

Perspectives of People with Type 2 Diabetes Mellitus Towards a Decision Aid Assessing Preferences of Glucose-Lowering Drugs: The Dilemma of Choosing

Sonia Roldan Munoz¹, Peter GM Mol¹, Femke de Vries², Peter R van Dijk³, Hans Hillege⁴, Douwe Postmus⁴, Sieta T de Vries¹

¹Department of Clinical Pharmacy and Pharmacology, University of Groningen, University Medical Center Groningen, Groningen, Netherlands;

²Faculty of Beta Science, Vrije Universiteit Amsterdam, Amsterdam, Netherlands; ³Division of Endocrinology, Department of Internal Medicine, University of Groningen, University Medical Center Groningen, Groningen, Netherlands; ⁴Department of Epidemiology, University of Groningen, University Medical Center Groningen, Groningen, Netherlands

Correspondence: Sieta T de Vries, Department of Clinical Pharmacy and Pharmacology, University of Groningen, University Medical Center Groningen, Groningen, Netherlands, Email s.t.de.vries@umcg.nl

Background: Treatment guidelines recommend metformin as initial drug in many people with type 2 diabetes (T2D) and low risk of cardiovascular disease, with the possibility to switch to or add other drug classes. A decision aid (DA) could be useful to incorporate a patient's preferences in the decision of which drug class to choose. We developed such a DA and assessed the perspectives of people with T2D towards its comprehensibility and usability.

Methods: The DA consists of a paper-based leaflet followed by a web-based preference elicitation exercise. The leaflet aims at informing patients about drug characteristics (eg, efficacy, safety). The relative importance of these drug characteristics for each participant are then assessed in a web-based exercise, which results in a ranking of the preferred drug classes. A qualitative study using semi-structured interviews was conducted among Dutch patients with T2D who were or had ever been under pharmacological treatment for T2D. The audio-recorded interviews were transcribed verbatim. Thematic analysis was conducted.

Results: Fifteen patients participated (median age 64 years, nine women, and most had T2D >10 years). Risk of hypoglycaemia was most often the characteristic to which patients attached the highest importance (n=5). A glucagon-like peptide-1-antagonist weekly injection fitted best the preferences of most patients (n=8). The interviews revealed improvements for text, pictograms and figures, and formatting, and increased comprehension of how patients completed the DA. Regarding usability, missing information was identified, as well as patients' perspectives about the usefulness of the DA and its role in shared-decision making.

Conclusion: The DA was considered promising for shared-decision making but further improvements regarding its comprehensibility and usability are needed, for which this study provides clear guidance.

Keywords: decision aid, diabetes mellitus, type 2, qualitative research, participant preference

Introduction

People with type 2 diabetes mellitus (T2D) have an increased risk of micro- and macrovascular complications.¹ Therefore, adequate management of the disease and associated risk factors for cardiovascular diseases, such as hypertension and smoking, is crucial. Guidelines for the management of T2D recommend starting with lifestyle changes (eg, adjusting food intake and increasing physical activity) and initiating pharmaceutical treatment if there is insufficient glycaemic control.² Metformin is considered the first-line pharmaceutical treatment for many patients, in particular in those with low risk of cardiovascular and renal diseases.^{3–5} A switch to or addition of other drug classes, such as dipeptidyl peptidase-4 (DPP-4) inhibitors, sulfonylureas, and sodium-glucose cotransport-2 (SGLT-2) inhibitors, is possible in case glycated haemoglobin (HbA1c) targets are not met or metformin is not well-tolerated.^{2,6}

Although these drug classes are all marketed for the treatment of diabetes, there are differences in their characteristics, such as in their mode and frequency of administration, efficacy, and profile of possible adverse drug reactions (ADRs).⁷ Previous studies have shown heterogeneity in preferences among patients towards such drug characteristics,⁸ and, in addition to clinical characteristics, treatment guidelines advise to incorporate patient preferences at the time of clinical decision-making.^{2,9} Involving patients in treatment decisions may increase commitment, satisfaction, and adherence, which may ultimately lead to better outcomes.^{10–12} A decision aid (DA) could be a useful tool when deciding on treatments in this so-called shared-decision making process between the healthcare professional (HCP) and the patient.^{13–16} A DA is a tool that provides information about clinical decisions, and helps patients on communicating the personal values they attach to the characteristics of the treatment options.¹⁷

In the field of diabetes, review studies have identified randomized controlled trials testing the effects of various DAs.^{16–18} These studies aimed, mainly, at testing the development of new DAs, exploring whether a DA improved communication with HCPs, enhanced informed clinical decisions, and/or improved treatment outcomes, among people with T2D or people in need to add preventive therapies, such as statins. In this paper, we describe a DA to elicit participants’ preferences towards specific treatment characteristics and drug classes to use in addition to or as a replacement of metformin. Also, we present the results of a pilot study that assessed the perspectives of people with T2D regarding the comprehensibility of the DA and its usability in clinical practice.

Materials and Methods

The DA contains five steps (Figure 1) and consists of a paper-based leaflet and web-based preference elicitation exercise in the Dutch language.

The leaflet (Figure 1-step 1) provides some basic information about T2D and the different treatment steps based on guidelines,^{2,6} and gives information about several drug characteristics using text, pictograms, and figures. The included drug characteristics are “mode and frequency of administration”, “effect on blood glucose”, “effect on cardiovascular risk reduction”, “effect on body weight”, “risk of hypoglycaemia”, and “risk of diarrhoea, nausea and vomiting”. These characteristics, so-called attributes, were selected because they were found important to patients in their preferences towards pharmacological treatments for T2D.^{8,19,20} For each attribute, there are two or three options, so-called levels, which are based on the actual attributes of the included drug classes in the DA (Table 1). The included drug classes are those currently marketed and mentioned in guidelines as options to treat high HbA1c levels when metformin (alone) is insufficient or causes intolerable

