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Author: Nouras Al-Tamimi, Natasha Slater, Reem Kayyali, Amr ElShaer

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Patients' with type 1 and 2 diabetes perceptions towards current and advanced technologies of blood glucose monitoring: A prospective study

Nouras Al-Tamimi MPharm¹, Natasha Slater MPharm¹, Reem Kayyali PhD¹,

Amr ElShaer PhD², *

Author Affiliations:

¹ School of Life Sciences, Pharmacy and Chemistry, Kingston University, Penrhyn Road, Kingston upon Thames, Surrey, KT1 2EE, United Kingdom

²Drug Discovery, Delivery and Patient Care (DDDPC), School of Life Sciences, Pharmacy and Chemistry, Kingston University, Penrhyn Road, Kingston Upon Thames, Surrey, KT1 2EE, United Kingdom

* Corresponding authors

Dr Amr ElShaer

Drug Discovery, Delivery and Patient Care (DDDPC)

School of Life Sciences, Pharmacy and Chemistry, Kingston University,

Penrhyn Road, Kingston upon Thames,

Surrey, KT1 2EE, UK

Email: a.elshaer@kingston.ac.uk

T +44 (0)20 8417 7416 (Internal: 67416)

Abbreviations: CGM, HbA1c, NICE, NHS, SMBG, T₁DM, T₂DM, WHO, UKPDS

Keywords: Complications, diabetes mellitus, monitoring, technology

Running Head: Patients' perceptions of blood glucose monitoring devices

Key messages: self-monitoring of blood glucose in patients with diabetes achieves optimal glucose control and reduces complications. Advanced blood glucose monitoring technologies such as wristband, contact lenses, earlobe sensors, saliva

analysers and tattoos can improve adherence to glucose monitoring. Patient factors such as gender, age and ethnicity are influential in device selection.

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Abstract

Background

Intensive self-monitoring of blood glucose levels in patients with diabetes achieves optimal glucose control, hence reducing the likelihood of complications.

Methods

This is a prospective, cross sectional study targeting adults with diabetes in community pharmacies and diabetes patient groups in Central and West London, over a period of 10 weeks.

Results and Discussion

In all, 207 adults with diabetes were included in the analysis of results. This study showed that 24.2% (n=50/207) of the participants were asked to monitor their blood glucose between 3-4 times per day when diagnosed, however only 14.0% (n=29/207) were compliant when the study commenced. A further decline in adherence, from diagnosis to study initiation, was seen in participants who had been asked to monitor their blood glucose levels at least five times per day. When questioned about their reasons for poor adherence, 59.2% (n= 123/207) of the cohort indicated that this is due to the painful, uncomfortable and inconvenience nature of testing. In addition, 75.8% (n=157/207) of the participants expressed their desire for a non-invasive monitoring device and 73% (n=151/207) would be satisfied using one of the pre-selected advanced technologies to monitor their blood glucose levels. The favoured advanced technology, selected by 49.8% (n=103/207) of participants, was the wristband. Statistical significance was seen between the type of diabetes and the device selected, with type 1 diabetes patients preferring contact lenses ($p=0.0219$) and tattoos ($p<0.0001$), whereas type 2 diabetes patients preferred earlobe sensors ($p=0.0009$) and saliva analysers ($p<0.0001$). Participant gender, age and ethnicity also influenced device selection.

Keywords: Complications, diabetes mellitus, monitoring, technology

1. Background

Diabetes mellitus is described by the World Health Organisation (WHO) as a global epidemic, with 422 million adults currently living with this chronic condition. [1] It is anticipated that this number will rise steeply to 552 million adults by 2030.[1] In the United Kingdom, diabetes mellitus costs the National Health Service (NHS) £10 billion per annum, with 80% of this figure allocated to treating complications associated with the condition.[2]

Individuals with diabetes can experience acute and chronic complications as a result of the condition. Acute complications of diabetes include episodes of hyperglycaemia and hypoglycaemia, where the blood glucose levels rise above 10 mmol/L or decrease below 4 mmol/L respectively. [3] Chronic complications experienced by diabetes patients range from heart attacks and strokes to retinopathy, renal failure, neuropathy and lower limb amputations. [4] To minimise the likelihood of diabetes complications, patients are encouraged to self-monitor their blood glucose levels in order to achieve optimum control [5]. This advice has been supported by the findings from many studies which have explored the relationship between blood glucose control and the incidence of diabetes complications. Research conducted by Martin S, Schneider B et al [6] investigated whether there was a relationship between self-monitoring of blood glucose (SMBG) and disease related morbidity and mortality, concluding that SMBG was associated with a reduction in diabetes complications. In addition, the results from a 20-year, multi-centre study, conducted by Holman R and Turner R [7], showed that complications associated with type two diabetes (T₂DM), could be significantly reduced by improving blood glucose control.

