



Feasibility and Acceptability of an Agenda-Setting Kit in the Care of People With Type 2 Diabetes: The QBSAFE ASK Feasibility Study

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This article reports on a study to assess the feasibility of research procedures and acceptability of QBSAFE, a set of conversation cards focused on quality of life, treatment burden, safety, and avoidance of future events in people with type 2 diabetes. The study enrolled 84 patients and 7 clinicians. Of the 58 patients who completed questionnaires, 64% agreed that the QBSAFE ASK helped them discuss their situation, 78% agreed that others could benefit from it, and 38% said they would use it again. Most clinicians felt confident responding to issues (in 89% of encounters) and said they would use the kit again (78%) and recommend it to colleagues (82%). The QBSAFE agenda setting kit can be feasibly implemented and holds promise in facilitating discussion and collaborative problem-solving.

People with diabetes experience a significant burden, which often affects their quality of life. The burden of disease (i.e., the impact of disease on functionality) and the burden of treatment (i.e., added demands) contribute significantly to a person's workload, and become problematic when exceeding the person's capacity (1). Described by the cumulative complexity model (1), the imbalance between an individual's capacity and workload leads to adverse outcomes and place people in a cycle of increasing disease burden and illness.

Adults with type 2 diabetes spend a significant proportion of their days tending to diabetes-specific tasks (2). Clinicians may contribute to this cycle by responding to a negative outcome by intensifying treatment and further increasing the workload (1,3). In addition, as individuals grapple with a high workload

KEY POINTS

- » Diabetes self-management can impose a significant workload on patients and treatment can be burdensome. These aspects of living with diabetes often go unaddressed by clinicians.
- » The QBSAFE agenda-setting kit is a novel approach to diabetes care that facilitates discussion about quality of life issues related to living with diabetes and collaborative problem-solving between people with diabetes and their clinicians.
- » Shifting care models from being A1C-centric to more patient-centric may increase individuals' capacity for self-care and thereby improve clinical outcomes.

and waning capacity, they are often held accountable for outcomes (3).

Current diabetes guidelines try to address these burdens by recommending a collaborative approach to treatment and individualized A1C goals (4). Yet, setting personalized A1C goals may not address the challenges or burdens faced by people living with diabetes. Prior research has shown that people with diabetes often raise concerns related to quality of life and treatment burden during clinical encounters, yet these issues often go unaddressed by clinicians (5). Shifting the focus from attaining A1C goals to providing more person-centered care may improve patients' capacity, reduce their workload, and potentially improve outcomes.

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We previously developed a set of conversation cards as an agenda-setting kit (ASK) to improve person-centered care for people with type 2 diabetes (6). Our specific goals were to promote conversations between people with diabetes and their clinicians, facilitating collaborative problem-solving while addressing issues related to diabetes care, including quality of life, the burden of treatment, safety, and avoidance of future events (QBSAFE). We initially developed 12 cards that corresponded to topics important to people living with diabetes based on literature review, surveys of people with diabetes, and clinician feedback. The QBSAFE ASK prototype was then refined and field-tested in usual outpatient care with people with diabetes. Based on our findings, we added two cards about successes in diabetes care.

In this study, we evaluated the feasibility and acceptability of the full set of 14 conversation cards in the QBSAFE ASK and assessed clinician responses to the kit, along with the conversations it elicited.

Research Design and Methods

Design, Setting, and Participants

This was a single-arm intervention trial to assess the feasibility and acceptability of the QBSAFE ASK. The study recruited primary care clinicians and diabetes specialists at three study sites: the Mayo Clinic (Rochester, MN), Yale University (New Haven, CT), and Trinity Health of New England (Waterbury, CT). Clinicians were recruited if they cared for adults (≥ 18 years of age) with diabetes. People with diabetes were recruited if they had a diagnosis of type 2 diabetes and were under the care of an enrolled clinician. Individuals who did not speak English, had severe vision/hearing impairment, or were unable to give consent were not eligible. Individuals were enrolled after learning about the study procedures and providing written informed consent. The Mayo Clinical Institutional Review Board approved all procedures (IRB #19-004560, ClinicalTrials.gov Identifier NCT04514523).