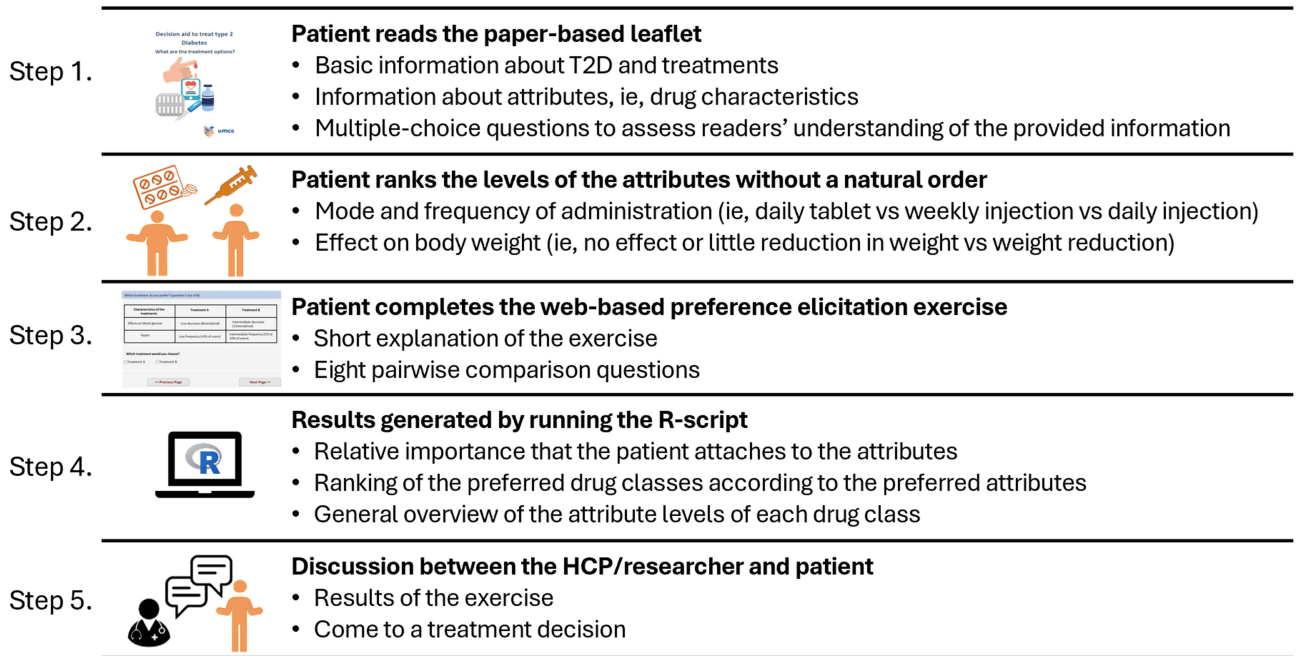


Figure 1 Overview of the decision aid.
Abbreviations: T2D, Type 2 diabetes; HCP, Healthcare professional.

Table 1 Attributes and Attribute Levels Included in the Decision Aid

Drug Attributes	Attribute Levels
Mode and frequency of administration	Oral daily
	Injectable daily
	Injectable weekly
Effect on blood glucose	Low decrease
	Intermediate decrease
	High decrease
Effect on cardiovascular diseases	No additional effect proven
	Additional effect proven
Effect on body weight	No change or small decrease
	Decrease
Risk of hypoglycaemic events	Low frequency
	Intermediate frequency
	High frequency
Risk of diarrhoea, nausea, or vomiting	Low frequency
	Intermediate frequency
	High frequency

ADRs, ie, DPP-4 inhibitors, glucagon-like peptide-1 (GLP-1) receptor agonists, SGLT-2 inhibitors, sulfonylureas, and insulin.^{2,4,6} Internists specialised in diabetes were consulted to finalize the included attributes and levels. An overview of the drug classes with their effects classified in the attribute levels^{21–25} is available in [Supplementary Table 1](#). At the end of the leaflet, four multiple-choice questions are presented to assess the reader's understanding of the provided information.

The web-based preference elicitation exercise ([Figure 1](#)-step 3) contains the attributes and attribute levels described in the leaflet. The exercise starts with a short explanation ([Supplementary Figure 1A](#)). Subsequently, patients have to respond to eight pairwise comparison questions in which they are asked to choose between two treatments (labelled as treatment A and treatment B) ([Supplementary Figure 1B](#)). The treatments are described by two attributes with different levels each time. The exercise is adaptive, meaning that the pairwise comparison questions change for each participant according to their answers. The question tree for this adaptive exercise was generated in R (version 4.0.2 R Foundation for Statistical Computing, Vienna, Austria. <https://www.R-project.org/>) using an entropy-based approach to find a sequence of pairwise comparison questions that maximizes the information gained at each node of the question tree.²⁶ For most attributes, a ranking in the levels is assumed in the question tree; for instance for “effect on blood glucose”, the largest and lowest decreases are considered the best and worst options, respectively. For the attributes “mode and frequency of administration” and “effect on body weight”, however, the best and worst levels may vary from person to person. Therefore, participants are asked about their preferred ranking for these attribute levels before starting the exercise ([Figure 1](#)-step 2). This variability in rankings could lead to nine possible combinations. However, we assumed that weekly injection would always be preferred over daily injection, reducing the number of possible combinations to six. To cover the six combinations, we generated six question trees, with the only variation of the best to worst attribute levels according to these previous choices. The question trees were implemented in the web application Research Electronic Data Capture 10.0.23 (REDCap – www.projectredcap.org). After completing the exercise, an R-script has to be run to generate the results ([Figure 1](#)-step 4). The outcome of the exercise is an overview

of the person's importance attached to the attributes via a radar plot, a ranking of the drug classes in a bar chart based on the importance attached to the attributes, and a general overview of the attribute levels of each drug class. An explanation of how to interpret the results is provided on top of the radar plot and the bar chart. The results can then be used to come to a shared decision (Figure 1-step 5).

We aimed to restrict the text of the DA to the B1 language level as advised in communication recommendations, and we considered the information in guidelines and tools for presenting the text, risks, pictograms, and figures.^{27–30}

Pilot Study

Design and Participants

We conducted a qualitative study using semi-structured interviews among people with T2D who were 18 years or older, were or had ever been under pharmacological treatment for T2D, and were able to speak and read the Dutch language. Participants were recruited through various means: general practitioners (GPs) and flyers distributed in community pharmacies in the north of the Netherlands, messages on social media and on the Dutch website for patients with diabetes (www.diabetesfonds.nl), emails to patients who had participated in a previous study of the Department of Clinical Pharmacy and Pharmacology at the University Medical Center Groningen (UMCG) and had agreed to be contacted for future studies, and via-via. Participants received a link to a digital letter with information about eg, the study aim, duration, compensation for participation (ie, a voucher of 25€), and the consent form which included agreement with the use of the provided information and anonymized data ([Supplementary Text 1](#)). After providing informed consent, participants were contacted to schedule a face-to-face interview at the UMCG or their home depending on their preference. A waiver for full ethical approval was obtained from the medical ethical committee of the UMCG (METc UMCG) (reference number M22.29778), who evaluated this study as not being a clinical research with human subjects as defined in the Medical Research Involving Human Subjects Act (WMO). The study was performed in line with the principles of the Declaration of Helsinki.

Procedure

Before the interview, participants completed a short web-based questionnaire with questions about demographic characteristics (eg, gender, age, educational level), health (eg, diabetes duration, current and previous treatments used for diabetes), perceptions regarding shared-decision making (two statements adapted from Levinson et al 2005)³¹ and self-reported health literacy (three items adapted to the Dutch language from Chew et al 2004).^{32,33} The semi-structured interviews (Figure 2) were conducted in Dutch and took place between June 15 and November 9 2022. The duration of the interviews ranged from 50 to 90 minutes. Two to three researchers (SRM, FdV and/or STdV) were present at the interview; one (FdV or STdV) was in the lead and the others took notes, asked additional questions when relevant, and ran the R script to generate the results of the exercise (SRM). The DA was adapted in an iterative process in which changes to notified issues, comments, and suggestions were implemented. Interviews were conducted until we reached saturation in identified topics. An English translation of the final version of the leaflet and an example of the results of the elicitation exercise are available in [Supplementary Text 2](#).

Analyses

Descriptive analyses in R were conducted to assess the answers of the questionnaire completed before the interviews, the multiple-choice questions at the end of the leaflet, and the outcome of the preference elicitation exercise. The interviews were audio-recorded and transcribed verbatim by FdV or STdV. The texts were then coded using Atlas.ti (2002–2023–ATLAS.ti Scientific Software Development GmbH version 4.15.2–2023-04-26) by one researcher and a second researcher went through the coding to add any further possible codes. Further analyses of the codes were done using Microsoft Excel® 2010 (Microsoft Corp., Redmond, WA, USA). We applied thematic analysis using both a deductive and inductive approach. For the deductive approach, we used the alpha testing phase for patients from the model of the development process for DAs and, therefore, assessed comprehensibility and usability.³⁴ Subsequently, the inductive approach was used for the identification of the themes within these concepts.

