, exercise, and physical fitness: definitions and distinctions for health-related research.* Public Health Rep, 1985. **100**(2): p. 126-31.
19. Corder, K., et al., *Assessment of physical activity in youth.* Journal of Applied Physiology, 2008. **105**(3): p. 977-987.
20. The Norwegian Directorate of Health, *Anbefalinger om kosthold, ernæring og fysisk aktivitet*, Helsedirektoratet, Editor. 2014.
21. The Norwegian Directorate for Education and Training, *GSI-tall 2013/2014*.
22. Ministry of Church and Education, *Education Act*. 2009.
23. Green, K., *Understanding physical education*. 2008, London: Sage. vii, 280 p.
24. Løndal, K., *Revelations in bodily play. A study among children in an after-school programme. Phd Dissertation*, in *The Norwegian School of Sport Sciences*. 2010a: Oslo.
25. Løndal, K. and C. Bergsjø, *Fysisk aktivitet i skolefritidsordningen. En undersøkelse i fire skolefritidsordninger i Oslo. HiO-rapport 2005.* 2005, Høgskolen i Oslo: Oslo.
26. Løndal, K., *Children's Lived Experience and their Sense of Coherence: Bodily Play in a Norwegian After-school Programme.* Child Care in Practice, 2010b. **16**(4): p. 391-407.
27. Kvello, Ø. and C. Wendelborg, *Nasjonal evalureing av skolefritidsordningen*, in *NTF-rapport 2002-4*. 2002: Steinkjær.
28. The Norwegian Directorate of Health, *Utviklingsstrategi for helsestasjons- og skolehelsetjenesten*, in *Rapport IS-1798*. 2010.
29. Michie, S., et al., *From Theory to Intervention: Mapping Theoretically Derived Behavioural Determinants to Behaviour Change Techniques.* Applied Psychology, 2008. **57**(4): p. 660-680.
30. Ryan, R.M. and E.L. Deci, *Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being.* American Psychologist, 2000. **55**(1): p. 68-78.
31. Markland, D., et al., *Motivational interviewing and self-determination theory.* Journal of Social and Clinical Psychology, 2005. **24**(6): p. 811-831.

32. Edmunds, J., N. Ntoumanis, and J.L. Duda, *Helping Your Clients and Patients Take Ownership over Their Exercise: Fostering Exercise Adoption, Adherence, and Associated Well-Being.* Acsms Health & Fitness Journal, 2009. **13**(3): p. 20-25.
33. Standage, M., F. Gillison, and D. Treasure, *Self-determination and motivation in physical education*, in *Intrinsic motivation ans self-determination in exercise and sports*. 2007, Human Kinetics: Champaign; IL. p. 71-87.
34. Orwehag, M.H., *Fritidspedagogisk didaktik -att vara lärare i fritidshem*, in *Fritidshemmets didaktik*, A.S. Pihlgren, Editor. 2013, Studentlitteratur: Lund.
35. Broström, s., *SFO som arena for læring*, in *SO- og fritidspedagogik -før, nu og i fremtiden*, I.T. Ankerstjerne, Editor. 2010, Dafolo: Fredrikshavn.
36. Cheon, S.H., et al., *The teacher benefits from giving autonomy support during physical education instruction.* J Sport Exerc Psychol, 2014. **36**(4): p. 331-46.
37. Craig, P., et al., *Developing and evaluating complex interventions: the new Medical Research Council guidance.* BMJ, 2008. **337**: p. a1655.
38. The Norwegian Directorate of Health, *[National guideline for weighing and measuring at health clinics and in the school health service]*. 2010.
39. Lund, T., *Combining Qualitative and Quantitative Approaches: Some Arguments for Mixed Methods Research.* Scandinavian Journal of Educational Research, 2012. **56**(2): p. 155-165.
40. Kolle, E., et al., *Fysisk aktivitet blant 6-,9- og 15 åringer i Norge. Resultater fra en kartlegging i 2011*, Helsedirektoratet, Editor. 2012: Oslo.
41. Haraldstad, K., et al., *Health related quality of life in children and adolescents: reliability and validity of the Norwegian version of KIDSCREEN-52 questionnaire, a cross sectional study.* Int J Nurs Stud, 2011. **48**(5): p. 573-81.
42. Cole, T.J., et al., *Establishing a standard definition for child overweight and obesity worldwide: international survey.* BMJ, 2000. **320**(7244): p. 1240-3.
43. Van den Broeck, A., et al., *Capturing autonomy, competence, and relatedness at work: Construction and initial validation of the Work-related Basic Need Satisfaction scale.* Journal of Occupational and Organizational Psychology, 2010. **83**(4): p. 981-1002.
44. Gagné, M., et al., *The Multidimensional Work Motivation Scale: Validation evidence in seven languages and nine countries.* European Journal of Work and Organizational Psychology, 2015. **24**(2): p. 178-196.
45. Lubans, D.R., et al., *A systematic review of the validity and reliability of sedentary behaviour measures used with children and adolescents.* Obes Rev, 2011. **12**(10): p. 781-99.
46. The KIDSCREEN Group Europe, *The KIDSCREEN questionnaires. Quality of life questionnaires for children and adolescents* 2006, Lengerich, Germany: Pabst Science Publishers.
47. Kvale, S., et al., *Det kvalitative forskningsintervju*. 2. utg. ed. 2009, Oslo: Gyldendal akademisk.

Kirsti Riiser
Institutt for fysioterapi
Høgskolen i Oslo og Akershus
Postboks 4, St. Olavs plass
0130 OSLO

Our date: 15.02.17 Our ref: 46008 / 3 / HJP/lr Your date: Your ref:

Affirmation

The Data Protection Official for Research at the Norwegian centre for research data (NSD) finds that the processing of personal data in relation to the project "Active play -an after-school-program intervention to promote physical activity and health-related quality of life in young children"' is in accordance with the Norwegian Personal Data Act, ref. our letter to Kirsti Riiser on 14.01.2016.

Sincerely,

Kjersti Haugstvedt
Head of Section

Hanne Johansen-Pekovic
Adviser

Fysiofondet | Fond til etter- og videreutdanning av fysioterapeuter

Oslo,14.02.2017

Confirmation

I hereby confirm that The Norwegian Fund for Post-Graduate Training in Physiotherapy, have approved the funding of the research project "Active play in ASP", project-ID 62707, with a funding total of NOK 3.640.000.

