

# Personalized preventive child health care

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# **Personalized Preventive Child Health Care**

## the “360°CHILD-profile” studies

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The research presented in this thesis was conducted at the School of Public Health and Primary Care (CAPHRI), Department of Social Medicine and Department of Epidemiology, Maastricht University. CAPHRI participates in the Netherlands School of Primary Care Research (CaRe).

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# **Personalized Preventive Child Health Care** the “360°CHILD-profile” studies

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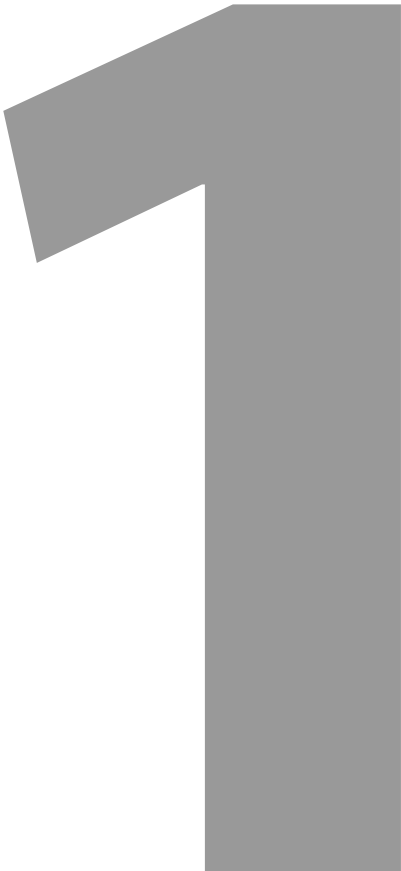


## List of abbreviations

BPS:	Bio-Psycho-Social model of health
CAHPS:	Consumer Assessment of Healthcare Providers and Systems
CGAS:	Children's Global Assessment Scale
CHC:	preventive Child Health Care
CQI:	Consumer Quality Index
CSS:	Cascading Style Sheets
DSM-5:	Diagnostic and Statistical Manual of Mental Disorders, 5th edition
EMD:	Electronic Medical Dossier
HIT:	supplemental items on Health Information Technology
ICD-11:	International Statistical Classification of Diseases and Related Health Problems, 11th revision
ICF:	International Classification of Functioning, Disability and Health
ICF-CY:	International Classification of Functioning, Disability and Health: Children and Youth version
ISO:	International Organization for Standardization
MD:	Medical Doctor
NOSIK:	"Nijmeegse Ouderlijke Stress Index, Korte versie", Nijmegen Parenting Stress Index, short version
PEDS:	Parents' Evaluation of Developmental Status
PHC:	Personalized Health Care
QUAN:	Quantitative
QUAL:	Qualitative
RCT:	Randomized Controlled Trial
SDQ:	Strengths and Difficulties Questionnaire
STEP:	"Standaard Taxatie Ernst Problematiek", Standard Taxation Problem Severity



**CHAPTER 1**



# Introduction

## **The Dutch preventive Child Health Care**

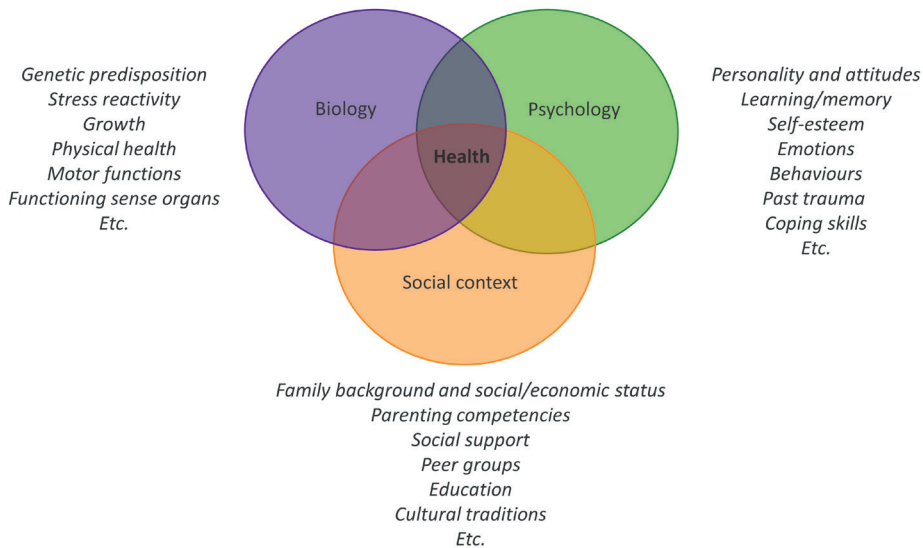
In the Netherlands, according to the Public Health Act all children have equitable access to preventive Child Health Care (CHC) [1,2]. Dutch municipalities pro-actively deliver these public health services free of charge for parents. From birth on, the CHC regularly invites each child for preventive consultations to monitor its health and development. While using this systematic and longitudinal approach, CHC-professionals focus on protecting and promoting children's health and providing context for optimal development [1-3]. During the lifelong continuum of development, CHC-professionals reference children's developmental and health aspects to normal demographic variance to timely detect a stagnation of development and/or emerging health problems. The aim of the CHC is to prevent progression towards developmental disorders and diseases at early stages of a "growing into deficit" when symptoms do not cluster to a diagnostic classification [4-6].

## **A broad biopsychosocial perspective on health**

Professionals, working within the preventive CHC, must have a broad perspective on health. For the CHC-context, a biomedical approach with focus on diagnosis and treatment does not suffice. Health is not merely the absence of disease but a state of complete physical, mental, and social well-being or even proposed the ability to adapt and self-manage in the face of social, physical, and emotional challenges [7,8]. From this perspective, the broad biopsychosocial (BPS) approach is more appropriate. The BPS-model conceptualizes health a result of complex, lifelong processes with multidimensional interactions between children's individual (biological-genetic) characteristics and contextual factors [6-11].

CHC-professionals aim to gain insight in these processes underlying health and the interrelatedness between the multiple personal traits and environmental situations. Therefore, the CHC collects and digitally registers a broad spectrum of information about health determinants in child and environment during the continuum of development [3,5,6].

However, gaining insight in the health processes and interrelatedness of health determinants can be rather challenging. The interactions between health determinants are multidimensional, for each individual child unique and change within each developmental stage (infancy, childhood, adolescence, adulthood) [12].



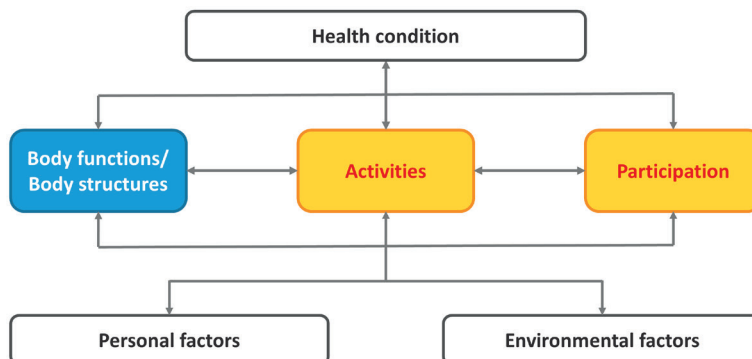
**Figure 1.1: The biopsychosocial model of health, adapted for the CHC-context.**

## Integral overview on health information with theoretical structuring of data

It is essential for preventive clinical reasoning to gain an integral overview of the collected health information to reach understanding of the complex processes underlying health. Theoretical structuring of health data should support CHC-professionals to gain insight in the multidimensional and dynamic interrelatedness between different health domains [1,13].

Within health care, several theoretical frameworks are available. The classification systems ICD-11 (International Classification of Diseases, 11th revision) and DSM-5-TR (Diagnostic and Statistical Manual of Mental Disorders, the first text revision of the version 5) are examples that are widely used within curative health care [16,17]. However, these frameworks do not fit the preventive CHC-context as they are based on the biomedical model of health and mainly focus on diseases and diagnosis. The WHO framework for measuring health and disability (at both individual and population levels), is the International Classification of Functioning, Disability and Health (ICF) [18]. For children and youth, a special version derived from the ICF was available (the ICF-CY) [19], which is now fully merged back into the ICF. Additional items of the ICF-CY were incorporated in the ICF-foundation layer or included in the ICF through the update process to ensure coverage and usage for the transition across the lifespan [20].

Due to this and the fact that it represents the BPS perspective on health, the ICF adequately fits the preventive CHC-context and enables to appropriately describe individual health situations [1].



**Figure 1.2: The International Classification of Functioning, Disability and Health (ICF).**

The ICF framework provides room for displaying a broad variety of information on characteristics of a child and its environment. It not only includes information on the health condition about presence of symptoms and diseases. On the first place, it enables to present information on child's functioning at the level of body functions/structures, activities and participation. Furthermore, it includes information regarding environmental- and personal factors and the coherence between the different health domains. It provides room for presenting strengths and protective factors, as well as vulnerabilities and challenges about health and development. The ICF formulates information in concrete, standardized and neutral, if not positive, terms with little to no valuation [18].

Although the ICF would fit the preventive CHC-context, the CHC does not use the ICF (or another theoretical classification system) for performing their preventive tasks, nor for structuring of health data within the electronic medical dossier (EMD) [1,2].

This urges two questions. First, does the CHC-context sufficiently supports the complex preventive clinical reasoning by CHC-professionals so they can optimally perform their preventive CHC-tasks? Next, do the non-theoretically structured EMD's adequately facilitate CHC-professionals in their clinical reasoning and the shared decision-making processes?

In real life practice, CHC-professionals appear to encounter obstacles regarding the registration and accessibility of CHC-data within the currently used EMD's [21-23]:

- integral overview on an overall picture on the relevant collected health information is lacking

- the mandatory reporting of CHC-data is very time-consuming for CHC-professionals (due to the high number of variables to register during each consultation).
- the datasets within the EMD are incomplete (with relatively more data available about vulnerabilities, problems and/or symptoms, and less about strengths and health promoting factors)
- the registered data lack unity of language
- to search for relevant data, registered within the EMD is time-consuming (due to sorting out collected health data in multiple compartments of the EMD).
- the EMD's do not conform to the international standards for representation of health information (ISO 9241-125, 2017) [24].
- and last but certainly not least, it is not possible for the CHC to commit to their legal tasks to:
  - provide parents with digital access to a summary of their child's health situation
  - adequately provide health information on a population level

The time-consuming data flow and the actual incomplete and inconsistent health data may substantially hinder the availability of relevant health data for the CHC-professionals during a visit, let alone for an adequate transfer of health information to parents [25].

Medical doctors working in the CHC experience that the lack of availability, integral overview and theoretically structuring of relevant health data hinders their clinical reasoning to a large extent. Preventive clinical reasoning requires a multifaceted inquiry and simultaneous thinking process to gain understanding of the interrelatedness between several planes of information about a child's individuality and its context [26]. As bits of information are stored within segmented compartments within the EMD, it costs CHC-professionals much effort and time to search for the required health information. Professionals cannot quickly and simultaneously retrieve data from the EMD nor gain an integral overview of data. This forces them into a reductionist and sequential approach instead of the preferred holistic and simultaneous one. Relevant factors fall outside professionals' scope and thus, are not considered during clinical reasoning.

The low accessibility of information on child's health situations for parents, hinders professionals in actively involving parents during thinking processes and shared decision-making towards preventive health interventions.

Furthermore, incomplete datasets and lack of uniformity of stored data hinder the CHC in providing health information on a population level with the consequence that the existing CHC-data insufficiently are suitable for governing policy and epidemiologic research [21-23].



## **The CHC: a unique platform to adopt Personalized Health Care**

More and more, prevention is acknowledged as an essential element for effectively addressing current health care issues and costs due to the increasing burden of current chronic diseases and long-term consequences of developmental problems. Substantial burden, stagnation of development and irreversible damage already can be present before criteria for diagnostic classifications are met [27]. To gain control over increasing health burden, it is crucial to prevent unnecessary irreversible damage by tracking health and early intervention in the evolution of disease.

Therefore, in literature, it is presented as a prerequisite for the current reactive health care system (with treatment after a diagnosis: “find it and fix it”) to transform towards Personalized Health Care (PHC) (“predict it and personalize it”) [28].

PHC stands for a lifetime, holistic and pro-active approach with offering preventive health care that includes prediction of health, personalization of care and active participation of care users [29,30]. The different PHC-concepts must and can be introduced in practice now. However, literature described that within the current overall, mainly reactive health care system, it appears to be challenging to fully adopt this a new approach [31,32].

The CHC offers a unique platform to adopt PHC in the short term, as it already pro-actively provides preventive care and monitors health and development during a lifelong continuum [6,33,34].

Within CHC, a paradigm shift is urgently needed as much focus is still on prevention of diseases by early detection and management of symptoms and referral to specialists [33]. Full adoption of PHC would require more attention on predicting health and actively involving parents (including the children themselves from a certain age; youngsters) [34,35].

Regarding prediction of health, it is essential to take (protecting and promoting) “health” as the starting point, instead of (preventing) “disease”, by more actively optimizing a child’s unique potential with regard to their physical, emotional, and social functioning.

First, it is essential to pay substantial attention to the strengths and health promoting factors within a child and its family and, next to detecting vulnerabilities and symptoms and preventing diseases, enhancing these strengths. Currently, the EMD’s contain relatively a large amount of information about vulnerabilities and symptoms.

Second, it requires essential room for the perspectives and active involvement of parents and adolescents when mapping and discussing a child's health situation. A timely shared decision-making process together with parents will have the potential to turn into concrete and effective strategies for optimizing child's health and development that fits the individually unique situation and needs of the child and its family [34].

To appropriately predict health and involve parents, both CHC-professionals and parents need to gain a clear, and summarized insight in the broad variety of relevant factors that determine health, as well as the interrelatedness between these factors within different health domains. Thus, for full adoption of the PHC-concepts, good accessibility of relevant high quality, longitudinal and holistic health information is crucial for both CHC-professionals and parents (and children themselves from a certain age) [30,32,34].

As mentioned above, the actual situation within CHC-practice is far from ideal. A burning issue is to find adequate solutions for obstacles concerning accessibility of CHC's health data due to the time-consuming data flow, incomplete and inconsistent data sets and the consequently lack of overview and lack of structuring of data.

The by CHC-professionals experienced need for better access and overview of meaningful health data, indispensable for interpretation and transferal of holistic health information, resulted in the initiative for the development of the research project, presented within this thesis.

## **The “360°CHILD-profile” studies: development and evaluation of a new tool for visualizing and ordering personalized holistic health information.**

The initiative for the development of the research project already started in 2012. At that time, the idea originated from CHC-practice to develop a novel approach for summarizing information about child and its environment and visualizing it in one image; the “**360°CHILDoc**” (*360° Child Health IntegraL Document*), also called the “360°CHILD-profile”.

### **Thesis aims:**

The goal of starting the PhD trajectory within this research project was to attain an innovative visualization tool that would fit the CHC-context and would be meaningful for the relevant stakeholders within this context.

To reach this goal, the aims were to gain insight in:

- A. How to develop a reliable and valid tool to visualize integral health information that is usable and meaningful within the CHC-context based on a theoretical concept.
- B. How to systematically introduce and evaluate this innovative visualization tool within real-life CHC-practice.

Among the important questions part A was focused on were:

- can data visualization be used to make personalized holistic health information accessible immediately?
- how can health data be structured in line with BPS-perspective on health and the ICF so that it appropriately represents children's health situations in concordance with the international standards for representation of health information (ISO 9241-125, 2017)?
- how can we reach a visualization tool that fits the CHC-context and optimally support CHC-professionals with regard to:
  - a comprehensible transfer of holistic health information to parents/youth and involved caregivers?
  - clinical reasoning and shared decision-making processes by means of intuitively guiding thinking in line with the recommended biopsychosocial and personalized perspective?
  - reaching comprehensive and uniform registration of relevant health data (on an individual- and population level)?
- which methodological approach is appropriate to develop and validate a visual representation of a comprehensive overview of theoretically structured health data?
- how can we optimally involve relevant stakeholders so that the new visualization tool sufficiently meets their needs within the CHC-context?
- how can relevant aspects of reliability and validity of an early representation of the visualization tool (360°CHILD-profile) be investigated?

Part B was focused on the research questions:

- is it realistic to implement the developed 360°CHILD-profile within the actual CHC-context?
- what is the usability of the developed 360°CHILD-profile within real-life CHC-practice?
- what are stakeholders' expectations about usefulness and meaningfulness of the implementation of the 360°CHILD-profile within the actual CHC-context?
- which research methodology is most appropriate to evaluate the 360°CHILD-profile's performance within real-life CHC-practice?

**Thesis outline:****Part A.**

**Chapter 2** presents the pilot study that evaluates aspects of inter- and intra-rater reliability and concurrent validity of an early on version of the 360°CHILD-profile based on the ICF for estimating child's functioning.

**Chapter 3** investigates the development and validation process of the subsequent version of the 360°CHILD-profile; an online accessible visualization of CHC-data, based on the theoretical concept of the International Classification of Functioning, Disability and Health. The goal of developing the 360°CHILD-profile is to deliver a dashboard that provides caregivers and parents/youth with a holistic view on children's health situation and "entry points" for preventive, individualized health plans. This chapter offers guidance on how to utilize a nested design model within a health care context to achieve visualization of a comprehensive overview of theoretically structured health data.

**Part B.**

**Chapter 4** describes the protocol for performing a Mixed Methods Feasibility Randomised Controlled Trial during the first and short introduction of the 360°CHILD-profile in real-life CHC-practice. The protocol describes the evaluation of usability and feasibility of the CHILD-profile, as well as methodological aspects of setting up an RCT.

**Chapter 5** shows the integrative quantitative and qualitative results of the part of the Mixed Methods feasibility study with focus on evaluating the usability and feasibility of the 360°CHILD-profile. To gain insight in how to proceed 360°CHILD-profile's implementation process, the level of use is assessed, as well as a broad variety of determinants that potentially influence the implementation process. These determinants relate to the CHILD-profile itself, its potential users, and the organizational and socio-political context.

**Chapter 6** discusses the integrative quantitative and qualitative results of the part of the Mixed Methods study with focus on methodological aspects of setting up an RCT. This study entails the initiation of the evaluation of the prerequisites of studying CHILD-profile's effectiveness within real-life health care practice. Within a pragmatic Mixed Method feasibility randomized trial, RCT-procedures are investigated thoroughly within the CHC-context and applicability of potential outcome measures for assessing accessibility and transfer of health information. The goal is to gain insight in the complexity of executing an RCT within the CHC-context and how to proceed 360°CHILD-profile's evaluation process.

**Chapter 7** describes a general discussion of the study's findings and considers further research developments and implications for practice.

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**CHAPTER 2**



# The 360°CHILD-profile, a reliable and valid tool to visualize integral child-information

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## Abstract

A 360°CHILD-profile with theoretically ordered integral child-information, visualized in one image, is designed by the Dutch preventive Child and Youth Health Care (CYHC). The introduction of this new data/information carrier gives an important incentive to enhance a transformation towards personalized health care for children and adolescents by supporting the complex medical thought process of CYHC-medical doctors (MD's). This information tool aims to effectively estimate child's functioning, detect emerging health problems and inform parents and caregivers.

This pilot study evaluated aspects of inter- and intra-rater reliability and concurrent validity of the 360°CHILD-profile when used by MD's to estimate functioning and needed intervention of 4-year-old children. After the development process, in January 2015, 360°CHILD-profiles (n = 26) were assessed by MD's, in the Netherlands. Each MD assessed two CHILD-profiles twice and was matched to another MD receiving exactly the same two profiles. The paired scores and rater's scores of both time-points were compared. Rater's scores also were compared with the 26 reference tests scores.

Reliability results showed Intraclass correlation coefficients between 0.71 and 0.82 (overall functioning), Cohen's kappa's between 0.61 and 0.80 (psychosocial functioning) and 0.46–0.47 (needed intervention). Validity results showed a Spearman's correlation coefficient of 0.78 (overall functioning), Cohen's kappa's of 0.43 and 0.77 (psychosocial functioning) and 0.52 (needed intervention).

In conclusion, in some domains, acceptable results regarding reliability and validity are found for the visualization of integral child information used by CYHC-MD's to assess child-functioning after only a short training. The 360°Child-profile's value on tracking change in functioning and decision-making on intervention needs further exploration.

## Introduction

A transformation of the current conventional health care, with treatment after a diagnosis (“find it and fix it”) to a predictive and personalized health care (“predict it and personalize it”) is needed (Doove et al., 2013, Snyderman and Langheier, 2006). Substantial burden and irreversible damage, present at time of diagnosis, can be prevented by tracking health and early intervention in the evolution of disease (Snyderman and Yoediono, 2006, Auffray et al., 2010). Preventive Child and Youth Health Care (CYHC), with surveillance of individual children’s health, is focused on early detection and management of symptoms. However, still a shift is needed towards a more predictive and personalized health care.

To enhance this paradigm shift in practice it is important to understand the continuous multidimensional interactions between biological-genetic vulnerability and many environmental factors, which determine health and functioning (Sameroff, 2010). The CYHC collects information on child’s health, biological-genetic vulnerability and environment. However, theoretical ordering is needed to make the individually unique and complex pathogenic processes accessible and tangible (Doove et al., 2013).

A 360°CHILD-profile, based on the “International Classification of Functioning, Disability and Health for Children and Youth” (ICF-CY), is designed within the Dutch CYHC (see figure 2.1).

On this newly developed child-profile, the child-information, already registered in the Electronic Medical Dossier (EMD) from birth by the CYHC, is ordered and visualized on one digital image.

The ICF-CY, based on the integrated Bio-Psycho-Social model of health, is chosen as a framework for ordering information as it is conceptually focused on health and functioning rather than on diseases and diagnosis like other classification systems, e.g. ICD-11 and DSM-5. Moreover, it offers an internationally standardized language for accessible communication with parents and other caregivers (World Health Organization, 2007).

The 360°CHILD-profile, designed to promote the CYHC transformation towards future proof care, is not a diagnostic instrument. However, it is a data/information carrier, which supports the professional (medical) thought process of MD’s during the surveillance of children’s health, development and functioning, early detection of emerging health problems and respectively pathogenic processes and symptom management on an individual level.

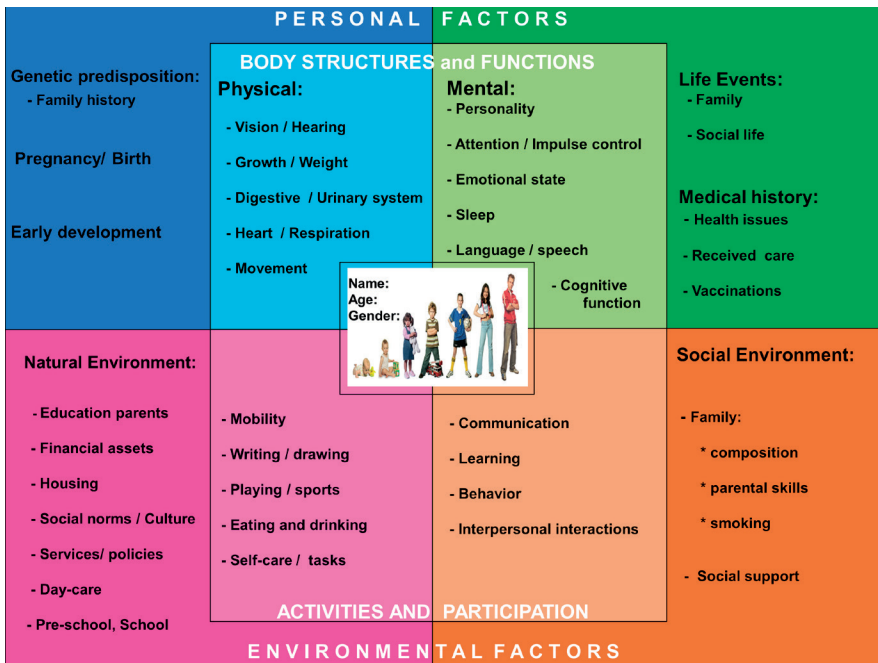


Figure 2.1a: A preliminary version of the 360° CHILD-profile.

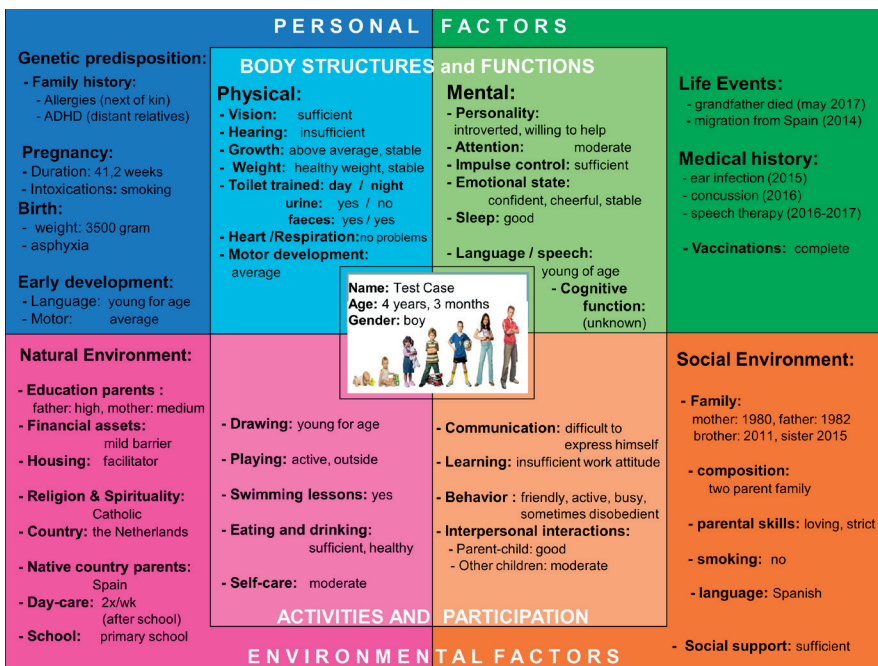


Figure 2.1b: an example of a preliminary version of a personal 360° CHILD-profile with information about a child.

Previous pilot studies with a mixed method design (an integration of qualitative and quantitative descriptive data), showed that the comprehensibility of the 360°CHILD-profile, as well as relevance, acceptance and feasibility is good according to parents, children, CYHC-workers and other caregivers (Weijers and van der Goot, 2013).

For a measurement tool used in clinical practice it is essential to develop knowledge regarding relevant aspects of reliability and validity (de Vet et al., 2013). The underlying theoretical construct of the 360°CHILD-profile is based on the framework of the ICF-CY, which is focused on child's health and functioning. In daily practice, CYHC-workers decide, based on integral child-information, what level of intervention is needed to promote health and lower risks. The aim of this study of the 360°CHILD-profile was to investigate the inter- and intra-rater reliability and concurrent validity in a population of CYHC-medical doctors (MD's) to estimate overall- and psychosocial functioning and needed intervention. For concurrent validity the results of the 360°CHILD-profile were compared with best practice results of MD's who have carried out the actual care of the children (overall functioning and needed intervention), and validated questionnaires (psychosocial functioning).

## Methods

### Study design

In this pilot study, a cross-sectional reliability and validity study was conducted.

Concerning reliability it was hypothesized that the Intraclass Correlation Coefficients (ICC) and quadratic weighted Cohen's kappa's between the scores of both rater's and the rater's scores of both time-points are at least 0.6. It was stated that 0.6 is acceptable in this stage of development as the tool was newly introduced as well as the outcome measure (after only a short training for the participating MD's).

For concurrent validity the formulation of hypothesis, as no references for these specific correlations were available, was based on theoretical grounds related to the constructs of the used measures and practical experience of the authors as epidemiologists and medical doctors in the CYHC. The following hypotheses were formulated:

1. Spearman correlation coefficient and quadratic weighted Cohen's kappa's between the scores based on the 360°CHILD-profile and the best practice- and questionnaire scores are between 0.5 and 0.8.
2. Spearman correlation coefficient between the overall functioning scores based on the 360°CHILD-profile and the best practice scores is between 0.6 and 0.75.

3. Quadratic weighted Cohen's kappa between the psychosocial functioning scores based on the 360°CHILD-profile and the validated questionnaire scores is between 0.5 and 0.65.
4. Quadratic weighted Cohen's kappa between the needed intervention scores based on the 360°CHILD-profile and the best practice scores is between 0.65 and 0.8.

### **Study population and material**

In January 2015, all 30 MD's working in two different CYHC-organizations (one for 0–4 year and one for 4–18 year old children) in the region of Southern of Limburg, the Netherlands, were asked to participate. Using a design in which various MD's participated, enables generalization of results to all CYHC-medical doctors. Before performing assessments, the MD's attended a short training with an introduction of the 360°CHILD-profile and the validated CGAS-scale to indicate overall functioning, exercise assessments and discussion.

The sample of children was selected from a representative cohort of a prospective cohort study within the real life CYHC practice in Maastricht; the "MOM-study" (Doove, 2010), a cohort obtained in 2010 of parents of children living in Maastricht and surroundings, between 1-1-2007 and 1-1-2010. During regular visits, performed by doctor-assistants and nurses of the CYHC, children with specific medical or complex issues are selected to be scheduled for consultation by a CYHC-MD. Therefore, the percentage of children experiencing problems in functioning seen by MD's is higher in comparison to children in the general population. An effort was made to obtain a sample of children reflecting a general population and to reach coverage of a substantial range of the measurement scale. The full cohort was divided into 3 groups with different levels of functioning ("high", "moderate" and "low") by using functioning scores obtained during the "MOM-study" (continuous scale 6 (high) to 30 (low)). Cut-off points of 11 and 17 were chosen to obtain a sufficient number of children in each group. From each group 10 children were randomly selected for this study.

For the experimental assessments, the researcher (MW; founder of the 360°CHILD-profile) filled out 360°CHILD-profiles of 30 selected 4 year old children out of the cohort. The information, obtained from the EMD at the time the data of the reference tests were collected, were transferred into the child-profile's categories: body structures and functions, activities and participation, personal- and environmental factors (Fig. 2.1).

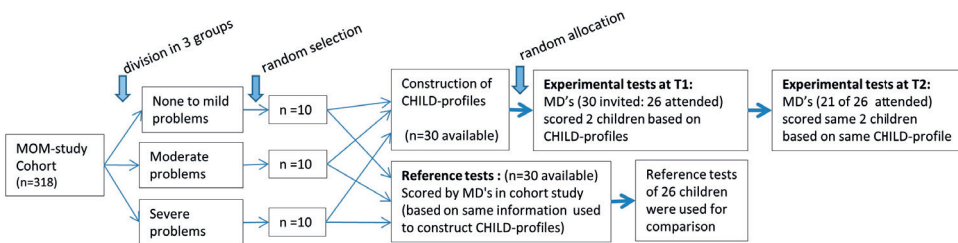
### **Measurements**

All MD's that attended the 360°CHILD-profile's introduction and short training assessed two randomly allocated 360°CHILD-profiles during a timeframe of 5 min (every child-profile was assessed by two MD's). Based on the information on the 360°CHILD-profile, they estimated

the level of overall and psychosocial functioning and needed intervention of the children. During assessments discussion was prohibited. After a time-interval of 4 months, the exact same profiles were reassessed in a random order by the same MD's during a regular MD-meeting.

The MD's indicated the estimated level of overall functioning of the child on a validated continuous scale: the Children's Global Assessment of Functioning (CGAS)-scale (Shaffer et al., 1983). The MD's indicated the estimated level of psychosocial functioning and needed intervention on a three-point ordinal scale.

The reference tests to assess concurrent validity were performed in the original cohort study. In that study, the MD's who carried out the actual care of the included children, scored the level of overall functioning on a continuous scale and needed intervention on a 3-point scale. In the original cohort study, psychosocial functioning was filled out on a validated questionnaire for parents (CBCL1,5-5: Child Behavior Check List for children between 1,5 and 5 years old) and for teachers (TRF1,5-5: Teacher Report Form) (Schmeck et al., 2001, NederlandsJeugdInstituut. Child Behavior Checklist, 2014). These questionnaires also were used as a criterion in other validation studies (Reijneveld et al., 2006). A flow chart of the study material and population is provided in Figure 2.2 and all comparators are described in Table 2.1.



**Figure 2.2. Flow chart of study material and population.**

The estimation of the level of functioning of children is a daily task of CYHC professionals, as well as the decision if a follow-up or (preventive) intervention has to be advised to parents.



**Table 2.1 Categories of comparisons and comparators derived from the hypotheses.**

<b>Inter-rater reliability:</b> Experimental scores at T1: MD1 versus MD2		
<b>Intra-rater reliability:</b> Experimental scores MD's T1 versus T2		
<b>Concurrent validity:</b> Experimental scores MD's at T1 versus Reference test scores		
<b>Comparators:</b>		
<b>Experimental scores:</b> Scores of MD's after perceiving 360°CHILD-profile for 5 minutes	Overall functioning	Estimation indicated on CGAS-scale 0-100: (severe dis-functioning to optimal functioning)
	Needed intervention	Estimation indicated on three-point ordinal scale: ("no intervention", "advice and/or extra CYHC-contact" or "refer to further help")
	Psychosocial functioning	Estimation indicated on three-point ordinal scale: ("normal", "borderline", "clinical")
<b>Reference test scores:</b> Best-practice scores: by MD's that carried out actual care of included children & Questionnaires for parents and teachers	Overall functioning	Estimation MD indicated on scale 6-30: (good- severe dis-functioning)
	Needed intervention	Decision MD indicated on three-point ordinal scale: ("no intervention", "advice and/or extra CYHC-contact" or "refer to further help")
	Psychosocial functioning	CBCL (parents) and TRF (teacher) questionnaires outcome: ("normal", "borderline", "clinical")

## Statistical analysis

Minimal sample size, calculated according to the formulas for ICC given in de Vet et al. (de Vet et al., 2013) for Spearman correlation (Berger et al., 2002), was 20 objects of study with two raters per object.

Descriptives of participating MD's (year of experience, educational level, and gender), included children (age, gender, level of functioning) and distributions of the scores and missing values were presented. Missing data were handled by pairwise deletion (only the specific missing values and the paired values were not included in the analysis).

To measure inter-rater reliability, scores of the same child at T1 by 2 MD's were compared paired-wise and for intra-rater reliability, the two scores of the same child by the same MD at T1 and T2 were compared. For continuous values of overall functioning, the Intraclass Correlation Coefficient-agreement (ICC-agreement) was calculated because we were not

only interested in consistency (i.e. ranking) but wanted to know if the raters draw the same conclusions about the functioning of a child (Terwee et al., 2007). The SCALE-analysis was performed and in addition the VARCOMP-analysis and analysis of variance (ANOVA) to obtain all variance components of the measurements. Standard Error of Measurement (SEM-agreement) was calculated conform the formula given by de Vet (de Vet et al., 2013). Bland and Altman-plots were constructed to define Limits of Agreement (LoA) and systematic error (Bland and Altman, 1986). For ordinal values of psychosocial functioning and needed intervention the quadratic weighted Cohen's kappa's were calculated as it adjusts for differences in misclassification between adjacent categories and distant categories (de Vet et al., 2013).

To test the hypothesis for concurrent validity scores of the 360°CHILD-profile at T1 are compared with best practice scores (overall functioning, needed intervention) and scores on validated questionnaires (psychosocial functioning). For the continuous value of overall functioning, the Spearman's correlation coefficient was calculated as experimental- and reference scores were not measured in the same units and it minimizes the effect of violation of normality and homoscedasticity. For ordinal values of psychosocial functioning and needed intervention the quadratic weighted Cohen's kappa was calculated.

The software package SPSS 21, SPSS Inc. Chicago, USA, was used for statistical analysis. In addition, the VassarStats-website was used to calculate quadratic weighted kappa's (VassarStats, n.d.).

## Results

### Descriptives

In total 26 MD's participated at T1 and 21 were also present at the second meeting (T2). Twenty six children were assessed by two different MD's (at T1) and 21 children were assessed by two MD's twice (at T1 and T2) (Fig. 2.2: Flow chart of study population). Characteristics of the medical doctors and the children are provided in Table 2.2.

The range of continuous scores was between 40 and 100 (CGAS) and 6–22 (reference scores) with 31–35% of the scores in the highest quintile (high functioning). The majority of scores of psychosocial functioning by the MD's (56%), the teachers (69%) and parents (80.8%) were in the "normal" category. The majority of needed intervention scores by the MD's were in the middle category "advice/extra CYHC-contact" (54%) while for the reference test this percentage was lower (23%).

