**De ALIKO-studie   
Amphi Lifestyle Interventions 4 Kids with Obesity**

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**Radboudumc  
  
  
  
  
Onderzoeksopzet**

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J.J.E.H.(Jenneke) Saat, MSc

G. (Gerdine) Fransen, PhD  
E. (Elke) Naumann, PhD  
W.J.J. (Pim) Assendelft, Professor

**Introduction**

**Childhood overweight** **and obesity** are serious health challenges of the early 21st century [1].   
One in five children suffers from these conditions [1,2]. Prevention is important, as it results in symptoms of depression, poor self-esteem and social stigma [3]. Moreover, being overweight/obese increases the likelihood that a child will be overweight/obese in adulthood [4], develop chronic diseases later in life (e.g. diabetes)[5]and participate less in society. These consequences contribute to rising healthcare costs [6] andseverely decrease a person’s health-related quality of life (HR-QOL) [3].

**Combined Lifestyle Interventions** (CLIs)[[1]](#footnote-1), offered in primary care, aim to improve HR-QOL, including self-esteem, self-confidence and mental health. ‘Combined’ means: the intervention focuses on nutrition behaviour, physical activity and mental health. Therefore, several healthcare professionals (HCPs) are involved:

* Dietician
* Physical therapist
* Psychologist

This multidisciplinary team supports children in **reaching and continue a healthy lifestyle**[[2]](#footnote-2). As a consequence, children’s bodyweight stabilise and, as they grow taller, their body mass index (BMI) decrease. Another goal of the team is to help the children to transfer to local sports facilities. In the end, this lowers the overall healthcare costs.   
  
CLIs offer weekly group meetings that include sports classes, nutrition lessons and consultations with a psychologist. Each meeting is carried out according to a protocol that describes the meeting’s content and how it must proceed. In practice, each CLI has **variations in protocol** to suit the needs of their community and network.

Important **network partners** are: the municipality, general practitioners, youth healthcare doctors, school nurses and local sports facilities. They help to embed the CLI in the local community, recruit children and support the transfer to local sports facilities.

Dutch CLIs are often **community-oriented** developed and implemented on a small scale by a local network of HCPs. Although CLIs perfectly suit the community needs and incorporate theoretical insights, they are not always scientifically based. Little is known about their long-term (i.e. two or more years) effectiveness and efficiency due to short research periods of effect studies.

As the effectiveness of CLIs is context sensitive, it is problematic that the limited available practice-oriented research has been carried out in other countries than in the Netherlands.

**Information is needed** on the evaluation of health effects, costs of the CLIs and on the evaluation of process regarding the implementation of the protocol and the collaboration within the HCP network.

**Insight is necessary** to improve CLIs to further optimize health outcomes in an lasting and efficient way. Furthermore, as long as the effectiveness and efficiency of CLIs remains unproven, it is difficult to get funding to continue offering CLIs. If a CLI can achieve a long-term improvement in HR-QOL, financiers will be more willing to finance. Therefore, policymakers need information about the benefits and costs of a CLI versus no professional care and/or self-management. Based on the National Health Service Economic Evaluation Database (NHS EED), we’re not aware of studies that provide insight into costs and benefits of Dutch community-oriented CLIs for obese children.

