D5.1 – Human factors identification

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FORGET DIABETES

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DEFINITIONS (To be completed according to the contents of each Deliverable)

- **Human factors** – Collective term for psychological, cognitive, and social influencing factors in socio-technical systems and human-machine systems. These factors describe potential influencing factors for acceptance, device uptake, and continuous and effective use.

ABBREVIATIONS (To be completed according to the contents of each Deliverable)

- **AID** – Automated insulin delivery
- **ANOVA** – Analysis of variance
- **BIP** – Bionic invisible pancreas
- **CGM** – Continuous glucose monitoring
- **CSII** – Continuous subcutaneous insulin infusion
- **GMSS** – Glucose management satisfcation survey
- **IPA** – Insulin pump attitudes questionnaire
- **MDI** – Multiple daily insulin injection
- **WP** – Work package

Executive Summary

The present document summarizes the completed work within task 5.1 “Semi-structured interviews in different user population subgroups”. Goal of this task was to identify relevant human factors as well as possible perceived benefits and barriers associated with the BIP. To achieve this, we conducted semi-structured interviews combining qualitative and quantitative methods. The semi-structured interviews were conducted in three groups:

1) Therapy with multiple daily injections (insulin pen) plus CGM
2) Therapy with CSII plus CGM
3) Therapy with an AID system (either self-built or commercially available)

In total, 38 people with type 1 diabetes participated in our surveys with a mean age of 35.8 ± 11.5 years. We achieved an equal distribution of participants within the three groups: 12 participants used an insulin pen, 14 participants used CSII therapy, and 12 participants used an AID system.

In sum, perceived benefits were more pronounced than perceived barriers. This resulted in an already high acceptance of the BIP as 29 participants (76.3%) said that they would use such a fully implantable system. Interestingly, indication to use the BIP was independent from type of therapy as the rate of potential users were comparable (Group 1: 75%; Group 2: 75.6%; Group 3: 75%).

The following perceived benefits and barriers of a fully implantable AID system emerged:

- **Perceived benefits**
  - Better and simpler diabetes and glucose management
  - More flexibility
  - More time and energy for other areas of life / less worries
  - Reduced visibility of diabetes (devices)
  - Feeling “more normal”
  - Fewer autonomous decisions
- **Perceived barriers**
  - Loss of control
  - Fear of complications during the implantation
  - Fear of side effects
  - Lack of possibility to actively intervene (especially regarding fluctuations)
  - Many technical problems

Participants highly appreciated the development of the BIP and were eager to learn more about the project. In general, the BIP already showed a large acceptance. These results are now used to develop an assessment tool to select participants who will likely benefit the most from the BIP.

1. Introduction

1.1 Purpose

Development of a fully implantable artificial pancreas or BIP is a highly ambitious project that has the potential to significantly change the treatment of people with diabetes. Possible effects can not only be expected regarding glycaemic outcomes, but also regarding patient-reported outcomes such as diabetes distress and quality of life.

Acceptance and dissemination of the BIP will be highly dependent on the inclusion of people with diabetes. The wishes and needs as well as perceived benefits and perceived barriers of people with diabetes should be assessed early on and integrated in the development process. Previous research on diabetes technologies have clearly demonstrated the importance of "human factors" for device uptake, continuous use, and efficacy of these diabetes technologies [1-3]. Since the BIP will be a paradigm shift in the treatment of diabetes, current research on human factors can only be applied in a limited way. Thus, analysing human factors specifically related to the BIP is important and could shape further developments.

Thus, the purpose of this task within WP 5 "Human factors and ethical implications" was to identify a possible set of human factors that are relevant for uptake of the BIP. In order to achieve this and get a first idea what possible users – people with type 1 diabetes – are thinking of such a fully implantable solution, we planned semi-structured interviews combining qualitative and quantitative methods.

2. Methods

2.1 Focus groups

For the semi-structured interviews, we planned the conduct of three focus groups representing different sub-groups with different levels of diabetes technology use. The first group represented people with type 1 diabetes using multiple daily insulin injections (insulin pen therapy). The second group represented people with type 1 diabetes using CSII therapy. The third group represented people with type 1 diabetes using an AID system, either a self-built AID system or a commercially available system. In each group, approx. 10 persons were planned to be recruited. Thus, it was our goal to recruit 30 participants in total. All participants used a CGM system.

This composition of three different focus groups allows us to compare the attitudes towards the BIP for people with type 1 diabetes with different levels of technology affinity.

2.2 Conduct of the interviews

Originally, the conduct of the interviews was planned as in-person group interviews. However, due to the Covid-19-related restrictions, sampling of groups within the Diabetes Clinic Mergentheim was no longer feasible.

Thus, we employed two strategies:

- First, in-person interviews and surveys were conducted separately with each participant. The interviewer had full vaccination and a hygiene protocol was in place to reduce the risk of infection.
- Second, online interviews and surveys were conducted, and participants were invited via online communities.

2.3 Content of the interviews

The semi-structured interviews used both open-ended as well as closed-ended questions. This way, we have achieved qualitative and quantitative data that provide a better overall picture of different attitudes, perceived benefits and barriers, as well as wishes of participants. Following the Technology Acceptance Model, we wanted to assess perceived benefits, perceived barriers, and ease of use.

The interview was structured as follows:

1. All: Short description of the project and the scope of the interview
2. All: Obtaining informed consent
3. All: Detailed description of the BIP with official video
4. All: Satisfaction with CGM system
    a. 5 items from the Glucose Monitoring Satisfaction Survey (GMSS) [4]
        i. Makes me think about diabetes more than I want to.
        ii. Takes too much time to use.
        iii. Makes me worry a lot.
        iv. Makes me feel more down and depressed.
        v. Helps me be more open to new experiences in life.
    b. Open-ended: Three advantages of CGM
    c. Open-ended: Three downsides of CGM
5. All: Pros and cons of CSII
    a. Open-ended: Three advantages of CSII
    b. Open-ended: Three downsides of CSII
6. All: Pros and cons of current AID systems

a. Open-ended: Three advantages of AID systems in general
b. Open-ended: Three downsides of AID systems in general

7. Only for those with CSII: Attitudes towards CSII
    a. 5 items from the Insulin Pump Attitudes Questionnaire (IPA) [5]
        i. With an insulin pump I can achieve a better HbA1c.
        ii. The insulin pump makes me feel more ill.
        iii. I'm constantly worried that my insulin pump might become defective.
        iv. It bothers me that I constantly have an insulin catheter in my body.
        v. Because of the insulin pump, other can immediately see that I have diabetes.
    b. Rating of the ease of use:
        i. Bolus function
        ii. Changing the catheter
        iii. Programming of the basal rate
        iv. Changing insulin
        v. General
    c. Open-ended: What would you wish for to make your insulin pump easier to use and operate?
8. Only for those with an AID system: Attitudes towards AID
    a. Rating of the ease of use of the AID system in general
    b. Open-ended: What would you wish for to make your AID system easier to use and operate?
9. All: Possible perceived benefits and barriers of the full implantable BIP
    a. By using this fully automated artificial pancreas, I expect ...
        i. more flexibility in everyday life.
        ii. better glucose values.
        iii. fewer hypoglycaemic episodes.
        iv. less high glucose values.
        v. to be able to do sports more easily.
        vi. to be able to eat easily without having to think about my glucose levels.
        vii. having to think less about diabetes.
        viii. less therapy effort in everyday life.
        ix. more protection from long-term complications.
        x. a loss of control over my therapy.
        xi. many technical problems.
        xii. complications during implantation.
        xiii. side effects (e.g., inflammations) due to the implanted pump/sensors.

xiv. that I feel too much at the mercy of the technology.
xv. that I feel "remote controlled".
xvi. problems with the accuracy of the glucose sensor.
xvii. problems with the accuracy of insulin dosing.
xviii. a greater sense of discomfort because I cannot intervene directly when glucose fluctuations occur.
xix. that I find it difficult to completely relinquish control to this system.

10. All: Open-ended questions about possible benefits and barriers of the BIP
    a. What aspects of your life with diabetes could benefit from a fully implantable AID system?
    b. What aspects of your life with diabetes might become more complicated with a fully implantable AID system?
    c. What information would you need to classify such a fully implantable AID system as safe?
    d. What would have to happen for you to forget about your diabetes because of such a fully implantable AID system?
11. All: Comparison with current situation
    a. Do you consider the fully implantable AID system to be an advance over current treatment options?
    b. Do you think you can reduce burdens from diabetes with a fully implantable AID system?
    c. Do you think you can achieve a better quality of life with a fully implantable AID system?
12. All: Potential use of the BIP
    a. Can you imagine using the fully implantable AID system?
    b. If yes: What do you expect from a fully implantable AID system? (open-ended)
    c. If no: What are the main arguments for you against using a fully implantable AID system? (open-ended)
13. All: Any further comments about the project

3. Results

3.1 Description of the sample

A total of 38 people with type 1 diabetes participated in the interviews. Group 1 consisted of 12 participants with CGM and MDI therapy, Group 2 consisted of 14 participants with CGM and insulin pump therapy, Group 3 consisted of 12 participants with an AID system. Mean age of the sample was 35.8 ± 11.5 years with a minimum age of 20 and a maximum age of 59.

Interestingly, participants already using an AID system had the highest mean age (Figure 1). Mean age of Group 3 differed significantly from Group 2 (p = 0.006).

