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# BMJ Paediatrics Open

## Improvement and Implementation of a National Individual Care Plan in Paediatric Palliative Care: A Study Protocol

Journal:	<i>BMJ Paediatrics Open</i>
Manuscript ID	bmjpo-2022-001677
Article Type:	Protocol
Date Submitted by the Author:	16-Sep-2022
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Keywords:	Palliative Care

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# Improvement and Implementation of a National Individual Care Plan in Paediatric Palliative Care: A

## Study Protocol

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**Word count: 2480**

## Abstract

**Introduction:** Paediatric palliative care (PPC) is care for children with life-threatening or life-limiting conditions, and involves complex high-tech care, which can last for months or years. In 2015, the National Individual Care Plan (ICP) for PPC was developed and has shown to be successful. The ICP can be seen as an instrument to facilitate coordination, quality and continuity of PPC. However, in practice an ICP is often completed too late and for too few children. We aim to improve the coordination, quality and continuity of care for every child with a life-threatening or life-limiting condition and his/her family by further developing and implementing the ICP in the Netherlands.

**Methods and analysis:** To evaluate the original ICP, ICP 1.0, interviews and questionnaires will be held among parents of children who have or have had an ICP 1.0 and HCPs who used ICP 1.0. Based on the results, ICP 1.0 will be further developed. An implementation strategy will be written and the renewed ICP, ICP 2.0, will be nationally tested in an implementation period of approximately seven months. During the implementation period, ICP 2.0 will be used for all children who are registered with Children's Palliative Care teams. After the implementation period, ICP 2.0 will be evaluated using interviews and questionnaires among parents of children who received ICP 2.0 and HCPs who worked with ICP 2.0. Based on these results, ICP 2.0 will be further optimized into the final version: ICP 3.0.

**Ethics and Dissemination:** This study received ethical approval. The ICP 3.0 will be disseminated through the Dutch Centre of Expertise in Children's Palliative Care, to ensure wide availability for the general public and HCPs within PPC. Additionally, we aim to publish study results in open-access, peer-reviewed journals and to present results at national and international scientific meetings.

**What is already known on this topic?**

- ICP's have shown to reduce fragmented care and to improve health outcomes, quality of care for complex patients and health status indicators.

**What this study hopes to add?**

- This study will identify the perceived barriers and facilitators for an ICP in PPC from the perspective of child/parents and healthcare professionals.
- This study will provide insight into which concrete improvements are an appropriate approach to implement an ICP fully and sustainably in PPC.
- This study will give insight into the process of drawing up and working with an ICP in PPC.

**How this study might affect research, practice or policy:**

- This study will result in a further developed nationally implemented ICP supported by parents and healthcare professionals for children who receive PPC.
- By further developing and implementing the ICP, the ICP will be an enrichment of care and will improve continuity of care for children who receive PPC.

## Introduction:

Paediatric palliative care (PPC) is care for children with life-threatening or life-limiting conditions (1). Most of the children eligible for PPC receive complex high-tech care, which can last for months or years (2,3). This care is often provided by many different healthcare professionals (HCPs) in different lines of care and organizations, which can lead to fragmentation of care and lack of continuity of care (3,4). Without established anticipatory care, e.g. an Individual Care Plan (ICP), PPC must be provided more often, with less expertise, in emergency situations, outside office hours and by non-regular practitioners, all with consequences for the continuity of care (5).

In 2013, the Dutch multidisciplinary, evidence based guideline 'palliative care for children' was published (6). The guideline aims to improve PPC by formulating recommendations, including recommendations for decision-making and organization of care. Currently, the Dutch guideline is being revised. Based on the recommendations of the guideline, an ICP for PPC was developed to translate the general recommendations into a personalised plan for the individual child (5). The ICP supports HCPs, and the child and his/her family to address all dimensions of PPC, i.e. physical, psychological, social and spiritual, in a structured manner. The ICP supports patient- and family centred care aligned to the family's needs, goals and preferences, provides a clear overview of their preferences and desires, and of shared goals of child/parents and HCPs.

Among adults, ICP's have shown to promote patients capability to self-manage their conditions and improve health status indicators (7). In children with cerebral palsy the use of an ICP has shown to facilitate family centred care, helped parents to navigate their child's care, decreased hospital admissions, shortened hospital stays and reduced fragmentation of care (8). The Dutch ICP has shown to facilitate high-quality care and the transitions of care between hospital and home (5). Despite promising results on the use of ICP in healthcare, there is little insight into the use of ICP's in PPC.

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3 Despite the increase of specialised PPC, the ICP is not completed for all children in PPC, and  
4 often drawn up in the terminal phase, while issues with fragmentation of care and continuity of care  
5 can exist from the start of PPC and not only in the terminal phase (4). Furthermore, advance care  
6 planning tools are not always used, while these could fit very well with the ICP process (9). It is  
7 therefore important to study which adjustments are necessary to have the ICP used to its full  
8 potential, what parents and HCPs value and dislike about the ICP, and what the process of drawing  
9 up and working with an ICP looks like. By studying this, we aim to improve the ICP document and  
10 user experiences, strengthen the patient- and family centeredness and integrate ACP, and thereby  
11 improving the quality and continuity of care for every child with a life-threatening or life-limiting  
12 condition and his/her family. In this paper we present our study protocol of the study: "Improvement  
13 and Implementation of a National individual Care Plan in Paediatric Palliative care".  
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## 28 **Methods:**

### 29 **Setting:**

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32 In the Netherlands, PPC is uniquely structured with the use of transmural Children's Palliative Care  
33 (CPC) teams and CPC networks. CPC networks provide consultation for families and HCPs across  
34 different healthcare domains (2). Multidisciplinary CPC teams form a bridge between hospital and  
35 home, and the teams provide support and guidance to families and HCPs (2,10).  
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### 44 **Study design:**

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46 Given the nature of the research questions, a mixed-methods approach is most appropriate, in which  
47 qualitative and quantitative research are combined in a cross-sectional study for child/parents and  
48 pre- and post-test design for HCPs. By integrating qualitative and quantitative methods in this  
49 multiphase mixed-method study, we aim to gain insight into the experiences of HCPs and  
50 child/parents with the ICP in practice and effectively tailor the ICP (11). This study consists of five  
51 phases. The current ICP, from now on ICP 1.0, will be evaluated and adapted into ICP 2.0, followed by  
52 an implementation period where ICP 2.0 will be implemented for evaluation purposes. After the  
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3 implementation period, ICP 2.0 will be evaluated and optimized into the final version: ICP 3.0 (*Figure*  
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5 *1.0*).

## 8 **Phases of the study**

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11 The five phases of the study are presented in figure 1.

### 14 **Phase 1**

#### 16 *Evaluation of ICP 1.0 and drawing up an implementation strategy*

17  
18 In phase 1 ICP 1.0 will be evaluated by exploring the “lived-experience” of HCPs and child/parents  
19  
20 using the ICP 1.0 in practice. The barriers and facilitators concerning the content and use of ICP 1.0,  
21  
22 will be evaluated in focus groups with HCPs and individual interviews with child/parents, and with an  
23  
24 online questionnaire for all respondents groups. Based on the results that emerge from the data, the  
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26 project group will jointly develop a strategy for the adaptation of ICP 1.0 and the implementation of  
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28 ICP 2.0.  
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#### 32 *Measurements*

33  
34 To identify the barriers and facilitators for the ICP 1.0 per target group a mixed methods approach  
35  
36 suitable to the RE-AIM framework with quantitative exploration of individual, social, organizational  
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38 and societal/economic factors using the MIDI (12) and qualitative exploration of context and  
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40 experience/needs aspects such as responsibility, motivation and perceived urgency (13,14) is used.  
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42 The questionnaire consists of the MIDI, the questions from the ICP 1.0 pilot study (5), study  
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44 describing the development of ICP 1.0, supplemented with questions about the reasons why the ICP  
45  
46 has or has not been completed. Guidance for these questions are the Hexagon tool (15).  
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49  
50 The focus group and individual interviews will mainly focus on experiences of parents and HCPs  
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52 involved in working with the ICP 1.0 in daily practice. An interview guide will be designed based on  
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54 literature and expertise from HCPs and the research team, on the basis of which respondents are  
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56 asked to share their experiences, see *Table 1*.  
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Table 1. Measurements overview of study phase 1.

