Study Protocol Health Childcare Centre of the Future

STUDY DATA			
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SUMMARY

Rationale: From 2015-2020, the 'Healthy Primary School of the Future' intervention took place in Parkstad. The school environment of four primary schools changed. Two schools became 'Healthy Primary Schools of the Future'; providing their students with a healthy lunch and structured physical activity (PA) sessions during lunch time breaks. Two other 'Physical Activity Schools' only implemented the structured PA sessions. METC Z previously decided that this study falls under non-WMO guidelines (METC-Z no. 14-N-142). Interim analyses showed promising effects of the intervention; at two-year-follow-up, the study showed a significant decrease in BMI z-score of children in the 'Healthy Primary Schools of the Future' as compared with children in control schools. Also, positive intervention effects on dietary and PA behaviours were observed. Following these promising results, childcare centres of educational board Prisma have expressed their interest in implementing changes fitting the 'Healthy Primary School of the Future' initiative. However, this is more complex than it seems to be, as budget to implement changes is lower than in the original trial, and all childcare centres have a unique context. Therefore, there is a need to investigate how 'Healthy Primary School of the Future' can successfully be implemented in various, real-life school-settings. It is hypothesised that to maximise implementation and sustainability, each childcare centre will need to put together a set of changes and interventions which fit the context and needs of all stakeholders involved (e.g., the school board, teachers, parents and children).

Objective: The main objective is to study the implementation process of 'Healthy Childcare Centre of the Future' in different school-contexts and develop guidelines that can be used to facilitate widespread dissemination of the initiative. Secondary objectives include evaluating the effects of the 'Healthy Childcare Centre of the Future' on children's BMI z-score, general health, dietary and PA behaviours and school well-being. To reach these objectives, a process evaluation, effect evaluation and cost-effectiveness evaluation will be executed.

Study design: A non-randomised, non-controlled, observational study design.

Study population: Children in study years four to six (at baseline) of twelve childcare centres located in Limburg.

Main parameters/endpoints: The main study parameter of the effect evaluation is the change in absolute BMI z-score, which will be compared between the childcare centres that are categorised based on their degree of implementation (using categories based on the Diffusion of Innovations Theory).

Methods: Data will be collected in the form of questionnaires (parents, children, teachers/pedagogical employees, directors), anthropometric measurements (children), interviews (teachers/pedagogical employees, directors), observations and analyses of minutes of meetings.

Nature and extend of the burden and risks associated with participation: No intervention is allocated in this study other than activities planned by childcare centres in accordance with wishes and needs of childcare centre staff and parents. All outcome measures are non-invasive. The measurement protocol was designed while taking into account both a minimal burden for participants and a relevant scientific output for stakeholders (e.g., school board, teachers, parents/caregivers and children). Burden of participants is minimalised by incorporating most measurements in the regular school day.

1. INTRODUCTION

In the Netherlands, the number of children suffering from overweight and obesity is increasing. In Peel en Maas, a region in the north of Limburg, 5.0% of 4.5-6 year-olds and 13.3% of 9-11 year-olds suffered from overweight in 2016. For obesity, these percentages were 1.8% and 2.0% respectively (1). The increasing prevalence of juvenile overweight and obesity is a public health concern, because they often have negative psychological and social consequences. Furthermore, they can increase the risk of developing certain non-communicable diseases (NCDs). The health risks associated with overweight and obesity also lead to an increase in health care costs, which puts a large economic burden on society (2–4).

Important causes of the increasing prevalence of juvenile overweight and obesity are unhealthy dietary and physical activity (PA) habits. (WHO, 2017). Despite the health benefits associated with engaging in healthy lifestyle behaviours, the present habits of Dutch children show room for improvement. Currently, only 42% of children aged 4–9 years consume at least 150 grams of fruit per day; this percentage drops to 20% for 9–12 year-olds. The prevalence of vegetable intake shows similar percentages: 41% of 4–9 year-olds and 25% of 9–12 year-olds eat at least 150 grams of vegetables per day (CBS, RIVM, & The Netherlands Nutrition Centre, 2017). Looking at PA habits, only 17.1% of Dutch children aged 4-11 reach the advised daily norm of 60 minutes of moderate to vigorous PA and only 29.9% reach the Fitnorm (i.e., 20 min three days/week exhaustive PA) (7). These numbers underpin the importance of promoting healthy lifestyle habits in young children. Doing so could not only contribute to improvements in health but also to increased well-being (i.e., better concentration, increased feelings of happiness and satisfaction).

The school setting is the ideal environment to promote healthy lifestyle habits as:
1) Health behaviours are learned at a young age, and healthy lifestyles learned early in life usually track into adulthood (8);
2) There is strong evidence that healthy lifestyles are correlated with high academic achievements (Bass, Brown, Laurson, & Coleman, 2013; Edwards, Mauch, & Winkelman, 2011; Florence, Asbridge, & Veugelers, 2008; Van Dusen, Kelder, Kohl, Ranjit, & Perry, 2011);
3) Children from all socio-economic classes will be reached;
4) Directors, teachers, parents/caregivers and children are all involved in school-based communities, thereby involving not only children, but an entire community.