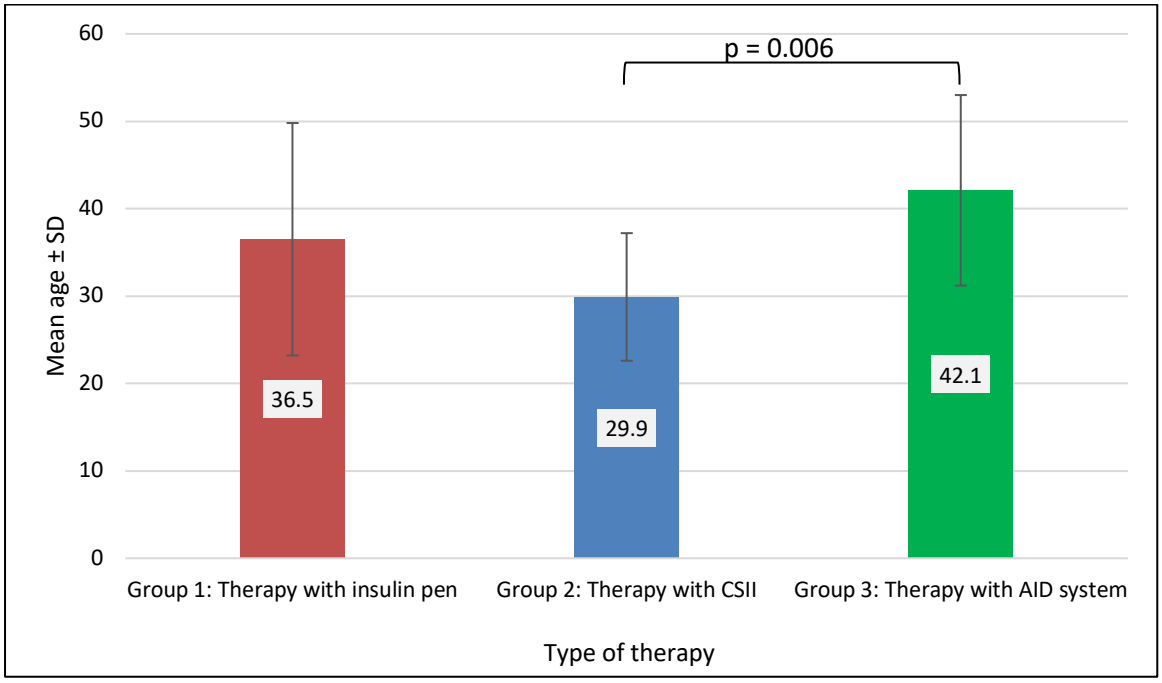

Figure 1. Age distribution in the different focus groups

3.2 Attitudes towards CGM systems

3.2.1 Quantitative results

All participants answered the items regarding satisfaction with their CGM system. Answers to the five items of the GMSS can be seen in Figure 2. Items were scored on a 5-point Likert scale from 1 (completely disagree) to 5 (completely agree).

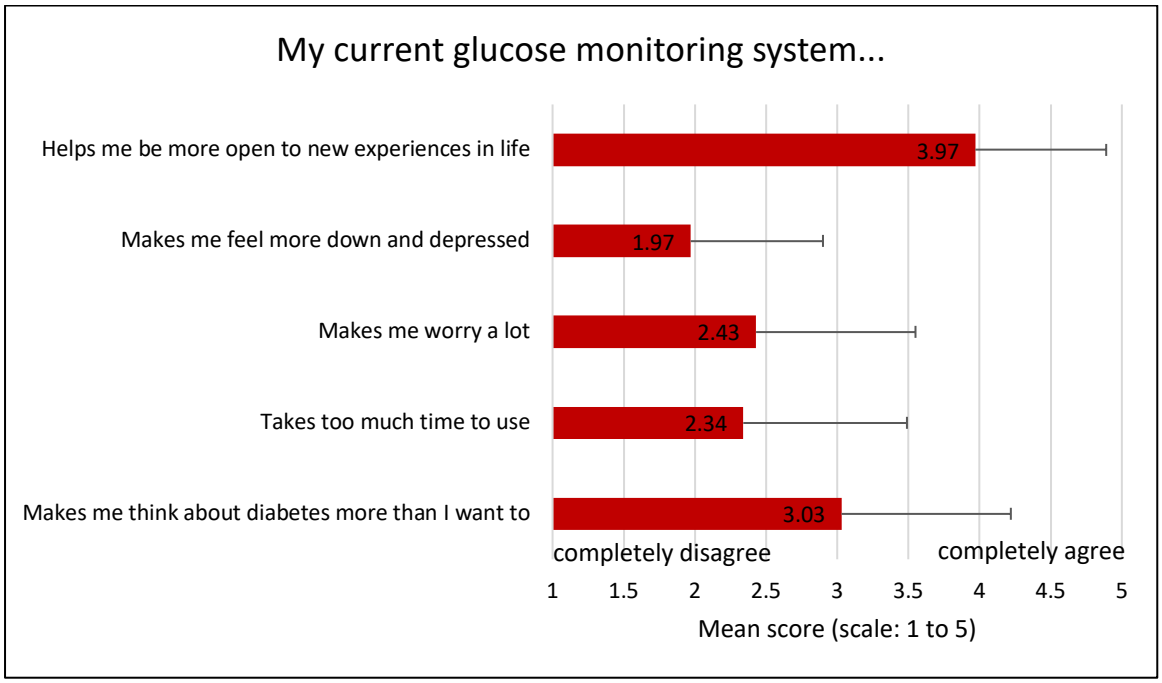

Figure 2. Mean scores on the five items of the Glucose Management Satisfaction Survey

As can be seen from Figure 2, participants were rather satisfied with their CGM system. The sample rather agreed that CGM helps to open new experiences in life and rather disagreed on a potentially negative impact on CGM on their life. However, responses on the item "Makes me think about diabetes more than I want to" (3.03 ± 1.19) also indicates that the constant feedback of CGM systems can be burdensome to people with diabetes. This could be a potential factor that can be improved by the BIP.

3.2.2 Qualitative results: Pros and cons of CGM

Analysing the open-ended questions, participants considered the following as biggest advantages of CGM:

- No more pricking of the finger
- Alarms
- Detailed insight
- Better control of glucose
- Sense of safety

The following downsides of CGM were mentioned most frequently:

- Visibility / size
- Operating life too short

- False alarms
- Waste
- Accuracy
- Skin problems

With regard to the development of the BIP, particularly the downsides of current CGM system can be addressed and used to convey the benefits of the BIP. People with diabetes seem to be increasingly aware of the waste associated with CGM. This could be an interesting factor in depicting the benefits of a fully implantable device.

3.3 Attitudes towards CSII

3.3.1 Quantitative results

Only participants of Group 2 (CSII therapy) answered the items of the IPA questionnaire assessing different attitudes or experiences with CSII (n=14). Answers to the five items of the IPA can be seen in Figure 3. Items were scored on a 5-point Likert scale from 1 (completely disagree) to 5 (completely agree).

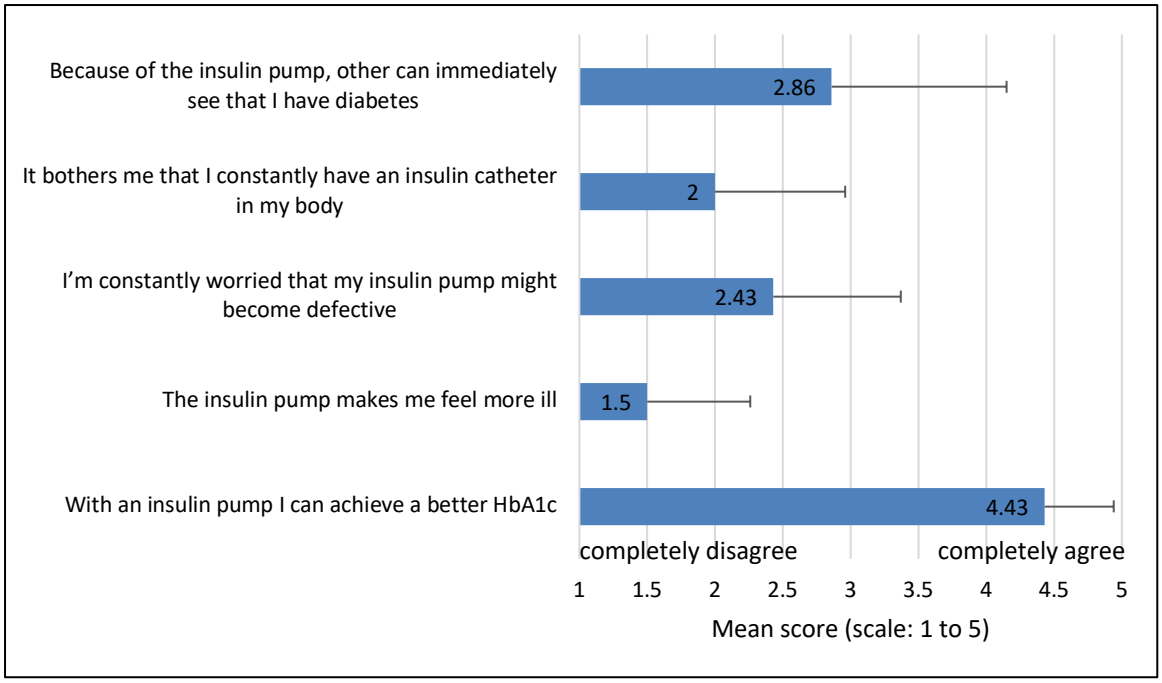

Figure 3. Mean scores on five items of the Insulin Pump Attitudes Questionnaire

Figure 3 clearly shows the perceived benefit of CSII users regarding better glycaemic control. This perceived benefit of CSII therapy has to be met with the BIP. In addition, issues around

body image and visibility of diabetes can be seen in the response to the item “Because of the insulin pump, others can immediately see that I have diabetes” (2.86 ± 1.29). Worries about malfunction of the insulin pump or catheter problems were rather uncommon.

Thus, body image issues and visibility are potential factors that can be perceived as highly beneficial regarding the BIP.

3.3.2 Qualitative results: Pros and cons

All participants (n=38) answered the open-ended questions about the pros and cons of CSII therapy. Participants that did not use CSII, were asked about their opinion regarding perceived pros and cons.