The Norwegian Fund for Post-Graduate Training in Physiotherapy employs peer reviewing of protocols prior to deciding on funding of projects.

Best regards,

Eline Rygh

Eline Rygh
General Manager

Kontoradresse: Stensberggt. 27, 8.etg. 0170 Oslo
Postadresse: Postboks 2704 St.Hanshaugen 0131 Oslo
E-post adresse: post@fysiofondet.no
Telefon: 22 93 30 90
Bankkonto: 6011.09.52638
Web adresse: www.fysiofondet.no

BMJ Open

Active Play in After School Programs -development of an intervention and description of a matched-pair cluster-randomized trial assessing physical activity play in after school programs

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-016585.R1
Article Type:	Protocol
Date Submitted by the Author:	26-May-2017
Complete List of Authors:	Riiser, Kirsti; Oslo and Akershus University College of Applied Siences Helseth, Sølvi; Oslo and Akershus University College of Applied Siences Ellingsen, Hanna; Sandefjord Municipality Fallang, Bjørg; Oslo and Akershus University College of Applied Siences Løndal, Knut; Oslo and Akershus University College of Applied Siences
Primary Subject Heading:	Public health
Secondary Subject Heading:	Paediatrics
Keywords:	Children, Physical activity, Play, After school programs, Intervention

Active Play in After School Programs -development of an intervention and description of a matched-pair cluster-randomized trial assessing physical activity play in after school programs

Kirsti Riiser
Department of Physiotherapy, Faculty of Health, Oslo and Akershus University College of Applied Sciences, Oslo, Norway

Sølvi Helseth
Department of Nursing and Health Promotion, Faculty of Health, Oslo and Akershus University College of Applied Sciences, Oslo, Norway

Hanna Ellingsen
Department of Family Health Services, Municipality of Sandefjord, Norway

Bjørg Fallang
Department of Physiotherapy, Faculty of Health, Oslo and Akershus University College of Applied Sciences, Oslo, Norway

Knut Løndal
Department of Primary and Secondary Teacher Education, Faculty of Education and International Studies, Oslo and Akershus University College of Applied Sciences, Oslo, Norway

Corresponding author
Kirsti Riiser
Department of Physiotherapy, Faculty of Health
Oslo and Akershus University College of Applied Sciences
PO Box 4 St. Olavsplass
N-0130 Oslo
Norway
Email: kirsti.riiser@hioa.no
Tel.: +4767236173

Word count: 4692

ABSTRACT

Introduction: Interventions delivered in after-school programs (ASP) have the potential to become a means of ensuring adequate physical activity among schoolchildren. This requires a motivational climate, allowing for self-determined play. If trained, ASP staff may represent a valuable resource for supporting such play. Increasing knowledge and supportive skills among ASP staff may also potentially increase their motivation for work. The purpose of this article is to describe the development of the "Active play in ASP" intervention, which aims to promote physical activity among first graders attending ASP, and to present a protocol for a matched-pair cluster-randomized trial to evaluate the intervention.

Methods and analysis: Informed by experiences from practice, evidence-based knowledge and theory, the intervention was developed in a stepwise process including focus group meetings and a small-scale pilot test. The intervention contains a course program for ASP staff to increase their skills in how to support physical activity through play. In a cluster RCT, the ASPs will be matched and randomly allocated to receive the 7 month intervention or to a control group. Outcomes will be assessed at baseline, after 7 months and 19 months. First graders attending the ASPs included are eligible. The primary outcome will be accelerometer-determined minutes in moderate to vigorous physical activity (MVPA) in the ASP. . The study uses a mixed methods approach including observations and interviews to provide rich descriptions of the concept of children's physical activity in ASP. Moreover, the trial will assess whether the ASP staff benefits from participation in the intervention in terms of increased work motivation. Lastly, process evaluations of program fidelity, satisfaction and suggestions on improvement will be performed.

Ethics and dissemination: The study is approved by The Data Protection Official for Research (ref. 46008). Results will be presented in conferences and peer-reviewed journals.

Trial registration number: NCT02954614

Strengths and limitations of this study

- *The Active play in ASP is the first randomized controlled physical activity study that is performed in an ASP setting in Scandinavia.*
- *The study will apply a mixed methods approach using accelerometers, observations and interviews to assess physical activity, providing an extensive insight into children's physical activity in ASP.*
- *A weakness may be that the intervention follow-up throughout the school year is limited to one meeting per month. The decision is made pragmatically due to a consideration of what is realistic should the intervention be translated into routine practice.*
- *Using local school physiotherapists to deliver parts of the intervention strengthens the external validity of the study, but may also increase variation in the results.*

BACKGROUND

The relationships between physical activity and children's health and well-being are widely acknowledged. Physical activity may positively influence a number of health factors (1, 2). Research has also begun to emphasize the role played by children's physical-motor functioning and activity levels in academic performance (3, 4), as well as its effect as a preventive mechanism against antisocial behaviour (5). Another important reason for focusing on children's physical activity levels is the preventive effect physical activity may have on overweight and obesity (6). Perhaps most importantly, physical activity may be a positive source for the development of children's well-being (5). However, as shown in research from the field of sports and physical education, in order to increase well-being, an autonomy supportive and mastery oriented motivational climate is required, allowing for the child's self-determination and the intrinsic values of the activity and the activity's character of play (5). In the present context, the term "physical activity play" refers to such play, incorporating subjective and experienced aspects of movements and self-driven and autotelically oriented activities (7, 8). Physical activity play includes vigorous locomotory movements, stabilizing postures and/or manipulative movements (8, 9). Physical activity, which is commonly described as any bodily movement produced by skeletal muscles that result in energy expenditure, (10) can take place in the household or domestic domain, the occupational domain, the transportation domain and the leisure time domain (11). Physical activity is thus considered a collective term including physical activity play as well as e.g. hiking or more organized forms of sports activities.