Worldwide, several high-quality health-promoting school initiatives have been evaluated (13,14). According to the WHO, a health-promoting school is one that constantly strengthens its capacity as a healthy setting for living, learning and working (15). In general, a school is considered health-promoting if interventions are given to reduce risk factors for NCDs (e.g., obesity, low PA levels, smoking, unhealthy nutrition), demonstrating active participation by the school and involving health-promoting activities in all or one or two of the following areas:
(a) the school ethos and/or environment, such as school policy;
(b) the school curriculum;
(c) the family and/or community.

The majority of studies on healthy school environment focus on obesity prevention (16,17). Several meta-analyses and reviews showed that school-based projects can be successful, although effects are often modest (14,16–19). In a meta-analysis which included eighteen school-based RCT intervention studies in children, significant Body Mass Index (BMI) reductions of -0.076 (95% CI -0.123 to -0.028, $p<0.01$) were found in intervention vs. control schools. However, results remain modest and several school-based interventions did not show reductions in BMI (20). The effects of health-promoting schools on lifestyle behaviours such as sedentary behaviour and dietary behaviour have frequently been studied as well. Saraf et al. showed that of all school-based interventions aimed at reducing risk factors associated with NCDs, 80% reported at least some evidence of a positive intervention effect (21). Examples of nutrition-related behaviours which can be improved with school-based interventions are consumption of high-fibre foods, healthier snacks, water, milk, fruit and vegetables (22). Also breakfast skipping, eating disorders, consumption of low-nutrient dense food, fatty and cream foods and sugar-sweetened beverages can be reduced in health-promoting schools. In a meta-analysis of Evans et al. (2012), a significant average improvement of 0.25 portions (95% CI: 0.06, 0.43 portions) of fruit and vegetable daily intake (fruit juice excluded) was found after implementation of school health interventions (23). Health-promoting schools are often accompanied with high exploitation costs for personnel, meals and logistics, which is a high barrier for implementation. However, health-promoting schools have the potential to be highly cost-effective, as effects on several outcome parameters are expected. Prior studies already showed that school-based programmes may be more cost-effective in terms of quality of life and BMI when compared with other obesity prevention programmes (24,25).

Despite the potential of school-based health interventions, they are often not integrated in the school system and are characterised by relatively low priority, a lack of coordination, and are often supply-driven, resulting in limited effects or effects that diminish in the long term (26,27). A major limitation of many school-based programmes is the lack of space in already full curricula, and time and financial concerns (20). In most of the school-based programmes, the physical and social environment is not adapted towards the 'individual-level' interventions. For example, Doak et al. highlight the difference between teaching children that they should be more active and eat more fruit and vegetables, and actually giving them the opportunity in terms of time, space and facilities to do so (28). Additionally, interventions are often not context-specific, although evidence suggests that there is a strong interaction between an intervention and the context in which it is being implemented (29). This means that what works in one school might not work in other schools, and therefore interventions should be adapted towards the specific context in which they are being implemented.

The above-mentioned flaws were taken into account in the development of 'The Healthy Primary School of the Future' (HPSF). HPSF is a Dutch initiative based on the Health Promoting School Framework (including e.g., a whole school approach, high involvement of parents/caregivers and partnerships). It acknowledges that implementation challenges can occur due to an interaction between the intervention and the context (30,31). In 2015, a quasi-experimental trial aiming to evaluate HPSF was initiated. This trial was previously registered on ClinicalTrials.gov (NCT02800616). It involved eight primary schools in the South of Limburg: four intervention schools and four control schools. Intervention schools introduced changes regarding the following key elements:

- **A healthy school lunch,** which children consume together. The lunch is provided by school or an external caterer and its contents are in accordance with the guidelines from the Netherlands Nutrition Centre (at least 80% of the products being served are from the Wheel of Five);
- **A longer lunch break** of at least one-and-a-half hour a day. In this way, there is more time for lunch (30 minutes), and PA and cultural activities (one hour);
- **Childcare staff** guide the lunch break. Although volunteers are still welcome to help, the lunch break is mainly guided by professionals;
- **Sport and cultural coaches** support childcare staff during the PA and cultural activities. External partners are active within the school environment;
- **Parents are actively involved** from the start of the project. They share their views on further development of the project and they volunteer during lunch breaks.

Two of the intervention schools implemented both a healthy school lunch and structured PA sessions during lunch break time (full HPSF schools). The other two intervention schools only implemented the structured PA sessions (partial HPSF schools). A detailed description of the study design, recruitment of participants and measurements can be found in Willeboordse et al. (32). Maastricht University is currently investigating the effects of HPSF on a broad range of effect measures (e.g., PA behaviour, BMI z-score, dietary behaviour). Although the project is still ongoing, interim analyses show promising effects. At two-year-follow-up, the study showed a significant decrease in BMI z-score of children in the HPSF schools as compared with children in control schools (33). Also, positive intervention effects on both dietary and PA behaviours were observed at two-year-follow-up (34).