Analysing the open-ended questions, participants considered the following as biggest advantages of CSII:

- Flexibility / spontaneity
- Precise regulation of insulin
- No injections
- Discreteness of insulin administration
- Better glycaemic control

The following downsides of CSII were mentioned most frequently:

- Object on the body
- Issues with catheter/cannula
- Visibility
- Technical problems / being dependent on the technology
- Skin problems

The downside of CSII “technical problems / being dependent on the technology” can also be applied to a fully implantable insulin pump. Furthermore, “object on the body” as a downside might not be fully resolved with the object being in the body. Thus, these issues must be taken seriously. Furthermore, issues around visibility and problems with catheter/cannula might be better resolved with the BIP. Current advantages of CSII can be further expanded with the BIP indicating a high potential for perceived benefits of a fully implantable insulin pump.

3.4 Attitudes towards currently available AID systems

3.4.1 Qualitative results

All participants answered the open-ended questions about the pros and cons of currently available AID systems. Participants not using AID systems, were asked what they would imagine to be pros and cons of currently available AID systems.

Participants considered the following as biggest advantages of currently available AID systems:

- Lower glucose fluctuations / less highs and lows
- Makes life easier
- Mental relief
- Higher quality of life
- Reduced need to make decisions about therapy (e.g., *"Switch to autopilot for a change, more time for me"*)
- Flexibility
- Better glycaemic control

The following downsides of currently available AID systems were mentioned most frequently:

- Transfer of control to the technology / being dependent on the technology
- Loss of body awareness
- Technical know-how required
- Technical problems
- Complicated
- Not officially approved

Interestingly, positive effects of AID systems on mental relief and a reduced need to make decisions about therapy were reported by participants. This directly relates to "forget diabetes" as a fully implantable AID system could expand these advantages even further. Current downsides of available AID systems might also apply to a fully implantable AID system. Particularly, loss of control and technical problems must be closely monitored. Interestingly, many participants mentioned a possible loss of body awareness or a sense of one's own body as a possible downside. This might relate to the ability to detect hypoglycaemia via adrenergic symptoms and also to a possible loss of control.

3.5 Ease of use of CSII and currently available AID systems

Only participants in Group 2 (CSII therapy; n = 14) were asked about the ease of use of their current insulin pump. Ease of use was assessed on a 11-point scale from 0 (very complicated) to 10 (very easy).

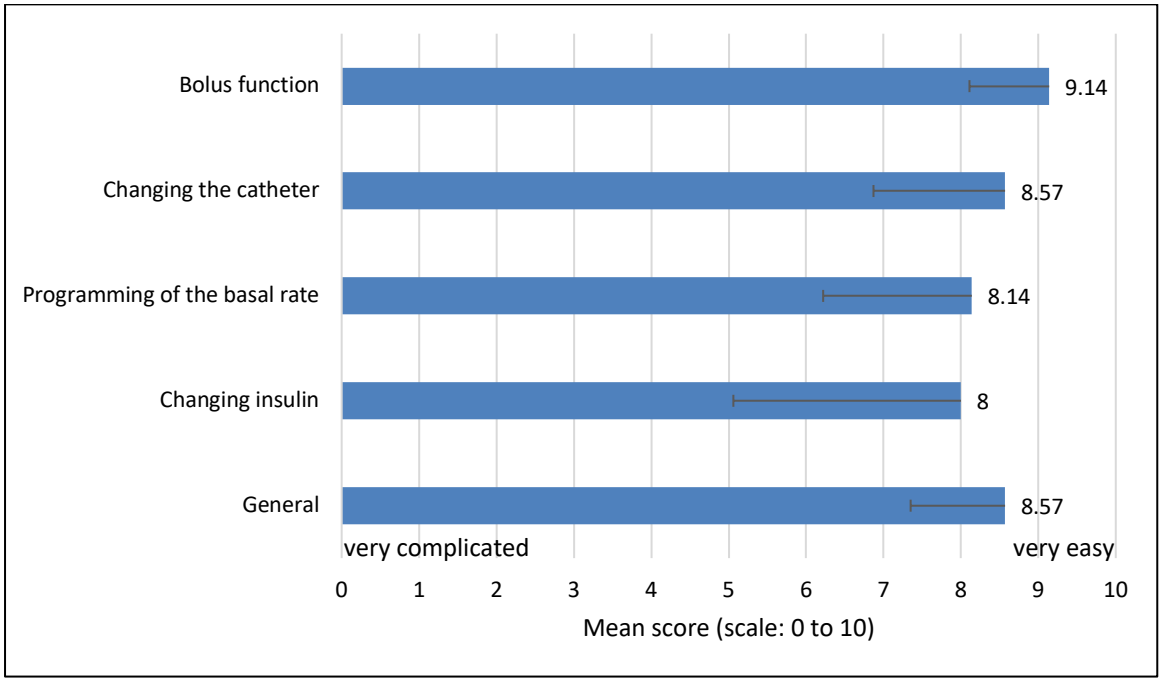

Figure 4. Mean scores on "ease of use" items of CSII

As can be seen in Figure 4, current CSII users find their insulin pump rather easy to handle. However, some of the ease of use criteria will no longer be applicable for BIP use.

In the open-ended question "What would you wish for to make your insulin pump easier to use and operate?", 6 out of 14 participants indicated their wish for controlling the insulin pump with their Smartphone.

To assess the ease of use of currently available AID systems, only Group 3 (AID system; n = 12) were asked to rate the general ease of use via one item on a 11-point scale from 0 (very complicated) to 10 (very easy). Ease of use was rather moderate with a mean rating of 6.75 ± 2.49. Figure 5 shows the comparison of general ease of use of CSII and general ease of use of AID systems.

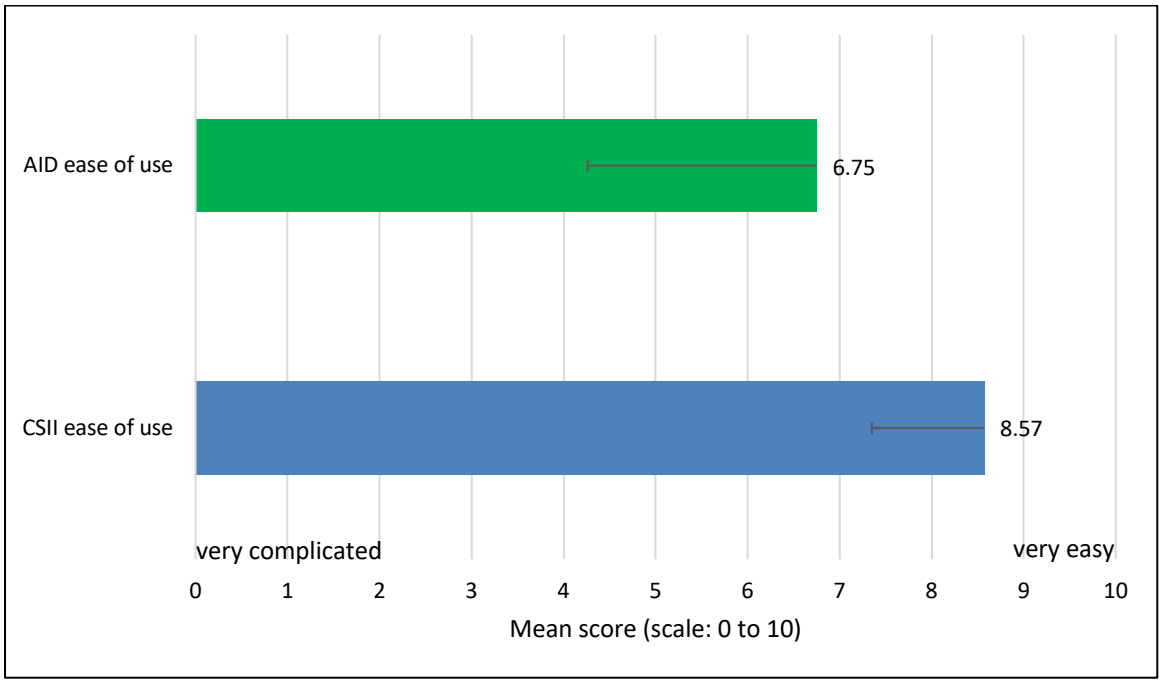

Figure 5. Comparison of CSII and AID regarding ease of use

Interestingly, ease of use of currently available AID systems were rated substantially lower compared to insulin pumps. This indicates some room for improvement of the currently available AID systems that can be addressed by the BIP.

Responses to the open-ended question "What would you wish for to make your AID system easier to use and operate?" indicated the following wishes. In sum, fewer external devices, faster response to glucose spikes and more flexibility are the main desires of current users of AID systems.

- **Individualisation/flexibility:**
  - *"More individualization in the algorithms of commercial systems, ketoacidosis protection (preventing the basal rate from being switched to 0%), better options for adapting the algorithm to changing life situations (e.g., sports) (possible with DIY, only possible to a limited extent with most commercial systems)."*
  - *"It would be nicer if it were more flexible in handling. Everyday life is not the same every day. Sometimes it is more stressful, sometimes quieter. But I can currently set my target value to 120 or 150. More is not possible. The basal rate can also not be finely controlled in percentage terms."*

- **CE approval:**
  - *"Availability on the market (without having to build the app yourself), compatibility with more devices, communication with smartwatch without phone."*
  - *"Use Android APS, not officially approved, so I am also on my own and my diabetologist may/can not give me advice. I have to hide the use from the health insurance.... Support and official approval would make it easier to handle."*
- **Simplicity:**
  - *"One device for everything."*
  - *"No more worrying about it."*
- **Technological improvements:**
  - *"Faster response of the system to values outside the target range. Reduced vulnerability of the technology."*

3.6 BIP: Perceived benefits and barriers

3.6.1 Quantitative results

To quantitively assess possible perceived benefits and barriers of the BIP, we developed a preliminary item pool. All participants (n = 38) completed this item pool.

Possible perceived benefits and the mean responses to each item can be seen in Figure 6.