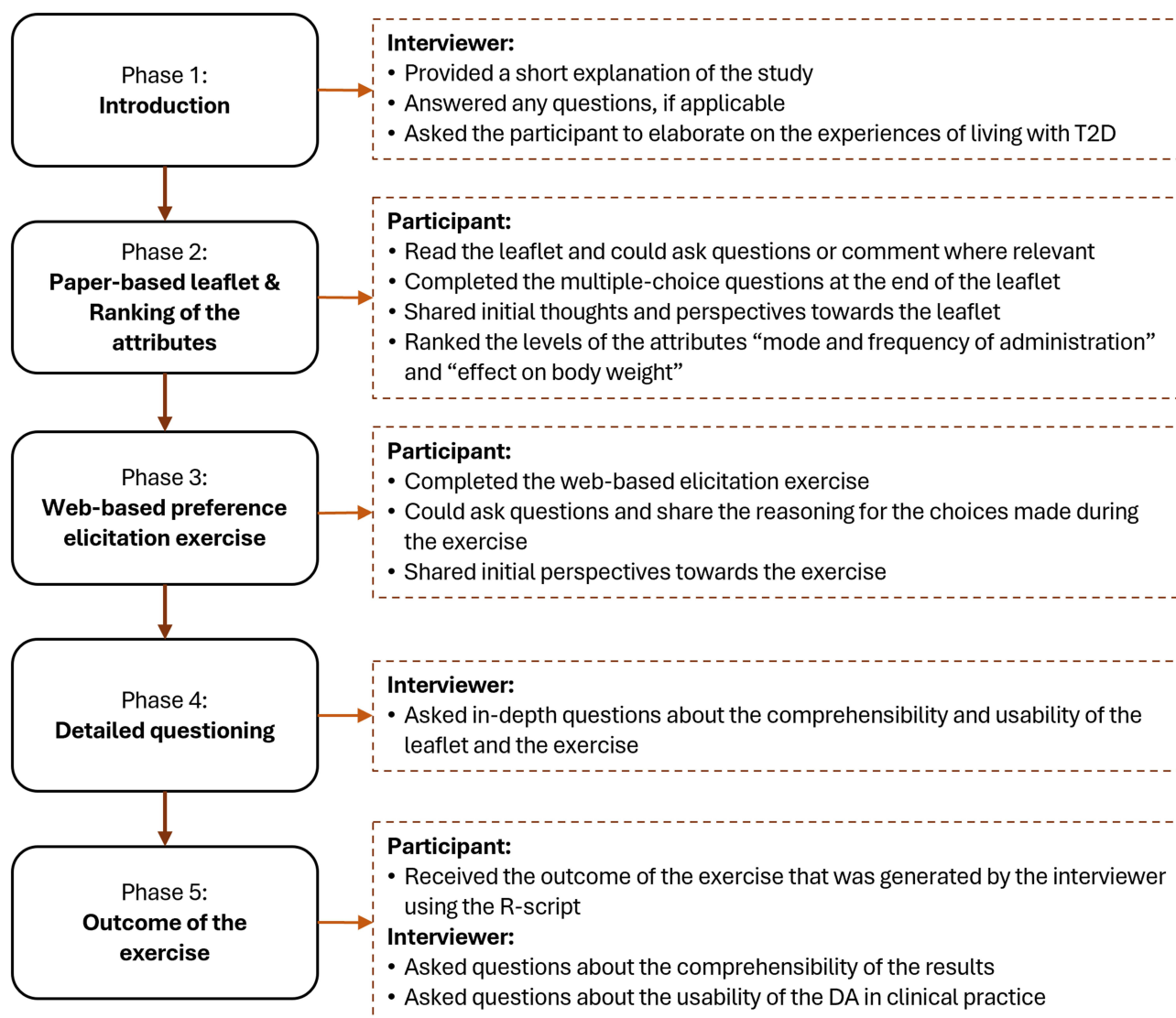


Figure 2 Outline of the semi-structured interviews.

Abbreviations: T2D, Type 2 diabetes; DA, Decision aid.

Results

Interviews were conducted among 15 people. Their median age was 64 years (interquartile range (IQR) 57–70), nine were women, and eight were higher educated. Most participants ($n=9$) had a self-reported T2D duration of more than ten years. The participants were in favour of shared-decision making and were health literate (Table 2). The multiple-choice

Table 2 Characteristics of the Participants (N=15)

Characteristic		N (%)
<i>Demographic characteristics</i>		
Age (IQR)		64 (56–69)
Gender	Female	9 (60)
	Male	6 (40)
	Other	0 (0)

(Continued)

Table 2 (Continued).

Characteristic		N (%)
Educational level ^a	Low	0 (0)
	Middle	5 (33)
	High	10 (67)
Body Mass Index (IQR) ^b		27 (25–28)
<i>Health</i>		
Diabetes duration	Less than 2 years	1 (7)
	Between 2 and 5 years	3 (20)
	Between 5 and 10 years	2 (13)
	More than 10 years	9 (60)
Current treatment diabetes	Lifestyle only	1 (7)
	Lifestyle + metformin	5 (33)
	Lifestyle + metformin + gliclazide	1 (7)
	Insulin	1 (7)
	Lifestyle + metformin + insulin	2 (14)
	Metformin + insulin	1 (7)
	Lifestyle + other tablet than metformin	1 (7)
	Metformin + other tablet	1 (7)
	Metformin + other injection than insulin	1 (7)
	Metformin + other tablet + insulin + other injectable	1 (7)
Past treatment diabetes	None reported	9 (60)
	Lifestyle only	1 (7)
	Metformin	2 (14)
	Other tablets than metformin	1 (7)
	Metformin + gliclazide	1 (7)
	Metformin + insulin	1 (7)
<i>Shared-decision making, median (IQR)^c</i>		
I would prefer my healthcare provider to present the treatment options to me and ask for my opinion on them instead of only discussing the treatment option that seems best to him/her		1 (1–2)
I prefer to leave decisions about my medication use to my healthcare provider rather than making those decisions myself		3 (3–5)
<i>Health literacy, median (IQR)^d</i>		
How often does someone help you read, for example, letters or leaflets from your general practitioner, the pharmacy, the hospital or other healthcare institutions? ^e		1 (1–2)
How sure are you that you correctly fill in medical forms, for example forms in the hospital or forms from the health insurer? ^f		1 (1–2)
How often do you have problems learning about your medical condition because of difficulty understanding written information? ^e		1 (1–2)

Notes: ^aEducational level was grouped as low (no formal qualifications), middle (secondary school, A level, or equivalent), and high (degree, postgraduate degree, or equivalent). ^bThe value of one participant was excluded because of an impossible value (stated height was 87 cm). ^cAnswer options were strongly agree, moderately agree, slightly agree, slightly disagree, moderately disagree, strongly disagree. Lower score indicate more agreement with the statement. ^dLower scores indicate higher literacy. ^eAnswer options were never, occasionally, sometimes, often, always. ^fAnswer options were extremely, quite a bit, somewhat, a little bit, not at all.

Abbreviation: IQR, Interquartile range.

questions at the end of the leaflet were answered correctly by all participants except two, who both answered one question incorrectly. For the ranking of the levels of the attribute “mode and frequency of administration” and “effect on body weight”, the most often chosen order was respectively weekly injection, daily tablet and daily injection, and decrease in body weight over a stable body weight (N=7) ([Supplementary Table 2](#)).

Based on the exercise in the DA, the risk of hypoglycaemia was most often the attribute to which patients attached the highest importance (n=5), followed by the risk of gastrointestinal complaints (N=4), and the effect on blood glucose level (N=3). None of the patients attached the highest importance to the effect on body weight ([Figure 3A](#)). The importance attached to the drug characteristics resulted in a GLP-1 agonist weekly injection being the preferred drug class for most participants (N=8) followed by an SGLT-2 inhibitor (N=5), and a GLP-1 daily tablet (N=2) ([Figure 3B](#)). Results at individual level are presented in [Supplementary Figure 2](#).