**Table 2.2 Characteristics of participating CYHC-medical doctors and the children of whom information is used to construct the 360°CHILD-profile profiles.**

<b>Medical Doctors</b>	<b>Categories</b>	<b>Number per category</b>	<b>N</b>
Education level	CYHC-introduction course	2	26
	Specialist CYHC	22	
	Missing	2	
Years of experience	0-5 years	1	26
	5-10 years	3	
	10 -15 years	4	
	> 15 years	17	
	Missing	1	
Gender	Male	3	26
	Female	23	
<b>Children</b>			<b>N</b>
Gender	Boys	10	26
	Girls	16	
Level of functioning	"high"	9	26
	"moderate"	8	
	"low"	9	
		<b>Mean (SD)</b>	
Age (in months)		47	26

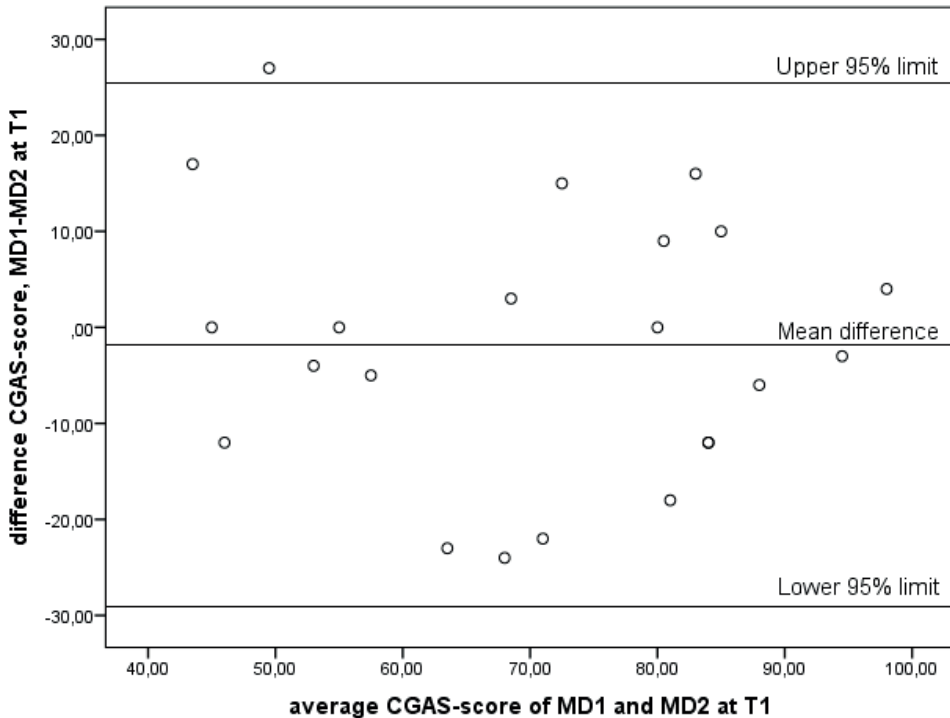
The assumption linearity was met for all relationships concerning the continuous scores.

At T1 there were two missing values on the score of overall functioning (the MD's forgot to fill it out). For intra-rater reliability additional missing values occurred as at T2 five MD's could not attend the second meeting.

### **Inter-rater reliability**

ICC-agreement concerning overall functioning was 0.71 (95%CI 0.42–0.87). The different variance components were: children 233.44; raters 0.00; and error 94.15 and the SEM-agreement was 9.7. The Bland and Altman-plot (Figure 2.3a) showed a mean difference of - 1.8 ( $P = 0.546$ ), LoA of  $\pm 27.3$  (39% of mean).

Concerning the psychosocial functioning and the needed intervention the quadratic weighted Cohen's kappa's were 0.80 (95%CI 0.72–0.88), respectively 0.47 (95%CI 0–0.96) and the % of agreement were 73%, respectively 69% (Table 2.3, main results).



**Figure 2.3a. Bland Altman plot of difference CGAS-score between two raters (MD's) against the average of both raters.**

### Intra-rater reliability

Intra-rater reliability for overall functioning the ICC-agreement was 0.82 (95%CI 0.68–0.90). The variance components were: children 242.12; time 2.89; error 48.10 and the SEM agreement was 7.14. The Bland and Altman-plot (Figure 2.3b) showed a mean difference of  $-3.03$  ( $P = 0.058$ ), LoA of  $\pm 19.2$  (27% of mean) and no obvious relationship between the measurement error and the true value. The differences were normally distributed.

Concerning the psychosocial functioning and the needed intervention the quadratic weighted Cohen's kappa's were 0.61 (95%CI 0.39–0.83), respectively 0.46 (95%CI 0.11–0.81) with % of agreement of 62% respectively 71% (Table 2.3).

**Table 2.3. Main results. Correlations between 360°CHILD-profile scores by two different MD's (inter-rater reliability), by MD's at different time-points (intra-rater reliability) and between 360°CHILD-profile- and reference-scores (concurrent validity) and agreement and measurement error.**

Assessment:	Correlation:	Value (95%CI)	Agreement/Measurement error
<b>Inter-rater reliability</b>			
Overall functioning (n=22)	ICC-agreement *	0.71 (0.42–0.87)	LoA** ± 27.3 (39% of mean) SEM-agreement*** 9.7
Psychosocial functioning (n=26)	Quadratic weighted kappa	0.80 (0.72–0.88)	
Needed intervention (n=26)	Quadratic weighted kappa	0.47 (0 – 0.96)	
<b>Intra-rater reliability</b>			
Overall functioning (n=40)	ICC-agreement	0.82 (0.68–0.90)	LoA ** ±19.2 (27% of mean) SEM-agreement*** 7.14
Psychosocial functioning (n=42)	Quadratic weighted kappa	0.61 (0.39–0.83)	
Needed intervention (n=42)	Quadratic weighted kappa	0.46 (0.11–0.81)	
<b>Concurrent validity</b>			
Overall functioning (n=48)	Spearman's rho	0.78 (0.63–0.86)	
Psychosocial functioning (TRF- teacher) (n=52)	Quadratic weighted kappa	0.77 (0.68–0.86)	
Psychosocial functioning (CBCL-parents) (n=52)	Quadratic weighted kappa	0.43 (0.11–0.75)	
Needed intervention (n=52)	Quadratic weighted kappa	0.52 (0.27–0.76)	

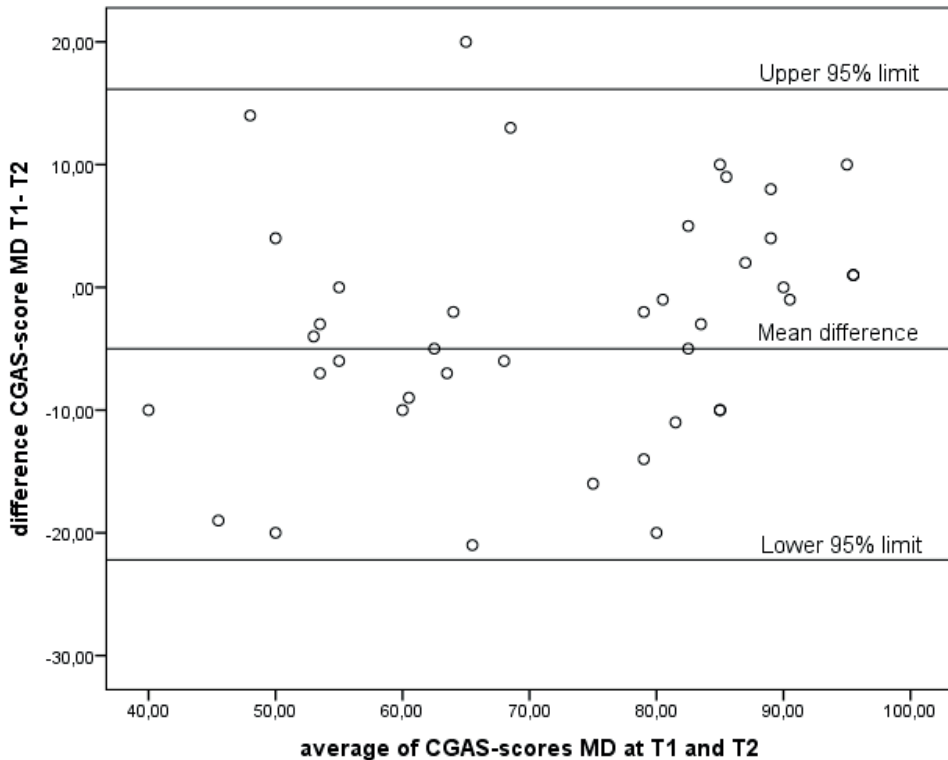
\*Intraclass correlation coefficient-agreement.

\*\*Limits of agreement.

\*\*\*Standard error of the mean-agreement.

### Concurrent validity

Concerning concurrent validity for overall functioning the Spearman correlation coefficient was  $-0.78$  (95% CI  $-0.86 - (-0.63)$ ). For psychosocial functioning the quadratic weighted kappa, with TRF-teachers form as reference, was  $0.77$  (95% CI  $0.68-0.86$ ) and with CBCL-parents form as reference it was  $0.43$  (95% CI  $0.11-0.75$ ). For needed intervention, the quadratic weighted kappa was  $0.52$  (95% CI  $0.27-0.76$ ) (Table 2.3).



**Fig. 2.3b. Bland Altman plot of difference between CGAS-scores MD's at T1 and at T2 against the average of the two scores.**

## Discussion

This study measured inter-rater and intra-rater reliability and concurrent validity of the newly developed 360°CHILD-profile when used by CYHC-MD's to estimate functioning and needed intervention of Dutch 4-year-old children in a heterogeneous population. This heterogeneous population is a realistic representation of the population MD's usually see in their practice.

### Main findings

Reliability outcomes for overall- and psychosocial functioning are promising with correlations widely above the minimal value in the hypothesis. For needed intervention, reliability outcomes are not satisfactory with correlations lower than hypothesized.

For validity correlations between the experimental scores and reference test scores for overall- and psychosocial functioning (if compared with teacher form) and needed intervention were, as hypothesized, between 0.5 and 0.8. The correlations for overall functioning and psychosocial functioning (if compared with teacher form) were higher and the correlations for psychosocial functioning (if compared with parent form) and needed intervention were lower than expected. Although further research is needed, positive indicators were revealed concerning validity.

### **Strengths and limitations**

This study has several strengths. First of all, this first reliability and validity study of the 360°CHILD-profile shows that, with only a short training in the child-profile and the CGAS-scale, good results can be reached for estimating overall- and psychosocial functioning. Secondly, the MD's were very willing to participate and enthusiastic about using the 360°CHILD-profile to assess children, which is a premise for successfully implementing a new tool in practice. Thirdly, outcomes of this study enable direct translation into CYHC-practice. Limitations of this study result from the fact that the tool is newly introduced and no earlier reliability and validity studies were performed yet. The lack of evidence and experience could have led to suboptimal hypothesis and systematic differences in the scores of the compared measurements. The sample size is rather small, however, the minimal sample size was reached and conclusions can be drawn regarding the continuation of development of the 360°CHILD-profile. Moreover, the majority of MD's of the participating organizations participated and all Dutch CYHC organizations follow the same national guidelines.

### **Reflection to other literature**

The enthusiastic, positive reaction of the CYHC-MD's on working with the 360°CHILD-profile is in concordance with earlier positive results of pilot studies on comprehensibility, relevance, acceptance and feasibility in practice (Weijers and van der Goot, 2013). As this was the first study to examine aspects of reliability and validity of the 360°CHILD-profile, no data are yet available in literature. As the minimum standard for reliability an ICC of 0.7 is considered and regarding the CGAS an inter-rater reliability study showed an ICC of 0.73. Our results are higher than expected: in line with these values and well above the chosen cut-off points in hypotheses (Schmeck et al., 2001, Terwee et al., 2007). No validity studies of the CBCL and TRF were found, but a study of test-retest reliability of these questionnaires showed correlations between 0.94 and 0.97 (Achenbach et al., 2008). The CBCL is used as a criterion for studies to validate short checklists, like the Strengths and Difficulties Questionnaire (SDQ), which is commonly used in CYHC to identify psychosocial problems. For the SDQ test-retest reliability correlations between 0.74 and 0.81 are known, while a correlation between the SDQ and CBCL of 0.68 is reported (Achenbach et al., 2008). Reliability outcomes for the 360°CHILD-profile of this study are comparable with the results of the SDQ and, as expected, lower than results of the extensive CBCL-questionnaire. A

rather strong correlation between the 360°CHILD-profile and CBCL was found in comparison with the reported correlation between the SDQ and CBCL.

In reflection to findings in literature, results of this study are promising when taking into account that the 360°CHILD-profile and CGAS-scale were newly introduced and the training given was short.

### **Clinical implications**

This pilot study was conducted to justify the need for further research on this tool. This study showed that this new CHILD-profile can be useful in daily CYHC-practice to quickly distinguish children in levels of overall- and psychosocial functioning in a population that visit the CYHC-MD.

Although the ICF-CY and 360°CHILD-profile are not yet commonly used in the CYHC, it seems to fit the field of the CYHC. The positive results on the rapid interpretation of functioning after only a short training enhance good and readily implementation in practice with rather low costs.

An explanation for the suboptimal results for needed intervention could be the fact that MD's might need an additional face to face consult to explore the needs of child and parents in order to decide on the exact intervention needed. Whether the 360°CHILD-profile is useful to select children for whom such a face to face contact is needed and/or supportive during these consultations, should be investigated in the future.

This study was part of a development project, with a continuous process of evaluation and adaptation that started in 2010. This study justifies continuation of development and evaluation of other aspects of the 360°CHILD-profile (e.g. responsiveness, predictive value) during step by step implementation. Algorithms are now being developed and tested to automatically transfer the most up-to-date information from the EMD into the child-profile's categories. Each version of the child-profile (generated at different time-points) can be stored in the EMD. After implementation, the empirical process will carry on and the CYHC-working methods with the support of the 360°CHILD-profile will be evaluated on efficiency of assessing and tracking child-functioning and early detection of emerging health problems. Eventually it is intended to evaluate the other important purposes of the 360°CHILD-profile like provision of visual support to transmit integrated child-information to parents, youth and other caregivers, facilitate tailored shared decision-making and early and personalized interventions and provision of standardized language to report data on a population (World Health Organization, 2007).



The goal of implementing this multifunctional tool is to contribute to the transformation towards a personalized care and an evidence-based working method in the Dutch CYHC.

### **Conclusion**

Our pilot study showed promising results regarding reliability and validity on relevant domains for the visualization of integral child-information used by CYHC-MD's to assess child-functioning. The 360°CHILD-profile's value on tracking change in functioning and decision-making on intervention needs further exploration. This newly developed tool for efficient estimation of functioning, early detection of emerging health problems and respectively pathogenic processes, shared decision making and personalized interventions, is enthusiastically received by CYHC-MD's. The positive reactions of the CYHC-MD's indicate that this original 360°CHILD-profile is rather easy to implement in practice.

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**CHAPTER 3**

**3**

# Designing a Personalized Health Dashboard: Interdisciplinary and Participatory Approach

Weijers M, Bastiaenen CHG, Feron FJM, Schröder K.

## **Abstract**

**Background.** Within the Dutch Child Health Care (CHC), an online tool (360°CHILD-profile) is designed to enhance prevention and transformation toward personalized health care. From a personalized preventive perspective, it is of fundamental importance to timely identify children with emerging health problems interrelated to multiple health determinants. While digitalization of children's health data is now realized, the accessibility of data remains a major challenge for CHC professionals, let alone for parents/youth. Therefore, the idea was initiated from CHC practice to develop a novel approach to make relevant information accessible at a glance.

**Objective.** This paper describes the stepwise development of a dashboard, as an example of using a design model to achieve visualization of a comprehensive overview of theoretically structured health data.

**Methods.** Developmental process is based on the nested design model with involvement of relevant stakeholders in a real-life context. This model considers immediate upstream validation within 4 cascading design levels: Domain Problem and Data Characterization, Operation and Data Type Abstraction, Visual Encoding and Interaction Design, and Algorithm Design. This model also includes impact-oriented downstream validation, which can be initiated after delivering the prototype.

**Results.** A comprehensible 360°CHILD-profile is developed: an online accessible visualization of CHC-data based on the theoretical concept of the International Classification of Functioning, Disability and Health. This dashboard provides caregivers and parents/youth with a holistic view on children's health and "entry points" for preventive, individualized health plans.

**Conclusions.** Describing this developmental process offers guidance on how to utilize the nested design model within a health care context.

## Introduction

The Dutch Preventive Child Health Care (CHC), as part of public health, monitors children's health and their continuum of development with focus on protecting and promoting health and providing context for optimal development. This implicates preventing disease progression at early stages of a "growing into deficit," when symptoms do not cluster to a diagnosis or are even absent yet [1]. It is not easy to timely redirect these complex dynamics underlying health. The Bio-Psycho-Social perspective on health (BPS) displays the complexity by conceptualizing health as a result of lifelong, multidimensional interactions between individual (biological–genetic) characteristics and contextual factors [2].

This makes prevention challenging, but it is crucial to effectively address current burden of chronic diseases [3]. It is even a prerequisite that the current health care system, which is mostly reactive (ie, treatment after a diagnosis), transforms toward personalized health care (PHC) [4]. According to Snyderman, PHC includes the concepts prevention, prediction, personalization, and participation and to fully adopt these concepts within practice, the availability of qualitative, holistic health information is required [5,6].

The preventive CHC offers a unique platform to adopt these PHC concepts, as CHC (from birth on) digitally registers a broad spectrum of information about interrelated health determinants in child and environment [1,7]. Yet, the holistic health information, stored in the CHC's electronic medical dossier (EMD), is insufficiently accessible to effectively perform PHC. The actual data flow is time-consuming due to an inconsistent, nontheoretical structure of the EMD [8-10]. This challenges CHC professionals to gain clear overview of relevant CHC data within the limited timeframe available during consultations with parents and other caregivers. Consequently, CHC professionals are hindered in obtaining integral insight into the interrelated health determinants in child and environment, let alone parents and youth.

To acquire better overview of meaningful data, indispensable for interpretation of holistic health information, the idea was initiated from CHC practice to develop a novel approach for summarizing health data about child and its environment in 1 image [2,11]. Visualization design offers efficient opportunities to make holistic health information accessible at a glance and conform to the relevant theoretical perspective [12,13].

The initial idea was first converted into rough drafts of representation of CHC health information. To enable generation of informal development ideas, the researchers presented first drafts to parents, youth, and CHC professionals and asked for their reaction. Stakeholder's feedback on these first drafts during interviews (parents) and focus group meetings (professionals) was positive concerning comprehensibility, relevance, acceptability, and feasibility. A pilot study of an early-on version of the 360°CHILD-profile



also showed positive results regarding reliability and validity, when used by CHC medical doctors to assess child functioning [14].

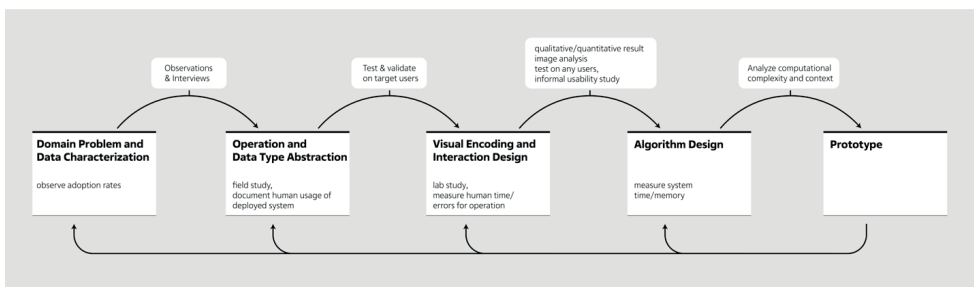
The 360°CHILD-profile seemed a promising new tool, but further development was needed to deliver a suitable and functional dashboard, ready to be introduced to CHC practice. To realize meaningful visualization of complex health information with sufficient user satisfaction and essential performance in practice, it is important that such a developmental process is guided by appropriate design models.

The main aim of this paper is to offer guidance on how to utilize a design model to visualize and structure health data in a health care context with a heterogeneous target group. As an example, we describe the systematic development and immediate validation (as far as possible) of a comprehensible 360°CHILD-profile: an online accessible visualization of CHC data. The ultimate goal of this multifunctional tool for preventive CHC practice is to visualize the coherence between health domains in a way that it guides analytic thought processes of both care providers and parents/youth in line with BPS perspective on health and PHC. This paper focusses on describing the overall development process of a visualization tool to offer a clear, representative content generalizable to various subfields and disciplines in health care.

## Methods

### Process development and prototype

The developmental process of the 360°CHILD-profile is based on a nested design model, adapted from Munzner [15] (Figure 3.1). This model describes different levels of design that are structured within 4 cascading levels that consider an immediate upstream validation (toward delivering a suitable prototype of the dashboard) as well as impact-oriented downstream validation of the prototype (toward the effective performance of the dashboard in daily CHC practice).



**Figure 3.1: The nested design model, adapted from Munzner. The upper part shows the relevant stages of upstream validation, while the bottom part shows the different dimensions of downstream validation.**

The prototype of the 360°CHILD-profile is developed within a user-centered design process [16] and relevant stakeholders were involved during every level of design. For each design level, new participants were recruited. During this project, we collaborated in an interdisciplinary expert group including CHC professionals and researchers with expertise on CHC context, epidemiology, human–computer interaction, and information visualization in health care. This approach, combining expertise from the medical field with expertise on information visualization, is rather new but particularly useful in this health care context to increase the likelihood of the intended health outcome [17].

The Medical Ethics Committee of the Maastricht University Medical Centre approved this design process (METC azM/UM 17-4-083).

Before starting the first level of the nested design model, a literature research was performed with focus on theoretical models for health and background of the Dutch preventive CHC to identify the information needed for each design level.

### **Domain problem and data characterization**

On the first level, it was of vital importance to bridge the information asymmetry between relevant stakeholders, researchers, and designers to get a common understanding of user, domain, and task [18]. To achieve this while considering the privacy of the users, we first conducted role games, in which CHC consultations were re-enacted in a real-life situation with key stakeholders (CHC professionals, parents, and youth). A schematic approach (summative representation of data to make sense of complex, nuanced information and enable team-based analysis) was used to observe and interpret interpersonal interactions [19]. In the second step, interviews with participants of the role games as well as other CHC professionals were carried out to get a deeper understanding of the process and related requirements from the perspective of individual stakeholders. Role games and interviews were audio recorded. Recordings were summarized and, after discussion by a team of researchers, relevant findings were listed.

Finally, the resulting conclusions about user's perspectives were immediately validated in real-life by observing consultation hours. During the observations, field notes were taken. Based on the information collected within the previous steps, personas and empathy maps were created to visualize users' characteristics, goals, and skills, to become more aware of their real needs and to help the research group align on a deep understanding of end users [20,21].

In parallel, the relevant domain knowledge was discussed and summarized with all involved stakeholders to ensure that the involved researchers/designers share a common

understanding of the underlying concepts and mechanisms. Furthermore, related work in the field and visual artifacts were discussed.

In summary, all our findings formed the domain-specific basis for the other levels (Figure 1).

### **Operation and data type abstraction**

The focus of the second level was on mapping the underlying data in a more abstract description of operations, data types, and structure to form the input required for the visual encoding stage.

Different theoretical frameworks were explored to choose the most relevant framework for prioritizing and ordering data. The International Classification of Functioning, Disability and Health: Children and Youth version (ICF-CY) framework appeared to be the most appropriate to comprehensively and accurately describe individual health situations [22]. The classification systems ICD-11 (International Classification of Diseases, 11th revision) and DSM-5 (Diagnostic and Statistical Manual of Mental Disorders, version 5), commonly used in health care, were also considered. However, these frameworks do not fit preventive CHC because they are based on a biomedical model of health and focus on diseases and diagnosis and not on prevention [23,24]. The ICF-CY framework was chosen because it represents the broad BPS perspective on health and adequately fits the preventive CHC. The ICF-CY framework enables to display the broad variety of information on characteristics of a child and its environment, collected by CHC. Strengths and protective factors, inevitable for protection and promotion of health and prevention of diseases, are included in the ICF-CY framework. Next, symptoms, diseases, and determinants that challenge health can be presented. And, last but not least, information is formulated in concrete and neutral, if not positive, terms with little to no valuation. The ICF-CY structure was customized to integrate it into a profile that fits CHC practice and theoretical background.

During 2 review group meetings, the 360°CHILD-profile was presented and profile's content, terminology, and ordering were discussed with experienced CHC professionals. During the review meetings, field notes were taken and summarized and discussed to reach consensus.

For immediate validation, a static, adapted, early-on version of the 360°CHILD-profile was presented to parents and youth and semistructured interviews were performed to gain insight into user experience (comprehensibility and usability), requirements, and coverage of meaningful topics. Audio recordings of the interviews were transcribed, field notes were taken, and data were analyzed according to previous steps.

Findings were discussed in brainstorming sessions with the research team to verify coherence with scientific and practical purpose of the profile and generate developmental

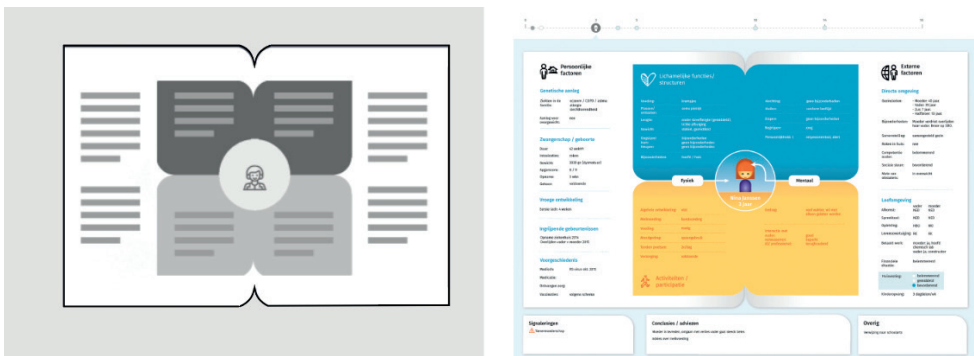
ideas. The resulting findings were not just limited to the data structure and detailed task definitions, but also included meaningful ordering of the information.

## Visual encoding and interaction design

The first 2 levels of design (Domain Problem Characterization and Operation and Data Type Abstraction) formed the primary input for the visual encoding and interaction design on a content level. The development of the formal level was based on 2 additional pillars: the consideration of international standards of human–computer interaction for information representation (ISO 9241-12) [25] as well as theoretical aspects of design based on prior research in this field [26,27] and the systematic integration of users within iterative validation and optimization cycles.

In early stages of the design process, prior findings were integrated into low-fidelity prototypes to conceptually visualize the relevant CHC data and test them with users.

A clear and accessible information structure appeared to be of vital importance to address requirements of the given scenario and a clear visual structure plays a major role in reducing the cognitive load and controlling the perceptual ordering [28]. Therefore, the design was developed based on a sectional grid system and information was structured into areas. The key areas were placed within the center (Figure 3.2, left) and to facilitate the understanding, key concepts were illustrated through icons in combination with text [29].



**Figure 3.2: Grid Layout on the left, prototype on the right**

The resulting sketch was operationalized into a digital prototype, suitable for informal, qualitative tests with relevant stakeholders (CHC professionals and parents). Participants performed tasks within representative scenarios (to prepare for or to reflect upon a CHC consultation) while considering the profile in all its bearings. Participants were asked to express their first impression on the profile, line out the profile's structure, seek and interpret specific information, and indicate comprehensibility of information. A researcher guided

and facilitated the participants during the sessions. To gain feedback on accessibility, comprehensibility, and usability of the 360°CHILD-profile for each user group, a “think aloud” procedure was conducted [30]. A second researcher observed the session and conducted interviews with the stakeholders. Audio recordings of the interviews were summarized, field notes were taken, and data were analyzed according to previous steps.

For this visualization in accordance with the ICF-CY framework, it is crucial that it stimulates viewers to take into account all domains and choose a routing from central (child) toward outside (environmental factors). Therefore, a gaze tracking evaluation was applied (Tobii X1 Light eye tracker 30 Hz) to gain indirect feedback on what parts of the profile the stakeholders looked at and in which order. Results were discussed in the research team meetings and eventually processed to deliver a digital application of the final version of the online accessible CHILD-profile.

### **Algorithm design**

The prototype was developed as a web application based on JavaScript and embedded within an HTML website to ensure an integration into real-life scenarios. Data parsing and mapping were realized through Data Driven Documents (D3) Version 4, while the interactions were implemented using jQuery, JavaScript, and CSS.

The technical implementation was immediately validated in 2 ways: the application was tested by analyzing computational complexity and content and optimized with Chrome DevTools (developer tools) as well as user tests with representative data samples.

### **Prototype and downstream validation**

Downstream validation at the level of algorithm design and visual encoding and interaction design was immediately tackled within the described levels: application test and user tests (see the “Algorithm Design” section) and informal qualitative tests (see the “Visual Encoding and Interaction Design” section).

Downstream validation of the delivered prototype at the level of operation and data type abstraction is beyond the scope of this article. For this dimension of validation, a field study is planned to evaluate CHILD-profile’s feasibility (usability and potential effectiveness) and feasibility of performing a randomized controlled trial (RCT) within the preventive CHC context [31]. This feasibility RCT aims at generating knowledge on how to build follow-up studies directed toward downstream validation at the level of domain problem and data characterization.

## Results

### Domain problem and data characterization

Within more age categories, a total of 3 role games were performed and all involved CHC professionals (nurses or medical doctors or both), parents, and in one case youth (age >12) were interviewed. For field validation, for 2 days, CHC consultation hours were observed in more age categories.

Observations and interviews showed that CHC nurses mainly perform regular, protocolled tasks, and CHC medical doctors mostly explore indicated concerns and problems more in depth. An example of schematic description of a professional within the CHC context (an integration of empathy map and persona) is provided in Addendum 3.1. One of the key challenges we could identify within this level was that the visual structure and interaction design of the current EMD did not sufficiently address the informational needs of the target group. During the interviews and observations, it became apparent that this leads to fundamental problems to fulfil several tasks in the given time due to an ineffective information and interaction structure. Both CHC nurses and medical doctors noted that data registration in the EMD is time-consuming and that they are hindered in quickly referring to registered data and gaining clear overview of health information. Discussion between researchers on visual artefacts revealed the lack of overview and theoretical ordering of data within the EMD. During consultations, CHC professionals pursue active participation of parents and youth but they indicated the need for visual support for communicating health information with parents. Parents indicated the importance of being able to decide for themselves and feeling free to make their own choices during the upbringing of their child. Related work regarding visual support on health communication and revealing parent's perspectives did not provide a holistic and structured display (in accordance with the ICF-CY framework) of the large and complex electronic CHC data sets [32].

Together with users we developed a description of formal requirements for the 360°CHILD-profile to be designed. The design of the 360°CHILD-profile should be:

- lively and user-friendly with neutral, serene, and warm (fear reducing) appearance to create a positive experience;
- targeted at supporting communication between CHC professionals and parents/youth and providing comprehensible and accurate overview of health determinants in child and its environment.

The pursued ordering effects were allocating the child in a central position, visualizing the coherence between the multiple features in child and context (in accordance with the ICF-CY framework), and making complex health information tangible. Technical requirements

for the application were suitability for desktop (for visual support during consultations) and online accessibility but it should also be printable as PDF (A4 format, to be used during house visits).

### **Operation and data type abstraction**

Content and data ordering for the 360°CHILD-profile were based on the ICF-CY framework, resulting in 4 domains: "Body structures and functions," "Activities and participation," "Environment," and "Personal factors." The specific content of each domain was customized to the specific Dutch CHC practice and is in accordance with CHC's professional framework and "toolbox" [33,34]. During 2 review group meetings, the CHC professionals (2 nurses and 2 medical doctors) indicated that the clear overview, ordering of data, and the use of colors were an improvement on accessibility in comparison to the currently used EMD. They proposed even more emphasis on neutral (nuanced) and positive formulations. Second, as not all items are equally relevant during the continuum from age 0 to 18, the review group prioritized specific content for the different age groups (0-15 months, 15 months to 4 years, 4-9 years, 9-12 years, and 12-18 years). Consensus was reached on expert agreement and adaptations were made on prioritization per age category and more positive terminology of data.

### **Visual encoding and interaction design**

The visualization was designed while taking into account the CHC context, user experiences of prototypes, user's desires, formal and technical requirements, and the indicated options for improvement of this data visualization.

The qualitative tests of prototypes (on average 30 minute sessions) showed that both target groups could handle the prototype well and performed most of the given tasks correctly (CHC professionals: 7 tasks of 9; parents: 6 tasks of 9). Most participants could link different domains in which health facilitators and barriers are described. Stakeholders feedback on the prototypes included mostly positive remarks such as "nice to build up information during lifetime", "nice that not only risks factors but also protective factors are included in the overview" and "good to see coherence between health determinants". However, some parents mentioned the following remarks: "it is a lot of data, in the beginning it is hard to know where to start", "it is important that formulations are clear". Participants indicated that in some CHILD-profiles they missed specific information about the child and that it is important to know where the data come from. As participants mentioned the importance of showing a timeline and a separate conclusion section to highlight critical information regarding the last consultation, these elements were incorporated in the final version of the CHILD-profile. Gaze-tracker output showed that all participants explored the profile by starting at the center (child icon/image) and clearly distinguished the middle planes from outer columns. Almost all domain titles were noticed except for "Activities & Participation"

and participating professionals often paid more attention to the “conclusion/advice” section than parents.

### **Algorithm design**

This algorithm design phase resulted in an application which automatically transfers CHC health data registered in the EMD. The application is built independently from the existing EMD and can be connected to any application programming interface that provides the related EMD data. The dashboard offers a “front end” summary to be linked to the EMD systems and online parent portal. The final version of the visualization design is tested and operational in the browsers used in the specific context (the CHC organizations uses Chrome and Firefox).

### **Prototype and downstream validation**

So far, the described procedure resulted in a comprehensible 360°CHILD-profile, usable on computer and mobile devices (laptop or tablet) and printable for home visits. This visualization of CHC data at a glance is validated on impact at the level of algorithm design and visual encoding and interaction design and is ready to be introduced to CHC practice. Field study with focus on downstream validation on the level of operation and data type abstraction is beyond the scope of this article. This field study will be separately presented in feasibility RCT’s protocol and result papers on this study which includes quantitative and qualitative research.

## **Discussion**

### **Overview**

This paper describes the stepwise development of a new dashboard, which combines visualization and theoretical ordering of health data based on the ICF-CY framework, to offer guidance on how to use the nested design model to achieve visualization of a comprehensive overview at a glance.

In this example, the practical implementation of the ICF-CY framework to summarize electronic health records is intended to display coherence between different health domains. The goal is to facilitate analytic thought processes during shared decision making toward preventive, individualized health plans directed at promoting health [26,32].

The 360°CHILD-profile is designed to optimally display a holistic overview of data from electronic health records in line with the ICF-CY framework and enables considering multiple perspectives on child’s development and health. Within the ongoing project, the dashboard itself was evaluated while taking into account several perspectives.



### **Strengths and limitations**

This project shows us which opportunities can arise from bringing together expertise/experience from the medical and information visualization/human–computer interaction field of knowledge. This collaboration, not yet common within health care, leads to synergy and optimal ground for realizing meaningful visualization of complex health information and sufficient adoption rate and essential performance in practice.

Additionally, the choice for a user-centered design approach, with active involvement of relevant stakeholders in every design level, increases the likelihood of usability within CHC practice and reaching the intended goals [17].

The currently experienced problems with EMD concerning accessibility of health data are avoided in this new information technology by considering international standards of human–computer interaction for information representation (ISO 9241-12 [25]) as well as theoretical aspects of design based on prior research in this field [26,27].

The nested design model is especially suitable for the context of data visualization within health care as it offers a holistic perspective on the design process [15]. For each level of design, evaluation during development (upstream validation) and after finishing the data-visualization design (downstream validation) is included. By integrating these design and evaluation methods, knowledge is generated on how to deliver a solid visualization with performance as intended as well as on how to measure actual effectiveness in practice and interpret the findings during implementation. However, it is important to note that the nested design model offers researchers a framework for structuring the design process on a rather abstract level. For each specific visualization, the choice for design and evaluation methods and the operationalization should be customized to the content and aim of the visualization and the context in which it will be implemented.