There is some evidence that physical activity interventions in school can be effective in increasing the proportion of children engaging in moderate and vigorous physical activity during school time as well as the duration of time spent on these activities (12). However, physical activity in school is often limited to physical education or recesses. Consequently, during school hours, the children are not provided with opportunities to be as physically active as recommended, that is at least one hour of moderate to vigorous physical activity a day (13). Interventions directed at *after-school programs* (ASPs) have the potential to become a means of increasing physical activity among young children (14). Previous research has indicated that ASP interventions emphasizing competence building among the staff can lead to increased levels of physical activity for the children (15-18). The studies indicate that effective programs should emphasize positive feedback and encouragement regarding physical activity, goal setting and evaluation of measures, development of schedules for physical activity, structuring and administration of the environment and arrangements for physical activity for the children. The present study builds on these findings by investigating a course program for increasing supportive skills and knowledge about children's play among ASP staff. No national educational objectives are associated with Norwegian ASPs. In contrast with the sports-dominated extracurricular physical education in several other European countries (19), Norwegian ASPs are expected to stimulate self-managed activities in the children's leisure time (20). Thus, the stage is set to provide various content appropriate to the interests of the children, for example various types of physical activity. As 62% of first to fourth graders and as many as 81% of first graders attend ASP, a large proportion of children in the relevant age group can be reached. Results from previous research in Norway show that children's physical activity during their stay in the ASP is extensive when they have time devoted to child-managed play outdoors (20, 21). Nevertheless, some children fall by the wayside, and this may hamper their activity level and their well-being (22). It also seems to be a trend that activities in ASPs are more organized than earlier (23). The staff are more engaged in arranging and managing various activities for groups of children, and their opportunities to attend to child-managed activities have diminished. This has weakened their possibility to initiate child-managed movement play among the least active children (23). It seems to be particularly important for the ASP staff to develop pedagogic skills in order to provide adapted frameworks for *all* children's

physical activity, in addition to providing child-managed physical activity play (24, 25). Thus, it is essential to know how to support such play. In Norway, only a minority of the employees in ASPs has formal pedagogical education, and there seems to be a lack of competence in how to approach and engage in children's play (26). If trained, ASP staff members may represent a valuable resource for supporting physical activity play and other forms of physical activities in everyday life for all children. Another potential benefit of an intervention addressing increased knowledge and skills among ASP staff is that the staff may experience a boost in their work motivation. This has previously been shown to be the case among physical education teachers (27). Physiotherapists have an essential role in the delivery of primary health care to children and adolescents in Norway (28). Within a school health context the physiotherapist initiates and participates in tasks focusing on health promotion, disease prevention and interventions that improve or maintain fitness, health and well-being. Their role includes provision of education and consultation with other professionals in the child's environment, making physiotherapists important contributors to an ASP based physical activity intervention. Few, if any, studies have evaluated efforts concerning the use of physical activity play as a health promoting strategy involving school physiotherapists.

AIM

The purpose of this article is to describe the development of the Active play in ASP intervention and to present a protocol for a matched-pair cluster-randomized trial. The Active play in ASP intervention comprises a course program for increasing knowledge and supportive skills among ASP staff. The aim of the planned trial is to assess the immediate and long-term (one-year after the intervention ends) efficacy of the intervention on first graders' physical activity in the ASP and their well-being, conceptualized here as quality of life. Moreover, we aim to investigate the characteristics of first graders' physical activity in ASP and the qualitative aspects of their understanding and experience of the activity. In addition, the trial will explore if the ASP staff can benefit from participation in the intervention in terms of increased motivation and work satisfaction. Lastly, we will perform a process evaluation of the intervention.

METHODS AND ANALYSIS

Development of the intervention

In the *first phase* of the Active play in ASP intervention development, we gathered information from the field, identified the evidence base and chose appropriate theory (Figure 1).

[Insert figure 1 here]

As emphasized by Craig et al (29), a key question in the development and evaluation of complex interventions is whether the intervention will work in everyday practice. In the present study, we draw on experiences from "Health Promoting ASP", a project previously run in five ASPs in a municipality in Norway. The project emphasizes healthy food, physical activity and well-being among the children during ASP time. It was initiated by local school physiotherapists in cooperation with school head masters and implemented throughout a school year. The project has been well received by the ASP staff and the school administrations. However, the project is insufficiently evaluated, which makes it difficult to determine the impact on the children's behaviour. In the present trial, we decided to limit the scope of the intervention and focus solely on how to support physical activity. A school physiotherapist from "Health Promoting ASP" and three employees representing three different ASPs participated in a semi-structured focus group meeting to share their experiences and to pinpoint possible barriers to and facilitators for implementation and potential successful outcomes. The focus group meeting was moderated by one of the researchers. Main features of the

Active play in ASP intervention, both content and structure, were outlined based on the summary of the focus group meeting.

Parallel to this process, previous research on physical activity interventions in ASPs was systematically reviewed and published in a master thesis (30). The review, which included 17 articles, found positive effects on the children's activity level only in interventions that incorporated flexible programs that were adaptable to each single ASP. Highly structured programs (i.e. standardized activity programs) were reported to be more difficult to implement, which may explain their limited effect on children's physical activity (31-33). The results of the review echoed the feedback given by the focus group, which also emphasized the value of an adaptable intervention. The focus group members stressed that it is essential to develop an understanding of how each ASP is organized. Contextual factors and professional experiences need to be acknowledged and included in the implementation process.

In this first phase, we also decided on a theoretical framework. *Self-determination theory* (SDT) is frequently utilized in health behaviour research as well as in educational research and was considered appropriate in the context of children's activity play. The theory has relevance for understanding motivated physical activity engagement. It emphasizes that being motivated by self-determined reasons leads to greater engagement and well-being than being motivated by controlled reasons (34). Self-determined motivation is associated with positive outcomes in children such as exercise behaviour, quality of life and a positive self-concept (35). According to SDT, social environments that support the individual's basic psychological needs (autonomy, competence and relatedness) will foster more self-determined motivation (36). Autonomy reflects the need to engage in activities with a sense of choice, competence represents the feeling that one will be able to accomplish tasks, while relatedness refers to the sense of being understood and respected by significant others (37). Autonomy support, structure and interpersonal involvement can support the basic psychological needs and thus facilitate adoption and maintenance of physical activity (38). Facilitating the children's choices and supporting their free expression are central to basic need support in play. In an ASP context, application of these principles implies that the staff should not intervene in play situations in a commanding or controlling manner, but rather support and gently encourage activities. Simultaneously, the self-chosen and child-managed character of play should be retained (39). In addition to informing the content of the present intervention, e.g. application of theoretically anchored principles for activity support, the self-determination theory has contributed to the modelling of the likely processes of change (40).