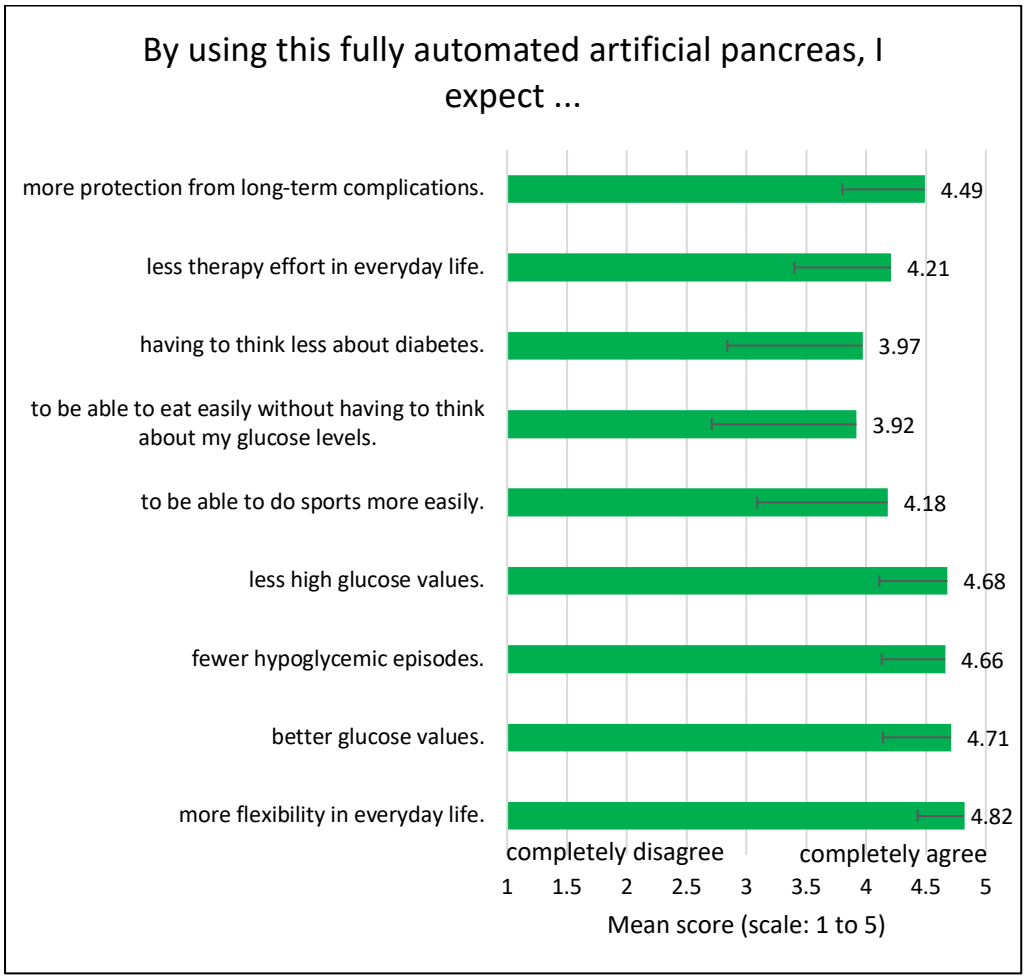

Figure 6. Mean scores regarding possible perceived benefits of the BIP

Overall, perceived benefits were rather high with a mean item score (across all items) of 4.41 ± 0.45. Interestingly, standard deviation was rather low resulting in a coefficient of variation of 10%. This indicates that participants uniformly believe that BIP has many potential benefits. Among the highest rated perceived benefits were glycaemic benefits such as “better glucose values”, “fewer hypoglycaemic values”, “less high glucose values”, “more protection from long-term complications”. Gaining “more flexibility” was rated the highest benefit while “having to think less about diabetes” was rated among the lowest.

Possible perceived barriers and the mean responses to each item can be seen in Figure 7.

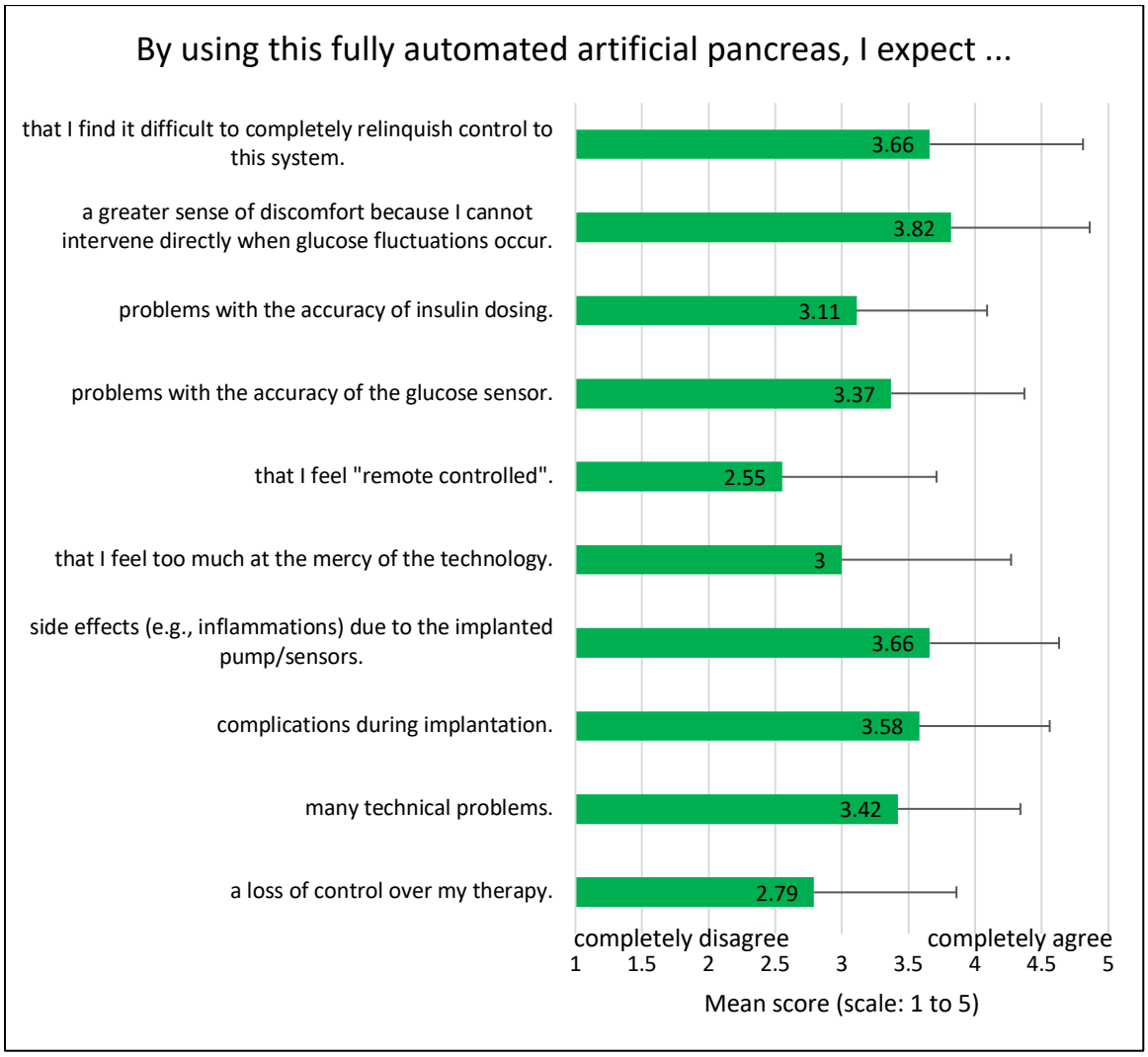

Figure 7. Mean scores regarding possible perceived barriers of the BIP

Overall, perceived barriers received lower ratings of agreement than perceived benefits. Across all items, perceived barriers had a mean item score of 3.29 ± 0.76. Coefficient of variation was 23% indicating some level of variation in perceived barriers. The most pronounced perceived barriers were “a greater sense of discomfort because I cannot intervene directly when glucose fluctuations occur”, “side effects”, and “complications during the implantation”. Interestingly, accuracy of insulin dosing and glucose sensing also appear to be issues that should be addressed in the further development of the BIP.

Figure 8 shows the comparison of mean item scores across all perceived benefits and barriers. The difference in mean item score for both scales results in an effect size of Cohens *d* = 1.46 in favour of perceived benefits of the BIP.

