Study Protocol

Questions raised by the committee – 13-01-2020

1. **First, please send us the ethical approval you already received, and second, we need to see the information brochure you are planning to hand to the participants.**

Attached to the e-mail I am sending you, you can find the ethical approval we received from METC Zuyderland for the 'larger study' we are going to conduct. Also attached to this e-mail are the information brochures that we are planning to hand to the participants in the **control group** and in the **intervention group**.

As previously explained to you, this larger study supplies the **control sample** for the present study that is under review by the FHML-REC. Therefore, the information brochure for the control group also includes information about measurements that are part of this 'larger study' and that are not for the purpose of the present study. The participants in the intervention group of the present study are waived for the purpose of the present study only, and therefore this information brochure only comprises information about the present study.

2. **Please provide us more information about the 'larger study' which has already been conducted, and especially about the intervention and control part of the research**

Contrary to what is stated in your question, the 'larger study' has not yet been conducted. Rather, ethical approval for the study has already been waived as can be seen in the attachment to this e-mail. The larger study will be conducted simultaneously with the present study that is currently under review by the FHML-REC (although the duration of the 'larger study' is longer).

Attached to this e-mail is the complete METC application for the larger study, which has already been approved by METC Zuyderland. The summary of this larger study is provided below:

***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.

As can be seen from the METC application, this larger study does not include an intervention and a control group, as there is no intervention that will be allocated in this study. Rather, childcare centres can plan their own activities fitting the main idea of the project. The research team will evaluate the implementation process and the effectiveness of these activities.

2.1 It is unclear, why you are asking for the FHML-REC approval only for the intervention part, if you already received one ethical approval previously.

As previously explained, the 'larger study' that will be conducted only delivers the participants of the **control group** of the present study that is under review by the FHML-REC.

To be able to adequately perform the present study, an **intervention sample** needs to be waived, as no such sample is already available in the 'larger study'. Therefore, the intervention group for the present study is not part of this 'larger study'; it is a sample that will specifically be waived for the purpose of the present study that is currently under review by FHML-REC. As the intervention group therefore involves a new sample and an intervention that is not part of the 'larger study', this has not been reviewed by the METC Zuyderland. Therefore, we are currently asking for FHML-REC approval.

Questions raised by the committee – 21-11-2019

1. In general, the FHML-REC needs more and better particulars on your study. Therefore, please revise the entire application form and provide more details on the study methodology & design, data processing and data storage, and safeguards to protect the research subjects.

Study Design

A non-randomised, pre-test post-test controlled trial will be conducted to answer the research questions. The participants in the intervention group will participate in the Learning Street, while the control group receives no intervention and continues with their regular curriculum. None of the participants is subjected to an intervention as part of this study, as children in the intervention group would also have participated in the Learning Street if the present study would not have taken place. The trial is non-randomised, as the intervention group consists of all study years five who participated in the Learning Street for the first time during school year 2019-2020. The school classes included in the control group are chosen from a pool of primary schools already participating in another study and where possible, they are matched to the intervention school classes with regard to potential confounders such as school location and number of students.

Participants and Procedures

Participants are students from study year five (age 8-10 years) of primary schools located in Northern Limburg, the Netherlands. Researchers and employees of Kids University for Cooking will inform children about the study. Information brochures are distributed and parents are asked to give permission for their children to participate in the study. Informed consent will be obtained from all parents of participating children.

Measures and Data Collection Instruments

Measures in the intervention group are performed before the start of the introduction lesson (T0), directly after finishing the evaluation lesson (T1) and three months after the evaluation lesson (T2). In the control group, a similar timing of the measurements will be utilised. At baseline, participants' demographic characteristics (age in years, gender (1=male, 2=female), (parental) birth country (1=western, 2=non-western) are collected via child-reported questionnaire. At all timepoints, children are asked to answer a short questionnaire assessing their psychosocial determinants (knowledge, taste preferences, intention, skills, and attitude) related to the food product that they encountered during their participation in the Learning Street.

Psychosocial Determinants - Questionnaire

Changes in psychosocial determinants of fruit and vegetable intake are selected as outcome measures. Based on the EnRG framework, other literature and the aims of the Learning Street, five relevant determinants are selected: (i) knowledge; (ii) taste preferences; (iii) intention; (iv) skills; and (v) attitude (1–4). Children's knowledge will be assessed by six questions based on what they were taught during the Learning Street.

Three questions are developed regarding the taste preferences (e.g., *'What do you think about the taste of the food product?'*) (scale from 1='never tried' to 6='I like it very much'). Questions assessing intention concern participants' plans to consume or cook a meal containing the specific food product in the future and will be assessed on a scale from 1='I don't know' to 6='yes I will'. For skills, children are asked if they are able to cook a meal with the specific food product ('I don't know', 'no', 'a little', 'yes'). Questions and scales for attitude *('How much do you think the target behaviours are clever/interesting and nice/cool/tasty?'*) are used as described by Ajzen and Fishbein and as previously used in comparable research. They are formulated in a way that is simple and understandable for children (scale from 1='no, not at all' to 5='yes, totally') (5,6). The questionnaires were previously used in a pilot study on the Learning Street (7) and appeared appropriate after small adaptations.

Teachers of participating school classes will be visited by Kids University for Cooking BV (intervention group) or researchers (control group) and they will receive a box with envelopes containing the three questionnaires (T0, T1, T2) for every child in their class. For each child, these questionnaires contain a unique ID number (equal for T0-T2 to allow for comparison over time) that cannot be traced back to the child. Teachers write the child's name on the envelope and at each time point, they distribute the right questionnaire to the right child. The questionnaires will be filled out in writing under supervision of the teacher, who will receive written and verbal instructions by researchers and/or employees of Kids University for Cooking regarding the questionnaire procedures. After the questionnaires are filled in, they are collected by the teacher and stored in a separate envelope in the box.