These promising effects have led to an increased interest among other primary schools to implement changes fitting the HPSF initiative. One of these interested parties is educational board Prisma. Prisma comprises several childcare centres in Peel en Maas, a region in the northern part of Limburg. Both childcare and primary education for children aged 0-12 years are located in these childcare centres, meaning that children are looked after by the same people prior, during and after school time. The goal of Prisma is to ensure a healthy development for all children. A means to achieve this goal is to implement changes fitting the HPSF initiative. However, this is more complex than it seems to be, as the budget to implement changes is lower than in the original HPSF trial, and all childcare centres have their own unique context. Therefore, there is a need to investigate how HPSF can successfully be implemented in various, real-life school-settings. To maximise

implementation and sustainability, each childcare centre will need to put together their own unique set of changes and interventions which fit the context and the needs of all stakeholders involved (e.g., the school board, teachers, parents and children). All changes will fall in one of the four categories:

- Healthy and sustainable nutrition;
- Sufficient physical activity;
- Sufficient rest and relaxation;
- Collaboration and social involvement

To aid childcare centres in the development and implementation process and to study programme effectiveness, the 'Healthy Childcare Centre of the Future' (HCCF) project was initiated in cooperation with a broad range of partners. The first part of this project was to assess the needs of various stakeholders involved in the project, which was done via questionnaires and interviews with several stakeholders. Thanks to this needs assessment, childcare centres now have a better idea of the views of important stakeholders such as parents, children and teachers. The second part of the project comprises the actual implementation of HCCF within the Prisma childcare centres. Maastricht University plays an important role in HCCF. Researchers will play an advisory role and study the implementation process of HCCF at the childcare centres. Additionally, researchers will study the project's (cost-) effectiveness and compare its effects with the results from the HPSF quasi-experimental trial. In this way, effectiveness and sustainability can be investigated and factors influencing implementation in various contexts can be identified and evaluated.

Conclusion

This observational study will show how and to what degree HCCF can effectively and sustainably be adapted and implemented in various contexts. In addition, barriers and facilitators of implementation will be identified and based on these factors, guidelines for widespread implementation will be formulated. Furthermore, the study will investigate the effects of HCCF on a range of outcome parameters among which health, lifestyle behaviours, and cost-effectiveness. The results of the effect-evaluation will be linked to the results of the process evaluation to identify implementation factors that influence effectiveness. In addition, the effects will be compared with the effects observed in the HPSF quasi-experimental trial to investigate the potential of HCCF to be implemented in a real-world setting.

1.1 Research questions

Process evaluation:

- How and to what degree is HCCF adapted and implemented in various school contexts (e.g., changes in school's practices, rules and regulations)?
- What are barriers and facilitators of implementation of HCCF in various school contexts?
- How can these barriers and facilitators be anticipated upon to facilitate maximum widespread implementation of HCCF?
- What are the experiences of different stakeholders with HCCF?

Effect evaluation:

- *Primary outcome*: At two-year follow-up, is there a difference in absolute BMI z-score between children from different childcare centres, which have been categorised based on their level of innovativeness and implementation?
- *Secondary outcomes:*
  - ➔ At two-year follow-up, is there a difference in waist/hip circumference between children from different childcare centres, which have been categorised based on their level of innovativeness and implementation?
  - ➔ At two-year follow-up, is there a difference in physical activity behaviours of children from different childcare centres, which have been categorised based on their level of innovativeness and implementation?

- ➔ At two-year follow-up, is there a difference in dietary behaviours of children from different childcare centres, which have been categorised based on their level of innovativeness and implementation?
- ➔ At two-year follow-up, is there a difference in health markers of children from different childcare centres, which have been categorised based on their level of innovativeness and implementation?
  At two-year follow-up, is there a difference in school well-being of children from different childcare centres, which have been categorised based on their level of innovativeness and implementation?

Cost-effectiveness evaluation:
- Will HCCF be cost-effective?