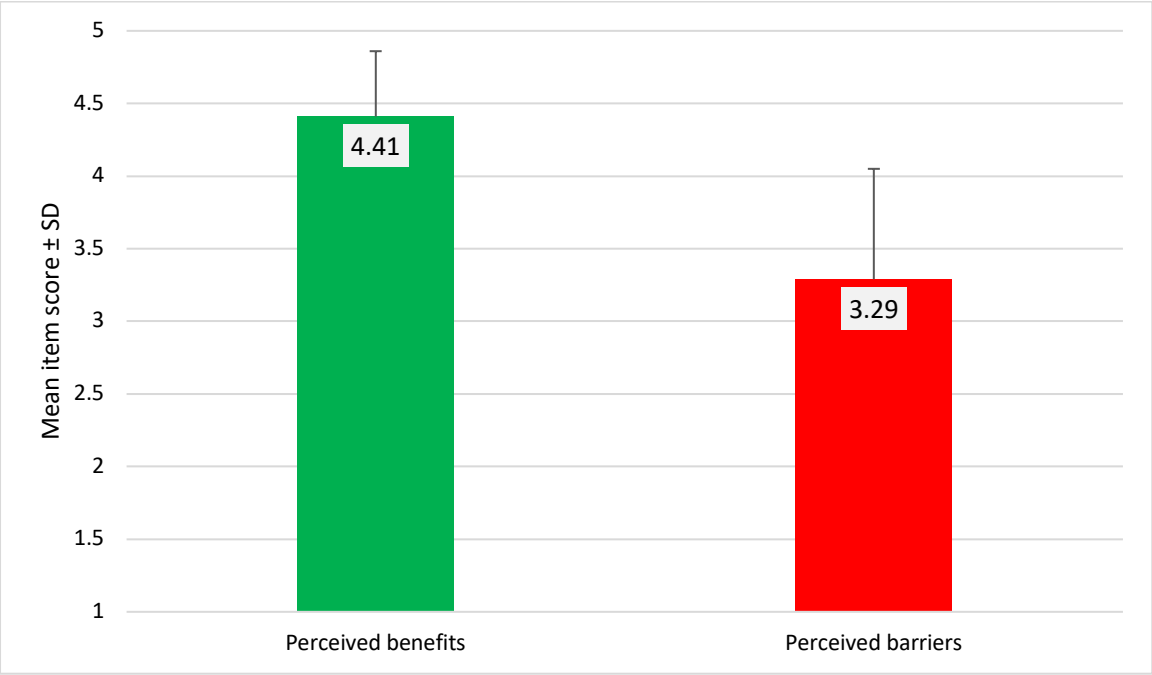

Figure 8. Comparison of perceived benefits and barriers of the BIP

3.6.1.1 Comparison between groups

The mean item scores for perceived benefits and barriers were compared between the three groups. Figure 9 shows that all three groups responded rather similarly. Univariate ANOVA showed no effect of group on neither perceived benefits ($p = 0.861$) nor perceived barriers ($p = 0.669$).

This has significant implications for the BIP, as perceived benefits and barriers do not seem to differ between groups that differed in their technological affinity regarding diabetes therapy.

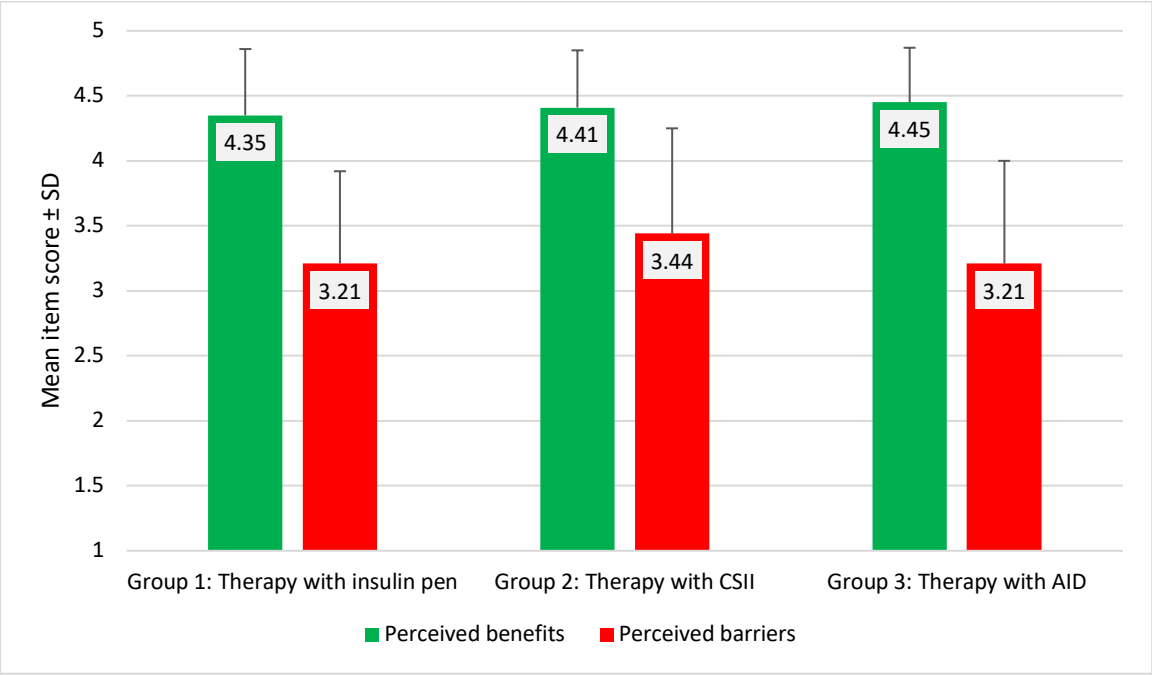

Figure 9. Comparison of perceived benefits and barriers across the three focus groups

Single items analysis of perceived benefits and barriers was also performed for each of the three groups.

The Top 3 perceived barriers for each group are depicted in Table 1:

Table 1. Comparison of perceived benefits for the three focus groups

Rank	Perceived benefit	M ± SD
Group 1: Therapy with insulin pen		
1	More flexibility in everyday life	4.92 ± 0.29
2	Better glucose values	4.67 ± 0.65
3	Less high glucose values	4.58 ± 0.67
Group 2: Therapy with CSII		
1	Less high glucose values	4.79 ± 0.58
2	Better glucose values	4.71 ± 0.61
3	More flexibility in everyday life	4.71 ± 0.47
Group 3: Therapy with AID		
1	Fewer hypoglycaemic episodes	4.92 ± 0.29
2	More flexibility in everyday life	4.83 ± 0.39
3	Better glucose values	4.75 ± 0.45

The Top 3 perceived benefits were rather similar with a focus on flexibility and better glycaemic control. Interestingly, participants already using an AID system rated fewer hypoglycaemic episodes as the most relevant perceived benefit of the BIP. Furthermore, even for this group for which a high flexibility can be expected, gaining more flexibility was an important perceived benefit.

The Top 3 perceived barriers for each group are depicted in Table 2:

Table 2. Comparison of perceived barriers for the three focus groups

Rank	Perceived barrier	M ± SD
Group 1: Therapy with insulin pen		
1	Many technical problems	3.67 ± 0.78
2	A greater sense of discomfort because I cannot intervene directly when glucose fluctuations occur	3.67 ± 0.99
3	Complications during implantation	3.5 ± 1.10
Group 2: Therapy with CSII		
1	A greater sense of discomfort because I cannot intervene directly when glucose fluctuations occur	4.07 ± 1.07
2	Side effects (i.e., inflammation) due to the implanted pump/sensors	3.86 ± 1.17
3	That I find it difficult to completely relinquish control to this system	3.71 ± 1.49
Group 3: Therapy with AID		
1	That I find it difficult to completely relinquish control to this system	3.83 ± 0.72
2	A greater sense of discomfort because I cannot intervene directly when glucose fluctuations occur	3.67 ± 1.07
3	Side effects (i.e., inflammation) due to the implanted pump/sensors	3.58 ± 0.79

The Top 3 perceived barriers also showed similarities between the three groups. Possible side effects or complications during the implantation are barriers for each group. Interestingly, only participants using an insulin pen rated technical problems as a potential top 3 barrier. Most strikingly, participants already using an AID system reported that they would find it difficult to completely relinquish control to this system. This could indicate that current AID users have already made the experience of losing control and thus have higher fears that this loss of control gets even more pronounced with a fully implantable AID system.

All groups indicated that it would be a barrier that they could not intervene directly when glucose fluctuations occur. This is something worth considering for the further development,

as some sort of “fail safe” or manual control override could increase peoples’ sense of control and empowerment.

3.6.2 Qualitative results

All participants (n = 38) were asked about the potential impact of the BIP in four areas with open-ended questions.

3.6.2.1 Aspects of life that could benefit

The following aspects were named that could benefit from using the BIP. The word cloud shows the importance of different aspects of life with a larger font size indicating more frequent mentions.

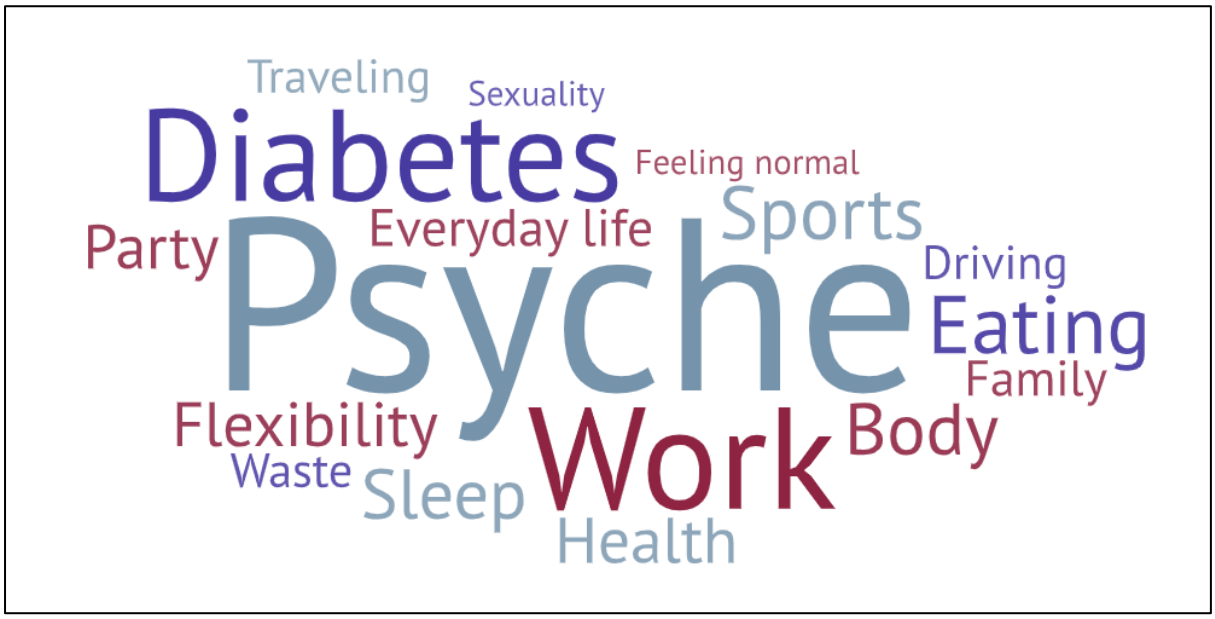

Figure 10. Aspects of life that could benefit from using a fully implantable AID system

The most frequently mentioned aspect that could benefit from using the BIP was psychological. Participants highly expected positive effects on quality of life, reduced burden (diabetes distress), and less thinking about diabetes. As expected, better glycaemic control and improvements regarding long-term complications (termed “Diabetes” in the word cloud) were also frequently mentioned as aspects that could benefit. Interestingly, participants also expected that their work life would benefit. As suggested above, participants also indicated that the reduced waste would be an aspect that could benefit from using the BIP.