As we can only understand how people use a new tool when it exists, we could only partly tackle downstream validation within this project. Early versions of the dashboard and prototype are technically tested and qualitative tests are performed with rather limited study populations. To complete downstream validation process, studies with higher numbers of participants must be performed to reach sufficient power to evaluate if the innovation contributes to experienced needs in practice and leads to the intended health outcomes.

### **Opportunities and challenges**

By utilizing the ICF-CY as a framework for ordering health data, professionals are provided with an interactional structure for aggregating details of an individual's unique health reality across several dimensions. This structure makes it not only possible to comprehensibly

display the multidimensionality of health but also the coherence between different health domains. Therefore, we hypothesize that the use of this new dashboard in CHC practice can:

- support to identify strengths, challenges, needs, and goals and “entry points” for health management;
- automatically guide (mostly subconsciously) “thinking processes” toward a more predictive, personalized, and participative approach of health;
- improve health literacy and facilitate shared decision making.

The modern information technologies, used to deliver a functional profile, allow greater direct access to health information for parents and youth (during visits and at home via online portal). By providing parents/youth insight into health facilitators and barriers, we think they will be empowered to take a more proactive, leading role during decision-making processes and make preventive health plans fit their context.

To study usability, adoption rate, and performance (regarding the intended goals) in practice, a field study and other follow-up studies need to be performed with sufficient power. To complete the validation process, it is important to measure ordering effects, visual salience, and bias effects, considering variables such as educational background and others. It is, however, a challenge to perform effect studies with sufficient sample sizes within the multidisciplinary and heterogeneous context of the preventive CHC. Therefore, the first study to be performed will be a pragmatic feasibility RCT, in which both 360°CHILD-profile’s feasibility and RCT’s feasibility aims will be evaluated. The RCT protocol and results will be published in separate articles [31]. Results of this field study will offer underpinning of necessary requirements for successful follow-up effect studies with sufficient power.

After completion of downstream validation and effective implementation of this new tool in CHC, we anticipate that using the 360°CHILD-profile within CHC will stimulate toward more complete and uniform data registrations. This would lead to availability of standardized and theoretically structured health data (in accordance with the ICF-CY framework), which are more fit for epidemiological research and future possibilities like automatic transformation toward internationally standardized ICF codes.

## Conclusions

This work is an important step toward bridging the information asymmetry between electronic health data, physicians, and patients and clients in general.

We propose the nested design model as a method to structure the design process while considering validation cycles for each level of design, both immediately during the process

and impact-oriented validation after implementation, considering the effects of individual aspects on performance in practice.

We provide guidance on how to utilize the design model in a health context based on a concrete example and specific guidelines on how to address heterogeneous capabilities within preventive CHC through visual means and interaction design.

In our design study we developed a working prototype of a comprehensible 360°CHILD-profile on which CHC data are visualized at a glance. The application automatically converts CHC health data, already registered in the EMD, into a visualization which represents the continuum-based context of children's health and development.

## Addendum 3.1: an integration of empathy map and persona



**Education level:**  
Higher professional (nurse)  
**Personality:**  
- Social, concerned  
- Dutiful, executive

### Consultations

**Goal**

- Explore health situation
- If needed, refer to CHC-medical doctor or other caregivers

**Work activities**

- Mostly regular consultations
- Some consultations on indication
- 8 - 10 children during one morning
- 20 - 30 minutes per consultation

**Competencies**

- Ability to assess the health situation
- Neutral and open communication
- Give appropriate attention to parent and child

- 1) Preparation: study EMD
- 2) Start conversation: introduction
- 3) Talk over checklist conform EMD
- 4) Go over questionnaire
- 5) Measurement of length and weight etc.
- 6) Conclusion + decision making

### Gains

**Overall wishes and needs**

- A clear overview of results/conclusions
- To quickly gain an overall view on how the child is doing
- Checklist of topics of conversation
- Active involvement of parents

"If you mark a signal item, it will show in the start screen"

**Wishes and needs concerning the 360°CHILD-profile:**

- To provide a clear overview of health data collected
- To provide the right signals
- The possibility to show parents cohesion between health domains
- To add several data:

"If I find a signal item relevant enough to re-read, I must be able to quickly find it back in the EMD"

- "The pro-social factors, the reciprocity is often forgotten"
- "You cannot retrace the performed tests"
- "A conclusion from every item"

### Pains

**The EMD**

- The Electronic Medical Dossier the CHC-nurses currently work with, hinders their work activities/ tasks.

"If signal items are not marked, relevant data are hard to find"

"It costs time to retrace information about medical history, as previous registrations must be opened"

**Time pressure**

- The CHC-nurse is bound to the limited timeframe per consultation.

"But I also have to type all registrations in the EMD"



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**CHAPTER 4**



# Evaluation of a New Personalized Health Dashboard in Preventive Child Health Care: Protocol for a Mixed Methods Feasibility Randomized Controlled Trial

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## Abstract

**Background.** A new dashboard, the 360°CHILD-profile, was developed to adopt personalized health care within preventive child health care. On this profile, holistic health data are visualized in a single image to provide parents, adolescents, and caregivers direct access to a manageable résumé of a child's medical record. Theoretical ordering, conforming to "International Classification of Functioning, Disability and Health for Children and Youth", guides clinical reasoning toward the biopsychosocial concept of health. It is yet unknown if and how this promising tool functions in practice, and a variety of feasibility questions must be addressed.

**Objective.** This paper describes the design and methods of a feasibility randomized controlled trial (RCT), with the aim of evaluating the RCT's feasibility (recruitment, response, measure completion, and intervention allocation) and 360°CHILD-profile's feasibility (usability and potential effectiveness).

**Methods.** A pragmatic mixed methods study design was chosen, starting with an RCT to measure feasibility and health literacy in 2 parallel groups (1:1). Qualitative research will then be used to understand and explain quantitative findings and to explore the stakeholders' perspectives on the potential of the 360°CHILD-profile. Participants will include child health care professionals ( $n \geq 30$ ), parents ( $n \geq 30$ ), and caregivers ( $n \geq 10$ ) of children who experience developmental problems (age 0-16 years). Children will only be able to participate if they are older than 11 years (adolescents,  $n \geq 10$ ). The 2 groups included in the study will receive standard care. The experimental group will additionally receive personalized 360°CHILD-profiles.

**Results.** After an intervention period of 6 months, quantitative outcomes will be measured, analyzed (descriptive feasibility statistics and preliminary between-group differences) and used to purposively sample for semi-structured interviews.

**Conclusions.** Study results will provide knowledge for building theory on the 360°CHILD-profile and designing future (effect) studies.

## Introduction

To more effectively address the increasing burden of preventable chronic diseases, it is a prerequisite for current reactive health care (treatment after a diagnosis) to make the transition to personalized health care (PHC) [1]. According to Snyderman [2], PHC stands for a lifetime, holistic approach of proactively offering predictive, preventive, personalized, and participatory care. The different PHC concepts can and must be introduced in practice as soon as possible, but it appears to be a challenging task to effectuate such a new approach within health care [2,3].

Dutch preventive child health care (CHC), as part of public health, offers a unique platform to adopt PHC in the short term. CHC proactively monitors children's development and health to detect early deviance from normal variance and diseases or symptoms, which cannot yet be clustered to a diagnosis. To fully apply PHC within the preventive CHC approach, a shift is needed toward prediction and prevention in the very early stages of disease progression when symptoms may not even be present [4,5]. To perform early detection and act upon disease progression is not an easy task because health processes are complex. The biopsychosocial model of health shows that health is a result of lifelong, multidimensional interactions between many biological–genetic characteristics and environmental factors. Therefore, to predict and protect health, insight into a broad set of health determinants is required. Critical to implementation of PHC is thus the availability and accessibility of high quality, relevant lifetime health data.

From birth on, CHC collects health data about the child and environment, which are stored in an electronic medical dossier (EMD). However, accessibility of data is profoundly hindered due to the actual structure of EMDs, and thus support for the complex clinical reasoning process is insufficient [6,7]. It is not possible to generate an adequate overview of registered data in coherence with the relevant theoretical concepts (ie, the biopsychosocial model) [8]. As a result, much of the CHC-data that are highly relevant to understanding the complex processes underlying health are not available within the timeframe of CHC visits or other consultations with caregivers and parents.

To address this problem, a 360°CHILD-profile (Figure 4.1), which visualizes health information about the child and environment in a single digital image, has been originally developed and examined within daily practice of the Dutch CHC system [9].

Relevant CHC data, visualized on the 360°CHILD-profile, are theoretically ordered according to the "International Classification of Functioning, Disability and Health for Children and Youth" (ICF-CY) [10]. The ICF-CY fits the CHC context and PHC concepts, as it is built on the integrated biopsychosocial approach of health and describes a broad variety of

individual characteristics and environmental factors in concrete, neutral (if not positive) formulations [10]. The 360°CHILD-profile was developed as a dashboard that provides a quick, systemic, and comprehensible representation of a child’s individually unique set of health determinants (protective and risk factors).

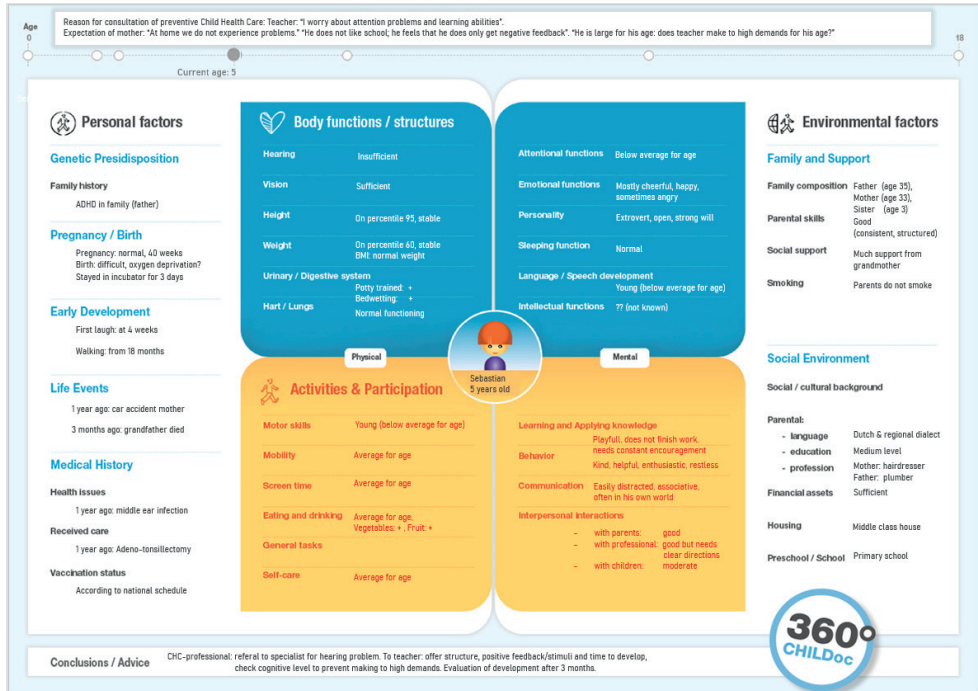


Figure 4.1: The 360°CHILD-profile

The goal of the 360°CHILD-profile is to provide direct access to a manageable résumé of holistic health information stored in the EMD to CHC professionals, parents, and adolescents, and to naturally guide thought processes in coherence with the chosen theoretical perspective (PHC). This dashboard supports health literacy in a way that can empower parents and adolescents to co-create personalized plans for managing their (children’s) health, in partnership with caregivers [11,12].

From the very start of the 360°CHILD-profile’s development and research project (2012), parents, adolescents, and CHC professionals have been actively involved. Formal ideas for designing the profile’s first drafts were generated, and pilot studies showed positive reactions of stakeholders for the comprehensibility, relevance, and acceptability of the design [9]. Promising results were generated in another study related to the 360°CHILD-profile’s reliability and validity when used by CHC medical doctors to assess child functioning [13]. In 2018, data visualization designers and researchers used their expertise and gained

input from stakeholders on CHC context, usability, and user experience to redesign the 360°CHILD-profile [9].

The current state of this newly developed 360°CHILD-profile offers a promising, online dashboard that is ready to be introduced into CHC practice. If and how it will actually function within daily practice is yet unknown, and it is foreseen that the evaluation of effectiveness in the multidisciplinary and preventive CHC context will be complex. Therefore, a pragmatic feasibility RCT will be performed to refine our practice-derived theory on the 360°CHILD-profile's feasibility and potential effectiveness and to build a rationale for designing future (effect) studies (including outcome measures and sample size calculations) [14,15]. The aim of this paper is to describe the design and methods of this study that will be performed within CHC.

## Methods

### Study design

For this pragmatic feasibility RCT, a sequential mixed methods design was chosen. First, quantitative research will be performed. Within the limitations of a feasibility study [16], an RCT will be executed with 2 parallel groups (experimental and control). Qualitative research will then be performed to understand and explain the quantitative findings and to explore the 360°CHILD-profile's potential benefit in CHC practice [17-19]. The study objectives will be to evaluate 2 types of feasibility: that of the 360°CHILD-profile and that of the RCT.

- The 360°CHILD-profile feasibility evaluation will include the following: usability, including the frequency and profundity of 360°CHILD-profile use during contacts between CHC professionals, parents, adolescents, and other caregivers; and the perspective of parents, adolescents, CHC professionals, and other caregivers on quantitative findings, requirements for the 360°CHILD-profile's use within CHC, and potential benefit and effectiveness.
- The RCT feasibility evaluation will include the following: recruitment, retention, and response rates; acceptance of and compliance to allocated interventions; measurement completion and protocol deviations; health literacy measurement, including the variance of parent's satisfaction on health literacy in the total and in each separate group, and a preliminary estimation of the between-group differences; the perspective of parents, adolescents, and CHC professionals on hindering and promoting factors for recruitment, retention, and response rates, acceptance and compliance to allocated intervention, measurement completion, and preliminary differences on health literacy.

### **Study population and sample size**

The study population will mainly consist of parents and CHC professionals (nurses and medical doctors) who are involved in the care of the parent's child (age 0-16 years) experiencing emerging problems. Adolescents (age >11 years) and other involved caregivers can also be included as participants, but children under the age of 12 years will not themselves participate. If parents or adolescents cannot comprehend the written health information (due to a language barrier or other reasons), they will not be included in this study.

For the quantitative phase, we aim to recruit 30 parents, 30 CHC professionals, 10 adolescents, and 10 other caregivers. For feasibility studies, in which outcome parameters like recruitment, response rates, and variance in the outcomes of questionnaires (SD) are measured, a sample size of 60-70 participants is justified [16,20,21]. For qualitative research with purposive sampling, it is estimated that saturation will be reached after including 20-30 participants (7-10 participants per target population; ie, parents and CHC professionals) [19,22].

### **Procedure**

All nurses and medical doctors working for CHC organizations in the Dutch region of South Limburg will be asked to participate. After providing informed consent, volunteers will attend a 2-hour long instructional workshop to receive information about the 360°CHILD-profile, study procedures (inclusion and randomization), and outcome measures.

Participating CHC professionals will identify and approach eligible parents during CHC visits and eligible caregivers at the moment they become involved in the care of the parent's children. If parents or caregivers are interested and give permission to be contacted by the researcher, researchers will start the information and informed consent procedures and enroll participants in the study after given permission.

At the end of the quantitative phase, quantitative findings will be used for purposive sampling for qualitative research to obtain a variety of perspectives from parents and caregivers and to reach a broad interpretation of the quantitative findings [19,22]. From each group within the study population (parents, adolescents, CHC professionals, and involved caregivers), 2 participants will be invited for each round of interviews. After analysis of the conducted interviews, both quantitative and qualitative findings will be used to select participants for the next round to enrich characteristics and opinions.

### **Randomization and concealed allocation**

After parents sign informed consent, they will be allocated to 1 of 2 parallel groups in a 1:1 ratio (experimental or control group) according to centralized randomization (by an

independent administrator based on a protocol). The randomization plan with central block randomization (blocks of 4 and 6) will be generated beforehand by CB (not involved in the enrolment and intervention) using an online randomization system. Each phase (enrolment, randomization, quantitative outcome measurement, and analysis) will be performed independently from the others (concealed allocation), and researchers will be blinded to randomization and allocation. Parents and professionals will be, as much as possible, kept unaware of the detailed study aims related to the allocation.

### Experimental and control intervention

For a period of 6 months, children of the participating parents in both groups will receive usual care. Additionally, for 50% of the children (the experimental group), CHC information from the EMD will be electronically transferred to a personalized 360°CHILD-profile. Directly after baseline measurement, the profile will be available in the EMD for CHC professionals to discuss with the parents or adolescents during the visit. After this visit, the profile also will be made accessible online for the parents or adolescents. During the 6-month follow-up

period, participants will be able to consult the profile and use it to contact the caregivers whenever they want. The individual child’s health data, as presented on the profile, will not be collected and used as scientific data in the study. After the last study measurements are completed, a personalized 360°CHILD-profile will also be generated for parents or adolescents in the control group (outside the context of the study). A flowchart of the RCT’s study protocol is provided in Figure 4.2.

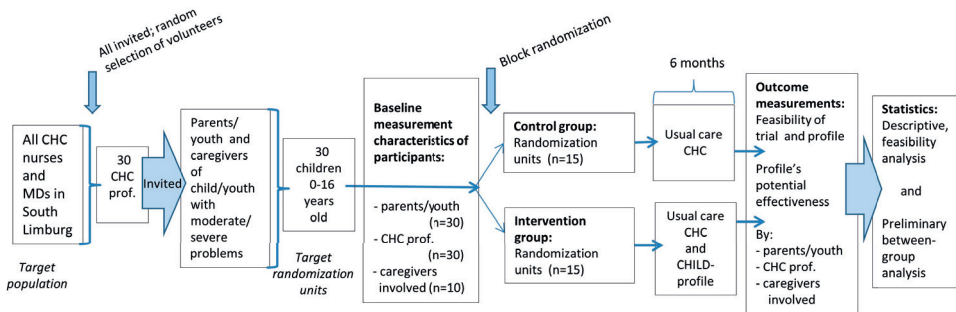


Figure 4.2 The flow chart

### Measures and measurements

Questionnaires will be used to obtain baseline measurements of the following characteristics: for participating adolescents and children, information on age, gender, and level of functioning and experienced problems as indicated by CHC professionals will be measured; for parents, information on age, gender, country of birth, educational level,



perspective on their child's health and development, parenting situation, and number and age of children will be collected; for CHC professionals and other caregivers, information on discipline, educational level, experience, and perspective on the use of information technologies in health care will be collected. An overview of the baseline measures regarding population characteristics are presented in Table 4.1.

**Table 4.1: Baseline measures for population characteristics.**

Measures	Measuring	Age group	Answer options	Reference
STEP <sup>a</sup>	Standardized professional's rating of child's functioning, experienced problems, quality of environment and needed care	0 to 16	5-point scale	[23]
CGAS <sup>b</sup>	Professional's rating of child's functioning	0 to 16	continuous scale	[13, 24]
PEDS <sup>c</sup>	Parent's questions and concerns about child's development	0 to 6	3-point scale and open ended	[25]
SDQ <sup>d</sup>	Parent's and youth's perspective on psychological attributes	3 to 16	3-point scale	[26, 27]
NOSIK <sup>e</sup>	Parenting Stress Index, Dutch short version, parent's perspective	2 to 13	6-point scale	[28]

<sup>a</sup>: "Standaard Taxatie Ernst Problematiek" (only available in Dutch);

<sup>b</sup>: Children's Global Assessment Scale;

<sup>c</sup>: Parents' Evaluation of Developmental Status;

<sup>d</sup>: Strengths and Difficulties Questionnaire;

<sup>e</sup>: "Nijmeegse Ouderlijke Stress Index, Korte versie"

Measurements will be conducted 6 months after baseline to measure the qualitative and quantitative outcomes of the 360°CHILD-profile's and RCT's feasibility.

### The 360°CHILD-profile's Feasibility

The evaluation of the 360°CHILD-profile's feasibility is described in this section. Quantitative outcomes on feasibility will include the following: frequency of use of the 360°CHILD-profile by CHC professionals during contacts with parents or adolescents, as registered by CHC professionals; the profundity in which the 360°CHILD-profiles are used during CHC visits, as indicated by CHC professionals on a questionnaire (using questions with answer options on a categorical scale).

Qualitative outcome (semi-structured interviews with parents, adolescents, CHC professionals, and other caregivers) will be collected for the follow purposes: to contextualize and further inform the understanding of quantitative findings on 360°CHILD-profile's

usability; and to explore the expectations of parents, adolescents, CHC professionals, and other caregivers regarding the 360°CHILD-profile's potential benefits in CHC practice.

## **RCT feasibility**

Evaluation of the RCT feasibility will occur in both group and is described in this section.

The quantitative measurements will include the following: recruitment rate (the percentages of volunteers versus invited and eligible participants); retention rate (the percentage of participants completing the study versus the participants that started); response rates (the percentages of participants per discipline who filled in and validated the questionnaire versus the number of participants who were requested); compliance to allocated intervention (the percentage of CHC professionals in the experimental group who used the 360°CHILD-profile during a CHC visit); measure completion (the percentages of completed measures versus incomplete measures and description of missing data); protocol deviations (the description of problems encountered and eventual adaptations to the protocol for properly addressing these problems); health literacy.

Health literacy will be evaluated using the validated Dutch version of the Consumer Quality Index (CQI). The CQI is based on the Consumer Assessment of Healthcare Providers and Systems (CAHPS) and is applicable for parents of children aged 0-18 year who visit CHC [29]. The validated CQI includes questions about accessibility, ability to understand, completeness and applicability of received care, and health information and advice, with answer options on a 2-, 3-, or 4-point scale (subscale reliability: Cronbach  $\alpha$  = .75-.82) [30]. Additionally, relevant questions from "Supplemental Items for the CAHPS on Health Information Technology" were translated from English to Dutch and incorporated into the CQI questionnaire [31]. The research team developed additional questions to ensure measurement of all dimensions of the construct's "access to healthcare and health information" [32]. The dimensions we indicated as relevant for the CHC context and this study are availability, accommodation, accessibility, and acceptability. Affordability is not relevant in this context because CHC care is offered for free to all children and parents. This set of additional questions (n=6) with answers options on a 5-point scale will be used for the first time, and no information on the diagnostic parameters is available yet.

The qualitative measurements for RCT feasibility will include semi-structured interviews with parents, adolescents, CHC professionals, and other caregivers, and will be performed for the following purposes: to contextualize and further inform the quantitative findings on recruitment, retention and response rates, compliance to allocated intervention, measurement completion, and health literacy; to explore CHC professionals' experiences during recruitment of parents and adolescents, and participants' satisfaction regarding

their study participation and allocated intervention and perspective on requirements for a future randomized trial.

All semi-structured interviews will be in person and audio-recorded. Recordings will be transcribed, and the collected data will be coded (participants will be allocated a participant number code to relate data to this code). Records will be stored in a locked place on the server separate from the other study data. Only the investigator collecting the data will have access to this documentation.

## **Statistical analysis**

Baseline characteristics of all participants will be presented using descriptive statistics (mean, SD, or frequencies and range) in a table. Data of parents, adolescents, and children will be presented for the total group and for both randomized groups separately.

### **Quantitative outcome data**

Descriptive analysis will be performed to present outcomes on the 360°CHILD-profile's and RCT's feasibility (usability). The descriptive analysis of the 360°CHILD-profile will include the following: the frequency in which the 360°CHILD-profile is used, for which the mean and variability will be calculated; and the profundity of use of the 360°CHILD-profile during a CHC visit, which will be presented as proportions per category.

The descriptive analysis for RCT feasibility will include the following: recruitment, retention, and response rates, compliance to allocated intervention, measurement completion, and missing data, which will be presented as logistic data and proportions; protocol deviations, which will be described using text; outcome on health literacy, including descriptions for the total sample and for each group, with continuous measures (presented as mean, SD, and CI) and categorical measures (presented as proportions).

Statistical between-group analysis will be performed to preliminarily calculate (estimates of) differences between groups (and 95% CIs), using linear mixed models. Potential confounders (for example health status, age, and education) will be evaluated and, if necessary, adjusted.

### **Qualitative outcome data**

Analysis of each transcript will be performed by 2 independent researchers. Discrepancies will be discussed by the research team and consensus will be reached concerning codes based on expert agreement. The analysis process will include thematic analysis with open coding at the start followed by axial coding. In each phase of the analysis process, data will

be reviewed using constant comparative methods. The units that will be used to describe themes and concepts can be words, sentences, or stories. Cycles of data collection and analysis will be repeated until data saturation is reached according to our research goals.

### **Connection Between Quantitative and Qualitative Results**

After quantitative results are described and interpreted, they will be used to refine or adjust research questions, purposeful sampling procedures, and data collection protocols of the qualitative phase. During qualitative analysis, data will be interpreted and described separately and in coherence with quantitative results to realize the advantages of mixing both research methods, which include complementarity, triangulation, and explanation of results.

We will discuss if and how the qualitative results further the understanding or explanation of the quantitative findings and how to formulate overall conclusions and recommendations regarding theory on the 360°CHILD-profile and the rationale for designing future (effect) studies within CHC.

## **Results**

The intended timeline for achieving the targeted results includes the acceptance for funding (December 2016), approval by The Medical Ethics Committee of the Maastricht University Medical Centre (no. METC azM/UM 2017-0089; July 2017), registration in the Netherlands National Register (6909; January 2018), enrolment of participants (May 2018 to September 2019), quantitative outcome data collection (March 2019 to September 2020), and qualitative data collection (October 2019 to February 2021). The results of the presented study will be available before the end of 2021.

## **Discussion**

This pragmatic quantitative–qualitative study will comprehensively evaluate the feasibility of the newly developed 360°CHILD-profile and the feasibility of conducting an RCT within the preventive setting of the CHC.

This practice-derived dashboard is new in providing a holistic and structured display (in accordance with the ICF-CY framework) of the large and complex electronic CHC data sets [13]. Earlier pilot studies, application tests, and qualitative user tests have already shown promising results for the relevance, comprehensibility, acceptability, reliability, and validity of the 360°CHILD-profile [9,13]. However, these pilots and validation tests

were all performed during sessions guided by researchers in order to optimize technical and visual aspects and to increase the likelihood of usability and effectiveness. Thus, this feasibility study will generate first results on usability of this promising tool within the real-life CHC practice. This study will also generate indispensable knowledge on how to test the efficacy of this practice-derived innovation in the CHC context and is a necessary and sound intermediate step in the overall multiyear mixed methods research project [15,16].

From a pragmatic viewpoint, we searched for design options that fit current research questions and CHC context. A mixed methods design with a sequential explanatory (quantitative–qualitative) setup was chosen to enable testing our a priori, practice-based hypotheses and to give voice to parents, adolescents, and caregivers to refine theory. The pragmatic approach of the feasibility RCT enables the execution of a randomized trial within the preventive and multidisciplinary field of work and generation of results that fit this context [17]. The investment of time by CHC professionals is limited as much as possible; only a short training period is needed, each professional will need to recruit only 1-2 parent(s), and professionals are left close to daily practice during the “intervention” period (care as usual). Furthermore, CHC professionals in the experimental group do not have to drastically change their working method; they will present the personalized profile to parents and adolescents, but after that, all participants are free in choosing how (often) to use it. The between-group difference might seem rather subtle, but we expect it will have substantial impact. Our hypothesis is that the availability of the dashboard will automatically lead to efficiency (there is less wasting of time to search for data in the EMD and better quality of health literacy and early prevention of disease progression). Moreover, we expect that the theoretical structure of the profile will intuitively guide clinical reasoning in line with the context of CHC and PHC.

Information bias will be reduced by the centralized randomization, blinding of researchers for randomization, and keeping participants unaware of the detailed study aims.

Children and their parents have been chosen as the level of randomization (and not CHC professionals) to avoid bias due to differences in professionals’ working methods, characteristics, and level of experience. Contamination is avoided by virtue of the fact that, for CHC professionals in the control group, it is not possible to obtain an overview of the holistic health data from the EMD, as it is simply not available.

From the original study population, a heterogeneous population of participants will be selected for semi-structured interviews to provide an in-depth insight into a broad spectrum of perspectives [33]. Interpretation of quantitative and qualitative data will be in coherence with each other, which strengthens the study’s internal validity and deepens our understanding of the findings.

This pragmatic study will ensure adequate evaluation of the currently relevant feasibility questions, and the findings will direct our decisions concerning the 360°CHILD-profile's implementation in Dutch CHC practice and the design of future (effect) studies. The eventual goal of this research project is to bridge the gap between the technical design of EMDs and clinical practice to enable EMDs to efficiently support CHC in its preventive tasks and give parents access to the EMD summaries. Therefore, CHC and parents can monitor health, detect deviation of normal variance and disease progression as early as possible, and co-create preventive strategies to protect and promote children's health—health plans that will fit each individually unique child.

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**CHAPTER 5**

**5**

# A digital dashboard for visual representation of child health information: results of a Mixed Methods study on usability and feasibility of a new CHILD-profile.

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## **Abstract**

**Background.** A digital 360°CHILD-profile, developed within Dutch preventive Child Health Care, visualizes and theoretically orders relevant health information in line with the International Classification of Functioning, Disability and Health. This comprehensible dashboard is designed to make electronic health data accessible and facilitate transformation towards Personalized Health Care.

**Methods.** In a pragmatic Mixed Methods study, 360°CHILD-profile's usability and feasibility was evaluated. The level of use was measured quantitatively, as well as determinants for implementation at the level of the CHILD-profile itself, its users and the organizational context. Qualitative methods were used to gain understanding of quantitative findings and explore CHILD-profile's potential benefits.

**Results.** Participating professionals (n=17) discussed personalized 360°CHILD-profiles with parents (n=27). Twelve interviews (parents and professionals) and two focus groups were performed. After integrating quantitative and qualitative data, the overall theme "readiness for implementation" emerged. Participants reacted enthusiastically about discussing the CHILD-profile and appreciated the quick overview on holistic health information. Hindering organizational issues were mentioned, including the non-structured electronic medical dossier.

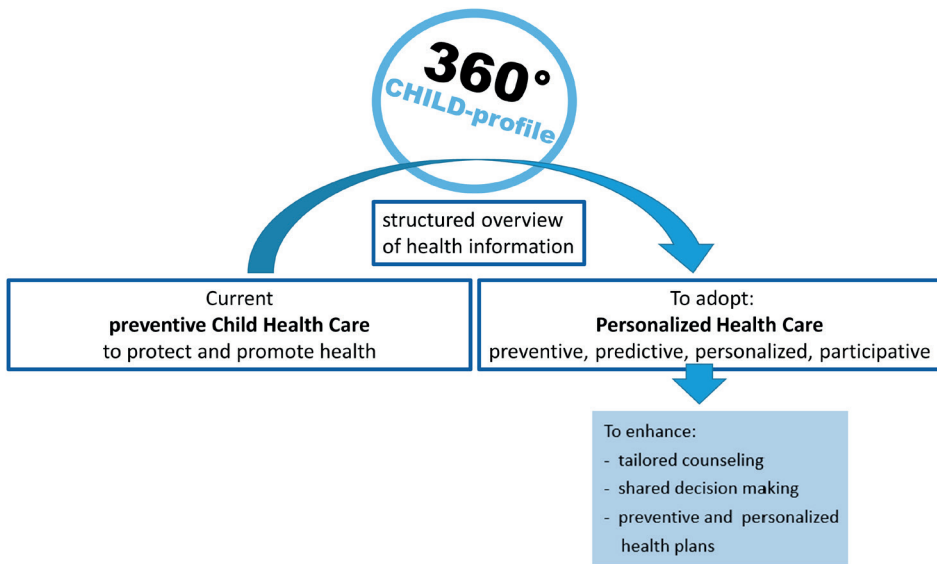
**Conclusions.** This study demonstrated the 360°CHILD-profile to be useful and efficient for CHC-practice. Users seem competent in handling and using the CHILD-profile within the CHC-context. Knowledge on how to get ready for implementation was generated.

## Introduction

The Dutch preventive Child Health Care (CHC) pro-actively monitors children's health from birth until the age of 18. Since CHC focuses on protecting and promoting children's health, it offers a suitable platform for adopting Personalized Health Care (PHC) (Doove et al., 2013; Syurina, 2014). PHC is said to be indispensable for addressing increasing burden and costs of chronic diseases (Snyderman and Yoediono, 2008; Snyderman, 2012). PHC includes personalized prevention, prediction and active participation of care-receivers (Pokorska-Bocci et al., 2014). An essential condition for fully integrating these PHC-concepts is access to high-quality information on children's health. Although CHC collects and registers longitudinal, holistic health data in an electronic medical dossier (EMD), access to representable data is currently hindered, due to EMD's non-theoretical structure and lack of overview (ISO 9241-125, 2017; Petterson, 2014; Greenhalg et al., 2009; Fragidis and Chatzoglou, 2017; Meuwissen, 2013).

Therefore, a 360°CHILD-profile was developed to visualize relevant health information retrieved from the EMD, in one image. This dashboard theoretically orders data in line with the International Classification of Functioning, Disability and Health, Children and Youth version (ICF-CY) to display the biopsychosocial concept of health in a cohesion of different health domains (body structures/functions, activities, participation, environmental and personal factors) (WorldHealthOrganization, 2007). This dashboard is designed to offer a comprehensible overview on complex, multidimensional health data (Weijers et al., 2021a) and provides professionals and parents with direct access to a manageable résumé of a child's medical record. The 360°CHILD-profile aims to facilitate clinical reasoning processes, tailored counselling and shared decision making toward preventive, personalized health plans (see Figure 5.1).

During the iterative design process, international standards for representing health information were applied. Professionals and parents were actively involved to increase usability and likelihood of reaching 360°CHILD-profile's goals (Weijers et al., 2021a; ISO 9241-125, 2017). A pilot study showed positive results on 360°CHILD-profile's validity and reliability (Weijers et al., 2018). Next, several tests revealed the 360°CHILD-profile was comprehensible for communication between professionals and parents (Weijers et al., 2021a). It was not known yet whether the 360°CHILD-profile might be useful within real life CHC-practice, nor whether implementation and evaluation of its effectiveness would be feasible.



**Figure 5.1: Overview of the role of the 360°CHILD-profile within the CHC**

Therefore, while introducing this 360°CHILD-profile within practice, a pragmatic Mixed Methods feasibility research project (Creswell, 2018; Feilzer, 2010) was carried out, comprising of two studies. The first study entailed an evaluation of 360°CHILD-profile's usability and feasibility. The second study concerned a parallel evaluation of executing a randomized trial within this setting, of which the results will be reported in a separate paper. The protocol of the entire research project is described in detail elsewhere (Weijers et al., 2021b).

The present paper presents the evaluation of 360°CHILD-profile's usability and feasibility in which usability was defined as "usable for presenting children's health situations" and "users expect it to be useful". Feasibility was defined as "potential attainability for implementation within CHC" (Rothstein et al., 2016).

This study was performed in line with the theoretical framework of Fleuren et al. (2014a), which focuses on how to systematically introduce and evaluate an innovation in a preventive health care setting. It also brings to surface the broad variety of determinants that potentially influence the implementation process. These determinants relate to the level of the 360°CHILD-profile itself, its users, and the organizational and socio-political context.

The following research questions were formulated:

1. What is the attainability of implementing the 360°CHILD-profile, regarded as its level of use and related key determinants?
2. How do parents and professionals experience the use of the 360°CHILD-profile and what are their perspectives on its usefulness and implementation within CHC?
3. What is the view of policy-makers on the 360°CHILD-profile's usefulness and future implementation within CHC?

## Methods

### Study design

This study comprises two parts with equal priority: a quantitative part, with a structured questionnaire in line with Fleuren's framework (research question 1), followed by a qualitative part, with semi-structured interviews and focus group meetings (research questions 2 and 3) (Creswell, 2018; Feilzer, 2010; Weijers et al., 2021b; Arain et al., 2010).