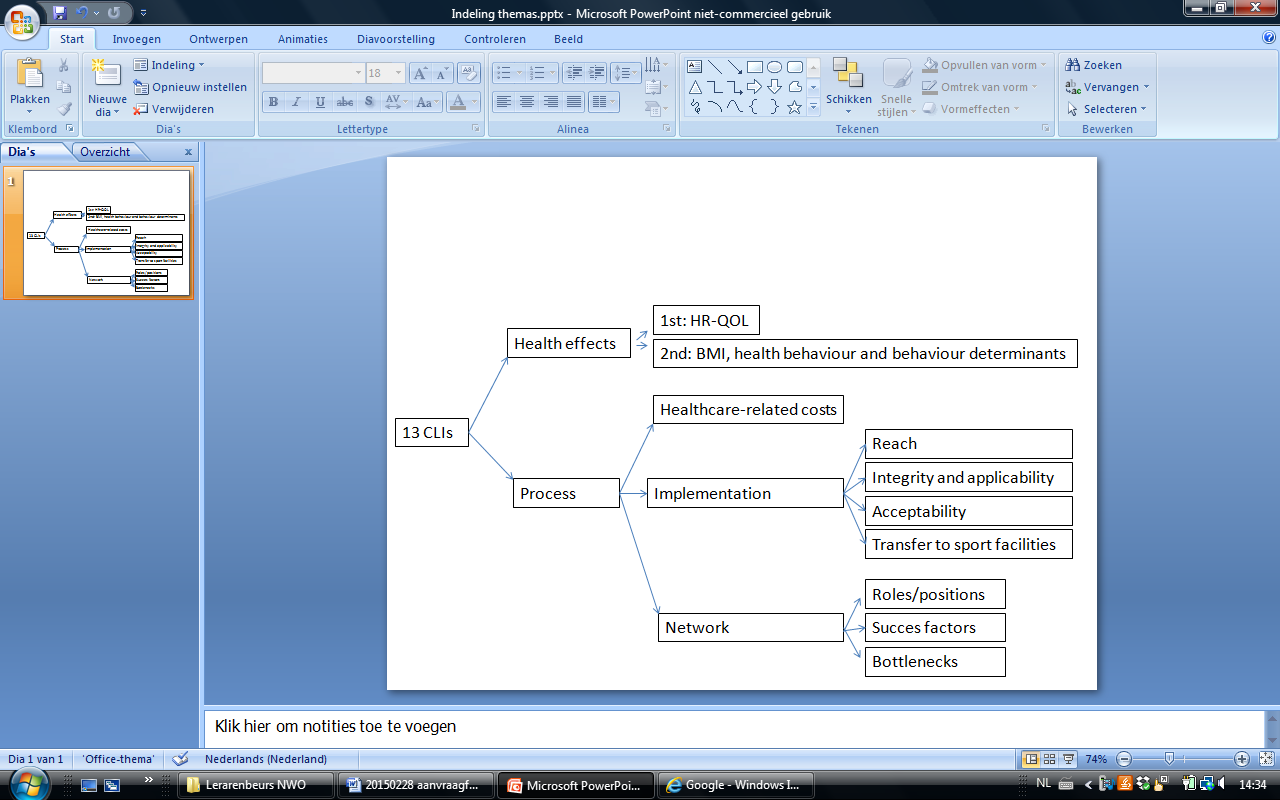
It is important that everyone’s HPPs role and position is clear, for the process to run ‘smoothly’ and HCPs to be able to reinforce each other and increase the likelihood to be effective.   
Nurses’ role in addressing childhood obesity has been explored [7], but there is a lack of studies on the specific   
**role and position of the other HCPs in the** CLI network. These insights are important for future HCPs to learn how to operate in a CLI network.

HCPs and financers of CLIs (municipalities and healthcare insurers) have expressed an **urgent need for clarity** **about the effectiveness and efficiency of Dutch community-oriented CLIs.**  
This proposal was written after exploration of the needs (together representing 13 different CLIs, currently implemented in Gelderland) to learn about the experiences of other HCPs and their willingness to optimize their CLI, and of the opportunities according to research experts (see: Curriculum vitae- Overige relevante activiteiten – Klankbordgroep).

**Research question:** How effective are Dutch community-oriented CLIs for obese children (aged 4-12 years) in realising health effects, and how efficient is the process regarding healthcare-related costs, implementation and the network of the CLIs? Sub-questions:

1. What are the short- and long-term health effects of participation in a CLI for children aged 4-12 years, in terms of: HR-QOL (primary outcome measure), BMI, health behaviour (nutrition and physical activity) and individual behaviour determinants (social influence, motivation, knowledge)?
2. What are the healthcare-related costs of CLIs?
3. How do the CLIs’ implementation processes work in practice in terms of: reach, integrity and applicability, acceptability, and transfer from CLI to local sports facilities, and what are the determinants of successful implementation?
4. How is the current CLI network designed, what are the roles and positions of the HCPs in this network, what are its success factors and bottlenecks, and what skills do future HCPs[[3]](#footnote-3) need to operate in a CLI network?

This study is schematically shown in Figure 1. The Medical Ethic Commission agreed.

  
Figure 1: Schematic representation of this study. Abbreviations: CLIs, combined lifestyle interventions; HR-QOL, health-related quality of life.