3.6.2.2 Aspects of life that could become more complicated

The following aspects were named that could become more complicated by using the BIP. The word cloud shows the importance of different aspects of life with a larger font size indicating more frequent mentions.

Figure 11. Aspects of life that could become more complicated by using a fully implantable AID system

Aspect that might become more complicated related mostly to technical or practical aspects of the BIP such as the implantation procedure, taking an insulin pill, and being dependent on the technology. Corroborating other findings within this report, loss of control is an aspect that should be closely monitored and considered in the further development. Interestingly, “sports” was mentioned as an aspect that could benefit and could become more complicated. Regarding possible complications during sport, these concerns mostly relate to questions around safety against rupture.

3.6.2.3 Information required for safety

The following types of information were named as necessary to perceive the BIP as safe. The word cloud shows the importance with a larger font size indicating more frequent mentions.

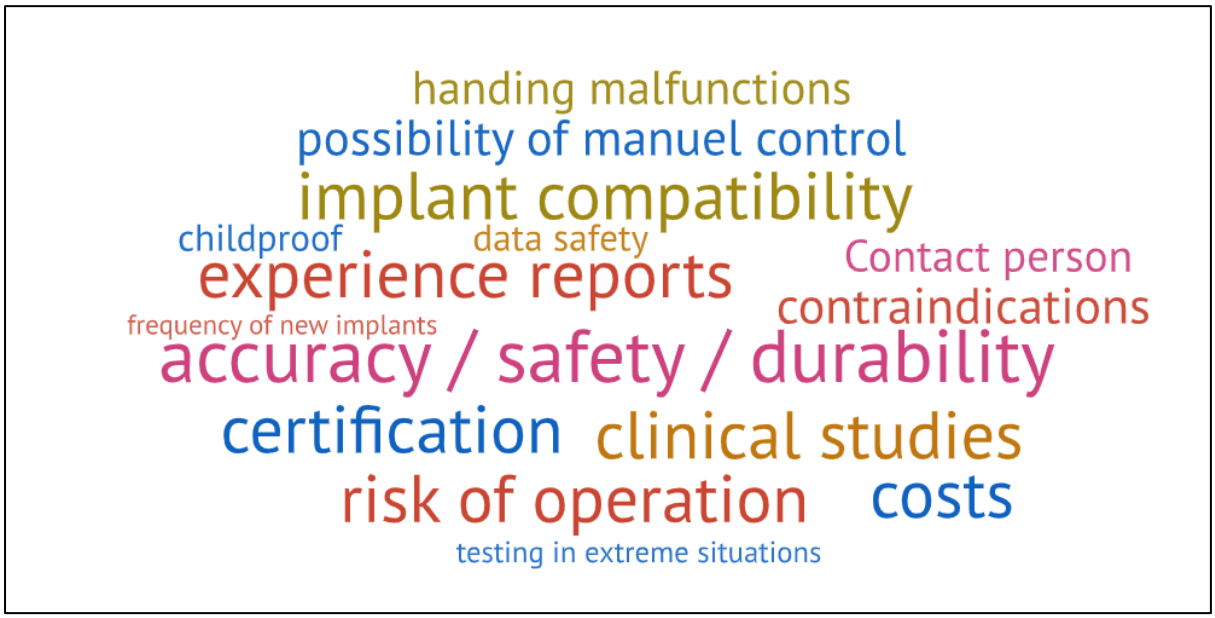

Figure 12. Required information to classify such a fully implantable AID system as safe

As expected, people with type 1 diabetes would need much information around accuracy and durability (particularly possible rupture of the insulin pill) as well as risks of the operation to consider the final BIP as safe to use. The requested need for clinical studies is very interesting and demonstrates the scientific awareness of people with type 1 diabetes. Participants also wished for experience reports from other users indicating the need to integrate people with type 1 diabetes early in the development and testing process. Also, having a contact person would be important; this should be someone from the diabetes team indicating the need to extensively train and educate diabetes teams in the specifics of the BIP.

3.6.2.4 Forget diabetes?

The following aspects were named that have to happen for people with diabetes to forget their diabetes using the BIP. The word cloud shows the importance with a larger font size indicating more frequent mentions.

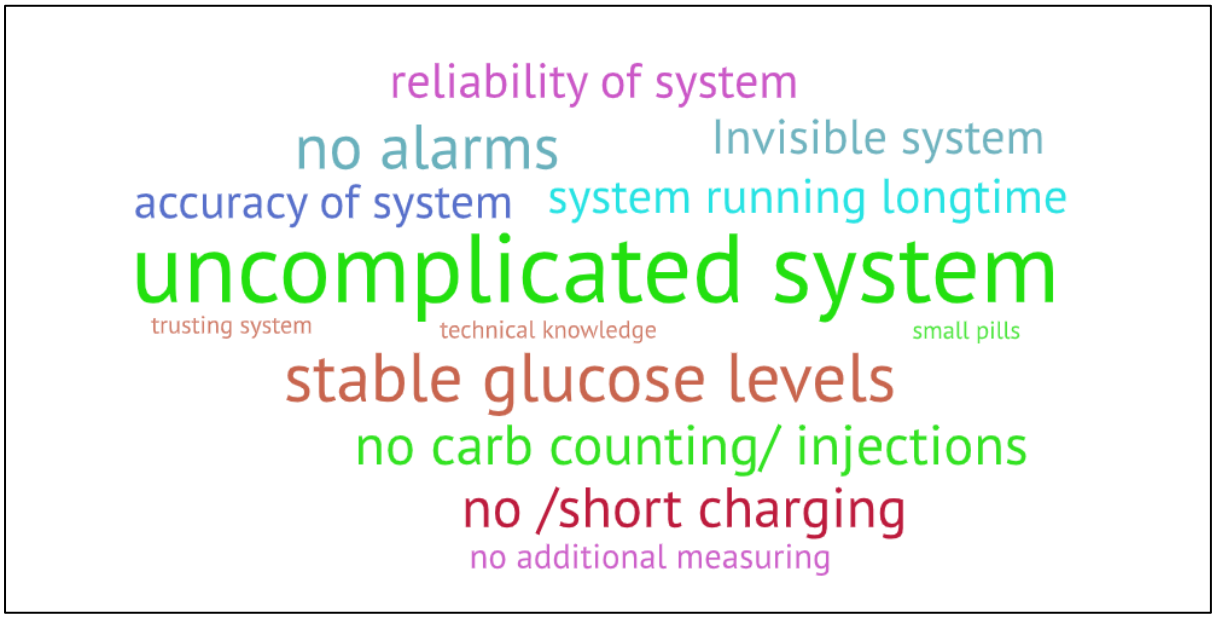

Figure 13. Requirements for forgetting diabetes due to using a fully implantable AID system

Many of the requirements for the BIP to let users forget their diabetes relate to technical aspects of the system such as being uncomplicated, accurate, easy to charge, having small pills, long running time, and reliability. Other factors that could lead to forgetting diabetes are achieving stable glucose levels and the elimination of having to estimate carbohydrates.

However, some participants explicitly stated that even with an AID system, forgetting diabetes would not be possible.

3.7 Comparison with current situation

All participants were asked to compare the potential usefulness of a fully implantable AID system with the status quo.

First, they were asked to what level the fully implantable AID system is an advancement over current treatment options. They indicated their response on a scale from 0 (no advancement) to 100 (very big advancement).

Second, participants were asked whether they could reduce burdens from diabetes with a fully implantable AID system. They rated the probability of such a reduction in diabetes distress on a scale from 0 (very unlikely) to 100 (very likely).

Third, participants were asked whether they could achieve a better quality of life with a fully implantable AID system. Again, the probability of such an improvement in quality of life was rated on a scale from 0 (very unlikely) to 100 (very likely).

Figure 14 shows the mean responses to these three questions. Overall, participants believed that a fully implantable AID system is a big advancement over current treatment options. They rated the probability to improve quality of life as higher as the reduction in diabetes distress.