Data Processing and Statistical Analyses

After the T2 measurement, the envelopes with filled-in questionnaires are collected by Kids University for Cooking BV (intervention group) or researchers (control group). The envelopes with the ID number and name of the child, in which the blank questionnaires were stored, are not collected and will remain at the school to be destroyed. This means that only anonymised data will be collected; all non-anonymised data (envelopes with ID number and child's name) will remain at school to be destroyed. Researchers therefore only have access to the anonymised data. All anonymised data will be delivered to the principal researcher at Maastricht University.

In the data analyses, the mean scores of the answers on the questions will be used. Since single unrelated questions will be asked to test different aspects of knowledge, a score of correct answers will be used in further analyses of this determinant.

IBM SPSS Statistics for Windows (version 25, IBM Corp, Armonk, NY, USA) will be used for descriptive analyses. First, the intervention group and control group will be compared on their sociodemographic characteristics by use of Pearson's chi-square tests and independent samples t-tests. Second, mean scores on the various determinants will be calculated. Third, change scores (i.e., the difference in mean score between the baseline measurement and the follow-up measurements) will calculated. Linear mixed model analyses will be used to assess the longitudinal effect of the intervention on the various determinants assessed in the questionnaire, as this method 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 will be repeated within participants, who are nested within classes, we will use a three-level model with classes as third level, participants as second level and measurements as first level. The fixed part of the model consists of group (intervention versus control), 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 class level will be included next to an unstructured covariance structure for the repeated measurements. Relative effect sizes will be calculated for each determinant. These will be expressed as Cohen's d: a Cohen's d of 0.2 is interpreted as a small, 0.5 as a medium and 0.8 as a large effect size (8). Results will be interpreted as significant when $p<0.05$ (two-sided).

Data Storage

The anonymised data from the questionnaires will be stored and transported in accordance with the Maastricht University Data Management Guidelines (Table 1 and 2). 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).

All data is anonymised using ID numbers so it is impossible to be traced back to a specific participant. Researchers involved in study will only have access to the anonymised research data; no personal data is available to any of the researchers.

Table 1: 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, anonymised 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, anonymised 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

Table 2: 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 anonymised data	No restrictions	No restrictions	Only in cloud and FTP services offered and approved by ICTS
Sensitive anonymised 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

* 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.

Safeguards to Protect Research Participants

Data will only be collected if parents of the child have signed the informed consent form provided by researchers. Subjects can withdraw from the study at any time for any reason if they wish to do so without any consequences. This is clearly stated in the information brochure and informed consent form. As the non-anonymised data (envelopes with ID numbers and child's name) will remain at the school, researchers only have access to anonymised data and therefore participants' privacy is safeguarded. Participants are not identifiable in any publications or other dissemination of research results.

1.1 The panel was especially concerned about the data ownership. This aspect was relatively vague in your application and thus, we would like you to clarify this point.

As only anonymised data are used in the present study, the GDPR does not require the draft of a Data Transfer Agreement or any comparable agreement between Maastricht University and Kids University for Cooking. After consulting the GDPR expert of Maastricht University, this agreement is therefore removed from the Appendix of the current application. All anonymised data is property of Maastricht University. The non-anonymised data (envelopes containing ID number and child's name) are property of the school and will not be collected as part of this study. They will remain at the school to be destroyed.

2. Moreover, the panel was wondering if the application was only considering the intervention group. However, in order to make an informed and well-grounded decision, we need to see the entire study.

The procedures considering the control group are comparable to the procedures considering the intervention group (as described in the application). The participants in the control group (children from study year five of various primary schools) are asked to answer the same questionnaires at the same three time points as the participants in the intervention group. However, the control group does not participate in the 'Learning Street', but will continue with their regular curriculum.

School classes in the control group will be waived from a pool of primary schools already participating in a larger study. This larger study examines the implementation process of various health-promoting initiatives at primary schools. As this study is a process evaluation, no intervention is imposed but the implementation process is followed. Schools participating in this research are free to choose if, when and how they want to implement health-promoting initiatives in their school context. Some schools participating in this research are not planning to implement any health-promoting initiatives any time soon. Therefore, these schools can serve as control schools in the present study, as they will continue with their regular curriculum for the duration of the present study. In these control schools, children from study year five and their parents will be informed about the larger study, including the measurements that will be used for the present study. Subsequently, they are asked to give their consent for their child to participate in the study. The information brochure for the control group is not included in this application. This is because this information brochure contains not only information about the procedures of the current study, but also about measurements and procedures related to the larger study, which are not relevant for the current study. If desired, this information brochure can be provided.

Ethics Review of niet-WMO-plichtig research with human participants

Please complete the following in a free style with a high level of detail. The ethics review process is looking to see that you have identified ethical issues and addressed them satisfactorily; further, that you are thinking about undertaking your research in an ethical manner, and can communicate this to your research participants and other people in society generally.

Please attach as an appendix any additional materials to support the application, particularly any information sheets and informed consent forms where relevant.

Return the completed form to:
fhml-rec@maastrichtuniversity.nl

Investigator Name: Marla Hahnraths
E-mail: mth.hahnraths@maastrichtuniversity.nl

Project Title: Kokkerelli Learning Street Effect Evaluation

Table of Contents

Study Protocol

1. The Study

1.1 What is the nature of the study? What are the key questions that you are seeking to address?

In 2012, the Kids University for Cooking Foundation BV has developed a nutrition education programme called 'Kokkerelli Learning Street'. This innovative programme aims to teach primary school students aged 8-12 years (study years 5-8) where food comes from, how it is processed, and how it can be used for the preparation of a healthy meal (1). The theoretical foundation of the Learning Street is based on the EnRG framework, which states that behaviour is influenced both by conscious and unconscious processes. These processes can (in)directly be influenced by environmental factors. In addition, several behavioural and personal factors are thought to moderate the causal path (2). An adapted EnRG framework with important influential factors on fruit and vegetable intake in children can be found in Figure 1.