Study Procedures

The full pilot protocol was published previously (6). Once enrolled in the study and before a scheduled appointment, people with diabetes were approached by study personnel either in person, by telephone, or via e-mail to review the QBSAFE ASK in a paper (Supplementary Figure S1) or electronic (<https://patientrevolution.org/qbsafe>) format. The kit was also made available in a paper format during in-person clinical encounters. People who needed to access

the kit during telehealth or telephone encounters were directed to the electronic format. Individuals could select up to three cards from the kit to discuss with their clinician during the encounter. Encounters were audio- or video-recorded, although individuals could decline recording and still participate in the study. After encounters, clinicians and patients completed a three-question post-encounter survey to assess acceptability (Supplementary Table S1).

Outcome Measures

We assessed the feasibility of research procedures to determine the effectiveness of the ASK and to assess the acceptability of using the QBSAFE ASK in practice. Research feasibility was evaluated by assessing the time it took the study team to enroll clinicians and people with diabetes, the percentage of those approached who were willing to participate, and the percentage of participants who completed all study procedures. ASK acceptability was assessed via the three-question survey obtained from participants by study personnel after clinical encounters.

Analysis

Two coders (S.H. and C.G.-L.) analyzed all recorded clinical encounters to assess the number and type of selected cards, measure the length of the encounter, and characterize the conversations about issues brought up using the QBSAFE ASK. A codebook to define clinician responses and conversations around the QBSAFE ASK was developed by using existing literature and data from prior video analysis. Clinicians' responses were coded as follows: ignored, addressed conversation card, asked more questions, recommended further/continued monitoring, recommended change in monitoring, recommended referral, suggested new or a change in medication or treatment plan, suggested behavioral change (diet/exercise), and/or made a change in the follow-up plan. The types of conversations elicited by the QBSAFE ASK were developed a priori and categorized into five groups: patient-directed conversations, clinician-directed conversations, collaborative conversations, confrontational conversations, or cards did not elicit discussion. Coders first had to achieve $>90\%$ calibration and then coded subsequent encounters independently. Coders discussed discrepancies or questions in coding to determine appropriate clinician response/conversation, and updates were made to the codebook. Data were recorded within RED-Cap (Research Electronic Data Capture) software and

analyzed via Stata statistical software. We reported simple percentages and averages, when applicable.

Results

Seven clinicians were recruited to participate, including five from the Mayo Clinic, one from Yale, and one from Trinity Health. Three clinicians were female, and most were diabetes specialists. Across the three study sites, 213 people with type 2 diabetes were potentially eligible and contacted for enrollment based on appointment lists of participating clinicians. Of these 213 people, 85 (39.9%) agreed to participate in study and were enrolled. Of these 85, 70 (82.4%) were ≥ 50 years of age (mean age 63 ± 14.7 years). Less than half ($n = 37$ [43.5%]) were female, and 71 (84.5%) self-identified as White. The majority ($n = 70$ [84.5%]) had an A1C measured 6 months before to 3 months after the recorded clinical encounter. The mean A1C was $7.48 \pm 1.17\%$ (Table 1).

Feasibility and Acceptability of QBSAFE ASK

Target accrual was reached in 145 days (seven clinicians and 85 people with diabetes). Most people with diabetes ($n = 66$ [77.7%]) agreed to have their clinical visit recorded, and all study procedures were completed for 58 patients (68.2%). Across 69 encounters for which clinicians completed surveys, clinicians usually agreed that they felt confident responding to issues raised through the use of the tool (in 62 encounters [89.9%]),

that they would use the tool again (in 54 encounters [78.2%]), and that they would recommend the tool to their colleagues (in 56 encounters [82.4%]). Among people with diabetes who completed study procedures, 37 (63.8%) agreed that the QBSAFE ASK helped them discuss their situation, 45 (77.6%) agreed that others could benefit from the tool, but only 22 (37.9%) said they would use the tool at their next visit.

QBSAFE ASK Tool Within Clinical Encounters

Clinical encounters were either in-person ($n = 36$ [54.6%]) or conducted via telehealth video ($n = 19$ [28.8%]) or telephone ($n = 11$ [16.7%]). The mean length of clinical encounters was 29.4 ± 12.1 minutes. The mean length of encounters was not significantly different based on the use of the ASK (29.9 minutes for encounters using with ASK cards selected vs. 27.7 minutes for those with no cards selected, $P = 0.59$).

The QBSAFE ASK was introduced in almost every recorded encounter ($n = 65$ [98.5%]) and in most cases the conversation cards were brought up by the clinician ($n = 46$ [69.7%]). Half of the participating people with diabetes with recorded encounters ($n = 33$) viewed the conversation cards via the electronic format. Fifty-five people with diabetes selected one or more cards (83.3%) across 66 recorded encounters. Every conversation card within the QBSAFE ASK was selected at least once. When people with diabetes used the QBSAFE ASK tool, they most often selected one card (median 1 [interquartile range 1–2]).

