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# BMJ Open

## It takes more than two to tango: technology enabling person-centered diabetes management

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Keywords:	ICT, eHealth, type 1 diabetes, chronic disease management, person-centred care

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4 **1 It takes more than two to tango: technology enabling**  
5 **2 person-centred diabetes management**  
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7 3

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## 21 *Original Research Paper*

22 It takes more than two to tango: technology enabling person-centred diabetes  
23 management

24

### 25 **Abstract**

26 *Objectives:* The aim of this paper is to construct a conceptual framework for  
27 Information and Communication Technology (ICT)-enabled partnership towards  
28 diabetes management.

29 *Design:* We conducted an inductive case study and held interviews on the  
30 development and use of an Artificial Pancreas (AP) system for diabetes  
31 management.

32 *Setting:* The study was carried out in the Netherlands with users of an AP system.

33 *Participants:* We interviewed six persons with type 1 diabetes, five healthcare  
34 professionals (two medical specialists, three diabetic nurses), and one policy advisor  
35 from the Ministry of Health, Welfare, and Sport.

36 *Results:* This study delved into the partnership enabled through ICT in chronic  
37 diabetes management. We build a new conceptual framework for ICT-enabled  
38 person-centred diabetes management, covering the central themes of self-managing  
39 the disease, shared analysing of (medical) data, and experiencing the partnership.  
40 We found an impact on carefree living through the semi-automated management by  
41 the device, new activities of data sharing and a new professional role of data devices  
42 in care providing.

43 *Conclusion:* The management of diabetes through ICT requires an adjustment of the  
44 partnership between persons with the chronic condition and the healthcare  
45 professional(s) in such a way that the potential for self-managing the condition by  
46 analysing the newly available (medical) data (from the AP system) together leads to  
47 an experience of partnership between patients and healthcare professionals.

48

### 49 **Strengths and limitations of this study**

- 50 • The strength of the inductive single-case study approach is that it provides in-  
51 depth insights into how the partnership between a person with type 1 diabetes  
52 and the healthcare professional(s) changes as a result of the use of an  
53 Artificial Pancreas system for diabetes management.

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3 54 • Another contribution of our study is that building theory from a case study, as  
4 55 we have done with our research, made it possible to create a conceptual  
5 56 framework from case-based empirical evidence.  
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7 57 • Grounded on in-depth insights and commonalities, this study broadens the  
8 58 scope to evidence-based support of eHealth.  
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10  
11 59 • A limitation of this study on the use of the eHealth technology is that it was  
12 60 under development during the research period, which is not decisive since the  
13  
14 61 focus of our study is not on the technology itself but on enabling the  
15  
16 62 professional-patient partnership.  
17  
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19 64 **Keywords:** ICT, eHealth, type 1 diabetes, chronic disease management, person-  
20 65 centred care  
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22 66

## 67 Introduction

68 Person-centred care (PCC) actively involves the patient in the care process as an  
69 equal partner in, and expert on, living with a chronic condition (1). Persons with a  
70 chronic condition have to make decisions on a day-to-day basis about self-managing  
71 their illness, which influences the healthcare professional-patient partnership  
72 concerning services of care (2).

73 Information and Communication Technology (ICT) for healthcare – also known as  
74 eHealth (3) – could support the professional-patient partnership in person-centred  
75 care services (4). This ICT-enabled partnership provides chronic disease  
76 management in the face of social, physical, and emotional challenges (5). Results of  
77 the first studies on ICT enabling person-centred care in chronic care are promising,  
78 with improved clinical outcomes, better health-related quality of life, and increased  
79 cost-effectiveness (6).

80 When applying the concept of partnership in person-centred care to ICT systems, the  
81 technology must be tailored to the needs of both patients and healthcare  
82 professionals (personalised ICT), whereby the personal context and situation of the  
83 patient informs and guides the decision making on the care pathway (7). However,  
84 this phenomenon of enabling the partnership through ICT is not fully understood and  
85 insights are lacking on how this partnership is influenced and transformed through  
86 ICT (8).

87 To address this gap, we studied an innovative ICT intervention that was developed  
88 into a person-centred approach towards chronic disease management so we could  
89 better understand how information and communication technology influenced the  
90 professional-patient partnership in the management of this disease. We chose to  
91 employ an inductive case study to focus on the dynamics present within a single  
92 setting (9) of one ICT intervention used in practice for the management of type 1  
93 diabetes namely an Artificial Pancreas-system, to answer the research question:  
94 How does ICT enable the partnership between healthcare professional(s) and the  
95 patient in chronic disease management?

96  
97 Research on diabetes management is highly relevant given its impact on individuals  
98 and society. Diabetes is on the rise: from 108 million in 1980 to 422 million patients in  
99 2014 (10). Diabetes is a severe and chronic disease, which occurs when the

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2  
3 100 pancreas is not producing insulin (type 1) or when the body does not respond well to  
4 101 the insulin produced (type 2). Management is essential to control the blood glucose  
5 102 levels of those with type 1 diabetes (11).  
6  
7 103 Training in self-management of type 1 diabetes through personalised insulin  
8 104 treatment leads to significant improvements in treatment satisfaction, psychological  
9 105 wellbeing, and quality of life measures (12). Even though diabetes management has  
10 106 improved considerably over the years, patients still suffer from short-term  
11 107 complications such as hypoglycaemia diabetic ketoacidosis ('hypo' for short) and  
12 108 hyperosmolar hyperglycaemic state ('hyper') and long-term complications such as  
13 109 retinopathy, neuropathy, cardiovascular disease, and nephropathy that could lead to  
14 110 complications such as loss of eyesight and amputation (13).  
15  
16 111 The treatment and care of patients with diabetes have seen fast progress and key  
17 112 innovations after the discovery of insulin in 1921, followed by engineered insulin; the  
18 113 introduction of blood glucose monitoring by tele monitoring systems, internet  
19 114 applications, and mobile devices (14). In addition, smart algorithms to control the  
20 115 blood glucose level have been developed (15). This innovation trajectory by applying  
21 116 smart algorithms to earlier discoveries culminated in the development of a first-  
22 117 generation system of an artificial pancreas that focuses on preventing unsafe blood  
23 118 sugar levels and aims to maintain the blood glucose level between approximately 70  
24 119 and 180 mg/dl (16). While a wide range of different categories of ICT interventions  
25 120 has become available to improve the control of the blood glucose level, the current  
26 121 management of the disease still requires a daily preoccupation with and awareness  
27 122 of preventing severe complications of 'hypo' and 'hyper'. Several companies  
28 123 worldwide are developing AP systems that take over the regulation of the glucose  
29 124 levels completely by automating insulin and glucagon delivery (17) (18). Over the last  
30 125 years significant progress has been made in AP development (19), and researchers  
31 126 have demonstrated the safety and feasibility of different AP systems in clinical  
32 127 research settings and more recently in outpatient 'real-world' environments (20).  
33 128 A systematic review of artificial pancreas systems showed that they could be an  
34 129 efficacious and safe approach for treating patients with type 1 diabetes (21). The  
35 130 greatest benefits of the AP are the reduced burden of diabetes management during  
36 131 the day and improved overnight control of glucose levels thanks to reduced risk of  
37 132 (nocturnal) hypoglycaemia and ketoacidosis (22) (23) (24). Although AP users with

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3 133 type 1 diabetes will still need to self-manage their illness, a closed loop system with  
4 134 data acted upon by the users could reduce the burden (25).

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## 7 8 136 **Methods**

### 9 10 11 137 **Design**

12 138 We conducted an inductive case study and held in-depth interviews with both  
13  
14 139 healthcare professionals and patients on their use of the Artificial Pancreas-system  
15  
16 140 (26). This case study looks in particular into the dynamics of the relations in the  
17  
18 141 professional-patient partnership and between different healthcare professionals, the  
19  
20 142 patient experience, and how introducing ICT enables a person-centred approach to  
21  
22 143 diabetes care.

### 23 144 **Setting**

24 145 As the case setting we have chosen the use of an AP system that automatically  
25  
26 146 controls the blood glucose level of patients with type 1 diabetes, and provides the  
27  
28 147 substitute functionality of both insulin and glucagon delivery of a healthy pancreas,  
29  
30 148 maintaining the blood glucose levels in the healthy range most of the time, without  
31  
32 149 restrictions with respect to factors such as diet and exercise.

### 33 34 150 **Case description**

35 151 The development of the person-centred AP-system was started in 1994 by an  
36  
37 152 engineer who himself was diagnosed with type 1 diabetes. His motivation for  
38  
39 153 inventing a semi-autonomous AP was driven by his dissatisfaction with the diabetes  
40  
41 154 care treatment and the support provided with products and software applications. He  
42  
43 155 started a company to develop the AP in an iterative manner, involving the users in  
44  
45 156 the different steps of its development.

46 157 The wearable artificial pancreas integrates the following features into one device: (i)  
47  
48 158 continuous glucose monitoring; ii) glucose control algorithms (decision-making  
49  
50 159 processor); iii) infusion pump; and (iv) other sensors (27) (see: figure 1).

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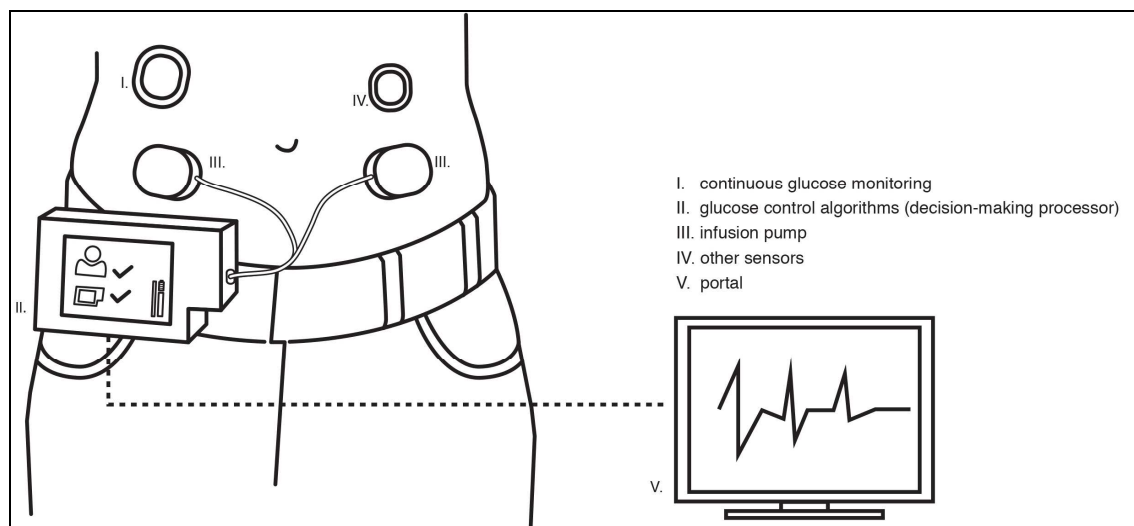


Figure 1 Components of the artificial pancreas system

The control unit (i + ii) replaces human decision making and makes more frequent dose adjustments than a person could. The AP device transmits data to a database that is accessible via a portal (v) featuring web services for monitoring.

The functions of the bihormonal AP (both insulin and glucagon) were tested with persons with type 1 diabetes in home treatment with the result that the AP provided better glucose control than traditional insulin pump therapy and that the treatment is safe (28). Related studies also indicated that patients anticipate to accept the device (29) and that for further technical development it will feature adaptive control (30).

### Participants

The participants were selected via a combination of purposive and snowball sampling. Criteria for inclusion were: the patients were diagnosed with type 1 diabetes, participants needed to be familiar with the AP, and the healthcare professionals worked with the AP in the treatment of their patients.

With purposive sampling we initially selected two types of participants, persons with type 1 diabetes and healthcare professionals who had used the AP and would potentially be able to provide rich, relevant, and diverse data pertinent to the partnership (31) (32). Subsequently, through snowball sampling in which interviewees identified further participants, we recruited both persons with type 1 diabetes and healthcare professionals (medical specialists and diabetic nurses) with knowledge relevant to the case study. We explored perspectives from these 'primary'

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3 185 participants to gain access to their experiences, feelings, and worlds (33). As a  
4 186 'secondary' participant, a policy advisor from the Ministry of Health, Welfare, and  
5 187 Sport was included because of their experience with the embedding of the AP in the  
6 188 healthcare context.

7  
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9 189 We approached the participants via telephone, email, and/or face-to-face. We sent  
10 190 an information letter by email with an introduction to and information about the case  
11 191 study, and an invitation to participate. All participants agreed to participate.  
12 192 We interviewed twelve participants: six persons with type 1 diabetes, five healthcare  
13 193 professionals (two medical specialists, three diabetic nurses), and one policy advisor  
14 194 from the Ministry of Health, Welfare, and Sport. Four attempts to recruit specific  
15 195 participants were rejected. One participant indicated he was too busy, while the other  
16 196 reasons for non-participation were that the participants (2) were not familiar with the  
17 197 AP or the subject was too sensitive (policy maker).

#### 198 **Data collection**

199 We held in-depth, semi-structured interviews with the participants. These interviews  
200 were guided by an interview protocol, with questions focusing on the overall  
201 experience with AP in clinical practice and how the AP supported and changed the  
202 professional-patient partnership in diabetes management.

203 One researcher, the first author, conducted the interviews via telephone/Skype or  
204 FaceTime either at home or at work. One participant was known from a previous  
205 study. No non-participants were present during the interviews. The interviews were  
206 conducted between February and April 2017. The interviews lasted between forty-  
207 seven and seventy-three minutes. Participants were recruited until no new  
208 knowledge was gained (data saturation) (34). No repeat interviews were conducted.  
209 The researcher audio-recorded the participants and took notes. We transcribed all  
210 interviews. We anonymised the data and allocated alphabet capital coding to each  
211 participant.

#### 212 **Analysis**

213 In this study, we used thematic analysis to identify patterns within the data, and  
214 grouped them under codes, categories, and themes, whereby we particularly sought  
215 to identify how ICT supported the partnership in diabetic/chronic disease  
216 management (35). The first two authors analysed the data in an iterative process of  
217 coding and use of NVivo software.

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3 218 We started with a line-by-line coding that was derived from the research question.  
4 219 From reading and analysing the data – in which we preserved (inter-)actions by using  
5 220 as many gerunds ('ing') as possible – we processed the coding (36). The first and  
6 221 second author reviewed the codes. After that, through focussed coding, we  
7 222 organised and grouped the coded data that shared characteristics into categories.  
8 223 In this phase, we left out codes that did not contribute to answering the research  
9 224 question from further analysis (such as data on specific treatment for children). We  
10 225 then moved to the process of theoretical coding – in which we clustered the  
11 226 categories into themes – to build a conceptual framework.

### 227 **Ethical considerations**

12 228 The research is executed in accordance to the guidelines of Helsinki declaration of  
13 229 the World Medical Association (2013). In our sample design we excluded the  
14 230 participation of vulnerable groups. The topic of our study was not sensitive. The  
15 231 principal researcher introduced the study orally, stressing the person's right to make  
16 232 an own choice to participate. All participants gave informed consent. The study  
17 233 participation was voluntary and participants could withdraw at any point. The  
18 234 researchers did not have access nor used personal information or datasets, they also  
19 235 did not collect nor used bodily material. All personal information was de-identified.  
20 236 We did not ask participants for private information or experiences. The quotes  
21 237 chosen were sufficiently general to preclude identification of individual participants.  
22 238 All methods used were checked and approved by the Vrije Universiteit Amsterdam  
23 239 along the questionnaire in place.

### 240 **Results**

24 241 Three themes of ICT-enabled person-centred care towards diabetes management  
25 242 resulted from our analysis: Self-managing disease (I); Shared (medical) data  
26 243 analysing (II), and Experiencing partnership (III) (see figure 2).  
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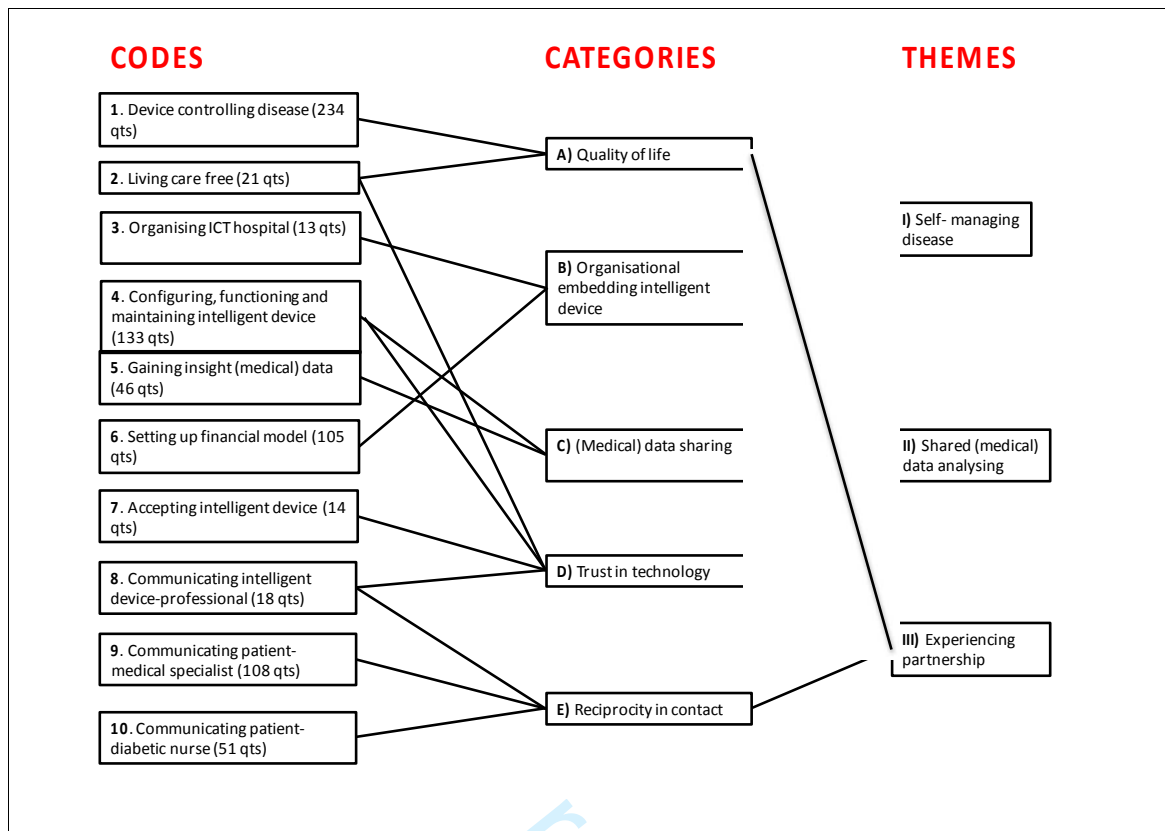


Figure 2 Conceptual framework of ICT enabling partnership in person-centred diabetes management

These three themes were based on five categories that shared characteristics resulting from ten codes originated from the research question.