Two years ago (sept 2013), we started this study, beginning to study the effectiveness and efficiency of one CLI, after which 12 other CLIs followed (see Table 1).   
  
Table 1: The 13 participating CLIs

|  |  |  |
| --- | --- | --- |
|  | **Name of CLI** | **Place implemented** |
| 1 | Door dik en dun | Culemborg |
| 2 | “ | Geldermalsen |
| 3 | “ | Tiel |
| 4 | “ | Lienden |
| 5 | “ | Herveld |
| 6 | Gezond onderweg | Arnhem |
| 7 | Fit & fun | Elst |
| 8 | Beweeg je fit | Nijmegen, Hatert |
| 9 | “ | Nijmegen, Lindenholt |
| 10 | “ | Nijmegen, West |
| 11 | LIJF: Lekker in je lijf | Huissen |
| 12 | KOALA (Kinderen met overgewicht anders leren activeren) | Oosterhout/Lent |
| 13 | Obesitas project | Oosterbeek |

The study named the ALIKO-study: the **A**MPHI **L**ifestyle**I**nterventions 4 **K**ids with **O**verweight-study.

AMPHI is an academic collaborative centre for health promotion, in which the Radboudumc (department of primary care), municipality Nijmegen, Hogeschool van Arnhem en Nijmegen and several local municipality health services (GGD-en) participate. AMPHI carries out practical and policy-oriented research, bridging the gap between policy, practice and scientific research. It is part of the Consortium Integrale Aanpak Overgewicht (CIAO).   
  
50 Baseline measurements and follow-up measurements concerning health effects have already taken place.  
In February 2015, the process evaluation began. Student interns in ‘Food & Nutrition’ were and will be involved (e.g. by developing and distributing questionnaires, interviewing HCPs and analysing data).

**Method**

**Evaluation of Health effects**Design: Quasi-experimental.  
Intervention group: 13 CLIs. The content is mostly: 20 weekly nutrition- , 20 weekly sports group meetings and 10 individual meetings with HCPs. Meeting theme’s: e.g. motivation, development of taste, self-esteem.

Control group: usual care (no professional care or self-management only).   
  
Below, in Figure 2, the design is shown.

