A SUPPLEMENTARY SMARTPHONE APPLICATION FOR AN INSULIN PUMP

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ABSTRACT

The paper presents the design of an appurtenant smartphone application constructed to facilitate user interaction with an insulin pump. An insulin pump is a technical life-supporting device controlling the blood glucose levels for diabetics by injecting insulin. Excessive levels of insulin or glucose in the blood can lead to life-threatening conditions. We believe that the pump is rejected by users due to a non-user-friendly design and that improvement in the design can facilitate all users' daily life. This paper aims to answer question research "How can a smartphone application be used in with an insulin pump conjunction improve the user interactions?". In order to find information about diabetes and current insulin pumps, a literature study was made. A qualitative study was then performed. Furthermore, a prototype of a smartphone application connected to the insulin pump was created and tested on users. The results showed that the users that participated in the test are currently not satisfied with the interaction with their insulin pump and that a smartphone application could be a supplement to the device. Although the prototype lacks some important functions in order to be used every day. We encourage further studies within the area to

performed since there is a demand by the users.

Keywords: Diabetes; Insulin pump; User Experience; User Interface; Usability;

1. INTRODUCTION

The insulin pump is the medical device for users with diabetes type 1 designed to maintain a stable level of blood glucose. Insulin pumps are in some cases deselected due to the inadequate design, even though the device provides the user with "better" results than other options. [9] There is the need to improve the interaction process to facilitate the use of such a life-supporting device without compromising the safety.

There are approximately 390,000 people in Sweden who suffer from diabetes. Of the 390 000, 42 000 are being treated for diabetes type 1, 8 500 for diabetes type 2, and a total of 24% use an insulin pump [7]. The pump is interacted with several times every day to manage the user's blood glucose levels, and as with all devices (especially with medical devices) it is of importance that those interactions are consistently safe, error-free, and efficient [4]. The insulin pump is a wearable and implantable delivery device, designed to replace the insulin pen. A significant feature

of the insulin pump, compared to other solutions, is the ability to measure the level of blood glucose in the human body and the fact that it is adapted to the user.

There are several components to the insulin pump, exterior, battery, sensor measuring glucose level, insulin reservoir compartment, tubes, physical buttons, and screen. [3] The study is delimited to the components related to user interactions, such as calibrating the current level of blood glucose and injecting insulin, and therefore the medical perspectives are neglected. This led us to explore the idea of a smartphone application, connected to the pump, containing the user interaction features. This study focuses on how the smartphone application could be used in conjunction with the insulin pump and does not discuss the security aspect of how medical data will be stored and accessed when using the smartphone application. However, we still believe that the security aspect should be considered in a later stage of the development.

The study aims to answer the research question: "How can a smartphone application be used in conjunction with an insulin pump to improve the user interactions?"

2. BACKGROUND

This section includes information about diabetes and a closer look at one of the insulin pumps on the market.

2.1 Diabetes

In order to understand the need for the insulin pump, one must be familiar with

diabetes. There are two types of diabetes, type 1 and type 2, the common denominator is that both types have varying levels of blood glucose. For type 1 the body's immune system attacks and destroys the insulin-producing cells in the pancreas, which eventually leads to total insulin deficiency, and for type 2 the body cannot produce enough insulin or the body cells lose their insulin sensitivity [3].

The insulin pump is mainly used by diabetics in type 1, but are in some cases used for diabetics in type 2. Type 1 is prioritized due to the constant need for insulin, and the insulin pump can provide a small amount of insulin injected continuously.

2.2 A closer look at an insulin pump

The MiniMed 670G System by Medtronic is one of the leading insulin pumps on the market. The reason why we focus on this specific insulin pump is because it has auto control mode which we consider is an important feature for the pump to facilitate the everyday life of the user. This enables the pump to inject insulin without the user needing to control every step. The buttons connected to the device are physical and positioned below the screen (see image 1). The left, right, up, and down buttons are used to navigate through the menu, (see image 2) and to enter values into fields. To select an item the select button is pressed. This button is also used to display the menu from the homepage. The back button is pressed to return to the previous screen. In order to put the screen into sleep mode, the graph button has to be pressed for two seconds. To wake up the pump from sleep

mode any button can be pressed. The screen then has to be unlocked by pressing the highlighted button.



Image 1. Map of the interactive buttons on the MiniMed 670G System.