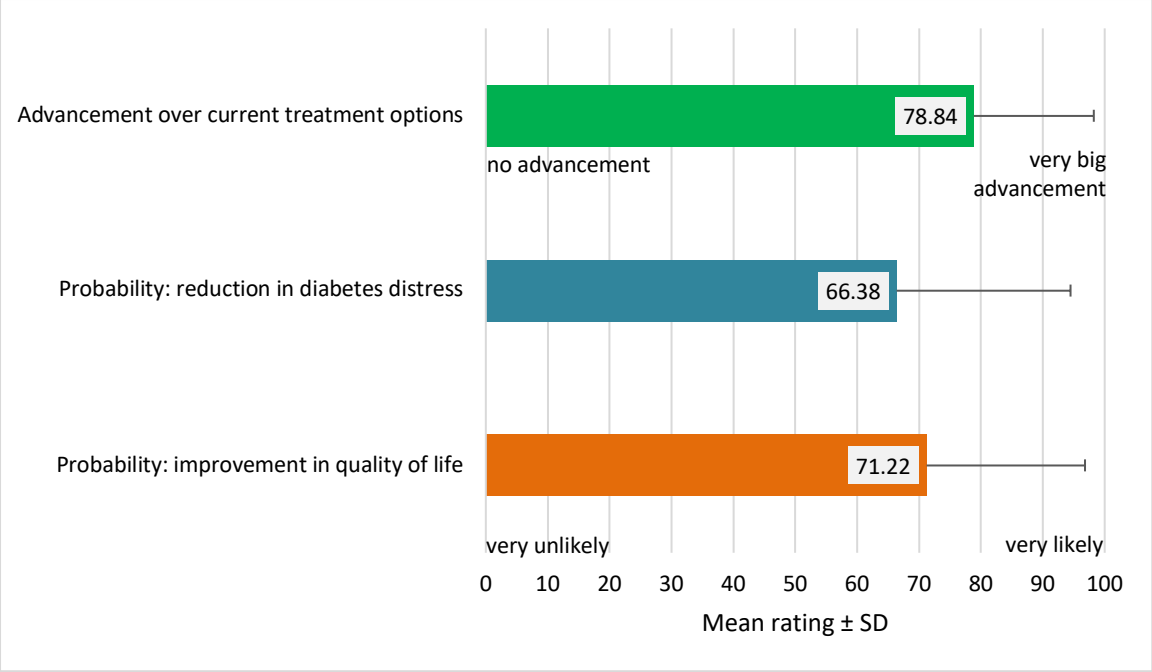

Figure 14. Comparison of the impact of a fully implantable AID system compared to status quo

The comparison of ratings regarding advancement over current treatment options for the three groups can be found in Figure 15 showing the box plots. As expected, participants with MDI therapy using insulin pen rated the advancement as highest, with the lowest rating in the most tech-savvy group (participants already using an AID system). However, ratings of advancement were very high across all three groups with no significant between-group differences ($p = 0.433$).

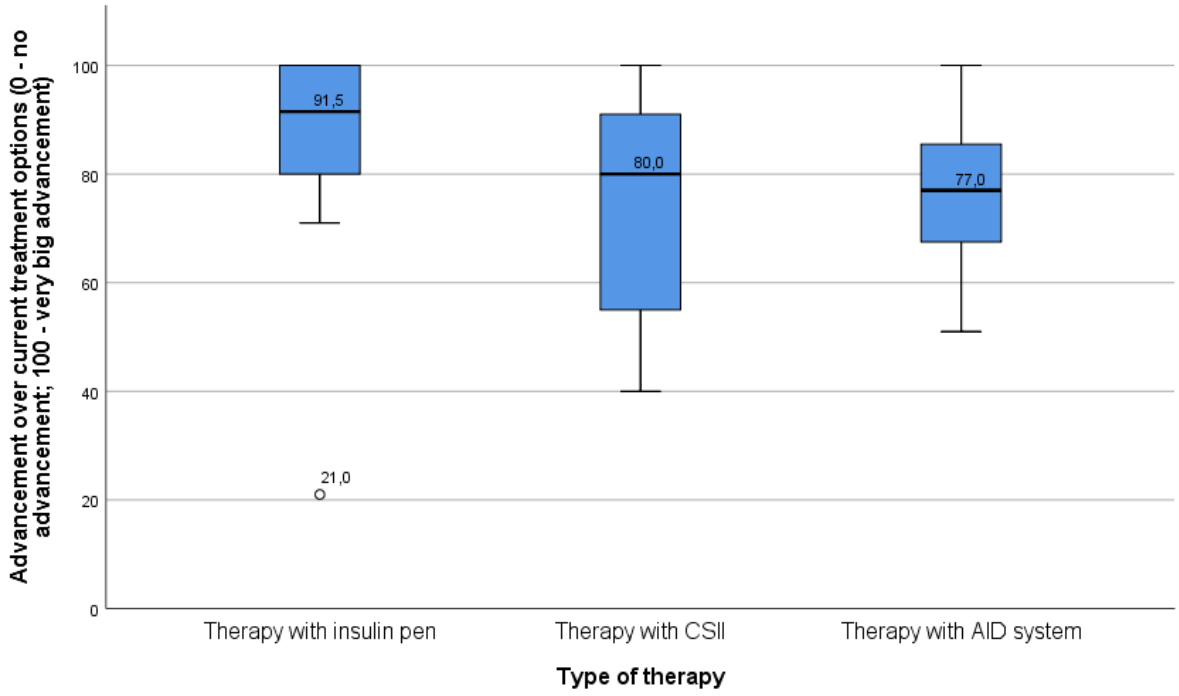

Figure 15. Advancement over current treatment options within each focus group

The comparison of ratings regarding the probability to reduce diabetes distress by using the BIP for the three groups can be found in Figure 16 showing the box plots.

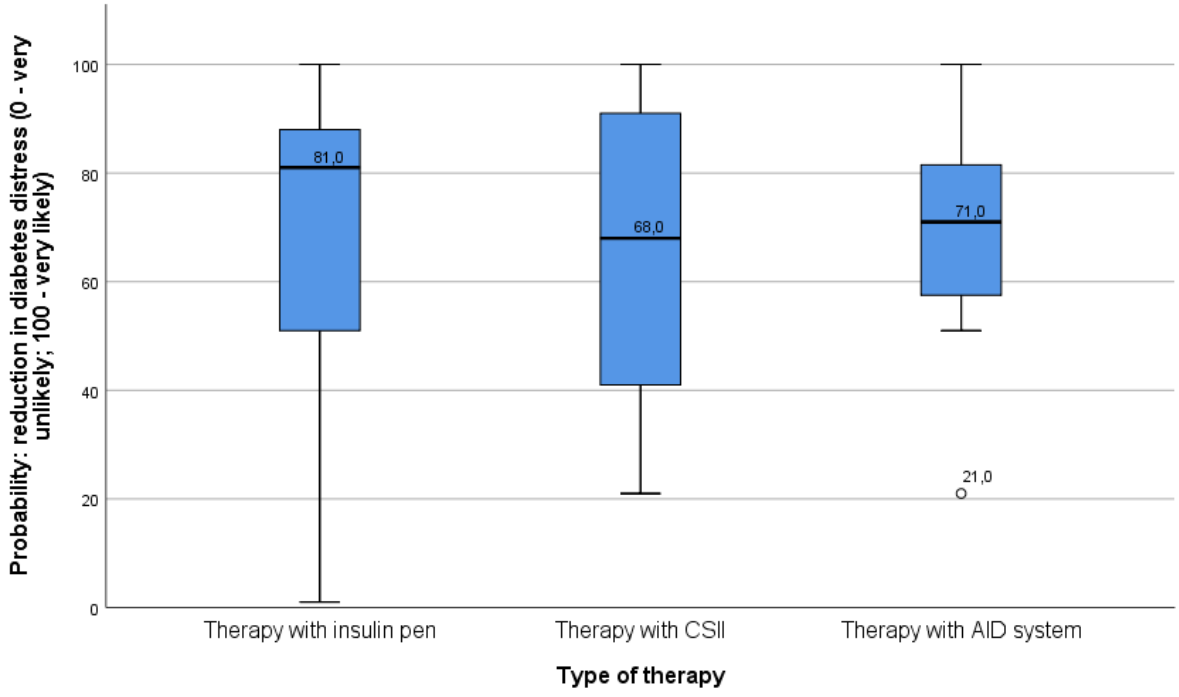

Figure 16. Probability to reduce diabetes distress by use of the BIP for the three focus groups

Participants with MDI therapy using an insulin pen indicated the highest potential to reduce diabetes distress by using the BIP. However, ratings were comparable between groups with no significant between-group differences (p = 0.976).

The comparison of ratings regarding the probability to improve quality of life by using the BIP for the three groups can be found in Figure 17 showing the box plots.

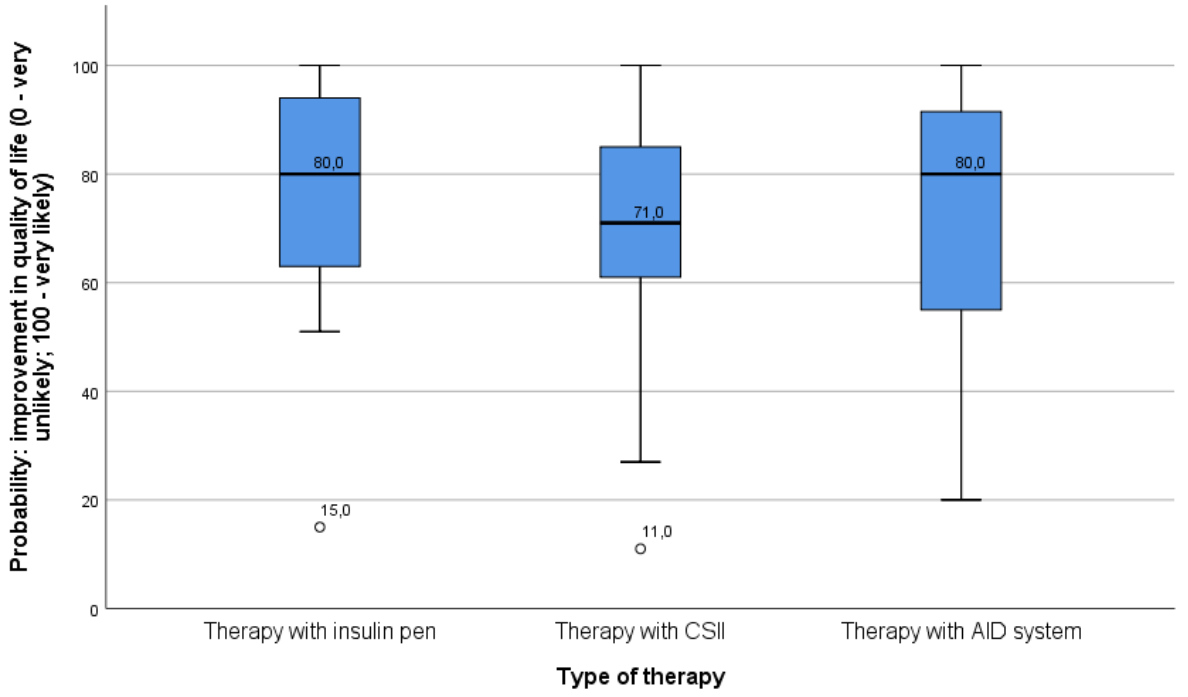

Figure 17. Probability to improve quality of life by use of the BIP for the three focus groups

All three groups showed comparable ratings of the potential of the BIP to improve their quality of life. Participants with CSII therapy indicated the lowest potential to improve quality of life, but still achieved a very high rating. There were no between-group differences (p = 0.901) corroborating the overall high potential of the BIP to improve quality of life in all three groups.

