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The Perceived Usefulness of a Contactless Sleep Monitor for Adults with Type 1 Diabetes: A Qualitative Study

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Abstract

When evaluating the potential of an alternative method to detect physiological changes that occur during hypoglycemia it is important to be aware of the perceived usefulness among potential users [17]. The aim of this study was to explore the perceived usefulness of a contactless monitor for detection of hypoglycemia among people with type 1-diabetes (T1D). Semi-structured interviews (n =8) were conducted after people with T1D used the contactless monitor at home. The interviews were analyzed using a thematic approach. Five overall themes were identified. Overall, the participants reported that the contactless monitor was an acceptable method to detect nocturnal hypoglycemia.

Keywords

Type 1 diabetes - Nocturnal Hypoglycemia - Contactless Monitor - Perceived Usefulness - Qualitative Interview

1 INTRODUCTION

Diabetes mellitus (DM) is one of the fastest growing health challenges of the 21st century [1]. DM increases the risk of developing several complications, depending on the degree and duration of hyperglycemia [2]. People with type 1 diabetes (T1D) are dependent on continuous exogenous insulin administration due to β -Cell loss or destruction, affecting the insulin secretion [2]. Exogenous insulin increases the risk of developing hypoglycemia. [3]. Hypoglycemia can be severe and potentially life-threatening [4], as the body depends on a continuous supply of glucose to maintain vital functions [3]. In hypoglycemia, several physiological changes occur, including increased heart rate (HR) and respiration rate (RR) [5,6].

Close to 50% of all severe hypoglycemic episodes occur during sleep. Nocturnal hypoglycemia can negatively impact the quality of life as it results in emotions such as fear, anxiety, and worry [7]. Fear of hypoglycemia may prevent insulin therapy from equaling good glycemic control [8]. To avoid hypoglycemia, people with T1D often manipulate their blood glucose levels higher, by taking less insulin than needed to achieve good glycemic control [9]. However, this increases the risks of serious late diabetic complications due to hyperglycemia [10].

Currently, a continuous glucose monitor (CGM) is used as the first and main tool for detection of hypoglycemia [11]. However, the use of CGM is associated with several disadvantages. Among other things, a deviation between measured glucose values with CGM and venous blood glucose has been observed. It remains unknown why this deviation occurs, but it may be due to people sleeping on the body site at which the CGM is placed [12]. Furthermore, skin irritation or allergic reactions may occur when using CGM [13]. People with T1D who don't have access to a CGM will have to

perform self-monitoring of blood glucose (SMBG). However, reducing complications in DM requires frequent use of SMBG, which can lead to scarring, pain, and reduced sensitivity [14,15].

There is an increasing interest in alternative detection methods related to the physiological changes that occur during hypoglycemia [11]. Detection of hypoglycemia based on physiological changes requires measuring vital parameters. In conventional clinical practice, contact-based sensors are used [16]. Contact-based sensors are inappropriate for prolonged and repeated measurements as detection of nocturnal hypoglycemia would require [16]. To the best of our knowledge, no studies have investigated the possibility of contactless detection of nocturnal hypoglycemia.

Besides the potential of contactless monitoring to detect nocturnal hypoglycemia, an alternative detection method must be aware of the acceptance among potential users, as it's an essential parameter for the successful implementation of new technology [17]. Perceived usefulness is essential for technology acceptance [17]. In this paper, potential users are people with T1D as people with T1D are the ones who are most likely to have nocturnal hypoglycemia. The aim of the study was to explore the experience of perceived usefulness of a contactless monitor for detection of nocturnal hypoglycemia among people with T1D.

2 METHODS

2.1 Participants

People with T1D aged ≥ 18 years were recruited through social media, see figure 1. The inclusion criteria were people with T1D using a Flash Glucose Monitor (isCGM) Freestyle Libre 1 or 2 and the ability to understand and speak in Danish or

English. Exclusion criteria were sleep apnoea, hypoglycemia unawareness, pregnancy, electronic implants, or children sleeping in bed. The study was performed between February 2022 and June 2022 at Aalborg University, Denmark. According to the Declaration of Helsinki, each participant signed a written informed consent.

The study wasn't found notifiable by the local ethics committee or Medical Research Ethics Committees (MREC).

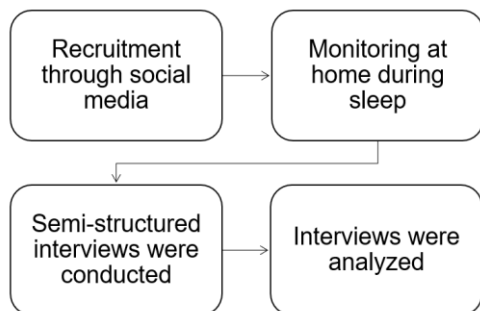


Figure 1. The flowchart illustrates the process from recruitment to analysis of the interviews.

2.2 Data and Procedures

The present study was originally a part of a mixed methods study and was therefore presented as a sub-study. The original study consisted of the present study and a quantitative part where it was investigated if contactless monitoring of heart rate and respiration rate could detect nocturnal hypoglycemia. The quantitative part is expected to be published elsewhere.