From the homepage, the user can iterate through two different screens, one displaying the current level of blood glucose, and one displaying a graph of blood glucose level over time. These two screens are also visible during the locked screen. If a calibration has been made with an associated sensor to the pump, a different homepage is shown where the user can enter the current level of blood glucose (see image 3). [5]



Image 2. The menu of the MiniMed 670G System.



Image 3. The homepage of MiniMed 670G System when in auto mode and calibration has been made.





Image 4, 5. The two different homepages of MiniMed 670G System.

3. RELATED RESEARCH

This section includes previous work related to the field of interest.

3.1 User experience

Schaeffer [10] (2012) discussed how the human factor (HF) method has the potential to prevent patient errors through design when applied during the design process of the insulin pump. Schaeffer concluded that the human factor could increase the safety for the user, as the method eliminated design flaws through the testing stage, performed by representative users in the proposed environment.

Pillalamarri et.al. [8] (2018) performed tests and evaluated the user experience of the key design choices for connected digital diabetes management platforms, and the layout of the homepage. With the result from the study the authors developed the Omnipod DASH PDM, and with the product their aim was to contribute to the development of new knowledge, as a blueprint for medical device manufacturers, to ensure that the design

meets the needs of the users. Aleppo and Webb [1] (2018) presented the perspective of the real-life experience of the insulin pump MiniMed 670G. The study gathered that the first year postrelease emphasizes that providers need to be trained to ensure successful use of the new systems. The issues addressed include strategies for psychosocial issues regarding the use of AID systems, barriers to use, cost of the systems, long-term glycemic control outcomes, and discontinuation rates.

3.2 Risks and safety

Petrie et.al. [2] exam the risks and safety continuous subcutaneous insulin infusion (CSII). Some of the common risks with the insulin pumps are insulin infusion set (ISS) blockage, insulin infusion failure, stability issues, infusion problems, or user errors. The human factors are also as in Schaffers discussed, and how the method is an important part of the evaluation process, they believe that more studies are required to optimize the design stage to the need of different representative user groups. The conclusion is that insulin pumps appear to provide increased benefits for people with diabetes, but there is room for improvement by approaching a more rigorous, standardized, transparent and safety.

4. PROBLEM DEFINITION & CONDUCTED RESEARCH

A literature study, as well as a qualitative study and a test of the prototype, were conducted.

4.1 Literature

The literature about diabetes and the insulin pump was found on Google Scholar with the search words "diabetes", "diabetes type 1", "insulin" and "insulin pump". More detailed information about existing pumps was found on the manual provided by the manufacturer's website.

4.2 Online Survey

The qualitative study consisted of an online survey to evaluate the target group's experience and attitude of the pump, as well to ascertain that there exists a problem. The survey was created in Google Forms as it is easy to create questions, collect, and analyze the data. It was then posted in the Facebook group "Diabetes Typ 1 Sverige" ("Diabetes Type 1 Sweden") with approximately 6 600 members. The participants were to evaluate questions regarding their experience of using an insulin pump or the decision of not using one. They were first asked to describe their relation to an insulin pump with one of the answers "I am currently using an insulin pump", "I have had one, but I am no longer using it" or "I have never used an insulin pump". The following questions depended on the answer to those questions. The questions were asked as open-ended in order to be more qualitative and avoid biased answers. At 69 answers the survey was closed. All participants were asked to leave their email address if they wanted to attend the following usability test.

4.3 Prototype of smartphone application

The prototype was built in HTML, CSS, and JavaScript using AngularJS as a framework in order to make it interactive. The functions added were based on either answers from

the online survey or functions from the MiniMed 670G System. The prototype was hosted on Github Pages [11].

4.4 Test of the prototype

To receive feedback on the prototype the volunteers from the online survey test group participated in a system usability scale (SUS) test. The method was selected due to typically covering efficiency, effectiveness and user satisfaction. It is prominent in identifying problems in the uncovering opportunities for improvement, learning about the target user's behavior. [6] The user has the scope to explore the product as desired, without expectations, obstacles, questions, hesitations. After interacting with the prototype, the user answered the system usability scale test with questions about the difficulty, meaningfulness, and likability of the interaction and the design. The answers are numbered on a scale from 1 to 5 where 1 is "Strongly disagree" and 5 is "Strongly agree".