Measurements	Phase 1	
	Parents	HCPs
<b>Qualitative</b>		
- Content of ICP: to what extent does the ICP cover the reality of the situation from the perspective of the people involved	x	x
- Procedures and goals: what is it like to create and maintain an ICP, reason and purpose regarding the ICP, shared process with child/parents, facilitators/barriers	x	x
- Position, contribution of child/parents and its translation in the ICP: how it was established, recognizability of own contribution/perspective, future-oriented, was the development supportive or burdening, what does it mean for the parent-professional relationship	x	x
<b>Quantitative</b>		
- Study specific questionnaire on background variables, content, process and lay-out of ICP	x	x
- MIDI		x

### Sample size

Due to the low number of children for whom an ICP is completed each year, in combination with the very low response for participation of children/parents in PPC research, no realistic power calculation can be made for the required number of participants. It is expected that a total of approximately 200 children per year will be cared for in the eight CPC teams. Based on this estimation, the estimated total sample size for the quantitative study of phase 1 is 200 HCPs and parents. For the qualitative study of phase 1, we expect that 10 parents and 25 HCPs is realistic, but achieving data saturation will be leading.

### Phase 2

#### Adaptation of ICP 1.0

Based on the finding of study phase 1, the content and form of ICP 1.0 will be adapted into ICP 2.0.

The accompanying manual, which provides information and tools for HCPs for all parts of the ICP, will be adapted accordingly.

**Phase 3***Implementation period of ICP 2.0*

Based on the implementation strategy developed in phase 1, ICP 2.0, will be implemented as the standard of care planning in the Netherlands. This implies adoption of the ICP by all CPC teams and other lines of care that provide PPC in the Netherlands. The implementation period of ICP 2.0 will last approximately seven months.

*Measurements*

During the implementation period, ICP 2.0 will be applied in practice by HCPs working in the eight CPC teams and in organisations connected to the CPC networks. At the end of the implementation period the number of ICPs drawn up of the total number of children in care at the CPC teams will be calculated.

*Sample size*

We estimate that during the implementation period, approximately 25-30 HCPs, of whom two nurses and one or two paediatricians per CPC team, will fill in ICP 2.0 several times. Most paediatricians and nurses in general hospitals and primary care will complete the ICP 2.0 once.

**Phase 4***Evaluation of ICP 2.0*

After the implementation period, ICP 2.0 will be evaluated using both qualitative and quantitative measures. Children and parents of children who received an ICP 2.0 will be asked to participate in an interview and/or questionnaire. HCPs who worked with ICP 2.0 will be invited to participate in a focus group and/or questionnaire.

*Measurements*

The measurements used are similar to those of phase 1. The interviews will focus on experiences with the ICP 2.0 in practice.

To gain insight into the quality of life of child/parents and family-centred care from the perspective of parents of children who have an ICP 2.0 several questionnaires are added to the quantitative measurements. At the time of writing, CPOS-2 (16) and the PREM Child Care (17) are the most appropriate tools for this, see *Table 2*.

*Table 2. Measurement overview of study phase 2.*

Measurements	Phase 4	
	Parents	HCPs
<b>Qualitative</b>		
- Content of ICP: to what extent does the ICP cover the reality of the situation from the perspective of the people involved	x	x
- Procedures and goals: what is it like to create and maintain an ICP, reason and purpose regarding the ICP, shared process with child/parents, facilitators/barriers	x	x
- Position, contribution of child/parents and its translation in the ICP: how it was established, recognizability of own contribution/perspective, future-oriented, was the development supportive or burdening, what does it mean for the parent-professional relationship	x	x
- Role of the ICP in shared decision making and/or family centred care.	X	x
<b>Quantitative</b>		
- Study specific questionnaire on background variables, content, process and lay-out of ICP	x	x
- MIDI		x
- CPOS-2	x	
- PREM Child Care	x	

### *Sample size*

Based on the estimations for the implementation period and the reasons mentioned previously for study phase 1, the estimated total sample size for the quantitative study of phase 4 is 100 HCPs and parents. For the qualitative study of phase 4 we expect that 10 parents and 25 HCPs is realistic, but data saturation will be leading.

The proportion of participants that are parents will differ from the participants in phase 1 in both the qualitative and quantitative study, because ICP 2.0 will not be drawn up for children who already received an ICP 1.0. The proportion of participants that are HCPs may have also participated in phase

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3 1 in the qualitative and/or quantitative study. If this is the case, this will be recorded and included in  
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5 the data analysis.  
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### 8 **Phase 5**

#### 9 *Optimizing into the final version of the ICP, ICP 3.0*

10 Based on the findings of phase 4, a final version of the ICP, ICP 3.0, and manual will be developed.

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13 The ICP 3.0 and manual will then be distributed via the Dutch Centre of Expertise in Children's  
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15 Palliative Care, CPC teams, CPC networks, and several parent- and patient associations for use in  
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17 practice.  
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### 22 **Inclusion criteria**

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24 The inclusion criteria are only relevant for study phases 1 and 4, see *Table 3*. The inclusion criteria are  
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26 the same for the qualitative and quantitative studies, except for children. Children are only invited to  
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28 participate in the qualitative study.  
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32 *Table 3. Inclusion criteria for study phase 1 and 4.*

33 <b>Inclusion criteria</b>	34 <b>Parents</b>	35 <b>HCPs</b>	36 <b>Children</b>
37 <b>Phase 1</b>	38 - Parent of a child with a life-limiting or life-threatening condition alive or deceased in the 36 months prior to the inclusion 39 - In possession of a completed ICP 1.0 40 - Able to understand and follow study procedures 41 - Can read and understand the Dutch language	42 - Has completed the ICP 1.0 of a child with a life-limiting or life-threatening condition or has worked with the ICP 1.0 in practice. 43 - Can read and understand the Dutch language	44 - Known with a life-limiting or life-threatening condition 45 - 12 years or older 46 - In care of a CPC team 47 - In possession of a completed ICP 1.0 48 - Deemed competent by parents and the lead physician 49 - Can read and understand the Dutch language
50 <b>Phase 4</b>	51 - Parent of a child with a life-limiting or life-threatening condition for whom a ICP 2.0 is in progress or completed within the implementation period 52 - Able to understand and follow study procedures	53 - Has completed the ICP 2.0 of a child with a life-limiting or life-threatening condition or has worked with the ICP 2.0 in practice. 54 - Can read and understand the Dutch language	55 - Known with a life-limiting or life-threatening condition 56 - 12 years or older 57 - In care of a CPC team 58 - In possession of a completed or in progress ICP 2.0 59 - Deemed competent by parents and the lead physician

	- Can read and understand the Dutch language		- Can read and understand the Dutch language
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### Recruitment:

Recruitment of participants will take place through the CPC teams and CPC networks. CPC teams are the main users of the ICP and can thus reach the largest group of participants. CPC networks contain a network of HCPs who use the ICP. They also offer support to families with a child who receives PPC, who already have an ICP or are eligible for an ICP. Therefore, CPC networks have connections to both HCPs and families. The CPC teams and networks will identify which HCPs, parents, and if possibly children are eligible to participate in the study based on the inclusion criteria. They will inform these potential participants by email on the content and importance of the study. The email also contains the email address of the researcher and reference is made to the project website for detailed information about the research and participation. If a respondent decides to participate, he/she can let the researcher know by email or via the website. Respondents can indicate whether they are interested in participating in the quantitative and/or qualitative research. Children will only be approached to participate in an interview. The researcher will contact the respondents who meet the inclusion criteria and who have indicated to want to partake in an interview by telephone to schedule an appointment. HCPs who meet the inclusion criteria will be contacted by the researcher to schedule an appointment for the focus groups.