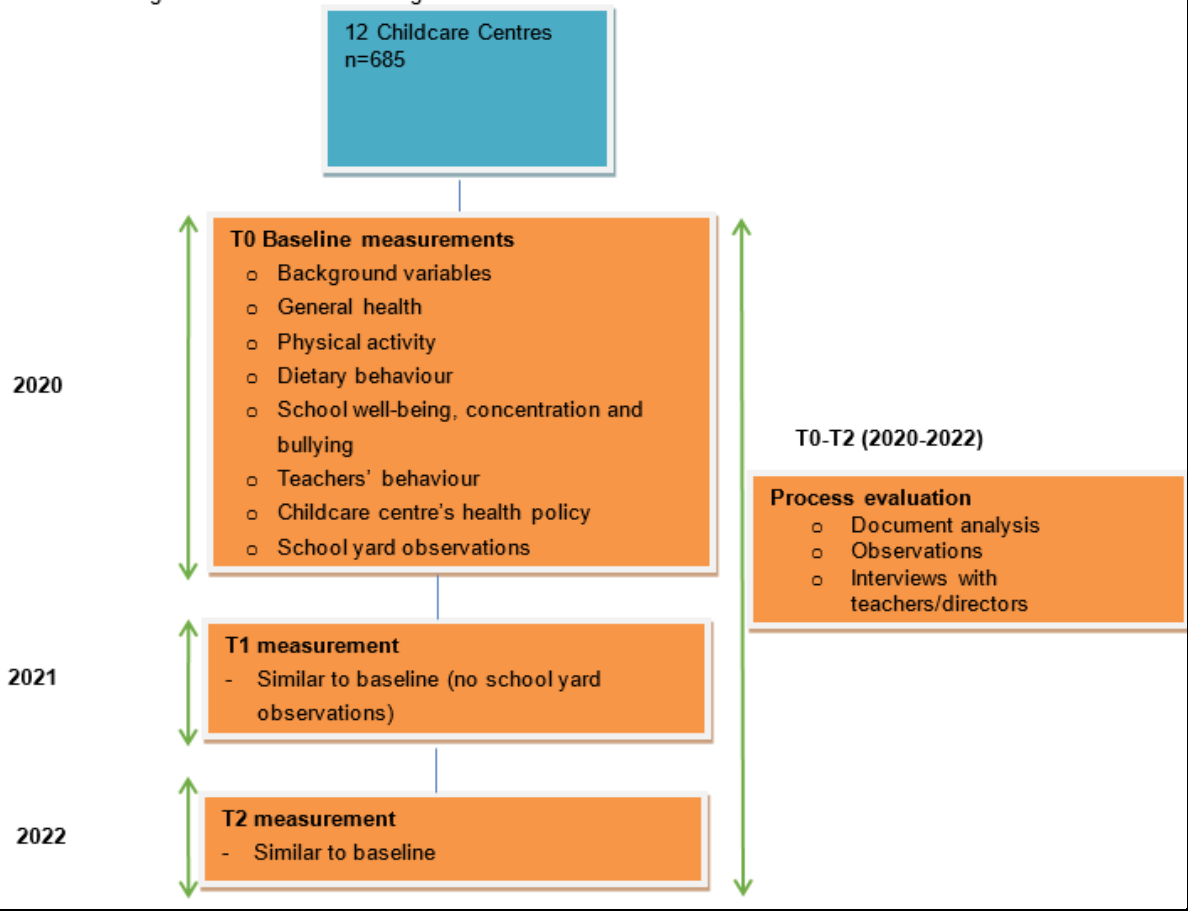
Comparison with original HPSF project:
- Will the (cost-)effectiveness of HCCF be comparable with the (cost-)effectiveness of the original HPSF intervention?

2. METHODS

2.1 Study procedure/study design

The current study involves twelve childcare centres from the Prisma educational board, which are all located in Peel en Maas. The childcare centres are selected based on their expressed interest to participate in the project. The childcare centres are free to choose if, when and how they want to implement changes fitting HCCF. To study programme effectiveness, a non-randomised trial will be executed. Instead of true intervention and control childcare centres, after the project, the centres will be divided into groups based on their implementation phase. This division will be based on the Diffusion of Innovations Theory by Rogers (1995). According to Rogers, there are five types of adopters, which all have different adoption rates of a given innovation. From fast to slow adoption rate, these types of adopters are: innovators, early adopters, early majority, late majority and laggards. These adopters vary in adoption rate due to a difference in innovativeness; the degree to which an individual/organisation adopts a new idea (35). When looking at the Prisma childcare centres, it is likely that some childcare centres will adopt changes fitting HCCF earlier than others. Therefore, the different childcare centres can be categorised using Rogers' categories, which will facilitate comparison between the different childcare centres. It is expected that the childcare centres can be divided in three categories: innovators/early adopters, early/late majority and laggards.
The total study duration will be four years, of which roughly the first six months are preparation and the last year is evaluation. Therefore, data will be collected for approximately two years. Figure 1 provides an overview of the study.

Figure 1. Flow Chart of Design and Measurements



2.2 Recruitment and selection of participants

Study population

A closed design will be used, meaning that at baseline (T0), all children in study year four to six of the Prisma childcare centres will be invited to participate in the study. At T1, these children will be students in study year five to seven, and at T2 they will be in study year six to eight. Based on the amount of children enrolled in school year 2019/2020, approximately 685 children are eligible to participate in the study.