4.5 Participants

The participants in the studies were between the ages of 19-65 and selected based on their diagnosis of diabetes type 1. A total of 68 participants submitted their answers to the online survey, one of them answered twice as he/she had used two different insulin pumps. In the usability test we sent the prototype to the participants from the online survey, of them participated anonymously. Furthermore. another participant with diabetes type 1 has been cooperating with the project since the start. When new ideas or proposals of the design arose he gave his personal opinion of it. This

participant did not take part in the usability test. All participants took part in the study voluntarily and did not receive any compensation.

4.6 Data analysis

When all data was collected it was compiled into Google Forms to facilitate overviewing and analysis. The data was divided into three categories, those who use a pump, those who used to have one but no longer use it, and those who have never had one. Within each category recurring statements and similarities were targeted.

4.7 Problem Definition

From the online survey we could define the problem statement. Insulin pumps are in some cases deselected due to the inadequate design, even though the device is the most recommended solution for people with diabetes type 1. There is a need to improve the interaction process to facilitate the use with the life-supporting device without compromising the safety.

5. RESULTS

This section includes the result from the online survey and the usability test of the prototype.

5.1 Online Survey

Out of the 68 participants, 52 were currently using an insulin pump, 14 had never used an insulin pump, and two had used one but are currently not using one. From the 15 that had never used an insulin pump, 11 of them wanted to use one, and four did not. The following graphs show the quantitative data which have been derived from the answers of the survey participants.

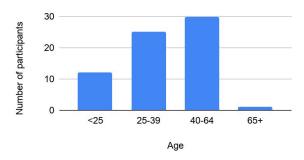


Chart 1. Age distribution among participants.

Chart 1 shows the age distribution among the survey participants within the spans of <25, 25-29, 40-64, and 65+. It discloses that the largest age group with 30 of the total of 68 participants are within the age span of 40-64 years old.

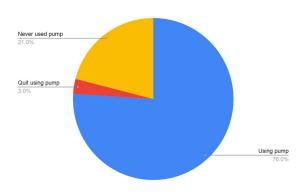


Chart 2. How many of the users that are currently using or have been using an insulin pump. 76.0% (blue) of all participants are currently using a pump, 21% (yellow) have never used a pump, and 3% (red) have had a pump but do not use it anymore.

Chart 2 shows a diagram of the participant's experience using an insulin pump. As the answer to that question determined the following questions of the survey, the following results will be presented in the same grouping.

5.1.1 Participants that have never used an insulin pump

12 participants who are currently not using an insulin pump are interested in starting to use one, while only two participants answered they were not. Of the participants who answered they were not interested, their main reason was that the pump itself is too big and bulky and that they are afraid the tube will get stuck and get ripped out. The most outstanding comment from the participants who were interested in getting one was that they wanted a more stable level of glucose.

The following question was "What is the main reason you are not using a pump?". One participant answered he/she had not been offered one by the nurse and another one had gotten the response that it is too early for a pump by his/her nurse. Four participants claimed the reason for not using a pump is that they are "new" to diabetes. The two participants who were not interested in getting a pump answered "I want control of my sickness", and "it is bulky and increases the risk of ketones".

Next, they were asked what features they thought were important for the insulin pump to have. Many answered, "a good automated function to control the glucose level". One participant said for the design to be reminding more of an iPhone and less of a hospital device. Two participants remarked on the importance of a warning system, notifying the user if the insulin level is too high or low. One participant said for the pump to communicate well with a smartphone and a smartwatch.

5.1.2 Participants that have used an insulin pump but no longer uses it

There were three answers that claimed they have had a pump but no longer uses it, but two of them were from the same person who had been trying two different pumps. The three pumps that had been used were Omnipod, Medtronic, and Animals. The reason they first got a pump was to ease the control of the glucose level during the night and to remember to take insulin at meals. The reason one of the participants had to stop using it was that it was difficult to use with an active lifestyle. The other user had eczema and got allergic reactions from the tape and the sensor.

When the participants were asked if they would change anything with the pump the first participant answered a longer tube and a smaller device to be able to use in sports. The other participant answered a different tape but was not satisfied with the pump in general without mentioning exactly why.

5.1.3 Participants that are currently using an insulin pump

52 of the 68 participants that attended in the study use an insulin pump today, and as seen in Chart 3, a big majority are relatively new to the disease.

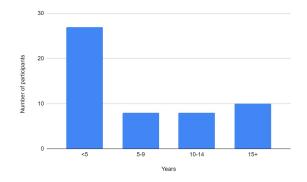


Chart 3. Years of usage of an insulin pump among current and previous pump users.