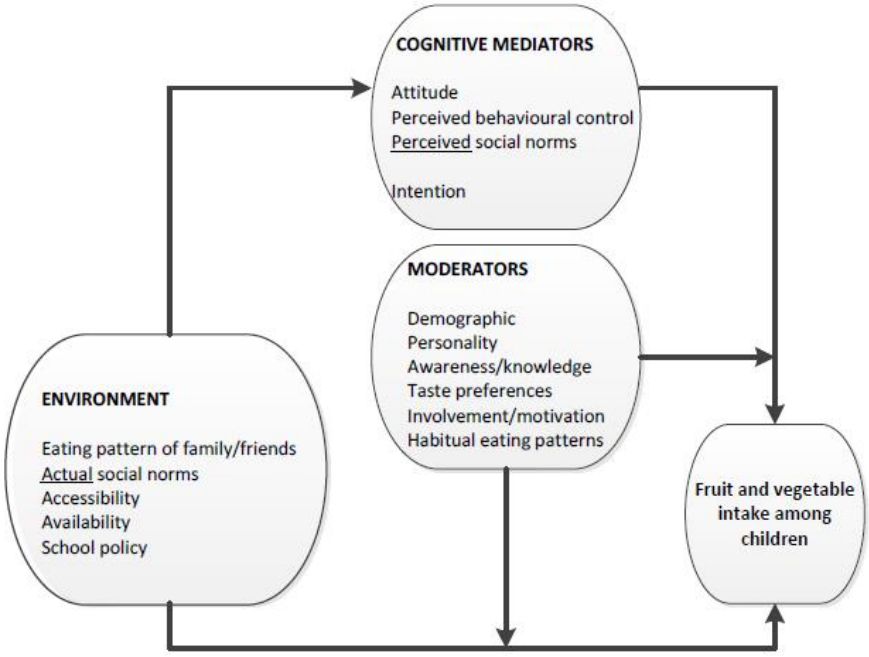

Figure 1. Overview of influential factors on fruit and vegetable intake in children

The Kokkerelli Learning Street is offered to primary school children in the region of Venlo, the Netherlands. It involves education based on concepts of the Self-Determination Theory, active learning, and imagineering (e.g., self-experience in an interactive environment, rather than conventional education) (1,3–5). The present study will investigate the effects of the Kokkerelli Learning Street on several determinants of children's fruit and vegetable intake. Based on the EnRG framework, other literature and the aims of the Learning Street, five relevant determinants are selected: (i) knowledge; (ii) taste preferences; (iii) intention; (iv) skills; and (v) attitude (1,2,6,7). The key questions which the present study will aim to answer are:
What are the short-term and longer-term effects of the Kokkerelli Learning Street on children's:

- *Knowledge regarding fruit and vegetable consumption?*
- *Intentions regarding fruit and vegetable consumption?*
- *Attitude regarding fruit and vegetable consumption?*
- *Liking of fruit and vegetables?*
- *Skills regarding fruit and vegetable preparation?*
- *Fruit and vegetable intake?*

1.2 What are the methodologies that you will employ in the study?

Study Design

A non-randomised, pre-test post-test controlled trial will be conducted to answer the research questions. The participants in the intervention group will participate in the Learning Street, while the control group receives no intervention and continues with their regular curriculum. None of the participants is subjected to an intervention as part of this study, as children in the intervention group would also have participated in the Learning Street if the present study would not have taken place. The trial is non-randomised, as the intervention group consists of all study years five who participated in the Learning Street for the first time during school year 2019-2020.

School classes in the control group will be waived from a pool of primary schools already participating in a larger study. This larger study examines the implementation process of various health-promoting initiatives at primary schools. As this study is a process evaluation, no intervention is imposed but the implementation process is followed. Schools participating in this research are free to choose if, when and how they want to implement health-promoting initiatives in their school context. Some schools participating in this research are not planning to implement any health-promoting initiatives any time soon. Therefore, these schools can serve as control schools in the present study, as they will continue with their regular curriculum for the duration of the present study. In these control schools, children from study year five and their parents will be informed about the larger study, including the measurements that will be used for the present study. Subsequently, they are asked to give their consent for their child to participate in the study. Where possible, the control schools are matched to the intervention school classes with regard to potential confounders such as school location and number of students.

Participants

Participants are students from study year five (age 8-10 years) of primary schools located in Northern Limburg, the Netherlands. Researchers and employees of Kids University for Cooking BV will inform children about the study. Information brochures are distributed and parents are asked to give permission for their children to participate in the study. Informed consent will be obtained from all parents of participating children.

Kokkerelli Learning Street

The Kokkerelli Learning Street focusses on one of the following nine products: kale, tomato, asparagus, pepper, strawberry, blue berry, mushroom, carrot, or leek. An overview of the different components of the Kokkerelli Learning Street is presented in Table 1 (1).

Table 1. Overview of the Kokkerelli Learning Street

Intervention Component	Description	Duration and Location	Materials	Delivery Channel
1. Introduction lesson	Before the introduction lesson, children are asked to fill in a questionnaire to measure their baseline taste preferences, knowledge, skills, intentions, attitude and intake regarding the Learning Street product. During the introduction lesson, children are introduced to (the taste of) the product. Children are familiarised with growing and harvesting processes, as well as with the importance of the product regarding health.	45 minutes at school	• Preparation of the product (e.g., three types of mushrooms) • Poster of the food guide pyramid • Poster with information on unnecessary food wastage • PowerPoint presentation for assistance during the lesson • Materials to fill in the questionnaires	Delivered by the responsible teacher, with help of guidelines provided by Kids University for Cooking Foundation BV