### I) Self-managing disease

The theme self-managing disease exposes that the use of the AP system primes to a substantial increase in *quality of life* thanks not only to the device, which takes over control of the disease (234 quotes), but also the insight in (medical) data (46 quotes) that is linked to the new activity of *(medical) data sharing* (see: figure 2).

#### *Quality of life*

Users of the artificial pancreas system commonly mentioned (21 quotes) that the ICT application offers the next level of treatment for persons with diabetes with carefree living, which adds to their quality of life.

*"If you do not have to measure five times a day, but you can just let the device do its job, that's a huge improvement for me. [...] That may seem like a very small thing for healthy people, but it is, when you have diabetes, a huge*

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263            *addition to the quality of life and leading a 'normal' life.*" (Person with diabetes  
264            D)

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266            This increased quality of life is linked to the technological advancement of the AP  
267            system that takes over the activities of controlling the disease through continuously  
268            sensing measurements and algorithms. The AP semi-automates the management of  
269            diabetes by monitoring the condition and regulating the insulin and glucagon supply  
270            accordingly, giving the patient new data overviews to manage his or her condition.

271

272            *(Medical) data sharing*

273            What will change the partnership is the self-management of diabetes that is enriched  
274            through the sharing of (medical) data amongst medical specialists, diabetic nurses,  
275            patients and the intelligent device professional.

276

277            *"I have given permission to my diabetic nurse to look into my data. How often*  
278            *do you do that? Well, if I go through a period of an illness, like the flu, then*  
279            *maybe every week. If things go well, maybe once every two months."* (Person  
280            with diabetes D)

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282            The introduction of the intelligent device (AP system) initiates a constant flow of  
283            (medical) data – physiological measurements and personal data – that is accessible  
284            through a portal (see: figure 1). The new activity of (medical) data sharing is fuelled  
285            by gaining insight into (medical) data. If we stand back, we see that the presence of  
286            an intelligent device professional changes the partnership between the healthcare  
287            professionals and the person with diabetes. Thus, the introduction of ICT could  
288            enable the (experience of the) partnership and the self-management of a disease,  
289            but it also introduces new demands on healthcare professionals, including the  
290            provision of ICT (device) support.

## 291            **II) Shared (medical) data analysing**

292            The second theme, shared (medical) data analysing, reveals the new activity in the  
293            partnership of *(medical) data sharing* when the ICT-device is *embedded in the*  
294            *organisation* (see: figure 2). This sharing of (medical) data relates to the configuring,  
295            functioning and maintaining of the device (133 quotes) and the insights in (medical)

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3 296 data gained through the device (46 quotes). A diabetic nurse described the data  
4 297 sharing as follows:

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7 299 *“So, you can watch the person over distance. But it is not the intention that we*  
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9 300 *watch 24/7.”* (Diabetic nurse C)

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12 302 For an eHealth service enabling the partnership, both healthcare professionals and  
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14 303 patients need to be supported by intelligent device-professionals. To enable both  
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16 304 patients and the healthcare professional(s) to share data from the AP and to gather  
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18 305 data and then to store, retrieve, and analyse it, the technology and its data must be  
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20 306 embedded in the organisation (see: figure 2).

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23 308 *“And of course you should also start looking at your organisation again. How*  
24  
25 309 *do you organise that? A lot is already done digitally in the hospital, but this*  
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27 310 *does not link with our system. And this way of support from the hospital is also*  
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29 311 *not financed, yet, at all. So, yes, there will of course also be stuff that has to do*  
30  
31 312 *with the embedding in the organisation.”* (Diabetic nurse C)

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34 314 This organisational embedding of the intelligent device should be linked to the  
35  
36 315 organisation of ICT in the hospital setting (13 quotes), and should be supported by  
37  
38 316 the setting up of a financial model (105 quotes) that allows the gained insights in  
39  
40 317 (medical) data (46 quotes) to support the professional-patient partnership (see: figure  
41  
42 318 2). The introduction of the AP system could thereby potentially lead to new and  
43  
44 319 rich(er) data that becomes available that could possibly be shared amongst the  
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46 320 person with diabetes and the healthcare professionals and enable treatment  
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48 321 improvements in diabetes management.

### 49 322 **III) Experience partnership**

50 323 How the partnership is experienced is based on the reciprocity in contact, the trust in  
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52 324 technology, (medical) data sharing, and the quality of life (see: figure 2).

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55 326 *Reciprocity in contact*

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3 327 Reciprocity in contact is linked to how the person with diabetes communicates with  
4 328 his or her medical specialist (108 quotes), diabetic nurse (51 quotes) and the  
5 329 intelligent device professional (18 quotes), and the other way around.  
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9 331 *“We will head towards more equal care, I think. At least, if the patient wants*  
10 332 *that too.”* (Medical specialist B)  
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14 334 The AP technology in use revealed different intensities of how the partnership was  
15 335 experienced by both the patient and the healthcare professionals. On the one hand,  
16 336 the interviewees foresaw a change in the moments of contacts with the medical  
17 337 specialist.  
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21 339 *“Once the AP system is well integrated into health care – I do not have the*  
22 340 *illusion that it heals people – the treatment is such that you can actually go to*  
23 341 *a much lower level of guidance by medical specialists.”* (Person with diabetes  
24 342 A)  
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29 344 On the other hand, they expected that the partnership with the diabetic nurse would  
30 345 become more intensive, as was already experienced with the insulin pump:  
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34 347 *“You actually see that when you make the switch from syringe to pump. Then*  
35 348 *suddenly the contact with the diabetic nurse becomes much more intensive*  
36 349 *and more accessible and then you can suddenly call outside office hours.”*  
37 350 (Person with diabetes B)  
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40  
41 352 Diabetic nurses anticipate a change in the partnership with the person with diabetes  
42 353 as a result of implementing the AP.  
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45  
46 355 *“I tell my patients they do not have to come to see me every three months*  
47 356 *when there is no direct need. What matters is that the person with diabetes is*  
48 357 *well set and if that is the case, I do not see what I could improve.”* (Diabetic  
49 358 nurse B)  
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3 360 The initiative for treatment can thus be initiated through the data instead of through  
4 361 existing care pathways.

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7 363 The fear that healthcare professionals would become surplus, is not grounded:

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10 365 *“In the case of the artificial pancreas, I do not expect that suddenly a whole*  
11 366 *group of healthcare professionals no longer have to come to the hospital*  
12 367 *because the technology takes over. They have enough other things to do.”*

13 368 (Policy maker)

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15 369

16 370 The findings also reveal another role in the partnership, namely the communication  
17 371 with the intelligent device professional (18 quotes) with whom patients or the  
18 372 healthcare professionals communicate about the technical part of the AP.

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21 374 *“If you do not have a psychological problem and if your diabetes does not*  
22 375 *bother you, if your parameters are all right and well-regulated through the AP*  
23 376 *system, you see each other less so the consultation is purely problem-*  
24 377 *oriented. When it is a technical issue, then it must be the device and you*  
25 378 *contact the AP professional. The partnership will change towards shorter*  
26 379 *duration and interventions. If it is not going well, what is going on?”* (Medical  
27 380 specialist B)

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30 382 How the partnership is experienced depends also on the configuration, functioning  
31 383 and maintenance of the intelligent device (133 quotes). When the person with  
32 384 diabetes checks the ICT technology (verifying that it has enough insulin and  
33 385 glucagon, the battery and sensors are OK, etc.), and he or she notices that the  
34 386 system is not working properly, then communication with the intelligent device  
35 387 professional (18 quotes) is necessary to make sure that the device is technically in  
36 388 working order.

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39 390 *Trust in technology*

40 391 The experience of the partnership, supported through ICT, was also connected with  
41 392 the category of trust in technology (see: figure 2). The trust in technology was vividly  
42 393 described by one of the patients:



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4 395 *“You are busy with the management of diabetes all day, and if that is no longer*  
5 *the case, and you have trust in the technology to take over the management of*  
6 *the disease and that you do not have to think for yourself anymore, that gives a*  
7 *lot of freedom.”* (Patient B)  
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12 400 Trust in technology is related to the feeling of living care free (21 quotes), the  
13 401 configuring, functioning and maintaining of the intelligent device (133 quotes), the  
14 402 acceptance of the intelligent device (14 quotes) and communication with the  
15 403 intelligent device professional (18 quotes).  
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20 405 *(Medical) data sharing*

21  
22 406 The sharing of data has influence on how the partnership is experienced, and how  
23 407 patients communicate with healthcare professionals. However, the AP does not cure  
24 408 the disease so yearly check-ups will still be necessary.  
25  
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27 409

28 410 *“Look, the patient still has to see his medical specialist every year. He remains*  
29 411 *responsible and needs to check certain parameters. That still has to be done*  
30 412 *because the patient still has diabetes. Even if the patient is doing well, he or*  
31 413 *she is not cured.”* (Diabetic nurse B)  
32  
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35 414

36 415 Both healthcare professionals and patients foresee that the self-management options  
37 416 ushered in by the AP system will result in a change in the partnership.  
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40 417

41 418 *Quality of life*

42  
43 419 The outcomes expose that the experience of the partnership is linked to the quality of  
44 420 life, which increased when the intelligent device takes over the daily controlling of the  
45 421 disease and reduces the feeling of stress involved in self-managing diabetes (see:  
46 422 figure 2).  
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50 423

51 424 *“The most important thing for patients is that they do not have to be busy with*  
52 425 *their condition all day long. So, a bit of freedom and just a cup of coffee*  
53 426 *without having to do all kinds of measurements and so forth. For the simple*  
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3 427 *things that are important for daily life, that is the profit of the artificial*  
4 428 *pancreas.” (Person with diabetes A)*  
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6 429

7 430 Or as a medical specialist framed it:  
8  
9 431

10 432 *“If you still want to get a lot out of this life as a child, adolescent, young or*  
11 433 *older adult, you obviously win a lot when using the AP. It is just great if you do*  
12 434 *not have to think about diabetes all the time.” (Medical specialist A)*  
13  
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16  
17 436 The AP replaces human decision making, which the participants experience as  
18 437 carefree living because they no longer have to make constant dose adjustments all  
19 438 the time.  
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23  
24 440 How persons experience the partnership, varies in extent from patient to patient, but  
25 441 patterns can be discerned. At one end stands the person with diabetes who  
26 442 completely trusts the technology in such a way that the system takes over the  
27 443 function of the pancreas and automatically manages the glucose levels. Such a  
28 444 person thus feels that he or she no longer requires the help of a medical specialist. At  
29 445 the other end stands the person with diabetes who just wants his healthcare  
30 446 professionals to take over. Therefore, the interaction between the technology and  
31 447 social components must also be considered (see: figure 3).  
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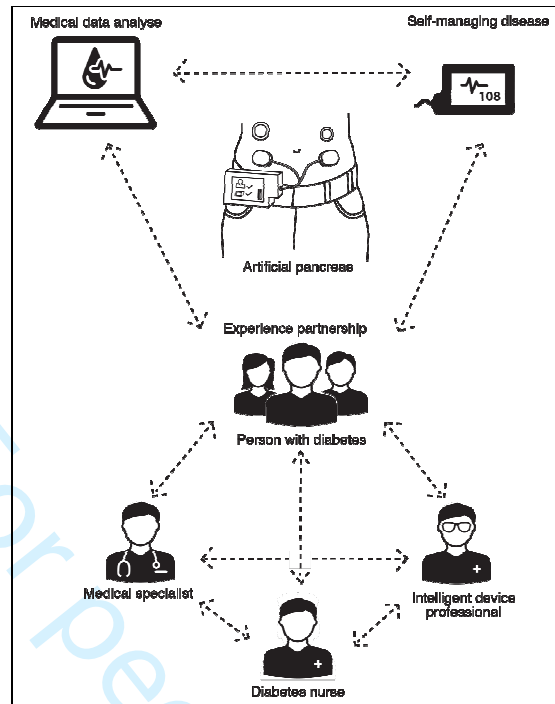


Figure 3 Partnership enabled through ICT (Artificial pancreas) system

The introduction of ICT simultaneously changes the partnership interaction between healthcare professionals and persons with a chronic condition, strengthens the interests of the patient (self managing disease), and yields precise analysed data on the clinical phenomenon (see: figure 3).

## Discussion

### Principal findings

Building on the analysis of in-depth qualitative data, this inductive study has revealed three interrelated themes; self-managing disease, shared (medical) data analysis and partnership experience (see: figure 2 and 3). We found an impact effect of carefree living through the semi-automated management by the device, new activities of data sharing and a new role of data professionals in the care providing. Our data suggests to embed the partnership into the organisation with adjustment of the organisation by new ICT-services and a viable financial model.

The induction of a new conceptual framework, provides insight into the dynamics how the partnership between healthcare professionals and persons with a chronic disease is enabled through ICT in chronic disease management of diabetes (see:

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2  
3 470 figure 3). The three themes are reordering the relationship between the person with  
4 471 diabetes, the internist, the diabetic nurse and the intelligent device professional. Thus  
5 472 the partnership interaction between healthcare professionals and persons with a  
6 473 chronic condition simultaneously changes the relationship, strengthens the interests  
7 474 of the patient (self-management), and yields precise data on the clinical  
8 475 phenomenon. This multinodal system is more complex than either the patient-  
9 476 technology or patient professional relation alone. Therefore, the outcomes are less  
10 477 predictable and neglecting the variation in the reactions of patients to the now more  
11 478 complicated entry points into the professional system, which can also lead to  
12 479 overestimation of the potential of disease self-management.

### 19 480 **Strengths and limitations**

20 481 The strength of the inductive single-case study approach is that we were able to gain  
21 482 detailed insight into how the characteristic of the partnership changed between a  
22 483 person with type 1 diabetes and the healthcare professional(s) as a result of the use  
23 484 of ICT. The benefit of a single-case study compared to multiple cases is that a single  
24 485 case enables the creation of a comprehensive conceptual framework build on the  
25 486 details of a particular case (26, 37). The development of this theoretical framework  
26 487 increases the understanding of person-centred healthcare and ICT-enabled health  
27 488 services that can have implications for practice (38).

28 489 Through qualitative research we delved into the anecdotal evidence of the interviews  
29 490 and used coding to show commonalities in the changes that the interviewees  
30 491 expected, through which we were able to build a framework that can broaden the  
31 492 scope of evidence-based medicine; good evidence goes further than the results of  
32 493 meta-analysis of randomised controlled trials (39).

33 494 We also acknowledge a limitation of the study. To study the partnership between  
34 495 patients and healthcare professionals in chronic disease management we chose an  
35 496 ICT application – the Artificial Pancreas system – that is still under development and  
36 497 was not as yet available on the market during the research period. However, since  
37 498 our focus is neither on the technology itself nor its acceptance, but on the enabling of  
38 499 the partnership, the case study does add to our knowledge on ICT in partnership and  
39 500 service provision based on digital healthcare applications.

40 501

### 41 502 **Comparison with other studies**

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3 503 In a recent study, it was concluded that ICT offers a viable environment to deliver  
4 504 person-centred care through ICT for patients with chronic conditions (8). However, to  
5 505 maximise the potential of ICT to enable patients to manage their condition, there is a  
6 506 need to integrate PCC principles into ICT and its organisation. These principles have  
7  
8 507 been worked out in determining the preconditions for ICT-enabled person-centred  
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10 508 care (7). Our study adds to the existing knowledge base with its finding that  
11  
12 509 developing PCC principles to enable chronic disease management is just one step,  
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14 510 and that the three themes are another input for ICT-enabled person centred care-  
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16 511 principles towards chronic disease management. ICT taking over the burden of self-  
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18 512 managing disease; shared (medical) data analysis implies ICT services and  
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20 513 professions embedded in the healthcare organisation, and the introduction of ICT  
21  
22 514 introduces new demands on healthcare professionals and patients, that influences  
23  
24 515 how the partnership is experienced.