Chart 3 presents how long current and previous users have used an insulin pump. The spans are divided into <5, 5-9, 10-14, and 15+ years. 27 of these 52 responded that they had been using a pump for less than 5

years.

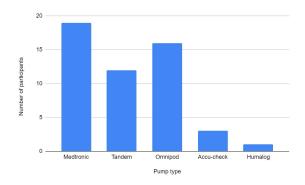


Chart 4. Distribution of insulin pump types/brands among current pump users.

Among the participants who were currently using an insulin pump there were three brands that were most popular: Medtronic with 19 users, Omnipod with 16, and Tandem with 12 users out of 52.

Next, the participants were asked for the main reason that they received a pump. 30 participants said to get better control of their blood glucose level, many mentioned it could be flapping otherwise. Four participants mentioned they needed it especially during the night. Eight participants thought the pump was a better option than the pens, either because they did not like the needles, because it was too much work, too difficult to keep a stable blood glucose level or that it was difficult with an active lifestyle. One of them was allergic to the needles, another one started to forget whether he/she already had taken the injection or not. One participant said her reason was that she was pregnant with her first child.

For the participants who were at the time using an insulin pump, the answers to the question if they trust the insulin pump to provide the right amount of insulin every day were categorized into three sections: 11

responded "Sometimes" or "Yes, but...", a further six participants responded "No" and 35 responded "Yes". Of the participants who answered "Yes, but.." three participants said they trust the machine, but not that their input data would always be correct. Two participants mentioned they trust the pump but they have experienced problems with the infusion set, whilst another participant who experienced the same problem with the set answered "No".

90% of all participants answered that they perceived the pump to be easy to use. Some participants commented that is because there are not so many options, some because they got a good introduction of how to use it, and some because they find technology easy to understand in general. However, a few mentioned that even if they find it easy to use, they know or can imagine that others difficulties face more using it. participants who claimed it was difficult mentioned that a lot of the settings and handling instructions were needed and that they felt that some parts were missing from the instructions.

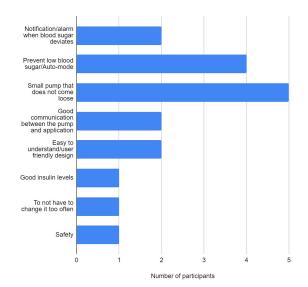


Chart 5. Responses to the question "If you would use a pump, which features do you think are important?"

The responses for Chart 7 were categorized into seven groups according to what was mentioned by 14 participants who were not using a pump. "Small pump that does not come loose" was mentioned by five participants, after which came "Prevent low blood sugar/Auto-mode" mentioned by four. After those, notifications, user-friendliness, and good communication between the pump and the application were equally mentioned two times each.

For the question regarding the usage of the pump in public, specifically: "How do you feel about using the pump in public?", the majority of users gave answers which showed that they were proud and not ashamed of their pump being seen by others. There were some replies which indicated technical or practical problems when using the pump in public. One user replied with "I have no problem using it in public as long as I don't need to "undress" me to reach it (if I wear a dress and have to wear the pump in a belt around my stomach under the dress for example)."

For the question: "What are your thoughts concerning a connected smartphone app, as an additional component to the pump, to enable regulation and access the data of the pump in your phone instead of having to interact with the device?" the large majority of responses were positive.

5.2 Prototype of smartphone application

5.2.1 Graphic Profile

The colors chosen were from the iOS color palette in order to resemble an iOS application instead of a hospital device as mentioned in the online survey. The main colors used were black, orange and gray in order to create a contrast between background and highlighted items or functions

5.2.2 Homepage

The homepage of the application displayed a graph of blood glucose level, current blood glucose value, four interactive menu buttons, and information on how much active insulin that is entered and if auto mode for the pump is enabled or not. The graph had five sub buttons below enabling the user to see blood glucose levels over time, "1 day" as default feature "1 week", "1 month", "3 months" or "6 months" since the option of seeing graph history was requested from the online survey. The four menu buttons were: "Bolus" to enter how much active insulin to inject, "Calibrate" to enter current blood glucose level measured from the sensor, "Settings" to change auto mode, enable/disable insulin dosage notification settings and "History" to show former events such as warnings of high or low blood glucose. Bolus and settings were added because of the most important functions on the insulin pump. History and settings were added since they were requested. In order for the user to easily interact with the application, the menu buttons were placed on the bottom of the screen



Image 6. The homepage of the prototype.