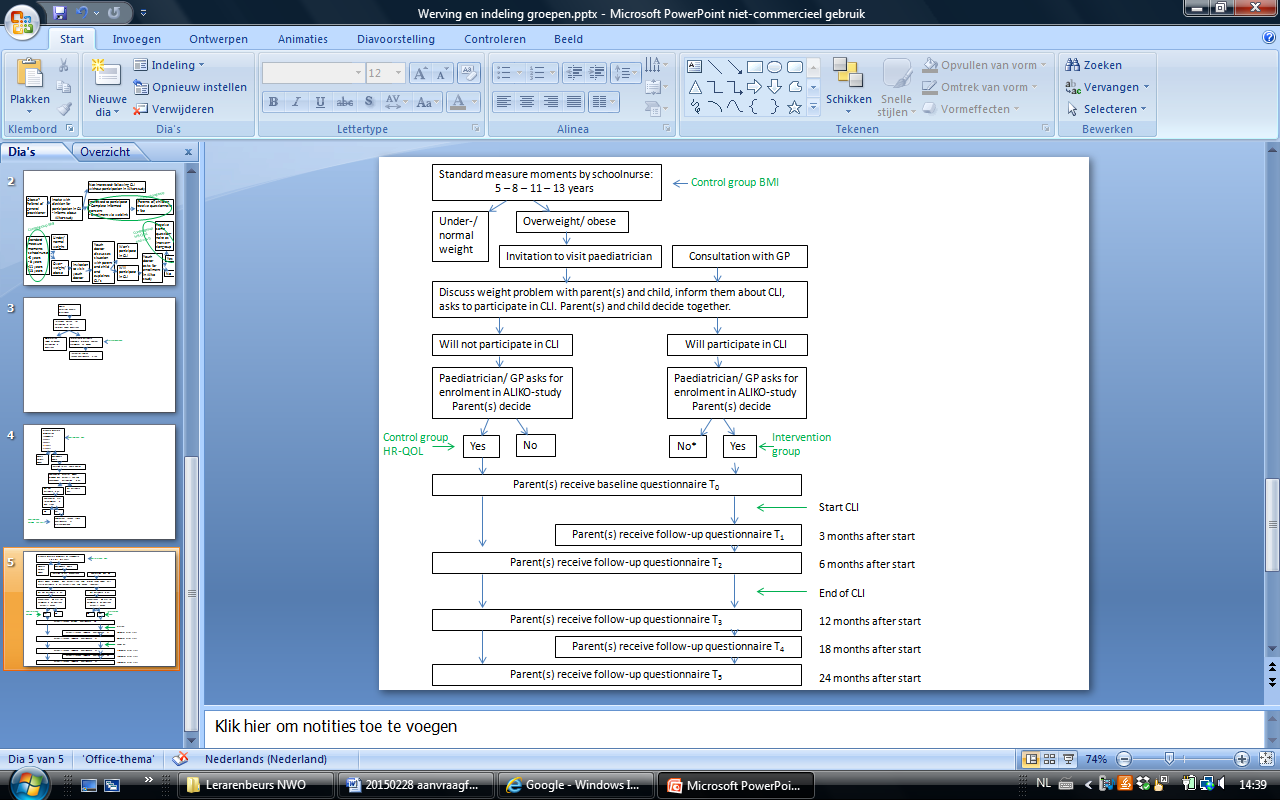


Figure 2: Flowchart design Evaluation of health effects. Abbreviations: GP, General practitioner; CLI, Combined lifestyle intervention; HR-QOL, health-related quality of life. \*The child may still participate in the CLI

Sample: Parents of children aged 4-12 years, participating in a CLI (N=100) or not (N=100).  
A number of the 13 CLIs starts multiple groups a year. Based on a post-hoc calculation and previous studies [3, 9-13], it is possible to remark significant improvements in the outcome measures.

Data collection  
Bodyweight and -height is measured by school nurses (as part of standardized care; controlgroup) and dieticians (part of CLI; interventiongroup) and provided to the researcher. Health effects identified on a questionnaire contains both multiple-choice questions and assertions to be ranked on a Likert scale. Dimensions:

1. demographics and characteristics
2. HR-QOL > primary outcome measure
3. health behaviour (eating behaviour and physical activity)
4. individual behaviour determinants (social influence, motivation, knowledge)
5. transfer from CLI to local sport facilities.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Algemeen | Gezondheid | Kwaliteit  v leven | Voeding | Beweging | Motivatie/  vertrouwen | Omgeving | Opvoeding | Kennis |
| T0 | Vóór start GLI | √ | √ | √ | √ | √ | √ | √ | √ | √ |
| T1 | 3 mnd na start | √ |  | √ | √ | √ | √ |  |  |  |
| T2 | 6 mnd na start | √ | √ | √ | √ | √ | √ | √ |  |  |
| T3 | 12 mnd na start | √ | √ | √ | √ | √ | √ |  | √ |  |
| T4 | 18 mnd na start | √ | √ | √ | √ | √ | √ | √ |  |  |
| T5 | 24 mnd na start | √ | √ | √ | √ | √ | √ | √ | √ | √ |

Questions from validated questionnaires are used, such as the TNO Research Institute and Monitor Covenant Healthy Weight, which are based on well-known reliable models, such as the I-change model [14].   
Questionnaires filled out online or on paper (in case of language or literacy problems: face-to-face interview).

After returning a complete questionnaire, the child will receive a €1 present as reward. After completing all six questionnaires, they receive a gift voucher for a toy store (worth €25). This also applies for the control group.

Data analyses  
Comparability of demographics and baseline characteristics between intervention- and control group will be evaluated using an independent sample t-test.  
Number and impact (selective loss) of dropouts will be investigated using a non-response analysis.  
BMI will be calculated as follows: bodyweight (kg) / height2 (m).Frequencies and mean grades of questionnaire dimensions 1-5 will be reported with descriptive statistics and differences between CLIs will be tested using independent t-tests.   
Changes in questionnaire dimensions 2-5 will be assessed using paired samples t-tests for continuous variables,   
chi-square tests for categorical variables, and Wilcoxon signed-rank tests for ordinal variables.