Type 1 diabetes (T₁DM) results from the autoimmune destruction of insulin-producing pancreatic beta cells. [8] Whereas T₂DM occurs due to an alteration in the balance between insulin sensitivity and insulin secretion. [9] At present the National Institute of Clinical Excellence (NICE) recommends that T₁DM patients should monitor their blood glucose levels at least four times per day and should aim for a glycosylated haemoglobin (HbA1c) value of less than 48mmol/mol (6.5%) [10]. For T₂DM patients, NICE specifies a HbA1c target between 48mmol/mol (6.5%) and 53mmol/mol (7.0%), although recent monitoring guidelines have changed [10]. The target for T₂DM varies depending on the type of diabetes management plan and whether the patient takes antihyperglycaemic agents, which may potentiate hypoglycaemia. Research by Mindera et al [11] revealed that when T₁DM participants (n=150) increased the number of SMBG tests per day, it resulted in a HbA1c value reduction. Their research showed that participants who practiced SMBG ≤ 4 per day, reported a reduction of -0.19% in HbA1c with each additional SMBG performed ($p < 0.001$). Similarly, a study

conducted by Ziegler et al [12] revealed that patients who monitored ≤ 5 times a day experienced a -0.2% decrease in HbA1c ($p < 0.001$), with each additional measurement of SMBG performed. Despite these findings, recommendations and the emphasis put on self-monitoring by UK healthcare professionals, research by Wagner J, Malchoff C et al [13] has shown that the level of non-adherence amongst patients with diabetes remains high, concluding that less-invasive SMBG technologies could enhance monitoring adherence.

Over the past four decades there has been a transition from measuring glucose concentrations using urine samples, to the development of SMBG meters [14] and reagent strip systems [14]. More than 60 glucose monitoring devices/strips are available in the UK with only few offered on the NHS. As the meters have evolved, they have become smaller, more varied in design and more advanced in their data management and connectivity functions. [14] To address some of the issues associated with SMBG adherence, several advanced technologies are currently undergoing development. For this research, six advanced SMBG technologies were selected, including contact lens sensors which measure ocular glucose concentrations [15], smart tattoos which change colour accordingly [16] and wristbands which function via reverse iontophoresis [17]. In addition to the aforementioned technology, saliva glucose analysers [18], skin sensors [19] and earlobe sensors, which detect glucose concentrations via ultrasound [20], were also chosen.

This study aimed to investigate patients' with diabetes perceptions towards current and advanced blood glucose monitoring technologies, in addition to exploring diabetes patients' expectations in relation to future SMBG devices.

2. Methods

A prospective, cross sectional, descriptive study was undertaken, in Central and West London, UK. These areas were selected because London has an ethnically diverse population, with 475,000 people currently living with diabetes. [21] A questionnaire was designated as the data collection tool

for this study. It was designed to investigate participants' perceptions towards current and advanced blood glucose monitoring devices, in addition to investigating factors that influence device acceptability. The questionnaires were anonymously distributed in community pharmacies and diabetes patient groups in Central and West London. Each participant was supplied with a copy of the questionnaire, a participant information sheet and an additional printed sheet, containing information regarding six, pre-selected advanced technology devices. The participants returned the questionnaire upon completion; however, they were able to retain the information sheets for future reference.

The questionnaire was composed of a mixture of open ended and closed ended questions, producing a total of 27 questions, which were separated into following six sub-sections: health perceptions (including several questions about diabetes complications), healthcare professionals, monitoring -past, monitoring-present, new technologies and demographics. Our questions about monitoring frequency were adapted from questions previously used by Barnard, K.D. et al [27]. One of the questions in the healthcare professional section utilised a five-point Likert scale to assess participant perceptions and attitudes towards their health care professional. Similarly, there was another question which utilised a five-point Likert scale in the new technologies section. In the latter, participants were asked to rate a number of potential design features for future blood glucose monitoring technology. There were also two questions within the monitoring-present section, which utilised a 10-point Likert scale to ask participants to describe how happy they were with their current blood glucose levels and current monitoring methods. By using Likert scale questions, participants were able to select the most appropriate option which aligned with their opinions. An open-ended question was used to ask the patients if they would use the new monitoring devices if available in the market and why they feel the new technology would be better than the current methods available. Also, participants were asked to identify any additional features they would like to see in a glucose monitoring device. Participants were not asked to provide any identifiable information.