In the *second phase* of development, we drafted a course program that subsequently was presented to the same ASP focus group that participated in the initial phase. The group was encouraged to respond to questions regarding the feasibility and usefulness of the intervention. A second draft was prepared building on their feedback. In the *third phase*, the intervention was tested in a small-scale pilot study including two ASPs over a period of 4 months. Along with the piloting of the intervention, we tested all outcome measures and measurement procedures at baseline and post intervention. The staff from the two pilot ASPs provided feedback by answering a short questionnaire with semi-structured questions related to their experience of the intervention. In addition, a strategic sample of three employees from each of the two ASPs participated in two focus group interviews moderated by one of the researchers. The focus group interview allowed the employees to speak more freely about their experiences with the intervention. Only minor changes had to be made to complete the final version.

Intervention content

Active play in ASP is a 7 month course program (October – May) aimed at ASP staff with the intention of increasing their knowledge and skills regarding how to support children's physical activity play. However, providing *activity support* is not merely the responsibility of the employee in interaction with one child or group of children. The program also emphasizes the potentials of *institutional activity support*, reflected in how the ASP is organized concerning time structure (time spent indoors/outdoors), routines and rules, and the ASP's access to and utilization of activity places and equipment. The intervention has the potential to reach all children in the ASP. However, as described later, only first graders are included in the measurements of the trial.

The ASP staff in each intervention ASP will participate in the course program as described below (Table 1). The initial part of the program is led by the researchers. The local school physiotherapist attends and contributes during the initial part (the intro-sessions, mapping and planning) and is responsible for the five monthly follow-up meetings after the first sessions. Thus, prior to the ASP course program, the physiotherapists are provided with an 8-hour introduction course presenting the intervention and how it is organized, emphasizing their role. To increase fidelity and adherence to the intervention, the physiotherapists receive a detailed workbook outlining the interventions' rationale, content and assignments for the ASP staff.

The ASP course program starts with two 3-hour sessions arranged locally at each participating ASP within a period of two weeks. All staff will attend. The sessions focus on children's physical activity in play, friends, activity place, ASP staff's interaction styles, motivation and activity support. The sessions include lectures, theme based discussions and group tasks. The staff are encouraged to give examples from their own practical experience. Moreover, in a separate meeting the ASP is mapped to document activity equipment and indoor and outdoor facilities. This information is used as a supplement in the following meetings. Subsequently the staff, supervised by the local school physiotherapist and a research group member, outline how the ASP will include new knowledge and previous experiences in strategies for supporting children's activity play during their time in the ASP. The program continues during the school year with monthly meetings for the staff and the local school physiotherapist where they work on predefined tasks related to physical activity play. See Table 1. Participation in the intervention and the study will not involve any additional costs for the ASPs.

	Component	Content
Introductory course for school physiotherapists	1-day course	Information on the intervention and the physiotherapists' role and responsibilities. Presentation of intervention workbook.
Course program ASP staff	3-hour session	Introduce research-based knowledge about children's physical activity in play. Increase the staff's awareness of how such play can be influenced and supported in ASP.
	3-hour session	Basic theoretical principles of SDT applied to physical activity and physical activity play among children; how to be activity supportive.
	Mapping	Thorough mapping of the ASP equipment and facilities.
	Planning (1-2 hour meeting)	Summary of intro-sessions; how to make use of new knowledge.
	5 meetings (monthly 1-2 hours) led by the local school physiotherapist	Discussions and practical tasks focusing - Motor learning in children - Equipment and environment - Mapping of staff competencies - Inclusion/exclusion in play - How to lead and support activity in groups

Table 1 Intervention components and course program content

In line with the basic principles of SDT, we also aim to create a supportive context for the staff during the course program. By providing a meaningful rationale for the intervention, acknowledge the staff's feelings, and give opportunities for choice and contribution, their autonomy is supported. Structure is provided through informative feedback, clear expectations and optimal challenges while interpersonal involvement will be ensured by devoting time, energy and affection to the staff before, during and after the course sessions (41, 42). An overview of the trial procedure is outlined in Figure 2.

Study design

The study is designed as a matched-pair cluster-randomized trial utilizing a mixed methods approach. The intervention group will receive the Active play in ASP intervention while the control ASPs receive no follow-up in addition to the usual afterschool program. A process evaluation is embedded in the trial (Figure 2).

[Insert figure 2 here]

Recruitment

The intervention follow-up and the trial rely on assistance from local school physiotherapists. Even though municipalities in Norway are strongly advised to ensure physiotherapy resources for health promotion activities in schools through the school health services, such resources are generally scarce. Thus, as a first step in the recruitment process, all school health services in centrally located municipalities (maximum 90 minutes' drive from the study office) in three counties in the eastern part of Norway will be approached and invited to participate (N≈45). As a sufficient number of school physiotherapists are located and have signed up, they are asked to assist in the further recruitment of ASPs in schools within their area of responsibility. This will provide us with a sample of schools

willing to participate. School administrators are required to provide written consent to participation. The consent is obtained before randomization and is considered binding. After randomization, the parents of all first grade pupils (age 5-6 years) attending the participating ASPs are informed about the study and asked for a written consent on behalf of their child. The age group is chosen based on the fact that nearly every first grader in Norway attends ASP and that we have less information about physical activity in this group compared to older children. All ASP staff and physiotherapists will be asked for a written consent to participation in the trial. The control ASPs will be offered the intervention after the study is completed.

Randomization

Prior to randomization, the clusters, that is the ASPs in the schools, will be paired based on available background information on size and geography. The categories "small", "medium" or "large" and "urban" or "rural" are chosen based on the assumption that the size of the school with regard to number of pupils as well as space and access to nature areas may have an impact on the children's activity level. Following matching, tags with the names of the ASPs are put in envelopes and sealed, and then randomly allocated to receive the intervention or to control. While the recruitment, enrolment of participants and the matching of clusters are done by the research team, the person revealing the allocation is not involved in the study. Due to the design of the study, a blinding of trial participants (ASP staff) and outcome assessors is not feasible.

Measures

Excepting the qualitative interviews and process evaluation performed in the intervention group post intervention, measures are obtained from both groups at three time points: at baseline (T0), immediately after the 7 months intervention (T1) and one-year post intervention (T2). A timeline for the intervention study is shown in Figure 2.