3.8 BIP: potential use

At the end of the interview, all participants were asked whether they would use a fully implantable AID system.

Overall, 76.3% (n = 29) participants indicated that they would use a fully implantable AID system such as the BIP (Figure 18). This high level of potential use did not differ between the three groups (p = 0.969).

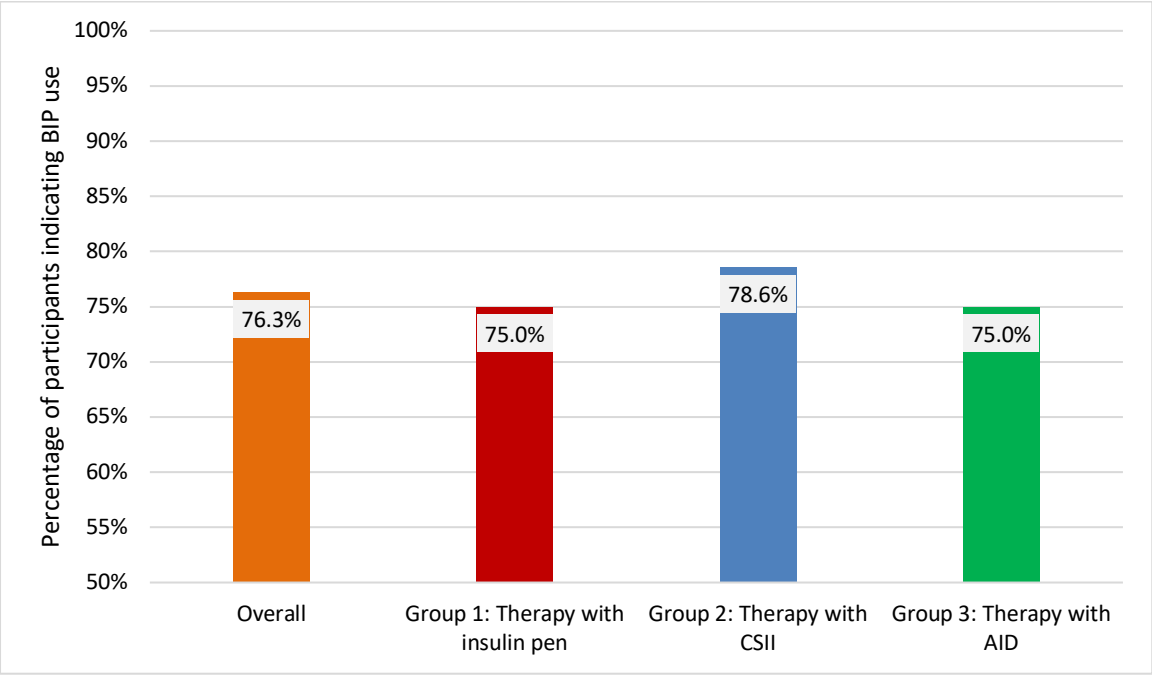

Figure 18. Percentage of participants indicating potential use of the BIP

These results indicate an already high acceptance of a fully implantable AID system that is independent of current use of diabetes technology.

3.8.1 Reasons for potential use of the BIP

Those participants indicating a potential use of the BIP were asked for their reasons and their expectations from using the BIP. In general, four topics emerged: Achieving better diabetes outcomes, aspects of practicability, advantages of functionality, and gaining flexibility.

- **Better diabetes outcomes (glycaemic control, quality of life, complications)**
  - *„Safer, better glycaemic control, joie de vivre, grow older"*
  - *"Less treatment effort with fewer/no hypoglycaemic episodes and no/hardly any blood glucose fluctuations."*
  - *"Better values, especially after eating, or after sports."*
  - *"Better values, less fluctuation, more safety"*
  - *"Closed-loop system that increases quality of life and makes everyday life easier."*
  - *"Fewer thoughts and worries about diabetes in everyday life…"*
- **Practicability**
  - *"That it does not have to be replaced but is also not visible or does not leave any scars."*

- *"… you no longer have to take things with you all the time."*
- *"No more problems with lipohypertrophies."*

- **Functionality**
  - *"… it virtually takes over the function of the pancreas and I no longer have to count carbohydrates and can eat what I want without thinking about it."*
  - *"… the functionality that it makes everyday life easier because you don't have to make decisions all the time.*
  - *"More safety in control and support for parents & people who need help in adjustment. Relief (mental and physical) for people with diabetes, who should also be relieved of time and energy by it."*
- **Flexibility**
  - *"No more worrying about not planning trips weeks in advance, eating when you want and what you want. More carefree life"*
  - *"Less need to worry about diabetes (calculation of carbohydrates, corrections, basal rate changes, etc.). More flexibility in everyday life (one would be "free" of objects such as pump and CGM and would also not have the corresponding luggage when traveling) - generally better glycaemic control."*
  - *"More flexibility in activities (vacations, sports, weekends,..). Less worries with allergies (patch allergy and it really bothers with diabetes!)."*
  - *"To be able to live a life like a non-diabetic without having to worry about it all the time."*
  - *"Freedom"*
  - *"Independence"*
  - *"Unburdened everyday life - being able to sleep through the night again"*
  - *"…being able to forget diabetes once in a while."*

3.8.2 Reasons against a potential use of the BIP

Those participants who said that they would not use a fully implantable AID system were asked for their reasons against potential use. Three topics emerged: Concerns about the implantation procedure with possible side effect, fear of loss of control, and concerns about technical aspects.

- **Implantation procedure / side effects**
  - *"A foreign material poses risks in terms of reliability of the technology, maintenance, health in terms of inflammation, adhesions, disruptive factor in the body."*

  - *“Operation, permanent foreign material in the body.”*
  - *“Great fear of side effects. What happens if the system is defective?*
- **Loss of control**
  - *“I prefer to have sole control over my diabetes.”*
  - *“High risks, few opportunities to intervene.”*
  - *“For the moment, still the fear of losing control over one's own therapy. With less involvement with one's own glucose levels and insulin consumption/need, one may at some point no longer know what to do if something doesn't work. In addition, technical problems may occur - what then?”*
  - *“I can not take it off myself.”*
- **Technical aspects**
  - *“Scepticism about the technology. Complex application.”*
  - *“Panic of not being able to intervene because the system is implanted and I can't see if the insulin capsule has arrived, burst, if the battery is really full and the system is working....”*

3.9 Closing comments

At the end, participants were given the opportunity to provide further thought and comments about the project and the BIP.

These statements were highly appreciative with not a single negative connotation. People with diabetes greatly supported the current development of the FORGETDIABETES project and expressed their thanks for conducting this type of research and development!

The verbatim translated statements were:

- *“The pill should not be too large. External control must be possible.”*
- *“It should be well thought out in terms of sleep (not like some CGM systems when you lie on your side, for example, it accidently "presses off" and it no longer transmits glucose values)”*
- *“Very exciting project, but big step to just "completely" hand over diabetes management after many years.”*
- *“I think research into ways to simplify diabetes therapy is very good and important. It takes some effort to adapt to something new, but with sufficient certainty it is possible. I am very curious to see how this project will develop and wish all partners good luck with the further development and research!”*
- *“I find it very exciting and good!”*

- *"The filling of insulin seems a bit strange (creepy), because it looks like it could be a weak point if the capsule gets stuck in the body or does not land where it should be. But it is great that such possibilities are considered, I hope in the future there will be something like that (also for people with little money)."*
- *"Would like to have more information about the current status of the project."*
- *"I am incredibly excited to see when this project moves into the clinical phase!"*
- *"Very very exciting! Thank you for letting me participate."*
- *"Thank you for researching and making life with diabetes easier!"*
- ***"Keep at it !!!!!!!!!!!!!!! You will help so incredibly many people !!!!! AND THANK YOU !!!!!!"***

4. Conclusions

4.1 Human factors

The semi-structured interviews provided interesting and novel insight in the attitudes, perceived benefits and barriers, as well as wishes and needs of people with type 1 diabetes regarding a fully implantable AID system.

The following conclusions can be drawn:

- **Potential acceptance**
  - Acceptance of a fully implantable AID system is already high: 76.3%
  - Acceptance is independent of the type of current therapy
- **Perceived benefits**
  - Better and simpler diabetes and glucose management
  - More flexibility
  - More time and energy for other areas of life / less worries
  - Reduced visibility of diabetes (devices)
  - Feeling "more normal"
  - Fewer autonomous decisions
- **Perceived barriers**
  - Loss of control
  - Fear of complications during the implantation
  - Fear of side effects
  - Lack of possibility to actively intervene (especially regarding fluctuations)
  - Many technical problems

- **Wishes and needs**
  - Manual override function or “emergency shutdown”
  - Extensive clinical studies
  - Small and safe insulin pill

The following **human factors** associated with a fully implantable AID system can be summarized from the findings:

- Perception of an expected improvement in glycaemic control
- Perception of practical aspects that simplifies everyday life
- Comprehension of the functionality
- Experience of gaining flexibility and independence
- Willingness to experience some loss of control
- Feeling safe regarding implantation and side effects

4.2 Further steps

The insights generated from the semi-structured interviews will now be used to development an assessment tool. This assessment tool will be designed to identify participants that will most likely benefit from using the BIP without having substantial barriers that might pose a safety issue.

4.3 First in-human testing

Some participants actively said that they would be willing to test the system once the clinical trials start.

5. References

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