Prior to commencing this research, a pilot study was conducted involving fourteen participants with diabetes. This sample size equated to 5% of our required sample size for the main study, and it had a ratio reflective of type 1 and type 2 diabetes. Participants were selected at random to participate in the pilot study, and their input was used for face and content validation of the questionnaire. Findings from the pilot study suggested that the survey structure was highly welcomed, and no adjustments were necessary. To minimise study bias, individuals who participated in the pilot study were excluded from main study.

To determine the sample size required for this study, a power calculation was carried out. Based on diabetes mellitus prevalence of 475,000 across London, the minimum sample size at 90% confidence level and 5% margin of error was 271. With a prevalence of 10% T1DM and 90% for T2DM in UK, at least 27 patients with T1DM should be recruited.[22]. For T2DM at least 244 patients should to be recruited to achieve CI of 90%.

The inclusion criteria required participants to have diabetes, have monitored their glucose level previously, aged over 18 years and able to speak and understand English in order to provide consent. Participants were excluded if they were aged below 18 years old, did not monitor their blood glucose, were unable to understand written or spoken English, had cognitive impairment, or were unwilling to participate. Participants were supplied with an information sheet which clearly explained that their consent would be implied if they were to complete the approved questionnaire; however, participants were informed that they could withdraw from the study at any point. In addition, patients were provided with monitoring device information sheet written in lay terms and described how to use the device and how the device works- in terms of monitoring glucose- and whether it was continuous or non-continuous glucose monitoring device. Participants were advised to speak to the pharmacist or the researcher or to contact the research team if they have any further queries.

The study was conducted over a ten-week period from January 2015 – March 2015. The completed questionnaires were collected immediately, if the researcher was present or left at the community pharmacies to be collected at the end of the data collection period. All collected questionnaires were checked for meeting the inclusion criteria before analysis. The collected data was tabulated and analysed using Microsoft Excel. A chi-square inferential test was used to identify correlations between demographics and responses provided. The level of statistical significance was set at $p < 0.05$. The questionnaire was approved by the Faculty of Science, Engineering and Computing Ethics Committee at Kingston University.

Results

A total of 377 questionnaires were distributed and 211 were returned. However, 16 were excluded as 4 participants did not have diabetes and 12 never monitored their glucose level therefore did not fit the inclusion criteria. Consequently, a 51.7% (195/377) response rate was achieved. Demographic details of the cohort are presented in Table 1. Although the sample size is under-representative for T2DM, it is over-representative for T1DM as 76 patients with T1DM were recruited.

Incidence of Diabetes Complications

This study identified that 42.1% ($n=82/195$) of the cohort had experienced diabetes complications. The following conditions: retinopathy, nephropathy, neuropathy, cardiovascular conditions and limb amputations, were defined in the questionnaire as complications. In addition, the results showed that 28.2% ($n=55/195$) of the cohort who had suffered from complications, had lived with diabetes for over 10 years (Figure 1). These findings demonstrate a positive correlation between time elapsed since diagnosis and the incidence of complications ($r=0.9$).

Participants were asked about their blood glucose control and their experiences of hyperglycaemic episodes (blood glucose level of 10 mmol/L or above) to determine whether complications were associated with poor control. Irrespective of diabetes type, all participants reported an HbA1c value

higher than that recommended by NICE. The results showed that 87.6% (n= 171/195) of the cohort had experienced hyperglycaemic episodes. In addition, the results also showed that increased frequencies of hyperglycaemic events were associated with poor diabetes control (r=0.9).