Because no measure is suitable for assessing both type, amount, intensity, variability, quality and experience of physical activity, several instruments and methods, quantitative as well as qualitative, will be used to capture as much information as possible. The primary outcome will be child physical activity intensity, which will be assessed objectively by ActiGraph© accelerometer during the time spent in ASP over a period of one week. Following a standardized procedure, the accelerometers will be fitted to the child by one of the staff members at the time of arrival and removed before leaving for home. In order to detect the intermittent activity patterns of small children, the accelerometer will collect data at 10-s epochs. Minutes spent in moderate and vigorous physical activity (MVPA), low physical activity and inactivity will be estimated with cut points with MVPA defined at equal to or above 2000 counts per minute, low activity between 100 and 1999 counts per minute and inactivity at less than 100 counts per minute (43). The length of time spent in the ASP will be accounted for. To supplement the accelerometer measurements, the schedule of the day, common activities (duration of different types of activities) and factors that may affect physical activity indoors and outdoors (number of staff, weather, special events) will be logged daily by ASP staff during the week of accelerometer measurements.

Moreover, a sub sample will be directly observed during ASP time. Registrations of both quantified physical activity (type, intensity, duration and frequency) and rich descriptions of physical activity during a day in ASP will be performed. Finally, qualitative interviews will be performed post intervention with a subsample of two children from each cluster in the intervention group. This sample will be strategically chosen by the ASP-leader. The interview will focus on the children's experiences with physical activity in the ASP.

Secondary outcomes include the child's experience of being in the ASP. Items are adjusted from a questionnaire from the Norwegian part of the Health Behaviour in School-aged Children (HBSC) study (44). The items are chosen based on how they correspond with key concepts of SDT. The questions are answered electronically by the child in cooperation with the parents. Furthermore, child well-being, in this study conceptualized as health-related quality of life, is assessed by the Kidscreen-27 proxy version and obtained electronically (45). Self-reported leisure time physical activity outside school and ASP will be measured by the UngKan2 questionnaire. This measure is widely used in national studies of child and youth physical activity, providing reference data for the present study. (43). The questionnaires will be completed electronically at home during the week of accelerometer measurements. An email with an invitation to a survey is sent to the parents of each participating child. Except for the Kidscreen-27, which is a proxy instrument, the questions are answered by the children in cooperation with their parents. Additionally, in order to control for body mass, the children's height and weight will be measured and body mass index (BMI) calculated (46). The local school nurse or school physiotherapist will be responsible for the measurements following a written procedure. Data on gender and age are collected.

For evaluation of if and how the intervention may benefit the ASP staff, self-report instruments will be used for assessing their work-related basic needs satisfaction (47), motivation for work (48), job satisfaction (49) and subjective well-being (50). At baseline, the staff will also be asked to report age, sex and duration of employment in the current ASP.

A process evaluation will be performed at the end of the intervention (51).. All ASP staff from the intervention ASPs will be asked to complete a short questionnaire including questions on the experience of participation, potential obstacles, gains and improvements. Contextual influences on the implementation, program fidelity, potential adjustments to the intervention and the number of employees attending the meetings, will be recorded. Data will be supplemented by summaries from the meetings and reviews of the intervention documents. A convenience sample of 3-5 staff members from each cluster will be asked to participate in semi-structured focus group interviews exploring views on impact of the intervention on the children, the ASP in general and on the staff. They are also asked questions regarding potential improvements. All physiotherapists will be invited to participate in a similar focus group.

Sampling

A rough estimate of the required sample size is based on the primary outcome physical activity as measured by ActiGraph© accelerometer. Due to the exploratory nature of our study, we keep the significance level alpha at 1% and power at 90% to correct for multiple testing. All tests will be two-sided. Based on the results of our pilot test and previous studies (14, 16), we consider 6 minutes increase in moderate and vigorous physical activity (MVPA) during ASP time to be of clinical importance, which represents 10% of the one hour of MVPA recommended by the guidelines. Based on the above, we estimate N to be 121 in each group without accounting for cluster effects. We plan to enrol 200 children in each group to secure sufficient power for additional analyses on cluster level. With an estimation of a minimum of 25 first graders in each ASP, we will have to include a maximum of 16 ASPs. Based on experiences from the pilot, we have reasons to assume that the majority of the parents will give their consent.

For the qualitative observations, a sample of three children from each cluster will be randomly drawn. Initially, the children are stratified based on gender to ensure equal distribution of boys and girls.

The children eligible for selection for the qualitative interviews will be in the intervention group. A roughly estimated sample size would be 16-20 children with 2-3 children from each ASP. A strategic sampling aimed at maximum variation according to gender and ethnicity is an appropriate sampling procedure.

The expected number of participating ASP staff depends on the size of the ASPs that accept the request for participation. A rough estimate is 8-10 employees per ASP, yielding a sample of approximately 150.

Analysis

The observations will be analysed and presented with descriptive statistics in addition to text summaries. The differences between the intervention group and the control group will be assessed by repeated measure analyses using linear mixed models for repeated measures as implemented in SPSS. This approach is flexible and it is possible to model the dependence between observations from the same individual. Intervention status and time period will be modelled as main effects while a cluster effect will be accounted for in the model as a random effect.

Information from the activity logs recorded by the ASP-staff will be quantified and categorized to be included in analysis of whether contextual factors (weather, indoor/outdoor, organized/unorganized physical activity) influence mean physical activity intensity.

. Qualitative interviews and field notes from the observations will be analysed by systematic text condensation, implying a hermeneutic approach to data collection and analysis (52, 53). The NVivo 10 software for qualitative analysis will be used. Process data will be summarized and the text will be analysed using simple content analysis (54).

Ethics

The study is reviewed and approved by The Data Protection Official for Research (NSD). Informed consent to participate in the study is requested from the parents on behalf of the children. In addition, age adjusted oral information will be given to the young children. Participants are guaranteed full confidentiality. Consent to participate in the trial will also be obtained from the ASP staff and the physiotherapists.

Information about participant identities will be stored separately from the study results. Data are anonymized in all publications and reports of the study. Participant data are protected in accordance with NSD's guidelines.

Dissemination

Results from the study will be published in scientific peer-reviewed journals and master thesis. Reports written in lay language will be provided to all participating ASPs and school administrations when the study is completed. Any changes or additions to the protocol will be reported to The Norwegian Centre for Research Data and registered in clinicaltrials.gov. Authorship is granted to project group members and others that fulfil the authorship criteria recommended by the International Committee of Medical Journal Editors.