25  
26 516 Other research has pointed to the need that human connectedness provides the  
27  
28 517 conditions for communication and cooperation on which formal relations of  
29  
30 518 partnership can be constructed (1, 4). Our study shows that introducing an ICT-  
31  
32 519 enabled PCC solution structures an integrated form of professional-patient  
33  
34 520 connectedness. The self-management of the disease, but also the analysis of  
35  
36 521 (medical) data and the experience of the partnership, shift the professional-patient  
37  
38 522 connectedness from the medical specialist to the diabetic nurse. New roles take  
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40 523 shape such as the one of the intelligent device professional, and a different network  
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42 524 will (have to) evolve around the patient. One of the lessons could be that it becomes  
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44 525 more important to look at the personal progression of the disease in addition to  
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46 526 following the existing rigid care pathways.

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48 527 Finally, when introducing ICT in a healthcare context, the technology should be  
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50 528 studied as part of a dynamic and networked healthcare environment, so-called 'fourth  
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52 529 generation studies' (40) and should take a participatory development approach to  
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54 530 guide the development, implementation and evaluation of eHealth technologies and  
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56 531 interventions (41). Our study suggests that these types of studies should also include  
57  
58 532 a focus on the partnership and how this is reshaped by the introduction of ICT. The  
59  
60 533 results of our study show that to support the partnership in a sustainable manner, ICT  
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535 534 needs to be embedded in healthcare organisations. As a result, the care pathways  
also need to be redesigned so we can move towards person-centred chronic disease

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3 536 management, offering treatment 'when needed, where needed' based on the  
4 537 availability of rich data generated by an ICT-system.

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### 7 539 **Future research**

8  
9 540 The expected changes in the role of healthcare professionals as a result of  
10  
11 541 introducing ICT-enabled PCC towards chronic disease self-management must be  
12  
13 542 addressed with the design of a new care model integrating the changing partnership.  
14  
15 543 The next steps should be to study how to design care models that fit these changes  
16  
17 544 of partnership as a result of ICT-enabled PCC, and how a sustainable financial model  
18  
19 545 should be determined for ICT-enabled person-centred chronic disease management.

### 20 546 **Conclusion**

21  
22 547 The management of diabetes through ICT requires an adjustment of the partnership  
23  
24 548 between persons with the chronic condition and the healthcare professional(s) in  
25  
26 549 such a way that the potential for self-managing the condition by analysing the newly  
27  
28 550 available (medical) data (from the intelligent device AP system) together leads to an  
29  
30 551 experience of partnership between patients and healthcare professionals.

### 31 552 **Acknowledgements**

32  
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34  
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36  
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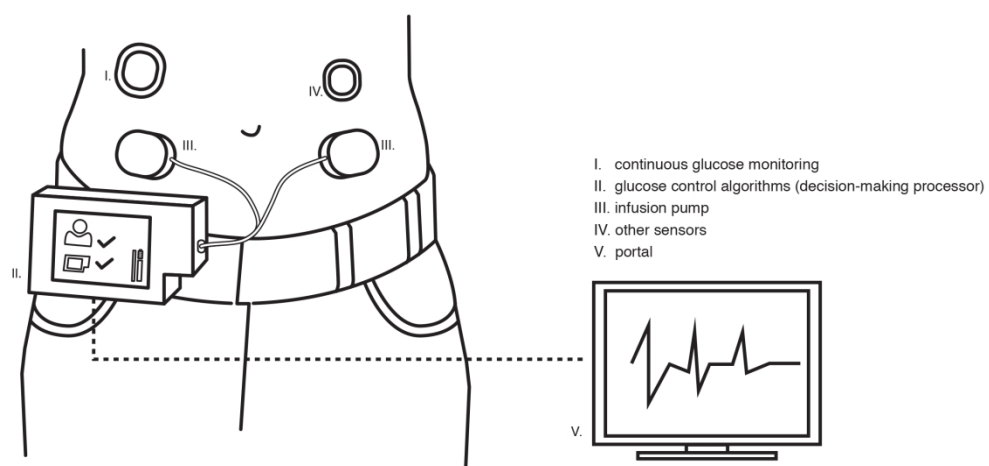


Figure 1 Components of the Artificial Pancreas system

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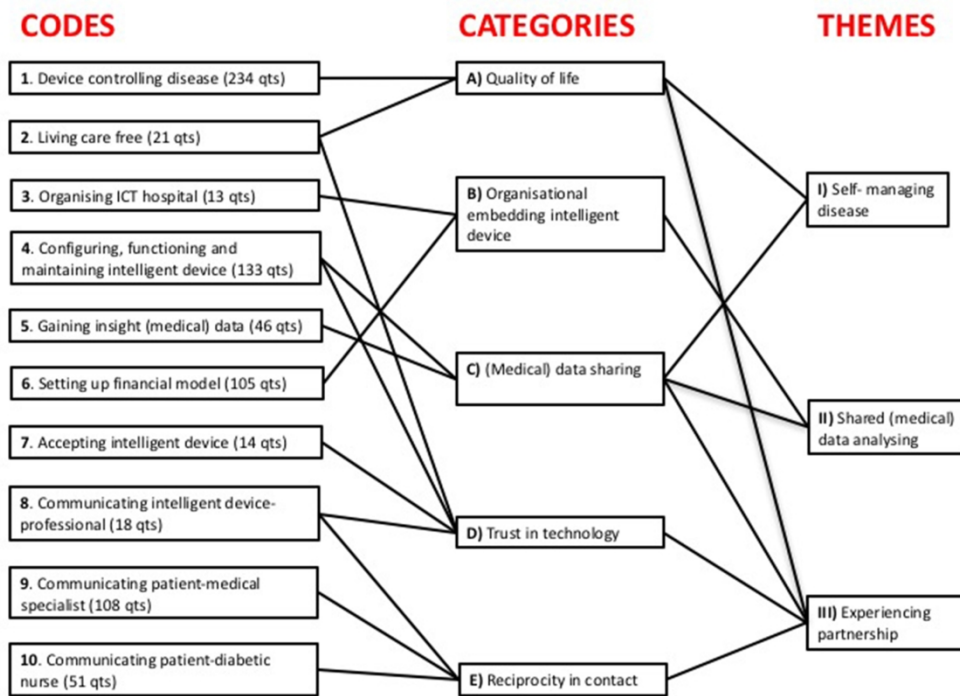


Figure 2 Conceptual framework of ICT enabling partnership in person-centred diabetes management

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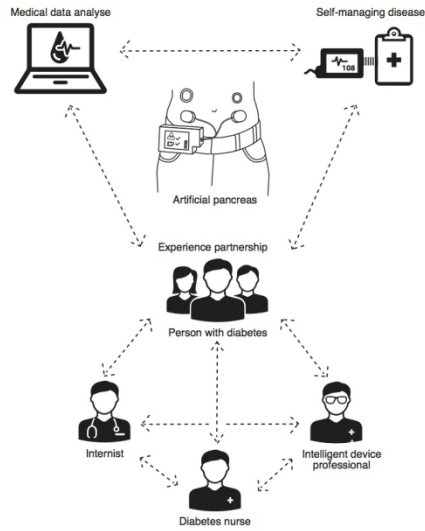


Figure 3 Partnership enabled through ICT (Artificial pancreas) system

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## Standards for Reporting Qualitative Research (SRQR)\*

<http://www.equator-network.org/reporting-guidelines/srqr/>

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### Title and abstract

<p><b>Title</b> - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	1/1
<p><b>Abstract</b> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	2/25-47

### Introduction

<p><b>Problem formulation</b> - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	4/68-93
<p><b>Purpose or research question</b> - Purpose of the study and specific objectives or questions</p>	4/94-95

### Methods

<p><b>Qualitative approach and research paradigm</b> - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	6/138-143
<p><b>Researcher characteristics and reflexivity</b> - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	8/197-199
<p><b>Context</b> - Setting/site and salient contextual factors; rationale**</p>	6/145-164
<p><b>Sampling strategy</b> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	7-8/168-191
<p><b>Ethical issues pertaining to human subjects</b> - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	No medical data nor personal data of the participants were used. Data were anonymized: 8/204-05

1 2 3 4 5	<b>Data collection methods</b> - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	8/199-225
6 7 8 9	<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	8/193-196, 203-205
10 11 12 13	<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	8/186-191
14 15 16 17	<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	8-9/218-222
18 19 20 21	<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	9/223-231
22 23 24 25	<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	9/225-226

## Results/findings

26 27 28 29 30 31	<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	9-10/233-240
32 33 34	<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	10-16/241-447

## Discussion

35 36 37 38 39 40 41 42	<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	16/451-471
43 44	<b>Limitations</b> - Trustworthiness and limitations of findings	17-18/486-92

## Other

45 46 47 48 49	<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	No conflicts of interest
50 51 52	<b>Funding</b> - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	19/545-7

1 \*The authors created the SRQR by searching the literature to identify guidelines, reporting  
2 standards, and critical appraisal criteria for qualitative research; reviewing the reference  
3 lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to  
4 improve the transparency of all aspects of qualitative research by providing clear standards  
5 for reporting qualitative research.  
6  
7

8 \*\*The rationale should briefly discuss the justification for choosing that theory, approach,  
9 method, or technique rather than other options available, the assumptions and limitations  
10 implicit in those choices, and how those choices influence study conclusions and  
11 transferability. As appropriate, the rationale for several items might be discussed together.  
12

13  
14 **Reference:**

15 O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative**  
16 **research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014  
17 DOI: 10.1097/ACM.0000000000000388  
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# BMJ Open

**Information and Communication Technology enabling partnership in person-centred diabetes management: Building a theoretical framework from an inductive case study in the Netherlands**

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3 1 Information and Communication Technology enabling partnership in person-centred  
4 2 diabetes management: Building a theoretical framework from an inductive case study  
5 3 in the Netherlands  
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3 22 *Original Research Paper*

4 23 **Information and Communication Technology enabling partnership in person-**  
5 **centred diabetes management: Building a theoretical framework from an**  
6 **inductive case study in the Netherlands**  
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10  
11 26 **Abstract**

12  
13 27 *Objectives:* The aim of this paper is to construct a theoretical framework for  
14  
15 28 Information and Communication Technology (ICT)-enabled partnership towards  
16  
17 29 diabetes management.

18 30 *Design:* We conducted an inductive case study and held interviews on the  
19  
20 31 development and use of an Artificial Pancreas (AP) system for diabetes  
21  
22 32 management.

23 33 *Setting:* The study was carried out in the Netherlands with users of an AP system.

24 34 *Participants:* We interviewed six individuals with type 1 diabetes, five healthcare  
25  
26 35 professionals (two medical specialists, three diabetes nurses), and one policy advisor  
27  
28 36 from the Ministry of Health, Welfare, and Sport.

29  
30 37 *Results:* We built a new theoretical framework for ICT-enabled person-centred  
31  
32 38 diabetes management, covering the central themes of self-managing the disease,  
33  
34 39 shared analysing of (medical) data, and experiencing the partnership. We found that  
35  
36 40 ICT yielded new activities of data sharing and a new role for data professionals in the  
37  
38 41 provision of care as well as contributed to carefree living thanks to the semi-  
39  
40 42 automated management enabled by the device. Our data suggested that to enable  
41  
42 43 the partnership through ICT, organisational adjustments need to be made such as  
43  
44 44 the development of new ICT-services and a viable financial model to support these  
45  
46 45 services.

46 46 *Conclusion:* The management of diabetes through ICT requires an adjustment of the  
47  
48 47 partnership between persons with the chronic condition and the healthcare  
49  
50 48 professional(s) in such a way that the potential for self-managing the condition by  
51  
52 49 analysing the newly available (medical) data (from the AP system) together leads to  
53  
54 50 an experience of partnership between patients and healthcare professionals.

55 51 **Strengths and limitations of this study**

- 56  
57 52 • The strength of the inductive case study approach is that it provides in-depth  
58  
59 53 insights into how the partnership is shaped between a person with type 1  
60

- 1  
2  
3 54 diabetes and the healthcare professional(s) as a result of the use of an  
4  
5 55 Artificial Pancreas system for diabetes management.  
6  
7 56 • Building theory from a case study, as we have done with our research, made it  
8  
9 57 possible to create a theoretical framework from case-based empirical  
10  
11 58 evidence.  
12  
13 59 • Our findings should be considered in the context of our study design and may  
14  
15 60 not be generalised to other AP systems nor long term use of the AP system on  
16  
17 61 a larger scale.  
18  
19 62 • A possible limitation of this study is that the studied technology was under  
20  
21 63 development during the research period; however, this is not a major  
22  
23 64 limitation, as the focus of our study is not on the technology itself but on  
24  
25 65 enabling the healthcare professional-patient partnership.  
26  
27 66

25 67 **Keywords:** ICT, eHealth, type 1 diabetes, chronic disease management, person-  
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27 68 centred care  
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## 70 Introduction

71 Person-centred care (PCC) actively involves the patient in the care process as an  
72 equal partner in, and expert on, living with a chronic condition (1). Persons with a  
73 chronic condition have to make decisions on a day-to-day basis about self-managing  
74 their illness, which influences the healthcare professional-patient partnership with  
75 respect to care services (2). The partnership between patients and healthcare  
76 professionals involves sustaining the relationship via deciding on goals, care  
77 planning and documentation (3). Information and Communication Technology (ICT)  
78 for healthcare – also known as eHealth (4) – might support the professional-patient  
79 partnership in person-centred care services and provide chronic disease  
80 management in the face of social, physical, and emotional challenges (5).

### 82 *Information and communication-enabled person-centred care*

83 ICT is increasingly used within chronic disease management to document and  
84 exchange information, monitor and interact. The results of the first studies on ICT  
85 enabling person-centred care (ICT-PCC) in chronic care are promising, with  
86 improved clinical outcomes, better health-related quality of life, and increased cost-  
87 effectiveness (6). However, there is a gap in knowledge how ICT shapes the  
88 professional-patient partnership when used in daily practice.

89 When applying the concept of partnership in person-centred care to ICT systems, the  
90 technology must be tailored to the needs of both patients and healthcare  
91 professionals (personalised ICT), whereby the personal context and situation of the  
92 patient informs and guides the decision making on the care pathway (7). However,  
93 this phenomenon of enabling the partnership through ICT is not fully understood and  
94 insights are lacking on how this partnership is influenced and transformed through  
95 ICT (8). In this study we selected a case in which an innovative ICT-enabled person-  
96 centred care intervention was used for diabetes management in order to better  
97 understand how ICT shaped the patient-professional partnership (9).

### 99 *Self-management of diabetes*

100 Training in self-management of type 1 diabetes through personalised insulin  
101 treatment leads to significant improvements in treatment satisfaction, psychological  
102 wellbeing, and quality of life measures (10). Even though diabetes management has

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2  
3 103 improved considerably over the years, patients still suffer from short-term  
4 104 complications such as hypoglycaemia ('hypo' for short) and hyperglycaemia ('hyper')  
5 105 progressing to diabetic ketoacidosis (DKA) and hyperosmolar hyperglycaemic  
6 106 syndrome (HHS), and long-term complications such as retinopathy, neuropathy,  
7 107 cardiovascular disease, and nephropathy that could lead to complications such as  
8 108 loss of eyesight and amputation (11).

9  
10 109 The treatment and care of patients with diabetes have seen fast progress and key  
11 110 innovations after the discovery of insulin in 1921: engineered insulin, the introduction  
12 111 of blood glucose monitoring by tele monitoring systems, internet applications, and  
13 112 mobile devices (12). In addition, smart algorithms to control the blood glucose level  
14 113 have been developed (13). This innovation trajectory of applying smart algorithms to  
15 114 earlier discoveries culminated in the development of a first-generation system of an  
16 115 artificial pancreas that focuses on preventing unsafe blood sugar levels and aims to  
17 116 maintain the blood glucose level between approximately 70 and 180 mg/dl (14).

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### 30 118 *ICT interventions for diabetes management*

31 119 Several companies worldwide are developing AP systems that take over the  
32 120 regulation of the glucose levels completely by automating insulin and glucagon  
33 121 delivery (15) (16) (17) (18). Over the last years significant progress has been made in  
34 122 AP development (19), and researchers have demonstrated the safety and feasibility  
35 123 of different AP systems in clinical research settings and more recently in outpatient  
36 124 'real-world' environments (20) (21).

37 125 A systematic review of artificial pancreas systems showed that they could be an  
38 126 efficacious and safe approach for treating patients with type 1 diabetes (22). The  
39 127 greatest benefits of the AP are the reduced burden of diabetes management during  
40 128 the day, and improved overnight control of glucose levels thanks to reduced  
41 129 glycaemic variability, improved time in target range, and reduced risk of nocturnal  
42 130 hypoglycaemia (23) (24) (25). Although AP users with type 1 diabetes will still need  
43 131 to self-manage their illness, a closed loop system with data acted upon by the users  
44 132 could reduce the burden (26).