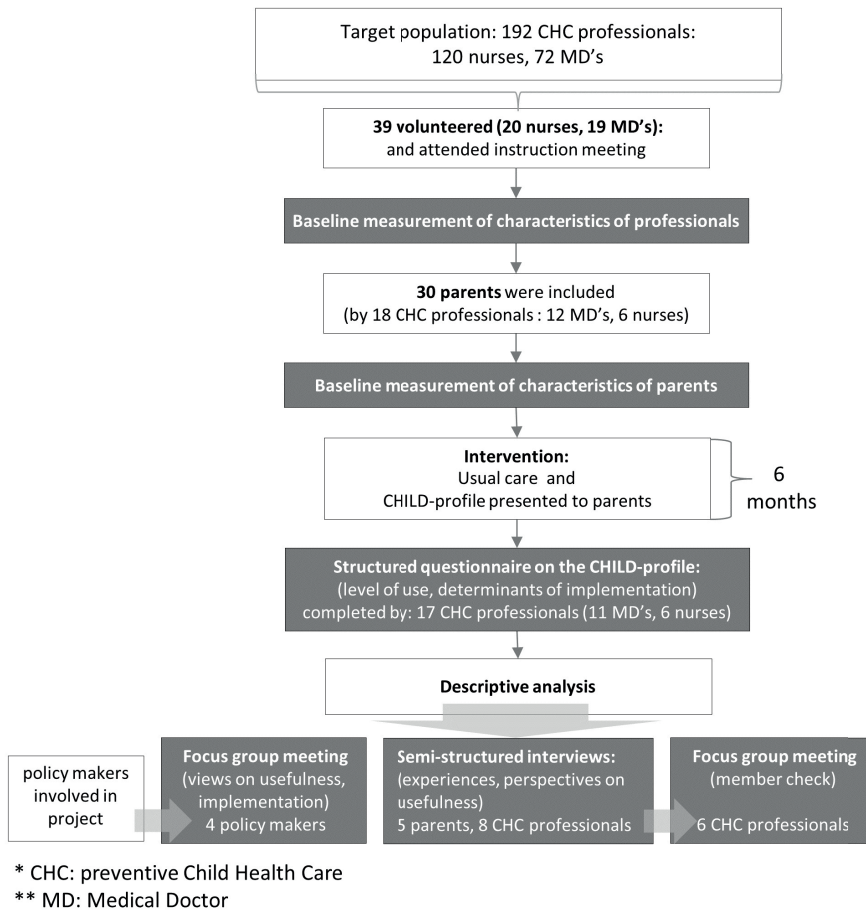
Quantitative and qualitative data were integrated by utilizing quantitative data to select participants for the interviews, refine topic lists and by comparing overarching themes for both types of data-sources.

### Study population and recruitment

All nurses (n=120) and medical doctors (n=72) from the CHC-departments in the South of the Netherlands were invited to participate. Volunteering professionals attended an instruction meeting and were expected to recruit one or two parents who visited their consultation hours. The only exclusion criterion for parents was a substantial language barrier that would hinder profile's readability.

For the interviews, a sub-sample of all included CHC-professionals and parents was purposefully selected to obtain a heterogeneous subgroup (Moser and Korstjens, 2018) with contrasting characteristics (parental stress, educational level, native country, their child's age and functioning and professionals' discipline and experience) and contrasting quantitative outcomes (parent's opinion on CHC, professional's satisfaction regarding the EMD). Policymakers (CHC-managers and representatives of local municipalities and the national CHC's knowledge center) were invited for a separate focus group meeting. In the final phase, all interviewed CHC-professionals were invited for a member check focus group meeting. All participants gave written informed consent. Figure 5.2 displays recruitment and flow of all participants.





**Figure 5.2: Flow of participants through the study.**

### Intervention period

The CHC-professionals provided care as usual and presented and discussed a personalized 360°CHILD-profile with all parents during a CHC-consultation. Randomly (Weijers et al., 2021b), for half of the parents, a personalized 360°CHILD-profile was offered shortly after recruitment and baseline measurement. For them the 360°CHILD-profile remained available during the six-month intervention period via an online portal (for parents) and the EMD (for CHC-professionals). The other half of the parents received a personalized 360°CHILD-profile during a CHC-consultation at the end of the study, after completing RCT's intervention period and follow-up measurements of the parallel executed study (Weijers et al., 2021b).

## Measurements

### *Measurement of characteristics at baseline:*

Baseline measurements assessed characteristics of professionals, parents and children for whom parents participated (see table 5.1 and 5.2). The protocol article describes the baseline measurements in more detail (Weijers et al., 2021b).

**Table 5.1: Baseline characteristics of participants.**

<b>Characteristics CHC*-professionals</b>		<b>Total group of CHC-professionals (n=38) Number (%)</b>		<b>CHC-professionals who successfully included parents (n=18) Number (%)</b>	
<b>Discipline:</b>	nurse	20	(53)	6	(33)
	medical doctor	18	(47)	12	(67)
<b>Target group:</b>	children age 0-4y.	18	(47)	10	(56)
	children age 4-18y.	20	(53)	8	(44)
<b>Educational level:</b>	no specific CHC-education	18	(47)	6	(33)
	introduction course	4	(11)	3	(17)
	CHC	16	(42)	9	(50)
	specialist CHC				
<b>Experience within CHC*:</b>	< 5 years	10	(26)	4	(22)
	5-10 years	0		0	
	> 10 years	28	(74)	14	(78)
<b>Satisfaction with current EMD</b>	satisfied	3	( 8)	0	
	rather satisfied	25	(66)	13	(72)
	rather unsatisfied	9	(24)	5	(28)
	unsatisfied	1	( 3)	0	
<b>Known with 360°CHILD-profile</b>	very known	4	(11)	2	(11)
	rather known	26	(68)	13	(72)
	little known	7	(18)	2	(11)
	not known	1	( 3)	1	( 6)
<b>Experience with 360°CHILD-profile</b>	much	0		0	
	rather much	3	( 8)	1	( 6)
	little	11	(29)	9	(50)
	no experience	24	(63)	8	(44)
<b>Opinion about possibility to use 360°CHILD-profile</b>	positive	23	(61)	12	(67)
	rather positive	14	(37)	6	(33)
	rather negative	1	( 3)	0	
	negative	0		0	
<b>Number of parents recruited/included:</b>		<b>Recruited</b>		<b>Included</b>	
	one	13	(34)	11	(61)
	two-three	8	(21)	5	(28)
	> four	3	( 8)	2	(11)

Table 5.2: Characteristics of parents and CHC professionals, who participated in the semi-structured interview.

Parents		Child's age group	Child functioning (STEP <sup>a</sup> ) 6-30 (high-low)	Parental stress (NOSIK <sup>b</sup> )	Educational Level	Birth country	Score for CHC 0-10
1	4-18	11	< average	intermediate	non-Dutch	8	
2	0-4	21	< average	high	Dutch	10	
3	0-4	19	> average	intermediate	Dutch	8	
4	0-4	6	average	high	Dutch	8	
5	4-18	-	-	intermediate	Dutch	-	
Professionals		Target age group	Discipline	Experience in CHC	Satisfaction with EMD		
1	0-4	medical doctor	>15y	rather satisfied			
2*	4-18	nurse	0-5y	rather unsatisfied			
3*	0-4	nurse	>15y	rather satisfied			
4*	4-18	medical doctor	>15	satisfied			
5*	4-18	medical doctor	0-5 y	rather satisfied			
6*	0-4	medical doctor	>15y	satisfied			
7*	0-4	nurse	5-10y	-			
8	4-18	medical doctor	>15 y	satisfied			

**Quantitative measurements:**

To address research question 1, professionals who included at least one parent and thus experienced working with a 360°CHILD-profile, received a questionnaire based on the Measurement Instrument for Determinants of Innovations (MIDI) after the intervention phase (Fleuren et al., 2014b).

To measure 360°CHILD-profile's level of use, the MIDI-questionnaire included questions on if (yes/no) and how profoundly (4-point scale) CHC-professionals discussed the personalized 360°CHILD-profiles with parents and/or spontaneously used it for other CHC-tasks (preparing visits, assessing child functioning, exploring parent's perspective, collaborating with colleagues/other caregivers). Additionally, professionals indicated their opinion (on a 5-point scale) on determinants that may affect the level of use (and thus implementation) at the level of the innovation (procedural clarity, completeness, relevance, correctness, compatibility with CHC), the users (self-efficacy, personal benefits (i.e. quick overview, added value for communication, clinical reasoning and empowering parents), personal drawbacks (i.e. cost of time)); the organization (formal ratification and facilitation (i.e. time, staff and level of turbulence)) (Fleuren et al., 2014b).

**Qualitative measurements:**

To answer research questions 2 and 3, semi-structured interviews were performed, as well as focus group meetings.

Topic lists for semi-structured interviews with CHC-professionals and parents included questions regarding their perspectives on CHC in relation to development and upbringing of children, and their experience with the 360°CHILD-profile (including potential benefits/drawbacks, requirements for implementation). Topic lists for individual interviews were slightly customized, considering already collected quantitative outcomes (individual and preliminary group findings) (Creswell, 2018).

During the member check focus group meeting, most relevant findings and preliminary interpretations were presented and professionals were asked whether these findings and interpretations reflected their experiences, and to further elaborate on and/or explain the findings (Birt et al., 2016; Doyle, 2007).

The topic list for the separate focus group meeting with policy-makers, included questions about their perspectives on the 360°CHILD-profile (relevance, strengths, weaknesses, its implementation) in relation with their vision on future care for children.

All interviews and focus group meetings, were audio recorded (after explicit informed consent) and transcribed verbatim.

## **Analysis**

### **Baseline characteristics**

Descriptive analyses were performed (means, standard deviations, frequencies and percentages) on data of parents and professionals. Characteristics of CHC-professionals are presented for the total group of initial volunteers and sub-group that actually recruited parents and discussed 360°CHILD-profiles. Participant characteristics of the qualitative sub-sample are presented separately.

### **Main quantitative analyses**

For quantitative measurement of 360°CHILD-profile's level of use and determinants of implementation by professionals, descriptive analyses were performed.

### **Qualitative analyses**

Qualitative analyses were performed by a team of multidisciplinary researchers with experience in quantitative and/or qualitative research. Three researchers have experience as a Medical Doctor in CHC-practice.

Transcripts were analyzed using the software program NVivo 12 Pro (QSR International Pty Ltd, 2018).

First, data retrieved from each interview/focus group were explored and analyzed by the first author and one other researcher, independently. Then, findings were discussed to reach consensus. After each round of analyzing 3-5 interviews, findings were discussed in the whole team to reflect on data and analyzes, broaden the analytical scope, and decide on further sampling and adapting topic lists.

During several phases, constant comparative analysis was performed and MW wrote reflective memos. The first inductive phase, included open coding of relevant text fragments. After analyzing three interviews, codes were arranged, renamed and/or related to each other to identify and pragmatically structure categories (axial coding). In the last, more abductive phase, the team related data to quantitative findings and knowledge from literature to identify core concepts and themes (selective coding) (Boeije and Bleijenbergh, 2019; Korstjens and Moser 2018). Codes and categories then were restructured in line with the most appropriate conceptual framework for the given context. After the team concluded no new, relevant elements were generated anymore, interpretations were described and validated during the "member check" focus group meeting (Boeije and Bleijenbergh, 2019; Korstjens and Moser 2018).

## Results

### Recruitment and baseline characteristics of all participants

Of the CHC-professionals, 46% included at least one parent and discussed a personalized 360°CHILD-profile. Almost all invited CHC-professionals completed the MIDI-questionnaire. In total, 30 parents were included. Due to loss to follow up, 27 personalized 360°CHILD-profiles were discussed with parents (see figure 5.2).

Baseline characteristics of participating CHC-professionals were heterogeneous regarding discipline, educational level and experience (see table 5.1). Most professionals were rather satisfied with the EMD, rather known with the 360°CHILD-profile, had positive expectations regarding 360°CHILD-profile's usability but had little to no prior experience with it.

Participating parents were rather heterogeneous regarding educational level, experienced problems, parental stress and their child's age and level of functioning, indicated by CHC-professionals (Table 5.1).

Eight out of ten invited CHC-professionals, participated in an interview. Five parents were invited for and participated in an interview. See table 5.2 for characteristics of parents and professionals.

All interviewed CHC-professionals were invited for the member check focus group meeting, of whom six participated. During a separate focus group meeting, four policy-makers participated: two managers of the CHC-organization, two advisors (one of the regional municipality and one of the CHC's national knowledge centre).

### Level of use of the 360°CHILD-profile

An overview of results regarding the level of use is presented in table 5.3. In total, 27 (of 30) 360°CHILD-profiles were discussed by 14 professionals. Less than half of the professionals discussed the profiles profoundly. The majority used them to prepare for CHC-consultations, show promoting factors for children's health and/or assess children's functioning. The profile was less often and/or profoundly used to gain insight in parents' perspectives, empower parents, or collaborate with colleagues/other caregivers.

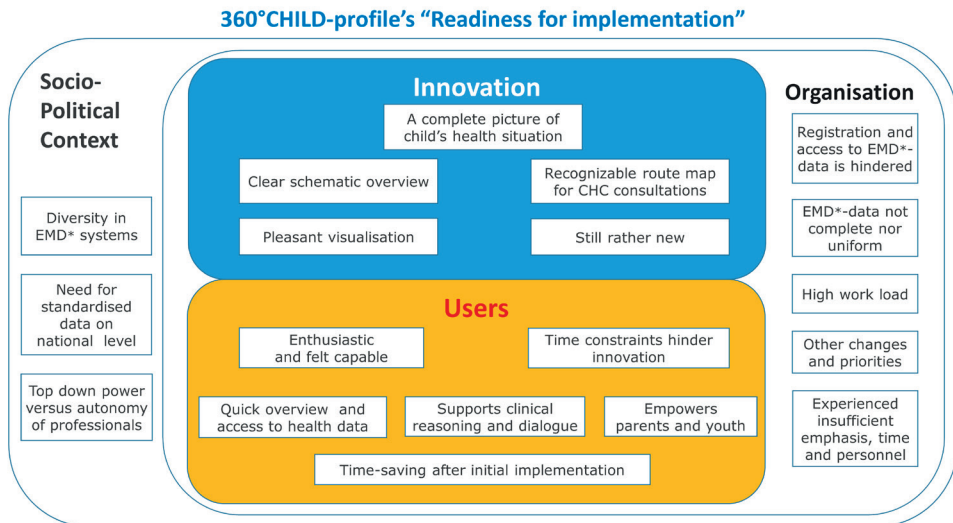
### Readiness for implementation

With regard to key determinants of the level of use and the context of research questions 2 and 3, integration of quantitative and qualitative data during qualitative analysis led to a repeatedly emerging theme: "readiness for implementation" (Figure 5.3). This theme provided insight in the current situation, future possibilities, and needs for further implementation regarding the 360°CHILD-profile itself, the people using it, the organization and the socio-political context.

Table 5.3: Level of use of the 360°CHILD-profile, including professionals' short explanations for the reported use.

Reported use of the 360°CHILD-profile. Questions:	Yes Nr. (%) (N=17)	Extensively* Nr./N used (%)	Reasons why; Reactions on open questions:	
			Why did you use and/or extensively use it?	Why did you not use or not extensively use it?
Did you present the 360°CHILD-profile to parents?	14 (82%)	6 /14 (43%)	- "In context of the study". - "To check if data were correct". - "There was time and parent was interested".	- "Limited time". - "Other goals of the visit". - "My colleague did it".
<i>If presented, did you also use the CHILD-profile to:</i>	<i>(applicable for n=14)</i>		Why did you not use or not extensively use it for other purposes:	
Show what goes well?	11 (79%)	2/9 (22%) (2 missings)	- "This was already addressed in other visits". - "The profile is a résumé, so it offers overall guidance. Beyond that, we addressed other goals of the visit".	
Assess child's functioning?	9 (64%)	5/9 (56%)	- "There were no particulars we had to extensively dive into".	
Prepare a visit?	9 (60%)	5/9 (56%)	- "The profile was not optimally filled due to missing data in the EMD".	
Explore parent's perspective?	7 (50%)	3/7 (43%)		
Collaborate with caregivers?	4 (29%)	1/4 (25%)		
Collaborate with school?	3 (21%)	0/3 ( 0%)		
Collaborate with colleagues?	1 ( 7%)	0/1 ( 0%)		

Therefore, Fleuren's theoretical framework (Fleuren et al., 2014a) was used to structure findings on readiness for implementation. Table 5.4 provides an integrative summary of qualitative and quantitative findings, including participants' quotes and original Fleuren's determinants. Figure 5.3 provides an overview of key findings based on both data types.



**Figure 5.3 Overview of key findings on 360°CHILD-profile's readiness for implementation.**

### *Determinants at the level of the innovation*

Quantitative results showed that most professionals stated that the 360°CHILD-profile offers sufficient and relevant information, fits CHC's working methods and clients, is based on adequate knowledge, and it was clear how to present it.

Integrating quantitative and qualitative data led to the following subcategories with respect to the 360°CHILD-profile itself (see table 5.4 for underlying quotes):

- A summative recap of a child's health situation.

Parents appreciated that the 360°CHILD-profile displays all essential information in one image. Professionals and policy-makers believe it offers a model to generate a complete picture of a child's health situation. However, professionals mentioned the need for a direct link to the EMD for viewing more detailed information as the CHILD-profile entails a compact, overall summary. Moreover, it appeared that not all profiles were complete (some data fields were empty) due to missing data in the EMD.



- Schematic overview and neutral visualization.

Both parents and professionals stated the neutral visualization of data was pleasant and the overview with ordering in subcategories was clear, as well as the provided instructions. The 360°CHILD-profile made the health information manageable and easy to find.

- Route map for CHC-consultations

Professionals mentioned that discussing the profile with parents fitted their regular CHC-visits and their longitudinal monitoring of development and health. The 360°CHILD-profile offers a recognizable route map for their dialogues with parents and adolescents, and displays for which topics and questions the CHC can be consulted.

- Experience

Professionals and parents felt they did not yet gain full insight in all potential benefits as this was their first, brief real-life experience with the profile. They expected that after full implementation and insight in benefits, an evaluation would generate even more positive results on usability. Professionals were eager to become more familiar with the profile and would appreciate possibilities to exercise in dialogue with colleagues.

### ***Determinants at the level of the users***

Quantitative data showed that most professionals felt capable to use the 360°CHILD-profile for describing and discussing a child's health situation. They agreed on the following benefits: it offers a quick overview on relevant health data and supports their medical reasoning. More than half of the professionals indicated that the 360°CHILD-profile supports their consultations and communication with parents. Less than half of the professionals agreed it stimulates empowerment and participation of parents. Half of the professionals indicated it costs extra time. One professional indicated the 360°CHILD-profile offers information which might be rather confronting for parents.

Integrating quantitative and qualitative data, revealed the following qualitative subcategories with respect to the users (for underlying quotes see table 5.4):

- Self-Efficacy

CHC-professionals were enthusiastic about their own profession and providing care for children and supporting parents. Parents acknowledged CHC-professionals as driven, competent caregivers who support and reassure concerned parents.

Parents and professionals were enthusiastic and interested in the 360°CHILD-profile. Most professionals felt capable to discuss the profile to parents. A few professionals contacted the researcher before discussing the profile with parents but stated that a short phone call was enough for reconfirmation of instructions.

- Access to health data

Parents said the 360°CHILD-profile showed them what data professionals register in the EMD and enabled them to easily consult background information between visits. Professionals appreciated the quick access to relevant holistic health data and the possibility to provide parents with relevant health information via the online portal. The importance of guaranteeing privacy protection was mentioned by both professionals and parents.

- Clinical reasoning and dialogue.

During visits, parents felt supported by the profile by reminding them about their child's upbringing and relevant issues and events in the past. Professionals stated that the ordering of data provides insight in the cohesion between different items. It supports the transfer of this insight to parents, and supports sharing visions on how imbalances between protective- and risk factors emerged. The 360°CHILD-profile could further support consulting colleagues and other caregivers and ease conversations with adolescents by creating a setting in which professional and adolescent share the same screen with information.

Some professionals wondered if it would benefit parents of children without evident developmental and/or health problems, while others emphasized the importance of having insight in every child's health information, including what goes well.

- Empowerment

Parents and professionals appreciated the display of positive aspects of a child and their family and the possibility to share data with other caregivers. During a consultation with several caregivers, the profile enabled a parent to formulate her family's needs and to take an active role during shared decision-making. Some professionals expected the profile might be confronting for low educated parents who experience severe problems, while others thought the neutral display of both facilitating and hindering factors makes it less confronting.

- Time investment

Most professionals experienced that, due to time constraints, it was hard to find time for their study tasks. At the end of a working day, they felt the urge to choose between tasks regarding actual daily care and the study. The majority tend to prioritize daily care tasks.

Most professionals think that 360°CHILD-profile's implementation and evaluation will cost some extra time. However, they believed that, after implementation, the quick access to health information will lead to efficiency and the 360°CHILD-profile will become timesaving.

### ***Determinants at the level of the organization***

Quantitative results showed that the majority of CHC-professionals indicated that, apart from this study, more changes within the organization took place, such as a merger and other innovations. The minority of professionals indicated their management sufficiently facilitated the innovation, stressed the importance of it, and that there was sufficient time and personnel available.

With respect to the organization, the following subcategories emerged after integrating quantitative and qualitative data (see table 5.4 for underlying quotes):

- Aspects of work load and emphasize

Professionals, for a long time already, experienced a high workload in completing their daily tasks. During the study period, other organizational changes were prioritized.

Professionals indicated that staff capacity was low and felt there was not enough time for testing this new tool. Professionals said that only the researcher communicated about the project. They were hardly informed by their managers about the project and the importance of the innovation.

- Registration and access to EMD-data

All professionals mentioned that registration and retrieval of data from the EMD is time consuming due to a lack of structure and overview of registered data. According to them, the 360°CHILD-profile provides better overview and support for executing their CHC-tasks.

Professionals stated that currently, EMD-data are registered inconsistently and not always complete. The 360°CHILD-profile can create awareness about which relevant information is missing within EMD-registries and could help to achieve more complete and structured registries.

### ***Determinants on the level of the socio-political context***

Determinants at the level of the socio-political context were not measured quantitatively. During the focus group meetings and some interviews, the national CHC-context was discussed. Qualitative analysis revealed the following subcategories (table 5.4 includes underlying quotes):

- EMD systems and standardized data on national level.

Policy-makers regard the presentation of health information on a population level (regionally and nationally) as an important CHC-task. They mentioned serious constraints in current CHC-data registries, such as the diversity in EMD systems and a common lack of theoretically structuring of data. Policy-makers referred to the 360°CHILD-profile as “a

golden egg". They stated that it is built on a solid vision and scientific background, and has great potential: a multifunctional tool for reaching standardized registration, stimulating ICF-thinking, optimising prevention and prediction, and empowering parents.

- Top down power versus professional autonomy

To solve problems concerning the electronic health-data registries and to enable the delivery of data on a population level, policy-makers stated the need for more top-down policy. At the same time, they realized that a certain level of autonomy is essential for health care professionals.

Policymakers listed several steps needed for preparing national implementation: to secure intellectual property, to collaborate with national stakeholders (i.e. knowledge centre CHC, association for Public Health), to build a sound marketing strategy, and to describe how the CHILD-profile could support other developments in the health domain in the Netherlands, such as Positive Health.

## Discussion

Study findings demonstrated the 360°CHILD-profile is useful for CHC-practice and promising for reaching more efficiency. The level of use during the study was satisfactorily, considering this study entailed a first and short introduction of the CHILD-profile within real life practice.

Integrating quantitative and qualitative findings yielded broad insight in the "readiness for implementation", which appeared to be strongly related to determinants at each of the four levels, described by Fleuren (Fleuren et al., 2014a).

The 360°CHILD-profile itself, as well as the potential users, seem to be ready for implementation. CHC-professionals and parents received the 360°CHILD-profile very favourably and appeared very well capable in handling and using the CHILD-profile within the CHC-context.

Quantitative and qualitative data supported 360°CHILD-profile's compatibility to CHC-practice and relevance. Qualitative research provided deeper understanding of its usefulness. Professionals and parents particularly appreciated the holistic and schematic overview on CHC-data. Compared to the EMD, it represents a child's health situation more accurately and provides quicker access to relevant health data. A potential hindering factor might be that on forehand, one professional thought the overview of data might be confrontational for low educated parents who experience severe problems. However,

this individual assumption was in contrast with the actual pleasant and empowering experiences of parents and professionals.

At the level of the organization, substantial barriers were revealed with regard to 360°CHILD-profile's readiness for implementation. The high workload and low staff capacity seem to hinder professionals in investing time in familiarizing with the 360°CHILD-profile and adopting it. Another hindering factor is the primary process of data registration within the EMD, 360°CHILD-profile's data source. This process is time consuming and sometimes leads to incomplete individual health data and consequently to missing data on personalized 360°CHILD-profiles. These missing data and the only short experience with the 360°CHILD-profile might partly explain the variation in the level of use during the study.

The experienced lack of facilitation and prioritization by CHC-management were in contrast with findings at the level of the socio-political CHC-context. Namely, policy makers (including CHC-managers) considered the 360°CHILD-profile to be a promising tool for realizing several relevant goals for the national CHC-context, including stimulating ICF thinking and proper provision of standardized data by the CHC.

This study provided insight in requirements for implementation, in how to target the implementation strategy, and in 360°CHILD-profile's potential benefits for CHC.

The following organizational issues should be prioritized to get ready for local implementation: secure sufficient emphasis on the innovation, facilitate professionals, provide a direct link with the EMD and safeguard privacy. Implementation on a national level, additionally requires sufficient top down power while maintaining professional autonomy, and a marketing communication plan toward national stakeholders.

Further recommendations for a successful implementation strategy include: offer continuous support to professionals as well as opportunities to exercise with the 360°CHILD-profile in dialogue with colleagues; display which EMD-data are used as data source for the 360°CHILD-profile and what benefits are per target group; monitor impact of diversity within the target population on usability.

As mentioned earlier, an essential future benefit of the 360°CHILD-profile for CHC is the quick access to structured health data and appropriate representation of child's health situations. Quick access will save professionals time during child related tasks. Proper representation of health situations facilitates simultaneous thinking processes, which are a prerequisite for the preventive clinical appraisal of a child's functioning. The segmented EMD-database, which does not display structured health data, currently hinders simultaneous thinking as

it forces professionals into a sequential, time-consuming process when retrieving relevant data.

Beyond primary expectations, the study revealed points for improving data registration. The 360°CHILD-profile exposes which of the numerous EMD-data entries are relevant for gaining overview on health situations, and which are more or less optional for registering detailed background information. The 360°CHILD-profile disclosed which relevant data are currently missing in the EMD and stimulated professionals to strive for more consistent data registration. Professionals wanted better insight in which EMD-data are displayed on the 360°CHILD-profile, which could give professionals more control (autonomy) over their access to health data. As correct registration of relevant EMD-data would lead to a complete 360°CHILD-profile, the 360°CHILD-profile can be seen as a motivational tool for setting priorities for EMD-registries and further professionalization toward consistent and structured registrations in accordance with the ICF-CY.

Last but not least, the 360°CHILD-profile would benefit the CHC by providing parents online access to a comprehensible summary of the EMD. Currently, CHC cannot commit to their legal duty (since 2020) to provide parents with digital access to EMD's health data. The recently implemented online CHC-portal for parents merely discloses growth charts and an overall advice. This means that digitally disclosing EMD-registries to parents is rather new for professionals. This might explain the reluctance of some professionals to present the 360°CHILD-profile to certain parents.

The enthusiastic reactions and positive results regarding usability and self-efficacy are in line with results of earlier pilot studies on the 360°CHILD-profile (Weijers et al., 2021, 2018). By introducing the 360°CHILD-profile within real-life practice, this study extended the validation process and generated more profound knowledge, crucial for transitioning from pre-implementation- towards implementation phase (Rothstein et al., 2016; Van Yperen et al., 2010). Results reaffirmed the importance of timely mapping determinants at the level of the organization (as stressed by Fleuren). Problems like high workload, low staff capacity and time consuming handling of the EMD were already known (Meuwissen, 2013; Fleuren et al., 2014a). In addition to earlier studies, this evaluation provided deeper insight in how time constraints, resulting from these problems, hinder the innovation process and which determinants must be addressed. During previous phases within the longitudinal research project, the focus was predominantly on the determinants of the 360°CHILD-profile itself and its potential users. Much attention was paid on realizing a usable, meaningful visualization of health data that properly represented the multidimensionality of health, and complied with the standards for human computer interaction (Weijers et al., 2021a).

As the practice derived 360°CHILD-profile is unique in providing a holistic display of complex electronic CHC-data sets in accordance with the ICF-CY framework, results cannot be easily compared to scientific research on other innovations. However, specific findings (e.g. the need for insight in benefits per target group, opportunities to familiarize with the innovation, organizational support, securing data exchange with the existing EMD) are in line with recently presented guidelines for successful implementation of e-health interventions within health care (Saldana, 2014; Cremers et al., 2021).

This study was a solid and logical step within the multiyear Mixed Methods research project. Integration of complementary quantitative and qualitative data allowed to gain an in depth and broad insight. Triangulation and the opportunity for participants to correct and react on researchers' interpretations, increased the validity of results.

Purposive sampling of a rather heterogeneous subgroup from the initial study population for the interviews enabled to gain insight in a variety of perspectives, with the limitation that the initial study population was rather small. The limited number of participants and the fact that this study entailed a once-only experience with the 360°CHILD-profile in a pre-implementation phase, were limitations for extensively measuring the level of use. Therefore, it was chosen to focus on measuring the frequency and profundity of use and not yet on evaluating if the 360°CHILD-profile was used as intended and if determinants were associated with the level of use. As it is important for professionals to get acquainted with the 360°CHILD-profile, it might be reasonable to use the profile during regular InterVision group meetings.

The time between experiencing the 360°CHILD-profile and the interviews and focus group was rather long. However, this could have enabled professionals to reflect on findings and preliminary interpretations from a more distant view.

The interviews with parents yielded relatively homogeneous (positive) responses and less in-depth insights. This might be explained by the fact that it was their first and single encounter with the 360°CHILD-profile. During qualitative analysis, it appeared to be essential to put relatively more focus on perspectives of professionals as they must take the first step to integrate the 360°CHILD-profile in practice. Therefore, it was decided to perform a member check focus group with merely professionals. It was anticipated that a member check with parents would not yield substantial new, more in-depth insights for this phase of the innovation process.

This study provided valuable knowledge on how to target the strategy and evaluation of further implementation, as well as on which organizational barriers currently hinder implementation. To appropriately address these barriers, future research is needed to

gain better understanding on contrasting findings regarding the experienced insufficient management support versus the positive views of (these) managers on 360°CHILD-profile's potential and relevance for the CHC-context.

The parallel study on RCT's feasibility will yield information on recruitment-, response- and retention rates, measure completion and protocol deviations. This information will be used to design future studies on performance and effectiveness of the 360°CHILD-profile within CHC-practice.

## **Conclusion**

This study demonstrated that the 360°CHILD-profile is a useful and efficient tool, compatible with CHC-practice. Users are competent in handling and using the 360°CHILD-profile within the CHC-context. This study generated valuable knowledge for targeting the implementation strategy and showed which organizational barriers should be addressed to get ready for implementation.

The 360°CHILD-profile, designed according to international standards of human computer interaction for information representation (ISO 9241-12), appears to appropriately represent children's health situations. The quick overview on holistic health data, provided by the 360°CHILD-profile, is promised to be time saving, enable a comprehensible transfer of health information to parents, support clinical reasoning and stimulate more consistent and structured registry of relevant health data within the CHC. These benefits are essential ingredients for reaching adequate preventive interventions and transformation towards a more predictive, personalized and participative health care.