2. Visit to the grower's farm	During the visit to the grower's farm, children are introduced to the precise planting, growing and harvesting procedures of the product. Children are allowed to enter the facilities (e.g., the greenhouse) and to closely observe and experience the farming of the product.	60 minutes at the grower's farm	No necessary material	Delivered by the farmer in cooperation with Kids University for Cooking Foundation BV
3. Cooking	Children observe and listen to the chef, while he/she explains each step that has to be taken for the preparation of the meal. Subsequently, children prepare their own portion of the meal with help of volunteers. After preparing the meal, children help to set the table and consume their self-prepared meal.	60-90 minutes at the cooking facilities of the local museum	• Cooking facilities such as a kitchen. • Cutting boards and knifes suitable for children. • Ingredients for the pre-chosen meals.	Delivered by a trained chef, assisted by two volunteers
4. Evaluation lesson	Children evaluate the Learning Street together. Directly after the evaluation lesson, children are asked to answer the same questionnaire that they filled in before the introduction lesson.	45 minutes at school	Materials to fill in the questionnaires	Delivered by the responsible teacher

Schools are free to plan the different components of the Learning Street in a way that suits their schedule. However, all components should be followed within a three-week period. Usually, the introduction is planned on a separate day. The visit at the grower's farm, the food processing and the cooking take place on the same day. Lastly, the evaluation lesson is again planned on a separate day.

Measures and Data Collection Instruments

Measures in the intervention group are performed before the start of the introduction lesson (T0), directly after finishing the evaluation lesson (T1) and three months after the evaluation lesson (T2). In the control group, a similar timing of the measurements will be utilised. At baseline, participants' demographic characteristics (age in years, gender (1=male, 2=female), (parental) birth country (1=western, 2=non-western) are collected via child-reported questionnaire. At all timepoints, children are asked to answer a short questionnaire assessing their psychosocial determinants (knowledge, taste preferences, intention, skills, and attitude) related to the food product that they encountered during their participation in the Learning Street. A timeline of the Kokkerelli Learning Street and measurements can be seen below (Figure 2). In the control classes, the same questionnaires are administered following the same timeline, although children do not participate in the Learning Street.

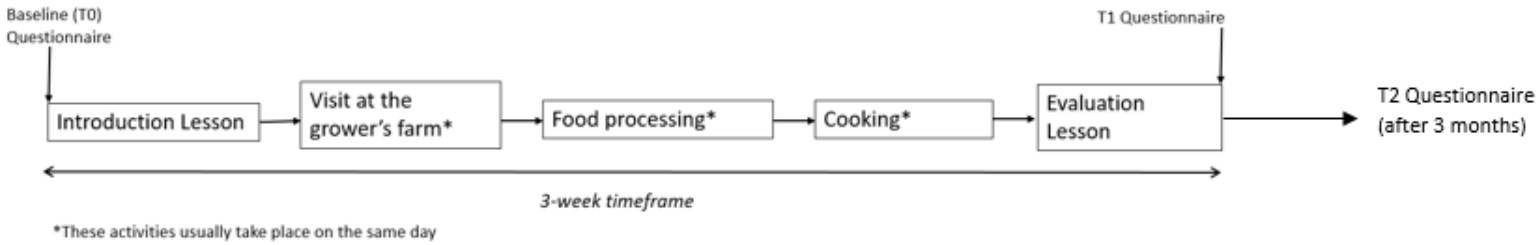

Figure 2. Timeline of the Kokkerelli Learning Street and measurements

Psychosocial Determinants - Questionnaire

Children's knowledge will be assessed by six questions based on what they were taught during the Learning Street. Three questions are developed regarding the taste preferences (e.g., *'What do you think about the taste of the food product?'*) (scale from 1='never tried' to 6='I like it very much'). Questions assessing intention concern participants' plans to consume or cook a meal containing the specific food product in the future and will be assessed on a scale from 1='I don't know' to 6='yes I will'. As the Learning Street also contains a cooking session, children are asked if they are able to cook a meal with the specific food product ('I don't know', 'no', 'a little', 'yes') to assess their skills. Questions and scales for attitude *('How much do you think the target behaviours are clever/interesting and nice/cool/tasty?'*) are used as described by Ajzen and Fishbein and as previously used in comparable research. They are formulated in a way that is simple and understandable for children (scale from 1='no, not at all' to 5='yes, totally') (8,9). The questionnaires were previously used in a pilot study on the Learning Street and appeared appropriate after small adaptations (10).

Teachers of participating school classes will be visited by Kids University for Cooking BV (intervention group) or researchers (control group) and they will receive a box with envelopes containing the three questionnaires (T0, T1, T2) for every child in their class. For each child, these questionnaires contain a unique ID number (equal for T0-T2 to allow for comparison over time) that cannot be traced back to the child. Teachers write the child's name on the envelope and at each time point, they distribute the right questionnaire to the right child. The questionnaires will be filled out in writing under supervision of the teacher, who will receive written and verbal instructions by researchers and/or employees of Kids University for Cooking regarding the questionnaire procedures. After the questionnaires are filled in, they are collected by the teacher and stored in a separate envelope in the box.

Data Processing and Statistical Analyses

After the T2 measurement, the envelopes with filled-in questionnaires are collected by Kids University for Cooking BV (intervention group) or researchers (control group). The envelopes with the ID number and name of the child, in which the blank questionnaires were stored, are not collected and will remain at the school. This means that only anonymised data will be collected, all non-anonymised data (envelopes with ID number and child's name) will remain at school. Researchers therefore only have access to the anonymised data. All anonymised data will be delivered to the principal researcher at Maastricht University.

In the data analyses, the mean scores of the answers on the questions will be used. Since single unrelated questions will be asked to test different aspects of knowledge, a score of correct answers will be used in further analyses of this determinant.