45 133 We chose to employ an inductive case study to focus on the dynamics of the patient-  
46 134 professional partnership shaped through an ICT intervention used in practice for the  
47 135 management of type 1 diabetes, namely an Artificial Pancreas system. The case  
48 136 study was applied to answer the research question: How does ICT enable the

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3 137 partnership between healthcare professional(s) and the patient in chronic disease  
4 management?  
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## 9 140 **Methods**

### 12 141 **Study design**

14 142 We conducted an inductive case study (27) and held in-depth interviews with both  
15 healthcare professionals and patients on their use of the Artificial Pancreas system  
16 143 (28). This case study looks in particular into the dynamics of the professional-patient  
17 144 partnership and between different healthcare professionals, the patient experience,  
18 145 and how introducing ICT enables a person-centred approach to diabetes care.  
19 146  
20 147

### 25 148 **Setting**

27 149 As the case setting we have chosen the use of an AP system that at the time of the  
28 study was only tested in the Netherlands. The system automatically controls the  
29 150 blood glucose level of patients with type 1 diabetes, and provides the substitute  
30 151 functionality of both insulin and glucagon delivery of a healthy pancreas. The AP  
31 152 system maintains the blood glucose levels in the healthy range most of the time,  
32 153 without restrictions with respect to factors such as diet and exercise.  
33 154  
34 155

### 40 156 **Case description**

42 157 The development of the person-centred AP system was started in 1994 in the  
43 Netherlands by an engineer who himself had been diagnosed with type 1 diabetes.  
44 158 His motivation for inventing a semi-autonomous AP was driven by his dissatisfaction  
45 159 with the diabetes care treatment and the support provided with products and software  
46 160 applications. He started a company to develop the AP in an iterative manner,  
47 161 involving the users in the different steps of its development.  
48 162

52 163 The wearable artificial pancreas integrates the following features into one device: (i)  
53 164 continuous glucose monitoring; ii) glucose control algorithms (decision-making  
54 165 processor); iii) infusion pump; and (iv) other sensors (26) (see: figure 1).  
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60 *[Figure 1 Components of the Artificial Pancreas system]*

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5 169 The control unit (i + ii) replaces human decision making and makes more frequent  
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7 170 dose adjustments than a person could. The AP device transmits data to a database  
8  
9 171 that is accessible via a portal (v) featuring web services for monitoring.  
10  
11 172 The functions of the bihormonal AP (both insulin and glucagon) were tested with  
12  
13 173 persons with type 1 diabetes in home treatment; the results indicated that the AP  
14  
15 174 provided better glucose control than traditional insulin pump therapy and that the  
16  
17 175 treatment is safe (29). Related studies also indicated that patients anticipate that they  
18  
19 176 will accept the device (30) and that for further technical development it will feature  
20  
21 177 adaptive control (31).  
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23 178

### 23 179 **Participants**

25 180 The participants were selected in the Netherlands via a combination of purposive and  
26  
27 181 snowball sampling. With purposive sampling we initially selected two types of  
28  
29 182 participants, persons with type 1 diabetes and healthcare professionals who had  
30  
31 183 used the AP and would potentially be able to provide rich, relevant, and diverse data  
32  
33 184 pertinent to the ICT-enabling of the partnership (32) (33). Subsequently, through  
34  
35 185 snowball sampling - in which interviewees identified further participants - we recruited  
36  
37 186 both persons with type 1 diabetes and healthcare professionals (medical specialists  
38  
39 187 and trained diabetes nurses) with knowledge relevant to the case study, and a policy  
40  
41 188 advisor.

42 189 We approached the participants via telephone, email, and/or face-to-face. We sent  
43  
44 190 an information letter by email with an introduction to and information about the case  
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46 191 study, and an invitation to participate. The principal researcher introduced the study  
47  
48 192 orally, stressing the person's right to make their own choice to participate.

49 193 We interviewed twelve Dutch participants: six persons with type 1 diabetes, five  
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51 194 healthcare professionals (two medical specialists; one paediatrician-endocrinologist  
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53 195 and one internist-endocrinologist, three diabetes nurses). One policy advisor from the  
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55 196 Ministry of Health, Welfare, and Sport was included because of his experience with  
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57 197 the embedding of the AP in the healthcare context.

58 198 Four attempts to recruit specific participants were rejected. One participant indicated  
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60 199 he was too busy, while the other reasons for non-participation were that the



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3 200 participants (2) were not familiar with the AP or the subject was too sensitive (policy  
4 201 maker).

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### 7 203 **Patient and public involvement**

8 204 The study was designed to understand the perspectives of the participants to gain  
9 205 access to their experiences, feelings and preferences with the use of an AP, of  
10 206 patients diagnosed with type 1 diabetes and others (34). The research question was  
11 207 developed in an iterative manner, and based on patients' and healthcare  
12 208 professionals' insights. The AP was chosen as a case study since it was a patient-  
13 209 driven innovation, developed by an engineer who was diagnosed with type 1  
14 210 diabetes patient himself. Patients were involved in the different phases of the study,  
15 211 and recruited through snow ball sampling, in which participants also supported in  
16 212 recruiting (other) patients.  
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### 28 214 **Data collection**

29 215 We held in-depth, semi-structured interviews with the participants. These interviews  
30 216 were guided by an interview protocol, with questions focusing on the overall  
31 217 experience with AP in clinical practice and how the AP supported and changed the  
32 218 professional-patient partnership in diabetes management. The interview protocol was  
33 219 provided in Dutch, and is available upon request.

34 220 The first author conducted the interviews via telephone/Skype or FaceTime, either at  
35 221 home or at work. One participant was known from a previous study. No non-  
36 222 participants were present during the interviews. The interviews were conducted  
37 223 between February and April 2017. The interviews lasted between forty-seven and  
38 224 seventy-three minutes. Participants were recruited until no new knowledge was  
39 225 gained (data saturation) (35). No repeat interviews were conducted. The researcher  
40 226 audio-recorded the participants and took notes. We transcribed all interviews. We  
41 227 anonymised the data and allocated alphabet capital coding to each participant.  
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### 55 229 **Analysis**

56 230 In this study, we used thematic analysis to identify patterns within the data, and  
57 231 grouped them under codes, categories, and themes, whereby we particularly sought  
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3 232 to identify how ICT supported the partnership in diabetic/chronic disease  
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5 233 management (36). The first two authors analysed the data in an iterative process of  
6  
7 234 coding and use of NVivo software, version 12.2.0.  
8  
9 235 We started with a line-by-line coding that was derived from the research question.  
10  
11 236 We processed the coding by reading and analysing the data – in which we preserved  
12  
13 237 (inter-)actions by using as many gerunds ('ing') as possible (37). The first and second  
14  
15 238 author reviewed the codes. After that, through focussed coding, we organised and  
16  
17 239 grouped the coded data that shared characteristics into categories.  
18  
19 240 In this phase, we left out codes that did not contribute to answering the research  
20  
21 241 question from further analysis (such as data on specific treatment for children). We  
22  
23 242 then moved to the process of theoretical coding – in which we clustered the  
24  
25 243 categories into themes – to build a theoretical framework.  
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27 244

### 245 **Ethical considerations**

246 The study was approved by the researchers' host institute. All participants, prior to  
247  
248 the interviews, agreed to participate. Participation was voluntary and participants  
249  
250 could withdraw at any point. The research complied with the Helsinki Declaration of  
251  
252 the World Medical Association (2013). In our sample design we excluded the  
253  
254 participation of vulnerable groups. The topic of our study was not sensitive. The  
255  
256 researchers did not use or have access to personal information or datasets; they also  
257  
258 neither collected nor used bodily material. All personal information was de-identified.  
259  
260 We did not ask participants for private information or experiences. The quotes  
261  
262 chosen were sufficiently general to preclude identification of individual participants.  
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### 265 **Results**

266 Our analysis yielded three themes of ICT-enabled person-centred care towards  
267  
268 diabetes management resulted from our analysis: Self-managing the disease (I);  
269  
270 Shared analysing of (medical) data (II), and Experiencing the partnership (III) (see  
271  
272 the theoretical framework in figure 2).  
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277 *[Figure 2 Theoretical framework of ICT enabling partnership in person-centred*  
278  
279 *diabetes management]*  
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3 264 These three themes were based on five categories that shared characteristics  
4  
5 265 resulting from ten codes originated from the research question.  
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### 8 266 **I) Self-managing the disease**

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10 267 The theme self-managing the disease indicates that the use of the AP system  
11 268 contributes to a substantial increase in *quality of life* thanks not only to the device,  
12  
13 269 which takes over control of the disease (234 quotes), but also insights based  
14  
15 270 (medical) data (46 quotes) that is linked to the new activity of *(medical) data sharing*  
16 271 (see: figure 2).  
17  
18 272

#### 19 20 273 *Quality of life*

21 274 Users of the artificial pancreas system commonly mentioned (21 quotes) that the ICT  
22  
23 275 application offers the next level of treatment for persons with diabetes, enabling  
24  
25 276 carefree living that adds to their quality of life.  
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27 277

28 278 *“If you do not have to measure five times a day, but you can just let the device*  
29  
30 279 *do its job, that's a huge improvement for me. [...] That may seem like a very*  
31  
32 280 *small thing for healthy people, but it is, when you have diabetes it's a huge*  
33  
34 281 *boost to your quality of life, enabling you to lead a 'normal' life.”* (Person with  
35 282 diabetes D)  
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37 283

38  
39 284 This increased quality of life is linked to the technological advancement of the AP  
40  
41 285 system that takes over the activities of controlling the disease through continuously  
42  
43 286 sensing measurements and algorithms. The AP semi-automates the management of  
44  
45 287 diabetes by monitoring the condition and regulating the insulin and glucagon supply  
46  
47 288 accordingly, giving the patient new data overviews to manage his or her condition.  
48  
49 289

#### 50 290 *(Medical) data sharing*

51 291 What will change the partnership is the self-management of diabetes, which is  
52  
53 292 enriched through the sharing of (medical) data amongst medical specialists, diabetes  
54  
55 293 nurses, patients and the intelligent device professional.  
56  
57 294

58 295 *“I have given permission to my diabetic nurse to look into my data. How often*  
59  
60 296 *do you do that? Well, if I go through a period of an illness, like the flu, then*

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3 297 *maybe every week. If things go well, maybe once every two months.*" (Person  
4 with diabetes D)  
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8 300 The introduction of the intelligent device (AP system) initiates a constant flow of  
9 (medical) data – physiological measurements and personal data – that is accessible  
10 301 through a portal (see: figure 1). The new activity of (medical) data sharing is fuelled  
11 302 by gaining insight into (medical) data. If we stand back, we can see that the presence  
12 303 of an intelligent device professional changes the partnership between the healthcare  
13 304 professionals and the person with diabetes. Thus, the introduction of ICT could  
14 305 enable the (experience of the) partnership and the self-management of a disease,  
15 306 but it also introduces new demands on healthcare professionals, including the  
16 307 provision of ICT (device) support.  
17 308

## 25 309 **II) Shared analysing of (medical) data**

26  
27 310 The second theme, shared analysing of (medical) data, reveals the new activity in the  
28 311 partnership of *(medical) data sharing* when the ICT device is *embedded in the*  
29 312 *organisation* (see: figure 2). This sharing of (medical) data relates to the configuring,  
30 313 functioning and maintaining of the device (133 quotes) and the insights in (medical)  
31 314 data gained through the device (46 quotes). A diabetic nurse described the data  
32 315 sharing as follows:  
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34 316

35  
36 317 *"So, you can watch the person over distance. But it is not our intention to*  
37 318 *watch patients 24/7."* (Diabetic nurse C)  
38  
39 319

40  
41 320 For an eHealth service enabling the partnership, both healthcare professionals and  
42 321 patients need to be supported by intelligent device professionals. To enable both  
43 322 patients and the healthcare professional(s) to share data from the AP and to gather  
44 323 data and then to store, retrieve, and analyse it, the technology and its data must be  
45 324 embedded in the organisation (see: figure 2).  
46 325

47 326 *"And of course you should also start looking at your organisation again. How*  
48 327 *do you organise this? A lot is already done digitally in the hospital, but this*  
49 328 *does not link with our system. And this type of support from the hospital has*  
50 329 *not been allocated any funding yet. So, yes, there will of course also be stuff*

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3 330 *that has to do with the embedding [of the device] in the organisation.”* (Diabetic  
4 nurse C)  
5 331

6 332  
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8 333 This organisational embedding of the intelligent device should be linked to the  
9 organisation of ICT in the hospital setting (13 quotes), and should be supported by  
10 334 the setting up of a financial model (105 quotes) that allows the insights gained from  
11 335 the (medical) data (46 quotes) to support the professional-patient partnership (see:  
12 336 figure 2). The introduction of the AP system could thereby potentially lead to the  
13 337 availability of new and rich(er) data that could be shared amongst the person with  
14 338 diabetes and the healthcare professionals and enable treatment improvements in  
15 339 diabetes management.  
16 340

### 23 341 **III) Experiencing the partnership**

24  
25 342 How the partnership is experienced is based on the reciprocity in contact, the trust in  
26 343 technology, (medical) data sharing, and the quality of life (see: figure 2).  
27 344

#### 30 345 *Reciprocity in contact*

31  
32 346 Reciprocity in contact is linked to how the person with diabetes communicates with  
33 347 his or her medical specialist (108 quotes), diabetic nurse (51 quotes) and the  
34 348 intelligent device professional (18 quotes), and the other way around.  
35 349

36  
37 350 *“We will head towards more equal care, I think. At least, if the patient wants*  
38 351 *that too.”* (Medical specialist B)  
39 352

40  
41 353 The AP technology in use revealed different intensities of how the partnership was  
42 354 experienced by both the patient and the healthcare professionals. On the one hand,  
43 355 the interviewees foresaw a change in the moments of contact with the medical  
44 356 specialist.  
45 357

46  
47 358 *“Once the AP system is well integrated into health care – I do not have the*  
48 359 *illusion that it heals people – the treatment is such that medical specialists can*  
49 360 *provide far less guidance [to patients].”* (Person with diabetes A)  
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3 362 On the other hand, they expected that the partnership with the diabetic nurse would  
4  
5 363 become more intensive, as was already experienced with the insulin pump:  
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8 365 *“You actually see that when you make the switch from syringe to pump. Then*  
9  
10 366 *suddenly the contact with the diabetic nurse becomes much more intensive*  
11  
12 367 *and more accessible and then you can suddenly call outside office hours.”*

13 368 (Person with diabetes B)  
14  
15 369

16  
17 370 Diabetes nurses anticipate a change in the partnership with the person with diabetes  
18  
19 371 as a result of implementing the AP.  
20  
21 372

22 373 *“I tell my patients they do not have to come see me every three months when*  
23  
24 374 *there is no direct need. What matters is that the person with diabetes is doing*  
25  
26 375 *well and if that is the case, I do not see what I could improve.”* (Diabetic nurse  
27 376 B)  
28  
29 377

30  
31 378 The initiative for treatment can thus be initiated through the data instead of through  
32  
33 379 existing care pathways.  
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35 380

36 381 The fear that healthcare professionals would become unnecessary is baseless:  
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38 382

39 383 *“In the case of the artificial pancreas, I do not expect that suddenly a whole*  
40  
41 384 *group of healthcare professionals no longer have to come to the hospital*  
42  
43 385 *because the technology takes over. They have enough other things to do.”*

44 386 (Policy maker)  
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46 387  
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48 388 The findings also reveal another role in the partnership, namely the communication  
49  
50 389 with the intelligent device professional (18 quotes) with whom patients or the  
51  
52 390 healthcare professionals communicate about the technical part of the AP.  
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54 391

55 392 *“If you do not have a psychological problem and if your diabetes does not*  
56  
57 393 *bother you, if your parameters are all right and well-regulated through the AP*  
58  
59 394 *system, you see each other less often so the consultation is purely problem-*  
60 395 *oriented. When it is a technical issue, then the device is at fault and you*

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3 396 *contact the AP professional. The partnership will change towards shorter*  
4 *duration and interventions. If it is not going well, what is going on?"* (Medical  
5 397  
6 specialist B)  
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10 400 How the partnership is experienced depends also on the configuration, functioning  
11 401 and maintenance of the intelligent device (133 quotes). When the person with  
12 402 diabetes checks the ICT technology (verifying that it has enough insulin and  
13 403 glucagon, the battery and sensors are OK, etc.), and he or she notices that the  
14 404 system is not working properly, then communication with the intelligent device  
15 405 professional (18 quotes) is necessary to make sure that the device is technically in  
16 406 working order.  
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22 407

#### 23 408 *Trust in technology*

24 409 The experience of the partnership, supported through ICT, was also connected with  
25 410 the category of trust in technology (see: figure 2). The trust in technology was vividly  
26 411 described by one of the patients:  
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30 412

31 413 *"You are busy with the management of diabetes all day. If that is no longer the*  
32 414 *case, and you have trust in the technology to take over the management of the*  
33 415 *disease and that you do not have to think for yourself anymore. That gives a lot of*  
34 416 *freedom."* (Patient B)  
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40 418 Trust in technology is related to the feeling of care free living (21 quotes), the  
41 419 configuring, functioning and maintaining of the intelligent device (133 quotes), the  
42 420 acceptance of the intelligent device (14 quotes) and communication with the  
43 421 intelligent device professional (18 quotes).  
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#### 49 423 *(Medical) data sharing*

50 424 The sharing of data has influence on how the partnership is experienced, and how  
51 425 patients communicate with healthcare professionals. However, the AP does not cure  
52 426 the disease so yearly check-ups will still be necessary.  
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57  
58 428 *"Look, the patient still has to see his medical specialist every year. He remains*  
59 429 *responsible and needs to check certain parameters. That still has to be done*

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3 430 *because the patient still has diabetes. Even if the patient is doing well, he or*  
4  
5 431 *she is not cured.” (Diabetic nurse B)*  
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8 433 Both healthcare professionals and patients foresee that the self-management options  
9 434 ushered in by the AP system will result in a change in the partnership.  
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11 435

### 13 436 *Quality of life*

15 437 The outcomes expose that the experience of the partnership is linked to the quality of  
16 438 life, which increased when the intelligent device took over the daily controlling of the  
17 439 disease and reduced the feeling of stress involved in self-managing diabetes (see:  
20 440 figure 2).  
21  
22 441

24 442 *“The most important thing for patients is that they do not have to be busy with*  
25 443 *their condition all day long. So, a bit of freedom and being able to enjoy a cup*  
26 444 *of coffee without having to do all kinds of measurements and so forth. For the*  
27 445 *simple things that are important for daily life. That is the benefit of the artificial*  
30 446 *pancreas.” (Person with diabetes A)*  
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32 447

34 448 Or as a medical specialist framed it:  
35  
36 449

37 450 *“If you still want to get a lot out of this life as a child, adolescent, young or*  
38 451 *older adult, you obviously gain a lot when using the AP. It is just great if you do*  
41 452 *not have to think about diabetes all the time.” (Medical specialist A)*  
42  
43 453

44 454 The AP replaces human decision-making, which the participants experience as  
45 455 carefree living because they no longer have to make constant dose adjustments all  
46 456 the time.  
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48 457

51 458 How persons experience the partnership varies in extent from patient to patient, but  
52 459 patterns can be discerned. At one end stands the person with diabetes who  
53 460 completely trusts the technology, allowing to take over the function of the pancreas  
54 461 and automatically manages the glucose levels. Such a person thus feels that he or  
55 462 she no longer requires the help of a medical specialist. At the other end stands the  
56 463 person with diabetes who just wants his healthcare professionals to take over.