The most frequently selected card was “I find it hard to follow your suggestions about diet and exercise” ($n = 19$ [34.5%]), followed by “I struggle with monitoring my blood sugar” ($n = 14$ [25.5%]), “I struggle with remembering, taking, or managing my medications” ($n = 11$ [20.0%]), and “I have another issue related to my diabetes that I’d like to talk about” ($n = 11$) (Figure 1).

In four of the 55 encounters where cards were selected, people with diabetes chose a positive conversation card (“Diabetes has had some positive impacts on my life” or “I have felt moments of pride while managing my diabetes”). The cards exclusively elicited a person-directed conversation, with clinicians asking elaborating questions.

Clinician Response

The most common clinician response to the selected conversation cards was to ask elaborating questions ($n = 45$ [81.8%]), followed by making a change in medication/treatment ($n = 19$ [34.5%]), recommending behavioral change ($n = 17$ [30.9%]), continued

TABLE 1 Baseline Characteristics of Participants Recruited for the Trial

	People With Diabetes (N = 85)	Clinicians (N = 7)
Age, years	63 \pm 14.7	NA
Female sex	37 (42.5)	3 (42.9)
Self-reported race		
White	71 (84.5)	NR
People of color	13 (15.5)	NR
Recruitment site		
Mayo Clinic	49 (57.7%)	5
Yale University	30 (35.5%)	1
Trinity Health of New England	6 (7%)	1
A1C, %	7.46 \pm 0.01	NA
Encounter type (N = 66)		
In-person	36 (54.6)	NA
Telehealth video	19 (28.8)	NA
Telephone	11 (16.7)	NA

Data are mean \pm SD or n (%). NA, not applicable; NR, not reported.