Data will quantitatively be analysed using IBM SPSS Statistics for Windows (version 25, IBM Corp, Armonk, NY, USA). Numerical variables will be presented as mean ± standard deviation (SD), where number (%) will be used for categorical variables. A two-tailed test is considered statistically significant with p-values ≤0.05. Questionnaire items for the determinants knowledge, intention, attitude, skills and taste preferences are combined into one variable per determinant for each time point. Differences in numerical baseline parameters between the control and intervention group will be tested with the independent-samples t-test or Mann-Whitney U-test where appropriate, while the Chi-square test, or Fisher's exact test, will be used for categorical variables. To investigate the in-

tervention effect on children's determinants, mean scores on the various determinants will be calculated. Then, change scores (i.e., the difference in mean score between the baseline measurement and the follow-up measurements) will calculated. Linear mixed model analyses will be used to assess the longitudinal effect of the intervention on the various determinants assessed in the questionnaire, as this method 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 classes, we use a three-level model with classes as third level, participants as second level and measurements as first level. The fixed part of the model consists of group (intervention versus control), 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 class level will be included next to an unstructured covariance structure for the repeated measurements. Relative effect sizes will be calculated for each determinant. These will be expressed as Cohen's d: a Cohen's d of 0.2 is interpreted as a small, 0.5 as a medium and 0.8 as a large effect size (11).

1.3 How will humans be participants in the study (either directly or indirectly, for example, through the use of their personal data)?

All children from the intervention and control classes whose parents have given their consent are asked to fill in the questionnaires. Only anonymised data will be collected and used in the present study.

1.4 Does your study re-use data that has already been gathered for another project or purpose? If so, do you have permission to re-use that data, and was there the relevant consent for this re-use in the first study? (Please explain, with reference to, for example, previous ethics committee decisions and informed consent protocols.)

In intervention classes, the data used in this study is collected as part of the Kokkerelli Learning Street. As only anonymised data will be used in the present study, the GDPR does not require the draft of a data transfer agreement or any other comparable agreement between Maastricht University and Kids University for Cooking BV.

In control classes, data is collected as part of another, larger study that will take place at the same time (further specified in an earlier section of this application). Ethical approval for this larger, ongoing study is under assessment by the Zuyderland Medical Ethics Committee. For both the intervention and control group, only data of participants whose parents/caregivers have given informed consent will be used in the present study. All anonymised data will be property of Maastricht University The non-anonymised data (envelopes with ID number and child's name) are property of the school and will therefore remain at school after data collection to be destroyed.

1.5 What sort of people will be involved? (For example, professionals in the course of their profession, members of the general public.)

Participants will be children aged 8-10 years old (study years five) from primary schools in Limburg, the Netherlands. Parents of these children will be informed by Kids University for Cooking BV (intervention group) or researchers from Maastricht University (control group) about the study. They will receive an information brochure about the study and are asked to give written consent for their child's participation in the study.

1.6 On what grounds did you determine the number of participants needed for the study?

As one of the primary aims of the Kokkerelli Learning Street is to improve children's knowledge with regard to fruit and vegetables, it is expected that the Kokkerelli Learning Street will have positive effects on participants' knowledge. Therefore, the sample size calculation was based on the primary outcome, i.e. to detect a difference in knowledge score between the intervention classes and the control classes three months after the intervention. Unfortunately, limited evidence is available regarding the effects of the Kokkerelli Learning Street or comparable programmes on

participants' knowledge. In 2014, Kasten et al. performed a one-group effect evaluation of the Kokkerelli Learning Street (10). In this study, the outcome measure that changed most significantly was the determinant knowledge (mean difference T2-T0: 0.41, SD: 0.93). However, this study did not include a control group and the outcomes therefore only indicate within-group differences instead of between-group differences, while the present study does include a control group. The following assumptions were used for the sample size calculation:

- Children are nested within school classes, with 25 participants per class, and seven intervention classes and seven control classes;
- A significance level (alpha) of 0.05;
- A power of 80%;
- Independent samples t-test on difference in knowledge scores;
- An Intraclass Correlation Coefficient of 0.04, based on values used by Battjes et al. (8);
- A dropout rate of 10%, as based on dropout rates observed by Bartelink et al. (12);
- An SD of 0.24 for the mean change in absolute knowledge score (T2-T0) in the population, as based on the effect evaluation of a comparable programme by Battjes et al. (8).

With these assumptions, we can demonstrate an effect size of 0.104 on absolute knowledge scores. The standardised effect size is then equal to 0.104/0.22 = 0.47, indicating a small to medium effect size (11).

1.7 On what grounds did you determine that this is a useful study?

The Kokkerelli Learning Street is a well-appreciated intervention that has been used by primary schools for several years. It has the potential to be implemented on a larger scale (e.g., on a national level). However, the effectiveness of the Learning Street is not evaluated well enough to facilitate widespread implementation. Kids University for Cooking BV therefore aims to have the Kokkerelli Learning Street included in the Dutch database for effective interventions. In order to achieve this goal, a good evaluation of its effectiveness is necessary. This study is useful as it enables us to evaluate the short-term and longer-term effects of the Kokkerelli Learning Street on several determinants of intake in a non-invasive way. When designing the study, both the use of sound and valid methodology as well as limiting participants' burden and safeguarding participants' privacy were kept in mind. Because of this, the study is expected to successfully evaluate the Learning Street while keeping the burden for participating children as low as possible.

1.8 Is this a 'one-off'/'stand-alone' project, or do you foresee that you will want to re-use the data in future (different) research, or to share the data with other researchers for their future research? How have you ensured consent for this from your participants?

It is expected that this study is a 'one-off' project and therefore the data collected in this study will not be re-used in future (different) research or shared with other researchers for their future research.

1.9 If relevant, what is your publication strategy?

It is intended to publish the article regarding the study's results in a journal such as BMC Public Health, International Journal of Behavioural Nutrition and Physical Activity (IJBNPA) or PLOS Medicine/PLOS One.

1.10 If the work is not to be undertaken only in the Netherlands, what are the countries involved, and is local Ethics Review required in the country/countries where the research is to be undertaken? How will this be achieved?

This question is not applicable to the present study, as this study will only be undertaken in the Netherlands.