Alle respondents who indicated to want to partake in the quantitative research will be send a link to the questionnaire. Participants of the questionnaire will be sent a reminder two weeks after the initial invitation to complete the questionnaire.

### Description of qualitative and statistical analysis

The interviews and focus groups will be videotaped. The videotapes will be transcribed verbatim and thereafter destroyed. We aim to gain insight into the experiences of various actors using the ICP in practice. This research therefore does not fit into a current trend. Thus, we use methods for 'generic'

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3 qualitative research. For the content analysis, use is made of open and axial coding and constant  
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5 comparison, in order to be able to make a good representation of the ICP in practice (18). The  
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7 qualitative analysis will be supported by the software program Atlas ti.  
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10 The questionnaires are completed on a Likert scale, two-point scale, and open questions. All  
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12 quantitative data will be descriptively analysed using mean,  $\pm$ SD, median and interquartile range  
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14 using the statistical software program SPSS. In addition, the satisfaction of HCPs with the ICP 1.0 and  
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16 the ICP 2.0 will be analysed for differences, taking into account repeated measurements using tests  
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18 such as paired samples T-test or mixed models.  
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### 22 **Patient and Public involvement**

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24 Patient and public were involved in the development of this protocol and will be part of the core  
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26 project team during the study. Patients are involved through representatives, including parents and  
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28 organisations such as the Dutch Foundation Child and Hospital.  
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### 32 **Ethics and Dissemination**

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34 This study does not require formal ethical approval as it is not subjected to the Dutch act WMO  
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36 ([https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-  
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60](https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-research-is-it-subject-to-the-wmo-or-not)). However, we still obtained ethical approval for study  
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42 phase 1 from all medical ethical committees of the seven University Hospitals and the Paediatric  
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44 Oncology Centre. For study phase 3, ethical approval will be sought as well using addendums to the  
45  
46 previous approved ethical approval requests.

48 Study participant are carefully and fully informed of the study and asked to give consent digitally.  
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50

### 51 *Dissemination*

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54 During the implementation period, study phase 3, the ICP 2.0 will be disseminated through the CPC  
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56 networks, CPC teams and the Dutch Centre of Expertise in Children's Palliative Care. At the end of the  
57  
58 study, the final version of the ICP, ICP 3.0, will be disseminated through the Dutch Centre of Expertise  
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60

in Children's Palliative Care, to ensure wide availability for the general public and HCPs within PPC. In addition, we aim to publish study results in open-access, peer-reviewed journals and to present results at national and international scientific meetings.

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### Authors’ contributions

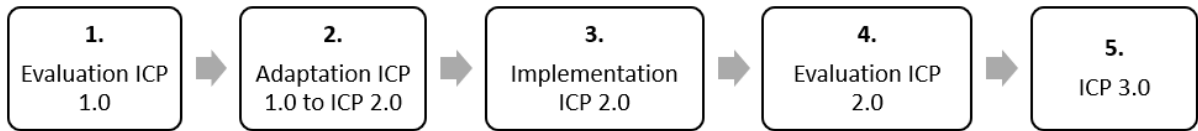
CJ drafted the manuscript. MK, LK, HR, EV and JA were major contributors to the development of the study protocol. All authors contributed to revising the protocol and manuscript. All authors have approved the final manuscript.

### Funding statement

This work was supported by ZonMw grant number 844001709.

### Competing interests statement

None Declared.



Confidential: For Review Only

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# BMJ Paediatrics Open

## Improvement and Implementation of a National Individual Care Plan in Paediatric Palliative Care: A Study Protocol

Journal:	<i>BMJ Paediatrics Open</i>
Manuscript ID	bmjpo-2022-001677.R1
Article Type:	Protocol
Date Submitted by the Author:	08-Nov-2022
Complete List of Authors:	Joren, Chantal; University of Groningen, University Medical Center Groningen, Beatrix Children's Hospital Kars, Marijke C.; Center of Expertise Palliative Care Utrecht, Julius Center of Health and Primary Care Kremer, Leontien; Princess Maxima Centre for Pediatric Oncology Rippen, Hester; Dutch Foundation Child and Hospital Verhagen, Eduard; University of Groningen, University Medical Center Groningen, Beatrix Children's Hospital Aris-Meijer, Judith; University of Groningen, University Medical Center Groningen, Beatrix Children's Hospital
Keywords:	Palliative Care

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# Improvement and Implementation of a National Individual Care Plan in Paediatric Palliative Care: A

## Study Protocol

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**Word count: 2747**

## Abstract

**Introduction:** Paediatric palliative care (PPC) is care for children with life-threatening or life-limiting conditions, and can involve complex high-tech care, which can last for months or years. In 2015, the National Individual Care Plan (ICP) for PPC was developed and has shown to be successful. The ICP can be seen as an instrument to facilitate coordination, quality and continuity of PPC. However, in practice an ICP is often completed too late and for too few children. We aim to improve the coordination, quality and continuity of care for every child with a life-threatening or life-limiting condition and his/her family by further developing and implementing the ICP in the Netherlands.

**Methods and analysis:** To evaluate the original ICP, ICP 1.0, interviews and questionnaires will be held among parents of children who have or have had an ICP 1.0 and HCPs who used ICP 1.0. Based on the results, ICP 1.0 will be further developed. An implementation strategy will be written and the renewed ICP, ICP 2.0, will be nationally tested in an implementation period of approximately seven months. During the implementation period, ICP 2.0 will be used for all children who are registered with Children's Palliative Care teams. After the implementation period, ICP 2.0 will be evaluated using interviews and questionnaires among parents of children who received ICP 2.0 and HCPs who worked with ICP 2.0. Based on these results, ICP 2.0 will be further optimized into the final version: ICP 3.0.

**Ethics and Dissemination:** This study received ethical approval. The ICP 3.0 will be disseminated through the Dutch Centre of Expertise in Children's Palliative Care, to ensure wide availability for the general public and HCPs within PPC. Additionally, we aim to publish study results in open-access, peer-reviewed journals and to present results at national and international scientific meetings.

**What is already known on this topic?**

- ICP's have shown to reduce fragmented care and to improve health outcomes, quality of care for complex patients and health status indicators.

**What this study hopes to add?**

- This study will identify the perceived barriers and facilitators for an ICP in PPC from the perspective of child/parents and healthcare professionals.
- This study will provide insight into which concrete improvements are an appropriate approach to implement an ICP fully and sustainably in PPC.
- This study will give insight into the process of drawing up and working with an ICP in PPC.

**How this study might affect research, practice or policy:**

- This study will result in a further developed nationally implemented ICP supported by parents and healthcare professionals for children who receive PPC.
- By further developing and implementing the ICP, the ICP will be an enrichment of care and will improve continuity of care for children who receive PPC.

## Introduction:

Paediatric palliative care (PPC) is care for children with life-threatening or life-limiting conditions (1). PPC begins when a life-limiting or life-threatening illness is diagnosed and continues regardless of whether or not the child receives curative treatment (2). PPC is the prevention and relief of physical, psychological, social and spiritual suffering of children and their family, and thereby aligns with patient- and family centred care (2). According to The Institute for Patient- and Family-Centered Care, patient- and family centred care is grounded in mutually beneficial partnerships among patients, families, and healthcare professionals (HCPs) in the planning, delivery and evaluation of care (3). Most of the children eligible for PPC receive complex high-tech care, which can last for months or years (4,5). This care is often provided by many different HCPs in different lines of care and organizations, which can lead to fragmentation of care and lack of continuity of care (5,6). Without established anticipatory care, e.g. an Individual Care Plan (ICP), PPC must be provided more often, with less expertise, in emergency situations, outside office hours and by non-regular practitioners, all with consequences for the continuity of care (7).