**Costs of CLIs**

Design: Quantitative   
  
Sample: Of every CLI, one HCP (N=13), in consultation with the complete CLI team

Data collection: Registration forms to indicate healthcare costs of the CLI, including:

* Materials
* Personnel (time x hourly tariff) for
  + Preparation, coordination and collaboration
  + Recruitment
  + Contact time/ meetings with children/parent(s)
  + Evaluation
* Origin of budget (e.g.: municipality, health insurers, contributions).

Data analyses: All cost of the 13 CLIs will be summed separately and compared with each other. Per CLI, costs in proportion to reached effects will be displayed, as well as average costs per child in the 13 separate CLIs.

**Evaluation of process: Implementation**

Design: Qualitative & quantitative  
Sample: Only the intervention group will take part in this evaluation. All children (N=100) and HCPs (N=52) from each of the 13 CLIs will participate.   
Data collection: As shown in Table 2, four commonly measured elements [10-14] will be evaluated by triangulation.

1. Reach: Proportion of intended target population participated in the CLI
2. Integrity and applicability: Extent to which the CLI is implemented as planned, and if the protocol of meetings is feasible for implementation in practice
3. Acceptability: Extent to which children and HCPs are satisfied with the CLI
4. Transfer: Children’s transfer from healthcare (CLI) to local sport facilities

Quantitative designs are used to collect data about the ‘what’ and qualitative designs will be used to collect information clarify ‘how and why’.

Table 2: Data collection Implementation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Design &method** | **Sample** | **Element** | **Topics (e.g.)** | **Origin** | **Moment** |
| Quantitative – monitoring report (N=26) | GP’s and youth doctors | Reach | Reasons for refuse participation in CLI or ALIKO-study | (Not applicable) | During consultation |
| Quantitative – monitoring report (N=52) | HCPs | Reach | Dates of meetings, children’s attendance,  reasons for early dropout. | (Not applicable) | During CLI |
| Quantitative – Questionnaire (N=52)  Assertions: answers on 5-point Likert scale. | HCPs | Integrity Applicability | Difficulties, deviations, determinants of successful implementation, completeness | Helmink et al.[10]  Duijzer et al. [11]  Martens et al. [13] | During CLI |
| Acceptability | Materials, time investment, contents of meetings, barriers and facilitators | Helmink et al.[10] |
| Transfer | Supply of information, cooperation between participants- HCPs - sports provider, finances, time | Helmink et al. [10] |
| Qualitative – Focus group (N=13) | HCPs | Integrity Applicability | See: questionnaire | See: questionnaire | When CLI is at least half way |
| Acceptability | See: questionnaire | See: questionnaire |
| Transfer | See: questionnaire | See: questionnaire |
| Quantitative – Questionnaire (N=100)   Assertions: answers can be given on a 5 or 10-point Likert scale. | Parent(s)[[4]](#footnote-4) / children | Transfer | Transfer/not, reason for transfer, reason for no transfer, plan after CLI | (Not applicable) | Part of T2 questionnaire  (6 months) ‘Health effects’ |
| Acceptability | Pleasantly, interesting, difficulty of meetings Rating of lessons and materials. Satisfaction with the HCPs (explicitly with dietician[[5]](#footnote-5)) (e.g. the level of the dietician’s expertise, suitability and motivating skills). | Barte et al. [12]  Martens et al.[13] |
| Qualitative – focus group (n=13) | Parent(s)4 / children | Acceptability | Reason(s) of participation, goals achieved, did and did not like, frequency of meetings, plans for follow-up. | Helmink et al. [10] | Last sport meeting |

Data analyses   
*Monitoring reports:* Overall summary reports will be showed for each CLI. These summaries will be checked by two trained student interns.

*Questionnaires:* Descriptive statistics will be used to show the results of the four elements. A t-test will be used to compare results between the CLIs.

*Interviews and focus group*: According the ‘Framework method’ [17], interviews and focus groups first will be tape-recorded and transcribed verbatim. Taken notes also transcribed. Subsequently, we organise, code and analyse the data from interviews transparently, using analysis program Atlas-Ti.   
Coding occurs during data collection using predefined codes based on the topics (top-down) and by 'free' coding (bottom-up) based on the research questions.   
Two researchers analyse independently of each other. Next, to ensure internal validity, results will be presented to participants (member check) to correct inaccuracies, after which data anonymised. In reporting results the ‘COnsolidated criteria for REporting Qualitative research (COREQ)’ [18] used.   
Member check will take place.