Frequency of blood glucose monitoring

The cohort was asked about how often they been asked to monitor their blood glucose levels and this data was compared to their current monitoring frequency enabling participant adherence to be assessed. The data shows that 43.4% (n=33/76) of participants with type 1 diabetes were asked by their healthcare team to monitor their blood glucose between three or four times a day. However, a tenth of those did not follow this recommendation as only 34.2% of the participants indicated following their recommended monitoring regimen. On the other hand, 42.9% (n=51/119) of participants with type 2 diabetes were asked to monitor their glucose between 3-4 times per day, however only 2.5% (n=3/119) were following this monitoring guidance. For type 2 participants, increasing the recommended number of glucose monitoring times per day was associated with a significant decline in adherence.

Current technology usage and perceptions

When the participants were asked about their current methods of monitoring glucose levels, 77.8% (n=158/195) reported using a finger prick test, whilst 6.6% (n=13/195) measured glucose levels using urine samples and 2.0% (n=4/195) used a continuous blood glucose monitor (CGM) (Figure 2a).

Using a Likert scale (0-10), participants were asked to ascribe a quantitative value to their level of satisfaction with their current blood glucose monitoring equipment. A value of 0 was given by participants who were unhappy with their current equipment whilst a value of 10 would be given by a participant who was very happy with their current equipment. Overall, 60.0% (n=117/195) participants rated their satisfaction level as ≤ 5 , showing a significant number of the cohort being

dissatisfied with the technology used. Reasons given for the rating provided were the monitoring device being uncomfortable [33.8% (n=66/195)], inconvenient [36.9% (n=72/195)] and painful [29.2% (n=57/195)]

(Figure 2b).

Desired features of future blood glucose monitoring technology

The cohort was asked to rate a number of potential design features for future blood glucose monitoring technology using a Likert scale with 1 being (lowest) to 5 (highest) rating, depending upon the perceived level of importance. The preferred choice, reported by 49.2% (n=96/195) of the participants, was the 'easy to use' design feature, also 49.2% (n=96/195) required the technology to be painless, thus improving the overall comfort level. The cohort ascribed low values to several design features including style (41.0%) and voice control (33.8%), suggesting that these features were perceived as less important when considering the future design of blood glucose monitoring technologies. More than three quarters (75.3%) of the participants provided details of their desire for non-invasive monitoring technologies. In addition, over half the participants (52.8%) preferred non-continuous glucose monitoring in comparison to CGM. The results showed a statistical significance ($p < 0.0001$) between type of monitoring preference and the daily frequency of diabetes testing, hence those who tested more frequently preferred CGM.

Perceptions towards advanced blood glucose monitoring technology

Participants were shown six potential blood glucose monitoring devices with 74.3% (n=145/195) of the cohort saying they would be happy using the new devices, which may be released in the near future. Overall 49.7% (n=97/195) of participants preferred the wristband option (Figure 3a). There was no statistical significance ($p > 0.05$) between the selection of wristbands and type of diabetes. However, there was statistical significance between type of diabetes and other device preferences.

T₁DM participants preferred contact lenses ($p<0.05$) and tattoos ($p<0.0001$), whereas T₂DM participants showed statistical significance preference towards earlobe sensors ($p<0.0001$) and saliva analysers ($p<0.0001$).

The study considered whether gender had an impact on device selection (Figure 3b). Males showed a statistical significance preference for the wristband ($p<0.05$). However, females showed a statistical significance preference towards contact lenses ($p<0.01$) and tattoos ($p<0.001$).

Additionally, the influence of age on device selection was also investigated. Results in Figure 3c show that tattoos were the preferred device choice for 47.2% ($n=17/36$) of participants, aged under 30 years old. However, tattoos were not selected by any participant aged over 30 years old. Participants preference towards saliva analysers varied across the age groups, with 53.7% ($n=29/54$) participants, aged between 50-59 years, selecting this device as their first choice whereas saliva analysers were not selected by any participant aged between 21-29 years old. When considering participants, who were 60 years of age or older, 73.8% ($n= 65/88$), preferred the wristband option (Figure 3c).

A difference between device selection and participant ethnicity was also observed (Figure 3d). All ethnic groups selected earlobe sensors; however this device was particularly popular amongst black participants. Interestingly smart tattoos, saliva analysers and skin sensors were selected by all ethnicities except black participants.

Discussion

It is widely recognised that elevated blood glucose levels, poor monitoring adherence and extensive disease duration are all contributory factors to the development of diabetes complications. This study has identified that all participants, irrespective of their diabetes type, failed to achieve a HbA_{1c} value within the target range, as specified by NICE, with 42.1% of participants experiencing complications.