In 2013, the Dutch multidisciplinary, evidence based guideline 'palliative care for children' was published (8). The guideline aims to improve PPC by formulating recommendations, including recommendations for decision-making and organization of care. Currently, the Dutch guideline is being revised. Based on the recommendations of the guideline, an ICP for PPC was developed to translate the general recommendations into a personalised plan for the individual child (7). The ICP is a written care plan that supports HCPs, and the child and his/her family to address all dimensions of PPC, i.e. physical, psychological, social and spiritual, in a structured manner. The ICP supports patient- and family centred care aligned to the family's needs, goals and preferences, provides a clear overview of their preferences and desires, and of shared goals of child/parents and HCPs. Advance care planning is an approach that facilitates appropriate future care planning which is integrated as part of the process of developing an ICP (9).



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3 Among adults, ICP's have shown to promote patients capability to self-manage their  
4 conditions and improve health status indicators (10). In children with cerebral palsy the use of an ICP  
5 has shown to facilitate family centred care, helped parents to navigate their child's care, decreased  
6 hospital admissions, shortened hospital stays and reduced fragmentation of care (11). The Dutch ICP  
7 has shown to facilitate high-quality care and the transitions of care between hospital and home (7).  
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9 Despite promising results on the use of ICP in healthcare, there is little insight into the use of ICP's in  
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PPC.

Despite the increase of specialised PPC, the ICP is not completed for all children in PPC, and often drawn up in the terminal phase, while issues with fragmentation of care and continuity of care can exist from the start of PPC and not only in the terminal phase (6). Furthermore, advance care planning tools are not always used, while these could fit very well with the ICP process (12). It is therefore important to study which adjustments are necessary to have the ICP used to its full potential, what parents and HCPs value and dislike about the ICP, and what the process of drawing up and working with an ICP looks like. By studying this, we aim to improve the ICP document and user experiences, strengthen the patient- and family centeredness and integrate advance care planning, and thereby improving the quality and continuity of care for every child with a life-threatening or life-limiting condition and his/her family. In this paper we present our study protocol of the study: "Improvement and Implementation of a National individual Care Plan in Paediatric Palliative care".

## Methods:

### Setting:

In the Netherlands, PPC is uniquely structured with the use of transmurals Children's Palliative Care (CPC) teams and CPC networks. CPC networks provide consultation for families and HCPs across different healthcare domains (4). Multidisciplinary CPC teams form a bridge between hospital and home, and the teams provide support and guidance to families and HCPs (4,13).

### Study design:

Given the nature of the research questions, a mixed-methods approach is most appropriate, in which qualitative and quantitative research are combined in a cross-sectional study for child/parents and pre- and post-test design for HCPs. By integrating qualitative and quantitative methods in this multiphase mixed-method study, we aim to gain insight into the experiences of HCPs and child/parents with the ICP in practice and effectively tailor the ICP (14). This study consists of five phases. The current ICP, from now on ICP 1.0, will be evaluated and adapted into ICP 2.0, followed by an implementation period where ICP 2.0 will be implemented for evaluation purposes. After the implementation period, ICP 2.0 will be evaluated and optimized into the final version: ICP 3.0 (*Figure 1.0*). Children who have received an ICP 1.0 will not receive an ICP 2.0 during the study period. Therefore, parents will be included in a cross-sectional way.

### Phases of the study

The five phases of the study are presented in figure 1.

#### **Phase 1**

##### *Evaluation of ICP 1.0 and drawing up an implementation strategy*

In phase 1 ICP 1.0 will be evaluated by exploring the “lived-experience” of HCPs and child/parents using the ICP 1.0 in practice. The barriers and facilitators concerning the content and use of ICP 1.0, will be evaluated in focus groups with HCPs and individual interviews with child/parents, and with an online questionnaire for all respondents groups. Based on the results that emerge from the data, the project group will jointly develop a strategy for the adaptation of ICP 1.0 and the implementation of ICP 2.0.

##### *Measurements*

To identify the barriers and facilitators for the ICP 1.0 per target group a mixed methods approach suitable to the RE-AIM framework with quantitative exploration of individual, social, organizational and societal/economic factors using the Measurement Instrument for Determinants of Innovations

(MIDI) (15) and qualitative exploration of context and experience/needs aspects such as responsibility, motivation and perceived urgency (16,17) is used. The questionnaire consists of the MIDI, the questions from the ICP 1.0 pilot study (7), study describing the development of ICP 1.0, supplemented with questions about the reasons why the ICP has or has not been completed. Guidance for these questions are the Hexagon tool (18).

The focus group and individual interviews will mainly focus on experiences of parents and HCPs involved in working with the ICP 1.0 in daily practice. An interview guide will be designed based on literature and expertise from HCPs and the research team, on the basis of which respondents are asked to share their experiences, see *Table 1*.

*Table 1. Measurements overview of study phase 1.*

Measurements	Phase 1	
	Parents	HCPs
<b>Qualitative</b>		
- Content of ICP: to what extent does the ICP cover the reality of the situation from the perspective of the people involved	x	x
- Procedures and goals: what is it like to create and maintain an ICP, reason and purpose regarding the ICP, shared process with child/parents, facilitators/barriers	x	x
- Position, contribution of child/parents and its translation in the ICP: how it was established, recognizability of own contribution/perspective, future-oriented, was the development supportive or burdening, what does it mean for the parent-professional relationship	x	x
<b>Quantitative</b>		
- Study specific questionnaire on background variables, content, process and lay-out of ICP	x	x
- MIDI		x

### *Sample size*

Due to the low number of children for whom an ICP is completed each year, no realistic power calculation can be made for the required number of participants. It is expected that a total of approximately 200 children per year will be cared for in the eight CPC teams. Based on this estimation, the estimated total sample size for the quantitative study of phase 1 is 200 HCPs and

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3 parents. For the qualitative study of phase 1, we expect that 10 parents and 25 HCPs is realistic, but  
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5 achieving data saturation will be leading.  
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## 8 **Phase 2**

### 9 *Adaptation of ICP 1.0*

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13 Based on the finding of study phase 1, the content and form of ICP 1.0 will be adapted into ICP 2.0.

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15 The accompanying manual, which provides information and tools for HCPs for all parts of the ICP, will  
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17 be adapted accordingly.  
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## 20 **Phase 3**

### 21 *Implementation period of ICP 2.0*

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25 Based on the implementation strategy developed in phase 1, ICP 2.0, will be implemented as the  
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27 standard of care planning in the Netherlands. This implies adoption of the ICP by all CPC teams and  
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29 other lines of care that provide PPC in the Netherlands. The implementation period of ICP 2.0 will last  
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31 approximately seven months.  
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### 34 *Measurements*

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38 During the implementation period, ICP 2.0 will be applied in practice by HCPs working in the eight  
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40 CPC teams and in organisations connected to the CPC networks. At the end of the implementation  
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42 period the number of ICPs drawn up of the total number of children in care at the CPC teams will be  
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44 calculated.  
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### 47 *Sample size*

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50 We estimate that during the implementation period, approximately 25-30 HCPs, of whom two nurses  
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52 and one or two paediatricians per CPC team, will fill in ICP 2.0 several times. Most paediatricians and  
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54 nurses in general hospitals and primary care will complete the ICP 2.0 once.  
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## 57 **Phase 4**

### 58 *Evaluation of ICP 2.0*

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After the implementation period, ICP 2.0 will be evaluated using both qualitative and quantitative measures. Children and parents of children who received an ICP 2.0 will be asked to participate in an interview and/or questionnaire. HCPs who worked with ICP 2.0 will be invited to participate in a focus group and/or questionnaire.

### Measurements

The measurements used are similar to those of phase 1. The interviews will focus on experiences with the ICP 2.0 in practice.

To gain insight into the quality of life of child/parents and family-centred care from the perspective of parents of children who have an ICP 2.0 several questionnaires are added to the quantitative measurements. At the time of writing, the Children's Palliative Outcome Scale (CPOS-2) (19) and the Patient Reported Experience Measures (PREM) Child Care (20) are the most appropriate tools for this, see *Table 2*.