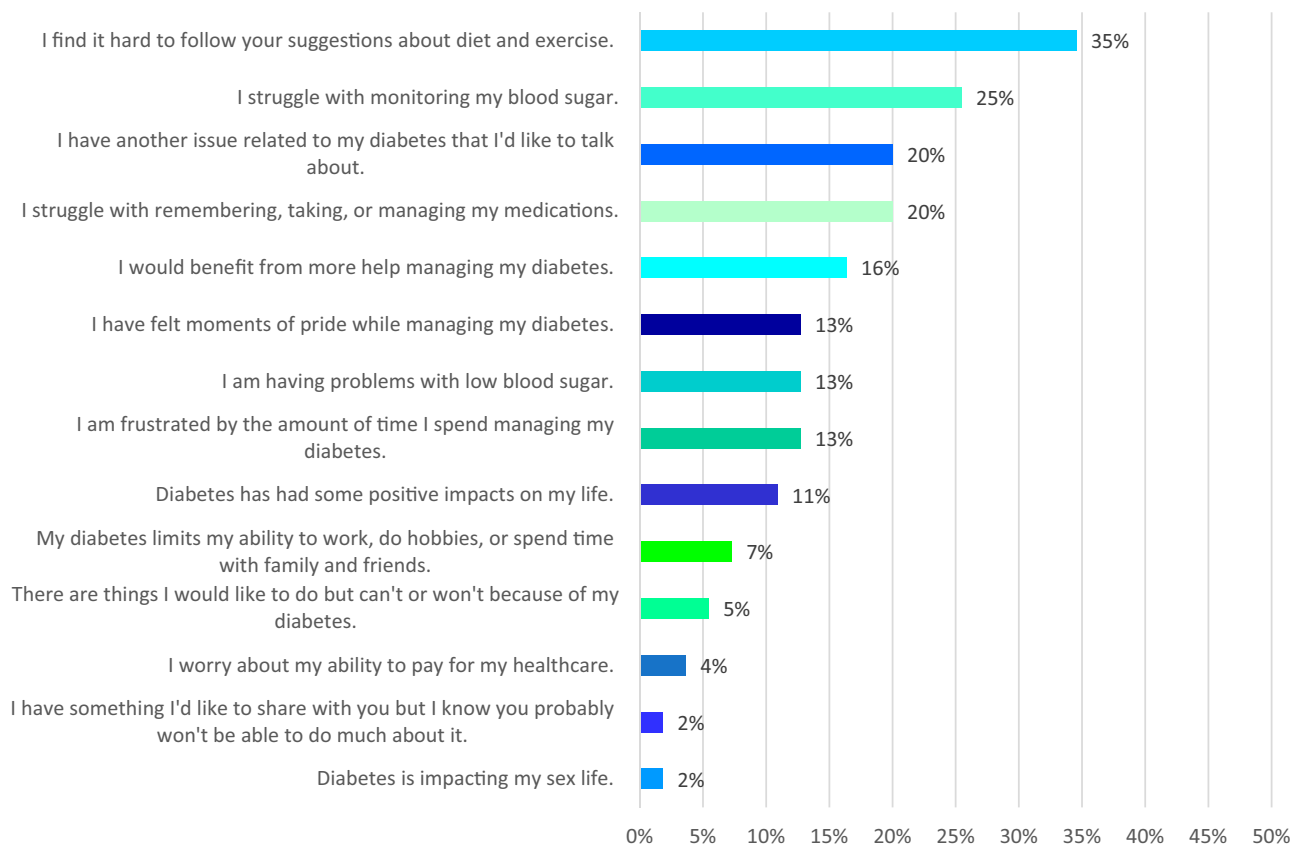


FIGURE 1 Frequency of QBSAFE ASK cards selected during routine clinical encounters of people with type 2 diabetes.

monitoring ($n = 12$ [21.8%]), and recommending referral ($n = 12$ [21.8%]) (Figure 2).

The QBSAFE ASK most often elicited collaborative conversation between clinicians and people with diabetes ($n = 29$ [52.7%]), followed by person-directed conversations ($n = 10$ [18.2%]) and clinician-directed conversations ($n = 6$ [10.9%]) with no confrontational or conflicted conversations observed. We did not capture the types of conversations elicited when the ASK was not used.

Discussion

In this single-arm intervention pilot and feasibility study, study procedures were feasible, and the QBSAFE ASK tool was generally acceptable to people with diabetes and their clinicians. Conversations elicited when the QBSAFE ASK tool was used were often collaborative and involved brainstorming to find a solution, often in response to challenges participants with diabetes experienced with their diabetes self-management. This approach led to clinicians asking elaborating questions and to occasional changes in treatment, with no significant difference in encounter length between those using and not using the ASK. These findings suggest that the

QBSAFE ASK holds promise in helping people with diabetes discuss their situation with clinicians and eliciting collaborative problem-solving.

Clinician-directed conversations during routine diabetes care often center around treatment targets, reinforced by guidelines (4). A treat-to-target approach narrowly focuses on metrics such as A1C goals without incorporating individuals' treatment burden or other quality-of-life issues related to living with diabetes. Particularly in people not meeting treatment goals and experiencing significant treatment burdens, this approach may lead to further treatment intensification, which can be ineffective and even harmful (1). Furthermore, as seen in our study, people who are at or near their goal A1C can still experience a significant burden of disease and treatment. With the QBSAFE ASK, we propose shifting the focus of clinical encounters from the treat-to-target approach that is entrenched in clinical care to one that is collaborative and responsive to problems identified by each person at that specific point in their life. Our findings suggest that the QBSAFE ASK may be an effective intervention that prioritizes individuals' concerns and leads to productive conversations about how to solve them (i.e., may help care fit) (7).