Comprehensibility

The concept of comprehensibility is used for two themes; participants’ comprehensibility of the DA and comprehension about how the participants completed the DA.

Participants’ Comprehensibility of the DA

The DA was generally considered clear and understandable, with an appropriate font size (leaflet: format A5, font Calibri, size 15.9, lines double spaced; exercise: font Open Sans, adaptable size), and well-explained information. Nevertheless, some difficulties were identified and mentioned by the participants, and suggestions were made to further improve the comprehensibility of the text, pictograms and figures, and formatting of the DA. Details are provided in [Supplementary Information 1](#). An important finding was unclarity with the aim of the leaflet and the link between the leaflet and the exercise ([Table 3](#); quote (Q)01). Some participants thought that the leaflet was providing general information about diabetes rather than more details about the drug characteristics used in the exercise ([Table 3](#); Q02), or they identified the link between the leaflet and the exercise while reading the leaflet ([Table 3](#); Q03). Unclarity with the aim of the leaflet may have contributed to a different interpretation of the levels of attributes ([Table 3](#); Q04). Some participants also had difficulties interpreting the exercise ([Table 3](#); Q05). After a short explanation, all participants were able to complete the exercise.

Comprehension About How the Participants Completed the DA

During the interviews, more insights were obtained about how participants completed the DA. These are grouped into application to current/own situation, interpretation of risks, and rationale for the choices made in the exercise.

Application to Current/Own Situation

It was not always clear to participants that the DA was about drug attributes in general and aimed at eliciting participants’ preferences for drug attributes and drug classes other than metformin, instead of gathering knowledge about what the participant was currently doing or using ([Table 3](#); Q06). The expected focus on metformin also resulted in discrepancies between the expectations and the content of the leaflet and the exercise ([Table 3](#); Q07). A specific example of the application to the own situation and the focus on metformin was a participant who tried to relate the presented levels of the attribute “effect on blood glucose” to the participant’s own effect of metformin ([Table 3](#); Q08). Also, a participant mentioned being content even towards the least favourable level of this attribute since the “low decrease” was better than the participant’s current glucose level ([Table 3](#); Q09), and the level “intermediate decrease” was interpreted as a person’s own average glucose (HbA1c) level ([Table 3](#); Q10).

Interpretation of Risks

The use of both text and pictograms influenced participants’ interpretation of risks ([Table 3](#); Q11). Some unrealistic optimism was noticed with the interpretation of pictograms ([Table 3](#); Q12-Q13). Moreover, the wording of the level “additional effect proven” of the attribute “additional effect on cardiovascular risk reduction” was in the participants’ opinion not in line with the risk reduction described, since the wording suggested to them a large effect ([Table 3](#); Q14), whereas the actual additional effect on cardiovascular risk reduction from 10% to 8% was considered very low. In

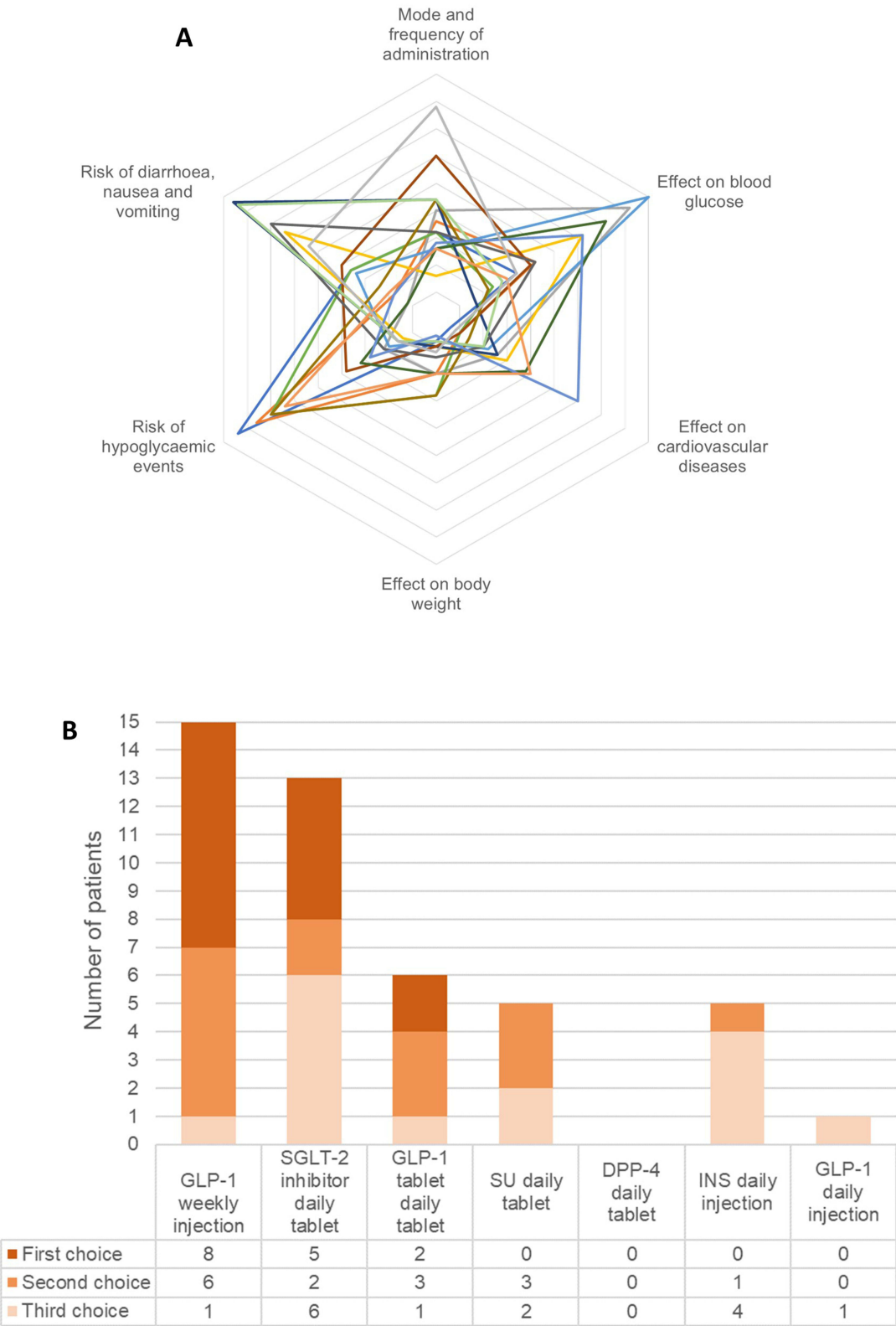


Figure 3 Outcome of the elicitation exercise with **(A)** the radar plot showing the scores by preferred attribute of each participant (with each color representing a different participant) and **(B)** an overview of the participants' top 3 drug classes best fitting their preferences.
Abbreviations: DPP-4, Dipeptidyl peptidase 4 inhibitor; GLP-1, Glucagon-like peptide-1 receptor agonist; INS, Insulin; SGLT-2, Sodium-glucose co-transporter-2; SU, Sulphonylurea.