*Table 2. Measurement overview of study phase 2.*

Measurements	Phase 4	
	Parents	HCPs
<b>Qualitative</b>		
- Content of ICP: to what extent does the ICP cover the reality of the situation from the perspective of the people involved	x	x
- Procedures and goals: what is it like to create and maintain an ICP, reason and purpose regarding the ICP, shared process with child/parents, facilitators/barriers	x	x
- Position, contribution of child/parents and its translation in the ICP: how it was established, recognizability of own contribution/perspective, future-oriented, was the development supportive or burdening, what does it mean for the parent-professional relationship	x	x
- Role of the ICP in shared decision making and/or family centred care.	x	x
<b>Quantitative</b>		
- Study specific questionnaire on background variables, content, process and lay-out of ICP	x	x
- MIDI		x
- CPOS-2	x	
- PREM Child Care	x	

### Sample size

Based on the estimations for the implementation period and the reasons mentioned previously for study phase 1, the estimated total sample size for the quantitative study of phase 4 is 100 HCPs and parents. For the qualitative study of phase 4 we expect that 10 parents and 25 HCPs is realistic, but data saturation will be leading.

The proportion of participants that are parents will differ from the participants in phase 1 in both the qualitative and quantitative study, because ICP 2.0 will not be drawn up for children who already received an ICP 1.0. The proportion of participants that are HCPs may have also participated in phase 1 in the qualitative and/or quantitative study. If this is the case, this will be recorded and included in the data analysis.

### Phase 5

#### *Optimizing into the final version of the ICP, ICP 3.0*

Based on the findings of phase 4, a final version of the ICP, ICP 3.0, and manual will be developed.

The ICP 3.0 and manual will then be distributed via the Dutch Centre of Expertise in Children's Palliative Care, CPC teams, CPC networks, and several parent- and patient associations for use in practice.

### Inclusion criteria

The inclusion criteria are only relevant for study phases 1 and 4, see *Table 3*. The inclusion criteria are the same for the qualitative and quantitative studies, except for children. Children are only invited to participate in the qualitative study.

*Table 3. Inclusion criteria for study phase 1 and 4.*

Inclusion criteria	Parents	HCPs	Children
<b>Phase 1</b>	- Parent of a child with a life-limiting or life-threatening condition alive or deceased in the 36 months prior to the inclusion	- Has completed the ICP 1.0 of a child with a life-limiting or life-threatening condition or has worked with the ICP 1.0 in practice.	- Known with a life-limiting or life-threatening condition - 12 years or older - In care of a CPC team

	<ul style="list-style-type: none"> <li>- In possession of a completed ICP 1.0</li> <li>- Able to understand and follow study procedures</li> <li>- Can read and understand the Dutch language</li> </ul>	<ul style="list-style-type: none"> <li>- Can read and understand the Dutch language</li> </ul>	<ul style="list-style-type: none"> <li>- In possession of a completed ICP 1.0</li> <li>- Deemed competent by parents and the lead physician</li> <li>- Can read and understand the Dutch language</li> </ul>
<b>Phase 4</b>	<ul style="list-style-type: none"> <li>- Parent of a child with a life-limiting or life-threatening condition for whom a ICP 2.0 is in progress or completed within the implementation period</li> <li>- Able to understand and follow study procedures</li> <li>- Can read and understand the Dutch language</li> </ul>	<ul style="list-style-type: none"> <li>- Has completed the ICP 2.0 of a child with a life-limiting or life-threatening condition or has worked with the ICP 2.0 in practice.</li> <li>- Can read and understand the Dutch language</li> </ul>	<ul style="list-style-type: none"> <li>- Known with a life-limiting or life-threatening condition</li> <li>- 12 years or older</li> <li>- In care of a CPC team</li> <li>- In possession of a completed or in progress ICP 2.0</li> <li>- Deemed competent by parents and the lead physician</li> <li>- Can read and understand the Dutch language</li> </ul>

#### Recruitment:

Recruitment of participants will take place through the CPC teams and CPC networks, and social media and newsletter from the Dutch Centre of Expertise in Children's Palliative Care, reaching those under care of CPC teams and those who are not. CPC teams are the main users of the ICP and can thus reach the largest group of participants. CPC networks contain a network of HCPs who use the ICP. They also offer support to families with a child who receives PPC, who already have an ICP or are eligible for an ICP. Therefore, CPC networks have connections to both HCPs and families. The CPC teams and networks will identify which HCPs, parents, and if possibly children are eligible to participate in the study based on the inclusion criteria. They will inform these potential participants by email on the content and importance of the study. The email also contains the email address of the researcher and reference is made to the project website for detailed information about the research and participation. If a respondent decides to participate, he/she can let the researcher know by email or via the website. Respondents can indicate whether they are interested in participating in the quantitative and/or qualitative research. Children will only be approached to participate in an interview. The researcher will contact the respondents who meet the inclusion

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3 criteria and who have indicated to want to partake in an interview by telephone to schedule an  
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5 appointment. HCPs who meet the inclusion criteria will be contacted by the researcher to schedule  
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7 an appointment for the focus groups.  
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10 Alle respondents who indicated to want to partake in the quantitative research will be send a link to  
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12 the questionnaire. Participants of the questionnaire will be sent a reminder two weeks after the  
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14 initial invitation to complete the questionnaire.  
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### 17 **Description of qualitative and statistical analysis**

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20 The interviews and focus groups will be videotaped. The videotapes will be transcribed verbatim and  
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22 thereafter destroyed. We aim to gain insight into the experiences of various actors using the ICP in  
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24 practice. This research therefore does not fit into a current trend. Thus, we use methods for 'generic'  
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26 qualitative research. For the content analysis, use is made of open and axial coding and constant  
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28 comparison, in order to be able to make a good representation of the ICP in practice (21). Three  
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30 researchers will be involved in the qualitative analyses (MK, JA and CJ). The three researchers will  
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32 independently read and code several transcripts in order to develop an initial code tree. Thereafter,  
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34 the codes and interpretations will be compared and categorized into themes and subthemes. Based  
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36 on this code tree CJ will code the rest of the transcripts. The code tree will be evaluated with the  
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38 team and adjusted during the coding process. Together the team will validate the themes and related  
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40 subthemes. The qualitative analysis will be supported by the software program Atlas ti.  
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45 The questionnaires are completed on a Likert scale, two-point scale, and open questions. All  
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47 quantitative data will be descriptively analysed using mean,  $\pm$ SD, median and interquartile range  
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49 using the statistical software program SPSS. In addition, the satisfaction of HCPs with the ICP 1.0 and  
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51 the ICP 2.0 will be analysed for differences, taking into account repeated measurements using a  
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53 paired samples T-test.  
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### 56 **Patient and Public involvement**

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59 Patient and public were involved in the development of this protocol and will be part of the core  
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3 project team during the study. Patients are involved through representatives, including parents and  
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5 organisations such as the Dutch Foundation Child and Hospital. Public is represented through the  
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7 involvement of the Dutch Centre of Expertise in Children's Palliative Care.  
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## 10 **Ethics and Dissemination**

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13 This study does not require formal ethical approval as it is not subjected to the Dutch act WMO  
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15 ([https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-](https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-research-is-it-subject-to-the-wmo-or-not)  
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17 [research-is-it-subject-to-the-wmo-or-not](https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-research-is-it-subject-to-the-wmo-or-not)). However, we still obtained ethical approval for study  
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19 phase 1 from all medical ethical committees of the seven University Hospitals and the Paediatric  
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21 Oncology Centre. For study phase 3, ethical approval will be sought as well using addendums to the  
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23 previous approved ethical approval requests.  
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26  
27 Study participant are carefully and fully informed of the study and asked to give consent digitally.  
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### 30 *Dissemination*

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32 During the implementation period, study phase 3, the ICP 2.0 will be disseminated through the CPC  
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34 networks, CPC teams and the Dutch Centre of Expertise in Children's Palliative Care. At the end of the  
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36 study, the final version of the ICP, ICP 3.0, will be disseminated through the Dutch Centre of Expertise  
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38 in Children's Palliative Care, to ensure wide availability for the general public and HCPs within PPC. In  
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40 addition, we aim to publish study results in open-access, peer-reviewed journals and to present  
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42 results at national and international scientific meetings.  
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#### Authors’ contributions

CJ drafted the manuscript. MK, LK, HR, EV and JA were major contributors to the development of the study protocol. All authors contributed to revising the protocol and manuscript. All authors have approved the final manuscript.