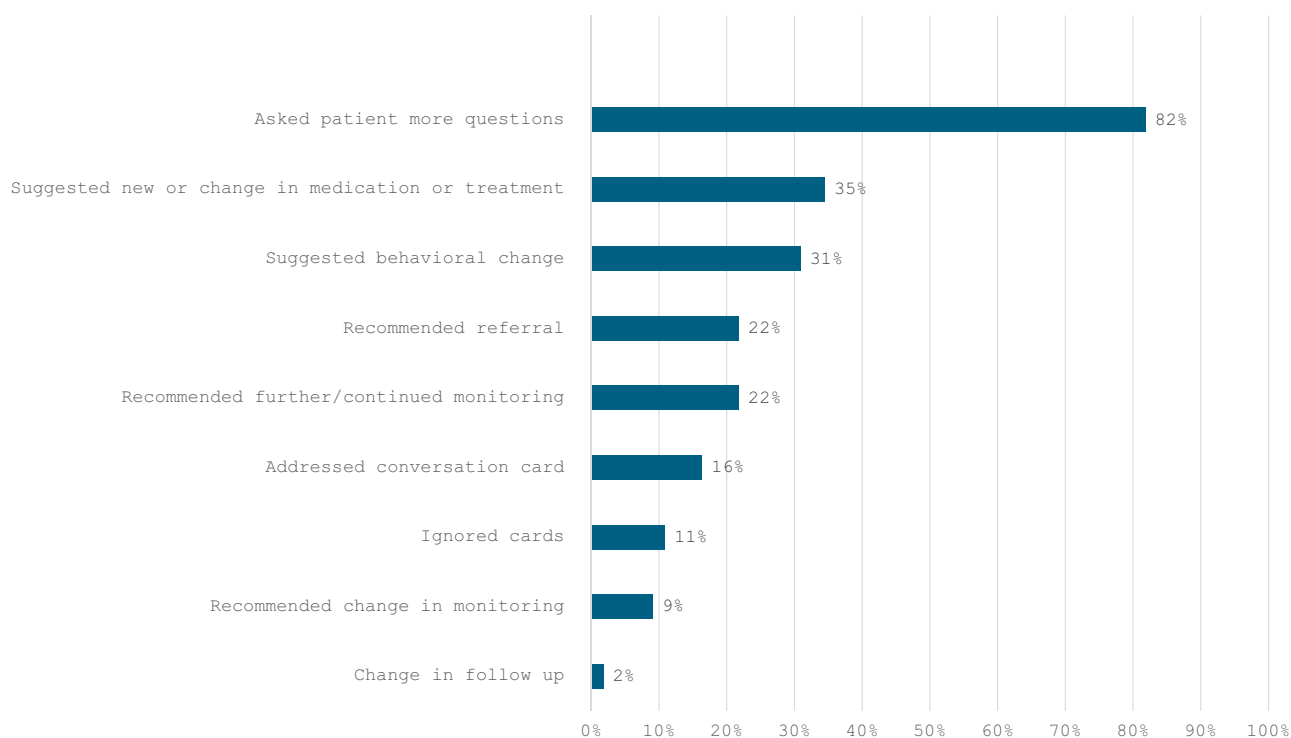


FIGURE 2 Frequency of the types of clinician responses to QBSAFE ASK cards, as determined from video analysis of clinical encounters with people with type 2 diabetes.

In recent years, professional societies and clinical guidelines have emphasized the need to engage people with diabetes in shared decision-making (4). Numerous tools have been developed to facilitate shared decision-making between individuals and clinicians (8–11). These tools have ranged from handouts outlining guideline recommendations (4) to interactive, Web-based resources (10). One study described the development of agenda-setting cards similar to the QBSAFE ASK to facilitate conversations between people with diabetes and clinicians (12). Most tools have demonstrated high levels of acceptability by both people with diabetes and clinicians (10–12). Tools involving conversation cards have focused on themes similar to those in the QBSAFE ASK, such as treatment burden and quality of life (12). People with diabetes found conversation cards useful in describing their experience, although one study described a subset of individuals who thought the cards would benefit others, but not themselves (12). However, prior studies have not evaluated responses to conversation cards in a clinical setting.

The QBSAFE ASK often elicited conversations related to diet/exercise, glucose monitoring, and medications. Prior studies have demonstrated that diabetes medications and monitoring are common concerns (13–15). Similarly, a prior qualitative study found that tasks such

as implementing complex medication regimens and making lifestyle changes were burdensome for some people (16). Clinicians most often responded to conversation cards by asking elaborating questions, similar to results from our prior study assessing clinicians' responses to patients' concerns (5). These forms of problem-solving conversations demonstrate purposeful shared decision-making (17) and illustrate how shared decision-making can be an effective method for care (18).

Limitations

There are some limitations to our study. This was a single-arm study trial, which means we could not compare the impact of the QBSAFE ASK with usual care versus usual care without the kit. Both clinicians and people with diabetes who participated in this study may have been more likely to use and positively respond to the conversation cards than the general population of clinicians and people with diabetes. Most participating clinicians were specialists and may have felt more comfortable addressing individuals' diabetes-specific concerns. Most participating people with diabetes were established patients and tended to be in an older age-group. The coronavirus disease 2019 pandemic occurred at the beginning of the trial, which limited and delayed recruitment. Finally, because this was a proof-of-concept feasibility trial, future studies are needed to assess

whether the findings are generalizable. Nevertheless, our findings support the subsequent evaluation of the QBSAFE ASK tool in a randomized trial to compare its effectiveness to that of usual care without the kit and to estimate the extent to which its use can reduce treatment burden and improve clinical outcomes.

Conclusion

The QBSAFE ASK received a positive response from clinicians and people with diabetes. The tool was used often in clinical encounters and elicited collaborative problem-solving conversations between individuals and their clinicians. Study procedures were feasible in the setting in which they were studied. Further research is needed to assess the tool's feasibility in other clinical settings and to determine its efficacy.