DISCUSSION

The apparent need for systematically developed physical activity interventions adaptable to Norwegian ASPs makes a strong case for the trial described. The article describes how a complex intervention to ensure physical activity play during ASP time is carefully developed in close cooperation with school physiotherapists and representatives from ASPs. That the intervention originates from practice, and that the practice experiences are combined with previous research

within a theoretical framework, are among the advantages of this study. Involvement of appropriate users in the different stages of an intervention study is likely to result in a higher chance of producing implementable data (29).

The present article also describes how the intervention will be explored in a matched-pair cluster-randomized trial. A strength of the planned trial is its combination of measures of physical activity. Interventions, whether they include physical activity as a primary or secondary outcome, tend to focus on the *quantity* of physical activity (duration, intensity and frequency), and not the *quality*. This study aims to mix objectively measured physical activity, logs and direct observations to be better able to give rich descriptions of the concept of children's physical activity in ASP. By including qualitative methods in the investigation, we gain information about the type of physical activity the children actually perform, where they perform the activity, with whom they spend time, and whether the activity is initiated and managed by the children themselves or by adults. Mixing methods in the same study may thus increase the possibility of evaluating the effect in addition to gaining an understanding of the mechanisms involved in the outcome of the intervention (55).

Trial Status

The intervention is ongoing with baseline data collection completed in October 2016. Short-term intervention (T1) data collection is due to be completed in June 2017 and long-term data in June 2018. The study was registered in Clinical Trials (NCT02954614) in October 2016, prior to start-up of the intervention.

Acknowledgments

We thank the ASP staff that have been involved in the development and piloting of the intervention and the trial. Their enthusiastic participation was decisive in the development of Active play in ASP.

FOOTNOTES

Contributors

All the authors contributed to the study's conception, planning and design. KR and HE were responsible for drafting the intervention and managing the pilot trial. KR had primary responsibility for writing the paper in close collaboration with KL. HE, BF and SH participated in revising the article by providing comments and revisions. All authors approved the final version for publication.

Funding

This project is funded by the Norwegian Fund for Postgraduate Training in Physiotherapy and Oslo and Akershus University College of Applied Sciences.

Competing interests

None declared.

Ethics approval

The study was first reviewed by The Regional Committee for Medical and Health Research Ethics. The Committee concluded that the study is not covered by the Health Research Act. Consequently, the study protocol was submitted and reviewed by The Data Protection Official for Research (NSD) to ensure that that the project is in accordance with the Personal Data Act and the Personal Health Data Filing System Act (reference number 46008).

Data sharing statement

Once the study is completed, we will publish all relevant results. Unpublished results could be made available on request by contacting the authors.

References:

1. Janssen I, Leblanc AG. Systematic review of the health benefits of physical activity and fitness in school-aged children and youth. The international journal of behavioral nutrition and physical activity. 2010;7:40.
2. Biddle SJ, Gorely T, Stensel DJ. Health-enhancing physical activity and sedentary behaviour in children and adolescents. J Sports Sci. 2004;22(8):679-701.
3. Biddle SJ, Asare M. Physical activity and mental health in children and adolescents: a review of reviews. British journal of sports medicine. 2011;45(11):886-95.
4. Fedewa AL, Ahn S. The effects of physical activity and physical fitness on children's achievement and cognitive outcomes: a meta-analysis. Research quarterly for exercise and sport. 2011;82(3):521-35.
5. Ommundsen Y, Løndal K, Loland S. Sport, children and well-being. In: Ben-Arieh A, Casas F, Frønes I, Korbin JE, editors. Handbook of child well-being. Dordrecht: Springer Reference; 2014.
6. Waters E, de Silva-Sanigorski A, Hall BJ, Brown T, Campbell KJ, Gao Y, et al. Interventions for preventing obesity in children. Cochrane database of systematic reviews. 2011(12):CD001871.
7. Gadamer H. Truth and method. London: Sheed and Ward; 1989.
8. Pellegrini AD, Smith PK. Physical activity play: the nature and function of a neglected aspect of playing. Child development. 1998;69(3):577-98.
9. Gallahue DL, Ozmun JC. Understanding motor development : infants, children, adolescents, adults. 6th ed. Boston ; London: McGraw Hill; 2006. xix, 524 p. p.
10. Caspersen CJ, Powell KE, Christenson GM. Physical activity, exercise, and physical fitness: definitions and distinctions for health-related research. Public Health Rep. 1985;100(2):126-31.
11. Warren JM, Ekelund U, Besson H, Mezzani A, Geladas N, Vanhees L, et al. Assessment of physical activity - a review of methodologies with reference to epidemiological research: a report of the exercise physiology section of the European Association of Cardiovascular Prevention and Rehabilitation. Eur J Cardiov Prev R. 2010;17(2):127-39.
12. Dobbins M, Husson H, DeCorby K, LaRocca RL. School-based physical activity programs for promoting physical activity and fitness in children and adolescents aged 6 to 18. Cochrane database of systematic reviews. 2013;2:CD007651.
13. The Norwegian Directorate of Health. [Norwegian guidelines on diet, nutrition and physical activity]. Oslo: The Norwegian Directorate of Health; 2014.
14. Beets MW, Beighle A, Erwin HE, Huberty JL. After-school program impact on physical activity and fitness: a meta-analysis. American journal of preventive medicine. 2009;36(6):527-37.
15. Beets MW, Weaver RG, Turner-McGrievy G, Huberty J, Ward DS, Pate RR, et al. Making policy practice in afterschool programs: a randomized controlled trial on physical activity changes. American journal of preventive medicine. 2015;48(6):694-706.
16. Cradock AL, Barrett JL, Giles CM, Lee RM, Kenney EL, deBlois ME, et al. Promoting physical activity with the out of school nutrition and physical activity (OSNAP) initiative: A cluster-randomized controlled trial. JAMA Pediatr. 2016;170(2):155-62.
17. Gortmaker SL, Lee RM, Mozaffarian RS, Sobol AM, Nelson TF, Roth BA, et al. Effect of an after-school intervention on increases in children's physical activity. Med Sci Sports Exerc. 2012;44(3):450-7.
18. Hughey SM, Weaver RG, Saunders R, Webster C, Beets MW. Process evaluation of an intervention to increase child activity levels in afterschool programs. Eval Program Plann. 2014;45:164-70.
19. Green K. Understanding physical education. London: Sage; 2008. vii, 280 p. p.
20. Løndal K. Revelations in bodily play. A study among children in an after-school programme. Phd Dissertation. Oslo2010.
21. Løndal K, Bergsjø C. [Physical activity in after-school programmes. A study of four after-school programmes in Oslo]. Oslo: Oslo Univeristy College; 2005.
22. Løndal K. Children's lived experience and their sense of coherence: Bodily play in a Norwegian after-school programme. Child Care in Practice. 2010;16(4):391-407.