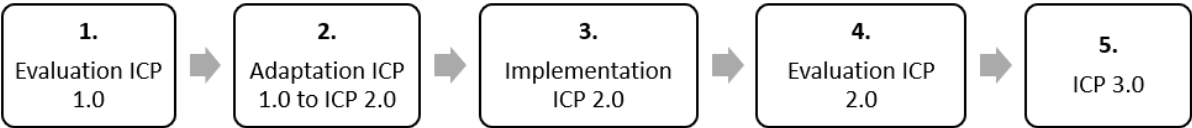
#### Funding statement

This work was supported by ZonMw grant number 844001709.

#### Competing interests statement

None Declared.

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# BMJ Paediatrics Open

## Improvement and Implementation of a National Individual Care Plan in Paediatric Palliative Care: A Study Protocol

Journal:	<i>BMJ Paediatrics Open</i>
Manuscript ID	bmjpo-2022-001677.R2
Article Type:	Protocol
Date Submitted by the Author:	26-Dec-2022
Complete List of Authors:	Joren, Chantal; University of Groningen, University Medical Center Groningen, Beatrix Children's Hospital Kars, Marijke C.; Center of Expertise in Palliative Care Utrecht, Julius Center of Health and Primary Care, UMC Utrecht Kremer, Leontien; Princess Maxima Centre for Pediatric Oncology Rippen, Hester; Dutch Foundation Child and Hospital Verhagen, Eduard; University of Groningen, University Medical Center Groningen, Beatrix Children's Hospital Aris-Meijer, Judith; University of Groningen, University Medical Center Groningen, Beatrix Children's Hospital
Keywords:	Palliative Care

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# Improvement and Implementation of a National Individual Care Plan in Paediatric Palliative Care: A

## Study Protocol

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**Word count: 2888**

## Abstract

**Introduction:** Paediatric palliative care (PPC) is care for children with life-threatening or life-limiting conditions, and can involve complex high-tech care, which can last for months or years. In 2015, the National Individual Care Plan (ICP) for PPC was developed and has shown to be successful. The ICP can be seen as an instrument to facilitate coordination, quality and continuity of PPC. However, in practice an ICP is often completed too late and for too few children. We aim to improve the coordination, quality and continuity of care for every child with a life-threatening or life-limiting condition and his/her family by further developing and implementing the ICP in the Netherlands.

**Methods and analysis:** To evaluate the original ICP, ICP 1.0, interviews and questionnaires will be held among parents of children who have or have had an ICP 1.0 and HCPs who used ICP 1.0. Based on the results, ICP 1.0 will be further developed. An implementation strategy will be written and the renewed ICP, ICP 2.0, will be nationally tested in an implementation period of approximately seven months. During the implementation period, ICP 2.0 will be used for all children who are registered with Children's Palliative Care teams. After the implementation period, ICP 2.0 will be evaluated using interviews and questionnaires among parents of children who received ICP 2.0 and HCPs who worked with ICP 2.0. Based on these results, ICP 2.0 will be further optimized into the final version: ICP 3.0.

**Ethics and Dissemination:** This study received ethical approval. The ICP 3.0 will be disseminated through the Dutch Centre of Expertise in Children's Palliative Care, to ensure wide availability for the general public and HCPs within PPC. Additionally, we aim to publish study results in open-access, peer-reviewed journals and to present results at national and international scientific meetings.



**What is already known on this topic?**

- ICP's have shown to reduce fragmented care and to improve health outcomes, quality of care for complex patients and health status indicators.

**What this study hopes to add?**

- This study will identify the perceived barriers and facilitators for an ICP in PPC from the perspective of child/parents and healthcare professionals.
- This study will provide insight into which concrete improvements are an appropriate approach to implement an ICP fully and sustainably in PPC.
- This study will give insight into the process of drawing up and working with an ICP in PPC.

**How this study might affect research, practice or policy:**

- This study will result in a further developed nationally implemented ICP supported by parents and healthcare professionals for children who receive PPC.
- By further developing and implementing the ICP, the ICP will be an enrichment of care and will improve continuity of care for children who receive PPC.

**Introduction:**

Paediatric palliative care (PPC) is care for children with life-threatening or life-limiting conditions (1). PPC begins when a life-limiting or life-threatening illness is diagnosed and continues regardless of whether or not the child receives curative treatment (2). PPC is the prevention and relief of physical, psychological, social and spiritual suffering of children and their family, and aligns with patient- and family centred care (2). According to The Institute for Patient- and Family-Centered Care, patient- and family centred care is grounded in mutually beneficial partnerships among patients, families, and healthcare professionals (HCPs) in the planning, delivery and evaluation of care (3). Most of the children eligible for PPC receive complex high-tech care, which can last for months or years (4,5). This care is often provided by a multitude of different HCPs in different lines of care and organizations, which can lead to fragmentation of care and lack of continuity of care (5,6). Without established anticipatory care, e.g. an Individual Care Plan (ICP), PPC must be provided more often, with less expertise, in emergency situations, outside office hours and by non-regular practitioners, all with consequences for the continuity of care (7).

In 2013, the Dutch multidisciplinary, evidence based guideline 'palliative care for children' was published (8). The guideline aims to improve PPC by formulating recommendations, including recommendations for decision-making and organization of care. Currently, the Dutch guideline is being revised. Based on the recommendations of the guideline, an ICP for PPC was developed to translate the general recommendations into a personalised plan for the individual child (7). The ICP is a written care plan that supports HCPs, and the child and his/her family to address all dimensions of PPC, i.e. physical, psychological, social and spiritual, in a structured manner. The ICP supports patient- and family centred care aligned to the family's needs, goals and preferences, provides a clear overview of their preferences and desires, and of shared goals of child/parents and HCPs. Advance care planning is an approach that facilitates appropriate future care planning which is integrated as part of the process of developing an ICP (9).

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3 Among adults, ICP's have shown to promote patients capability to self-manage their  
4 conditions and improve health status indicators (10). In children with cerebral palsy the use of an ICP  
5 has shown to facilitate family centred care, helped parents to navigate their child's care, decreased  
6 hospital admissions, shortened hospital stays and reduced fragmentation of care (11). The Dutch ICP  
7 has shown to facilitate high-quality care and the transitions of care between hospital and home (7).  
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9 Despite promising results on the use of ICP in healthcare, there is little insight into the use of ICP's in  
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PPC.

Despite the increase of specialised PPC, the ICP is not completed for all children in PPC, and often drawn up in the terminal phase, while issues with fragmentation of care and continuity of care can exist from the start of PPC and not only in the terminal phase (6). Furthermore, advance care planning tools are not always used, while these could fit very well with the ICP process (12). It is therefore important to study which adjustments are necessary to have the ICP used to its full potential, what parents and HCPs value and dislike about the ICP, and what the process of drawing up and working with an ICP looks like. By studying this, we aim to improve the ICP document and user experiences, strengthen the patient- and family centeredness and integrate advance care planning, and thereby improving the quality and continuity of care for every child with a life-threatening or life-limiting condition and his/her family. In this paper we present our study protocol of the study: "Improvement and Implementation of a National individual Care Plan in Paediatric Palliative care".

## Methods:

### Setting:

In the Netherlands, PPC is uniquely structured with the use of transmurals Children's Palliative Care (CPC) teams and CPC networks. CPC networks provide consultation for families and HCPs across different healthcare domains (4). Multidisciplinary CPC teams form a bridge between hospital and home, and the teams provide support and guidance to families and HCPs (4,13).