2. Identifying Harms

2.1 What are the possible harms that participation in your study could bring for the human participants? (These could be, for example, physical, psychological, economic, harms, harms relating to privacy, etc.)

The measurements of this study are non-invasive. No risks are involved in any of the measurement instruments of this study. No NAW data is collected as only the anonymised answers to the questionnaires will be available for use in the study. To ensure participants' privacy, all data will be collected using ID numbers (equal for T0-T2 to allow for comparison over time), which cannot be retraced to the subject (e.g., not based on initials and/or birth date). Therefore, risks relating to participants' privacy are also considered to be low.

2.2 How will you ensure integrity in the use of other researchers' data and published work?

No data or published work from other researchers will be used in the present study.

2.3 How will you ensure within your team that the highest standards of academic integrity are maintained, and that there are mechanisms to raise and discuss concerns within the team (and to the University Integrity Officer)?

A data management plan according to the FAIR principles (Findable, Accessible, Interoperable, and Reusable) will be developed for this study to ensure that the highest standards of academic integrity are maintained. 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. The principal investigator will make sure that everybody involved in the study will adhere to this plan and agreement and she will provide the opportunity to discuss the plan and potential concerns regarding academic integrity in regular project meetings. Additionally, she will make sure that everybody involved in the study will sign a confidentiality agreement. If concerns or doubts arise about academic integrity concerning the study, researchers will contact the University Integrity Officer.

3. Safeguards

3.1 How will you inform participants about their participation in your study? (Please also comment on any re-use of data issues.)

Children from intervention classes will be informed about the study by Kids University for Cooking BV and their teacher. Before the start of the Learning Street, children from the intervention classes receive a brochure with information about the study (Appendix I). They are asked to show this brochure to their parents. Participants from control classes are informed about the questionnaires via another information brochure that is provided by researchers from Maastricht University to students and their parents. This information brochure contains information about the complete implementation study of which these questionnaires are a small part (as discussed in a previous section of this application). This complete study is under assessment by the Zuyderland Medical Ethics Committee.

3.2 Will individuals be invited to participate in your study through informed consent, or are you appealing to, for example, the public interest in undertaking the work (for example, you might be undertaking a participant observation)?

Please supply details (and, where appropriate, drafts of any forms) of your informed consent process (i.e. both how you will gain informed consent from your participants and how you will evidence that consent), and the information sheets that you will use.

Participants from intervention classes will be invited to participate in the study through informed consent. Before the start of the Learning Street, children from the intervention classes receive a brochure with information about the study and two informed consent forms (Appendix I). This brochure will be handed out by Kids University for Cooking BV. As participants in the study are children, parents are asked to deliver a filled-in informed consent form to their child's teacher before the start of the Learning Street. Kids University for Cooking BV will collect and process these informed consent forms. Participants from control classes will also be invited to participate in the study through an informed consent procedure. This informed consent comprises participation in the complete implementation study of which these questionnaires are a small part. The informed

consent forms of the control group are collected and processed by Maastricht University. This implementation study is currently under assessment by the Zuyderland Medical Ethics Committee. The information brochure for the control group is not included in this application. This is because this information brochure contains not only information about the procedures of the current study, but also about measurements and procedures related to the larger study, which are not relevant for the current study. If desired, this information brochure can be provided.

3.3 How will you process any personal data in the project?

You should explain the safeguards in place throughout the processing of the data from gathering the data, analysing the data, storing the data, and destroying the data at the end of the period.

Teachers of participating school classes will be visited by Kids University for Cooking BV (intervention group) or researchers (control group) and they will receive a box with envelopes containing the three questionnaires (T0, T1, T2) for every child in their class. For each child, these questionnaires contain a unique ID number (equal for T0-T2 to allow for comparison over time) that cannot be traced back to the child. Teachers write the child's name on the envelope and at each time point, they distribute the right questionnaire to the right child. The questionnaires will be filled out in writing under supervision of the teacher, who will receive written and verbal instructions by researchers and/or employees of Kids University for Cooking regarding the questionnaire procedures. After the questionnaires are filled in, they are collected by the teacher and stored in a separate envelope in the box After the T2 measurement, the box with filled-in questionnaires is collected by Kids University for Cooking BV (intervention group) or researchers from Maastricht University (control group). The envelopes with the ID number and name of the child, in which the blank questionnaires were stored, are not collected and will remain at the school to be destroyed. This means that only anonymised data will be collected, all non-anonymised data (envelopes with ID number and child's name) will remain at school to be destroyed. Researchers therefore only have access to the anonymised data. All anonymised data will be delivered to the principal researcher at Maastricht University.

The anonymised data from the questionnaires is property of Maastricht University and will be stored and transported in accordance with the Maastricht University Data Management Guidelines (Table 2 and 3). 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).

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, anonymised 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, anonymised 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

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 anonymised data	No restrictions	No restrictions	Only in cloud and FTP services offered and approved by ICTS
Sensitive anonymised 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

* 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.

3.4 Who will have access to the personal data?
In particular, will you use de-identification methods (coding, anonymising, etc.) as a protection? Will you engage in "open data" methods of data sharing for integrity issues? Under what conditions will they have access?

All data is anonymised using ID numbers so it is impossible to be traced back to a specific participant. Researchers involved in the study will only have access to the anonymised research data; no non-anonymised data is available to any of the researchers. Non-anonymised data (the envelopes with the ID number and child's name) are property of the school and will remain at the school after data collection to be destroyed.

3.5 Will there be any reimbursement, remuneration or reward for participation? If so, what is your reasoning for this and is it proportionate and appropriate?

Participants will not receive a (financial) compensation for completion of the questionnaires. This is considered proportionate and appropriate as the measurements are non-invasive and part of the educational programme (Kokkerelli Learning Street) in which they participated (in case of the intervention classes).

3.6 Are there any further safeguards that you have put in place?

N.a.

3.7 In what circumstances and to what extent will your participants have the opportunity to withdraw their participation? How will this be communicated to them?