**Table 5.4: Integrative summary of the mixed methods findings: qualitative findings, participants' quotes, quantitative results of the MIDI questionnaire and the original Fleuren's categories.**

	<b>Qualitative quotes</b> parents, professionals, policy-makers	<b>Quantitative results</b> professionals *	<b>Original Fleuren</b> <b>determinants</b>
<b>Determinants at the level of the innovation:</b>			
A complete picture of child's health situation	<p><b>Parents:</b>                      Nr.1: "All information from birth on is documented on the profile."                      Nr.4: "You see all essentials at a glance in a comprehensible way. You do not need to flip through many pages."                      Nr.5: "It would be easy if we could link back to information behind it, like the growth chart in EMD."</p>	<p>It contains sufficient relevant information.                      - Agree: 15 (88%)                      - Neutral: 2 (12%)                      - Disagree: 0</p>	<p>Completeness and Relevance</p>
(A summative recap of child's health situation)	<p><b>Professionals:</b>                      Nr.2: "It provides me with a complete picture."                      Nr.3: "It includes all elements that CHC professionals take into account. A synthesis of all EMD domains."                      Nr.6: "As some profiles were incomplete, I wondered if I registered all data well in the EMD."                      Nr.5: "The profile offers a résumé, shows a global picture. For detailed information you still need a link to the EMD"</p>	<p>It is based on adequate knowledge.                      - Agree: 11 (65%)                      - Neutral: 6 (35%)                      - Disagree: 0</p>	<p>Correctness</p>
Clear schematic overview and pleasant visualisation	<p><b>Parents:</b>                      Nr.2: "It is schematic with categories, which makes it very clear how and where to find information."                      Nr.5: "I think it has a very pleasant, calm look."</p> <p><b>Professionals:</b>                      Nr.4: "It offers a clear overview and it would be beneficial if you can go, by clicking on a domain within the overview, to more detailed information about that domain."</p>	<p>It is clear how to present it.                      - Agree: 14 (82%)                      - Neutral: 3 (18%)                      - Disagree: 0</p>	<p>Procedural clarity</p>
(Schematic overview and neutral visualisation)	<p>Nr.6: "I found it very pleasant to present the profile and the parents thought so too."                      Nr.7: "It looks clear and joyful. The EMD contains much more letters and needs much more reading, doesn't it?"                      Nr.8: "The instructions given during the instruction meeting were loud and clear as well as the written information."</p>		
Recognizable route map for CHC consultations	<p><b>Parents:</b>                      Nr.4: "I think it would be fit for all parents, from all different layers of the population and would be comprehensible and clear for all levels of intelligence."  <b>Professionals:</b>                      Nr.8: "It fits the CHC very well, it shows what we take into account when checking the balance between protecting and risk factors."                      Nr.5: "The profile supports my usual approach and offers a route map for my consultations with parents."                      Nr.6: "It shows for what questions/topic parents can consult the CHC"                      Nr.7: "I think I could start with the CHLD-profile right away in regions where not too many parents live who experience a lot of problems, have low educational level or with a language barrier."</p>	<p>It fits CHC's:                      -Working method.                      - Agree: 13 (77%)                      - Neutral: 4 (23%)                      - Disagree: 0</p> <p>-Clients.                      - Agree: 12 (71%)                      - Neutral: 5 (29%)                      - Disagree: 0</p>	<p>Compatibility</p>
(Route map for CHC consultations)			

Still rather new	<p><b>Parents:</b> Nr.2: "As it is new, it is important that parents know what the added value is. Then I think they will be up for it."</p> <p><b>Professionals:</b> Nr.1: "It is still new for me. That's why I found it hard to explain what the benefits for parents are." Nr.3: "I filled in the questionnaire while having only little experience with the CHILD-profile. If we would work with it more extensively, the outcome of the questionnaires will be even more positive." Nr.2: "I find it hard to do something new immediately in the face of parents. I would firstly like to practice with colleagues to get more acquainted with it."</p>	
<b>Determinants at the level of the users:</b>		
Enthusiastic and felt capable	<p><b>Parents:</b> Nr.3: "I found it very interesting so I would make it very big, this project, because I think you can do a lot with it." Nr.2: "The CHC-professionals are friendly and competent and supports parents very well!"</p> <p><b>Professionals:</b> Nr.4: "CHC-professionals know what domains are important and we are used to try to gain an overall picture of the child. So, I think we are all capable to work with this clear and insightful overview." Nr.8: "I always work with mind maps to support my overall view on children's health. As the CHILD-profile perfectly fits my way of thinking, it did not feel new working with it." Nr.5: "It works itself out. Well the first time, I did call the researcher to ask her how to discuss the profile with parents but it did not really differ from how I usually approach consultations."</p>	<p>Self-efficacy</p> <p>Felt capable to: - Present the profile - Agree: 13 (76%) - Neutral: 3 (18%) - Disagree: 0 (1 missing)</p> <p>- Assess functioning - Agree: 12 (71%) - Neutral: 4 (23%) - Disagree: 0 (1 missing)</p>
(Self-Efficacy)		
Quick overview and access to health data	<p><b>Parents:</b> Nr.4: "During consultations, many questions are asked and information is registered in the EMD and we look at the graphic of growth together. With the profile, the professional can show me on one digital image all EMD-data." Nr.1: "The availability on the online CHC portal, offers me the opportunity to consult information between CHC visits and to provide access to other persons for whom the information is important."</p> <p><b>Professionals:</b> Nr.3: "Added value, in comparison with EMD, is that you can quickly show summary of information to parents and colleagues." Nr.6: "It would be very nice to make this overview accessible for parents via the online portal."</p>	<p>Personal benefits and/or drawbacks</p> <p>It provides quick overview - Agree: 15 (88%) - Neutral: 1 (6%) - Disagree: 1 (6%)</p>
(Access to health data)		
Supports clinical reasoning and dialogue	<p><b>Parents:</b> Nr.2: "It is like a medicine list, visible for anyone. If you must go to the emergency room and you don't remember it all, you can easily find back all information." Nr.4: "It is nice to be able to look back at how I was doing then and see how I am doing now."</p> <p><b>Professionals:</b> Nr.4: "The CHILD-profile offers the opportunity to also show adolescents the whole picture; how different health domains are connected and how imbalances did occur." Nr. 5: "It is nice and clear for health literacy and consultations with colleagues and other care givers" Nr.2: "I do not know if it has added value if all goes well." Nr.6: "I think it would be a good idea to use the profile for all children as it is nice and beneficial for all parents to see what goes well. And that the child is our central interest and that the features of the child are connected with the environment in which the child grows up."</p>	<p>It supports:</p> <p>* Thought processes. - Agree: 14 (84%) - Neutral: 3 (18%) - Disagree: 0</p> <p>* CHC consultations. - Agree: 10 (59%) - Neutral: 7 (41%) - Disagree: 0</p> <p>* Communication. - Agree: 10 (59%) - Neutral: 7 (41%) - Disagree: 0</p>
(Clinical reasoning and dialogue)		

<p>Empowers parents and youth  (Empowerment)</p>	<p><b>Parents:</b>                  Nr. 4: "The compact information makes me analyse much better what is going on and formulate my question."                  Nr.1: "It will support me during the intake consultation I will have with a caregiver. As all information is available on the profile, so that I do not forget to mention things."  <b>Professionals:</b>                  Nr.5: "I used the profile during a care match consultation with other caregivers who did not know anything about the child yet. The mother used the profile to guide her in describing her child and her family, what the history looked like and what problems they encounter."                  Nr.2: "Reading the information on the profile might be problematic for parents who do not understand Dutch and confronting for parents with low education who experience a lot of problems."                  Nr.3: "As it provides an overview, it makes discussing barriers less confronting then in the current situation because the profile also contains information about what goes well".</p>	<p>Personal benefits and/or drawbacks</p> <p>It stimulates:                  -An integral approach                  - Agree: 11 ( 71%)                  - Neutral: 4 ( 23%)                  - Disagree 1 ( 6%)                  -To empower parents                  - Agree: 8 (47%)                  - Neutral: 8 (47%)                  - Disagree 1 ( 6%)                  -Parents' participation                  - Agree: 7 (41%)                  - Neutral: 10 (59%)                  - Disagree 0 ( 0%)</p>
<p>Time constraints hinder innovation (Time investment)</p> <p>Time-saving after initial implementation  (Time investment)</p>	<p><b>Professionals:</b>                  Nr.7: "I love my job and do it with much passion. However, it is very busy and at the end of the day I have to prioritise and then I choose to finish urgent tasks related to clients."  <b>Parents:</b>                  Nr.1: "The profile provides me quickly with a summary of my child's health situation. That is nice and could save time."                  Nr.2: "If, during puberty, my child will again experience problems, with one click on the computer, you get information about what happened in the past, who performed earlier psychological examinations and what the outcome was."  <b>Professionals:</b>                  Nr.3: "After becoming familiar with the profile, it can be time-saving as you can start with showing what has been discussed the last time and how is it going now?"                  Nr.5: "The profile enables me to form a picture of the family and the child before I see a them for the first time. That will save me much time. Now I must open many tabs in EMD to prepare for a visit."                  Nr.2: After a while it will make us finish work faster but implementation will costs extra time while we already experience high work load. So, you might encounter some resistance during first stages."</p>	<p>It costs extra time                  - Agree: 9 (53%)                  - Neutral: 5 (29%)                  - Disagree 2 (12%)                  It is confronting for parents                  - Agree: 1 ( 6%)                  - Neutral: 11 (65%)                  - Disagree 5 (29%)</p>

Determinants at the level of the organization:		Management does:	Formal ratification by management
Experienced insufficient emphasis, time and personnel <i>(Aspects of work load and emphasis)</i>	<b>Professionals:</b> Nr.4: "All professionals in our team know about the project and expect for it to get implemented but it takes very long" Nr.5: "The only communication about the project comes from the head researcher. Besides that, I hear very little about the project and it does not feel like we are all really going for it" Nr.4: "I don't remember how I exactly answered these questions within the questionnaire, it was quite a while ago. But I am not surprised about the overall low scores on ratification and facilitation by the management."	-Stress importance: (23%) -Agree (23%) -Facilitate sufficiently (23%) -Agree (23%)	
	<b>Parents:</b> Nr.3: "I don't remember which questionnaire was about this project as I also received another one concerning the new online portal for parents." <b>Professionals:</b> Nr.5: The workload is very high due to insufficient personnel; it never stops. I like the fact that my job is diverse but I struggle with how to prioritise." Nr.8: "My agenda was already overloaded due to the high demand for care within area I work in." Nr.4: "It was a tumultuous time, with the fusion of different CHC-organisations." Nr.6: "I still discovering what information to provide to parents on the recently introduced online portal for parents."	There is sufficient: -Personnel (23%) -Agree (23%) -Time available (29%) -Agree (29%)	Staff capacity Time available
<i>(Aspects of work load and emphasis)</i>	<b>Professionals:</b> Nr.5: The workload is very high due to insufficient personnel; it never stops. I like the fact that my job is diverse but I struggle with how to prioritise." Nr.8: "My agenda was already overloaded due to the high demand for care within area I work in." Nr.4: "It was a tumultuous time, with the fusion of different CHC-organisations." Nr.6: "I still discovering what information to provide to parents on the recently introduced online portal for parents."	Other developments took place in organisation -Agree (71%)	Turbulence within organisation
Registration and access to EMD-data is hindered <i>(Registration and access to EMD-data)</i>	<b>Parents:</b> Nr.4: "I think the profile has added value for the EMD as information will be better stored." <b>Professionals:</b> Nr.5: "I hear many colleagues complain about the current EMD. How slow the system works, about the multiple spots where you can register information. And, searching for information in the current EMD is terrible, very time consuming" Nr.2: "I miss structure in the way we register data in the EMD, there are many differences in data registration by professionals. We need to better structure what data we register and where." Nr.4: "I think the EMD is very unclear and much to extensive and it feels like I have to register data on hundred different places within the EMD."		
EMD-data not complete, nor uniform <i>(Registration and access to EMD-data)</i>	<b>Professionals:</b> Nr.5: "Not all professionals do consistently fill all data fields. Especially if a child does not experience problems concerning a certain domain, these fields are often empty. We need to create more unity and I think the CHILD-profile can help to standardise data" Nr.2: "Everyone should register information about a certain topic in the same field, otherwise it cannot be shown in the CHILD-profile."		

Determinants at the level of the socio-political context		Legislation
<p>Diversity in EMD systems (EMD systems standardised data on national level)</p>	<p>"In the Netherlands, several different EMD's are in use even when several CHC organisations use the same EMD, every CHC organisation has employed the EMD software differently so we will not be able to generate comparable data. As the Dutch CHC knowledge centre (NCJ) we decide that we want to do something about it."</p>	<p>Legislation</p>
<p>Need for standardised data on national level</p>	<p>NCJ: "It shows the complete picture of child's health and intuitively guides professionals to consider all domains of the biopsychosocial model of health as it shows if all components are covered."                      Manager: "There is a need for more standardised data. On a national level, a measure is in preparation for the collection of data on a population level!"</p>	
<p>(EMD systems and standardised data on national level)</p>	<p>NCJ: "The current BDS Basic data set to be collected by CHC includes more than 1000 items while this innovation has prioritised about 100 items to display a child's health situation. That is very interesting and national implementation is important."                      Manager: To gain reliable data for policy making, it is better to register a limited number of data well then to register a high number of data while this is not doable and leads to incomplete datasets. Therefore, it is important to present this project on national (governmental) level (GGD GHOR NL/Actiz, Managers CHC, VWS).</p>	
<p>Top down power versus autonomy of professionals</p>	<p>Manager: "The need for standardised data require a more top down approach while keeping the balance and leave room for enough autonomy for professionals                      "It asks for a change in the way professionals think, that is the biggest challenge."  <b>Professionals:</b></p>	
<p>(Top down power versus professional autonomy)</p>	<p>Nr.8: "It must be clear for all professionals in what EMD-fields to register the data to get them displayed in the profile."                      Nr.6: "If professionals realise their responsibility for providing relevant data for the profile will stimulate better registration."</p>	

\* Percentage of CHC-professionals who agree (indicated they did agree or totally agree), were neutral (indicated they did not agree nor disagree) or disagree (indicated they did disagree or totally disagree). (Total answer options were: totally agree, agree, neutral, disagree, totally disagree.)

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# CHAPTER 6



# A feasibility Randomised Controlled Trial as a first step towards evaluating the effectiveness of a digital health dashboard in preventive child health care: A Mixed Methods approach

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## Abstract

**Background.** Within preventive Child Health Care (CHC) the 360°CHILD-profile has been developed. This digital tool visualizes and theoretically orders holistic health data in line with the International Classification of Functioning, Disability and Health. It is anticipated that evaluating effectiveness of the multifunctional 360°CHILD-profile within the preventive CHC-context is complex. Therefore, this study aimed at investigating feasibility of RCT-procedures and applicability of potential outcome measures for assessing accessibility and transfer of health information.

**Methods.** During the first introduction of the 360°CHILD-profile in CHC-practice, a feasibility RCT with an explanatory-sequential mixed methods design was executed. CHC-professionals (n=38) recruited parents (n=30) who visited the CHC for their child (age 0-16). Parents were randomized to “care as usual” (n=15) or “care as usual with, in addition, the availability of a personalized 360°CHILD-profile during six months” (n=15). Quantitative data on RCT-feasibility were collected on recruitment, retention, response, compliance rates and outcome data on accessibility and transfer of health information (n=26).

Subsequently, thirteen semi-structured interviews (5 parents, 8 CHC-professionals) and a member check focus group (6 CHC-professionals) were performed to further explore and gain deeper understanding of quantitative findings.

**Results.** Integration of qualitative and quantitative data revealed that recruitment of parents by CHC-professionals was problematic and influenced by organizational factors. The used randomization strategy, interventions and measurements were executable within the setting of this specific study. The outcome measures showed skewed outcome data in both groups and a low applicability to measure accessibility and transfer of health information. The study revealed points to reconsider regarding the randomization and recruitment strategy and measures in the next steps.

**Conclusions.** This Mixed Methods feasibility study enabled to gain a broad insight in the feasibility of executing an RCT within the CHC-context. Trained research staff should recruit parents instead of CHC-professionals. Measures, potentially for evaluating 360°CHILD-profile’s effectiveness, need further exploration and thorough piloting before proceeding the evaluation process. Overall findings revealed that executing an RCT within the context of evaluating 360°CHILD-profile’s effectiveness in the CHC-setting will be much more complex, time-consuming and costly than expected. Thereby, the CHC-context requires a more complex randomization strategy than executed during this feasibility study. Alternative designs including Mixed Methods research must be considered for the next phases of the downstream validation process.

**Trial registration:** NTR 6909; <https://www.trialregister.nl/trial/6731>

## Background

Within the practice of the Dutch preventive Child Health Care (CHC), children's health and development are systematically monitored. CHC-professionals focus on protecting and promoting children's health. For preventive clinical reasoning, it is essential to gain integral overview of the collected health information and theoretically structure health data. Access to relevant health data, registered within the Electronic Medical Dossier (EMD), is currently hindered due to its non-theoretical structure and lack of overview. Therefore, together with fellow CHC-medical doctors and researchers, the first author initiated the development of a digital health dashboard, the first version of the 360°CHILD-profile [1]. The actual dashboard visualizes and theoretically orders holistic health data based on the International Classification of Functioning, Disability and Health, Children and Youth version (ICF-CY) [2, 3]. The 360°CHILD-profile is designed to facilitate the CHC's transfer of health information to parents and youth, clinical reasoning processes, tailored counselling and shared decision-making. Although this digital dashboard is promising to offer the CHC a multifunctional tool [1], it is not yet known how it meets expectations in real-life practice.

During an iterative mixed methods design process, qualitative development processes were followed up with a quantitative validation process and again sequential qualitative processes to improve the design until the final representation was reached to be used in the actual feasibility study. International standards for representing health information were applied during the design of the 360°CHILD-profile. During the whole trajectory, professionals of different backgrounds and parents were actively involved and evaluation methods were integrated during development of the 360°CHILD-profile to achieve a solid and applicable visualization with a high probability to perform as intended [1, 4, 5]. As described in detail elsewhere [1], a nested design model adapted from Munzner was used for guidance on how to integrate design and evaluation methods within each level of the design process. This model provides insight in how and when to apply quantitative- and qualitative evaluation methods during the developmental phase (i.e. upstream validation), as well as during implementation of the delivered data-visualization design (i.e. impact oriented downstream validation) [4].

So far, the 360°CHILD-profile's downstream validation process included pilot tests of the delivered prototype. These showed positive results on comprehensibility, acceptability, reliability, and validity [1, 6].

Next steps within the downstream validation process were to evaluate implementation, usability, and effectiveness of the 360°CHILD-profile within real-life CHC-practice [1, 4]. Evaluating the effectiveness of the 360°CHILD-profile in the preventive CHC-context was expected to be complex because the tool has multiple functions. Thereby, effects of preventive interventions (especially effects at the level of health outcomes) cannot all be expected to be evident shortly after implementing an innovative tool. Moreover, the target group was heterogeneous as it included: parents of children from 0 to 18 years old, with a normal development until a development characterized by severe health problems; parents with different educational levels, birth country or experienced levels of parental stress; and health care professionals including different disciplines and professional experience. To prepare for solid evaluation of the effectiveness of this promising tool, it was essential to timely address feasibility questions regarding how to set up robust effect studies [7, 8, 9]. Before spending much time and effort in executing an RCT, it is important to ensure the availability of appropriate recruitment strategies, randomization plans, and outcome measures that are suitable for capturing significant differences of interest between the experimental- and control-interventions [9, 10]. A feasibility RCT, integrating quantitative- and qualitative methods, enables a thorough evaluation of practicability and acceptability of methodological conditions of an RCT within the given context [8, 9, 10]. Moreover, valuable knowledge can be generated on organizational factors that potentially interfere with the performance of a methodological well-designed RCT.

To initiate the evaluation of the prerequisites of studying 360°CHILD-profile's effectiveness within real-life health care practice, a feasibility RCT was executed [9]. This study, which evaluated methodological aspects of setting up an RCT, was part of a larger Mixed Methods research project that also studied the implementation and usability of the 360°CHILD-profile, which is published elsewhere [11, 12].

The feasibility RCT was performed during an early stage of 360°CHILD-profile's implementation. Therefore, the focus was on most immediate expected outcomes of implementing this experimental intervention within the CHC: better access to electronic health data and a more comprehensible transfer of health information to parents [1, 13, 14].

Considering the actual phase of the downstream validation process, the following objectives were formulated:

1. To evaluate feasibility of RCT-procedures within the given organizational context of the Dutch CHC (recruitment, retention, response, compliance to the allocated intervention and measure completion) and define (if possible) points for improvements regarding the procedures.

2. To explore measures as potential conditional outcomes related to accessibility and transfer of CHC's health information:
  - usability of the selected outcome measures within the CHC-context
  - the variance in the received outcome options of the measurement scale(s), also in relation to a future sample size calculation within the target population.

## Methods

### Study design

This research with an explanatory-sequential Mixed Methods design included a quantitative and sub sequential a qualitative part [11, 15, 16]. Within a small-scale RCT, quantitative measurements were performed. Then, qualitative methods (semi-structured interviews and focus groups) were used to gain a deeper understanding of the quantitative findings regarding feasibility of performing an RCT [11, 15, 16]. Our reporting follows the CONSORT guidelines (see CONSORT-checklist in supplemental files) [17].

Integration of quantitative and qualitative data took place at different levels. Quantitative data were used to direct the sampling strategy of the qualitative part and for refining topic lists. Furthermore, during qualitative analysis, the quantitative findings were considered and intensively compared in the discussion of overarching themes/categories [11].

### Study population

All nurses and medical doctors from the local CHC-departments in Southern part of the Netherlands were eligible and invited to participate in the study with the aim to recruit at least 30 CHC-professionals [18]. No further exclusion criteria were applied. After an information and instruction meeting and an informed consent procedure, the group of participating CHC-professionals became responsible for recruiting parents. It was aimed to include at least 30 parents who visited the CHC with their child between the age of 0 and 16 years. Additionally, other caregivers involved in the care of these children and the children (adolescents) aged between 11 and 16 also could be invited to participate. There were no exclusion criteria, besides the presence of barriers that could hinder the profile's readability (like a substantial language barrier or severe cognitive disorder).

For the qualitative part of this study, subgroups of participating CHC-professionals and parents were selected. Purposive sampling was used to obtain heterogeneous subgroups [19] with contrasting characteristics (CHC-professionals: discipline, experience within the CHC, satisfaction about the electronic medical dossier (EMD); parents: parental stress, educational level, birth country, opinion on CHC, and their child's age and level of functioning).

## **Randomization and concealed allocation**

Within the actual organizational structure of the Dutch CHC, choosing a proper method for randomization turned out to be a challenge. The preferred randomization program where each CHC-professional only would be confronted with either the experimental or the control intervention was not possible without using a cluster randomization schedule. As such a schedule would require multiplying the sample size of participants, this option was not possible within this feasibility study. Randomization was performed at the level of individual parents by an independent person, who used a central block randomization application to assign recruited parents to one of the two study arms (with blocks of 4 and 6) [11].

## **Interventions**

During the intervention period of six months, all parents received care as usual. A personalized 360°CHILD-profile was generated for the experimental group, directly after completing the informed consent and randomization procedure. During the subsequent consultation, CHC-professionals discussed this 360°CHILD-profile with parents. Within the intervention period, the personalized 360°CHILD-profiles were accessible for CHC-professionals within the Electronic Medical Dossier (EMD) and for parents via an online portal. Both CHC-professionals and parents were free to consult the profile anytime and/or use it for other tasks and/or in contact with other involved caregivers. Parents of the control group received a personalized 360°CHILD-profile six months after baseline, after completing the intervention period including all RCT-outcome measurements.

## **Measurements**

### ***Baseline characteristics of participants***

At baseline, demographics and other characteristics were collected from CHC-professionals, parents, and their children (table 6.1 and 6.2). The information on CHC-professionals included discipline, education, their experience with the EMD and the 360°CHILD-profile, and their use of technologies to share health information with parents (like e-mail, WhatsApp). The information on parents included gender, educational level, birth country, their concerns about their child's health/development, and parental stress [20]. The information on the children whose parents visited the CHC included age, gender, level of functioning [21, 22], and experienced health problems. Baseline measurements are described in more detail in the protocol article [11].

### ***RCT procedures measures***

During the execution of the RCT, the following variables were collected: number of invited and included participants, follow-up, reasons for dropout, measurement completion, missing data, and compliance to allocation. The first author documented occurring problems and adaptations made to the procedures to address these problems.

### ***Quantitative outcome measures***

Outcomes regarding accessibility and transfer of health information were measured six months after baseline. The search for an appropriate outcome measure, validated within the Dutch CHC-setting, led to the “Consumer Quality Index (CQI) for the preventive CHC” (based on the “Consumer Assessment of Healthcare Providers and Systems” (CAHPS®)) [23, 24]. To the CQI, fifteen applicable items from “Supplemental items on Health Information Technology” (HIT) (available via the CAHPS®-website) were added [24, 25]. Additionally, six original questions were developed and incorporated in the measurement procedures about relevant dimensions of the construct “access to healthcare and health information” (availability, accommodation, accessibility and acceptability) [26]. Those questions had answer options on a two to five-point scale [23, 24, 25]. Outcome measures are described in more detail in the protocol article [11].

### ***Qualitative measures***

Semi-structured interviews with CHC-professionals and parents were conducted to explore new perspectives on feasibility of the RCT-procedures.

To obtain relevant information from the CHC-professionals and parents, topic lists included questions about their view on the CHC, transfer of health information, and their experiences regarding their study participation. Topic lists were slightly customized for each individual participant, considering already available individual quantitative data.

During a “member check” focus group meeting, the most relevant findings and preliminary interpretations were presented to professionals that joined the first rounds of interviews. CHC-professionals were asked whether the findings and interpretations reflected their experiences and to further elaborate on and/or explain those findings [27, 28].

Both, the interviews and the subsequent focus group meeting were audio recorded (after explicit informed consent) and transcribed verbatim.

## **Analysis**

### ***Baseline characteristics of participants***

For baseline characteristics of CHC-professionals and parents, descriptive analyses were performed. Characteristics of CHC-professionals are presented for the total group that initially volunteered to participate as well as for the sub-group of professionals that included parents and actively participated during all phases within the RCT (table 6.1). Characteristics of parents are presented for the total group and each randomized group separate (table 6.2). Participant characteristics of the selected sub-samples for the qualitative part are presented in a separate table (table 6.3).



### ***RCT procedures measures***

For quantitative measurements, descriptive analyses were performed. Descriptive data and proportions are presented for recruitment rates, retention rates, response rates, compliance to the allocated interventions, measurement completion, as well as the amount and nature of missing values. As this was a feasibility study with a rather small sample size, missing values were not imputed.

### ***Quantitative outcome measures***

Outcome data on accessibility and transfer of health information are presented for the total group and intervention- and control-group separately. Variance within data is displayed by presenting the proportions per category for categorical variables and the mean and standard deviation (SD) for continuous variables, in relation to total range of the scales.

### ***Qualitative measures***

Qualitative analysis was performed by a multidisciplinary research team (MW, FF, CB, JZ and NB), embodying expertise in both quantitative and qualitative research. The team included three medical doctors with experience in CHC-practice, a health scientist and an epidemiologist.

Transcripts were analyzed using the software program NVivo 12 Pro [29].

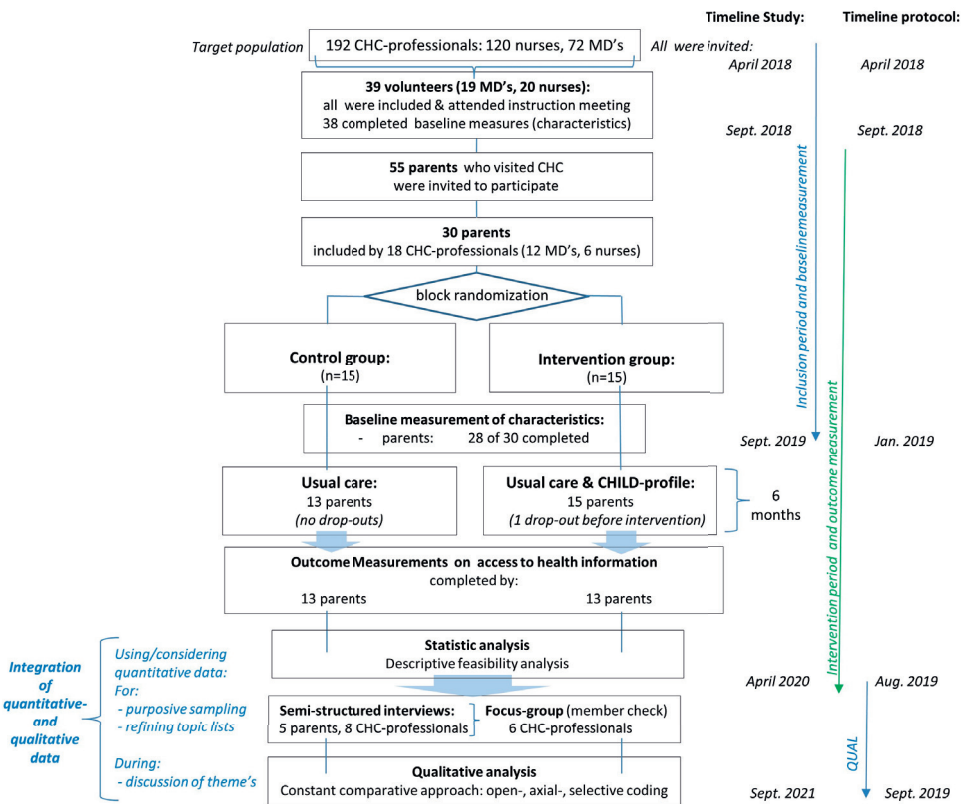
Two researchers (MW and JZ or NB or CB), independently explored and analyzed the data retrieved from the interviews/focus groups, after which they discussed the findings to reach consensus. After each round of analyzing 3 to 5 interviews, discussion took place within the whole research team to reflect on the data and analyses, to broaden the analytical scope if it seemed necessary, and to decide on further sampling or adapting topic lists. The first author (MW) wrote reflective memos. The qualitative analysis comprised of a constant comparative approach, which started with open coding of relevant text fragments during an inductive phase. After analyzing three interviews, axial coding was performed by arranging, renaming and/or relating codes to each other and identifying and pragmatically structuring categories. Then, during a more abductive phase, selective coding was conducted by the research team by relating the data to knowledge from literature and to the quantitative findings. During this phase, overarching core concepts and themes were identified and codes and categories were restructured [30, 31]. After concluding that no new and relevant elements were generated anymore, the team decided to describe the findings and validate them during a “member check” focus group meeting [27, 28] with CHC-professionals.

## Results

### Flow and baseline characteristics of participants

From the 192 eligible and invited CHC-professionals, 39 CHC-professionals volunteered to participate, of which 38 completed baseline measurements and started recruiting parents, adolescents and involved other caregivers.

In total 30 parents were included by 18 CHC-professionals. The participant flow throughout the study period is presented in Figure 6.1. As only one adolescent and one other caregiver were initially included, it was decided not to present their data.



**Figure 6.1: Participant flow throughout the study.**

- CHC: preventive Child Health Care
- MD: Medical Doctor

The total group of included CHC-professionals (n=38) and sub-group of professionals who included  $\geq 1$  parent (n=18) were both heterogeneous regarding discipline, target



group (age children), education level and experience (see table 6.1). On forehand, most participating professionals were known with and positive about the 360°CHILD-profile but had no experience with using it in daily practice.

CHC-professionals mostly used their computer and e-mail to provide information to parents and sometimes a tablet and/or WhatsApp for this purpose.

**Table 6.1: Baseline characteristics of participating CHC-professionals.**

Characteristics CHC-professionals	CHC-professionals		
	Total group (n=38) Number (%)*	Subgroup (n=18): (included ≥ 1 parent) Number (%)**	
<b>Discipline:</b>			
Nurse	20 (53)	6 (33)	
Medical Doctor	18 (47)	12 (67)	
<b>Age of target group they work with:</b>			
Children age 0-4y.	18 (47)	10 (56)	
Children age 4-18y.	20 (53)	8 (44)	
<b>Specific CHC-education:</b>			
No specific CHC-education	18 (47)	6 (33)	
Introduction course CHC	4 (11)	3 (17)	
Specialist CHC	16 (42)	9 (50)	
<b>Experience within CHC:</b>			
<2 years	5 (13)	2 (11)	
2-5 years	5 (13)	2 (11)	
5-10 years	0	0	
10-15 years	4 (11)	4 (22)	
>15 years	24 (63)	10 (56)	
<b>Providing parents with information in current care:</b>			
via computer	(almost) always	30 (79)	14 (78)
	rather often	6 (16)	2 (11)
	sometimes	2 ( 5)	2 (11)
	(almost) never	0	0
via tablet	(almost) always	5 (13)	2 (11)
	rather often	3 ( 8)	2 (11)
	sometimes	2 ( 5)	0
	(almost) never	28 (74)	14 (78)
via e-mail	(almost) always	6 (16)	4 (22)
	rather often	14 (37)	8 (45)
	sometimes	11 (29)	2 (11)
	(almost) never	7 (18)	4 (22)
via WhatsApp	(almost) always	0	0
	rather often	2 ( 5)	0
	sometimes	8 (21)	3 (17)
	(almost) never	28 (74)	15 (83)

<b>Use of technology during current consultations with parents:</b>			
via computer	(almost) always	27 (71)	15 (83)
	rather often	3 ( 8)	1 ( 6)
	sometimes	5 (13)	2 (11)
	(almost) never	3 ( 8)	0
via tablet	(almost) always	4 (10)	2 (11)
	rather often	1 ( 3)	0
	sometimes	4 (11)	1 ( 6)
	(most) never	29 (76)	15 (83)
via e-mail	(almost) always	4 (10)	3 (17)
	rather often	14 (37)	6 (33)
	sometimes	12 (32)	5 (28)
	(almost) never	8 (21)	4 (22)
via WhatsApp	(almost) always	0	0
	rather often	0	0
	sometimes	8 (21)	3 (17)
	(almost) never	30 (79)	15 (83)
<b>Opinion on current EMD</b>			
	satisfied	3 ( 8)	0
	rather satisfied	25 (66)	13 (72)
	rather unsatisfied	9 (24)	5 (28)
	unsatisfied	1 ( 2)	0
<b>Known with 360°CHILD-profile</b>			
	very known	4 (11)	2 (11)
	rather known	26 (68)	13 (72)
	little known	7 (18)	2 (11)
	not known	1 ( 3)	1 ( 6)
<b>Level of acquired experience with 360°CHILD-profile</b>			
	High	0	0
	rather high	3 ( 8)	1 ( 6)
	low	11 (29)	9 (50)
	no experience	24 (63)	8 (44)
<b>Opinion about possibility to use 360°CHILD-profile</b>			
	Positive	23 (61)	12 (67)
	rather positive	14 (37)	6 (33)
	rather negative	1 ( 2)	0
	negative	0	0
<b>Opinion about possibility to use E-health</b>			
	Positive	16 (42)	9 (50)
	rather positive	21 (55)	8 (44)
	rather negative	1 ( 3)	1 ( 6)
	negative	0	0
<b>Number of parents recruited/included:</b>			
	Recruited	Included	
	None	14 (37)	0
	one	13 (34)	11 (61)
	two-three	8 (21)	5 (28)
	four-five	1 ( 2)	2 (11)
	> five	2 ( 5)	0

\* Completed baseline measures

\*\* Completed baseline measures and included parents

**Table 6.2: Baseline characteristics of participating parents**

<b>Parents' Characteristics</b>	<b>Total group (n=28) Number (%)</b>	<b>Control group: Usual Care (n=13) Number (%)</b>	<b>Intervention group: Usual care and 360°CHILDoc (n=15) Number (%)</b>
<b>Relation to child:</b>			
Mother	27 (96)	13 (100)	14 (93)
Father	1 ( 4)		1 ( 7)
<b>Age:</b>			
18-25 years	1 ( 4)		1 ( 6)
25-35 years	14 (50)	7 (54)	7 (47)
35-45 years	13 (46)	6 (46)	7 (47)
<b>Number of children:</b>			
1 child	9 (32)	3 (23)	6 (40)
2 children	18 (64)	9 (69)	9 (60)
3-4 children	0	0	0
5 or more children	1 ( 4)	1 ( 8)	0
<b>Education<sup>a</sup>:</b>			
Low	5 (18)	2 (15)	3 (20)
Medium	12 (43)	4 (31)	8 (53)
High	11 (39)	7 (54)	4 (27)
<b>Birth country:</b>			
Of participating parent: the Netherlands	26 (93)	13 (100)	13 (87)
other than the Netherlands	2 ( 7)	0	2 (13)
Of other parent: the Netherlands	24 (86)	11 (85)	13 (87)
other than the Netherlands	4 (14)	2 (15)	2 (13)
<b>Perceived physical health</b>			
Good	24 (86)	10 (77)	14 (93)
Mediocre	3 (11)	2 (15)	1 ( 7)
Poor	1 ( 3)	1 ( 8)	
<b>Perceived mental health</b>			
Good	27 (96)	13 (100)	14 (93)
Mediocre	1 ( 4)		1 ( 7)
Poor	0		
<b>NOSIK<sup>b</sup> (parental stress)</b>			
Below average	9 (53)	4 (50)	5 (56)
Average	5 (29)	3 (38)	2 (22)
Above average	2 (11)	1 (12)	1 (11)
High	1 ( 6)		1 (11)
Missing values: (only applicable for age 2-13)	11	5	6
<b>Rating of CHC (on continuous scale of 0-10)</b>			
(mean, SD)	8.1 (1.0)	8.0 (1.1)	8.1 (0.9)
<b>Children's characteristics</b>			
<b>Gender</b>			
Boy	15 (54)	7 (54)	8 (53)
Girl	13 (46)	6 (46)	7 (47)
<b>Age</b>			
(mean in years, SD)(range of age)	3.9 (3.6)(0.3-2.3)	3.3 (2.7)(0.3-7.6)	4.5 (4.3) (0.3-12.3)
<b>CGAS-score<sup>c</sup></b>			
Functioning (mean, SD)	71.8 (16.7)	72.4 (18.5)	71.2 (15.6)

<b>STEP<sup>d</sup></b>			
Functioning (mean, SD)	12.1 (5.7)	11.0 (6.1)	13.1 (5.3)
Quality environment (mean, SD)	8.6 (4.3)	8.5 (4.7)	8.7 (4.0)
Level of needed care (mean, SD)	7.0 (3.9)	6.3 (4.2)	7.6 (3.7)
<b>Problems</b> (more domains possible)			
<i>Total children with one or more problem(s)</i>	19 (86)	8 (62)	11 (73)
- Psychosocial	6 (21)	3 (23)	3 (20)
- Physical	8 (29)	4 (31)	4 (27)
- Cognitive	6 (21)	2 (15)	4 (27)
- Family/upbringing	5 (18)	1 ( 8)	4 (27)
- Youth & Environment	6 (21)	2 (15)	4 (27)
<b>CHC-contacts</b> last 6 months			
1 time	11 (39)	7 (54)	4 (27)
2-3 times	11 (39)	4 (31)	7 (46)
> 3 times	6 (22)	2 (15)	4 (27)
<b>Other caregivers involved</b>			
	13 (46)	6 (46)	7 (47)
<b>Characteristics CHC-prof. involved with specific child/parent</b>			
<b>Discipline</b>			
Nurse	10 (36)	5 (39)	5 (33)
Medical Doctor	18 (64)	8 (61)	10 (67)
<b>Target group CHC</b>			
children age 0-4 year	19 (32)	9 (69)	10 (67)
children age 4-18 year	9 (68)	4 (31)	5 (33)

\* CHC: preventive Child Health Care

<sup>a</sup> Low education: no education up to and including low vocational training.

Medium education: basic vocational training through middle management/specialist training

Higher education: upper secondary education up to and including doctoral degree at research universities

<sup>b</sup> NOSIK: Dutch short version of parenting Stress Index; parents' perspective on an ordinal scale [20]

<sup>c</sup> CGAS: Children's Global Assessment Scale; professional's rating of child functioning: continuous scale (from 0 to 100) [21]

<sup>d</sup> STEP: Dutch standardised professional's rating on a reversed continuous scale of Functioning (from 30 to 6), Quality environment (from 25 to 5) and level of needed care (from 5 to 3) [22]

The subgroup of 18 CHC-professionals, who included parent(s) and thus actively participated during the intervention period, consisted of twelve medical doctors and six nurses. Baseline characteristics of CHC-professionals (of the total- and sub-group of professionals) are presented in table 6.1.

Participating parents were mostly mothers (1 father), Dutch (2 non-Dutch) and were rather positive to very positive about the provided care by CHC. The group of participating parents was heterogeneous regarding their education level, their children's level of functioning and experienced problems, and their parental stress. The baseline characteristics of parents in the intervention group were rather comparable with those in the control group and total group (see table 6.2).

Ten CHC-professionals were invited for the semi-structured interviews. Eight participated and two professionals declined (one was too busy; one did not provide a reason). Five of the participating parents were invited and participated in an interview. Characteristics of the parents and CHC-professionals are displayed in table 6.3.