Table 3 Quotes Supporting the Results

Quote Number	Quote	Participant
Comprehensibility		
<i>Participants' comprehensibility of the decision aid</i>		
01	"I have to say honestly that I did not get that for a minute, no. [...] I have the information I got from this, I did use it, erm, but I was not immediately aware of it. So, when answering the questions, I understood like, oh, it is, in fact, about these results, and you have to weigh up what you actually want, what do you choose".	Participant 9
02	"To help me understand what diabetes actually is, what it means to be a diabetic".	Participant 7
03	"I think first that I thought of, oh it is just information, information and at a certain point I thought, something like, something like oh, probably it is about that these are the areas where you can make a choice, you know".	Participant 15
04	"Some people are on the same drug, but for you, it's more effective, for me less effective. That's how I read this. [...] That a drug can have very different effects on someone. [...] For you, it works well, for me, it's kind of average, and for you, it does not work. That's how I read it, honestly".	Participant 11
05	"[...] I am really bad at puzzles. And I think this is category puzzles. And I am terrible at them. I could never do them. I was never good at maths either. [...] I find it complicated".	Participant 14
<i>Comprehension about how the participants completed the decision aid</i>		
<i>Application to current/own situation</i>		
06	Example from leaflet: "But I have noticed that you assume that people take metformin twice a day, but I take it three times a day. And there are many others like me who take it three times a day". Example from exercise: "Er, characteristics of, how and how often. You inject the drug daily. No. [...] I take a tablet every day [...]."	Participant 1 and 14, respectively
07	Example about leaflet: "But I had actually expected that after the information, there would be a table like this [table about frequency of administration] with crosses and this [is] metformin [metformin included in the summary table with drug characteristics]." Example about exercise: "I had completely different thoughts about the questions. [...] That you would look more at the alternatives to metformin, say, and put them side by side."	Participant 5 and 12, respectively
08	"[...] what I missed is that I do not know the, er [...] my own initial value, I think that's a pity [...] I really wanted to, er, before I came here, I did not know that you could have low, average and a lot of decrease. [...] That you have those criteria. [...] How much has metformin helped me. And that's what I am missing for myself now."	Participant 11
09	"Not much decrease. So it remains 8. Yes, I would like that, but that has not been working out lately."	Participant 14
10	"Now, I very often see an average decrease. Is that the average of everyone, or? [...] Yes, er, I did notice something like that, but I just think, haha. B, yes. Because my average is way too high."	Participant 2
<i>Interpretation of risks</i>		
11	"Here [with the text], you think, oh, from ten to eight, yes that is still 20% and with this [pictograms] I think, oh, with those faces, I think it's only two faces."	Participant 11
12	"It would be very unlikely if you coincidentally, [...] if you then coincidentally would be one of those two."	Participant 8
13	"A big disadvantage of these kinds of pictures is always, let us say, the 'it will never happen to me' effect. [...] when you see this, whether you see this or that, you think, many people think, 'I'm in that category'. While, of course, that does not have to be the case at all."	Participant 12

(Continued)

Table 3 (Continued).

Quote Number	Quote	Participant
14	"because proven effect, then you think that it's major proof."	Participant 8
15	"but I can kind of imagine that most people find it a bit abstract, what is 10% or what is 8%, let's say."	Participant 12
16	"I think that, that it would become clearer if you could say like gosh, you have this much more chance of it yourself because now it is, yeah, well, if I am one of those 90 people then there is nothing wrong."	Participant 15
Rationale for the choices made in the exercise		
17	"But I do know my girlfriend suffers a lot from hypos. And yes, she might make a different choice."	Participant 5
Usability		
Missing information		
18	"I think it's a good length. Not too short because then it is immediately like, oh, yes. And not too long either [...]. Not too much [information should be included in the leaflet]. It would be better to have a follow-up leaflet, I think."	Participant 4
19	"[...] So am I not doing it well enough then, and do I have to do even more."	Participant 15
20	"And I have a bit of a problem with, and it is obviously all relative, er nausea, how often will you be nauseous? Are you nauseous the whole day? Or is it just for about an hour after you did the injection? I am just naming some things. [...] How bad is it and you have to see that in relation to that 2%. What is 2%? Will I then live a month less, so to speak? Or is it a year or two years? And what is your quality of life then?"	Participant 9
Usability of the elicitation exercise		
21	"Short but sweet."	Participant 3
22	"You also indicate that there are eight, that always helps, that you know how far you are."	Participant 12
23	"It was nice that each question was on a separate screen and not all the questions underneath each other."	Participant 2
24	"Sometimes I thought like, oh, I just said this, and now I am saying something else, so er, yes, why do you choose, do you make that other choice? But then you actually get into a struggle [...] that from my own point of view, I say, well, I do not want to inject insulin and then at the end of the exercise you think like, well, if it is just once a week, then it is maybe still an option if your blood sugar is definitely low."	Participant 8
25	"Is this correct? If you have a big drop in your glucose, that you then have a lot of hypos?"	Participant 11
26	"So I actually have to choose from the one drug where the blood sugar goes down, then you also know that it has an effect, er, has a positive effect on your heart, er disease, no not disease, your heart and blood vessels so to speak. And with the other, you see a bigger drop than with the other, and then there is no effect. But then you actually say that treatment A leads to a higher, er, a lower blood sugar but that the effect is more positive. Am I understanding that correctly?"	Participant 9
27	"that I answered a bit too quickly, but then you have to read better."	Participant 10
28	"This is me. This is what I find most important." And: "It is remarkable that I, er, obviously I score very high on how and how often I do or do not want to swallow or inject something. [...] I do think it's remarkable that that comes out higher than what I think of my blood glucose levels. That's quite funny."	Participant 2, and 8, respectively
29	"Is this a peculiar figure?" And: "Is it rather average, or is it different?"	Participant 8 and 10, respectively

(Continued)

Table 3 (Continued).

Quote Number	Quote	Participant
30	"As a participant, I would only like to see which drugs then, which based on my answers, would be preferable. [...] One and two, for instance, in this case, since there are seven and then you choose between one and two. And you could also say, well, let us say this one is much lower, and it will not be like that but that the difference is big, then you also have, er, or that the difference is actually small, that you say, well we can also add the third because that one has basically the same score, only just a few points less causing it to be one spot lower."	Participant 9
Usefulness of the decision aid		
31	"I think so. [...] And here you can also make choices about what is important to you."	Participant 7
32	"Yes, for me [the overview would be sufficient]. Look, I cannot look inside other people's heads, obviously, but for me that would be a thing. [...] I do read it all, right, but for me, it's actually about the blood glucose sugar."	Participant 3
33	"This [the exercise] makes you think, like, what do I actually want? What kind of effect do I still want to accept?"	Participant 9
34	"Gosh, what a lot, [...] A lot of information." And: "That [the exercise] does help. [...] because here you secretly have to make the same choice that you have to make there, but then you also have to make them here too [...] so then you make that choice one time instead of one time per thing"	Participant 4 and 12, respectively
35	"If you want a general overview of well, these are the options of types of drugs, these are and those, er, you could use that additionally, that questionnaire, to find out what your preference is, but maybe you can also say that directly with this, like if you see this, is there one that stands out to you."	Participant 15
Shared-decision making		
36	"It can also be a support for the doctor to get a certain perspective"	Participant 7
37	"Then I think it is much more of an open conversation. And then doctors may also notice, like yes, but that diarrhoea is that important for that woman, we do have to do something about it."	Participant 4
38	"I am still [...] assuming like, well, I will sit down, and I will be told what drugs I need and then, well, if it does not work or I do not feel comfortable with it, then I can give feedback and then I will hear from them again what the plan is."	Participant 15
39	"You might be giving patients false hope if they think like I can choose one of those six while the general practitioner or pharmacist or I do not know who, then just crosses that one off."	Participant 12
40	"So then you would have to know which drug actually causes which decrease. But that is again, er, patient focused. Because it has more effect on one patient than on another. When I went down from my 90 kilos, almost 100, to 68, I was getting much metformin."	Participant 1
41	"[...] whether you have one consulting specialist or another, that makes quite a difference. I now have one who explains it all well, but she is still a bit like, yes, but I do know it all well."	Participant 4
Where to use the decision aid		
42	"If people fill this in beforehand. [...] That a doctor can see, the preference is this. Does that go with the rest of the drugs that are being taken."	Participant 6
43	"I could also do this here at home. Just the first question, you had to know a bit like, er [...] but once you know that, then I also could have done it by myself."	Participant 2

(Continued)

Table 3 (Continued).