Subjects can withdraw from the study at any time for any reason if they wish to do so without any consequences. This is clearly stated in the information brochure and informed consent form.

3.8 Is participation in the study confidential? In particular, will participants be identifiable in any publications or other dissemination of research results? If so, will you have a specific consent for this use of the data? If participants will be unidentifiable, how will you ensure this in your publications?

Participation in the study is confidential. Participants will not be identifiable in publications or other dissemination of research results. This is due to the fact that researchers will only collect anonymised data (using ID numbers), which cannot be traced back to a specific participant.

3.9 How will the data be stored, and for how long will it be stored?
As a default, you should use the UM data archiving facilities and procedures to store your data. If you are not proposing to use this, why not?

Anonymised data from the questionnaires will be stored in accordance with the Maastricht University Data Management Guidelines using the UM data archiving facilities and procedures. Non-sensitive data will be stored without restrictions (both non-digital and digital data). Sensitive, anonymised non-digital data (both with and without ID) will be stored in a locked closet in a locked room. Digitally, the data will be stored on network discs only. Back-ups of all data will be made on network discs.

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).

4. Self-evaluation

4.1 On the basis of your answers in the above sections, do you see this research as posing a "high" or a "low" risk to participants?

HIGH ☐	LOW ■

4.2 Are there particular reasons for this evaluation?

This research poses a low risk to participants, as measurements of this study are non-invasive. Additionally, risks related to participants' privacy are considered to be low as only anonymised data will be collected for the purpose of this study.

5. Any other ethics observations that you wish to make.

Here you might indicate how you will communicate your ethics strategy to the broader society.
N.a.

References

1. Kids University for Cooking BV. Theoretical and empirical foundations of the Learning

Street. 2009.
2. Kremers SP, de Bruijn G-J, Visscher TL, van Mechelen W, de Vries NK, Brug J. Environmental influences on energy balance-related behaviors: A dual-process view. Int J Behav Nutr Phys Act [Internet]. 2006 May 15 [cited 2019 Jan 3];3(1):9. Available from: http://ijbnpa.biomedcentral.com/articles/10.1186/1479-5868-3-9
3. Deci EL, Ryan RM. Self-determination theory. In: Handbook of theories of social psychology. Thousand Oaks, CA: Sage Publications Ltd.; 2012. p. 416–36.
4. Bonwell CC, Eison JA. Active learning: creating excitement in the classroom. Washington, DC: School of Education and Human Development, George Washington University; 1991.
5. Nijs D, Peters F. Imagineering. Een verhaal van betekenis. [A Story of Significance.]. Breda; 2002.
6. Haß J, Hartmann M. What determines the fruit and vegetables intake of primary school children? - An analysis of personal and social determinants. Appetite [Internet]. 2018 Jan 1 [cited 2018 Apr 12];120:82–91. Available from: https://www.sciencedirect.com/science/article/pii/S0195666317312291
7. Blanchette L, Brug J. Determinants of fruit and vegetable consumption among 6-12-year-old children and effective interventions to increase consumption. J Hum Nutr Diet [Internet]. 2005 Dec 1 [cited 2018 Apr 10];18(6):431–43. Available from: http://doi.wiley.com/10.1111/j.1365-277X.2005.00648.x
8. Battjes-Fries M. Effectiveness of nutrition education in Dutch primary schools [Internet]. Wageningen University; 2016. Available from: https://www.smaaklessen.nl/upload_mm/1/1/a/a27959d0-42f1-4802-9dc1-67b886781f79_Proefschrift Effectiveness of nutrition education in Dutch primary schools.pdf
9. Ajzen I, Fishbein M. Understanding Attitudes and Predicting Social Behavior. Prentice-Hall N, editor. Englewood Cliffs; 1980.
10. Kasten S, Kremers S, Assema P Van, Bisschops S. The effectiveness of the Learning Street regarding children's knowledge, liking, intention, and fruit and vegetable intake. Maastricht University; 2014.
11. Cohen J. Statistical Power Analysis for the Behavioral Sciences. Second. Lawrence Erlbaum Associates; 1988.
12. Bartelink NHM, van Assema P, Kremers SPJ, Savelberg HHCM, Oosterhoff M, Willeboordse M, et al. One- and two-year effects of the healthy primary school of the future on children's dietary and physical activity behaviours: A quasi-experimental study. Nutrients. 2019;11(3):1–18.

Appendix I. Information Brochure for Parents (Intervention Group)

INFORMATION FOR PARENTS

The Kokkerelli Learning Street: Does it work?

School year 2019-2020

Dear Parents/Guardians,

Soon your child will visit Kokkerelli in Venlo. During this visit, your child will harvest, prepare, and taste vegetables and fruit. We would like to invite your child to participate in a study about the Kokkerelli Learning Street. To participate, your written consent is required. Before you decide, you will receive information about what the study involves. This letter contains all important details so that you can make an informed choice. Please read it carefully and ask the researcher or teacher if you have questions. You may also discuss it with your partner, child(ren), friends, or family. The decision is entirely up to you.

What is the aim of the study?
Soon your child will participate in the Kokkerelli program at school, which focuses on vegetables and fruit. We expect that children who take part in the Kokkerelli Learning Street will develop a more positive attitude toward fruit and vegetables. To test this, we invite your child to join our short study. You can also check the website: www.kokkerelli.nl

Who will take part?
We are inviting children from several primary schools in the Venlo region. In total, more than 350 children are invited to participate.

How will the study be conducted?
During the Kokkerelli Learning Street, your child will complete a few short questionnaires. These questionnaires are part of the program. In total, your child will complete three questionnaires during school hours, when the Kokkerelli activities take place. The questions are about your child's attitude toward fruit and vegetables. Each questionnaire takes about five minutes. Your child will complete them with the help of their teacher. Only if you provide consent will the anonymous questionnaire data be shared with Maastricht University for research purposes.