**Table 6.3: Parents and CHC-professionals, participating in the semi-structured interviews.**

Parents	Child's age group	Child functioning (STEP <sup>a</sup> ) 6-30 (high-low)	Parental stress (NOSIK <sup>b</sup> )	Educational level	Birth country	Rating of CHC 0-10
1	4-18	11	< average	medium	other than the Netherlands	8
2	0-4	21	< average	high	the Netherlands	10
3	0-4	19	> average	low	the Netherlands	8
4	0-4	6	Average	high	the Netherlands	8
5	4-18	-	-	medium	the Netherlands	-
CHC-professionals	Target age group	Discipline	Experience in CHC	Satisfaction about EMD		
1	0-4	medical doctor	>15y	rather satisfied		
2 *	4-18	nurse	0-5y	rather unsatisfied		
3 *	0-4	nurse	>15y	rather satisfied		
4 *	4-18	medical doctor	>15	satisfied		
5 *	4-18	medical doctor	0-5 y	rather satisfied		
6 *	0-4	medical doctor	>15y	satisfied		
7 *	0-4	nurse	5-10y	-		
8	4-18	medical doctor	>15 y	satisfied		

<sup>a</sup> STEP: Dutch standardised professional's rating of child's functioning on a (reversed) continuous scale [22]

<sup>b</sup> NOSIK: Dutch short version of parenting Stress Index; parents' perspective on an ordinal scale [20]

\*also participated in member check focus group meeting.

All interviewed CHC-professionals were invited for a member check focus group meeting, of which six participated. Two professionals (table 3) could not attend the meeting due to other obligations.

## RCT procedures measures

### *Recruitment.*

Recruitment rates are presented in table 6.4. Indicated reasons for invited parents deciding not to participate were: too busy (n=11), concerns about privacy due to online availability of health data (n=3), no expected added value of the 360°CHILD-profile (n=2), language barrier (n=2), already disappointed regarding offered CHC-care (n=1), non-acceptance of randomization (n=1). For five invited parents, the reason not to participate could not be verified.

**Table 6.4: Recruitment-, response- and retention-rates, measure completion.**

<b>Recruitment rates</b>	<b>Percentage</b> (number included participants/ number invited to participate)
CHC-professionals	20% (39/192)
Parents	55% (30/55)
<b>Response rates</b>	<b>Percentage</b> (number returned/ number sent questionnaires)
Baseline measurements:	
- CHC-professionals	97 % (38/39) (regarding their own characteristics)
- Parents	100% (30/30) (child's level of functioning/experienced problems)
	96% (28/30)
Outcome measurements by parents	93% (26/28)
<b>Missing values</b>	<b>Percentage</b>
Baseline measurements:	
- CHC-professionals	0.2% (regarding their own characteristics)
- parents	5% (child's level of functioning/experienced problems)
Outcome measurements by parents	0.3%
	2%
<b>Retention rate</b>	<b>Percentage</b> (number of participants finishing RCT/number of included participants)
- CHC-professionals	44% (17/39) (regarding total group)
- parents	94% (17/18) (regarding subgroup of professionals who included parents)
	87% (26/30)

\*CHC: preventive Child Health Care

### *Response to measurements.*

For baseline measurements, response rates are presented in table 4. The reason for parents' non-response to outcome measurements was that they were too busy.



***Measurement completion.***

The percentages of missing values in returned questionnaires were between 0.2 and 5% (table 6.4). The missing values mostly concerned questions that were of low importance regarding the main topics of this study.

***Retention.***

Retention rates are presented in table 6.4. Loss to follow up of parents enclosed not responding to baseline questionnaire (n=2) or outcome questionnaire (n=1) and not responding to the invitation for the CHC-consultation in which the intervention would be performed (n=1). Within the group of CHC-professionals, one did not return the questionnaire at baseline, 20 could not start or finish the intervention period because they did not succeed in including a parent and/or quitted working at the CHC. Of the CHC-professionals who did include a parent and started the intervention period, 94% finished their tasks within RCT.

***Compliance to allocated intervention.***

There was one case of non-compliance to intervention in experimental group. The mother cancelled her CHC-appointment after randomization.

***Adaptation of RCT-procedures.***

The inclusion of parents remained behind schedule. After prolonging the original recruitment period (of four months) with two months, 15 CHC-professionals were active in recruiting parents and 16 parents signed informed consent. Therefore, the recruitment period was prolonged with another six months and three additional activities were executed to stimulate recruitment: 1) A poster with information about the study was distributed; 2) Four students from the Maastricht Medical School were trained to support CHC-professionals during recruitment by observing consultation hours and providing eligible parents with information on the study right after the visit; and 3) CHC-professionals were provided with extra information, reminders and advice (via e-mail) on how to enhance recruitment.

The 360°CHILD-profile appeared to be not yet fully integrated within the EMD and online CHC-portal for parents. Therefore, the personal 360°CHILD-profiles had to be completed by hand by the researcher and an internal part of the CHC-website (secured with sms-authentication) had to be used to provide parents with online access to their child's 360°CHILD-profile.

**Table 6.5: Outcome of Consumer Quality Index for parents.**

Items Consumer Quality Index for parents	Answer options	Total group N=28 Number (%)	Intervention group (CHILD-profile) n=15 Number (%)	Control group n=13 Number (%)
1. Before the CHC-visit, was it clear for you what to expect from the consultation?	No	4 (15)	3 (23)	1 (8)
	Yes	22 (85)	10 (77)	12 (92)
	Missing values	2	2	
2. Did you receive advice during the visit?	No	6 (23)	4 (31)	2 (15)
	Yes	20 (77)	9 (69)	11 (85)
	Missing values	2	2	
3. Was the advice from CHC applicable in your family situation?	No	0	0	0
	Yes	20 (100)	9 (100)	11 (100)
	Not applicable	8	6	2
4. In what extend was it a problem to reach contact with CHC by telephone?	A big problem	1 (6)	1 (13)	0
	A small problem	4 (23)	3 (37)	1 (11)
	No problem	12 (71)	4 (50)	8 (89)
	Not applicable	9	5	4
	Missing values	2	2	
5. In the past 6 months, did you send CHC an e-mail to ask CHC a question?	No	22 (85)	13 (100)	9 (69)
	Yes	4 (15)		4 (31)
	Missing values	2	2	
6. Did you timely receive a reply on your mail?	Never	0		0
	Sometimes	1 (25)		1 (25)
	Often	0		0
	Always	3 (75)		3 (75)
	Not applicable	24	15	9
7. Did you receive an answer to your question?	Never	0		0
	Sometimes	1 (25)		1 (25)
	Often	0		0
	Always	3 (75)		3 (75)
	Not applicable	24	15	9
8. Did you have contact with a nurse and/or a MD?	No	13 (48)	5 (38)	8 (67)
	Yes	12 (52)	8 (62)	4 (33)
	Missing values	3	2	1
9. Was the MD/nurse kind?	No	0	0	0
	Yes	12 (100)	8 (100)	4 (100)
10. Was the MD/nurse competent?	No	0	0	0
	Yes	12 (100)	8 (100)	4 (100)
11. Did you experience room to ask questions?	No	0	0	0
	Yes	12 (100)	8 (100)	4 (100)
12. Did you experience room to share your view?	No	0	0	0
	Yes	12 (100)	8 (100)	4 (100)
13. Did the MD/nurse provide good answers to your questions?	No	0	0	0
	Yes	12 (100)	8 (100)	4 (100)
14. Did the MD/nurse provide comprehensible explanation?	No	0	0	0
	Yes	12 (100)	8 (100)	4 (100)

15. Was the MD/nurse well informed about the medical history of the child?	No	1 (10)	0	1 (25)
	Yes	9 (90)	6 (100)	3 (75)
16. Were you referred well to other caregivers, if needed?	No	1 (7)	1 (13)	0
	Yes	14 (93)	7 (87)	7 (100)
	Not applicable	13	7	6
16. Did you have contact with other caregivers with regard to your child?	No	12 (48)	7 (58)	5 (39)
	Yes	13 (52)	5 (42)	8 (61)
	Missing values	3	3	
17. Did CHC collaborate well with other caregivers?	No	3 (12)	2 (17)	1 (8)
	Yes	22 (88)	10 (83)	12 (92)
	Missing values	3		
18. Are you sufficiently informed about the extra service the CHC offers?	No	11 (46)	6 (55)	5 (38)
	Yes	13 (54)	5 (45)	8 (62)
	Missing values	4	4	
19. Would you desire a broader service to be offered by CHC?	Yes	0	0	0
	No	24 (100)	11 (100)	13 (100)
	Missing values	4		
20. Was it clear for you what you could expect from CHC?	No	4 (15)	3 (23)	1 (8)
	Yes	22 (85)	10 (77)	12 (92)
	Missing values	2	2	
21. Would you recommend CHC for other parents?	Definitely not	0	0	0
	Probably not	2 (8)	1 (8)	1 (8)
	Probably yes	16 (64)	7 (59)	9 (69)
	Definitely yes	7 (28)	4 (33)	3 (23)
	Missing values	3	3	
22. Overall score for CHC		(mean, SD)	(mean, SD)	(mean, SD)
	Score 0-10	7.68 (1.15)	7.83 (0.94)	7.54 (1.33)

### Quantitative outcome measures

Outcomes of the used outcome measures (Consumer Quality Index (CQI), supplemental items on Health Information Technology (HIT) and additional original questions on accessibility of health-care and information) showed that for the majority of the items, 75-100% of the parents chose positive answer options, while negative answer options were chosen by 0-25% of the parents (see table 6.5-6.7). Items 6-15 out of the HIT were appointed as not applicable by the majority of parents (table 6).

**Table 6.6: Outcome of supplemental Health Information Technology-items from the CAPHS©-website**

<b>Supplemental items from Health Information Technology</b>	<b>Answer options</b>	<b>Total group Number (%)</b>	<b>CHILD- profile group Number (%)</b>	<b>Control group Number (%)</b>
1. Did medical doctor/nurse use a computer, smartphone or tablet used during visit?	No	10 (38)	7 (54)	3 (23)
	Yes	16 (62)	6 (46)	10 (77)
	Missing values	2	2	
2. Has medical doctor/nurse looked up information?	No	4 (27)	0	4 (40)
	Don't know	5 (33)	2 (40)	3 (30)
	Yes	6 (40)	3 (60)	3 (30)
	Not applicable	13	10	3
3. Did medical doctor/nurse show information?	No	3 (19)	0	3 (30)
	Yes	13 (81)	6 (100)	7 (70)
	Not applicable	12	9	3
4. Was the use of the computer useful?	No	0	0	0
	Yes, a little bit	3 (19)	0	3 (30)
	Yes, absolutely	13 (81)	6 (100)	7 (70)
	Not applicable	12	9	3
5. The use of the computer made communication:	Harder	0	0	0
	Not harder/not easier	7 (44)	1 (17)	6 (60)
	Easier	9 (56)	5 (83)	4 (40)
	Not applicable	12	9	3
6. Did CHC make information online accessible?	No:	9 (35)	3 (23)	6 (46)
	Don't know:	11 (42)	4 (31)	7 (54)
	Yes	6 (23)	6 (46)	0
	Missing values	2	2	0
7. Did you look up information during the last 6 months?	No	5 (71)	5 (71)	0
	Yes	2 (29)	2 (29)	0
	Not applicable	21	8	13
8. If so, how often did you look up information?	1-2x	1 (50)	1 (50)	0
	3-4x	1 (50)	1 (50)	0
	5-6x	0	0	0
	>6x	0	0	0
	Not applicable	26	13	13
9. How easy was it to find information?	Very easy	1 (50)	1 (50)	0
	Rather easy	1 (50)	1 (50)	0
	Not very easy	0	0	0
	Not easy at all	0	0	0
	Not applicable	26	13	13
10. How understandable was the given information?	Very	0	0	0
	Rather	2 (100)	2 (100)	0
	Not very	0	0	0
	Not at all	0	0	0
	Not applicable	26	13	13

11. To whom did you show the information?	Nobody	2 (100)	2 (100)	0
	Family member(s)	0	0	0
	Caregiver(s)	0	0	0
	Other(s)	0	0	0
	Not applicable	26	13	13
12. Did CHC give you access to conclusions?	No:	15 (56)	5 (38)	10 (77)
	Don't know:	10 (40)	7 (54)	3 (23)
	Yes:	1 (4)	1 (8)	0
	Missing values	2	2	0
13. How did CHC give you access to conclusions?	On paper	1 (100)	1 (100)	0
	Via internet	0	0	0
	Via email	0	0	0
	Other way	0	0	0
	Not applicable	27	14	13
14. Did you read the conclusions?	No	0	0	0
	Yes	1 (100)	1 (100)	0
	Not applicable	27	14	13
15. How understandable were the conclusions?	Very	1 (100)	1 (100)	0
	Rather	0	0	0
	Not very	0	0	0
	Not at all	0	0	0
	Not applicable	27	14	13

### Qualitative measures

During qualitative analysis, while reflecting on both qualitative and quantitative data to gain a deeper understanding of the quantitative findings regarding feasibility of performing an RCT, five categories emerged: "Interest, willingness and self-efficacy regarding study participation", "Emerging difficulties with recruitment of parents by CHC-professionals", "Overall study participation, randomization and intervention", "Points for improvement of RCT-procedures" and "Outcome measures on accessibility and transfer of health information".

For each category, findings are described and related quotes are presented in a box.

"Interest, willingness and self-efficacy regarding study participation"

Quantitative findings showed that within the given period, a sufficient number of CHC-professionals volunteered to participate in the study. During the interviews, CHC-professionals and parents said they were interested in the 360°CHILD-profile and willing to help. Professionals were satisfied about clearness of the provided instructions and, on forehand, felt capable to recruit enough parents and perform their study tasks.

**Table 6.7: Outcome of added original questions on accessibility of health-care and information.**

Additional questions	Answer options	Total group (n=28)	CHILD-profile group Number (%)	Control group Number (%)
		Number (%)		
1. I know for what questions/problems I can contact the CHC	"I totally disagree"	0	0	0
	"I disagree"	3 (12)	2 (15)	1 (8)
	"I do not agree/not disagree"	0	0	0
	"I agree"	17 (65)	8 (62)	9 (69)
	"I totally agree"	6 (23)	3 (23)	3 (23)
	Missing values	2	2	
2. It is clear for me how to contact CHC for questions etc.	"I totally disagree"	0	0	0
	"I disagree"	1 (4)	0	1 (8)
	"I do not agree/not disagree"	2 (7)	1 (8)	1 (8)
	"I agree"	14 (54)	8 (61)	6 (46)
	"I totally agree"	9 (35)	4 (31)	5 (38)
	Missing values	2	2	
3. The way I get advice/information from CHC fits my needs	"I totally disagree"	0	0	0
	"I disagree"	1 (4)	0	1 (8)
	"I do not agree/not disagree"	4 (15)	0	4 (31)
	"I agree"	18 (69)	11 (85)	7 (53)
	"I totally agree"	3 (12)	2 (15)	1 (8)
	Missing values	2	2	
4. If I have questions, it is easy for me to get in contact with CHC.	"I totally disagree"	0	0	0
	"I disagree"	1 (4)	1 (8)	0
	"I do not agree/not disagree"	4 (15)	2 (15)	2 (15)
	"I agree"	16 (62)	7 (54)	9 (70)
	"I totally agree"	5 (19)	3 (23)	2 (15)
	Missing values	2	2	
5. The CHC radiates trust and a positive ambiance.	"I totally disagree"	0	0	0
	"I disagree"	1 (4)	0	1 (8)
	"I do not agree/not disagree"	6 (23)	4 (31)	2 (15)
	"I agree"	13 (50)	6 (46)	7 (54)
	"I totally agree"	6 (23)	3 (23)	3 (23)
	Missing values	2	2	
6. I am a person who, when having concerns and/or questions, quickly asks for advice and/or help.	"I totally disagree"	0	0	0
	"I disagree"	6 (23)	3 (23)	3 (23)
	"I do not agree/not disagree"	7 (27)	2 (15)	5 (38)
	"I agree"	10 (38)	6 (47)	4 (31)
	"I totally agree"	3 (12)	2 (15)	1 (8)
	Missing values	2	2	

**Box 1: Quotes related to “Interest, willingness and self-efficacy regarding study participation”.**

Parent 2:

*“I was very interested and it was really nice to see the mapped health information”.*

CHC-professional 4:

*“I see added value and my colleagues also have a warm heart for the 360°CHILD-profile”.*

CHC-professional 1:

*“After the instruction meeting, I thought it would be very easy because every professional only had to find a few parents”.*

CHC-professional 8:

*“My thought was that it should work, I will at least do that. That thought came from a feeling of commitment, dedication and seeing the value of the 360°CHILD-profile.”*

**“Emerging difficulties with recruitment of parents by CHC-professionals”**

During the RCT, recruitment of parents by CHC-professionals appeared to be seriously hindered. Most CHC-professionals mentioned a high workload due to a lack of staff and time. They prioritized tasks directly related to the regular care of children. Some professionals had a clear picture about the specific target group to recruit while others felt a bit uncertain about that. Some CHC-professionals mentioned that the 360°CHILD-profile was new for them, as it was not yet fully integrated within the EMD. This made it harder to inform parents about the 360°CHILD-profile and made parents reluctant to participate.

A small number of professionals mentioned they felt some reluctance to burden parents who already experience substantial problems concerning their child’s upbringing. A few CHC-professional mentioned they tended to ask parents they were on good terms with.

**Box 2: Quotes related to:  
“Emerging difficulties with recruitment of parents by CHC-professionals”**

CHC-professional 3:

*“It faded away from my attention and due to low staff capacity, I already had to do extra work and couldn’t find time to fill in a questionnaire. That was frustrating.”*

CHC-professional 7:

*"My job is very busy and at the end of the day I have to prioritise. Then I mostly choose finishing urgent tasks related to clients."*

*"The 360°CHILD-profile is still new and unknown for parents, which made them reluctant. Once it would be fully integrated within CHC, I'm sure parents would like it."*

CHC-professional 2:

*"During implementation, we as professionals should be provided with extra time, but after a while it will make us finish work faster".*

CHC-professional 1:

*"I did not want to ask parents, who experienced severe problems because I wondered if they would have time for it and if the burden would be in balance with the added value for them."*

**"Overall study participation, randomization and intervention"**

Qualitative data showed congruence with the positive quantitative findings on retention, randomization and intervention. Parents and CHC-professionals mentioned the study procedures were clear and easy. They were positive about the provided communication and reminders by researchers. Parents who participated in the study said that the randomization process was clear and acceptable. However, one of the recruited parents decided (before randomization) not to participate because she would not know if she would receive the 360°CHILD-profile during the study period. Parents appreciated the intervention and, once they found time for their study tasks, they did not perceive these tasks as a major burden.

**Box 3: Quotes related to**

**"Overall study participation, randomisation and intervention".**

Parent 3:

*"The study participation did not burden me. It was actually very nice that my child's health information is presented on a profile."*

*"It was clear for me that I would receive the 360°CHILD-profile immediately of after 6 months. I would not know why that would be a problem."*

Parent 1:

*"It all was clear and went well. No difficulties."*



CHC-professional 5:

*"The instructions were very clear and it was nice to receive the instruction map. Very professional"*

CHC-professional 8:

*"Presenting the 360°CHILD-profile went well. It fits my way of working and it was clear for parents."*

CHC-professional 6:

*"My participation didn't cost me much extra time. It actually went very well"*

#### **"Points for improvement of RCT-procedures"**

The support of trained students, which was initiated when recruitment appeared to be difficult, was very much appreciated and improved recruitment. Qualitative data also revealed additional considerations for improving RCT-procedures (like using social media and invitation letters for regular CHC-visits, rehearse presenting the 360°CHILD-profile shortly with researcher and/or colleagues, and sufficiently facilitate professionals to familiarize with the intervention).

#### **Box 4: Quotes related to "Points for improvement of RCT-procedures"**

Parent 5:

*"You could also use social media or newsletters from schools to recruit parents."*

CHC-professional 5:

*"Maybe inform all parents by a letter, prior to the CHC-visit. Then, during the visit I can ask if they did read the letter."*

CHC-professional 3:

*"The student's support was great, a big relief. When she informed parents, I could do other tasks"*

CHC-professional 4:

*"Well, presenting the 360°CHILD-profile for the first time felt challenging. It would have been a good idea if I had taken the researcher up on her offer to firstly discuss it together."*

CHC-professional 6:

*"If we would have rehearsed with the 360°CHILD-profile within small groups of colleagues, that would have yielded more binding with the innovation and motivation to use it"*

CHC-professional 2:

*"Take time for implementation, so professionals can familiarize with the 360°CHILD-profile."*

CHC-professional 1:

*"Keep evaluating the 360°CHILD-profile during implementation."*

**"Outcome measures on accessibility and transfer of health information"**

Interviewed parents mentioned that completing the questionnaire was only a little effort. They found the questionnaire acceptable and comprehensible. A few parents explained why they chose certain answer options. However, not all parents could explicitly remember which questionnaire it concerned. During the study period, they also received other questionnaires related to usual care and related to a new digital parent portal.

**Box 5: Quotes related to "Outcome measures on accessibility and transfer of health information".**

Parent 4:

*"The questionnaire was all right: nothing difficult or taxing and I finished it pretty quickly."*

Parent 2:

*"I completed several questionnaires for the CHC. I can't remember which one came from you."*

*"On the question if CHC made health information available via a website I chose answer option "no". But, yes indeed, the 360°CHILD-profile was online available. I got an e-mail with a link and code and got secured access to an online portal. I would call that an online environment and not via a website."*

Parent 3:

*"Yes, I chose answer option "no" for the question if I have had contact with the CHC-nurse or medical doctor. I thought that that only counted for extra contacts when something was wrong, not a regular CHC-contact."*

## Discussion

This feasibility RCT was a first step towards evaluating 360°CHILD-profile's effectiveness. It provided insight in the complexity of performing an RCT within the organizational CHC-context. The use of a Mixed Methods approach enabled to thoroughly investigate feasibility of RCT-procedures (objective 1) and the applicability of potential outcome measures for

studying 360°CHILD-profile's impact on access and transfer of health information (objective 2).

With regard to the first objective, positive findings were generated on practical feasibility of the used randomization schedule, measurements and experimental intervention (the 360°CHILD-profile) within the CHC. However, recruitment of parents by CHC-professionals appeared to be problematic, and was hindered by organizational factors within the CHC-context.

Regarding the second objective, the used outcome measures showed skewed results consisting of high percentages of positive scores in both groups. In addition, outcomes revealed low applicability of, by the researchers beforehand assumed as relevant, items on accessibility and transfer of health information (table 6, HIT-items 6-15).

Overall, integrative findings revealed that conducting a robust RCT-design within the given context will probably be even more complex, time-consuming and costly than initially expected.

This research project identified several hindering organizational factors like the organizational structure (within each geographically sub-region, one medical doctor and one nurse are responsible to provide care to all the children living in that sub-region), which influences the applicability of the preferred randomization method. Next, the research project (which concerned both 360°CHILD-profile's implementation and evaluation) was insufficiently prioritized and facilitated by CHC-management, which hindered recruitment of parents by CHC-professionals.

### **Randomization**

The inevitable choice of randomization on the level of individual parents, led to the possibility that CHC-professionals who included more parents, were to perform both the usual care and the experimental intervention. Although within this feasibility study, participating professionals did not perceive this as problematic, this situation should be avoided in a future RCT as much as possible. Cluster randomization might be required and consequently, more complex analysis and much larger sample sizes.

### **Emerging difficulties with recruitment of parents by CHC-professionals**

The CHC-professionals seemed motivated and felt capable to recruit parents. Although motivation and self-efficacy are facilitators for recruitment [32, 33, 34], in daily practice, recruitment appeared to be more problematic than expected by the CHC-professionals. It could be that, on forehand, professionals overestimated their motivation and self-efficacy and tended towards socially desirable answers. However, study findings also

revealed hindering contextual factors like insufficient prioritization and facilitation by CHC-management. This led to a perceived high workload and prioritization of daily care tasks by CHC-professionals. They tended to postpone tasks related to participating in this study, which they seemed to perceive as tasks, less fitting to their job profile. CHC-professionals were not yet familiar with this intervention due to the lack of a technical integration of the 360°CHILD-profile within the EMD.

It was known that the used recruitment strategy (CHC-professionals recruiting parents) was not the optimal option [35]. However, researchers anticipated that recruiting the restricted number of one to two parents by each professional should be doable. This was enforced by the, on forehand, enthusiastic reactions and positive expectations of participating professionals. Study participation was expected not to be perceived as burdensome because the intervention was assumed to fit the CHC-working method based on former results [1, 6]. Nevertheless, some professionals appeared to expect the whole research process to be a possible burden to parents who experienced problems around their child's upbringing. They seemed reluctant to ask parents in problematic situations to participate in the study. Next, qualitative data led to the impression that CHC-professionals preferred inviting parents they were in good terms with. These findings provided insight in how professionals' relationship with parents, as their caregivers, influenced recruitment, potentially leading to selection bias.

This study enabled to adopt an alternative and more successful strategy for recruiting parents; deploying trained research staff for this task. Research staff, independent from CHC-care, is likely more equipped to support parents during their decision-making process whether to participate and sign informed consent [32, 35]. However, it must be taken into account that for large studies, this strategy requires substantial more research staff and a complex planning.

### **Outcome measures**

Outcome measures revealed severe skewness to one direction (positive answer options) which might limit the interpretation of data. Moreover, the number of relevant items on accessibility and transfer of health information appeared to be rather limited and oftentimes not applicable for a substantial part of the participants. The used outcome measures were validated within the CHC to measure accessibility of the CHC [11, 23]. This theoretical construct might have been formulated with too less detail to be sufficiently applicable for evaluating 360°CHILD-profile's impact on the access and transfer of health information within CHC.

## **Strengths and limitations**

Integration of quantitative and qualitative data enabled to strengthen the validity of findings through triangulation [36]. More approaches were incorporated to strengthen trustworthiness of the qualitative findings [36]. To enhance researchers' reflexivity during qualitative analysis, the original research team (MW, CB, FF) was expanded by two researchers, external of the project so far (JZ, NB). They often played a role as critical reviewer, questioned methods and researchers' interpretations and assumptions. Researchers repeatedly returned to the raw data and memos to search for consistent and/or disconfirming data regarding interpretations and categories. Finally, participants were given the opportunity to correct and react on researchers' interpretations (member check focus group).

The rather heterogeneous group of parents and CHC-professionals and purposive sampling for interviews enabled to consider a variety of perspectives. Insight in these perspectives led to deeper understanding of quantitative data and identification of hindering contextual factors within the CHC-organization and uncertainties concerning applicability of outcome measures. Moreover, valuable qualitative data led to better insight in how organizational factors influenced RCT-procedures and how to improve these procedures. The engagement of stakeholders, consideration of context, identification of uncertainties and refinement of theory are elements that are identified as core elements for evaluating complex interventions [37]. These core elements are described in a recent publication of Skivington, who presents a new framework for development and evaluation of complex interventions [37].

Although valuable qualitative data were generated within this study, this was rather limited with regard to gaining deeper understanding on the outcomes of the used outcome measures. Probably this was influenced by the time passed between measure completion and the interviews and parents' confusion with other questionnaires that were send out during the same period. During qualitative analysis, it became clear that the time-span between the active participation of the parents and the interview more often led to rather a limited extend of memories of parents about their study participation and questionnaires. Therefore, it was decided that performing a member check focus group with parents would not yield substantial new, more in-depth insights regarding this phase of the evaluation process.

Other limitations were the rather small study population and the fact that participants might have been relatively more positive about CHC and the 360°CHILD-profile.

## Future research

This study revealed the importance of considering the specific CHC-context when designing future research. This organizational context requires a more complex randomization strategy and, consequently, larger sample sizes. Next, an active role of management should not be underestimated in order to facilitate CHC-professionals sufficiently. Preferably, professionals should be provided with sufficient time, recurrent communication, pro-active and continuous support, training and opportunities to rehearse study tasks with colleagues [33, 34]. Thereby, management should properly prioritize the ICT-integration within the currently used EMD, which helps professionals to familiarize with the 360°CHILD-profile. Foremost, it is essential that professionals are capable to perform the intervention, while recruitment of parents can and preferably should be performed by trained research staff, independent from CHC-care.

Finally, further evaluation of 360°CHILD-profile's implementation and future effectiveness within CHC requires a thorough search for and/or development of appropriate outcome measures. Potential measures must be extensively investigated by using qualitative and subsequently quantitative clinimetric methods.

During next implementation phases, the focus will be firstly on identifying outcome measures for valid assessment of 360°CHILD-profile's impact on the accessibility and transfer of health information. After full implementation, additional outcome measures should be identified: outcome measures that will be applicable for evaluating expected potential impact of the 360°CHILD-profile on the quality of shared decision-making and most importantly the complex preventive clinical reasoning within the CHC [1]. Namely, the 360°CHILD-profile is designed to enable parents to be more actively involved in decision-making processes and to intuitively guide thinking processes of all stakeholders in line with the biopsychosocial concept of health and personalized health care [1, 38].

Based on the integrative findings of this pragmatic feasibility RCT, it should be questioned whether an RCT is the most appropriate design for the future steps of the 360°CHILD-profile's implementation and evaluation process within CHC-practice. The research group of Skivington supports the questioning of an RCT-design within the setting of evaluating complex interventions [37]. The strive for executing an RCT for gaining evidence on effectiveness should not lead to postponing and/or hindering implementation of promising interventions. In case of the 360°CHILD-profile, consistent positive findings on usability and benefits for CHC-practice so far, justify a next step in the implementation process [37]. For complex interventions and settings, like the 360°CHILD-profile and the CHC-setting, it might be equally, or even more essential to build a theory on how the intervention impacts practice and how the complex context influences outcomes [37]. This asks for a deliberate, flexible approach and consideration of alternative designs. A quasi-experimental

design and Mixed Methods process evaluations must be considered with a focus on generating outcomes on implementation and/or impact in practice [37]. Gaining input from all stakeholders is important to enable identification of key uncertainties, mechanisms of change, important contextual factors and relevant outcome measures. Foremost, for complex interventions, knowledge should be generated that is needed for taking decisions on if and how to proceed the implementation and evaluation process [37].

### **Conclusions**

This Mixed Methods feasibility RCT was an essential and robust step within the iterative impact oriented downstream validation process of the 360°CHILD-profile. The study revealed how organizational factors within the CHC-context interfere with the execution of an RCT with the aim of generating valid outcomes regarding intended goals. This context would require a more complex randomization strategy and the deployment of trained research staff for recruiting parents. Measures, potentially for evaluating 360°CHILD-profile's implementation and effectiveness must be further explored and thoroughly piloted before proceeding the evaluation process.

Overall, integrative findings led to questioning the RCT as the most appropriate design for evaluating 360°CHILD-profile's effectiveness within the CHC-context. Preparing for and executing an RCT is expected to be very complex and time-consuming and could hinder implementation of this promising innovation with obvious benefits for CHC-practice. Alternative designs and Mixed Methods research must be considered during next implementation phases. The focus should be on generating valuable knowledge for deciding if and how to proceed to the next phase within the implementation and evaluation process.

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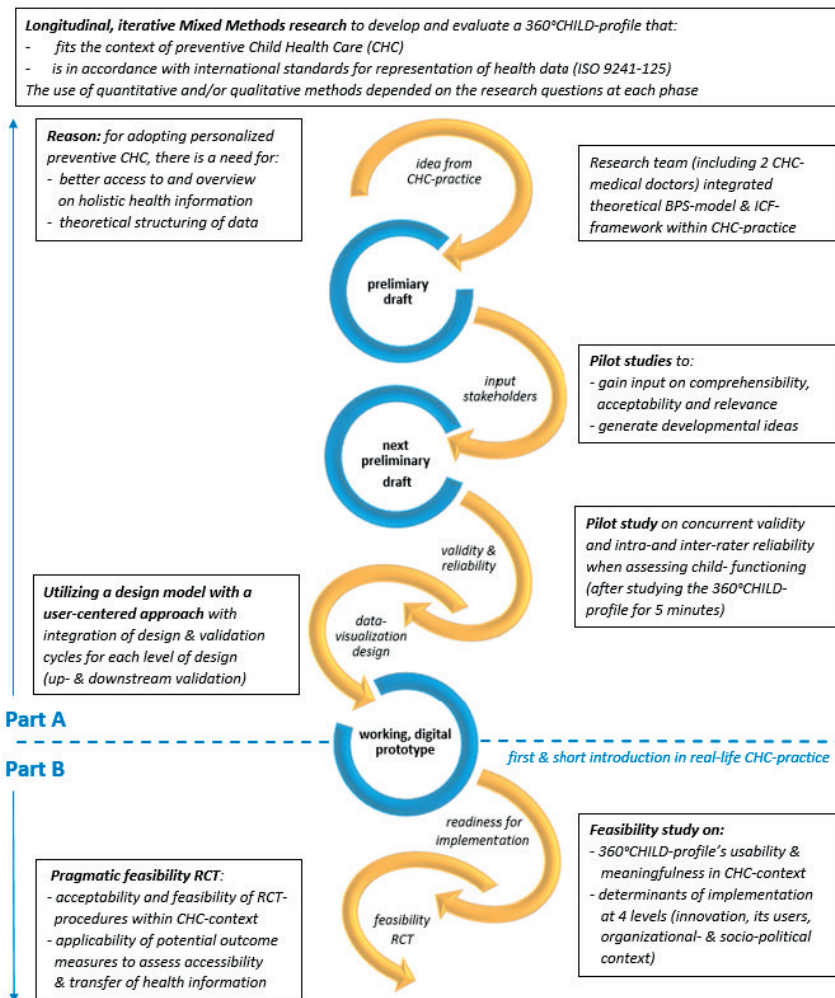
**CHAPTER 7**



# General discussion

## Reflections on main findings

The goal of this PhD-trajectory was to develop and evaluate an innovative tool for visualizing and ordering personalized holistic information on child and adolescent health. It was intended to deliver a 360°CHILD-profile that would fit the context of the preventive Child Health Care (CHC) and support a transformation towards a personalized preventive CHC (see introduction). The 360°CHILD-profile's longitudinal Mixed Methods research project consisted of part A (development) and part B (evaluation). For an overview of the project, see figure 1. Reflections on the main findings will be presented in separate paragraphs for part A and B.



**Figure 7.1: the longitudinal Mixed Methods development and evaluation process of the 360°CHILD-profile.**

**Part A: Data-visualization allows immediate access to holistic personal health information.**

The main goal of part A of this thesis was to develop a reliable, valid and usable dashboard that visualizes integral health information in line with the biopsychosocial perspective on health. The ICF (International Classification of Functioning, Disability and Health for Children and Youth) was used to structure the health data [1,2]. It was intended to deliver a tool that would support the early detection of a “growing into deficit” and the adoption of the concepts of a personalized preventive CHC. The 360°CHILD-profile was designed to support preventive and personalized clinical reasoning processes and shared-decision making. Within this context, several sub-questions were formulated. The following paragraph, discusses an integral vision on the results of part A.

Outcomes of research within part A (chapter 3) demonstrated that, by means of data-visualization, immediate access to personalized holistic health information can be attained. The unique collaboration of health care researchers with experts in the field of data-visualization and human-computer interaction led to a synergy and novel approaches for developing a solid visualization tool. The fruitful collaboration offered optimal ground for displaying holistic health data in one image in such a way that it is accessible, appropriately represents children’s individual health situations and shows the coherence between health domains in line with the ICF [2].

Besides considering the expertise of researchers from different disciplines, the perspectives of potential users also were taken into account throughout the development process. Relevant stakeholders (CHC’s professionals and management, as well as parents and youth) could be involved already from very early stages of development.

Actually, the initiative for optimizing overview on holistic data on relevant health variables came from a professional (MW), working within CHC-practice. Together with the research team, including experienced CHC-medical doctors, the initiative resulted in immediate integration of theoretical knowledge on the relevant frameworks (the biopsychosocial model and the ICF) within the CHC’s theoretical background and CHC-practice [1-4].

The immediate integration of different theoretical backgrounds and experience from practice enabled the research team to quickly convert the initial idea for summarizing health data in one image in a preliminary draft that was presented to the relevant stakeholders. Timely insight could be gained in their views on the preliminary representation of CHC-health information.