Screening/selection

Both researchers and teachers will motivate parents/caregivers and children to enrol in all scientific measurements. Researchers will visit every childcare centre to inform teachers and children about the measurements. Children from study years four to six will receive a brochure from researchers with information about the research that is appropriate for their parents/caregivers as well as for themselves. Experience from the HPSF trial showed that this personal approach of researchers directly motivating children and teachers facilitated recruitment of participants. Besides motivating children and teachers through childcare centre visits, researchers will join regular, already-planned information meetings for parents at the childcare centres. If needed, new information meetings for parents will be organised as well. In this way, parents will be informed and encouraged to participate in the research.

Inclusion- and exclusion criteria

In order to be eligible to participate in the study, a subject must meet all of the following criteria:

- Student of study year four to six at one of the participating childcare centres of Prisma;
- Informed consent signed by both caregivers.

No exclusion criteria are applicable as this is a real-life study and all students who meet the inclusion criteria will be included for participation in this study.

Number of anticipated participants

Childcare centres are free to choose if, when and to what degree they implement HCCF changes in their childcare centre. After data collection, the twelve childcare centres will be divided into three categories based on the Diffusion of Innovations theory (innovators/early adopters, early/late majority, laggards) (35). Because this categorisation occurs after data collection, it cannot yet be predicted which childcare centres will fall under which category. However, based on the childcare centres' intentions that have become clear during preliminary discussions about the project, three potential scenarios can be illustrated where childcare centres are categorised within the three groups. These scenarios are further illustrated in the light of three sample size calculations that allow for clustered sampling. For the calculations, the following website is used: http://www.sample-size.net/means-effect-sizeclustered/ (36).

The sample size calculation was based on the primary outcome, i.e. to detect a difference in mean absolute BMI z-score between innovators/early adopters and laggards after two years intervention. The following general assumptions were used for the sample size calculation:

- Independent-samples t-test on difference in absolute BMI z-scores;
- Children are nested within schools;
- A significance level (alpha) of 0.05;
- A power of 80%;
- A dropout rate of 10%, as based on dropout rates observed by Bartelink et al.(33);
- An Intraclass Correlation Coefficient of 0.01, as based on Amorim et al. (37);
- Unequal cluster sizes with a relative efficiency of 90% (38);
- An average absolute BMI-z of 0.76 and an SD of 0.60 in the population (as no data was available for the population in Peel en Maas, these values were calculated over all children aged between 4 and 11 living in region Parkstad who visited the Youth Health Department in 2013).

Scenario 1

- *Innovators/early adopters:* three childcare centres, number of participants (N1)=120
- *Laggards:* four childcare centres, number of participants (N3)=220
- Average size of each cluster (m): 50
- With these assumptions we can demonstrate a Cohen's d of **0.369**, which means we can detect medium effect sizes on absolute BMI z-scores. A difference in mean absolute BMI z-score of **0.22** between innovators/early adopters and laggards can be detected. The detection of this difference is feasible in this population, as in a school-based longitudinal study with comparable intervention components, a mean difference between intervention and control group of -0.26 (CI 95%: 0.32, -0.21) BMI z-score was found (39).

Scenario 2

- *Innovators/early adopters:* four childcare centres, number of participants (N1)=217
- *Laggards:* four childcare centres, number of participants (N3)=217
- Average size of each cluster (m): 55
- With these assumptions we can demonstrate a Cohen's d of **0.331**, which means we can detect medium effect sizes on absolute BMI z-scores. A difference in mean absolute BMI z-score of **0.20** between innovators/early adopters and laggards can be detected. The detection of this difference is feasible in this population, as in a school-based longitudinal study with comparable intervention components, a mean difference between intervention and control group of -0.26 (CI 95%: 0.32, -0.21) BMI z-score was found (39).

Scenario 3

- *Innovators/early adopters:* four childcare centres, number of participants (N1)=217
- *Laggards:* five childcare centres, number of participants (N3)=303
- Average size of each cluster (m): 55
- With these assumptions we can demonstrate a Cohen's d of **0.314**, which means we can detect medium effect sizes on absolute BMI z-scores. A difference in mean absolute BMI z-score of **0.19** between innovators/early adopters and laggards can be detected. The detection of this difference is feasible in this population, as in a school-based longitudinal study with comparable intervention components, a mean difference between intervention and control group of -0.26 (CI 95%: 0.32, -0.21) BMI z-score was found (39).

2.3 Data collection

Methods

As the present study's results will be compared with the results of the HPSF quasi-experimental trial (NCT02800616), the majority of the outcome measures and data collection methods used in the present study will be equal to the outcome measures and data collection methods used in the HPSF trial. The main difference with the original HPSF trial is the fact that the amount of measurements within this project will be smaller than in the original trial.

Study Procedures

As shown in Table 1, outcome measurements will be gathered via various sources. Via the school system, data will be gathered regarding background variables and school absenteeism, which was also done in the HPSF trial. At Prisma, one contact person is assigned for HCCF. This person is also responsible for data supply for this study. With regard to the data collected from the school system, a data transfer agreement between educational board Prisma and Maastricht University has been composed and will be signed after ethical approval of the study has been obtained.