In this study participants were asked about how frequently they had been recommended to monitor their blood glucose levels, compared to their actual monitoring frequency. This enabled participant adherence to be assessed. There was a noticeable decline in participant adherence from what had been recommended by their healthcare team. Non-adherence to monitoring can lead to disease related to complications. The research conducted by Martin S, Schneider B et al, [6] investigated the incidence of disease related complications and mortality in diabetes sufferers. Their findings showed that the incidence of complications was lower in the group who regularly monitored their blood glucose in comparison to the group who failed to monitor. Rodriguez-Gutierrez [28] acknowledged the wealth of evidence surrounding blood glucose monitoring in diabetes; however, they also report discordance in the literature surrounding frequent monitoring and the reduction of diabetic complications. Further research into the association between frequent monitoring and diabetic complications is required.

This study aimed to investigate patients' with diabetes perceptions towards current and advanced blood glucose monitoring technologies. When participants were questioned about their reasons for their poor adherence, it was interesting to discover that most of the cohort was relatively dissatisfied with their current monitoring technology, citing their reasons for dissatisfaction as painful, inconvenient and uncomfortable testing. These findings have been supported by qualitative research conducted by Wong O, Siew C et al [23] which recognised that the uptake of self-monitoring is low in many countries and reported that the factors influencing this uptake include the painful nature, inconvenience and complexity of currently available self-monitoring blood glucose (SMBG) equipment.

Self-monitoring is an integral part of diabetes management, aimed at achieving optimum blood glucose control however a review by Benjamin EM [24], recognised that the true potential of blood glucose monitoring has not yet been reached, thus providing support for new, innovative technologies to improve monitoring adherence. This study differentiates itself from previous

research by asking participants about their attitudes and perceptions towards advanced technologies while considering the factors that may influence their choice when selecting a monitoring device. When questioned, almost three-quarters of the cohort were prepared to try a less invasive, advanced technology to monitor their blood glucose levels. These findings are supported by research conducted by Wagner et al [13] which showed that over two-thirds of their study participants reported avoiding blood glucose monitoring, due to the invasive nature of testing. It was also reported that invasive technology was associated with increased levels of anxiety and suggested that this was another serious barrier to self-monitoring of blood glucose levels [13]. The psychological impact of SMBG is beyond the scope of this study; however, the number of non-compliant participants was similar in both studies.

Participants were asked about desired design features for advanced technology devices. They cited an easy to use, pain free and comfortable product was most important to them, whereas design features such as style and voice control were considered less important. Furthermore, this study aimed to investigate whether patient factors influenced advanced technology device acceptability. Prior to commencing this study, six advanced technologies, which have been proposed for future development, were selected. Over three-quarters of the participants were prepared to try an advanced technology monitoring device. The preferred device, selected by 49.7% of participants was the wristband. There was no statistical significance between the selection of wristbands and type of diabetes. However, there was statistical significance between the type of diabetes and other device preferences. T₁DM participants preferred contact lenses and smart tattoos, whereas T₂DM participants preferred earlobe sensors and saliva analysers. Looking closely at T1DM participants who opted for tattoos, it was found that all the participants were under the age of 29 years old with 82.3% of those being females (n=14/17).

The results from this study also show that gender can influence advanced technology device acceptability. Statistical significance was detected between males and their preference for the

wristbands, whereas females showed a statistical significance in their preference towards contact lenses and smart tattoos. The results come in line with the previous findings by Kelvin et al [24] who surveyed 1850 persons aged between 12-55 years old. It was concluded that young, highly educated females tend to wear contact lenses more often for cosmetic reasons. Tattoos are perceived by females as a body art, nonetheless previous studies did not report any significance difference between gender and prevalence of tattoos [26, 27].

Furthermore, the influence of age and ethnicity of device acceptability was also investigated. The results showed that participants under 30 years old preferred smart tattoos, whereas participants who were 60 years or older preferred wristbands. Participant preference towards the other devices varied across the age ranges, with saliva analysers being the most popular type of monitoring device in participants aged between 50 and 59 years. When considering the influence on ethnicity on device selection, earlobe sensors were the most popular choice amongst black participants, whereas smart tattoos, saliva analysers and skin sensors were selected by all ethnicities apart from black participants. Thus this study shows that diabetes patients are open to try new monitoring devices and patients' demographics will affect their selection of future glucose monitoring devices.