### Study design:

Given the nature of the research questions, a mixed-methods approach is most appropriate, in which qualitative and quantitative research are combined in a cross-sectional study for child/parents and pre- and post-test design for HCPs. By integrating qualitative and quantitative methods in this multiphase mixed-method study, we aim to gain insight into the experiences of HCPs and child/parents with the ICP in practice and effectively tailor the ICP (14,15). This study consists of five phases. The current ICP, from now on ICP 1.0, will be evaluated and adapted into ICP 2.0, followed by an implementation period where ICP 2.0 will be implemented for evaluation purposes. After the implementation period, ICP 2.0 will be evaluated and optimized into the final version: ICP 3.0 (*Figure 1.0*). Children who have received an ICP 1.0 will not receive an ICP 2.0 during the study period. Therefore, parents and children will be included in a cross-sectional way.

### Phases of the study

The five phases of the study are presented in figure 1.

#### **Phase 1**

##### *Evaluation of ICP 1.0 and drawing up an implementation strategy*

In phase 1 ICP 1.0 will be evaluated by exploring the “lived-experience” of HCPs and child/parents using the ICP 1.0 in practice. The barriers and facilitators concerning the content and use of ICP 1.0, will be evaluated in focus groups with HCPs and individual interviews with child/parents, and with an online questionnaire for all respondents groups. Based on the results that emerge from the data, the project group will jointly develop a strategy for the adaptation of ICP 1.0 and the implementation of ICP 2.0.

##### *Measurements*

To identify the barriers and facilitators for the ICP 1.0 per target group a mixed methods approach suitable to the RE-AIM framework with quantitative exploration of individual, social, organizational and societal/economic factors using the Measurement Instrument for Determinants of Innovations

(MIDI) (16) and qualitative exploration of context and experience/needs aspects such as responsibility, motivation and perceived urgency (17,18) is used. The questionnaire consists of the MIDI, the questions from the ICP 1.0 pilot study (7), study describing the development of ICP 1.0, supplemented with questions about the reasons why the ICP has or has not been completed. Guidance for these questions are the Hexagon tool (19).

The focus group and individual interviews will mainly focus on experiences of parents and HCPs involved in working with the ICP 1.0 in daily practice. An interview guide will be designed based on literature and expertise from HCPs and the research team, on the basis of which respondents are asked to share their experiences, see *Table 1*.

*Table 1. Measurements overview of study phase 1.*

Measurements	Phase 1	
	Parents	HCPs
<b>Qualitative</b>		
- Content of ICP: to what extent does the ICP cover the reality of the situation from the perspective of the people involved	x	x
- Procedures and goals: what is it like to create and maintain an ICP, reason and purpose regarding the ICP, shared process with child/parents, facilitators/barriers	x	x
- Position, contribution of child/parents and its translation in the ICP: how it was established, recognizability of own contribution/perspective, future-oriented, was the development supportive or burdening, what does it mean for the parent-professional relationship	x	x
<b>Quantitative</b>		
- Study specific questionnaire on background variables, content, process and lay-out of ICP	x	x
- MIDI		x

### *Sample size*

Due to the low number of children for whom an ICP is completed each year, no realistic power calculation can be made for the required number of participants. It is expected that a total of approximately 200 children per year will be cared for in the eight CPC teams. Based on this estimation, the estimated sample size for the quantitative study of phase 1 is 170 HCPs and 30

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3 parents. For the qualitative study of phase 1, the estimated sample size is 10 parents and 25 HCPs,  
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5 but achieving data saturation will be leading.  
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## 8 **Phase 2**

### 9 *Adaptation of ICP 1.0*

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13 Based on the finding of study phase 1, the content and form of ICP 1.0 will be adapted into ICP 2.0.

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15 The accompanying manual, which provides information and tools for HCPs for all parts of the ICP, will  
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17 be adapted accordingly.  
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## 20 **Phase 3**

### 21 *Implementation period of ICP 2.0*

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25 Based on the implementation strategy developed in phase 1, ICP 2.0, will be implemented as the  
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27 standard of care planning in the Netherlands. This implies adoption of the ICP by all CPC teams and  
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29 other lines of care that provide PPC in the Netherlands. The CPC teams and other lines of care that  
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31 provide PPC have committed themselves to this research project and thereby to the implementation  
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33 of ICP 2.0. The implementation period of ICP 2.0 will last approximately seven months.  
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### 36 *Measurements*

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40 During the implementation period, ICP 2.0 will be applied in practice by HCPs working in the eight  
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42 CPC teams and in organisations connected to the CPC networks. At the end of the implementation  
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44 period the number of ICPs drawn up of the total number of children in care at the CPC teams will be  
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46 calculated.  
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### 49 *Sample size*

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52 We estimate that during the implementation period, approximately 25-30 HCPs, of whom two nurses  
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54 and one or two paediatricians per CPC team, will fill in ICP 2.0 several times. Most paediatricians and  
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56 nurses in general hospitals and primary care will complete the ICP 2.0 once.  
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#### Phase 4

##### Evaluation of ICP 2.0

After the implementation period, ICP 2.0 will be evaluated using both qualitative and quantitative measures. Children and parents of children who received an ICP 2.0 will be asked to participate in an interview and/or questionnaire. HCPs who worked with ICP 2.0 will be invited to participate in a focus group and/or questionnaire.

##### Measurements

The measurements used are similar to those of phase 1. The interviews will focus on experiences with the ICP 2.0 in practice.

To gain insight into the quality of life of child/parents and family-centred care from the perspective of parents of children who have an ICP 2.0 several questionnaires are added to the quantitative measurements. At the time of writing, the Children's Palliative Outcome Scale (CPOS-2) (20) and the Patient Reported Experience Measures (PREM) Child Care (21) are the most appropriate tools for this, see *Table 2*.

*Table 2. Measurement overview of study phase 2.*

Measurements	Phase 4	
	Parents	HCPs
<b>Qualitative</b>		
- Content of ICP: to what extent does the ICP cover the reality of the situation from the perspective of the people involved	X	X
- Procedures and goals: what is it like to create and maintain an ICP, reason and purpose regarding the ICP, shared process with child/parents, facilitators/barriers	X	X
- Position, contribution of child/parents and its translation in the ICP: how it was established, recognizability of own contribution/perspective, future-oriented, was the development supportive or burdening, what does it mean for the parent-professional relationship	X	X
- Role of the ICP in shared decision making and/or family centred care.	X	X
<b>Quantitative</b>		
- Study specific questionnaire on background variables, content, process and lay-out of ICP	X	X
- MIDI		X
- CPOS-2	X	

- PREM Child Care	x	
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### Sample size

Based on the estimations for the implementation period and the reasons mentioned previously for study phase 1, the estimated sample size for the quantitative study of phase 4 is 80 HCPs and 20 parents. For the qualitative study of phase 4 we expect that 10 parents and 25 HCPs is realistic, but data saturation will be leading.

The proportion of participants that are parents will differ from the participants in phase 1 in both the qualitative and quantitative study, because ICP 2.0 will not be drawn up for children who already received an ICP 1.0. The proportion of participants that are HCPs may have also participated in phase 1 in the qualitative and/or quantitative study. If this is the case, this will be recorded and included in the data analysis.

### Phase 5

#### *Optimizing into the final version of the ICP, ICP 3.0*

Based on the findings of phase 4, a final version of the ICP, ICP 3.0, and manual will be developed.

The ICP 3.0 and manual will then be distributed via the Dutch Centre of Expertise in Children's Palliative Care, CPC teams, CPC networks, and several parent- and patient associations for use in practice.

### Inclusion criteria

The inclusion criteria are only relevant for study phases 1 and 4, see *Table 3*. The inclusion criteria are the same for the qualitative and quantitative studies, except for children. Children are only invited to participate in the qualitative study.