Quote Number	Quote	Participant
44	"Then I could imagine that you say you do that at home, but you do go back to the consulting specialist with the result."	Participant 15
45	"That always helps because, er, I do let you know, er, what my dilemmas are. [...] And if I have to do that alone, then I just fill in something. [...] And why I made that choice, and if someone listens who also has an influence on my choice of a drug that person can think along with me."	Participant 11

general, the interpretation of percentages might be difficult for patients (Table 3; Q15). A suggested easier way was to present risks of the individual participant instead of at a population level (Table 3; Q16).

Rationale for the Choices Made in the Exercise

Several themes were identified when participants' reasoned out loud about the choices they had to make between drug attributes and attribute levels in the exercise (Table 4). The themes varied widely, from heredity to general beliefs and from quality of life to the interpretation of the presented risks. Most of the themes came up for several attributes, such as (the lack of) experience with the drug characteristics and the (lack of) other options to manage drug effects. Other themes came up for a specific attribute only, eg, (non)adherence and ease of use for mode of administration. Participants were aware that preferences could differ between people (Table 3; Q17).

Table 4 Overview of Identified Themes in Participants' Considerations for Evaluating the Various Drug Characteristics or Levels

Themes	Examples of Attribute with Quote
Beliefs	Mode and frequency of administration: "but I think, anyway, injecting it means that it's absorbed faster." (Participant 3)
	Risk of hypoglycaemia: "... also because of those complications. The fewer hypos, the less chance of complications, we hope." (Participant 2)
Concerns	Risk of hypoglycaemia: "Hypos are scary obviously if you live alone." (Participant 14)
Considered (most/more) important	Effect on blood glucose: "I would choose B because of the, er, the effect on the blood glucose, because I think that that's important." (Participant 5)
	Additional effect on cardiovascular risk reduction: "Proven additional effect. Yes. I find that proven additional effect, I think that's very important." (Participant 14)
Current/own situation	Effect on blood glucose: "Look, because mine is always too high so then I can reduce it" (Participant 13)
	Effect on body weight: "Well I think, hmm 61 kilos, let me just stay at my weight" (Participant 4)
(Lack of) Experience	Risk of diarrhoea, nausea and vomiting: "I am used to having diarrhoea regularly" (Participant 14)
	Risk of hypoglycaemia: "So I do not have hypos, never, so then, er, the effect on it, erm, is [less important for me]" (Participant 5)
	"Hypos are really not pleasant." (Participant 6)
	Additional effect on cardiovascular risk reduction: "The annoying thing is I already have it. [...] So I have that trigger to reduce it, I do not have that [referring to another attribute]." (Participant 11)
	Mode and frequency of administration: "I do not have a preference myself. I am very easy about taking pills. Injecting is not a problem for me, either." (Participant 2)

(Continued)

Table 4 (Continued).

Themes	Examples of Attribute with Quote
Experiences of others	Risk of diarrhoea, nausea and vomiting: "I have a lot with, er, oncology patients, and they say the absolutely worst thing is the nausea. And the constant vomiting." (Participant 11)
Quality of life	Mode and frequency of administration: "I would rather go a bit more for, er, to have a nice, pleasant life instead of all that er..." (Participant 7)
	Risk of diarrhoea, nausea and vomiting: "because if you go out and every time you need to go to the toilet, that is not pleasant." (Participant 7)
	Risk of hypoglycaemia: "Then I would choose A, because hypos [...] because that, er, means problems with your driving licence, and other activities that I do. Then someone will say hey, you are no longer insured. You are no longer allowed this, you are no longer allowed that." (Participant 1)
Convenience	Mode and frequency of administration: "If you have that once a week, well, then it is already just much easier.[...] You cannot just start injecting at a, at a dinner, then you have to go to the toilet, and that, so it is, it is really, tablets are much easier." (Participant 5)
(Non) Adherence	Mode and frequency of administration: "The less, the better, so once a week, I would find even better. Because then I do not have to think about how I cannot forget it." (Participant 3)
Wanting to avoid	Risk of hypoglycaemia: "I do not want any hypos at all, that chance must also be minimized. [...] Those hypos, I do not want to think about them." (Participant 10)
	Mode and frequency of administration: "I prefer to, er, take pills. I hate needles." (Participant 11)
Heredity	Additional effect on cardiovascular risk reduction: "I do find that very important. Also because cardiovascular disease is very common in the family." (Participant 2)
Presented risks	Risk of diarrhoea, nausea and vomiting: "diarrhoea, nausea or vomiting that is also a lot, er. Then I think 10 to 20%, I think, well, that is quite a lot. If you have that 20%." (Participant 8)
	Additional effect on cardiovascular risk reduction: "I am not going to lower my standard of living for that 2%" (Participant 9)
(Lack of) Other options	Risk of hypoglycaemia: "because I think you can, of course, also eat hypos away again" (Participant 8)
	Risk of diarrhoea, nausea and vomiting: "Look, then I will also not eat all those chia seeds and stuff, and linseeds anymore. Because you also get diarrhoea from that." (Participant 14)
	Effect on blood glucose: "Look, you can also take, er, it into account yourself with diet and everything." (Participant 13)
	Effect on body weight: "I just think diarrhoea, nausea or vomiting, that is something that really bothers you. And additionally, it is hard to compensate for that. And losing weight is good as well, obviously, but I can also achieve that in a different way". (Participant 5)

Usability

Regarding the usability of the DA, the following overarching themes were identified from the interviews: missing information, usability of the elicitation exercise, usefulness of the DA, shared-decision making, and where to use the DA.

Missing Information

During the interviews, participants mentioned several things that they felt were missing in the DA (eg, information about neuropathy, kidney function, hyperglycemia, costs [particularly the amount rather than whether or not a patient would need to pay for a drug]) but they also preferred a short leaflet. The current leaflet was considered to have an adequate length, and more information could be provided in different ways (Table 3; Q18). The use of QR codes to reliable sources of information was considered a useful possibility, although not all participants knew how to use QR codes and therefore

preferred a web-link. It was also mentioned that the importance of lifestyle changes for the treatment of diabetes could be further emphasized. Another participant, however, mentioned that in general information about lifestyle as an option to treat diabetes makes you feel like you are doing insufficient yourself (Table 3; Q19).

With regard to the attribute “effect on body weight”, some participants were surprised that an increase in body weight was not among the effects. Providing more details of the currently included attributes was also considered relevant, such as the role of food for the attribute “mode and frequency of administration” (eg, any food restrictions) and details of the attribute “risk of diarrhoea, nausea and vomiting” (eg, information about transiency, or options to manage the ADR) (Table 3; Q20).

Participants expressed interest in receiving details on the effects per drug class. Although some participants were not interested in such details, an overview of the drug effects per drug class – which was initially not included in the DA – was added to the outcome of the exercise. Some participants, however, preferred to have the overview in the leaflet already instead of at the end of the DA. Many participants had never heard of all the different drug classes and it was questioned why metformin was not included as one of the possible preferred drugs.