23. Løndal K, Lund S, Bergsjø CH. [Facilitating physical activity in after-school programmes in Oslo]. Tidsskriftet FoU i praksis. 2016;10(2):43-61.
24. Dowda M, Pate RR, Trost SG, Almeida MJ, Sirard JR. Influences of preschool policies and practices on children's physical activity. J Community Health. 2004;29(3):183-96.
25. Constantinides P, Montalvo R, Silverman S. Teaching processes in elementary physical education classes taught by specialists and nonspecialists. Teach Teach Educ. 2013;36:68-76.
26. Løndal K, Greve A. Didactic approaches to child-managed play: Analyses of teacher's interaction styles in kindergartens and after-school programmes in Norway. International Journal of Early Childhood. 2015;47(3):461-79.
27. Cheon SH, Reeve J, Yu TH, Jang HR. The teacher benefits from giving autonomy support during physical education instruction. Journal of sport & exercise psychology. 2014;36(4):331-46.
28. The Norwegian Directorate of Health. [Strategy for the public health center- and the school health service]. Rapport IS-1798. Oslo: The Norwegian Directorate of Health; 2010.
29. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337:a1655.
30. Øygardslia H. [Interventions to increase physical activity in after-schhool programmes; a systematic review] [Master thesis]. ODA Open Digital Archive: Oslo and Akershus University College of Applied Sciences; 2016.
31. Huberty JL, Dinkel DM, Beets MW. Evaluation of GoGirlGo!; A practitioner based program to improve physical activity. BMC Public Health. 2014;14:118.
32. Iversen CS, Nigg C, Titchenal CA. The impact of an elementary after-school nutrition and physical activity program on children's fruit and vegetable intake, physical activity, and body mass index: Fun 5. Hawaii Med J. 2011;70(7 Suppl 1):37-41.
33. Thaw JM, Villa M, Reitman D, DeLucia C, Gonzalez V, Hanson KL. Evidence-based fitness promotion in an afterschool setting: implementation fidelity and its policy implications. New Dir Youth Dev. 2014;2014(143):103-31.
34. Ryan RM, Deci EL. Active human nature. In: Hagger MS, Chatzisarantis NL, editors. Intrinsic motivation and self-determination in exercise and sport. Champaign: Human Kinetics; 2007. p. 1-21.
35. Standage M, Gillison F, Treasure D. Self-determination and motivation in physical education. In: Hagger MS, Chatzisarantis NLD, editors. Intrinsic motivation and self-determination in exercise and sports. Champaign; IL: Human Kinetics; 2007. p. 71-87.
36. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. American Psychologist. 2000;55(1):68-78.
37. Ryan RM, Patrick H, Deci EL, Williams GC. Facilitating health behaviour change and its maintenance: Interventions based on Self-Determination Theory. The European Helath Psychologist. 2008;10:2-5.
38. Edmunds J, Ntoumanis N, Duda JL. Testing a self-determination theory-based teaching style intervention in the exercise domain. Eur J Soc Psychol. 2008;38(2):375-88.
39. Broström s. SFO som arena for læring. In: Ankerstjerne IT, editor. SO- og fritidspedagogik -før, nu og i fremtiden. Fredrikshavn: Dafolo; 2010.
40. Fortier MS, Duda JL, Guerin E, Teixeira PJ. Promoting physical activity: development and testing of self-determination theory-based interventions. Int J Behav Nutr Phy. 2012;9.
41. Edmunds JK, Ntoumanis N. Perceived autonomy support and psychological need satisfaction in exercise. In: Hagger MS, Chatzisarantis NLD, editors. Intrisic motivation and self-determination in exercise and sport. Champaign, IL: Human Kinetics; 2007.
42. Reeve J. Self-determination theory applied to educational settings. In: Deci EL, Ryan RM, editors. Handbook of self-determination research. Rochester, NY: University of Rochester Press; 2002.
43. Kolle E, Stokke J, Hansen B, Andersen S. [Physical activity among 6-,9,- and 15 year olds in Norway 2011.]. Oslo; 2012.
44. Samdal O, Leversen I, Torsheim T, Manger MS, Brunborg GS, Wold B. [Trends in health and lifestyle among children and adolescents 1985-2005. Norwegian results from the study "Health

behavior among school children. A WHO study in several countries]. Bergen: HEMIL-senteret, University of Bergen; 2009.
45. The KIDSCREEN Group Europe. The KIDSCREEN questionnaires. Quality of life questionnaires for children and adolescents Lengerich, Germany: Pabst Science Publishers; 2006.
46. Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child overweight and obesity worldwide: international survey. BMJ. 2000;320(7244):1240-3.
47. Van den Broeck A, Vansteenkiste M, De Witte H, Soenens B, Lens W. Capturing autonomy, competence, and relatedness at work: Construction and initial validation of the Work-related Basic Need Satisfaction scale. Journal of Occupational and Organizational Psychology. 2010;83(4):981-1002.
48. Gagné M, Forest J, Vansteenkiste M, Crevier-Braud L, Van den Broeck A, Aspeli AK, et al. The Multidimensional Work Motivation Scale: Validation evidence in seven languages and nine countries. European Journal of Work and Organizational Psychology. 2015;24(2):178-96.
49. Andersen IA, Andersen JR. [Validation of an instrument to measure job satisfaction]. Sykepleien Forskning. 2012;7:334-40.
50. Pavot W, Diener E. Review of the satisfaction with life scale. Psychological assessment. 1993;5(2):164.
51. Atkins S, Odendaal W, Leon N, Lutge E, Lewin S. Qualitative process evaluation for complex interventions. In: D.A R, Hallberg IR, editors. Complex interventions in health; An overview of resarch methods. New York: Routhledge; 2015.
52. Kvale S, Rygge J, Brinkmann S, Anderssen TM. Det kvalitative forskningsintervju. 2. utg. ed. Oslo: Gyldendal akademisk; 2009.
53. Malterud K. Systematic text condensation: A strategy for qualitative analysis. Scand J Public Healt. 2012;40(8):795-805.
54. Schreier M. Qualitative Content Analysis in Practice. Thousand Oaks, CA: Sage Publications LTD; 2012.
55. Hallberg IR. Knowledge for health care practice. In: Richards DA, Hallberg IR, editors. Complex interventions in health: An overview of research methods. New York: Routhledge; 2015.