This study has some limitations. Firstly, the sample size for this study was relatively small and participants were selected from an urban community in Greater London, which may limit the generalisability of our results. Also, participants choice of monitoring device may have been influenced by confounding factors; however, we were not able to account for confounding factors in our statistical analysis. Further work with a larger sample size is required to enable a clear conclusion of variable influencing the monitoring device preference.

Conclusion

This research, despite the small sample size, has provided a remarkable insight into patient perceptions towards advanced technologies for blood glucose monitoring. The results showed that a

significant proportion of participants would be willing to try an advanced technology to monitor their blood glucose levels. Additionally, this research has also identified that patient factors such as type of diabetes, gender, age and ethnicity may be influential in device selection. For instance T1DM participants preferred contact lenses and tattoos, whilst T2DM participants opted for earlobe sensors and saliva analysers. The results from this study could be used to inform future monitoring device design and manufacturing.

These initial findings call for further research to be conducted, in order to identify other patient factors which may influence advanced technology device acceptability. This research considered six different advanced technology devices, thus further work should consider alternative monitoring devices.

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Author Disclosures

The authors have no competing interests to declare.

Contribution Statement

Reem Kayyali and Amr ElShaer conceived and designed the study, Nouras Al-Tamimi collected the results; Nouras Al-Tamimi and Natasha Slater analyzed the data; Natasha Slater, Reem Kayyali and Amr ElShaer wrote the manuscript.

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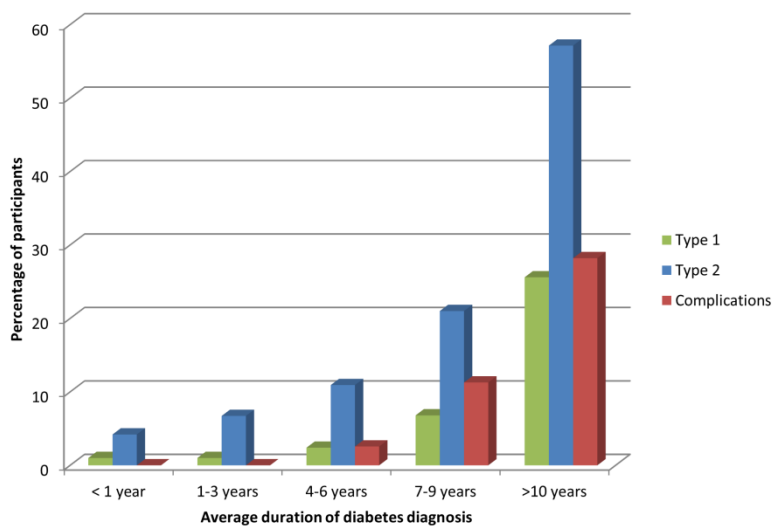
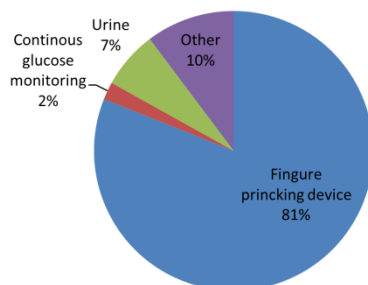


Figure 1: The number of diabetes complications and average duration of diagnosis in study population (n=195).

a



b

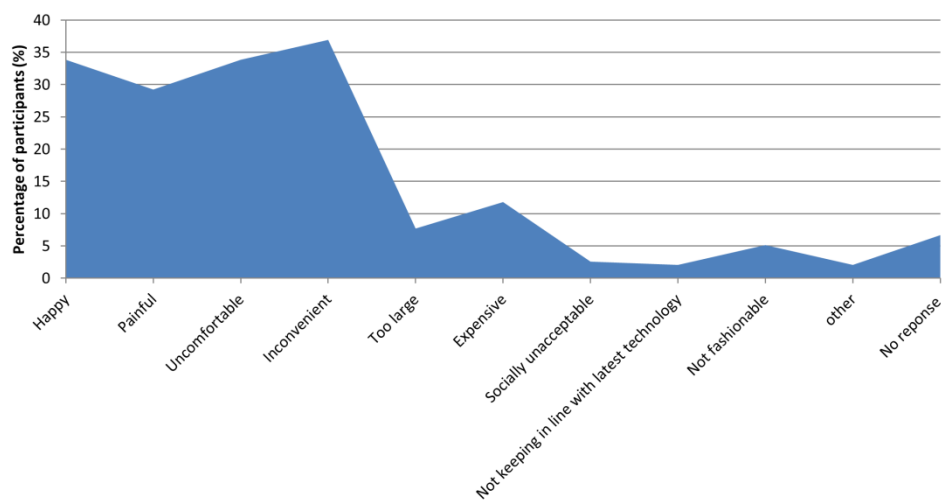


Figure 2: Current methods used to monitor glucose by participants (a) and their perceptions of the selected glucose-monitoring techniques (b) (n=195).