*Table 3. Inclusion criteria for study phase 1 and 4.*

Inclusion criteria	Parents	HCPs	Children
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<b>Phase 1</b>	<ul style="list-style-type: none"> <li>- Parent of a child with a life-limiting or life-threatening condition alive or deceased in the 36 months prior to the inclusion</li> <li>- In possession of a completed ICP 1.0</li> <li>- Able to understand and follow study procedures</li> <li>- Can read and understand the Dutch language</li> </ul>	<ul style="list-style-type: none"> <li>- Has completed the ICP 1.0 of a child with a life-limiting or life-threatening condition or has worked with the ICP 1.0 in practice.</li> <li>- Can read and understand the Dutch language</li> </ul>	<ul style="list-style-type: none"> <li>- Known with a life-limiting or life-threatening condition</li> <li>- 12 years or older</li> <li>- In care of a CPC team</li> <li>- In possession of a completed ICP 1.0</li> <li>- Deemed competent by parents and the lead physician</li> <li>- Can read and understand the Dutch language</li> </ul>
<b>Phase 4</b>	<ul style="list-style-type: none"> <li>- Parent of a child with a life-limiting or life-threatening condition for whom a ICP 2.0 is in progress or completed within the implementation period</li> <li>- Able to understand and follow study procedures</li> <li>- Can read and understand the Dutch language</li> </ul>	<ul style="list-style-type: none"> <li>- Has completed the ICP 2.0 of a child with a life-limiting or life-threatening condition or has worked with the ICP 2.0 in practice.</li> <li>- Can read and understand the Dutch language</li> </ul>	<ul style="list-style-type: none"> <li>- Known with a life-limiting or life-threatening condition</li> <li>- 12 years or older</li> <li>- In care of a CPC team</li> <li>- In possession of a completed or in progress ICP 2.0</li> <li>- Deemed competent by parents and the lead physician</li> <li>- Can read and understand the Dutch language</li> </ul>

#### Recruitment:

Recruitment of participants will take place through the CPC teams and CPC networks, and social media and newsletter from the Dutch Centre of Expertise in Children's Palliative Care, reaching those under care of CPC teams and those who are not. CPC teams are the main users of the ICP and can thus reach the largest group of participants. CPC networks contain a network of HCPs who use the ICP. They also offer support to families with a child who receives PPC, who already have an ICP or are eligible for an ICP. Therefore, CPC networks have connections to both HCPs and families. The CPC teams and networks will identify which HCPs, parents, and if possibly children are eligible to participate in the study based on the inclusion criteria. They will inform these potential participants by email on the content and importance of the study. The email also contains the email address of the researcher and reference is made to the project website for detailed information about the research and participation. If a respondent decides to participate, he/she can let the researcher

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3 know by email or via the website. Respondents can indicate whether they are interested in  
4 participating in the quantitative and/or qualitative research. Children will only be approached to  
5 participate in an interview. The researcher will contact the respondents who meet the inclusion  
6 criteria and who have indicated to want to partake in an interview by telephone to schedule an  
7 appointment. HCPs who meet the inclusion criteria will be contacted by the researcher to schedule  
8 an appointment for the focus groups.  
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12 Alle respondents who indicated to want to partake in the quantitative research will be send a link to  
13 the questionnaire. Participants of the questionnaire will be sent a reminder two weeks after the  
14 initial invitation to complete the questionnaire.  
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### 17 **Description of qualitative and statistical analysis**

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19 The interviews and focus groups will be videotaped. The videotapes will be transcribed verbatim and  
20 destroyed after transcription. We aim to gain insight into the experiences of parents, children and  
21 HCPs using the ICP in practice. This research therefore does not fit into a current trend. Thus, we use  
22 methods for 'generic' qualitative research. For the analysis, use is made of open and axial coding and  
23 constant comparison, in order to be able to make a good representation of the ICP in practice (22).  
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25 Three researchers will be involved in the qualitative analyses (MK, JA and CJ). MK is an experienced  
26 qualitative researcher in the PPC field, JA and CJ are trained in qualitative analysis. The three  
27 researchers will independently read transcripts to get familiarized with the data and code several  
28 transcripts in order to develop an initial code tree (15). Thereafter, the codes and interpretations will  
29 be compared and categorized into themes and subthemes. Based on this code tree CJ will code the  
30 remaining transcripts. The transcripts from parents and HCPs will be first analysed separately and  
31 thereafter compared. The code tree will be evaluated with the team and adjusted during the coding  
32 process. Member-checking will be used by presenting a summary of the main results to key  
33 participants in the study (15). The qualitative analysis will be supported by the software program  
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3 The questionnaires are completed on a Likert scale, two-point scale, and open questions. All  
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5 quantitative data will be descriptively analysed using mean,  $\pm$ SD, median and interquartile range  
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7 using the statistical software program SPSS. In addition, the satisfaction of HCPs with the ICP 1.0 and  
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9 the ICP 2.0 will be analysed for differences, taking into account repeated measurements using a  
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11 paired samples T-test.  
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15 The quantitative and qualitative data will be analysed separately after which the separate results will  
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17 be integrated (15).  
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### 19 20 **Patient and Public involvement**

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22 Parents, children and HCPs are the end users of the ICP, and therefore it is important that they are  
23  
24 involved in the improvement of the ICP beyond participating in an interview and/or questionnaire.  
25  
26 Therefore, patient and public were involved in the development of this protocol and are part of the  
27  
28 project team during the study either by participating themselves or through representatives. During  
29  
30 the study, parents are involved through a parent panel, which will be involved in de rewriting of the  
31  
32 ICP and accompanying manual to ensure the renewed ICP will be understandable and usable for  
33  
34 parents and their children.  
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### 37 38 **Ethics and Dissemination**

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41 This study does not require formal ethical approval as it is not subjected to the Dutch act WMO  
42  
43 ([https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-](https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-research-is-it-subject-to-the-wmo-or-not)  
44  
45 [research-is-it-subject-to-the-wmo-or-not](https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-research-is-it-subject-to-the-wmo-or-not)). However, we still obtained ethical approval for study  
46  
47 phase 1 from all medical ethical committees of the seven University Hospitals and the Paediatric  
48  
49 Oncology Centre. For study phase 3, ethical approval will be sought as well using addendums to the  
50  
51 previous approved ethical approval requests.  
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54  
55 Study participant are carefully and fully informed of the study and asked to give consent digitally.  
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### 58 *Dissemination*

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3 During the implementation period, study phase 3, the ICP 2.0 will be disseminated through the CPC  
4 networks, CPC teams and the Dutch Centre of Expertise in Children's Palliative Care. At the end of the  
5 study, the final version of the ICP, ICP 3.0, will be disseminated through the Dutch Centre of Expertise  
6 in Children's Palliative Care, to ensure wide availability for the general public and HCPs within PPC. In  
7 addition, we aim to publish study results in open-access, peer-reviewed journals and to present  
8 results at national and international scientific meetings.  
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44 sociale+kindergeneeskunde,Metabole+Ziekten,Neurologie,Palliatief](https://www.nvk.nl/themas/kwaliteit/richtlijnen/richtlijn?componentid=6881317&tagtitles=Erfe)
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**Authors' contributions**

CJ drafted the manuscript. MK, LK, HR, EV and JA were major contributors to the development of the study protocol. All authors contributed to revising the protocol and manuscript. All authors have approved the final manuscript.

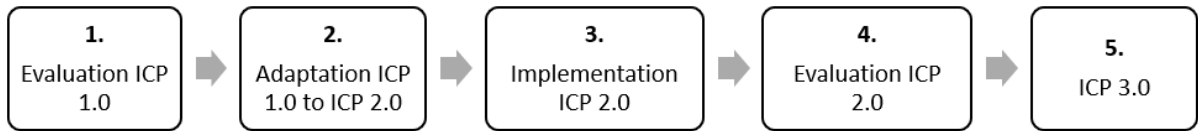
**Funding statement**

This work was supported by ZonMw grant number 844001709.

**Competing interests statement**

None Declared.

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