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DUALITY OF INTEREST

No potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

S.H. analyzed data and wrote manuscript. C.G.-L., M.B., V.M.M., and K.J.L. analyzed data and reviewed and edited the manuscript. J.C., D.L.G., S.A.H., and B.S. collected data and reviewed and edited the manuscript. K.R.B. reviewed and edited the manuscript. S.H. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

REFERENCES

1. Shippee ND, Shah ND, May CR, Mair FS, Montori VM. Cumulative complexity: a functional, patient-centered model of patient complexity can improve research and practice. *J Clin Epidemiol* 2012;65:1041–1051
2. Shubrook JH, Brannan GD, Wapner A, Klein G, Schwartz FL. Time needed for diabetes self-care: nationwide survey of certified diabetes educators. *Diabetes Spectr* 2018;31:267–271
3. May CR, Eton DT, Boehmer K, et al. Rethinking the patient: using Burden of Treatment Theory to understand the changing dynamics of illness. *BMC Health Serv Res* 2014;14:281
4. American Diabetes Association. 12. Older adults: *Standards of Medical Care in Diabetes—2021*. *Diabetes Care* 2021;44(Suppl. 1):S168–S179

5. Haider S, El Kawkgi O, Clark J, et al. Beyond hemoglobin A1c: a videographic analysis of conversations about quality of life and treatment burden during clinical encounters for diabetes care. *Endocrine* 2021;73:573–579
6. Clark JE, Boehmer KR, Breslin M, et al. Quality of life, burden of treatment, safety, and avoidance of future events (QBSAfe) protocol: a pilot study testing an intervention to shift the paradigm of diabetes care. *Pilot Feasibility Stud* 2021;7:196
7. Kunneman M, Griffioen IPM, Labrie NHM, Kristiansen M, Montori VM; Making Care Fit Working Group. Making care fit manifesto. *BMJ Evid Based Med* 2023;28:5–6
8. Kunneman M, Branda ME, Hargraves IG, et al.; Shared Decision Making for Atrial Fibrillation (SDM4AFib) Trial Investigators. Assessment of shared decision-making for stroke prevention in patients with atrial fibrillation: a randomized clinical trial. *JAMA Intern Med* 2020;180:1215–1224
9. Austin CA, Mohottige D, Sudore RL, Smith AK, Hanson LC. Tools to promote shared decision making in serious illness: a systematic review. *JAMA Intern Med* 2015;175:1213–1221
10. Downing J, Gleeson H, Clayton PE, et al. Communication with young people in paediatric and adult endocrine consultations: an intervention development and feasibility study. *BMC Endocr Disord* 2017;17:33
11. den Ouden H, Vos RC, Reidsma C, Rutten GE. Shared decision making in type 2 diabetes with a support decision tool that takes into account clinical factors, the intensity of treatment and patient preferences: design of a cluster randomised (OPTIMAL) trial. *BMC Fam Pract* 2015;16:27
12. Lomborg K, Munch L, Krøner FH, Elwyn G. "Less is more": A design thinking approach to the development of the agenda-setting conversation cards for people with type 2 diabetes. *PEC Innov* 2022;1:100097
13. Boehmer KR, Dobler CC, Thota A, et al. Changing conversations in primary care for patients living with chronic conditions: pilot and feasibility study of the ICAN discussion aid. *BMJ Open* 2019;9:e029105
14. González-Saldivar G, Millan-Alanis JM, González-González JG, et al. Treatment burden and perceptions of glucose-lowering therapy among people living with diabetes. *Prim Care Diabetes* 2022;16:568–573
15. Bohlen K, Scoville E, Shippee ND, May CR, Montori VM. Overwhelmed patients: a videographic analysis of how patients with type 2 diabetes and clinicians articulate and address treatment burden during clinical encounters. *Diabetes Care* 2012;35:47–49
16. Espinoza P, Varela CA, Vargas IE, et al. The burden of treatment in people living with type 2 diabetes: a qualitative study of patients and their primary care clinicians. *PLoS One* 2020;15:e0241485
17. Kunneman M, Gionfriddo MR, Toloza FJK, et al. Humanistic communication in the evaluation of shared decision making: a systematic review. *Patient Educ Couns* 2019;102:452–466
18. Montori VM, Allwood D. Careful, kind care is our compass out of the pandemic fog. *BMJ* 2022;379:e073444