During the iterative development process, a Mixed Methods design was executed to evaluate whether it was justified to proceed the project and how to set up the next step

in the development, implementation and evaluation process. The use of quantitative and/or qualitative methods depended on the research questions that were relevant for each phase of the project. Qualitative methods were used to generate informal ideas on how to develop, implement and/or evaluate the 360°CHILD-profile. Quantitative methods enabled to test hypotheses that were based on research questions (of part A) so far. Subsequently, qualitative methods also were used to gain deeper understanding of quantitative findings and further explore stakeholders' views and expectations.

Stakeholders' views on the comprehensibility and acceptability of the preliminary draft and its potential relevance for the CHC-context resulted in a lot of developmental ideas for a dashboard that would fit the CHC-context and needs of its potential users.

The promising results of a pilot study on comprehensibility, acceptability and relevance and a pilot study on aspects of reliability and validity of a preliminary version of the 360°CHILD-profile, justified the continuation of development (chapter 2).

During this phase, the research team felt challenged by the question how to realize an accessible visualization of holistic data on relevant health variables that appropriately represents a child's health situation and the interrelatedness between different data. This perceived challenge, as well as researchers' commitment to deliver a functional and meaningful dashboard for CHC-practice, led to the crucial choice to invite data-visualization experts to join the research team.

The data-visualization experts informed the health care researchers about efficient opportunities that data-visualization can offer health care. Data visualization design enables to set up a clear framework and make data from many variables accessible at a glance. Thereby, data visualization allows users to process a high amount of information simultaneously [5]. In this way, it facilitates an efficient transfer of holistic health information to parents and youth. By theoretically structuring health variables, the dashboard displays the interrelatedness of variables from different health domains in a way that it intuitively guides preventive clinical reasoning and thought processes in line with the relevant theoretical perspective (the ICF and related preventive and personalized health perspectives). The registries of currently used EMD's are based on a standard dataset, established at a national level (the Dutch "Basisdataset" for CHC) [6], which is not based on a theoretical model. Moreover, it is not in line with the "growing into deficit" thinking and the biopsychosocial concept of health.

A significant point is that the data-visualization experts also alerted the researchers to the fact that the used EMD's within the present CHC do not conform to the international standards for representation of health information (ISO 9241-125, 2017) [7]. The perceived

usability problems with the current EMD partly could be caused by not being in line with these ISO standards. The currently used EMD's within the CHC are in line with some standards, however only concerning informative security [8] and the electronic exchange of health data [9].

While designing the 360°CHILD-profile, researchers also explicitly focused on conforming to the important ISO 9241-125 standards for representation of health information to enable achieving an appropriate and accessible representation of a child's health situation. Thereby, design-theoretical aspects were used as an important input to achieve a design that intuitively guides the simultaneous thinking processes. Simultaneous thinking processes are required for preventive clinical reasoning, performed at early stages of a "growing into deficit" as well as shared decision-making within a personalized preventive CHC (which is personal, preventive, predictive and actively involves care users) (chapter 3) [5].

Besides using a Mixed Methods methodology, the data-visualization experts introduced a user-centered design approach to actively involve relevant stakeholders during the design process [10,11]. In the case of the together with data-visualization experts developed working prototype of the 360°CHILD-profile, this approach included methods such as observations of re-enacted CHC-consultations, combined with interviews and thinking aloud methods, eye-tracking and schematic summative representations of data for team-based analyses (chapter 3).

Finally, yet essentially, the design models used within the data-visualization research field can offer the health care setting appropriate methodological approaches to structure the developmental and evaluation process.

Within the case of developing the multifunctional 360°CHILD-profile, a design model adapted from Munzner with a user-centered design approach was chosen to guide the iterative design process [12]. The model integrates validation cycles for each level of the design, immediately during the process (upstream validation) and after delivering a working prototype for practice (impact-oriented downstream validation). By using this model and the user-centered approach, the influence of individual aspects on performance in practice could continuously be considered (chapter 3).

Overall, the chosen interdisciplinary and participative approach made it possible to customize the visualization and ordering of data based on the theoretical framework of the ICF to the CHC-context. Hereby, this project delivered a meaningful dashboard for CHC-practice that has a solid scientific background, a sufficient user satisfaction and a high potential that implementation will lead to the intended goals (chapter 3).



## **Part B: Implementation and Evaluation; Consensus in theory, Paradox in practice?**

Part B focusses on the question how to introduce and evaluate the delivered prototype of the 360°CHILD-profile in the CHC-practice in a systematic way.

### *Paradoxes related to the implementation- and evaluation process*

Considering the research questions with a focus on how realistic it is to introduce and implement the 360°CHILD-profile within the actual used EMDs in the CHC-context, the Mixed Methods research of part B unlocked a paradox.

On one hand, the relevant stakeholders, including CHC-managers, were enthusiastic about the 360°CHILD-profile and perceived it as a usable and meaningful dashboard for the regional as well as national CHC-context. On the other hand, there seemed to be a lack of decision-making by CHC-management to sufficiently prioritize and facilitate the implementation of this promising tool within the actual CHC-practice. In fact, 360°CHILD-profile's implementation process turned out to be seriously hindered by a lot of substantial organizational barriers as insufficient formal ratification of management, limited staff capacity and the feeling not having enough time available for innovation on the work floor, as well as, a reshuffle within the organization (chapter 5).

For evaluating the readiness for implementation, it was decided to use the by Fleuren suggested strategy to broadly map determinants at the level of the innovation itself, the potential users, the organization and socio-political context [13,14] (chapter 5).

When it comes to essential determinants of the innovation itself as correctness, completeness, procedural clarity, relevance and its potential users including self-efficacy and personal benefits, this project showed positive results that were in line with the promising results on reliability and validity that were reached after only a short training (Part A, chapter 2).

During the first and short introduction in practice, a feasibility study revealed that CHC-professionals and parents received the 360°CHILD-profile with enthusiasm and interest (chapter 5). They especially appreciated the quick overview on holistic health information. Importantly, parents and CHC-professionals appeared to be very well capable in handling and using the 360°CHILD-profile within the CHC-context. Moreover, parents experienced the 360°CHILD-profile as a comprehensible tool and, empowering to take a leading role during the shared decision-making processes. All and all, participants perceived the 360°CHILD-profile as a meaningful tool for CHC-practice because it provides quicker access to relevant health data and represents a child's health situation more accurately, compared to the currently used EMD.

Despite the promising results on the innovation itself and its users, the mapping of determinants at the level of the organization revealed substantial barriers for implementation (chapter 5). The integration of quantitative and qualitative data enabled to gain insight in what factors might have contributed to these paradoxical findings.

Within the CHC-organization, the staff capacity was low and the handling of the actual used EMD's is very time-consuming and insufficiently support CHC-professionals in their daily tasks. The EMD's do not sufficiently provide overview on relevant health data and do not conform to the international standards for representation of health information.

Besides the low staff capacity and problems concerning the non-theoretical structured EMD, the CHC-professionals experienced turbulence related to a reshuffle within the organization. Several ideas for innovations were initiated and carried out simultaneously, in a period in which also a merger of four already participating CHC-organizations was undertaken. Consequently, in daily practice, CHC-professionals experienced a high workload, and perceived the 360°CHILD-profile project as insufficiently facilitated and prioritized by the CHC-management. During normal working days, CHC-professionals' investment in time regarding adopting and evaluating the new 360°CHILD-profile, was limited (chapter 5).

Another hindering factor for implementation was the fact that both CHC-management and the EMD-provider eventually did not commit to their agreement to invest in making relevant EMD-data accessible. Furthermore, a secure link between the delivered 360°CHILD-profile application and the EMD was not arranged by the provider, which hindered the full integration within the EMD and the CHC-working methods (chapter 5).

The qualitative findings regarding the socio-political context revealed that managers and policy makers apparently do consider the 360°CHILD-profile as a promising tool for realizing their relevant goals regarding the regional and national CHC-context (i.e. more standardized data registry and ICF-thinking). During a focus-group meeting, participating managers and policy makers themselves suggested that, for solving problems concerning the diversity of the EMD-registries, more Top-down power on a national level might be required. They also popped up the question if, while leaving enough autonomy of professionals, more Top-down power is needed and even justified for implementing such a promising and well scientifically founded innovation like the 360°CHILD-profile (chapter 5).

Furthermore, the integrative findings revealed an issue that, on one hand, hinders 360°CHILD-profile's implementation. On the other hand, this issue brought to light an essential potential benefit of this new tool. The issue concerns the experienced problems with CHC's EMD-registries, from which the personal 360°CHILD-profile retrieves its data. The lack of theoretically structuring of and overview on health data within the EMD-registries

leads to time-consuming data registration and a substantial amount of missing data. As the EMD-registries are the 360°CHILD-profile's unique data-source, the already existing missings within the EMD also led to missing data on the personalized 360°CHILD-profiles. This might partly hinder 360°CHILD-profile's potential to provide access and overview on holistic health variables. However, beyond expectations, qualitative data on this subject revealed a potential of the 360°CHILD-profile to break through the negative vicious cycle towards inaccessibility of health data. The 360°CHILD-profile shows CHC-professionals which of the multiple variables to be registered are highly relevant for clinical reasoning (and which have less added value). Moreover, the 360°CHILD-profile's exposes which relevant data are yet missing within the EMD-registries, while the current missing data in the EMD-registries can easily be overlooked due to the lack of overview on data within the EMD's. These insights enable CHC-professionals to prioritize during data registration and stimulate them to strive for more consistent data registration. CHC-professionals may gain more control (autonomy) over their registration and access to relevant EMD-data, which could support further professionalization toward consistent and structured registrations in accordance with the ICF (chapter 5).

The findings of the present project also revealed a paradox regarding the evaluation process. In theory, managers and policy-makers strive for evidence-based innovations and need evidence before deciding on whether to broadly implement an innovation in practice. This strive and need for evidence seemed to be in contradiction with the actual situation in which valid evaluations within the present project were not sufficiently prioritized and facilitated by the management (chapter 6).

The researchers, on forehand, did not expect that the organizational context would hinder 360°CHILD-profile's implementation and evaluation to such an extent as it turned out to be.

Expectations beforehand about the organizational context were more optimistic because this project was initiated from CHC-practice and directed towards finding efficient solutions for the major, within practice experienced, problems concerning the accessibility of CHC's health data. Thereby, the initiative for the project was warm heartedly supported by both CHC-professionals and CHC-management. In addition, although a substantial part of this project was financially supported by the Dutch subsidy provider ZonMw, the CHC-organization also profoundly invested in the project by facilitating one of their medical doctors to spend a substantial amount of time on the development and evaluation of this innovation.

These factors led to the initial assumption of researchers that CHC-managers also would sufficiently prioritize the 360°CHILD-profile project and commit to the promised facilitation of CHC-professionals and their own tasks within the project's implementation and

evaluation plan. However, this project revealed that these initial positive assumptions of researchers regarding the facilitation and prioritization of the project by managers were not in line with the actual situation while performing the evaluation.

### ***Additional major issues regarding the evaluation process***

Another essential research question was focused on which research methodology is most appropriate to evaluate the performance of the delivered multifunctional 360°CHILD-profile within real-life CHC-practice. Regarding this research question, this project revealed that CHC's organizational context also has serious impact on that choice (chapter 6). Namely, the organizational CHC-context leads to additional major issues. Firstly, the CHC's organizational structure (each professional being responsible for providing care in a certain sub-region) requires a more complex randomization-strategy and substantially higher sample sizes. For recruiting and randomizing the required number of parents and youth, additional trained research staff must be deployed. Secondly, the challenging search for measures that potentially are valid, responsive and reliable for the context of evaluating 360°CHILD-profile's implementation and effectiveness in CHC-practice, still requires further exploration. And, when identifying potentially appropriate measures, it is essential to thoroughly pilot them before proceeding the evaluation process (chapter 6).

These findings suggest that executing an effectiveness RCT to evaluate 360°CHILD-profile's performance within the CHC is very challenging, because it turned out to be even more complex and time-consuming than already expected. It is important to prevent that striving for performing a valid design like an effectiveness RCT leads to postponing the implementation of the promising 360°CHILD-profile within CHC-practice. The dilemma on what the most appropriate design is to thoroughly evaluate the performance of this promising tool in CHC-practice will be further discussed at the end of the first paragraph of "Future research".

## **Further reflections on methodological aspects**

### **Introducing a nested design model with a user-centered approach within health-care.**

The unique collaboration of health care researchers including an epidemiologist with experts in the field of data-visualization and human-computer interaction was crucial for achieving an accessible visualization tool that displays holistic CHC-variables including data immediately in one overview. This collaboration allowed to appropriately represent the continuum-based context of children's health and development. Thereby, it allowed to display the coherence between health domains in line with the theoretical framework

of the ICF (International Classification of Functioning, Disability and Health for Children and Youth) [2].

The by the data-visualization experts introduced nested design model with a user-centered approach, allowed to structure the design process within an epidemiological context and include validation cycles within all relevant stages of the design process; immediately during the process as well as impact oriented under consideration of the inheritance effects of individual aspects on underlying levels [10,11,12].

This resulted in delivering an operating prototype of a digital 360°CHILD-profile with sufficient user satisfaction; an application that can automatically transfer a set of CHC-health data into the visualization.

### **Longitudinal, iterative and participative Mixed Methods research**

Within this stepwise Mixed Methods research project with active participation of relevant stakeholders, much attention is paid on the integration of quantitative and qualitative data.

Integration took place at several levels. Firstly, qualitative data allowed to build theory on how to develop, implement and/or evaluate the 360°CHILD-profile and generate new research questions could be evaluated by quantitative methods. Within the present project, quantitative data also were subsequently used to prepare for qualitative research (to select participants for the interviews and refine topic lists). Next, the qualitative methods were used to gain deeper understanding of quantitative findings (by comparing overarching themes out of both types of data-sources during analyses) and the further exploration of stakeholders' views and expectations. This iterative cycle was repeated several times.

This project demonstrated that integrating both complementary data sets in a valid way is of much significance for gaining a more in depth and broad insight and understanding. Valuable insight is generated in both the chances and barriers for implementing and evaluating this innovation within the preventive health care context, as well as in how to target the implementation and evaluation strategy. It revealed positive aspects and opportunities, as well as the paradoxes and unresolved questions regarding implementation and evaluation of the 360°CHILD-profile that must be addressed in future research.

Besides the generated broad and in-depth insights, the Mixed Methods approach also facilitated triangulation of data and the opportunity for participants to react on researchers' interpretations, which increased the validity of results.

More approaches were incorporated to strengthen trustworthiness of the qualitative findings. During qualitative analysis of the feasibility studies, external researchers

were asked to critically review the used methods and researchers' interpretations and assumptions to enhance researchers' reflexivity. Thereby, researchers repeatedly returned to the raw data and memos to investigate consistent and/or disconfirming data regarding interpretations and categories. Moreover, at the end of qualitative analysis, participants were invited to react on the findings and researchers' interpretations during a member check focus-group meeting.

The feasibility studies included purposive sampling to gain a rather heterogeneous subgroup out of the initial study population for the interviews, relevant for a broad range of perspectives. The subgroup of parents was heterogeneous regarding educational level, native country, parental stress, opinion on CHC and their child's functioning. The subgroup of CHC-professionals was heterogeneous regarding their educational level, experience within CHC-practice and their opinion on the EMD.

Limitations include the so far limited number of participants, as well as the fact that the feasibility research entailed a once-only experience with the 360°CHILD-profile in a pre-implementation phase. These factors limited for example the extent to which the level of use could be measured. The frequency and profundity of use could be measured, but not yet if it was used to the full extent and if determinants for implementation were associated with the level of use.

The fact that for parents it was their first and only encounter with the innovation and the time between experiencing the 360°CHILD-profile and the interviews with parents might partly explain why these yielded relatively homogeneous responses and less in-depth insights. This especially limited the possibility to gain profound understanding of the outcomes of the used potential outcome measures for evaluating the accessibility and transfer of relevant health information.

During the studies, executed so far, relatively more focus was on perspectives of professionals and policy-makers as they must take the first step to integrate the 360°CHILD-profile in practice. In further stages of research on implementation, it is intended to pay attention on how to gain more in-depth insight in parents' perspectives, as well as on the views of youth on the 360°CHILD-profile.

## **Future perspectives**

### **How to get ready for implementation?**

For the continuation of this project that is focused on providing fruitful ground for the CHC to adopt the concepts of Personalized Health Care, it is essential to reflect on the

findings concerning the readiness of implementation. Special attention is required for the organizational obstacles within the CHC-context.

Although the Mixed Methods research provided rather broad understanding in the barriers, the project also generated yet unresolved questions that must be addressed in following steps within this research project.

Within the CHC-context, changes take place continuously; changes due to evolving needs from society as well as shifts in demands from municipalities and adaptation of the organizational structure. It is important to gain insight in and understand how innovations or changes within CHC-organization are prioritized and planned. During the period of undertaking this project, it seemed to be more or less, just as it pops up in the organization and rather often coincidentally simultaneously. The first most obvious question regarding consideration which innovation or change should be given priority reflecting on the availability of time and staff capacity and its relation to CHC's core business, seemed to be not common-practice yet.

A clear definition of CHC-core business and, in coherence with this definition, (re)defining tasks, functions and working procedures in daily practice could support preventing problems concerning adequately finishing running projects like this one. The continuation of this project requires exploration whether the experienced problems within CHC-practice, i.e. the EMD-problems, are perceived as urgent and solvable. Regarding urgency, it is important to gain more understanding in whether or not professionals and managers do realize to what extent the current issues around the EMD-registries are undermining the CHC's core business: monitoring children's development and health situations and actively protecting and promoting health at both an individual and a population level. Regarding the solvability of the problems, it is essential to gain more insight in the extent in which managers working in local CHC-organizations actually do have a mandate to demand adaptation from commercial software providers of EMD's. Does a local CHC-management have sufficient mandate to demand solving the problems concerning the EMD-registries and access to data from different health variables and/or work on innovative developments like arranging a secure link for integration between an EMD and the 360°CHILD-profile application? For EMD-companies in contrast, such investments only are opportune after the commitment that more organizations will work with the innovation, as only then, they would gain enough profits. This, together with the fact that some Dutch CHC-organizations only decide if they will work with an innovation as the 360°CHILD-profile after it is operational and evaluated, is a major issue for a successful implementation of innovations like the 360°CHILD-profile. This issue must be addressed first to unlock the current impasse.

Concerning the question how innovative projects are prioritized and planned, it may be that the perspective of the research team of the present project is different from the managers' perspectives. The initiation of this research project by the medical doctors as part of the research-team was based on an urgent need for solving the by medical doctors perceived problems concerning working with the actual EMD to maintain their professional autonomy combined with the quality of care they provide. Furthermore, an important incentive for the initiation was the need for quality improvement of CHC; the in literature and in practice experienced prerequisite for a transformation towards Personalized Health Care.

A crucial unsolved question also is if managers are pursuing the same goals and feel the same urgent need for change to ensure the quality of care as the medical staff of the shop floor perceives.

Another topic to address is the connection between daily CHC-practice and scientific research within the CHC-context. As stated in policy papers, in theory the CHC intends to establish evidence-based practice. In practice however, there seems to be a gap between scientific research and daily CHC-practice. Adopting and integrating an innovation like the 360°CHILD-profile is a challenging and long-term process. Researchers, together with the field of practice, are facing a challenge in tackling an iterative process of scientifically developing, implementing and evaluating an innovative tool like the 360°CHILD-profile. This process includes from both sides checking assumptions based on knowledge generated so far, encountering problems, revealing uncertainties, gaining better understanding of why things do or do not work and how to deliver a usable and meaningful innovation and successfully implement it in practice.

Regarding enhancing the bottom-up power for implementation, other questions remain unresolved regarding the contradiction between enthusiasm of participating professionals who expressed that they desire to work with the 360°CHILD-profile, and their tendency to postpone tasks related to this project in daily practice.

Raised issues concerning the contradiction between the primary enthusiasm of CHC-professionals and managers and their actual performance of study task in daily practice must be further explored.

In general, it is known to be challenging for professionals to try something new outside their regular routines in daily practice and, therefore, change their way of working. Not being used to work with a tool and no or less opportunity to exercise with it in a safe environment may negatively influence the adoption rate.



To target these factors, CHC-professionals need time and possibilities to exercise in a safe environment and in dialogue with colleagues to gain insight in the benefits of this innovation. It is of much importance to also extensively provide CHC-managers, who play a major role in the implementation process, with insight in the 360°CHILD-profile's benefits, as well as to support the dialogue on the topic between the shop floor and the management (chapter 5).

Besides these recommendations for future steps within this research project, the feasibility study generated more suggestions for improving the implementation strategy. These suggestions include securing sufficient attention for and emphasis on the innovation; offering continuous support to professionals during implementation and evaluation; integrating the 360°CHILD-profile within the EMD and displaying which specific EMD-data are used as data source for the 360°CHILD-profile (chapter 5).

Implementation on a national level, would additionally require a solid marketing communication plan toward national stakeholders at the level of management and policy making. Furthermore, for national implementation the search for a balance between providing a certain amount of top-down power on one hand and, on the other hand, maintaining sufficient autonomy for local organizations and professionals (chapter 5) is a difficult one and can be improved in dialogue with the relevant stakeholders.

Findings regarding requirements for implementation of the 360°CHILD-profile are in line with a recent study on crucial factors for successful implementation of e-health interventions in health care. Their list of determinants also includes familiarity with the innovation, insight in effectiveness, predefined suitable patient groups, organizational support and provision of sufficient resources, connection and data exchange with the existing EMD and safeguarding information transfer [15,16].

### **How to evaluate CHILD-profile's performance without hindering implementation?**

By using a design model, adapted from Munzner, part A of this research project incorporated studies with focus on delivering a 360°CHILD-profile that performs as intended (upstream validation) and practice-based evaluating if the delivered prototype works (downstream validation) [12]. The downstream validation started with technical and qualitative tests of the delivered digital prototype of the 360°CHILD-profile (chapter 4). During the first and short introduction of the 360°CHILD-profile in real-life CHC-practice, the validation process continued by Mixed Methods feasibility studies of part B (chapter 5 and 6). This research phase included a study on 360°CHILD-profile's usability and meaningfulness and a feasibility RCT, which was the first step towards evaluating 360°CHILD-profile's performance. The findings so far demonstrate that the 360°CHILD-profile seems very promising to

benefit CHC-practice. However, findings suggest that it will be very challenging and even more complex and time-consuming than already expected, to execute an effectiveness RCT as a last step within this context. It is important that the strive for executing a well-designed pragmatic effectiveness RCT does not lead to postponing or even cancellation the implementation of this promising tool. More methodological valid projects within the downstream validation may support a successful implementation and the search for valid scientific evaluation methods.

The 360°CHILD-profile can be seen as a complex intervention supporting a broad variety of tasks (from the transfer of health information to preventive clinical reasoning and shared decision-making), respectively serving several target groups (parents and youth, CHC-professionals, other care-givers and CHC-managers and policy makers). The preventive CHC-context in which the 360°CHILD-profile must be evaluated is complex as well. The CHC has the most heterogeneous target group there is as it is built up out of the complete national population 0-18 year.

In literature, it is suggested that for complex interventions, an effectiveness RCT might not be the most appropriate design for evaluating performance and/or effectivity in practice [16]. For complex interventions, it might be necessary to rethink the current research priorities as they require a broader approach for evaluation; an approach in which, similar to the 360°CHILD-profile project so far, specific phases are defined during the development and implementation process. Each phase would then end with a go/no go moment. For the implementation and evaluation of complex innovations like the 360°CHILD-profile, process evaluations and feasibility studies (randomized or not) in all stages of knowledge can be considered as adequate designs for such go/no go moments. While research restricted to an efficacy or effectiveness perspective does not generate the required knowledge for policy makers to make decisions on whether or not to proceed implementation. A wider range and combination of research methods need to be used by researchers (and supported by funders). For intervention research in a preventive and public health care setting like the CHC, greater priority should be given to mixed methods. Mixed methods research is sensitive to the complexity of an innovation and the context in which it is implemented and may improve understanding and identification of important implications for future steps within a research project [17].

The call for a change in research priorities resulted in literature in the development of a framework for "Developing and Evaluating Complex Interventions"; the Framework of Skivington [17].

The goal of this framework is to reach optimal impact of health care research on complex interventions. Evaluation of a multifunctional tool as the 360°CHILD-profile requires

attention on understanding how and under what circumstances the innovation works and taking account of how it interacts with the context in which it is implemented. Knowledge must be generated that can be used to support real world decision making during each phase of the project.

The framework of Skivington presents a common set of core elements for each phase—considering context, developing and refining program theory, engaging stakeholders, identifying key uncertainties, refining the intervention, and economic considerations.

Besides economic considerations, this longitudinal Mixed Methods research project already did incorporate most of the core elements presented by Skivington. So far, stakeholders were extensively engaged and the context was considered in order to continuously refine theory, identify uncertainties on the innovation and the context and to make adaptations to the development, implementation and evaluation process.

### **Future research**

For continuation of this project, it is essential to work out a marketing communication plan based on the findings of this project toward national stakeholders at the level of management and policy making (to increase Top-down power). This communication plan also should be targeted on Dutch professionals that work within preventive CHC (to increase bottom-up power).

The first step of communication toward Dutch professionals within child health care is already initiated by the following project that was granted by ZonMw: the development of a website called “Personalized Child Health Care based on the 360°CHILD-profile” and an online course on preventive clinical reasoning within Personalized Child Health Care.

Then, what would be a next step of the implementation process and the evaluation of 360°CHILD-profile’s performance? The implementation study with larger sample sizes should be conducted including process evaluations and assessments of the level of use and relevant determinants of implementation at the level of the 360°CHILD-profile, the potential users, the CHC-organization and CHC’s socio-political context. This would enable assessment of the influence of the different determinants on the level of use. Additionally, differences in usability within the diverse target population should be monitored. Conducting studies with a Mixed Methods design will enable to provide better understanding of the quantitative results, how to address found barriers for implementation and how to specifically target the implementation strategy.

Concerning reliability and validity, so far, positive results were generated about intra-rater and inter-rater reliability and concurrent validity. However, 360°CHILD-profile’s value also

regarding a tracking change in functioning using the actual version will need further exploration.

Regarding the evaluation of 360°CHILD-profile's performance in practice, conducting an effectiveness RCT does not seem feasible and not the most appropriate next step. Continuing the actual design with the already discussed new research questions might be preferable as a substantial number of uncertainties concerning the most appropriate implementation strategy, evaluation design and outcome measures remain unresolved.

The choice of outcome measures needs further and extensive exploration, as it seems a crucial aspect of the evaluation design. Researchers, together with stakeholders, have to define which outcomes are most important, and how to deal with multiple outcomes in the analysis with due consideration of statistical power and transparent reporting.

A pragmatic feasibility study with a flexible and emergent Mixed Methods approach might be appropriate to enable address the different research questions and overcome current obstacles to implementation and evaluation. Thereby, it is essential that further research incorporates all six, by Skivington recommended, core elements for evaluating complex interventions, including economic considerations. Insight in costs and benefits will help to answer questions that matter most to managers and policy makers who will decide whether to prioritize and facilitate the implementation and evaluation of this innovation. Cost-benefit analysis to assess the likelihood that the expected benefits of the intervention justify the costs (including the cost of further research) will often be more suitable for complex interventions than narrower approaches such as cost effectiveness analysis.

## Conclusions

This participative Mixed Methods research project is an important step toward bridging the information asymmetry between electronic health data, health-professionals and care-users. This project delivered a dashboard which visualizes relevant digital CHC-data on one image by theoretically structuring data in line with the ICF. Thereby, it is designed in accordance with international standards of human computer interaction for information representation (ISO 9241-12).

The participative approach and the collaboration between health care researchers including an epidemiologist and researchers within the field of data-visualization provided fruitful ground for delivering a working prototype of a comprehensible, usable and meaningful 360°CHILD-profile. The utilization of a nested design model with a user-centered approach to structure the design and validation process, enabled to develop a visualization tool

with appropriate representation of the continuum-based context of children's health and development.

By describing the 360°CHILD-profile's design and validation process, this work offers guidance on how to utilize a nested design model within a preventive and heterogeneous health care context. An important asset of the used model was that it integrates validation cycles at each level of design, immediately during the design process (upstream validation), as well as after delivering and introducing the working prototype in practice (impact-oriented validation).

The evaluation processes, executed so far within the 360°CHILD-profile's validation process, demonstrated that it is useful and efficient tool, compatible with CHC-practice.

The integration of qualitative and quantitative data appeared to be essential to gain broad understanding of which, mostly organizational, barriers should be addressed to get ready for implementation and on how to target an implementation strategy.

By performing a pragmatic feasibility randomized trial, broad insight also could be generated in the complexity of a probable execution of an effectiveness RCT within the CHC-context. This context seems to require a more complex randomization strategy, additional employment of trained research staff to recruit parents and further exploration of measures, potentially for evaluating 360°CHILD-profile's effectiveness. Thus, executing an RCT within the context of evaluating its effectiveness in the CHC-setting will be much more complex, time-consuming and costly than already expected. Alternative designs, including Mixed Methods research, have a high priority to be considered while proceeding with the downstream validation process. It should be prevented that a strive for executing a valid randomized trial focusing on (cost)effectiveness postpones or even that the implementation of a promising tool like the 360°CHILD-profile never comes.

The 360°CHILD-profile is a promising multifunctional tool. It appeared to more appropriately represent children's health situations than the current EMD alone (without the integration of the theoretical structured 360°CHILD-profile within the EMD). The quick overview on holistic health data, provided by the 360°CHILD-profile based on data from the EMD, has several advantages. It is likely to be time saving and to enable the CHC to comprehensibly transfer health information to parents. This summary of relevant data on a child's health situation enables the CHC to commit to the, since 2020, legal duty to provide parents and youth with online access to CHC's data stored in the EMD [18]. Most importantly, it specifically is designed to intuitively guide clinical reasoning and stimulating more consistent and structured registry of relevant health data within the CHC. These benefits are essential

ingredients for reaching adequate preventive interventions and transformation towards a more predictive, personalized and participative health care.

Age  
0 4 18

**Personal factors**

Genetic Predisposition

Family history

Pregnancy / Birth

Early Development

Life Events

Medical History

Health issues

Received care

Vaccination status

**Body functions / structures**

Hearing

Vision

Height

Weight

Urinary / Digestive system

Heart / Lungs

**Attentional functions**

Emotional functions

Personality

Sleeping function

Language / Speech development

Intellectual functions

**Environmental factors**

Family and Support

Family composition

Parental skills

Social support

Smoking

**Activities & Participation**

Motor skills

Mobility

Screen time

Eating and drinking

General tasks

Self-care

**Mental**

Learning and Applying knowledge

Behavior

Communication

Interpersonal Interactions

**Social Environment**

Social / cultural background

Parental:

- language
- education
- profession

Financial assets

Housing

Preschool / School

**360° CHILDoc**

Conclusions / Advice

Addendum 7.1: Final version of 360°CHILD-profile

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# Summary

## Summary

This present thesis describes the results of the longitudinal Mixed Methods research project with the aim to develop and evaluate a new tool for visualizing and theoretically ordering personalized health information of a child's health situation: the 360°CHILD-profile.

**Chapter 1** elaborates on the background, goals and aims of the thesis.

The initiative for this novel approach for visualizing and theoretically structuring holistic health data in one image originated from the preventive Child Health Care-practice (CHC). Within the CHC-context, there was a need for gaining better access to and overview on relevant health data to support the simultaneous thinking processes required for preventive clinical reasoning. The experienced need led to the idea to theoretically structure health data in line with the ICF. Moreover, it was intended to reach an appropriate visual representation of a child's health situation that would facilitate the CHC to adopt the different concepts of personalized health care: prevention, prediction, personalization and active participation of care-users.

This PhD trajectory included the development and evaluation of a 360°CHILD-profile with the aim to deliver the CHC a suitable digital dashboard that provides direct access to and overview of the relevant health data. The ultimate goal was to facilitate preventive, personalized clinical reasoning and shared decision-making and to ignite a transformation towards a personalized CHC.

Part A focused on gaining insight in how to develop a reliable and valid tool for visualizing integral health information that is usable and meaningful within the CHC-context based on a theoretical concept.

Within Part B, the focus was on gaining insight in the question how to systematically introduce and evaluate this innovative visualization tool within real-life CHC-practice.

**Chapter 2** presents the results of the pilot study on aspects of inter- and intra-rater reliability and concurrent validity of a preliminary version of the 360°CHILD-profile.

Medical doctors, working within the Dutch CHC used the 360°CHILD-profile to estimate functioning and needed intervention of 4-year-old children. In total 26 personalized 360°CHILD-profiles were assessed. Each 360°CHILD-profile was assessed by two medical doctors at T1 and at T2 (4 months after T1).

Regarding inter- and intra-rater reliability, results showed Intra-class correlation coefficients of respectively 0.71 and 0.82 for overall functioning and Cohen's kappa's of 0.47 and 0.46 for needed intervention. Validity results showed a Spearman's correlation coefficient of 0.78 for overall functioning and a Cohen's kappa of 0.52 for needed intervention. After only a short training, acceptable results regarding reliability and validity were generated for the 360°CHILD-profile if used to assess child functioning. The 360°CHILD-profile's value on tracking change in functioning and decision-making on intervention needs further exploration.

**Chapter 3** describes the stepwise development and validation process of the subsequent version of the 360°CHILD-profile. The delivered dashboard is an online accessible visualization of CHC-data that is based on the theoretical concept of the International Classification of Functioning, Disability and Health (ICF) and represents a child's health situation in accordance with international standards for representation of health data (ISO 9241-125).

This chapter offers an example of how to use a nested design model within the health care context to achieve visualization of a comprehensive overview of theoretically structured health data. The utilized model considers immediate upstream validation within four cascading design levels: Domain Problem and Data Characterization, Operation and Data Type Abstraction, Visual Encoding and Interaction Design, and Algorithm Design. The model also includes impact-oriented downstream validation, which can be initiated after delivering the prototype. During the developmental, a user-centered design was utilized to actively involve relevant stakeholders within a real-life context to deliver a 360° CHILD-profile that fits the CHC-context.

The delivered dashboard provides caregivers and parents/youth with online access to a comprehensible visualization of CHC data based on the ICF and offers a holistic view on children's health and "entry points" for preventive, individualized health plans.

**Chapter 4** describes the study protocol of a pragmatic Mixed Methods feasibility research project, executed during the first and short introduction of the 360°CHILD-profile within real-life CHC-practice.

The research project comprised of two studies. The first study entailed an evaluation of CHILD-profile's usability and feasibility. The second study focused on evaluating the feasibility of executing a randomized controlled trial.

The project started with executing a feasibility RCT, which included measurement of the accessibility and transfer of health information in two parallel groups (1:1) of parents. Both

groups received standard CHC-care and the experimental group additionally received personalized 360°CHILD-profiles. Quantitative measurements on the accessibility and transfer of health information were executed after an intervention period of 6 months. Then, when RCT's measurements were completed, quantitative measurement of 360°CHILD-profile's usability and feasibility were performed. After descriptive analysis of quantitative data, qualitative methods were used to reach deeper understanding of quantitative findings and to further explore the stakeholders' perspectives on the potential benefits of the 360°CHILD-profile. Quantitative data were used to purposively sample for semi-structured interviews and refine topic lists. Overarching themes for both types of data-sources were compared to generate integrative findings.

**Chapter 5** presents and discusses the integrative quantitative and qualitative results of the part of the Mixed Methods feasibility study with focus on evaluating the usability and feasibility of the 360°CHILD-profile.

Usability was defined as "usable for presenting children's health situations" and "users expect it to be useful". Feasibility was defined as "potential attainability for implementation within CHC". In line with the framework for systematically introducing and evaluating an innovation in a preventive health care setting, presented by Fleuren, the level of use was assessed, as well as a broad variety of determinants that potentially influence the implementation process. These determinants related to the CHILD-profile itself, its potential users, and the organizational and socio-political context.

Participating professionals (n=17) discussed personalized CHILD-profiles with parents (n=27). Twelve interviews (parents and professionals) and two focus groups were performed. After integrating quantitative and qualitative data, the overall theme "readiness for implementation" emerged. Participants reacted enthusiastically about discussing the 360°CHILD-profile and appreciated the quick overview on holistic health information. The 360°CHILD-profile appeared to be useful and efficient for CHC-practice and users seemed competent in handling and using the CHILD-profile within the CHC-context. However, implementation appeared to be hindered by substantial organizational issues, including the non-structured electronic medical dossier. This study generated valuable knowledge on how to get ready for implementation.