The majority of the additional data will be gathered during a 'research week' in the class. All measurements in children will be administered during class hours. At the beginning of this week, participants will receive two questionnaires that are similar to those used in the HPSF trial. The estimated time to complete these questionnaires is 40 minutes. The questionnaires contain questions regarding children's PA and dietary behaviours and children's well-being. Unlike in the HPSF trial, where the questionnaires were filled out in writing, the questionnaires will be completed digitally in the current study. This is done as all children have access to a tablet with a working WIFI-connection. Filling out the questionnaires digitally will limit time and effort for both participants and researchers. Most children will fill out the questionnaires independently. However, the children in study year four will fill out the questionnaires together with a researcher in the class. Next to these two questionnaires, children will fill out a short questionnaire regarding their psychosocial determinants of fruit and vegetable intake. This questionnaire will be administered in writing during the first research week, three weeks after the first research week and three months after the first research week. Measurements of bodyweight, height and waist/hip circumference will be done during the research week, using the same protocol that was used in the HPSF trial and by integrating measurements in the school hours that are allocated to PA education. A team of researchers will supervise administration of all measurements. The researchers will be trained according to a strict protocol (equal to the HPSF protocol) to prevent interrater differences. Additionally, trained research assistants will observe the schoolyard during lunch breaks to investigate any differences in children's free play. Parents/caregivers will also receive a digital questionnaire (similar to the questionnaire used in the HPSF trial) during the research week. The digital questionnaire contains questions regarding children's PA and dietary behaviours and children's health and well-being. Parents/caregivers are asked to complete the questionnaire within ten days. They can return the questionnaire online, or if preferred, by means of a letterbox in the school or regular postal mail.

Teachers will receive a short online questionnaire regarding their students' behaviour in class (e.g., concentration during lessons, class atmosphere), their activities regarding health in class and their appreciation of the project. Pedagogical employees will also receive a short online questionnaire assessing their appreciation of the project. Lastly, childcare centre directors will receive a questionnaire in which they are asked to describe the childcare centre's health-related policies.

Data collection

The principal investigator, together with research assistants and students, will collect all data for this study.

Standardising

The researchers will be trained according to a strict protocol to prevent interrater differences. This protocol is equal to the protocol used in the original HPSF trial and is therefore already available for use.

2.4 Data analyses

Data inspection

Extreme and missing values will be identified and handled in IBM SPSS Statistics for Windows (version 25, IBM Corp, Armonk, NY, USA). This will be done using the same syntaxes that were used in the HPSF trial. Using these syntaxes, missing values will automatically be coded, while differentiating between system missing values and user missing values. The cut-off scores for extreme values of questionnaires and anthropometric measurements used in the HPSF trial will again be used in the current study. Additionally, longitudinal cleaning checks will be executed.

Normal distribution

Normal distribution of the data will be tested in IBM SPSS Statistics for Windows (version 25, IBM Corp, Armonk, NY, USA) using histograms and Q-Q plots.

Descriptive statistics

Using IBM SPSS Statistics for Windows (version 25, IBM Corp, Armonk, NY, USA), descriptive statistics will be used to describe participants' background characteristics.

(Interim)analyses

Linear mixed model analysis techniques will be used to assess the longitudinal effect of HCCF on numerical outcome variables, as this technique corrects for correlation within individuals within groups, which occurs in repeated-measures research designs. Another advantage of this technique is that it naturally handles missing values, in case data are missing at random. Since measurements are repeated within participants, who are nested within childcare centres, we use a three-level model with childcare centres as third level, participants as second level and measurements as first level. The fixed part of the model consists of group (distribution based on Diffusion of Innovations Theory), time (time-points at which the measurements are taken) and the interaction term group*time. Baseline variables that are related to missing data and/or outcome will also be included to obtain unbiased results and/or to gain precision. As for the random part of the model, a random intercept on childcare centre level will be included next to an unstructured covariance structure for the repeated measurements.

For categorical outcome variables, a logistic mixed model analysis technique will be used, where the model is similar as described for the numerical outcome variables.

Coding and interpretation

All qualitative data will be recorded, transcribed and coded using Nvivo software. Coding will be performed by two independent researchers. Peer consultation between researchers will frequently take place. Major themes and discrepancies will be discussed with a third senior researcher. All researchers involved in data collection and analyses will keep a self-reflective diary to evaluate their own subjective views on the interpretation of the data.

Software programme

Quantitative data will be analysed using IBM SPSS Statistics for Windows (version 25, IBM Corp, Armonk, NY, USA). Qualitative data will be analysed using Nvivo software.

2.5 Data management

Location

To assure correct and safe data management and to ensure that the highest standards of academic integrity are maintained, a data management plan according to the FAIR principles (Findable, Accessible, Interoperable, and Reusable) will be developed for this study. This plan outlines the plans for storage, sharing and preservation of the data during and after the study. Additionally, it describes the security measures that will be taken and the restrictions that will apply given the nature of the data.
All data will be stored according to the Maastricht University Data Management Guidelines (Table 2).