A qualitative interview study was performed to explore the perceived usefulness of a contactless monitor among people with T1D. To provide a realistic experience of using the contactless monitor, the participants were instructed to monitor HR and RR during sleep throughout a period of 5-8 weeks at home. The contactless monitoring system consisted of a monitor (Sleepiz One, Sleepiz AG, Switzerland) and a wifi hotspot (Huawei 4G Mobile WiFi). The monitor used radar technology and collected HR and RR. Each participant was instructed to place the monitor at the bedside. The hotspot was placed in the same room as the monitor. All participants were instructed to remain on their usual insulin therapy and continue their normal lifestyle throughout the study. The participants turned on the monitor before they went to bed and turned off the monitor after waking up in the morning. If the participants woke up during the night, they could get out of bed leaving the monitor turned on.

At the end of the study period, a 3-8 minute semi-structured interview was conducted with all participants. A semi-structured interview is characterized by the possibility of making the interview relevant to the desired focus by preparing an interview guide with research and interview questions in advance [18]. The interview guide was based on, perceived usefulness [17], which formed the basis for research and interview questions. Perceived usefulness was the overall keyword that formed the framework for the four interview questions, see figure 2. The interviews were conducted by one

of the researchers of the team using telephone or Microsoft Teams. All interviews were audio-recorded, transcribed verbatim, and fully anonymized.

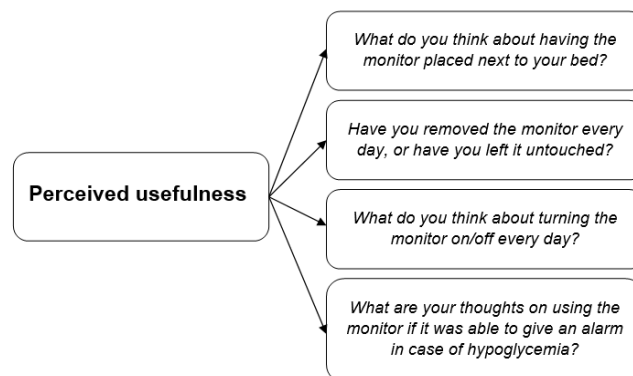


Figure 2. The keyword, perceived usefulness, and related interview questions.

2.3 Data Analysis

The interview data were analyzed using Kvale and Brinkman's meaning coding, meaning condensation, and meaning interpretation [19].

Three authors (KHS, TFH, and JE) independently did the meaning coding by reading through the transcripts, while relevant themes were identified and coded [18,20]. Afterward, the identified themes were unified. In case of overlapping themes, these were compiled. The themes were arranged in a matrix with accompanying quotations from the transcripts. The quotations for each theme were compressed into short and precise formulations by meaning condensation [18]. The results were based on self-understanding as the context of interpretation [18].

3 RESULTS

3.1 Participant Characteristics

Eight participants aged 24-68 years (48.5 ± 14.7) with T1D were included in the study. Diabetes duration ranged from 0.67-53 years. For an overview of baseline characteristics see Table 1.

Parameter	Mean	\pm SD
$N = 8$		
Female ($n = 4$)		
Age (years)	48.5	14.7
Diabetes duration (years)	21.7	16.7

Table 1. Baseline characteristics of participants in this study

3.2 Overall Themes

All participants completed a semi-structured interview. It was assessed that data saturation was achieved, as no new themes emerged in the final two interviews. Five overall themes were identified, see figure 3.

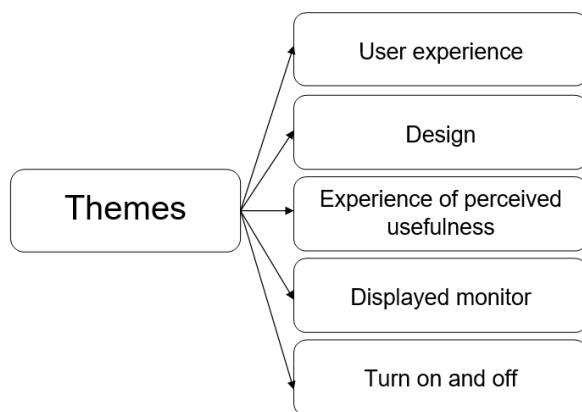


Figure 3. Overview of themes based on semi-structured interviews

3.3 User Experience

The overall experience of using the contactless monitor was that it was easy and clear to use. It quickly became a habit to use the monitor.

'It means nothing for me to turn it on, it's like turning off my night light. It's that easy and clear. (...) So for me, it just quickly became a habit, also because it just stands right there. So, it's super easy. I wish everything with diabetes was so easy. That would be great.' (P1)

A few participants described a feeling of surveillance but found this insignificant in terms of use.

'Well, something is monitoring me at night. It's strange, but there is nothing in it, I can't keep up with anything, so I don't know.' (P7)

One participant experienced some frustrations using the monitor due to repeated defects consisting of problems with transferring data. Except for problems due to defects, the participant found the actual use of the monitor unproblematic.