**Evaluation of process: Inter-professional network**

Design: Quantitative & qualitative   
  
Sample: All HCPs (N=52)   
  
Data collection:

*1. Literature review*

Factors that hinder or facilitate the success of (primary care and prevention) networks and important influences on a CLI network, will be reviewed and used to define topics for questionnaire and focus groups.

*2. Questionnaires (N=52)*

Questionnaires, to create an overview of the CLI network, will be based on the Network Analysis Tool by Zaalmink et al [19]. Topics include: connection, position, role, tasks and responsibility.

*3. Focus group interviews (N=13)*

A sketch of the network analysis will be discussed in focus group interviews by each of the 13 CLIs, and then confirmed.   
To map the quality of the network, topics will be defined based on results from the network evaluation study of the Beweegkuur [10], on the literature review and on the HALL framework [20]. The framework identifies three clusters of factors that either hinder or facilitate the success of networks.   
Topics include: experiences, characteristics of the network and disturbing and stimulating factors.

Data analyses

Results of the questionnaires will be used to map the design in 13 network graphs (of each CLI).

For focus group analyses, see: ‘Data analyses evaluation of implementation – focus groups’.

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Daarbij ook nog onderstaande literatuur gebruikt bij de procesevaluatie onderdeel ‘implementatie’, welke niet is opgenomen in bovenstaande versie:  
Inleiding:

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* Saunders RP, Evans MH, Joshi P. Developing a process-evaluation plan for assessing health promotion program implementation: a how-to guide. Health Promot Pract. 2005 Apr;6(2):134-47.
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* Hulscher, M., Laurant, M., & Grol, R. (2003). Process evaluation on quality improvement interventions. Quality & Safety in Health Care, 12(1), 40–46. doi:10.1136/qhc.12.1.40

Tevredenheid, Vragenlijst, HCP:

* Helmink, J.H.M., Van Boekel, L.C. & Kremers, S.P.J. (2011). Implementatie van de Beweegkuur; Monitorstudie onder zorgverleners, najaar 2010. Universiteit Maastricht
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Tevredenheid, Interviews, HCPs:

Helmink JH, Kremers SP, Van Boekel LC, Van Brussel-Visser FN, Preller L, De Vries NK. [The BeweegKuur programme: a qualitative study of promoting and impeding factors for successful implementation of a primary health care lifestyle intervention for overweight and obese people.](http://www.ncbi.nlm.nih.gov/pubmed/22399560) Fam Pract. 2012 Apr;29 Suppl 1:i68-i74.

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Tevredenheid, Vragenlijst, Kinderen:

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* Barte JC, ter Bogt NC, Beltman FW, van der Meer K, Bemelmans WJ. [Process evaluation of a lifestyle intervention in primary care: implementation issues and the participants' satisfaction of the GOAL study.](http://www.ncbi.nlm.nih.gov/pubmed/22020404) Health Educ Behav. 2012 Oct;39(5):564-73

Transfer sport, interviews, HCPs:

* Van zorg naar sport en bewegen. Interviews met zorgverleners en sportaanbieders over de doorstroom van Beweegkuur-deelnemers vanuit de eerstelijns gezondheidszorg naar het locale sport- en beweegaanbod. Van Dijk, M., Wigger, S. (2012)

1. Because both overweight and obesity lead to every kind of health problems mentioned above, it is desirable to treat children with overweight as well as obesity.   
   CLIs therefore include both overweight and obese children. In this proposal, overweight and obesity are called: obesity. [↑](#footnote-ref-1)
2. By a healthy lifestyle we mean healthy behaviours, which includes amongst others, healthy eating- and physical activity behaviours and can be attained when factors called ‘individual behaviour determinants’ are positive (for example: social influence, motivation, knowledge). [↑](#footnote-ref-2)
3. *Specially focus on dieticians, because of the education institute associated with the applicant.* [↑](#footnote-ref-3)
4. Parents will help the children complete the questionnaire. [↑](#footnote-ref-4)
5. To determine which skills are rated low among current HCPs to determine which skills future dieticians need to learn [↑](#footnote-ref-5)