How long does the study last?
Your child will be asked to complete three questionnaires during this school year. The exact timing depends on when the class participates in the program.

Possible advantages and disadvantages
There are no direct advantages or disadvantages for you or your child. You do not need to do anything different in daily life. Your child's participation is important to help us evaluate whether the Kokkerelli Learning Street is effective.

Can my child stop during the study?
Yes, your child can stop at any time, even during the study, without any consequences. Your child will still take part in the Kokkerelli program itself. You don't need to provide a reason, but please inform the researcher.

Has the study been reviewed by a committee and insurer?
This study has been reviewed by the Medical Ethics Committee of Maastricht University. The committee decided that the study does not fall under the Medical Research Involving Human Subjects Act (WMO), since no interventions are imposed. They also determined there are no risks requiring insurance, so no additional insurance was arranged.

End of the study
Your child's participation ends when:
- The study is completed
- Your child chooses to withdraw
- The ethics committee decides to stop the study

What happens with the data?
The collected data will be securely stored. Only the principal researchers know the passwords. Your child's data will be coded, and their name will not be known to the researchers. We are obliged to store the data for 15 years and then destroy it. By giving consent, you agree to this. For general information on your rights regarding personal data, you can consult the Dutch Data Protection Authority.

Who is informed about participation?
We work together with your child's school. The teacher and Kokkerelli staff will be informed if your child participates. No one else will be notified.

What happens after the study?
The results will be published in a scientific article, but only group results will be shown. Personal data will remain anonymous.

Is there any compensation?
No, there is no compensation. Participation does not involve extra costs for you or your child.

How to give consent?
Participation is voluntary. Attached you will find two consent forms (Appendix 3). One is for your own records. Please return the other to your child's teacher, signed by both parents/guardians. On the form, indicate whether you do or do not agree to your child's participation.

Questions?
If you have any questions, please contact:

Suzanne Bisschops, director Kokkerelli
Tel.: 077-8503029
Email: suzannebisschops@kokkerelli.nl

Marla Hahnraths, researcher, Maastricht University
Tel.: 043-3882188
Email: mth.hahnraths@maastrichtuniversity.nl

Kind regards,

Suzanne Bisschops, director Kokkerelli
Tel.: 077-8503029
Email: suzannebisschops@kokkerelli.nl

Marla Hahnraths, researcher, Universiteit Maastricht
Tel.: 043-3882188
Email: mth.hahnraths@maastrichtuniversity.nl

Appendix 1. Information for children

Hi!

Soon you will go with your class to the Kokkerelli Learning Street. You will harvest, prepare, and taste fruit and vegetables. This visit also includes a study, and we'd like to ask you to join. We will ask you to fill in three questionnaires. Your parents know about the study. If you don't understand something, you can ask them. It's up to you whether you want to join or not.

Who can join?
All children who go to the Kokkerelli Learning Street, including children from other schools nearby, may participate. Altogether, more than 350 children are invited.

Why are we doing this study?
We want to find out if children enjoy fruit and vegetables more after participating.

It's your choice!
Talk about it with your parents. If you don't want to, that's fine. If you do, tell your parents.

What do I have to do?
You will just do what you always do. During this school year, you will fill in three short questionnaires in class. The questions are about fruit and vegetables.

Questions?
You can always call or email us. Our details are below.

Kind regards,

Suzanne Bisschops, director Kokkerelli
Tel.: 077-8503029
Email: suzannebisschops@kokkerelli.nl

Marla Hahnraths, researcher Maastricht University
Tel.: 043-3882188
Email: mth.hahnraths@maastrichtuniversity.nl

Informed consent

The Kokkerelli Learning Street: Does it work?

Please hand this completed form to your child's teacher.

I have been asked to give permission for my child to participate in this study:

Child's name: ……
Child's school: ……..
Child's class/group: …….

I have read the information letter for parents. I was able to ask additional questions, and these were answered satisfactorily. I have had enough time to decide whether my child may participate. I understand that participation is entirely voluntary. I also understand that I may withdraw my child at any time without giving a reason. I give permission for the collection and use of my child's data for answering the research questions in this study. I understand that only the research team will have access to my child's data. I consent to the use of the data for the purposes described in the information letter.

I DO / DO NOT (please cross out what does not apply) agree for my child to participate in this study.

Parent/guardian name: ……..
Signature: …… Date: __ / __ / ____

Parent/guardian name: ……..
Signature: …… Date: __ / __ / ____

If only one parent/guardian is raising the child, please check below:
☐ My child is raised by a single parent/guardian.

Information below to be completed by the researcher:

I hereby declare that I have fully informed the above-mentioned persons about this study. If new information arises during the study that may affect consent, I will inform him/her in time.

Researcher's name: Marla Hahnraths
Signature: …… Date: __ / __ / ____

Informed consent
The Kokkerelli Learning Street: Does it work?

Please keep this form for yourself

I have been asked to give permission for my child to participate in this study:

Child's name: ……
Child's school: ……..
Child's class/group: …….

I have read the information letter for parents. I was able to ask additional questions, and these were answered satisfactorily. I have had enough time to decide whether my child may participate. I understand that participation is entirely voluntary. I also understand that I may withdraw my child at any time without giving a reason. I give permission for the collection and use of my child's data for answering the research questions in this study. I understand that only the research team will have access to my child's data. I consent to the use of the data for the purposes described in the information letter.

I DO / DO NOT (please cross out what does not apply) agree for my child to participate in this study.

Parent/guardian name: ……..
Signature: …… Date: __ / __ / ____

Parent/guardian name: ……..
Signature: …… Date: __ / __ / ____

If only one parent/guardian is raising the child, please check below:
☐ My child is raised by a single parent/guardian.

Information below to be completed by the researcher:

I hereby declare that I have fully informed the above-mentioned persons about this study. If new information arises during the study that may affect consent, I will inform him/her in time.

Researcher's name: Marla Hahnraths
Signature: …… Date: __ / __ / ____