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3 464 Therefore, the interaction between the technology and social components must also  
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5 465 be considered (see: figure 3).  
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8 467 *Figure 3 Partnership enabled through ICT (Artificial Pancreas system)*  
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10 468

11 469 The introduction of ICT simultaneously changes the partnership interaction between  
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13 470 healthcare professionals and persons with a chronic condition, strengthens the  
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15 471 interests of the patient (self managing the disease), and yields precise analysed data  
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17 472 on the clinical phenomenon (see: figure 3).  
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19 473

20  
21 474 **Discussion**  
22

23 475 **Principal findings**

24 476 The aim of our study was to answer the research question: How does ICT enable the  
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26 477 partnership between healthcare professional(s) and the patient in chronic disease  
27  
28 478 management? Building on the analysis of in-depth qualitative data, this inductive  
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30 479 study has revealed three interrelated themes of ICT-enabled person-centred care  
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32 480 towards diabetes management namely self-managing the disease, shared analysing  
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34 481 of (medical) data and experiencing the partnership. We found that ICT yielded new  
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36 482 activities of data sharing and a new role for data professionals in the provision of care  
37  
38 483 as well as contributed to carefree living thanks to the semi-automated management  
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40 484 enabled by the device. Our data suggests that to enable the partnership through ICT,  
41  
42 485 organisational adjustments need to be made such as the development of new ICT-  
43  
44 486 services and a viable financial model to support these services.

45 487 In a recent study, it was concluded that ICT offers a viable environment to deliver  
46  
47 488 person-centred care through ICT for patients with chronic conditions (8). However, to  
48  
49 489 maximise the potential of ICT to enable patients to manage their condition, there is a  
50  
51 490 need to integrate PCC principles into ICT and its organisation. These principles have  
52  
53 491 been worked out in determining the preconditions for ICT-enabled person-centred  
54  
55 492 care (7). Our study adds to the existing knowledge base with its finding that  
56  
57 493 developing PCC preconditions to enable chronic disease management is just one  
58  
59 494 step, and that the three defined themes are another input for ICT-enabled person  
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495 centred care-principles towards chronic disease management.

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3 496 The introduction of a new theoretical framework provides insight into the dynamics of  
4  
5 497 how the partnership between healthcare professionals and persons with a chronic  
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7 498 disease is enabled through ICT in chronic disease management of diabetes (see:  
8  
9 499 figure 2). The three themes entail reordering the partnership between the person with  
10  
11 500 diabetes, the internist, the diabetic nurse and the intelligent device professional. Thus  
12  
13 501 the partnership interaction between healthcare professionals and persons with a  
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15 502 chronic condition simultaneously changes the partnership, strengthens the interests  
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17 503 of the patient (self-management), and yields precise data on the clinical phenomenon  
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19 504 (see: figure 3). This multinodal system is more complex than either the patient-  
20  
21 505 technology or patient professional relationship alone. Therefore, the outcomes are  
22  
23 506 less predictable and neglecting to consider the variation in the reactions of patients to  
24  
25 507 the now more complicated entry points into the professional system, which can also  
26  
27 508 lead to overestimation of the potential of disease self-management.  
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29 509 Over the last years, a growing body of scholarly work has been focusing on the use  
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31 510 of (semi-)automated devices for diabetes management (14) (15). The results of, for  
32  
33 511 example, continuous glucose monitoring (CGM) systems and automated insulin  
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35 512 delivery systems are promising in showing the benefits for type 1 diabetes by  
36  
37 513 improving glycaemic control through personalized models of predictive control (17)  
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39 514 (18). Furthermore, researchers have demonstrated the safety and feasibility of  
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41 515 different Artificial Pancreas systems in clinical research settings and more recently in  
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43 516 outpatient 'real-world' environments (20) (21). In addition to these feasibility- and  
44  
45 517 efficacy-focused studies on (semi-)automated devices for diabetes management,  
46  
47 518 also the *experiences* of patients using these type of devices have been studied. A  
48  
49 519 previous study on perspectives of experienced users of hybrid closed loop systems  
50  
51 520 among people with diabetes reported how context-, system-, and person-level factors  
52  
53 521 influenced patients' trust in an AP system (38). Tanenbaum et al. (2017) concluded  
54  
55 522 that when patients lacked trust in the system, they made an attempt to override the  
56  
57 523 system, while trusting the system decreased stress and also decreased self-  
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59 524 management burdens, which in our study was described by the participants as  
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525 carefree living.  
526 Additionally, a recent study highlighted the findings that acceptance of an AP system  
527 depends more on a stronger bond of the users with product characteristics (such as  
528 usefulness, complexity, and compatibility) than technology readiness (such as  
529 innovativeness, and insecurity) (39). However, the researchers also concluded that

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3 530 the results differed between self-selected and invited persons, so researchers and  
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5 531 product developers should be cautious when relying only on self-selected persons in  
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7 532 the design, testing and development of AP systems. While the experiences and  
8  
9 533 acceptance of AP systems has been the focus of some studies, further research  
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11 534 directions on patient experiences will yield a better understanding what factors  
12  
13 535 influence the acceptance of such automated technology. Our study suggests to take  
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15 536 the healthcare professional-patient partnership into account as one of the factors that  
16  
17 537 affect the acceptance and the use of AP systems.

18 538

### 20 539 **Strengths and limitations**

22 540 The strength of the inductive case study approach is that we were able to gain  
23 541 detailed insight into how the characteristic of the partnership changed between a  
24 542 person with type 1 diabetes and the healthcare professional(s) as a result of the use  
25 543 of ICT. A case study enables the creation of a comprehensive theoretical framework  
26 544 built on the details of a particular case (27, 40). The development of this theoretical  
27 545 framework increases the understanding of person-centred healthcare and ICT-  
28 546 enabled health services that can have implications for practice (41).

29 547 Through qualitative research we delved into the anecdotal evidence of the interviews  
30 548 and used coding to show commonalities in the changes that the interviewees  
31 549 expected, through which we were able to build a framework that can broaden the  
32 550 scope of evidence-based medicine; good evidence goes further than the results of  
33 551 meta-analysis of randomised controlled trials (42).

34 552 We also acknowledge limitations of the study. Our findings should be considered in  
35 553 the context of our study design. One of the inclusion criteria to participate in the study  
36 554 was experience with an AP system. This system was tested as part of a separate trial  
37 555 during which the participants were closely monitored by clinical researchers. The use  
38 556 of the system was reduced to a relatively short duration. Therefore, the results may  
39 557 not be generalised to other AP systems nor to a long term use of the system on a  
40 558 larger scale.

41 559 Furthermore, to study the partnership between patients and healthcare professionals  
42 560 in chronic disease management we chose an ICT application – the Artificial Pancreas  
43 561 system – that is still under development and was not as yet available on the market

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3 562 during the research period. However, since our focus is neither on the technology  
4 563 itself nor its acceptance, but on the enabling of the partnership, the case study does  
5 564 add to our knowledge on ICT in partnership and service provision based on digital  
6 565 healthcare applications.  
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### 11 567 **Implications for practice and research**

12 568 In order for ICT to take over the burden of self-managing disease through shared  
13 569 (medical) data analysis, it is necessary to embed ICT services and professions in the  
14 570 healthcare organisation. The introduction of ICT introduces new demands on  
15 571 healthcare professionals and patients, influencing how the partnership is  
16 572 experienced.  
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20 573 In addition, when introducing ICT in a healthcare context, the technology should be  
21 574 studied as part of a dynamic and networked healthcare environment, so-called 'fourth  
22 575 generation studies' (43) and should take a participatory development approach to  
23 576 guide the development, implementation and evaluation of eHealth technologies and  
24 577 interventions (44). Our study suggests that these types of studies should also include  
25 578 a focus on the partnership and how this is reshaped by the introduction of ICT. The  
26 579 results of our study show that to support the partnership in a sustainable manner, ICT  
27 580 needs to be embedded in healthcare organisations. As a result, the care pathways  
28 581 also need to be redesigned so we can move towards person-centred chronic disease  
29 582 management, offering treatment 'when needed, where needed' based on the  
30 583 availability of rich data generated by an ICT-system.  
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34 584 Previous research has pointed to the fact that human connectedness provides the  
35 585 necessary conditions for communication and cooperation on which formal relations of  
36 586 partnership can be constructed (1, 3). Our study shows that introducing an ICT-  
37 587 enabled PCC solution structures an integrated form of professional-patient  
38 588 connectedness. The self-management of the disease, but also the analysis of  
39 589 (medical) data and the experience of the partnership, shift the focus of professional-  
40 590 patient connectedness from the medical specialist to the diabetic nurse. New roles  
41 591 take shape such as the one of the intelligent device professional, and a different  
42 592 network will (have to) evolve around the patient. One of the lessons could be that it  
43 593 becomes more important to look at the personal progression of the disease in  
44 594 addition to following the existing rigid care pathways.  
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3 595 The expected changes in the role of healthcare professionals as a result of  
4 596 introducing ICT-enabled PCC towards chronic disease self-management must be  
5 597 addressed with the design of a new care model integrating the changing partnership.  
6 598 The next steps should be to study how to design care models that fit these changes  
7 599 partnership as a result of ICT-enabled PCC, and how a sustainable financial model  
8 600 should be determined for ICT-enabled person-centred chronic disease management.  
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## 14 601 **Conclusion**

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16 602 The management of diabetes through ICT requires an adjustment of the partnership  
17 603 between persons with the chronic condition and the healthcare professional(s) in  
18 604 such a way that the potential for self-managing the condition by analysing the newly  
19 605 available (medical) data (from the intelligent device AP system) together leads to an  
20 606 experience of partnership between patients and healthcare professionals.  
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29  
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31  
32

## 33 611 **Contributor ship statement**

34 612 Wildevuur conceived the presented idea. Wildevuur, Simonse and Groenewegen  
35 613 developed the theory. Wildevuur wrote the interview protocol that was checked by  
36 614 author Groenewegen and Klink. Wildevuur conducted the interviews, had them  
37 615 transcribed and checked them. Wildevuur and Simonse analyzed the data in iterative  
38 616 steps, which was supervised - including the methodology - by Groenewegen and  
39 617 Klink. Wildevuur and Simonse took the lead in writing the manuscript. Groenewegen  
40 618 and Klink supervised the findings of this study.  
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46 619 All authors take responsibility for the content. They all have contributed to the  
47 620 development of the research question, the conducted research and the reported  
48 621 results. All authors provided critical feedback and helped shape the final manuscript.  
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51  
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55  
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58

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6 629

### 8 630 **Data sharing statement**

9  
10 631 Interview protocol and unpublished data (in Dutch) are available upon request. Data  
11 can be obtained from first author.  
12 632  
13 633

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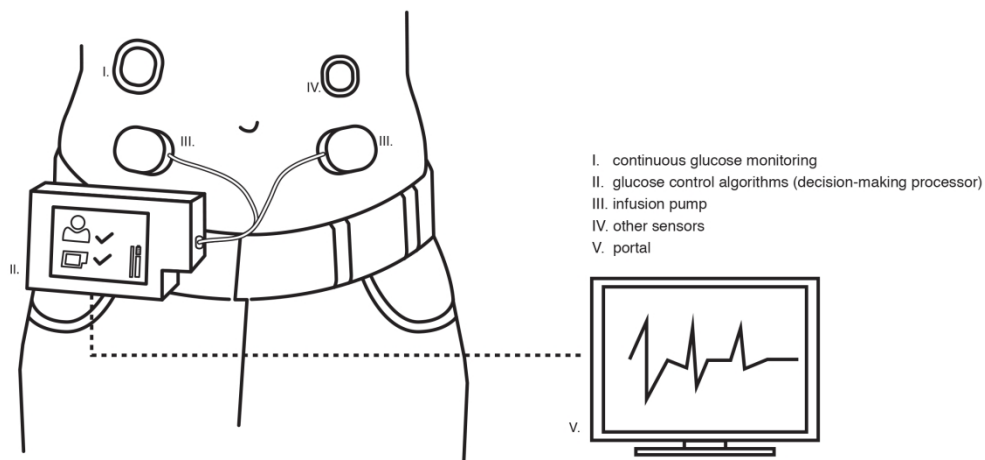


Figure 1 Components of the Artificial Pancreas system

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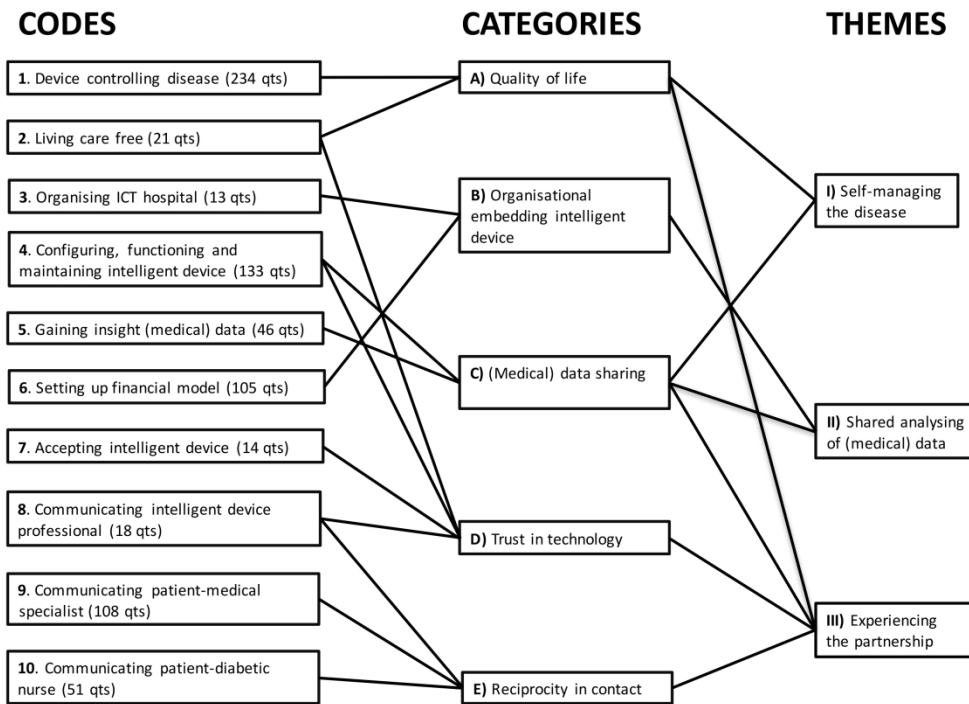


Figure 2 Theoretical framework of ICT enabling partnership in person-centred diabetes management

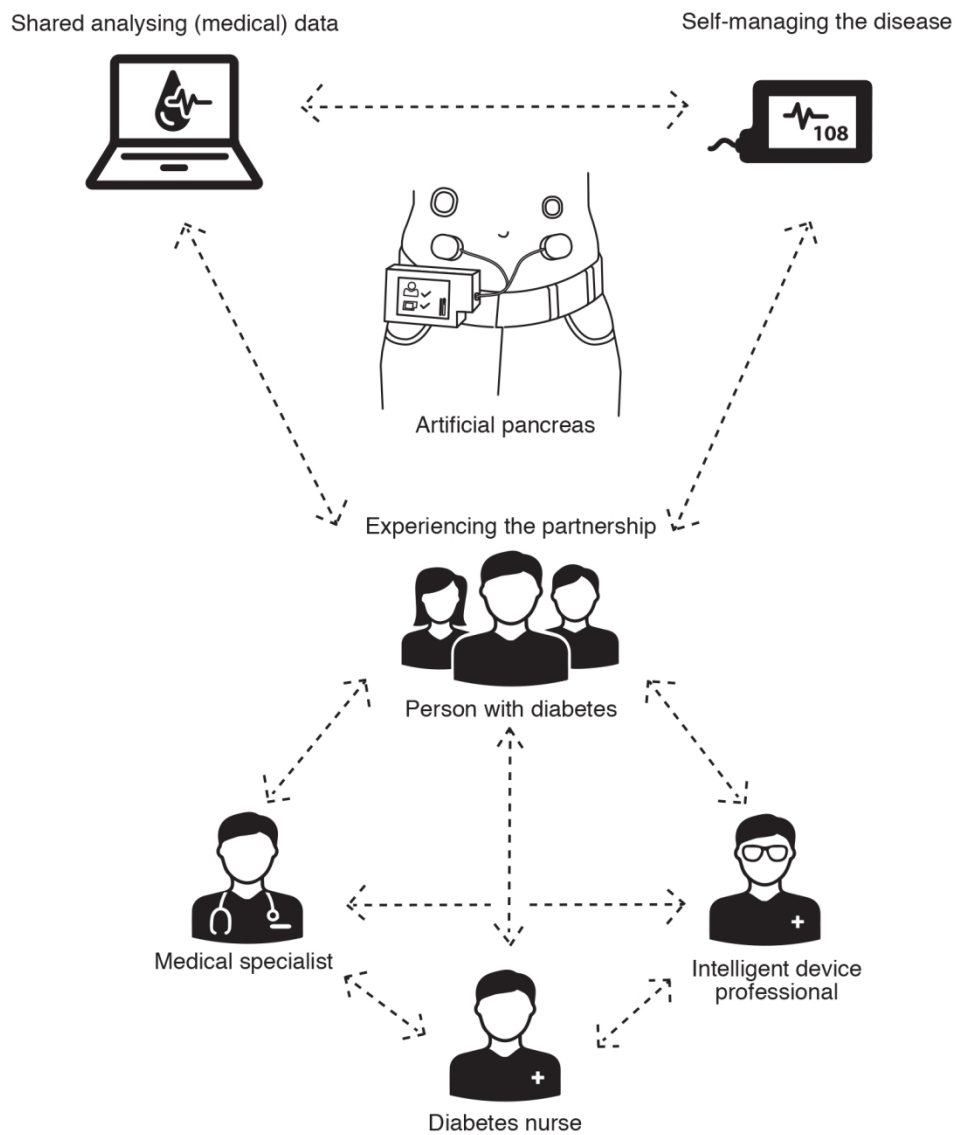


Figure 3 Partnership enabled through ICT (Artificial Pancreas system)

138x159mm (300 x 300 DPI)

## Standards for Reporting Qualitative Research (SRQR)\*

<http://www.equator-network.org/reporting-guidelines/srqr/>

Page/line no(s).