Usability of the Elicitation Exercise

The length of the elicitation exercise was considered adequate (Table 3; Q21). Also, it was appreciated that the number of choice sets was mentioned beforehand (Table 3; Q22) and that each choice set was presented on a separate page (Table 3; Q23). Nevertheless, participants considered it difficult to choose between the two treatment options in the exercise (Figure 4). These difficulties were partly due to the forced choice nature of the exercise, ie, no possibility of skipping a question or choosing none of the alternatives. The forced choice of the ranking of the levels of the attributes “mode and frequency of administration” and “effect on body weight” before starting the exercise was also considered difficult for some people. Another reason for the experienced difficulties with making the choices in the exercise was participants’ willingness to answer consistently (Table 3; Q24). Similarly, some participants asked whether a choice set was repeated during the exercise, and a participant specifically mentioned that it is common in questionnaires that consistency is assessed with a control question. Participants also questioned the independence between some of the attributes when completing the exercise (Table 3; Q25-Q26). Furthermore, few participants initially selected the treatment that was not in

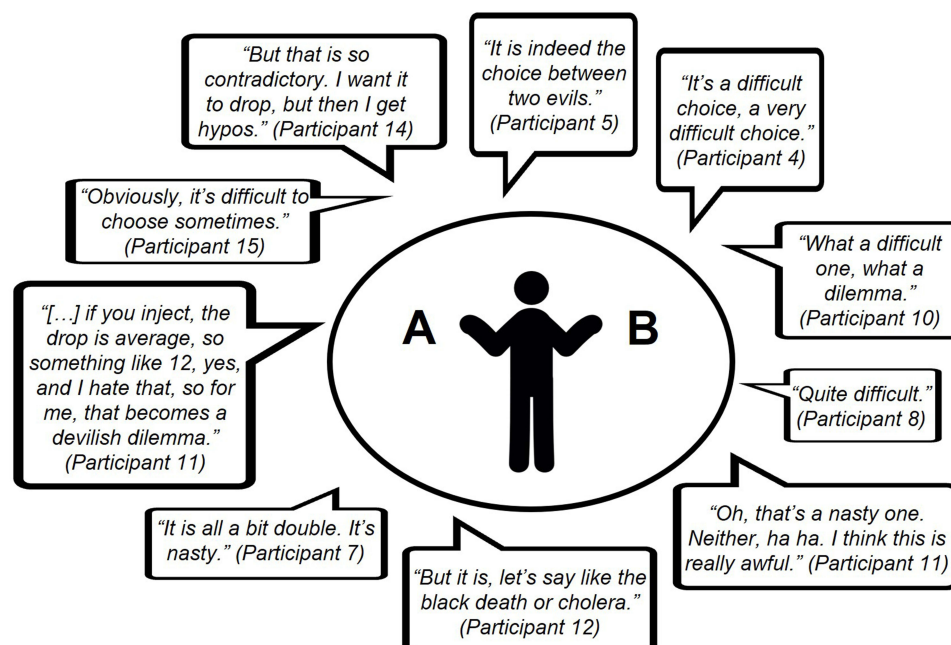


Figure 4 Examples of quotes illustrating the difficulties participants experienced when having to choose between the two treatment options in the elicitation exercise of the decision aid.

line with their out loud stated preference. This was partly due to some initial difficulties in the wording or due to incorrect reading (Table 3; Q27).

The outcome of the exercise in terms of the importance attached to the drug effects was generally in line with participants' expectations. One participant, however, was slightly surprised about the results (Table 3; Q28). Also, some participants expressed feelings of insecurity with the results shown in the radar plots (Table 3; Q29). The bar chart showing the order of the preferred drug classes was appreciated by the participants but there were discrepancies in their preferences towards the number of drug classes presented (ie, preferences for an overview of all drug classes versus an overview of only those drug classes most related to the preferences) (Table 3; Q30).

Usefulness of the DA

The difficulties in choosing between the alternatives and the sometimes mistakenly selected alternative in the exercise introduced the discussion about the added value of the exercise – and the DA in general – compared to an overview of the characteristics per drug class only. Some participants expected that an overview would be sufficient for them (Table 3; Q31). This might specifically apply to participants who are focusing (primarily) on one drug characteristic (Table 3; Q32). Other participants saw an added value of the exercise as it made them actively think (Table 3; Q33). When presenting an example of an overview with drug characteristics only, mentioned disadvantages were the large amount of information at once with still the requirement of making a decision (Table 3; Q34).

There was discussion about the added value of having a leaflet and an exercise in the DA. A participant mentioned that it would have been possible to complete the exercise without the leaflet but that the leaflet is a nice addition. It was suggested to add an overview of the characteristics of the drug classes at the end of the leaflet and offer the exercise as an optional next step for assessing the preferred drug class (Table 3; Q35).

Shared-Decision Making

Taking a patient's perspective into account when making treatment decisions was generally considered appropriate and important. A participant mentioned being often involved in the decision but lacking knowledge. The DA would increase participants' knowledge about possible treatment options and their characteristics, improving the control over their own treatment, which might result in being taken more seriously. The DA could also be an advantage for the HCP since it would facilitate the conversation with the patient, not only by identifying preferences, but also supporting the patient anamnesis and understanding the rationale of their preferences for a specific treatment (Table 3; Q36-Q37).

Nevertheless, a DA might not be necessary for everyone and could be relevant for specific patients, such as those who are modest and do not dare to ask for other treatment options or those who are not yet used to be involved in treatment decisions. Also, other patients might still prefer to leave the decision to the HCP (Table 3; Q38). Furthermore, it was mentioned that the DA should be used with help from a HCP since they have more knowledge and should always be involved in the decision-making. A concern raised was that not all included drug classes might fit an individual and that the HCP therefore might have reasons not to prescribe a drug class included in the DA (Table 3; Q39). Other remarks related to personalized medicine were that the effects of the drugs may differ between participants as well as within an individual over time (Table 3; Q40).

Regarding which HCP should be involved in the DA, participants had the impression that GPs will not have the time to use the DA. Discussing the DA with a nurse practitioner was therefore considered a better option, although this might not work with all nurse practitioners (Table 3; Q41).

Where to Use the DA

Participants mentioned that the preference for completing the DA at home or during a consultation with an HCP would depend, for instance, on whether people were recently diagnosed with diabetes or had little experience with computers. Differences in preferences between participants were indeed identified. Some preferred to complete the DA at home with the advantage of HCPs having more time to look at the outcome of the exercise (Table 3; Q42). Others mentioned that it would be possible to complete the DA at home although some instructions beforehand might be needed (Table 3; Q43) and that the results would still need to be discussed with a HCP (Table 3; Q44). Nonetheless, many participants preferred

to complete the DA together with an HCP. Several advantages were mentioned for both parties; patients, eg, having the possibility to ask questions and discuss further with their HCP, and HCPs gathering knowledge about the dilemmas a patient faces while making the choices, information about the rationale of the choices, or the possibility to explain or clarify certain information to the individual patient (Table 3; Q45).

Discussion

This study assessed the comprehensibility and usability of a DA developed to elicit preferences of people with T2D towards drugs that may be prescribed in addition to or as a replacement of metformin. The DA was generally considered comprehensible and usable, however, concrete aspects regarding the text, pictograms and figures, and formatting to further improve the comprehensibility were identified. Also, it became clear that factors like the participants' current/own situation, their interpretation of risks, and their rationale for the choices made in the exercise influence how people complete the DA. Finally, insights about missing information, the usability of the exercise, the usefulness of the DA, shared-decision making in general, and where to use the DA should be considered to further improve the usability of the DA.