5.2.3 Bolus

Bolus opens a modal window allowing the user to enter how many units of active insulin to queue for injection. The title was chosen because of the name of the short-acting insulin that the user enters after each meal. Each time the user adds a unit, it is summed up with the current level which then shows on the homepage. The modal window was chosen in order to limit number redirections in the application. We aimed for the application to be easy to use as requested. This by limiting the redirections and displaying the essential information on the homepage. After the user has entered the value, a confirmation button has to be pressed in order to avoid errors. A confirmation text is then shown to amplify the result of the action.

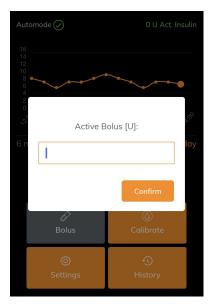


Image 7. The bolus page of the prototype.

5.2.4 Calibrate

Calibrate works in the same way as the bolus interaction except that the user enters the current level of blood glucose per mmol/l instead of insulin units. The title was chosen due to the name of the interaction on the pump.



Image 8. The calibrate page of the prototype.

5.2.5 Settings

On the settings page the user can enable/disable auto mode, insulin dosage, warnings for high or low blood glucose level

and change the volume of sound and vibration. If the user disables the auto mode or insulin dosage it shows on the homepage by a cross for the auto mode and a red text for the active insulin units followed by the test "Dosage paused". This is convenient if the user plugs out the pump and wants to pause the injection of insulin. For the enabling/disabling actions an on/off button was chosen just like the ones in iPhone settings to make the action look familiar to the user. For changing the volume of sound and vibration, a slider was used for the same reason as above.

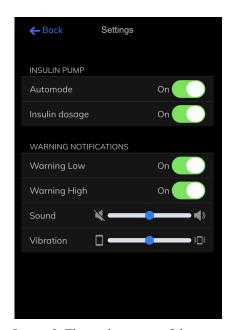


Image 9. The settings page of the prototype.

5.2.6 History

The history page enables the user to see previous happenings with some information including a timestamp. This feature was added in order for the user to get an overview of the change made and to avoid errors from happening, for instance track how often warnings of low or high blood glucose occur and what could be the reason based on the timestamp.

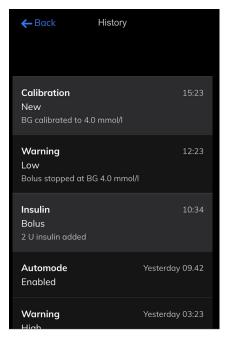


Image 10. The history page of the prototype.

5.3 Usability test

Following are the first 8 questions and their average score between 1-5, where a score of 1 stands for "Strongly disagree" and 5 for "Strongly agree".

Survey question	Average score
I think that I would like to use this application everyday.	3,4
I found this application unnecessarily complex.	1,6
I think that I would need assistance to be able to use this application.	1,7
I found all information and different buttons meaningful.	4,0
I think the application is inconsistent and misses some parts.	3,4
I would imagine that most people would learn to use this application very quickly.	4,5
I like the design of the application	4,0
I trust that this application would work well.	3,5

Table 1. Questions and average results from the usability test.

A summary of the final open question suggests that more advanced settings would be useful, such as being able to enter carbohydrates consumed and activity level so that the app can predict the amount of insulin needed with a bolus calculator. Also the ability to manually regulate the value of insulin, as this is often a set value.

6. DISCUSSION

This section discusses the results, choice of method, and our thoughts on further development.

6.1 Results

From the qualitative survey the results were perceptible homogenous in the attitude towards the insulin pump, as the satisfaction of the device was consistent. Some of the common negative feedback from the results of insulin pump use was: numerous tubes, radiates being sick, and not trustworthy. The test data from the survey confirmed the problem statement, that there is a need to improve the user interaction with the insulin pump.

The design seemed important for some participants as they mentioned it already in the first survey. As they wished the design like was more an iPhone, a nice, user-friendly device for simplifying everyday life, rather than a big "hospital device" reminding them of being sick. The idea of an additional application on a smartphone or smartwatch was mentioned by one of the participants before our suggestion in the survey.

As three participants mentioned, the human factor could provide a risk, even if the machine works without error. It is difficult to eliminate the human error completely, but a design choice we made to decrease the risk was to both use a confirmation button that needs to be pressed to confirm the value of the manually typed glucose value, and a confirming window that again shows what value you confirmed to. Warnings with sound and vibration when the sensor loses connection or the tube gets pulled out are also important. The objects can not be too strictly attached to the body since that could cause injuries. Instead, the objects will get pulled out more easily, which increases the importance of warning the user to make an action and attach the object again.