### Title and abstract

<p><b>Title</b> - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	1/1
<p><b>Abstract</b> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	2/25-47

### Introduction

<p><b>Problem formulation</b> - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	4/68-93
<p><b>Purpose or research question</b> - Purpose of the study and specific objectives or questions</p>	4/94-95

### Methods

<p><b>Qualitative approach and research paradigm</b> - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	6/138-143
<p><b>Researcher characteristics and reflexivity</b> - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	8/197-199
<p><b>Context</b> - Setting/site and salient contextual factors; rationale**</p>	6/145-164
<p><b>Sampling strategy</b> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	7-8/168-191
<p><b>Ethical issues pertaining to human subjects</b> - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	No medical data nor personal data of the participants were used. Data were anonymized: 8/204-05

1 2 3 4 5	<b>Data collection methods</b> - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	8/199-225
6 7 8 9	<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	8/193-196, 203-205
10 11 12 13	<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	8/186-191
14 15 16 17	<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	8-9/218-222
18 19 20 21	<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	9/223-231
22 23 24 25	<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	9/225-226

## Results/findings

26 27 28 29 30 31	<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	9-10/233-240
32 33 34	<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	10-16/241-447

## Discussion

35 36 37 38 39 40 41 42 43	<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	16/451-471
44 45	<b>Limitations</b> - Trustworthiness and limitations of findings	17-18/486-92

## Other

46 47 48 49	<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	No conflicts of interest
50 51 52	<b>Funding</b> - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	19/545-7

1 \*The authors created the SRQR by searching the literature to identify guidelines, reporting  
2 standards, and critical appraisal criteria for qualitative research; reviewing the reference  
3 lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to  
4 improve the transparency of all aspects of qualitative research by providing clear standards  
5 for reporting qualitative research.  
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8 \*\*The rationale should briefly discuss the justification for choosing that theory, approach,  
9 method, or technique rather than other options available, the assumptions and limitations  
10 implicit in those choices, and how those choices influence study conclusions and  
11 transferability. As appropriate, the rationale for several items might be discussed together.  
12

13 **Reference:**

14 O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative**  
15 **research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014  
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# BMJ Open

## Information and Communication Technology enabling partnership in person-centred diabetes management: Building a theoretical framework from an inductive case study in the Netherlands

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<b>Primary Subject Heading</b>:	Patient-centred medicine
Secondary Subject Heading:	Health informatics, Qualitative research, Communication
Keywords:	ICT, eHealth, type 1 diabetes, chronic disease management, person-centred care

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3 1 Information and Communication Technology enabling partnership in person-centred  
4 2 diabetes management: Building a theoretical framework from an inductive case study  
5 3 in the Netherlands  
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3 22 *Original Research Paper*

4 23 **Information and Communication Technology enabling partnership in person-**  
5 **centred diabetes management: Building a theoretical framework from an**  
6 **inductive case study in the Netherlands**  
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11 26 **Abstract**

12 27 *Objectives:* The aim of this paper is to construct a theoretical framework for  
13 Information and Communication Technology (ICT)-enabled partnership towards  
14 diabetes management.  
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17 30 *Design:* We conducted an inductive case study and held interviews on the  
18 development and use of an Artificial Pancreas (AP) system for diabetes  
19 management.  
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21 32

22 33 *Setting:* The study was carried out in the Netherlands with users of an AP system.

23 34 *Participants:* We interviewed six individuals with type 1 diabetes, five healthcare  
24 professionals (two medical specialists, three diabetes nurses), and one policy advisor  
25 from the Ministry of Health, Welfare, and Sport.  
26  
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28 37 *Results:* We built a new theoretical framework for ICT-enabled person-centred  
29 diabetes management, covering the central themes of self-managing the disease,  
30 shared analysing of (medical) data, and experiencing the partnership. We found that  
31 ICT yielded new activities of data sharing and a new role for data professionals in the  
32 provision of care as well as contributed to carefree living thanks to the semi-  
33 automated management enabled by the device. Our data suggested that to enable  
34 the partnership through ICT, organisational adjustments need to be made such as  
35 the development of new ICT-services and a viable financial model to support these  
36 services.  
37  
38 45

39 46 *Conclusion:* The management of diabetes through ICT requires an adjustment of the  
40 partnership between persons with the chronic condition and the healthcare  
41 professional(s) in such a way that the potential for self-managing the condition by  
42 analysing the newly available (medical) data (from the AP system) together leads to  
43 an experience of partnership between patients and healthcare professionals.  
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55 51 **Strengths and limitations of this study**

- 56  
57 52 • The strength of the inductive case study approach is that it provides in-depth  
58 insights into how the partnership is shaped between a person with type 1  
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3 54 diabetes and the healthcare professional(s) as a result of the use of an  
4  
5 55 Artificial Pancreas system for diabetes management.  
6  
7 56 • Building theory from a case study, as we have done with our research, made it  
8  
9 57 possible to create a theoretical framework from case-based empirical  
10  
11 58 evidence.  
12  
13 59 • Our findings should be considered in the context of our study design and may  
14  
15 60 not be generalised to other AP systems nor long term use of the AP system on  
16  
17 61 a larger scale.  
18  
19 62 • A possible limitation of this study is that the studied technology was under  
20  
21 63 development during the research period; however, this is not a major  
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23 64 limitation, as the focus of our study is not on the technology itself but on  
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25 65 enabling the healthcare professional-patient partnership.  
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67 **Keywords:** ICT, eHealth, type 1 diabetes, chronic disease management, person-  
68 centred care

## 70 Introduction

71 Person-centred care (PCC) actively involves the patient in the care process as an  
72 equal partner in, and expert on, living with a chronic condition (1). Persons with a  
73 chronic condition have to make decisions on a day-to-day basis about self-managing  
74 their illness, which influences the healthcare professional-patient partnership with  
75 respect to care services (2). The partnership between patients and healthcare  
76 professionals involves sustaining the relationship via deciding on goals, care  
77 planning and documentation (3). Information and Communication Technology (ICT)  
78 for healthcare – also known as eHealth (4) – might support the professional-patient  
79 partnership in person-centred care services and provide chronic disease  
80 management in the face of social, physical, and emotional challenges (5).

### 82 *Information and communication-enabled person-centred care*

83 ICT is increasingly used within chronic disease management to document and  
84 exchange information, monitor and interact. The results of the first studies on ICT  
85 enabling person-centred care (ICT-PCC) in chronic care are promising, with  
86 improved clinical outcomes, better health-related quality of life, and increased cost-  
87 effectiveness (6). However, there is a gap in knowledge how ICT shapes the  
88 professional-patient partnership when used in daily practice.

89 When applying the concept of partnership in person-centred care to ICT systems, the  
90 technology must be tailored to the needs of both patients and healthcare  
91 professionals (personalised ICT), whereby the personal context and situation of the  
92 patient informs and guides the decision making on the care pathway (7). However,  
93 this phenomenon of enabling the partnership through ICT is not fully understood and  
94 insights are lacking on how this partnership is influenced and transformed through  
95 ICT (8). In this study we selected a case in which an innovative ICT-enabled person-  
96 centred care intervention was used for diabetes management in order to better  
97 understand how ICT shaped the patient-professional partnership (9).

### 99 *Self-management of diabetes*

100 Training in self-management of type 1 diabetes through personalised insulin  
101 treatment leads to significant improvements in treatment satisfaction, psychological  
102 wellbeing, and quality of life measures (10). Even though diabetes management has

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3 103 improved considerably over the years, patients still suffer from short-term  
4 104 complications such as hypoglycaemia ('hypo' for short) and hyperglycaemia ('hyper')  
5 105 progressing to diabetic ketoacidosis (DKA) and hyperosmolar hyperglycaemic  
6 106 syndrome (HHS), and long-term complications such as retinopathy, neuropathy,  
7 107 cardiovascular disease, and nephropathy that could lead to complications such as  
8 108 loss of eyesight and amputation (11).

9  
10 109 The treatment and care of patients with diabetes have seen fast progress and key  
11 110 innovations after the discovery of insulin in 1921: engineered insulin, the introduction  
12 111 of blood glucose monitoring by tele monitoring systems, internet applications, and  
13 112 mobile devices (12). In addition, smart algorithms to control the blood glucose level  
14 113 have been developed (13). This innovation trajectory of applying smart algorithms to  
15 114 earlier discoveries culminated in the development of a first-generation system of an  
16 115 artificial pancreas that focuses on preventing unsafe blood sugar levels and aims to  
17 116 control blood glucose around a target of 120 mg/dL (=6.7 mmol/L) (14).

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### 29 118 *ICT interventions for diabetes management*

30 119 Several companies worldwide are developing AP systems to regulate basal insulin  
31 120 delivery, by taking over the regulation of the glucose levels completely through  
32 121 automating insulin – and still in a development stage, also glucagon - delivery (15)  
33 122 (16) (17) (18). Over the last years significant progress has been made in AP  
34 123 development (19), and researchers have demonstrated the safety and feasibility of  
35 124 different AP systems in clinical research settings and more recently in outpatient  
36 125 'real-world' environments (20) (21). Most of the studies are about developing AP  
37 126 systems that would still require user entry of carbohydrate intake (hybrid closed loop  
38 127 systems). Several meta-analyses focused on AP performance across different  
39 128 studies, and concluded that artificial pancreas systems could be an efficacious and  
40 129 safe approach for treating patients with type 1 diabetes (22) (23) (24) (25). The  
41 130 greatest benefits of the AP are the reduced burden of diabetes management during  
42 131 the day, and improved overnight control of glucose levels thanks to reduced  
43 132 glycaemic variability, improved time in target range, and reduced risk of nocturnal  
44 133 hypoglycaemia (26) (27) (28). Although AP users with type 1 diabetes will still need  
45 134 to self-manage their illness, a closed loop system with data acted upon by the users  
46 135 could reduce the burden (29).

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2  
3 136 We chose to employ an inductive case study to focus on the dynamics of the patient-  
4 professional partnership shaped through an ICT intervention used in practice for the  
5 137 management of type 1 diabetes, namely an Artificial Pancreas system. The case  
6 138 study was applied to answer the research question: How does ICT enable the  
7 139 partnership between healthcare professional(s) and the patient in chronic disease  
8 140 management?  
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## 143 **Methods**

### 144 **Study design**

145 We conducted an inductive case study (30) and held in-depth interviews with both  
146 healthcare professionals and patients on their use of the Artificial Pancreas system.  
147 This case study looks in particular into the dynamics of the professional-patient  
148 partnership and between different healthcare professionals, the patient experience,  
149 and how introducing ICT enables a person-centred approach to diabetes care.  
150

### 151 **Case study**

152 We have chosen as a case the use of an AP system that at the time of the study was  
153 only tested in the Netherlands. The system automatically controls the blood glucose  
154 level of patients with type 1 diabetes, and provides the substitute functionality of both  
155 insulin and glucagon delivery of a healthy pancreas. The AP system maintains the  
156 blood glucose levels in the healthy range most of the time, without restrictions with  
157 respect to factors such as diet and exercise.

158 The development of the person-centred AP system was started in 1994 in the  
159 Netherlands by a person who himself had been diagnosed with type 1 diabetes. His  
160 motivation for inventing a semi-autonomous AP was driven by his dissatisfaction with  
161 the diabetes care treatment and the support provided with products and software  
162 applications. He started a company to develop the AP in an iterative manner,  
163 involving the users in the different steps of its development. The AP system has been  
164 described in detail by Blauw and the research group *Portable bihormonal Closed*  
165 *Loop for Diabetes (PCDIAB)* (31).  
166

### 167 **Device characteristics**

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3 168 The wearable artificial pancreas integrates the following features into one device: (i)  
4 169 continuous glucose monitoring; ii) glucose control algorithms (decision-making  
5 170 processor); iii) infusion pump; and (iv) other sensors (see: figure 1).  
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10 172 *[Figure 1 Components of the Artificial Pancreas system]*  
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13 174 The control unit (i + ii) replaces human decision making and makes more frequent  
14 175 dose adjustments than a person could. The AP device transmits data to a database  
15 176 that is accessible via a portal (v) featuring web services for monitoring.

16 177 The functions of the bihormonal AP (both insulin and glucagon) were tested with  
17 178 persons with type 1 diabetes in home treatment; the results indicated that the AP  
18 179 provided better glucose control than traditional insulin pump therapy and that the  
19 180 treatment is safe (32). Related studies also indicated that patients anticipate that they  
20 181 will accept the device (33) and that for further technical development it will feature  
21 182 adaptive control (34).  
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### 30 31 184 **Participants**

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33 185 The participants were selected in the Netherlands via a combination of purposive and  
34 186 snowball sampling. With purposive sampling we initially selected two types of  
35 187 participants, persons with type 1 diabetes and healthcare professionals who had  
36 188 used the AP and would potentially be able to provide rich, relevant, and diverse data  
37 189 pertinent to the ICT-enabling of the partnership (35) (36). Subsequently, through  
38 190 snowball sampling - in which interviewees identified further participants - we recruited  
39 191 both persons with type 1 diabetes and healthcare professionals (medical specialists  
40 192 and trained diabetes nurses) with knowledge relevant to the case study, and a policy  
41 193 advisor.  
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49 194 We approached the participants via telephone, email, and/or face-to-face. We sent  
50 195 an information letter by email with an introduction to and information about the case  
51 196 study, and an invitation to participate. The principal researcher introduced the study  
52 197 orally, stressing the person's right to make their own choice to participate.

53 198 We interviewed twelve Dutch participants: six persons with type 1 diabetes, five  
54 199 healthcare professionals (two medical specialists; one paediatrician-endocrinologist  
55 200 and one internist-endocrinologist, three diabetes nurses). One policy advisor from the  
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3 201 Ministry of Health, Welfare, and Sport was included because of his experience with  
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5 202 the embedding of the AP in the healthcare context.

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7 203 Four attempts to recruit specific participants were rejected. One participant indicated  
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9 204 he was too busy, while the other reasons for non-participation were that the  
10  
11 205 participants (2) were not familiar with the AP or the subject was too sensitive (policy  
12  
13 206 maker).

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### 15 208 **Patient and public involvement**

16  
17 209 The study was designed to understand the perspectives of the participants to gain  
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19 210 access to their experiences, feelings and preferences with the use of an AP, of  
20  
21 211 patients diagnosed with type 1 diabetes and others (37). The research question was  
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23 212 developed in an iterative manner, and based on patients' and healthcare  
24  
25 213 professionals' insights. The AP was chosen as a case study since it was a patient-  
26  
27 214 driven innovation, developed by an engineer who was diagnosed with type 1  
28  
29 215 diabetes patient himself. Patients were involved in the different phases of the study,  
30  
31 216 and recruited through snow ball sampling, in which participants also supported in  
32  
33 217 recruiting (other) patients.

34 218

### 35 219 **Data collection**

36  
37 220 We held in-depth, semi-structured interviews with the participants. These interviews  
38  
39 221 were guided by an interview protocol, with questions focusing on the overall  
40  
41 222 experience with AP in clinical practice and how the AP supported and changed the  
42  
43 223 professional-patient partnership in diabetes management. The interview protocol was  
44  
45 224 provided in Dutch, and is available upon request.