Table 2: Storage Locations and Back-Up

	Non-digital data (e.g., paper)	Digital data	Back-up
Non-sensitive data	No restrictions	No restrictions	Network discs
Sensitive, pseudonymised data	Locked closet in a locked room	Only on network discs. When the file size is too large to store on network discs, an alternative and safe storage location will be chosen after consultation of the principal investigator.	Network discs
Sensitive, pseudonymised data with ID	Locked closet in a locked room	Only on network discs. When the file size is too large to store on network discs, an alternative and safe storage location will be chosen after consultation of the principal investigator.	Network discs
Sensitive data with personal data	Locked closet in a locked room	Only on a separate network disc. Only the principal investigator and the coordinating investigator have access to this data.	Only on a separate network disc. Only the principal investigator and the coordinating investigator have access to these back-ups.

Data access

All researchers involved in data collection procedures during the project will have access to research data. The principal investigator, the coordinating investigator and the research assistants will have access to the complete data set (i.e., sensitive data with personal data). The project leader will have access to the pseudonymised data set.

Data storage

All data will be kept fifteen years after data-collection (GCP) and ten years after publication of the results in a peer-reviewed journal, unless a participant requests otherwise as stated in article 455 book 7 of the Civil law book (in Dutch: Burgerlijk Wetboek). No human material will be gathered during this study.

Data protection

All data will be stored and transported (Table 3) according to the Maastricht University Data Management Guidelines. All research data will be stored separate from delicate, private information and will be handled confidentially according to the Dutch Personal Data Protection Act (Wet Bescherming Persoonsgegevens). As previously mentioned (Table 2), sensitive data will be stored in restricted, locked environments to keep them inaccessible for people not involved in the study.

Table 3: Storage Mediums and Transport

	Email	Encrypted transport on mobile device	Cloud and FTP
Non-sensitive data	No restrictions	No restrictions	Only in cloud and FTP services offered and approved by ICTS
Sensitive pseudonymised data	No restrictions	No restrictions	Only in cloud and FTP services offered and approved by ICTS
Sensitive pseudonymised data with ID	Permitted when data is encrypted*	Permitted when data is encrypted* and only when strictly necessary	Only in cloud and FTP services offered and approved by ICTS
Sensitive data with personal data	Not permitted	Permitted when data is encrypted* and only when strictly necessary	Only in cloud and FTP services offered and approved by ICTS, with encryption*

* Encryption is done via a difficult to hack password. This contains of at least twelve characters in a non-logical order. The password is not used for other purposes. When a password needs to be shared with another person, this can only be done via separate communication channel.

Coding

Before data collection at baseline, all subjects will receive an ID, which cannot be retraced to the subject (e.g., not based on initials and/or birth date). The principal investigator is responsible for this ID coding. In this way, the collected data will be pseudonymised.

Code key

The keys to the subject identifier code list, the source data and passwords will be safeguarded by the principal investigator and coordinating investigator on their personal network discs.

Privacy protection

As previously mentioned, all research data will be stored separate from delicate, private information and will be handled confidentially according to the Dutch Personal Data Protection Act (Wet Bescherming Persoonsgegevens). Sensitive data will be stored in restricted, locked environments to keep them inaccessible for people not involved in the study. The principal investigator will make sure that everybody involved in the study will sign a confidentiality agreement and will adhere to the previously developed Data Management Plan. She will provide the opportunity to discuss the plan and potential concerns regarding privacy and academic integrity in regular project meetings. If concerns or doubts arise about academic integrity concerning the study, researchers will contact the University Integrity Officer.

In case of a (presumed) data breach, the principal investigator will report this as soon as possible to the Servicedesk ICTS of Maastricht University. Additionally, this breach will be reported to all those affected, i.e., the people whose data has been leaked. If there is a (presumed) data breach, Maastricht University will also report this to the Dutch Data Protection Authority (*Autoriteit Persoonsgegevens* or AP) within 72 hours.

Data sharing

It is not our intention to share the data of this study with other persons or organisations.

3. ETHICAL CONSIDERATIONS

3.3 Burden, risk and incentives for participants

Additional Burden for Participants

Participants are asked to complete a number of questionnaires and participate in measurements (children only). Burden of participants is minimalised by conducting measurements during school hours were possible (thereby minimising the extra time that needs to be invested), and by making measurements attractive, age-appropriate, and fun for children (e.g., by adding pictures to questionnaires). Additionally, burden of participants is minimalised by combining measurements of this study with already existing data-infrastructure, i.e., data from school systems.

Risk Assessment

The measurements of this study are non-invasive. No risks are involved in any of the measurement instruments of this study. Stakeholders (e.g., childcare centre directors, teachers, parents/caregivers) have been involved in the selection of outcome measurements. The measurement protocol was designed while taking into account both a minimal burden for participants and relevant high-quality scientific output for stakeholders.