The majority of the participants in the usability test were positive to the prototype. In the feedback section of the prototype the participants agreed on the lack of more advanced functions, there was the common interest to feature basal-programs. From the user interface perspective one of the participants thought that the theme was "dark" or "boring". The prototype is designed according to the iOS user interface, in the updated prototype there could be the feature, as with the iOS devices, to switch between the "dark" and "light" theme.

The majority of the participants in this investigation were between 40-64 years old. Everyone uses social media as that is how we reached them. It is important to keep in mind that in this way we were not able to reach people who are not active on social media and that there is a risk that they might not even have a smartphone or if they do, this prototype could be perceived as more challenging for them. However, the usability test showed that the participants thought the

application was easy to understand and that they did not feel in need of assistance.

The score from the usability test shows that the participants were not convinced they could fully trust the application. There is a risk that the users did not fully understand how this application is supposed to be connected to the pump, or what will happen if for example the battery of the phone dies. That could be due to a lack of explanation from our side, also inadequate English skills from the user since that was mentioned in a comment. However, 3.5 is a low average compared to the other scores, (as shown in Table 1) and should be further investigated before creating such an application. The results also showed that the participants were not convinced they would like to use this application every day. Since we did not speak to them we are not sure if they are critical to the whole idea of using a supplementary application or if they just did not like the actual prototype.

The report is proposed to reach practitioners that manufacture medical devices. For them, the report would be used as a blueprint to develop the user interaction with the insulin pump.

The qualitative online survey provided representative results of the common opinion on the insulin pump, as we identified commonly requested features for us to address in the initial design. The foremost method for us would have been to observe the participants' behavior interacting with the insulin pump and listen for feedback on the experience. It would have resulted in a better understanding of real-life

situations, and additional feedback to justify our design choices for the prototype. In the usability test we received quantitative feedback on how useful the prototype was. The foremost method for both of the tests would instead include user experience methodologies. If the preferred methods would have been applied it would have been more desirable to track each individual tester, asking further follow-up questions to achieve more substance in the responses. The methods used in the study are still appropriate as they enable us to get an overview of the opinions by the users and answer the aforementioned questions.

6.2 Further research

For further research on the topic there could have been frequent input from the participants, representing a variety of potential user groups for a broader perspective. For instance insulin pump users, insulin pen users, user experience practitioners, medical device manufacturers, and nurses.

By relocating the majority of the interaction with the device to a smartphone, we believe the experience will feel more modern and normal and decrease the feeling of being sick. If the majority of the interaction with the pump was through an additional application, the device itself could be smaller, as the screen and buttons could be made smaller if only needed when the phone is lost or out of battery. That could impair the user-friendliness of the direct interaction with the device, and a smaller device showed to be desired by a large majority.

6.3 Personal Assessments

All members of the team were engaged in leading the project forward and creating as good studies as possible within the given time frame. The work was divided into three main parts: writing on the report, analyzing the data from the tests, and implementing the prototype. Once the test and the prototype were finished everyone was engaged in writing on the different parts of the report.

By choosing a subject that lies outside of our knowledge span we were more eager to commit ourselves to learn. Since none of us have the experience of living with diabetes, it was of great interest to us all to learn more about the diagnosis. It was also essential to obtain Self-Directed Learning in order to be able to provide a solution that was respectful to the users and participants in the tests.

We were astonished by the number of people that suffer from diabetes and that several of them use an insulin pump. When we introduced the project in the Facebook group "Diabetes Typ 1 Sverige" the positive feedback was overwhelming, which made us contribution realize that our appreciated. This made us realize that the disease needs more recognition, and we got the impression that an updated medical solution is longed for. None of us are diabetic, therefore there was a lack of knowledge about the disease and understanding of using an insulin pump. When it comes to engaging with a life-threatening disease, knowledge significant, and in future studies further knowledge is required for us to cover the user experience spectrum of an insulin pump user.

7. CONCLUSION

The results from the studies showed that there is a demand for improving usability of the insulin pumps. smartphone application could supplement to the device. Although, for the application to work fully it has to contain more complex functions than included in the prototype created for this study. To obtain this resources with medical goal, qualifications within diabetes are proposed to be included in future work, as well as people with technical skills within mobile application development.

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