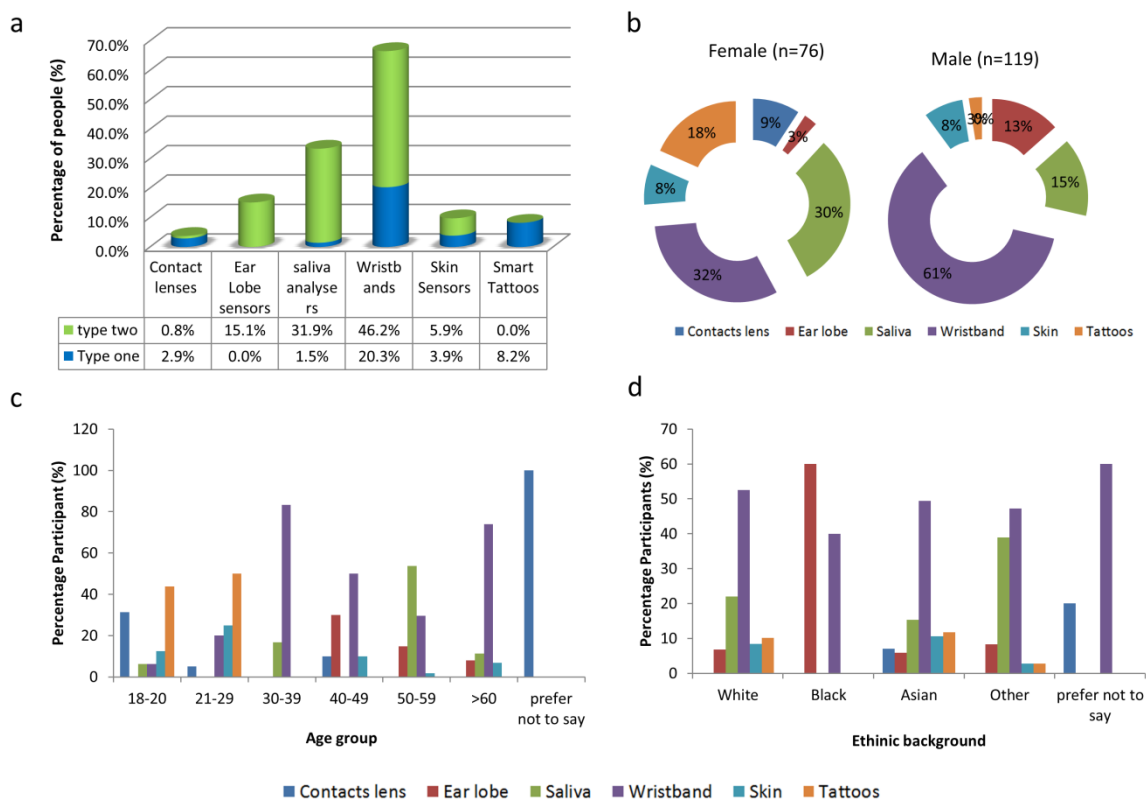


Figure 3: Patients' preferred choice of advanced glucose monitoring technologies (a) and patients' choice of the selected monitoring devices by gender (b), age group (c) and ethnicity (d) (n=195)

Table 1: Demographics of eligible study participants

Parameter	Type 1 diabetes	Type 2 diabetes
Diabetes type %	38.9 (n=76)	61.1 (n=119)
Modal Age Range	>60 years	>60 years
Gender (<i>male/female</i>) %	56.6 (n= 43) / 43.4 (n=33)	63.8 (n=76) / 36.1 (n=43)
Ethnicity (<i>White/Black/Asian/Other/ Prefer not to say</i>) %	35.5 /5.3/47.4/7.9/3.9	26.9/5.0/41.2/25.2/1.7