'Besides the fact that it sometimes doesn't work, it has not really been that bad (...) But I can just say that if it had caused any more problems, then I probably would not bother anymore.' (P3)

3.4 Design

Two participants suggested changing the design of the monitor, to improve the perceived usefulness. It was suggested to extend the range of the monitor so it could be placed on e.g. a shelf or a bedside table. Furthermore, it was suggested to change the location of the indicator light on the monitor, to avoid nuisance from the light during sleep.

'(...) You could redesign it on the back, then it would be smart. Or on the other side, but if you then sleep on the other side of the bed, it will still light right in your face. So, if it's in the back where you put the power plugin, then that's fine.' (P1)

One participant expressed concerns about using the monitor, due to lack of aesthetic expression.

'(...) It's not that pretty [contactless monitor], and I would say that in the long run, it would be annoying to have it there.' (P6)

3.5 Experience of Perceived Usefulness

All participants evaluated that if the contactless monitor could give an alarm in case of hypoglycemia, it was an acceptable supplement to existing methods of detection. Thus, they found that the monitor has the potential to provide greater security during the night, leading to better sleep quality.

'Well, I think that for me it's an indispensable tool [isCGM]. So, you can say that I experience low blood sugar occasionally, and it gives me enormous peace of mind that something is waking me up. Then I think my sleep quality is better because there is something that wakes me up. Whether it's the alarm [contactless monitor] or the device [isCGM], it wouldn't matter to me. The security about sleeping is just nice.' (P6)

Two participants did not fear nocturnal hypoglycemia, and therefore found alarms for hypoglycemia irrelevant.

'(...) I have turned off my alarms because sometimes I am too high and other times, I am too low. So, but it still runs with me, it's not like I get completely down [hypoglycemia].' (P3)

3.6 Displayed Monitor

All participants had the monitor displayed during the entire study period. The majority stated that it made it easy to use the monitor daily. Some participants indicated that it would probably cause frustration to remove it every day.

'I left it untouched [contactless monitor]. Because then it's so easy. Then it's just to press a button twice a day. If I had to set it up and remove it, I think it would be a much more difficult thing to do and a much more tiring experience.' (P2)

3.7 Turn On and Off

All participants turned the contactless monitor on and off without any problems. However, all participants experienced that it could be difficult to remember turning it on and off. Several participants described that it quickly became a routine to turn the monitor on and off during use.

'Well, it meant nothing to me. In the evening I turn it on [contactless monitor] and then I go out and brush my teeth. In the morning when I have measured blood glucose and stuff like that I turn it off. So, it's just a rhythm.' (P4)

4 DISCUSSION

4.1 Perceived Usefulness

The aim of the study was to explore the experience of perceived usefulness of a contactless monitor for detection of nocturnal hypoglycemia among people with T1D. Overall, the participants reported that the contactless monitor was an acceptable alternative for existing nocturnal hypoglycemia detection methods if the monitor was able to give an alarm in case of hypoglycemia. Some participants emphasized that their use of isCGM gave a feeling of safety during sleep and mentioned that the monitor had the potential to provide equivalent safety. These findings support previous research in which CGM was able to provide a feeling of safety during sleep [21]. Furthermore, the use of CGM gave fewer disturbances during sleep and made people with T1D fall asleep more easily [21]. Though most of the participants found the opportunity of an alarm in case of hypoglycemia essential, a few participants experienced no fear of nocturnal hypoglycemia and found the alarm less relevant. Among some participants, there were divided opinions on whether alarms from their isCGM disturbed sleep. Previous research found that alarms from CGM were essential but could disturb sleep [21]. Moreover, too many alarms were annoying and made some people with T1D turn off the alarms [21].

The participants' acceptance of the monitor as an alternative method might increase the opportunity for a successful implementation since perceived usefulness promotes use and acceptance [22]. Perceived usefulness may be affected by usability, whereby it indirectly has an impact on the acceptance of a new technology [22]. The participants stated that the contactless monitor was easy and clear to use. The use of the monitor only required the participants to turn the monitor on and off every day, which was not associated with difficulties. The usability is thus assessed to have a positive influence on perceived usefulness and therefore increase a successful implementation [22].

4.2 Strengths and Limitations

One of the main strengths of the present study is that the results address an important gap of knowledge according to perceived usefulness of an unexplored alternative detection method. Another strength is that the participants included in the study are diagnosed with T1D, who are the potential end users of the contactless monitoring system. Their perspectives according to perceived usefulness will gain important insight to promote future successful implementation [17].

A limitation is that the interview was conducted using a telephone as it can influence the interaction between interviewer and participant [18]. Another limitation is that the recruitment of participants through social media might have influenced the results. Participants using social media might have a greater acceptance and understanding of technology. One way to reduce this potential confounder could be recruitment through e.g., general practitioners or diabetes clinics. Finally, a limitation is the short duration of the interviews.

5 CONCLUSION

The participants reported that the contactless monitor was an acceptable alternative to detect hypoglycemia compared to existing detection methods. Future research would be needed to further evaluate the potential of contactless detection of nocturnal hypoglycemia.

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