**Chapter 6** presents and discusses the integrative quantitative and qualitative results of the feasibility RCT, which thoroughly investigated RCT-procedures and explored applicability of potential outcome measures for assessing accessibility and transfer of health information.

CHC-professionals (n=38) recruited parents (n=30) who visited the CHC for their child (age 0- 16). Parents were randomized to "care as usual" (n=15) or "care as usual with, in addition,

the availability of a personalized CHLD-profile during six months" (n=15). Quantitative data on RCT-feasibility were collected on recruitment, retention, response, compliance rates and outcome data on accessibility and transfer of health information (n=26). Subsequently, thirteen semi-structured interviews (5 parents, 8 CHC-professionals) and a member check focus group (6 CHC-professionals) were performed to further explore and gain deeper understanding of quantitative findings.

The used randomization strategy, measurements and interventions were feasible. Recruitment of parents by CHC-professionals appeared to be problematic and influenced by organizational factors within the CHC-context like insufficient facilitation by CHC-management. The used outcome measures for assessing the accessibility and transfer of health information showed skewed outcome data, with relative high percentages of positive scores in both groups and a low applicability of relevant items on accessibility and transfer of health information.

The Mixed Methods feasibility study enabled to gain a broad insight in the complexity of executing an RCT within the CHC-context. This context seemed to require a more complex randomization strategy and trained research staff instead of CHC-professionals to recruit parents. Measures, potentially for evaluating 360°CHILD-profile's effectiveness, must be further explored and thoroughly piloted before proceeding the evaluation process. Overall findings revealed that executing an RCT within the context of evaluating CHLD-profile's effectiveness in the CHC-setting will be much more complex, time-consuming and costly than already expected. Alternative designs including Mixed Methods research should be considered for the next phases of the downstream validation process.

Finally, **Chapter 7**, summarizes the development and evaluation process of the 360°CHILD-profile while reflecting on the methodological aspects of the longitudinal research project, especially the advantages of the choice for participative Mixed Methods design. Moreover, this chapter discusses the integrative main findings, which revealed some paradoxes.

On one hand, promising results were found on the usability and potential benefits of the 360°CHILD-profile for relevant stakeholders (parents, youth, CHC-professionals, other care-providers and policy-makers) and perceived self-efficacy by CHC-professionals and parents. On the other hand, the project revealed substantial (mostly organizational) barriers within the preventive CHC-context (insufficient prioritization and facilitation by management and a complex organizational structure) with regard to the implementation and evaluation process. Last but not least, chapter 7 further reflects on what the findings entail regarding future perspectives. Important questions addressed are how to get ready for implementation within the CHC-context and how to evaluate performance of the promising 360°CHILD-profile within this context. The quick overview on holistic health



data that this tool provides is likely to be time saving and enables a comprehensible transfer of health information to parents. Moreover, it stimulates a more consistent and structured registry of relevant health data within the CHC. Most importantly, the 360°CHILD-profile specifically is designed to intuitively guide clinical reasoning in line with a more predictive, personalized and participative child health care.





# Samenvatting

## Samenvatting

Dit proefschrift beschrijft de resultaten van een longitudinaal “Mixed Methods” onderzoeksproject gericht op de ontwikkeling en evaluatie van een nieuw digitaal dashboard met visualisatie en theoretische ordening van gepersonaliseerde informatie over de gezondheidssituatie van een kind: het 360°CHILDoc (een 360°KIND-profiel).

**Hoofdstuk 1** geeft toelichting op de aanleiding en doelstellingen van dit proefschrift. Het initiatief voor deze innovatieve benadering voor visualisatie en theoretische structurering van holistische gezondheidsinformatie in één digitaal beeld vond zijn oorsprong in de praktijk van de preventieve Jeugdgezondheidszorg (JGZ). Binnen de JGZ-context bestond en bestaat er een grote noodzaak voor betere toegankelijkheid en overzichtelijke weergave van relevante gezondheidsdata. Om ervoor te zorgen dat de Digitale Dossiers JGZ (DDJGZ) het preventief klinisch redenerproces van professionals beter kunnen ondersteunen is het plan ontstaan om gezondheidsdata te visualiseren en te structureren in lijn met het biopsychosociale (BPS) model van gezondheid. Als uitgangspunt is gekozen voor een classificatiesysteem dat gebaseerd is op dit BPS-model: “the International Classification of Functioning, Disability and Health (de ICF). Een belangrijk doel was het komen tot een adequate representatie van de gezondheidssituatie van een kind. Dit is essentieel om de JGZ-activiteiten, gericht op het beschermen en bevorderen van gezondheid van kinderen, doeltreffend te ondersteunen, evenals het streven naar een meer gepersonaliseerde JGZ. Een gepersonaliseerde JGZ omvat optimale predictie van gezondheid, preventie van gezondheidsproblemen, personalisatie van zorg en actieve participatie van zorggebruikers.

Dit promotietraject bestaat uit de ontwikkeling en evaluatie van een 360°KIND-profiel (het 360°CHILDoc) met als resultaat een prototype van een digitaal dashboard dat past binnen de JGZ-context en directe toegang biedt tot de relevante gezondheidsdata. Het ontwerp van het dashboard is specifiek gericht op ondersteuning van het preventief klinisch redenerproces en de gezamenlijke besluitvorming in lijn met een gepersonaliseerde JGZ.

Het proefschrift bestaat uit twee delen: deel A en deel B.

In deel A ligt de focus op het verkrijgen van inzicht in hoe een betrouwbare en valide dashboard te ontwikkelen dat integrale gezondheidsinformatie in lijn met een theoretisch concept visualiseert én dat toepasbaar en waardevol is voor de JGZ-context.

Deel B is gericht op het verkrijgen van antwoorden op de vraag hoe deze innovatieve visualisatie tool systematisch geïntroduceerd en geëvalueerd kan worden binnen de levensechte JGZ-praktijk.

**Hoofdstuk 2** presenteert de resultaten van de pilotstudie naar aspecten van betrouwbaarheid en validiteit van een eerste versie van het 360°CHILDoc.

Jeugdartsen, werkzaam binnen de JGZ in Zuid-Limburg hebben deze versie van het 360°CHILDoc gebruikt om het functioneren en eventuele benodigde vervolgvacatieën van 4-jarige kinderen te beoordelen. In totaal zijn 26 gepersonaliseerde 360°CHILDocs beoordeeld. Elk 360°CHILDoc is beoordeeld door twee Jeugdartsen op twee meetmomenten (T1 en op T2, 4 maanden na T1).

Met betrekking tot de inter- en intra-beoordelaarsbetrouwbaarheid laten de resultaten voor het globale functioneren Intra-class correlatiecoëfficiënten zien, die ruim boven de in de hypothese geformuleerde minimale waarde van 0.6 liggen (0.71 - 0.82). De berekende Cohen's kappa's voor de benodigde vervolgvacatieën liggen onder de 0.6 (0.46 - 0.47). Betreffende de ("concurrent") validiteit lagen de berekende Spearman's correlatiecoëfficiënten en Cohen's kappa's binnen de in de hypothese geformuleerde reikwijdte van 0.5 - 0.8.

Na een 2 uur durende training van de JGZ-professionals zijn acceptabele resultaten gevonden met betrekking tot betrouwbaarheid en validiteit van het 360°CHILDoc, indien gebruikt voor het beoordelen van het functioneren van een kind. Verder onderzoek is nodig om op een adequate wijze in te schatten wat de waarde van het 360°CHILDoc is voor evaluatie in het functioneren over een kortere of langere periode in tijd en voor de besluitvorming rondom welke vervolgvacatieën nodig zijn.

**Hoofdstuk 3** beschrijft het iteratief ontwikkel- en validatieproces van een op basis van de pilotstudie bijgestelde versie van het 360°CHILDoc dat heeft geleid tot het uiteindelijke prototype van het dashboard. Dit dashboard is een online toegankelijke visualisatie van relevante JGZ-data met ordening van data op basis van de ICF, het theoretische concept van het Internationale Classificatiesysteem voor het in kaart brengen van het functioneren en de gezondheid in de brede zin van het woord. Daarnaast is de presentatie van de gezondheidssituatie van een kind in lijn met de internationale standaarden voor representatie van gezondheidsdata (ISO 9241-125). Dit hoofdstuk biedt een voorbeeld van het belang van een designmodel ("a nested design model") binnen onderzoek in de gezondheidszorg om te komen tot een toegankelijk en integraal visueel overzicht van theoretisch gestructureerde gezondheidsdata. Dit model integreert een directe "upstream" validatie gedurende vier opeenvolgende en typische stadia van design: Domein probleem en Data kenmerken; Werking en Type van data abstractie; Visuele codering en Interactioneel design; en Algoritme design. Vervolgens komt, na het beschikbaar komen van een werkend prototype, de impact-georiënteerde "downstream" validatie aan de orde. Gedurende de ontwikkeling van het prototype is een methodiek gebruikt waarbij de gebruikers centraal

staan: “a user-centered design”. Deze methodiek maakt het mogelijk om binnen een levensechte JGZ-context de relevante stakeholders actief te betrekken en zodoende een prototype van het 360°CHILDoc te realiseren dat zo veel als mogelijk passend is binnen die context.

Het huidige prototype van het dashboard kan zorgprofessionals, evenals ouderen en jongeren online toegang bieden tot een integrale visualisatie van JGZ-data in lijn met de ICF. Het biedt het een holistisch beeld van de gezondheidssituatie van een kind en hiermee zicht op aanknopingspunten voor proactieve, gepersonaliseerde acties. Het doel is om te komen tot slagvaardige preventieve plannen om de ontwikkeling en gezondheid van kinderen te beschermen en bevorderen.

**Hoofdstuk 4** beschrijft het studieprotocol van een pragmatisch “Mixed Methods” haalbaarheidsonderzoek, uitgevoerd tijdens een eerste korte introductie van het 360°CHILDoc binnen de levensechte JGZ-praktijk. Binnen deze studie is de bruikbaarheid en uitvoerbaarheid van het 360°CHILDoc zelf is geëvalueerd, evenals de uitvoerbaarheid van een RCT (Randomized Controlled Trial), gericht op de effectiviteit van het 360°CHILDoc in de JGZ-context. Binnen de haalbaarheids-RCT met een gerandomiseerd parallel-groepsdesign, zijn potentiële uitkomstmaten gebruikt om de toegankelijkheid en overdracht van gezondheidsinformatie te meten in twee groepen (1:1) van ouders. Beide groepen hebben standaard JGZ zorg ontvangen. De ouders in de experimentele groep hebben daarnaast een gepersonaliseerd 360°CHILDoc tot hun beschikking gehad. Voorafgaande aan en na een interventieperiode van 6 maanden zijn relevante kwantitatieve data verzameld bij alle deelnemers van de studie gericht op de uitvoerbaarheid van de RCT. Na afronding van de RCT-metingen, zijn ook gepersonaliseerde 360°CHILDocs gepresenteerd aan de ouders in de controlegroep. Vervolgens hebben alle deelnemende ouders vragenlijsten ingevuld, gericht op het verzamelen van kwantitatieve data met betrekking tot de bruikbaarheid en uitvoerbaarheid van het 360°CHILDoc zelf. Na beschrijvende analyse van de kwantitatieve data hebben interviews en focusgroepen plaatsgevonden. De kwalitatieve data zijn gebruikt om de kwantitatieve bevindingen te verklaren en/of beter te begrijpen en om het perspectief van de stakeholders op de potentiële voordelen van het 360°CHILDoc te exploreren. Integratie van beide databronnen heeft plaatsgevonden op verschillende niveaus. Ten eerste zijn kwantitatieve data gebruikt om participanten doelgericht uit te kunnen nodigen voor deelname aan semigestructureerde interviews en tot een populatie te komen, die heterogeen was op relevante kenmerken. Daarnaast zijn kwantitatieve data gebruikt om de topic lijsten te verfijnen. Ten slotte zijn beide typen data-bronnen vergeleken om de resultaten integraal te analyseren en te komen tot overkoepelende thema's.

**Hoofdstuk 5** beschrijft de integraal vormgegeven kwantitatieve en kwalitatieve resultaten van de evaluatie van de bruikbaarheid en uitvoerbaarheid van het 360°CHILDoc zelf. Binnen deze evaluatie is bruikbaarheid gedefinieerd als “bruikbaar voor het presenteren van de gezondheidssituatie van kinderen” en “gebruikers verwachten dat het nuttig is”. Uitvoerbaarheid is gedefinieerd als “potentieel haalbaar om te implementeren in de JGZ”. Deze evaluatie is uitgevoerd in lijn met het raamwerk voor het systematisch introduceren en evalueren van een innovatie in een preventieve gezondheidszorg setting, ontwikkeld en beschreven door Fleuren et al. In de studie is de mate van gebruik gemeten, evenals een groot aantal determinanten die potentieel het gebruik en het implementatie proces kunnen beïnvloeden. Deze determinanten zijn gerelateerd aan het 360°CHILDoc zelf, haar potentiële gebruikers, maar ook de organisatorische- en socio-politieke context.

Tijdens de studie bespraken deelnemende professionals (n=17) de gepersonaliseerde 360°CHILDocs met de betreffende ouders (n=27). Ouders hebben vragenlijst ingevuld, gebaseerd op het door Fleuren et al. ontwikkelde Meet Instrument voor Determinanten van Innovaties. Vervolgens hebben twaalf interviews (ouders en professionals) en twee focus groep bijeenkomsten plaatsgevonden. Na integratie van de verzamelde kwantitatieve en kwalitatieve data, is in de analyse fase een belangrijk overkoepelend thema naar boven gekomen; “readiness for implementation”. Kenmerkend voor dit thema is dat deelnemers enthousiast hebben gereageerd ten aanzien van het bespreken van het 360°CHILDoc en het snelle overzicht over holistische gezondheidsinformatie hebben gewaardeerd. Tevens is het 360°CHILDoc beschreven als nuttig en efficiënt voor de JGZ-praktijk en gebruikers lijken goed in staat om het 360°CHILDoc te hanteren en te gebruiken binnen de JGZ-context. Echter, de implementatie zelf is lastig gebleken en heel duidelijk gehinderd door substantiële organisatorische issues, zoals onvoldoende facilitering en prioritering door management, een tekort aan personeel en een ervaren hoge werkdruk. Deze issues blijken deels gerelateerd aan het huidige in gebruik zijnde, niet theoretisch gestructureerde Digitaal Dossier JGZ. Deze studie heeft waardevolle kennis opgeleverd over hoe de implementatie strategie verbeterd kan worden.

**Hoofdstuk 6** presenteert de integraal vormgegeven kwantitatieve en kwalitatieve resultaten van de haalbaarheids-RCT. Naast de grondige evaluatie van de RCT-procedures zelf, is de toepasbaarheid van potentiële uitkomstmaten voor het meten van de toegankelijkheid en overdracht van gezondheidsinformatie geëxploreerd.

JGZ-professionals (n=38) hebben ouders (n=30) geworven, tijdens JGZ-contactmomenten van kinderen met een leeftijd tussen 0 en 16 jaar. Na het verkrijgen van informed consent zijn ouders gerandomiseerd en toegewezen naar een van de twee groepen; in dit geval “gebruikelijke zorg” (n=15) oftewel “gebruikelijke zorg met beschikbaarheid van een gepersonaliseerd 360°CHILDoc gedurende zes maanden” (n=15). Er zijn kwantitatieve



data verzameld over de haalbaarheid van het uitvoeren van een RCT met betrekking tot de werving, retentie, naleving van de interventie en respons op vragenlijsten. Daarnaast zijn uitkomstdata met betrekking tot de toegankelijkheid en overdracht van gezondheidsinformatie (n=26) verzameld. Aansluitend zijn 13 semigestructureerde interviews (5 ouders, 8 CHC-professionals) en een “member-check” focus groep (6 CHC-professionals) uitgevoerd om de verkregen kwantitatieve data beter te kunnen begrijpen, verklaren en verder te exploreren.

De in deze studie gebruikte randomisatie strategie, vragenlijsten en interventies waren uitvoerbaar binnen de context van deze studie. De werving van ouders door JGZ-professionals bleek problematischer dan verwacht. De werving is beïnvloed door organisatorische factoren binnen de JGZ-context (bijvoorbeeld een hoge werkdruk) en eigen prioritering door professionals (zoals voorrang geven aan zorg-gerelateerde taken boven onderzoekstaken). De gebruikte uitkomstmaten voor het meten van de toegankelijkheid en overdracht van gezondheidsinformatie zijn onvoldoende toepasbaar gebleken.

Al met al heeft de “Mixed Methods” haalbaarheidsstudie zicht gegeven op de complexiteit van het uitvoeren van een RCT binnen de JGZ-context. De organisatiestructuur vereist een complexere randomisatie strategie. Voor de werving van ouders, lijkt het beter om getrainde onderzoekers in te zetten in plaats van JGZ-professionals. Welke uitkomstmaten het meest geschikt zijn voor het potentieel evalueren van de effectiviteit van het 360°CHILDoc zal verder geëxploreerd en grondig uitgetest moeten worden alvorens het evaluatieproces te continueren. Over het algemeen laten de bevindingen zien dat het uitvoeren van een RCT binnen de context van het evalueren van de effectiviteit van het 360°CHILDoc in de JGZ-setting veel complexer, tijdrovender en duurder is dan van tevoren reeds gedacht.

Tot slot vat **Hoofdstuk 7** het ontwikkel- en evaluatieproces van het 360°CHILDoc samen waarbij gereflecteerd wordt op de methodologische aspecten van het longitudinale onderzoeksproject, met speciale aandacht voor de voordelen van de keuze voor het “Mixed Methods” design. Bovendien beschrijft dit hoofdstuk de discussie over de belangrijkste integratieve bevindingen, waarbij enkele opvallende paradoxen zijn geïdentificeerd.

Aan de ene kant zijn veelbelovende resultaten gevonden over de bruikbaarheid en potentiële voordelen van het 360°CHILDoc voor relevante stakeholders (ouders, jongeren, JGZ-professionals, andere zorgverleners en beleidsmakers) en eigen effectiviteitsverwachting van JGZ-professionals en ouders om het te gebruiken. Aan de andere kant heeft het project substantiële (vooral organisatorische) barrières blootgelegd. Binnen de preventieve JGZ-context wordt het implementatie- en evaluatieproces gehinderd door onvoldoende prioritering en facilitering door het management. Bovendien vereist de organisatorische

structuur een veel complexere en duurdere designvorm inclusief randomisatiesstrategie dan gebruikelijk.

Ten slotte reflecteert hoofdstuk 7 op de betekenis van de bevindingen voor het toekomstperspectief. Belangrijke vragen die worden geadresseerd zijn: a) wat is binnen de JGZ-context nodig om gereed te zijn voor implementatie; en b) hoe kunnen we het veelbelovende 360°CHILDoc evalueren opdat we daadwerkelijk weten hoe het dashboard functioneert binnen deze context.

Het snelle overzicht over holistische gezondheidsdata dat dit dashboard biedt, is potentieel tijdbesparend en kan een begrijpelijke en integrale overdracht van gezondheidsinformatie aan ouders en jongeren mogelijk maken. Bovendien zijn er duidelijke aanwijzingen dat het stimuleert tot een meer consistente en gestructureerde registratie van relevante gezondheidsdata binnen de JGZ. Het meest belangrijke is dat het 360°CHILDoc specifiek ontworpen is om het preventief redeneren te ondersteunen en de denkprocessen intuïtief te sturen in de richting van een meer predictieve, gepersonaliseerde en participatieve jeugdgezondheidszorg.



Impact

## Impact

The initiative for the presented research project arose from my own professional experiences as a medical doctor working within the preventive Child Health Care (CHC). These experiences ignited the search for efficient solutions for problems concerning accessibility of representative child's health data. The aim was to create direct impact on the CHC-practice by enabling to gain better access to and overview on holistic health data. Quick access and a theoretically structured overview of health data is highly relevant for the interpretation and transfer of holistic health information within a preventive CHC and for the needed transformation toward a more personalized preventive CHC.

Initially, the 360°CHILD-profile was developed to facilitate different stakeholders in the CHC-context (care-providers, parents, youth, managers, policy-makers). However, this tool, as well as the knowledge generated during this thesis, also are relevant for health research and medical education with focus on prevention and personalization of health care.

### **Relevance of the 360°CHILD-profile for stakeholders within CHC-practice:**

This pragmatic research project resulted in delivering a meaningful dashboard for CHC-practice with a valid scientific background, a sufficient user-satisfaction, and a high potential that the intended goals can be reached. To the best of our knowledge, this practice-derived dashboard is unique in providing a holistic and structured display of the actual large and complex electronic CHC-data sets in accordance with the ICF-framework. This multifunctional 360°CHILD-profile is customized to the CHC-context to fit the actual CHC's EMD-data sets.

The potential pragmatic values of the 360°CHILD-profile are:

- providing CHC-professionals, parents, youth and other involved care-providers with:
  - o direct and quick access to holistic health data, collected by preventive CHC from birth until the age of 18.
  - o an appropriate representation of a child's health situation in accordance with international standards (ISO 9241-125).
- enabling the CHC to adequately commit to her legal duty to provide parents and youth with (digital) access to health data.
- supporting preventive clinical reasoning by intuitively guiding thinking processes in line with the desired theoretical concepts of a personalized preventive CHC by:
  - o providing overview on the many factors within child and environment that positively or negatively influence health and development.

- displaying the coherence between different health domains by theoretically structuring data of relevant health variables in line with the biopsychosocial model and the ICF.
- facilitating to gain insight in the complex processes underlying health, including a “growing into deficit” in early phases, when symptoms cannot yet be clustered to a diagnose.
- enabling to identify entry points for pro-actively protecting and promoting health and prevent progression towards a disease.
- empowering parents/youth to actively participate during shared decision-making.
- stimulating a more consistent and structured data registration with more unity in language (in line with ICF)
- enabling the CHC to present structured health data on a population level.

The 360°CHILD-profile’s provision of quick access to relevant EMD-data is highly essential for decreasing the enormous effort and time CHC-professionals currently must put in extracting data of relevant variables from the multiple compartments of the EMD.

Moreover, the overview on personal EMD-data exposes which data are (from a theoretical basis) relevant to assess variables and what relevant data are yet missing within the current EMD-registries. Therefore, CHC-professionals gain direct control (autonomy) over their access to collected health data and improve their data-registration by firstly registering information about the most relevant variables. This supports their multifaceted inquiry during CHC-consultations to map the broad (biopsychosocial) health situation of a child.

Furthermore, the 360°CHILD-profile facilitates the transfer of holistic health information to parents during conversations about their child’s health. The 360°CHILD-profile creates a positive ambience and a situation in which parents and youth look at a set of comprehensible health information together with CHC-professionals. This situation invites and empowers parents and youth to share their perspectives on the child’s health situation and actively get involved in identifying “entry points” for managing health.

During multidisciplinary consultations with other involved care-providers, the 360°CHILD-profile supports parents and youth to take an active role during shared decision-making. Their involvement is crucial for establishing preventive, personalized health plans that are practicable and fit the family’s context and lead to improving a child’s health situation.

The preventive clinical reasoning and shared decision-making processes are rather complex and require simultaneous thinking, which is elicited and supported by the 360°CHILD-profile. In fact, its design intuitively (mostly subconscious) guides the thinking processes of care-providers and parents/youth in line with the preferred theoretical (personalized and

preventive) perspective. This differs from the current situation in which CHC-professionals feel insufficiently supported by the content and theoretical unstructured organization of the EMD's. The actual Dutch standard datasets for the EMD's are not based on a theoretical framework, nor the CHC's preventive and broad perspective on health.

Importantly, the 360°CHILD-profile is suitable for providing parents and youth digital access to a summary of data of relevant health variables, stored in the EMD. Access via the online portal for parents (and children from age of 12) practically can make them in charge of the information because they may provide family members and other care-providers with access to relevant health information. This is not yet possible in the current situation of the online CHC-portal for parents as it only presents the grow-chart and vaccination status.

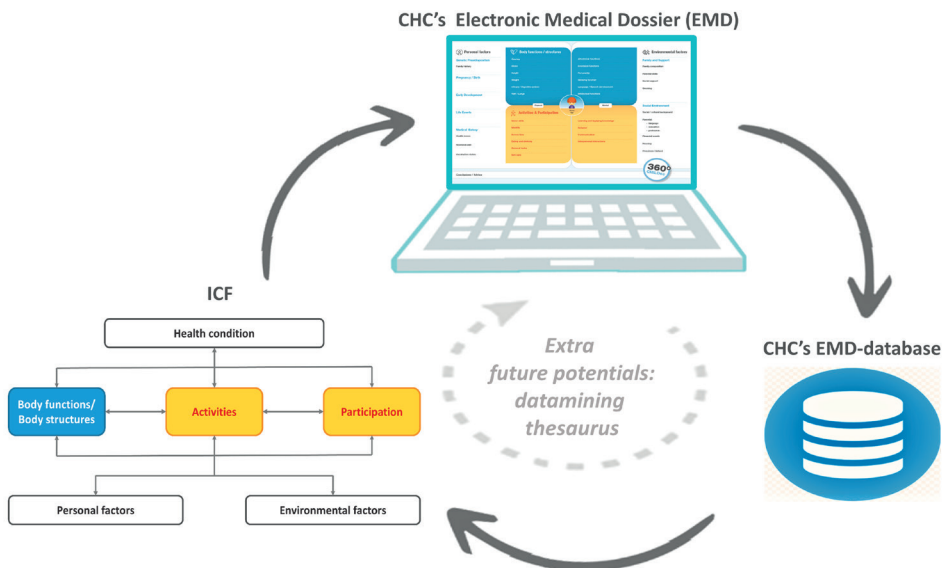
Access to a personal 360°CHILD-profile via the online CHC-portal, also would enable parents/youth to regularly check their child's health information in the periods between CHC-consultations. In future, they also may add or change information on the 360°CHILD-profile and discuss implications for their child's health situation with CHC-professionals via the online portal. This would provide the CHC with opportunities to be more flexible in offering online and/or face-to-face consultations, depending on the parents and children's possibilities and needs.

The 360°CHILD-profile enables quick and adequate informing other involved care-providers about the child's health situation (by e-mail or by adding it to a referral letter).

By generating a personal 360°CHILD-profile, many health data (including developmental milestones, medical history, family history, life events, environmental factors) are extracted from the EMD. During multi-disciplinary consultations, all involved care-providers gain a holistic overview on the different health domains of a child's health and insight in for which health domain each care-provider is involved. The 360°CHILD-profile provides all involved stakeholders with an adequate level of information and supports the communication and coordination of care.

Implementing the 360°CHILD-profile can be of high interest for CHC-managers. It is promised to be timesaving, support a more efficient data and workflow on a qualitative higher level and facilitate the urgently needed transformation toward a personalized preventive CHC. Thereby, the 360°CHILD-profile enables the CHC to commit to the, since 2020, legal duty to provide parents and youth with online access to a summary of EMD's health data [<https://assets.ncj.nl/docs/416f7354-d0d3-4a6f-85ff-474b2949cc0c.pdf>]. Currently, the CHC is not yet able to commit to this duty, let alone to provide an appropriate representation of a child's health situation in accordance with the international standards for representing health information (ISO 9241-125).

The 360°CHILD-profile's potential to stimulate further professionalization toward more consistent and structured registrations with more unity in language is a prerequisite for the CHC's task to also display standardized and theoretically structured health data on a population level. Although all Dutch CHC-organizations follow the same national guidelines, actually, the CHC cannot yet commit to this duty neither. The latest presentation of Dutch data about child health, were based on databases of the national statistical office, Statistics Netherlands (CBS) and the general practitioners' network. In future, the 360°CHILD-profile based on the ICF offers digital possibilities (e.g., thesaurus or datamining) for automatic transformation of health information, registered in the EMD, toward internationally standardized ICF-codes. This high potential to extract from the EMD's more standardized data of multiple health variables on a population level would enable the CHC to present and exchange valuable health data for national and regional health policy (see figure A).



**Figure A: potential positive vicious circle towards better access of CHC's health data on an individual and population level based on integrating 360°CHILD-profile in line with the International Classification of Functioning in CHC's Electronic Medical Dossier.**

### **Relevance of the 360°CHILD-profile and generated knowledge for researchers.**

The 360°CHILD-profile's potential to realize standardized and structured data-registration and to present health data a population level also would lead to the availability of health data that are suitable for epidemiological research. The theoretical foundation (ICF) facilitates research with focus on gaining better insight in children's functioning and the influence of different interactive health variables on health and development. The foreseen



future possibilities for automatic transforming registered health information toward ICF-codes provide additional opportunities to deliver data suitable for epidemiological research. (see figure A)

This thesis generated valuable knowledge for health research with focus on data-visualization within a health care setting. This research presents an example on how data-visualization and interaction design can be used to reach intended goals within a preventive and heterogeneous health care setting. Furthermore, it shows what opportunities can arise from collaboration with experts within the field of data-visualization and the use of a design model to display and attain immediate digital access to personalized holistic health information.

The integrated quantitative and qualitative findings generated broad insight in how to target the implementation strategy and evaluation of this complex intervention within the preventive CHC-context.

This research project demonstrated the importance of considering the specific CHC-context when proceeding the implementation process and an active role of the management in prioritizing ICT-integration of a tool like the 360°CHILD-profile within an EMD and facilitating professionals. The results also highlighted the importance for implementation to adequately inform all target groups (CHC-professionals, parents, youth, managers, policy-makers) about the benefits of the 360°CHILD-profile for the CHC-context. Implementation on a national level, requires a solid marketing communication plan toward national stakeholders like CHC-professionals (for more bottom-up power) and managers, policy-makers (for more top-down power).

A next project is already initiated with focus on increasing the bottom-up power by communicating the assets of this thesis to Dutch CHC-professionals. This project, granted by ZonMw, includes the development of a website (Home - 360CHILDDoc (360child-profile.nl)) and an online course with focus on distributing information about concepts of Personalized CHC and 360°CHILD-profile's research projects and training competencies needed for executing preventive, personalized reasoning.

This research generated valuable knowledge on how to design future studies on performance and effectiveness of the 360°CHILD-profile within CHC-practice.

Insight was provided in how complex it is to perform an RCT within the organizational CHC-context, especially regarding the randomization strategy and appropriate measurement of outcome on 360°CHILD-profile's performance and effectiveness. Therefore, a deliberate,

flexible approach should be considered with alternative designs and Mixed Methods research.

### **Relevance of the 360°CHILD-profile and generated knowledge for medical education.**

Within the current Master of Medicine at Maastricht University, students are educated about preventive CHC during their internship “family medicine and social medicine”. They are trained in essential competencies for preventive consultations (individual and multidisciplinary) and for executing a more preventive, predictive, personalized and participative health care. During lectures and trainings on these topics, I (MW) introduced the 360°CHILD-profile to visualize a case in line with the ICF and visually support the training on communication and preventive clinical reasoning processes.

As prevention is more and more recognized as an essential ingredient of medical care, at the UM, it is decided to address the topic prevention more extensively already within the Bachelor of Medicine. Therefore, prevention and the need for transformation toward personalized CHC is proposed to be covered within the first year of this bachelor and the 360°CHILD-profile is considered as a support tool for addressing these topics.

Regarding post-academic education, the described ZonMw-project that follows this thesis, will result in an online course that is available for professionals working within CHC and adjacent working fields like pediatrics, child psychiatry, child rehabilitation, youth work. Within this online course, the 360°CHILD-profile will be utilized as a support tool. The comprehensible and adequate visual representation of a child’s health situation, based on the ICF especially supports the training of competencies regarding preventive clinical reasoning in line with personalized preventive CHC. The 360°CHILD-profile shows an example of how to gain insight in children’s individual health situation, which is needed for personalizing care. Moreover, the 360°CHILD-profile displays how professionals, together with parents/youth can identify strengths and vulnerabilities and entry-points for pro-active optimization of health and development.



# List of publications

## List of publications:

1. Weijers M, Feron FJM, Bastiaenen CHG. The 360(0)CHILD-profile, a reliable and valid tool to visualize integral child-information. *Prev Med Rep.* 2018;9:29-36; doi: 10.1016/j.pmedr.2017.12.005. <https://pubmed.ncbi.nlm.nih.gov/29318107/> .  
*Status: published in Preventive Medicine Reports March 2018.*
2. Weijers M, Bastiaenen CHG, Feron FJM, Schröder K. Designing a Personalized Health Dashboard: Interdisciplinary and Participatory Approach. *JMIR Form Res* 2021;5(2):e24061; doi:10.2196/24061. <https://formative.jmir.org/2021/2/e24061>.  
*Status: published in JMIR Formative Research February 2021.*
3. Weijers M, Feron FJM, van der Zwet J, Bastiaenen CHG. Evaluation of a New Personalized Health Dashboard in Preventive Child Health Care: Protocol for a Mixed Methods Feasibility Randomized Controlled Trial. *JMIR Res Protoc* 2021;10(3):e21942; doi: 10.2196/21942. <https://www.researchprotocols.org/2021/3/e21942> .  
*Status: published in JMIR research protocols March 2021.*
4. Weijers M, van der Zwet J, Boumans NPG, Feron FJM, Bastiaenen CHG. A digital dashboard for visual representation of child health information: results of a Mixed Methods study on usability and feasibility of a new CHILD-profile.  
*Status: accepted for publication in Journal of Pediatrics, Perinatology and Child Health.*
5. Miriam Weijers, Nicolle P.G. Boumans, Jonne Van der Zwet et al. A feasibility Randomised Controlled Trial as a first step towards evaluating the effectiveness of a digital health dashboard in preventive child health care: A Mixed Methods approach, Pilot Feasibility Stud 9, 25 (2023). <https://doi.org/10.1186/s40814-022-01214-w>





Dankwoord



## Dankwoord

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# Curriculum Vitae

## Curriculum vitae

Miriam Weijers was born on September 26<sup>th</sup>, 1972 in Sittard, the Netherlands. She finished secondary education at Rombouts College in Brunssum in 1990, after which she was admitted to medical school at Maastricht University (UM). An elective in Rehabilitation Medicine got her acquainted with considering a wide range of health determinants when mapping someone's functioning. Her enthusiasm for such a broad perspective on health and her interest in child development led to her choice for an elective internship in Preventive Child Health Care (CHC).

The year after receiving her medical degree in 1997, she combined teaching medical skills at the Skillslab of UM with working as a substitute medical doctor within several CHC-organizations. Soon after gaining a position at the CHC-department of the Regional Public Health Services at Southern of Limburg (GGD ZL), she started her residency at TNO-Leiden. In 2001, she was officially registered as a medical specialist in Community Health and Social Medicine in the field of CHC.

In 2011, she expanded her work at GGD ZL with teaching within the internship Social Medicine at UM. In that period, developments within the CHC-field ignited her wish to find solutions to experienced bottlenecks. This was reinforced by inspiring presentations of professor Frans Feron (department of Social Medicine) about the potential of a Personalized CHC. Supervised by Frans Feron, local innovation funds and a ZonMw-grant enabled her to start the development and evaluation of the 360°CHILD-profile.

In 2013, her desire to obtain more knowledge about scientific research led her to do the master in Epidemiology at UM, where she graduated Cum Laude in 2015. Her master thesis focused on evaluating 360°CHILD-profile's validity and reliability and was supervised by Caroline Bastiaenen, associate professor at the department of Epidemiology. The in 2017 obtained ZonMw-grant was the start of her PhD trajectory, supervised by Frans Feron and Caroline Bastiaenen. During her PhD, she attended the Oxford Course Mixed Methods Designs in Health Care at Oxford University.

To disseminate knowledge generated during her PHD, a follow-up grant from ZonMw was obtained in 2021. Within this project and her work as a teacher at UM, she is developing educational programs on preventive clinical reasoning in line with Personalized CHC for the bachelor and master of Medicine, the residency Public Health Medicine and post-academic education for professionals working within the CHC-context.

Until 2022 she worked as a CHC-medical doctor at the GGD ZL, after which she started to work at a medical day care/treatment centre (Xonar) in the same position.

Miriam was a member of the scientific committee of GGD ZL (2002 – 2007), a member/chair of the board of the day care organization “Stichting Kinderopvang Nuth” (2007-2015). Since 2015, she is a member of the ZonMw guideline committee for preventive CHC.

She is married to Ramon Ottenheijm with whom she has two sons: Yannick and Sem. Her private life includes several passions like hiking, dancing, yoga, playing music and gardening.