46 225 The first author conducted the interviews via telephone/Skype or FaceTime, either at  
47  
48 226 home or at work. One participant was known from a previous study. No non-  
49  
50 227 participants were present during the interviews. The interviews were conducted  
51  
52 228 between February and April 2017. The interviews lasted between forty-seven and  
53  
54 229 seventy-three minutes. Participants were recruited until no new knowledge was  
55  
56 230 gained (data saturation) (38). No repeat interviews were conducted. The researcher  
57  
58 231 audio-recorded the participants and took notes. We transcribed all interviews. We  
59  
60 232 anonymised the data and allocated alphabet capital coding to each participant.

233

## 234 **Analysis**

235 In this study, we used thematic analysis to identify patterns within the data, and  
236 grouped them under codes, categories, and themes, whereby we particularly sought  
237 to identify how ICT supported the partnership in diabetic/chronic disease  
238 management (39). The first two authors analysed the data in an iterative process of  
239 coding and use of NVivo software, version 12.2.0.

240 We started with a line-by-line coding that was derived from the research question.

241 We processed the coding by reading and analysing the data – in which we preserved  
242 (inter-)actions by using as many gerunds ('ing') as possible (40). The first and second  
243 author reviewed the codes. After that, through focussed coding, we organised and  
244 grouped the coded data that shared characteristics into categories.

245 In this phase, we left out codes that did not contribute to answering the research  
246 question from further analysis (such as data on specific treatment for children). We  
247 then moved to the process of theoretical coding – in which we clustered the  
248 categories into themes – to build a theoretical framework.

249

## 250 **Ethical considerations**

251 The study was approved by the researchers' host institute. All participants, prior to  
252 the interviews, agreed to participate. Participation was voluntary and participants  
253 could withdraw at any point. The research complied with the Helsinki Declaration of  
254 the World Medical Association (2013). In our sample design we excluded the  
255 participation of vulnerable groups. The topic of our study was not sensitive. The  
256 researchers did not use or have access to personal information or datasets; they also  
257 neither collected nor used bodily material. All personal information was de-identified.  
258 We did not ask participants for private information or experiences. The quotes  
259 chosen were sufficiently general to preclude identification of individual participants.

260

## 261 **Results**

262 Our analysis yielded three themes of ICT-enabled person-centred care towards  
263 diabetes management resulted from our analysis: Self-managing the disease (I);  
264 Shared analysing of (medical) data (II), and Experiencing the partnership (III) (see  
265 the theoretical framework in figure 2).

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5 267 *[Figure 2 Theoretical framework of ICT enabling partnership in person-centred*  
6 268 *diabetes management]*

8 269 These three themes were based on five categories that shared characteristics  
9 270 resulting from ten codes originated from the research question.

### 13 271 **I) Self-managing the disease**

14 272 The theme self-managing the disease indicates that the use of the AP system  
15 273 contributes to a substantial increase in *quality of life* thanks not only to the device,  
16 274 which takes over control of the disease (234 quotes), but also insights based  
17 275 (medical) data (46 quotes) that is linked to the new activity of *(medical) data sharing*  
18 276 (see: figure 2).

#### 23 277 24 278 *Quality of life*

25 279 Users of the artificial pancreas system commonly mentioned (21 quotes) that the ICT  
26 280 application offers the next level of treatment for persons with diabetes, enabling  
27 281 carefree living that adds to their quality of life.

28 282  
29 283 *“If you do not have to measure five times a day, but you can just let the device*  
30 284 *do its job, that’s a huge improvement for me. [...] That may seem like a very*  
31 285 *small thing for healthy people, but it is, when you have diabetes it’s a huge*  
32 286 *boost to your quality of life, enabling you to lead a ‘normal’ life.”* (Person with  
33 287 diabetes D)

34 288  
35 289 This increased quality of life is linked to the technological advancement of the AP  
36 290 system that takes over the activities of controlling the disease through continuously  
37 291 sensing measurements and algorithms. The AP semi-automates the management of  
38 292 diabetes by monitoring the condition and regulating the insulin and glucagon supply  
39 293 accordingly, giving the patient new data overviews to manage his or her condition.

#### 40 294 41 295 *(Medical) data sharing*

42 296 What will change the partnership is the self-management of diabetes, which is  
43 297 enriched through the sharing of (medical) data amongst medical specialists, diabetes  
44 298 nurses, patients and the intelligent device professional.

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5 300 *"I have given permission to my diabetic nurse to look into my data. How often*  
6 301 *do you do that? Well, if I go through a period of an illness, like the flu, then*  
7 302 *maybe every week. If things go well, maybe once every two months."* (Person  
8 303 with diabetes D)  
9  
10  
11  
12 304

13 305 The introduction of the intelligent device (AP system) initiates a constant flow of  
14 306 (medical) data – physiological measurements and personal data – that is accessible  
15 307 through a portal (see: figure 1). The new activity of (medical) data sharing is fuelled  
16 308 by gaining insight into (medical) data. If we stand back, we can see that the presence  
17 309 of an intelligent device professional changes the partnership between the healthcare  
18 310 professionals and the person with diabetes. Thus, the introduction of ICT could  
19 311 enable the (experience of the) partnership and the self-management of a disease,  
20 312 but it also introduces new demands on healthcare professionals, including the  
21 313 provision of ICT (device) support.  
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## 30 314 **II) Shared analysing of (medical) data**

31  
32 315 The second theme, shared analysing of (medical) data, reveals the new activity in the  
33 316 partnership of *(medical) data sharing* when the ICT device is *embedded in the*  
34 317 *organisation* (see: figure 2). This sharing of (medical) data relates to the configuring,  
35 318 functioning and maintaining of the device (133 quotes) and the insights in (medical)  
36 319 data gained through the device (46 quotes). A diabetic nurse described the data  
37 320 sharing as follows:  
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44 322 *"So, you can watch the person over distance. But it is not our intention to*  
45 323 *watch patients 24/7."* (Diabetic nurse C)  
46  
47  
48 324

49 325 For an eHealth service enabling the partnership, both healthcare professionals and  
50 326 patients need to be supported by intelligent device professionals. To enable both  
51 327 patients and the healthcare professional(s) to share data from the AP and to gather  
52 328 data and then to store, retrieve, and analyse it, the technology and its data must be  
53 329 embedded in the organisation (see: figure 2).  
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3 331 *“And of course you should also start looking at your organisation again. How*  
4 *do you organise this? A lot is already done digitally in the hospital, but this*  
5 332 *does not link with our system. And this type of support from the hospital has*  
6 333 *not been allocated any funding yet. So, yes, there will of course also be stuff*  
7 334 *that has to do with the embedding [of the device] in the organisation.”* (Diabetic  
8 335  
9 nurse C)  
10  
11  
12 336  
13  
14 337

15 338 This organisational embedding of the intelligent device should be linked to the  
16 339 organisation of ICT in the hospital setting (13 quotes), and should be supported by  
17 340 the setting up of a financial model (105 quotes) that allows the insights gained from  
18 341 the (medical) data (46 quotes) to support the professional-patient partnership (see:  
19 342 figure 2). The introduction of the AP system could thereby potentially lead to the  
20 343 availability of new and rich(er) data that could be shared amongst the person with  
21 344 diabetes and the healthcare professionals and enable treatment improvements in  
22 345 diabetes management.  
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### 30 346 **III) Experiencing the partnership**

31  
32 347 How the partnership is experienced is based on the reciprocity in contact, the trust in  
33 348 technology, (medical) data sharing, and the quality of life (see: figure 2).  
34  
35

#### 36 349 *Reciprocity in contact*

37 350  
38 351 Reciprocity in contact is linked to how the person with diabetes communicates with  
39 352 his or her medical specialist (108 quotes), diabetic nurse (51 quotes) and the  
40 353 intelligent device professional (18 quotes), and the other way around.  
41  
42  
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45 354  
46 355 *“We will head towards more equal care, I think. At least, if the patient wants*  
47 356 *that too.”* (Medical specialist B)  
48  
49

50 357  
51 358 The AP technology in use revealed different intensities of how the partnership was  
52 359 experienced by both the patient and the healthcare professionals. On the one hand,  
53 360 the interviewees foresaw a change in the moments of contact with the medical  
54 361 specialist.  
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3 363 *“Once the AP system is well integrated into health care – I do not have the*  
4 *illusion that it heals people – the treatment is such that medical specialists can*  
5 364 *provide far less guidance [to patients].”* (Person with diabetes A)  
6  
7 365  
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9 366

10 367 On the other hand, they expected that the partnership with the diabetic nurse would  
11  
12 368 become more intensive, as was already experienced with the insulin pump:  
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14 369

15 370 *“You actually see that when you make the switch from syringe to pump. Then*  
16 *suddenly the contact with the diabetic nurse becomes much more intensive*  
17 371 *and more accessible and then you can suddenly call outside office hours.”*  
18 372  
19  
20 373 (Person with diabetes B)  
21  
22 374

23  
24 375 Diabetes nurses anticipate a change in the partnership with the person with diabetes  
25  
26 376 as a result of implementing the AP.  
27  
28 377

29 378 *“I tell my patients they do not have to come see me every three months when*  
30 *there is no direct need. What matters is that the person with diabetes is doing*  
31 379 *well and if that is the case, I do not see what I could improve.”* (Diabetic nurse  
32  
33 380  
34 381 B)  
35  
36 382

37  
38 383 The initiative for treatment can thus be initiated through the data instead of through  
39  
40 384 existing care pathways.  
41  
42 385

43 386 The fear that healthcare professionals would become unnecessary is baseless:  
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45 387

46 388 *“In the case of the artificial pancreas, I do not expect that suddenly a whole*  
47 *group of healthcare professionals no longer have to come to the hospital*  
48 389 *because the technology takes over. They have enough other things to do.”*  
49  
50 390  
51 391 (Policy maker)  
52  
53 392

54  
55 393 The findings also reveal another role in the partnership, namely the communication  
56  
57 394 with the intelligent device professional (18 quotes) with whom patients or the  
58  
59 395 healthcare professionals communicate about the technical part of the AP.  
60  
60 396

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3 397 *“If you do not have a psychological problem and if your diabetes does not*  
4 398 *bother you, if your parameters are all right and well-regulated through the AP*  
5 399 *system, you see each other less often so the consultation is purely problem-*  
6 400 *oriented. When it is a technical issue, then the device is at fault and you*  
7 401 *contact the AP professional. The partnership will change towards shorter*  
8 402 *duration and interventions. If it is not going well, what is going on?”* (Medical  
9 403 *specialist B)*  
10  
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17 405 How the partnership is experienced depends also on the configuration, functioning  
18 406 and maintenance of the intelligent device (133 quotes). When the person with  
19 407 diabetes checks the ICT technology (verifying that it has enough insulin and  
20 408 glucagon, the battery and sensors are OK, etc.), and he or she notices that the  
21 409 system is not working properly, then communication with the intelligent device  
22 410 professional (18 quotes) is necessary to make sure that the device is technically in  
23 411 working order.  
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### 30 413 *Trust in technology*

31 414 The experience of the partnership, supported through ICT, was also connected with  
32 415 the category of trust in technology (see: figure 2). The trust in technology was vividly  
33 416 described by one of the patients:  
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36  
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38 417

39 418 *“You are busy with the management of diabetes all day. If that is no longer the*  
40 419 *case, and you have trust in the technology to take over the management of the*  
41 420 *disease and that you do not have to think for yourself anymore. That gives a lot of*  
42 421 *freedom.”* (Patient B)  
43  
44  
45

46 422

47 423 Trust in technology is related to the feeling of care free living (21 quotes), the  
48 424 configuring, functioning and maintaining of the intelligent device (133 quotes), the  
49 425 acceptance of the intelligent device (14 quotes) and communication with the  
50 426 intelligent device professional (18 quotes).  
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### 55 428 *(Medical) data sharing*

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3 429 The sharing of data has influence on how the partnership is experienced, and how  
4 430 patients communicate with healthcare professionals. However, the AP does not cure  
5 431 the disease so yearly check-ups will still be necessary.  
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8 432  
9

10 433 *“Look, the patient still has to see his medical specialist every year. He remains*  
11 434 *responsible and needs to check certain parameters. That still has to be done*  
12 435 *because the patient still has diabetes. Even if the patient is doing well, he or*  
13 436 *she is not cured.”* (Diabetic nurse B)  
14  
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17 437

18 438 Both healthcare professionals and patients foresee that the self-management options  
19 439 ushered in by the AP system will result in a change in the partnership.  
20  
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22 440  
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#### 24 441 *Quality of life*

25 442 The outcomes expose that the experience of the partnership is linked to the quality of  
26 443 life, which increased when the intelligent device took over the daily controlling of the  
27 444 disease and reduced the feeling of stress involved in self-managing diabetes (see:  
28 445 figure 2).  
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32 446  
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34 447 *“The most important thing for patients is that they do not have to be busy with*  
35 448 *their condition all day long. So, a bit of freedom and being able to enjoy a cup*  
36 449 *of coffee without having to do all kinds of measurements and so forth. For the*  
37 450 *simple things that are important for daily life. That is the benefit of the artificial*  
38 451 *pancreas.”* (Person with diabetes A)  
39  
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43 452

44 453 Or as a medical specialist framed it:  
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47 454

48 455 *“If you still want to get a lot out of this life as a child, adolescent, young or*  
49 456 *older adult, you obviously gain a lot when using the AP. It is just great if you do*  
50 457 *not have to think about diabetes all the time.”* (Medical specialist A)  
51  
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53 458  
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55 459 The AP replaces human decision-making, which the participants experience as  
56 460 carefree living because they no longer have to make constant dose adjustments all  
57 461 the time.  
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3 463 How persons experience the partnership varies in extent from patient to patient, but  
4 464 patterns can be discerned. At one end stands the person with diabetes who  
5 465 completely trusts the technology, allowing to take over the function of the pancreas  
6 466 and automatically manages the glucose levels. Such a person thus feels that he or  
7 467 she no longer requires the help of a medical specialist. At the other end stands the  
8 468 person with diabetes who just wants his healthcare professionals to take over.  
9 469 Therefore, the interaction between the technology and social components must also  
10 470 be considered (see: figure 3).  
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17 471  
18 472 *Figure 3 Partnership enabled through ICT (Artificial Pancreas system)*  
19 473

20 474 The introduction of ICT simultaneously changes the partnership interaction between  
21 475 healthcare professionals and persons with a chronic condition, strengthens the  
22 476 interests of the patient (self managing the disease), and yields precise analysed data  
23 477 on the clinical phenomenon (see: figure 3).  
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## 31 479 Discussion

### 32 480 Principal findings

33 481 The aim of our study was to answer the research question: How does ICT enable the  
34 482 partnership between healthcare professional(s) and the patient in chronic disease  
35 483 management? Building on the analysis of in-depth qualitative data, this inductive  
36 484 study has revealed three interrelated themes of ICT-enabled person-centred care  
37 485 towards diabetes management namely self-managing the disease, shared analysing  
38 486 of (medical) data and experiencing the partnership. We found that ICT yielded new  
39 487 activities of data sharing and a new role for data professionals in the provision of care  
40 488 as well as contributed to carefree living thanks to the semi-automated management  
41 489 enabled by the device. Our data suggests that to enable the partnership through ICT,  
42 490 organisational adjustments need to be made such as the development of new ICT-  
43 491 services and a viable financial model to support these services.  
44 492 In a recent study, it was concluded that ICT offers a viable environment to deliver  
45 493 person-centred care through ICT for patients with chronic conditions (8). However, to  
46 494 maximise the potential of ICT to enable patients to manage their condition, there is a  
47 495 need to integrate PCC principles into ICT and its organisation. These principles have  
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3 496 been worked out in determining the preconditions for ICT-enabled person-centred  
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5 497 care (7). Our study adds to the existing knowledge base with its finding that  
6  
7 498 developing PCC preconditions to enable chronic disease management is just one  
8  
9 499 step, and that the three defined themes are another input for ICT-enabled person  
10  
11 500 centred care-principles towards chronic disease management.

12 501 The introduction of a new theoretical framework provides insight into the dynamics of  
13  
14 502 how the partnership between healthcare professionals and persons with a chronic  
15  
16 503 disease is enabled through ICT in chronic disease management of diabetes (see:  
17  
18 504 figure 2). The three themes entail reordering the partnership between the person with  
19  
20 505 diabetes, the internist, the diabetic nurse and the intelligent device professional. Thus  
21  
22 506 the partnership interaction between healthcare professionals and persons with a  
23  
24 507 chronic condition simultaneously changes the partnership, strengthens the interests  
25  
26 508 of the patient (self-management), and yields precise data on the clinical phenomenon  
27  
28 509 (see: figure 3). This multinodal system is more complex than either the patient-  
29  
30 510 technology or patient professional relationship alone. Therefore, the outcomes are  
31  
32 511 less predictable and neglecting to consider the variation in the reactions of patients to  
33  
34 512 the now more complicated entry points into the professional system, which can also  
35  
36 513 lead to overestimation of the potential of disease self-management.