[Figure 1 Process of development of Active play in ASP]

[Figure 2 Flow chart of the study design]

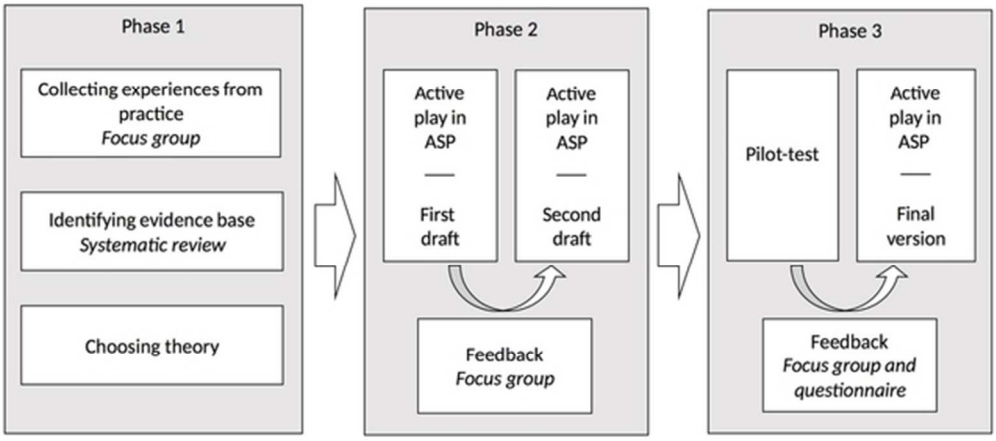


Figure 1 Process of development of Active play in ASP

54x23mm (300 x 300 DPI)

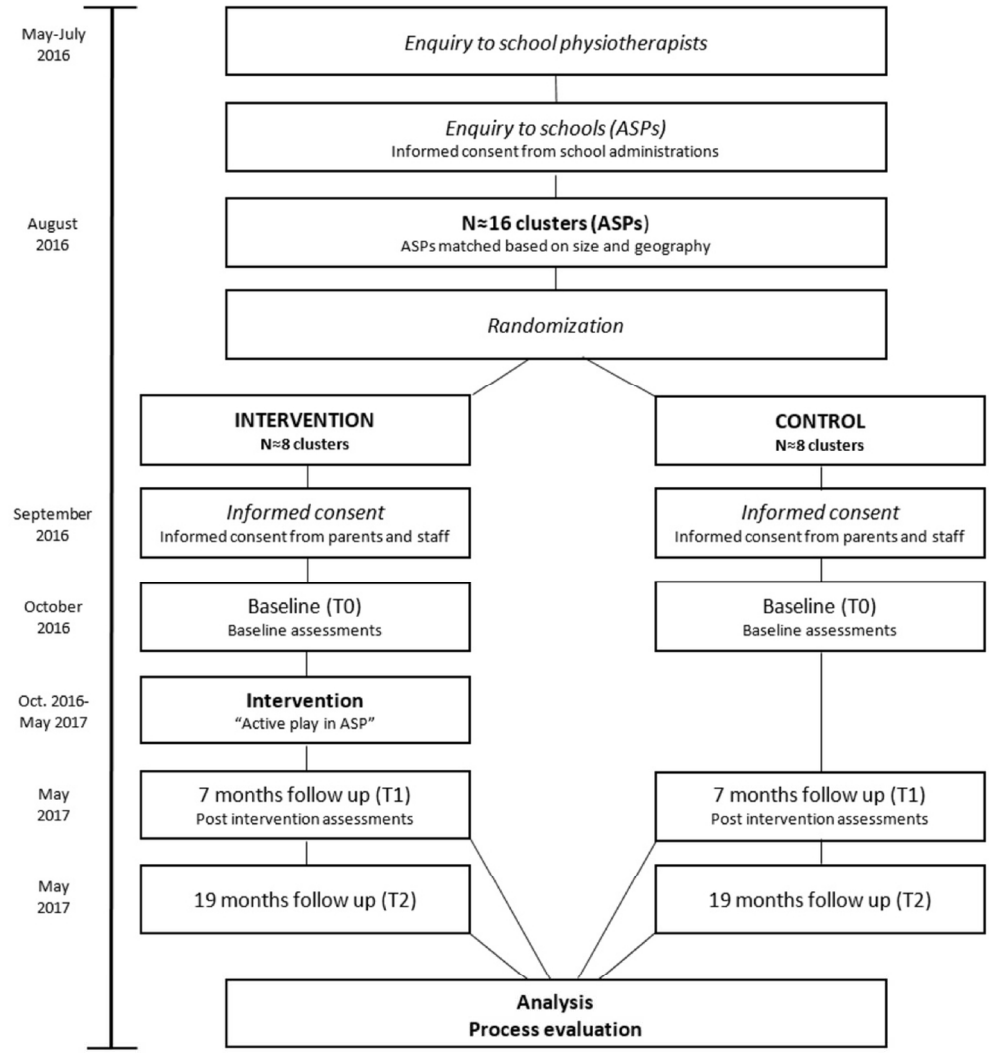


Figure 2 Flow chart of the study design

99x107mm (300 x 300 DPI)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	_1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_2_____
	2b	All items from the World Health Organization Trial Registration Data Set	_____
Protocol version	3	Date and version identifier	_____
Funding	4	Sources and types of financial, material, and other support	_12_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_1,11_____
	5b	Name and contact information for the trial sponsor	_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_____

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	_2,3_____
	6b	Explanation for choice of comparators	_____
Objectives	7	Specific objectives or hypotheses	__3_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	__6,7_____
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	__7_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	__7,8_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	__5,6_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	___8,9_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	___7_____

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7,9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7,8
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8,9
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	___9,10_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	___9_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	__9,11_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	__10_____

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	__9_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	__10_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	__11_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	__10_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_____
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.