With regard to the results of the elicitation exercise, the most relevant attribute was the risk of hypoglycaemic events, followed by gastrointestinal complaints. The importance of these two attributes has also been shown in previous patient preference studies.^{35–37} Nevertheless, it should be noted that participants in our study mentioned that to be fully capable of making choices in the elicitation exercise, essential information about the presented ADRs (eg, its severity or duration) was missing. Some of such information, however, is not systematically reported in public reports from clinical trials.³⁸ The inclusion of patients' perspectives in the set-up of clinical trials could be a way forward to ensure that all relevant information to patients is collected during the trials.

The effect of the drug on weight change was never elicited as the most important drug characteristic in our study. This result differs from previous studies showing that the effect on body weight is a highly influencing factor at the time of choosing among treatments for T2D.^{8,39} Some of the reasons of the discrepancy might be differences in the included population (ie, a mean body mass index of 27 kg/m² in our study versus >30 kg/m² in others), and differences in the included attribute levels (ie, weight reduction and no effect on weight versus the additional level of weight gain). The drug classes most frequently aligning with the participants' preferences in our study were GLP-1 weekly injectables and SGLT-2 inhibitors. This is supporting the latest guideline recommendations, which position these drug classes as the first step at the time of treating people with T2D and high risk of cardiovascular diseases.^{2,5,6,40} However, currently in the Netherlands, whether SGLT-2 inhibitors and GLP-1 weekly injectables are reimbursed depend on patient factors such as body mass index (www.medicijnkosten.nl/). Reimbursement rules may, however, change over time (eg, when new evidence becomes available). This relates to the findings related to personalised medicine, as participants mentioned that not all drug classes might fit an individual patient and that drug effects may differ between individuals. In general, the result of the DA for an individual patient should not be seen as binding for the decision-making but rather as support in the conversation between the HCP and the patient to come to a shared decision.

A personalised approach also seems to be useful for the design and content of the DA, as there was variation in participants' perspectives with regard to, eg, the use of figures and pictograms, and the content and quantity of information included. With regard to the latter, guidelines for the development of DAs recommend including information that is directly related to the aim of the DA and relevant to patients.^{34,41} Nevertheless, the leaflet in our DA also contains some additional information about diabetes in general. For some patients, this was indeed redundant information, which may have caused confusion about the aim of the DA, but others considered this a nice and useful introduction.

Differences about how participants interpreted the presented risks were noted. Most participants stated that they understood the information but it became clear that there were incorrect interpretations. Difficulties with the understandability and interpretation of risks have been shown previously, and it is influenced by factors such as an individual's numeracy.^{42–44} This is in general concerning as patients have increasing access to information and are more often involved in treatment-related decisions, but do not necessarily have the skills to understand it,⁴⁵ impairing the possibility of making proper informed decisions.

A specific case of an identified incorrect risk interpretation was unrealistic optimism. Unrealistic optimism is defined as the prediction of a personal outcome being more positive than the one suggested by objective data⁴⁶ and has been

previously shown in the context of T2D; for instance, a large number of people believe that other persons are at higher risk of developing diabetes than themselves.^{47,48} While this effect might be psychologically protective, it can also lead to accentuated risk behaviours.⁴⁹ Our study suggests that unrealistic optimism might also influence patients' preferences when interpreting risks. The influence of how risks are presented (eg, via text or pictograms) and the best way to present risks in a DA should be further assessed.

Besides the possible role of unrealistic optimism, our study showed that several other factors influenced the participants' choices in the exercise, including experiences and beliefs. This is in line with previous studies assessing patient preferences as well as actual behavior showing, for instance, higher treatment acceptability when health is declining,⁵⁰ differences in the preferences for the mode and frequency of administration based on experiences with injectable treatments,³⁶ and an effect of beliefs about the necessity of medicines and expectations of ADRs on the use of medicines.^{51–53} These results show that preferences are influenced by factors that may change over time, making them dynamic. A discussion of patient preferences, possibly with the use of a DA, should therefore be considered at several moments during the treatment.

It was mentioned that the reasoning for the choices made in the exercise could be useful background information for the HCP. Nevertheless, participants had the impression that GPs might not have the time to use the DA or might not want to discuss treatment options with patients. In the Netherlands, patients with T2D without complications are treated in primary care,⁵⁴ where relative short consultation times are allocated.⁵⁵ Suggestions were proposed by participants to optimise its implementation, such as the use of the DA only in those patients who struggle with eg, treatment satisfaction or adherence, the use of the DA with other HCPs than GPs (eg, diabetes nurses), or a further improved version of the DA that can be used by patients at home. Nevertheless, we found again differences between participants regarding their preferences about where to complete the DA.

Taken together, the observed heterogeneity among the participants pleads for a personalised approach in both the design and content of the DA and its use in clinical practice. While it is challenging to develop such DAs (eg, adjusting the formatting or quantity of information per person), the increasing progresses made in the field of artificial intelligence could be useful in their further development. Although the use of artificial intelligence is in its infancy,⁵⁶ there are indications of its usefulness.⁵⁷ Until such personalised tools are available, the use of DAs that provide patients with comprehensible information and that trigger the interaction between the patient and the HCP seems usable to elicit patient preferences in clinical practice.

Strengths and Limitations

A diverse sample of participants with regard to their gender and age was included in this study. Although we conducted interviews until saturation in identified topics, the sample size was small. The views of the participants might not represent those of the overall T2D population, as in our study participants considered shared-decision making highly important and self-reported health-literacy was high. Similarly, digital resources were part of this study (ie, a digital information letter and consent form) and are included in the DA (ie, a web-based preference elicitation exercise) which restricts participation to individuals who have access to and are comfortable using digital devices. Also, it should be noted that not all participants reasoned out-loud when making the choices in the exercise, or not necessarily did this for each of the choice sets. This implies that the themes identified for the rationale for the choices made in the exercise might not be exhaustive. Another limitation is that only patients were included in this study. Future studies are needed to assess the perspectives of HCPs.

A general limitation of preference elicitation exercises is that the elicited preferences can vary depending on the included attributes and attribute levels. To address this limitation, we aimed at including the most relevant attributes and accurate levels, basing the decisions on literature and the input of internists specialised in diabetes.^{2,21–25} Nonetheless, other possibly relevant attributes and attribute levels were mentioned by the participants (eg, costs), and should be considered in the further development of DAs. The inclusion of additional attributes and/or attribute levels will, however, increase the number of choice sets to be completed and its feasibility should, therefore, be examined. Finally, the DA distinguished treatment options by drug class instead of by specific drugs. Although there are some differences between drugs within a class,² the use of all specific drugs would have substantially increased the number of choice sets to be completed, lowering the feasibility of the exercise.

Conclusion

In this study, we identified factors related to the comprehensibility and usability of a DA developed to elicit the preferences of a person with T2D towards drug classes to be prescribed in addition to or as a replacement of metformin. Aspects regarding the text, pictograms and figures, and the formatting were identified and applied to further improve the comprehensibility of the DA. Information about how participants relate the given information to their current/own situation, their interpretation of risks, and their rationale for the choices made in the exercise increased the comprehension of how people complete the DA. Regarding the usability, we obtained insights about relevant information being missing, about the usability of the exercise, the usefulness of the DA, shared-decision making in general, and about where to use the decision aid. Although this type of DA was considered a potentially useful tool to incorporate individual patient preferences in treatment decisions, the identified factors indicate that a personalized approach with regard to both the content and the formatting of the DA should be considered in its further development and/or implementation.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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