37 514 Over the last years, a growing body of scholarly work has been focusing on the use  
38  
39 515 of (semi-)automated devices for diabetes management (14) (15). The results of, for  
40  
41 516 example, continuous glucose monitoring (CGM) systems and automated insulin  
42  
43 517 delivery systems are promising in showing the benefits for type 1 diabetes by  
44  
45 518 improving glycaemic control through personalized models of predictive control (17)  
46  
47 519 (18). Furthermore, researchers have demonstrated the safety and feasibility of  
48  
49 520 different Artificial Pancreas systems in clinical research settings and more recently in  
50  
51 521 outpatient 'real-world' environments (20) (21). In addition to these feasibility- and  
52  
53 522 efficacy-focused studies on (semi-)automated devices for diabetes management,  
54  
55 523 also the *experiences* of patients using these type of devices have been studied. A  
56  
57 524 previous study on perspectives of experienced users of hybrid closed loop systems  
58  
59 525 among people with diabetes reported how context-, system-, and person-level factors  
60  
61 526 influenced patients' trust in an AP system (41). Tanenbaum et al. (2017) concluded  
62  
63 527 that when patients lacked trust in the system, they made an attempt to override the  
64  
65 528 system, while trusting the system decreased stress and also decreased self-

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3 529 management burdens, which in our study was described by the participants as  
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5 530 carefree living.  
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7 531 Additionally, a recent study highlighted the findings that acceptance of an AP system  
8  
9 532 depends more on a stronger bond of the users with product characteristics (such as  
10  
11 533 usefulness, complexity, and compatibility) than technology readiness (such as  
12  
13 534 innovativeness, and insecurity) (42). However, the researchers also concluded that  
14  
15 535 the results differed between self-selected and invited persons, so researchers and  
16  
17 536 product developers should be cautious when relying only on self-selected persons in  
18  
19 537 the design, testing and development of AP systems. While the experiences and  
20  
21 538 acceptance of AP systems has been the focus of some studies, further research  
22  
23 539 directions on patient experiences will yield a better understanding what factors  
24  
25 540 influence the acceptance of such automated technology. Our study suggests to take  
26  
27 541 the healthcare professional-patient partnership into account as one of the factors that  
28  
29 542 affect the acceptance and the use of AP systems.  
30

543

### 544 **Strengths and limitations**

545 The strength of the inductive case study approach is that we were able to gain  
546 detailed insight into how the characteristic of the partnership changed between a  
547 person with type 1 diabetes and the healthcare professional(s) as a result of the use  
548 of ICT. A case study enables the creation of a comprehensive theoretical framework  
549 built on the details of a particular case (30, 43). The development of this theoretical  
550 framework increases the understanding of person-centred healthcare and ICT-  
551 enabled health services that can have implications for practice (44).

552 Through qualitative research we delved into the anecdotal evidence of the interviews  
553 and used coding to show commonalities in the changes that the interviewees  
554 expected, through which we were able to build a framework that can broaden the  
555 scope of evidence-based medicine; good evidence goes further than the results of  
556 meta-analysis of randomised controlled trials (45).

557 We also acknowledge limitations of the study. Our findings should be considered in  
558 the context of our study design. One of the inclusion criteria to participate in the study  
559 was experience with an AP system. This system was tested as part of a separate trial  
560 during which the participants were closely monitored by clinical researchers. The use

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2  
3 561 of the system was reduced to a relatively short duration. Therefore, the results may  
4 562 not be generalised to other AP systems nor to a long term use of the system on a  
5 563 larger scale.

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7  
8 564 Furthermore, to study the partnership between patients and healthcare professionals  
9 565 in chronic disease management we chose an ICT application – the Artificial Pancreas  
10 566 system – that is still under development and was not as yet available on the market  
11 567 during the research period. However, since our focus is neither on the technology  
12 568 itself nor its acceptance, but on the enabling of the partnership, the case study does  
13 569 add to our knowledge on ICT in partnership and service provision based on digital  
14 570 healthcare applications.

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### 21 572 **Implications for practice and research**

22 573 In order for ICT to take over the burden of self-managing disease through shared  
23 574 (medical) data analysis, it is necessary to embed ICT services and professions in the  
24 575 healthcare organisation. The introduction of ICT introduces new demands on  
25 576 healthcare professionals and patients, influencing how the partnership is  
26 577 experienced.

27 578 In addition, when introducing ICT in a healthcare context, the technology should be  
28 579 studied as part of a dynamic and networked healthcare environment, so-called 'fourth  
29 580 generation studies' (46) and should take a participatory development approach to  
30 581 guide the development, implementation and evaluation of eHealth technologies and  
31 582 interventions (47). Our study suggests that these types of studies should also include  
32 583 a focus on the partnership and how this is reshaped by the introduction of ICT. The  
33 584 results of our study show that to support the partnership in a sustainable manner, ICT  
34 585 needs to be embedded in healthcare organisations. As a result, the care pathways  
35 586 also need to be redesigned so we can move towards person-centred chronic disease  
36 587 management, offering treatment 'when needed, where needed' based on the  
37 588 availability of rich data generated by an ICT-system.

38 589 Previous research has pointed to the fact that human connectedness provides the  
39 590 necessary conditions for communication and cooperation on which formal relations of  
40 591 partnership can be constructed (1, 3). Our study shows that introducing an ICT-  
41 592 enabled PCC solution structures an integrated form of professional-patient  
42 593 connectedness. The self-management of the disease, but also the analysis of  
43 594 (medical) data and the experience of the partnership, shift the focus of professional-

1  
2  
3 595 patient connectedness from the medical specialist to the diabetic nurse. New roles  
4  
5 596 take shape such as the one of the intelligent device professional, and a different  
6  
7 597 network will (have to) evolve around the patient. One of the lessons could be that it  
8  
9 598 becomes more important to look at the personal progression of the disease in  
10  
11 599 addition to following the existing rigid care pathways.

12 600 The expected changes in the role of healthcare professionals as a result of  
13  
14 601 introducing ICT-enabled PCC towards chronic disease self-management must be  
15  
16 602 addressed with the design of a new care model integrating the changing partnership.  
17  
18 603 The next steps should be to study how to design care models that fit these changes  
19  
20 604 partnership as a result of ICT-enabled PCC, and how a sustainable financial model  
21  
22 605 should be determined for ICT-enabled person-centred chronic disease management.

## 23 606 **Conclusion**

24  
25 607 The management of diabetes through ICT requires an adjustment of the partnership  
26  
27 608 between persons with the chronic condition and the healthcare professional(s) in  
28  
29 609 such a way that the potential for self-managing the condition by analysing the newly  
30  
31 610 available (medical) data (from the intelligent device AP system) together leads to an  
32  
33 611 experience of partnership between patients and healthcare professionals.

## 34 612 **Acknowledgements**

35  
36 613 The authors thank all the interviewees who participated in this study for their  
37  
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## 41 616 **Contributor ship statement**

42  
43 617 Wildevuur conceived the presented idea. Wildevuur, Simonse and Groenewegen  
44  
45 618 developed the theory. Wildevuur wrote the interview protocol that was checked by  
46  
47 619 author Groenewegen and Klink. Wildevuur conducted the interviews, had them  
48  
49 620 transcribed and checked them. Wildevuur and Simonse analyzed the data in iterative  
50  
51 621 steps, which was supervised - including the methodology - by Groenewegen and  
52  
53 622 Klink. Wildevuur and Simonse took the lead in writing the manuscript. Groenewegen  
54  
55 623 and Klink supervised the findings of this study.

56  
57 624 All authors take responsibility for the content. They all have contributed to the  
58  
59 625 development of the research question, the conducted research and the reported  
60  
61 626 results. All authors provided critical feedback and helped shape the final manuscript.

1  
2  
3 6274  
5 628 **Competing interests**

6 629 None declared.

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8 6309  
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14 63415  
16 635 **Data sharing statement**17 636 Interview protocol and unpublished data (in Dutch) are available upon request. Data  
18 637 can be obtained from first author.19  
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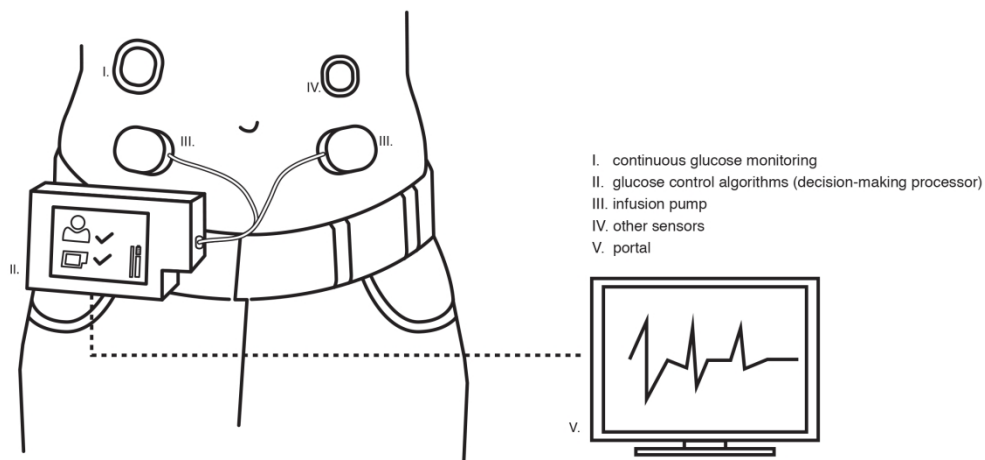


Figure 1 Components of the Artificial Pancreas system

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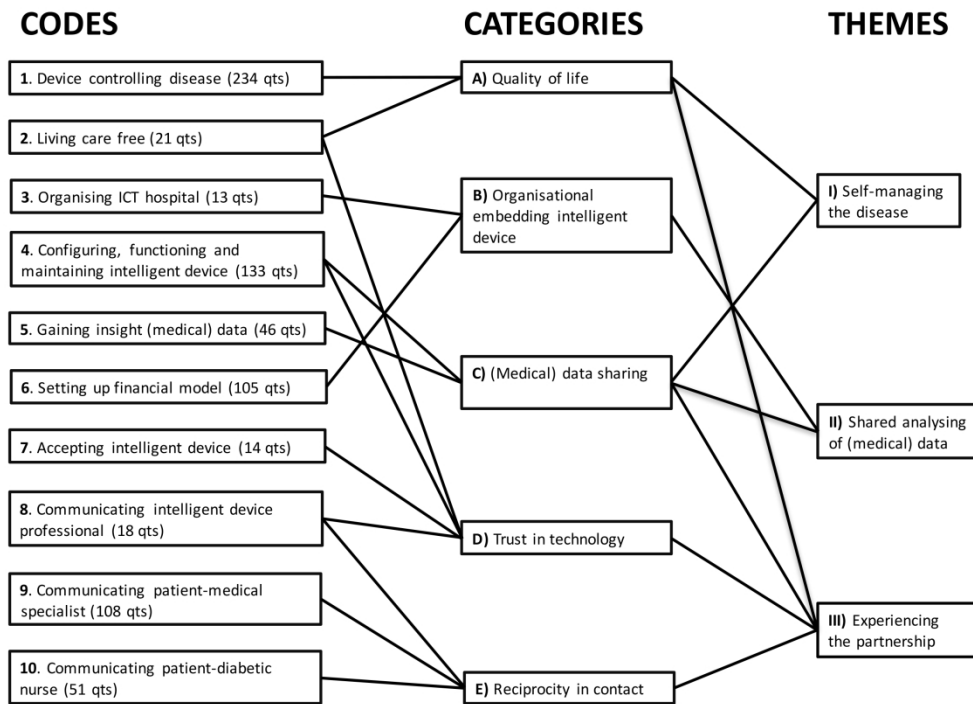


Figure 2 Theoretical framework of ICT enabling partnership in person-centred diabetes management

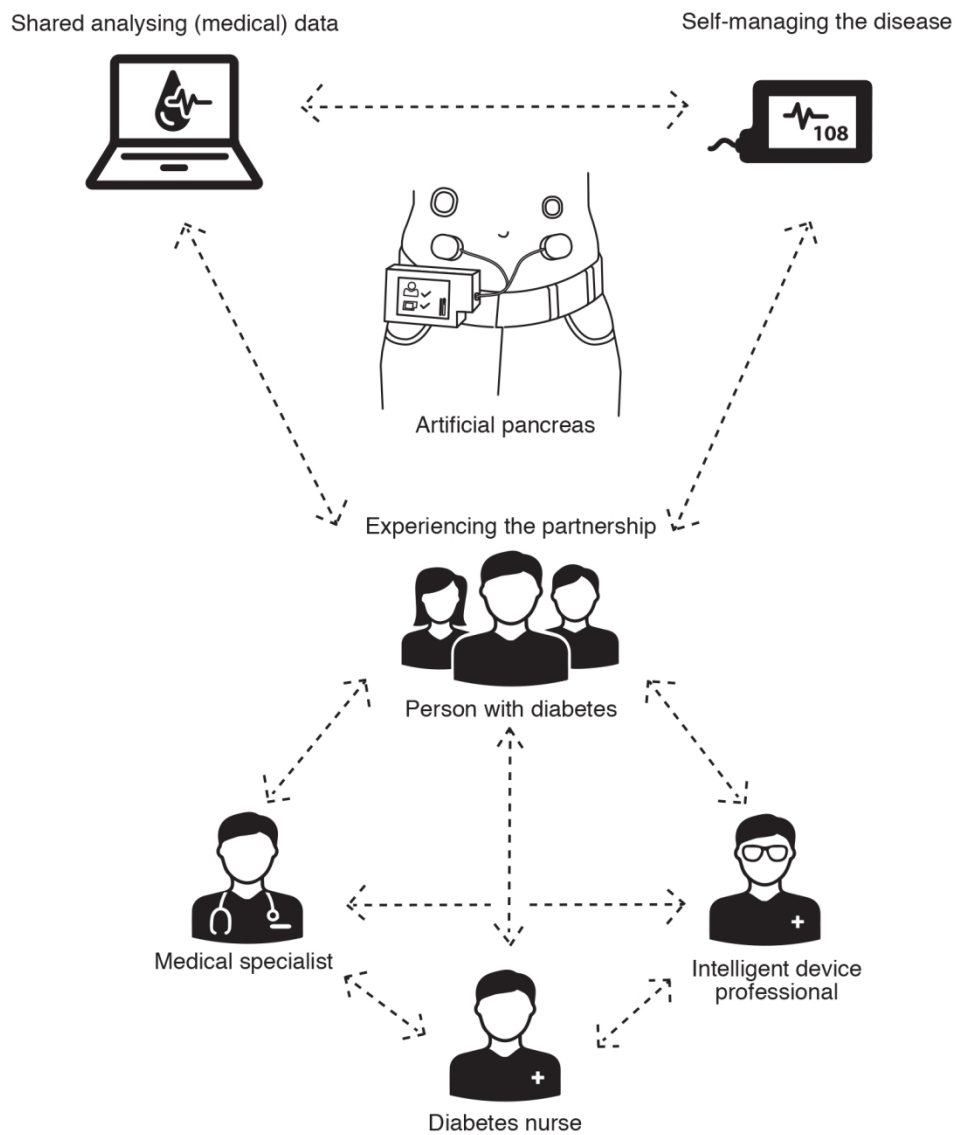


Figure 3 Partnership enabled through ICT (Artificial Pancreas system)

138x159mm (300 x 300 DPI)

## Standards for Reporting Qualitative Research (SRQR)\*

<http://www.equator-network.org/reporting-guidelines/srqr/>

Page/line no(s).

### Title and abstract

<p><b>Title</b> - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	1/1
<p><b>Abstract</b> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	2/25-47

### Introduction

<p><b>Problem formulation</b> - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	4/68-93
<p><b>Purpose or research question</b> - Purpose of the study and specific objectives or questions</p>	4/94-95

### Methods

<p><b>Qualitative approach and research paradigm</b> - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	6/138-143
<p><b>Researcher characteristics and reflexivity</b> - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	8/197-199
<p><b>Context</b> - Setting/site and salient contextual factors; rationale**</p>	6/145-164
<p><b>Sampling strategy</b> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	7-8/168-191
<p><b>Ethical issues pertaining to human subjects</b> - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	No medical data nor personal data of the participants were used. Data were anonymized: 8/204-05

1 2 3 4 5	<b>Data collection methods</b> - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	8/199-225
6 7 8 9	<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	8/193-196, 203-205
10 11 12 13	<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	8/186-191
14 15 16 17	<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	8-9/218-222
18 19 20 21	<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	9/223-231
22 23 24 25	<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	9/225-226

## Results/findings

26 27 28 29 30 31	<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	9-10/233-240
32 33 34	<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	10-16/241-447

## Discussion

35 36 37 38 39 40 41 42 43	<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	16/451-471
44 45	<b>Limitations</b> - Trustworthiness and limitations of findings	17-18/486-92

## Other

46 47 48 49	<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	No conflicts of interest
50 51 52	<b>Funding</b> - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	19/545-7

1 \*The authors created the SRQR by searching the literature to identify guidelines, reporting  
2 standards, and critical appraisal criteria for qualitative research; reviewing the reference  
3 lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to  
4 improve the transparency of all aspects of qualitative research by providing clear standards  
5 for reporting qualitative research.  
6  
7

8 \*\*The rationale should briefly discuss the justification for choosing that theory, approach,  
9 method, or technique rather than other options available, the assumptions and limitations  
10 implicit in those choices, and how those choices influence study conclusions and  
11 transferability. As appropriate, the rationale for several items might be discussed together.  
12

13 **Reference:**

14 O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative**  
15 **research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014  
16 DOI: 10.1097/ACM.0000000000000388  
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