Incentives

Participants will not receive a (financial) compensation for completion of the measurements.

3.4 Participants' consent

Approaching participants	Parents/caregivers will be informed about the study by two information brochures (i.e., a brochure for parents/caregivers and an age-specific brochure for children). These brochures will be distributed to all children of study years four to six. Researchers will distribute these brochures while providing additional information about the research and giving potential participants the opportunity to ask questions. Besides informing children and teachers through childcare centre visits, researchers will join regular, already-planned information meetings for parents at the childcare centres. If needed, new information meetings for parents will be organised as well. In this way, parents will be informed and encouraged to participate in the research.
Informing participants	Parents/caregivers will be informed about the study both personally (by researchers attending regular, already-planned information meetings for parents at the childcare centres and if needed via new information meetings) and by two information brochures (i.e., a brochure for parents/caregivers and an age-specific brochure for children) which children receive from researchers visiting the childcare centres and/or from their teachers. Informed consents (IC) will only be send out once the representative advisory boards of the school has given their approval of HCCF. Parents/caregivers are asked for consent by sending an IC to the researchers. Children will be informed about the study by researchers, their parents/caregivers and their teachers. During the entire study, the principal investigator is the contact point regarding study-related questions.
Consideration time	Participants will be given a period of ten days to consider their decision. If no IC has been returned to the principal investigator after ten days, parents/caregivers will receive a reminder.
Signing informed consent	ICs will be signed in duplicate by the principal investigator and both parents before baseline measurements. One copy of this signed IC will be stored by the principal investigator, while the second copy is for the participant.

4. VALORISATION AND PUBLICATION

Valorisation

This unique topic is of great societal and scientific importance. It may affect cultural aspects of our society i.e., norms and values about education and parenting. In this way, it may alter the traditional Dutch educational system by enabling the implementation of structured health-promoting activities in the school environment. By developing guidelines for implementing HCCF changes in various school-contexts, the study's results can be beneficial for schools all throughout the Netherlands, thereby increasing the study's potential impact. If HCCF is effective at improving the child-related outcome measures monitored in this study, widespread implementation of HCCF might improve children's overall health. Considering that lifestyle habits formed during childhood often track into adulthood, HCCF might result in a healthier adult population in the long run, thereby reducing health care costs and costs associated with sick leave (WHO, 2006, 2017, 2018).

Publication

It is intended to report the study's results at conferences such as the *Nederlands Congres Volksgezondheid (NCVGZ)* and the *International Society of Behavioural Nutrition and Physical Activity (ISBNPA)* conference. Additionally, it is intended to publish articles regarding the study's results in journals such as *BMC Public Health*, *International Journal of Behavioural Nutrition and Physical Activity (IJBNPA)* and/or *PLOS Medicine/PLOS One*.

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APPENDICES

Appendix I. Table Data Collection

Table 1. Data Collection Methods

	School	Additional			Time point
		Parents	*Children*	*Teachers/childcare centre staff*	
Background variables					
Birth date	X				T0, T1, T2
School class	X				T0, T1, T2
Sex	X				T0, T1, T2
Ethnicity		X			T0, T1, T2
Family composition		X			T0, T1, T2
Postal code home	X				T0, T1, T2
Socio-economic status (parental education level)		X			T0, T1, T2
Childcare use outside school hours			X		T0, T1, T2
Sleep		X			T0, T1, T2
School absenteeism	X				T0, T1, T2
General health					
Weight			X		T0, T1, T2
Length			X		T0, T1, T2
Waist/hip circumference			X		T0, T1, T2
Visits to GP, disease status		X			T0, T1, T2
Quality of life *(parental PedsQL)*		X			T0, T1, T2
Behavioural problems *(parental SDQ)*		X			T0, T1, T2
Physical activity					
PA level *(PAQ-C + additional questions)*			X		T0, T1, T2
PA behaviour		X			T0, T1, T2
Free play during lunch time *(structured observations)*			X		T0, T2
Dietary Behaviour					
Food + water consumption, habits and preferences			X		T0, T1, T2
Lunch intake			X		T0, T1, T2

Food + drinking behaviour		X			T0, T1, T2
Psychosocial determinants of fruit and vegetable intake			X		-T0 -Three weeks after T0 -Three months after T0
School well-being					
Class atmosphere and students' behaviour *(My Class Inventory-Short Form for Teachers, adapted version + self-constructed questions)*				X	T0, T1, T2
Satisfaction, concentration, bullying behaviour *(Multidimensional Students' Life Satisfaction Scale: School Satisfaction Subscale + self-constructed questions)*			X		T0, T1, T2
Process evaluation					
Health-related rules, regulations and practices at childcare centre				X	T0, T1, T2
Teachers'/Pedagogical employees' health-related practices at childcare centre, process parameters and satisfaction				X	T0, T1, T2
Interviews and observations to evaluate satisfaction and process parameters				X	Between T1 and T2