Received: 8 October 2025 | Accepted: 22 November 2025

DOI: 10.1111/dme.70185

DIABETIC Medicine

RESEARCH ARTICLE

Treatment

User evaluation of the Hypo-METRICS app: A tool for real-time symptom reporting of hypoglycaemia

Monika Cigler[1] | Uffe Søholm[2,3,4] | Melanie Broadley[2] | François Pouwer[2,5,6] | Evertine J. Abbink[7] | Namam Ali[7] | Bastiaan E. de Galan[7,8,9] | Eric Renard[10] | Mark Evans[11,12] | Julie Maria Bøggild Brøsen[13] | Ulrik Pedersen-Bjergaard[14] | Rory J. Mc Crimmon[15] | Simon Heller[16] | Sharon Caunt[17] | Stephanie A. Amiel[18] | Patrick Divilly[19] | Natalie Zaremba[20,21,22] | Pratik Choudhary[20] | Julia K. Mader[1] | on behalf of the Hypo-RESOLVE consortium

Correspondence
Julia K. Mader, Division of Endocrinology and Diabetology, Department of Internal Medicine, Medical University of Graz, 8036 Graz, Austria.
Email: julia.mader@medunigraz.at

Funding information
Innovative Medicines Initiative 2; Grant agreement 777460; EU Horizon 2020; EFPIA

Abstract

Aims: Hypoglycaemia remains a barrier to optimal diabetes management, with few tools for capturing real-time person-reported hypoglycaemia (PRH). This study evaluated the Hypo-METRICS app, originally developed for a multinational 10-week prospective study of hypoglycaemia. It enables real-time reporting of hypoglycaemic episodes and their impact on daily functioning using Ecological Momentary Assessment (EMA), thereby overcoming limitations of retrospective self reports.

Methods: After completing the Hypo-METRICS study, 120 participants with type 1 diabetes mellitus (T1D) or type 2 diabetes mellitus (T2D) from Austria, Denmark, the Netherlands, and the United Kingdom were invited to complete a web-based questionnaire assessing app content, functionality, intervention effects, user engagement and the influence of the Covid-19 pandemic.

Results: Ninety-six participants (80%; 29 T1D, 67 T2D) completed the questionnaire (40% women; mean age 57.2 ± 16.1 years; 26% impaired hypoglycaemia awareness; HbA1c 60 ± 13 mmol/mol (7.6 ± 1.1%); diabetes duration 20.4 ± 11.3 years). App content and functionality were rated highly (>8/10 and >7/10, respectively). Some reported declining engagement, likely due to study length. COVID-19 had a minimal impact on app use.

Conclusions: The Hypo-METRICS app was well accepted, with strong ratings for usability and functionality. Given its unique strengths, the app has the potential to become an essential instrument for researchers aiming to capture the real-world burden and impact of hypoglycaemia.

Hypo-RESOLVE consortium—See 'Funding' section for details.

For affiliations refer to page 8.

KEYWORDS
app, CGM, continuous glucose monitoring, diabetes, diabetes management, hypoglycaemia, Hypo-METRICS

1 | INTRODUCTION

Despite advancements in continuous glucose monitoring (CGM) and automated insulin delivery (AID) systems, individuals with insulin-treated diabetes continue to experience hypoglycaemia, which can significantly disrupt daily life.[1,2] While CGM and AID can significantly reduce time spent in hypoglycaemia,[3–8] even more so when combined with psychoeducational interventions,[9] these systems do not capture the real-world burden of hypoglycaemia from the perspective of those living with diabetes. In particular, they cannot account for the subjective perception of symptoms or the extent to which episodes interfere with daily functioning. Mild to moderate, self managed episodes occur frequently and have negative effects on the quality of life as well as mood, sleep and energy levels,[2,10] yet they remain relatively underexplored.

Available data are typically based on retrospective self reporting, which is susceptible to recall bias and tends to underestimate both the frequency and consequences of these episodes.[11] A lot of data in this field come from questionnaire studies that may also have a recruitment bias towards those who feel most impacted by hyperglycaemia.[12,13] This limitation underscores the need for a more dynamic, person-centred, real-time method of capturing hypoglycaemic episodes and their impacts.

To address this gap, the Hypo-METRICS app was developed as a real-time reporting tool using Ecological Momentary Assessment (EMA) methodology—the collection of real-time data on individuals' experiences and behaviours in their natural everyday environments[10,14]—designed for use in the multinational Hypo-METRICS study.[15,16] This study aimed to investigate hypoglycaemia experience in people with diabetes using insulin, employing blinded CGM and activity monitors over a 10-week period.

Quantitative outcomes using data from the Hypo-METRICS app have been published showing that person-reported hypoglycaemia (PRH) was associated with impairments across multiple functional domains, whereas asymptomatic, sensor-detected hypoglycaemia (SDH), not reported on the app, had little to no observable effect.[10] Notably, nearly two thirds of SDH episodes were not perceived by participants, while a substantial proportion of PRH episodes occurred above standard CGM thresholds (>70 mg/dL).[17]

What's new?

What is already known?

- Hypoglycaemia remains a major barrier to optimal diabetes management.
- Real-time, person-reported assessment of hypoglycaemia is limited.

What this study has found?

- A mobile application using Ecological Momentary Assessment enables real-time, person-reported capture of hypoglycaemia.
- The application allows documentation of hypoglycaemic episodes and their impact on daily functioning.

What are the implications of the study?

- Real-time person-reported hypoglycaemia assessment may improve understanding of hypoglycaemia burden in everyday life.
- Such tools could support more person-centred diabetes management and future intervention development.

Considering the limitations of traditional assessment methods and the added value demonstrated by real-time data in the Hypo-METRICS study, we aimed to formally evaluate the usability and acceptability of the Hypo-METRICS app itself. Specifically, we sought to assess how participants perceived the app in terms of understandability, relevance, content, functionality, user engagement and changes in diabetes self management. This quantitative evaluation was conducted alongside a mixed-methods interview study, which explored the content validity, acceptability and feasibility of the app.[18]

2 | MATERIALS AND METHODS

Participants from four countries (Austria, Denmark, the Netherlands and the United Kingdom) who had

completed the 10-week Hypo-METRICS study by June 2023, were invited to complete a web-based questionnaire designed to explore their experiences with the app and gather feedback to inform potential future applications, particularly in research settings.

2.1 | The Hypo-METRICS App

The app consists of two distinct components: one enabling participants to record hypoglycaemic episodes, and another capturing their effects on daily functioning—including mood, cognition, sleep and energy—through structured daily check-ins. One key feature of the app is the Hypo-METRICS 'motif', a patented flower-shaped interface designed by the app hosting platform uMotif,[19] in which each of eight petals represents a common symptom of hypoglycaemia. By tapping the relevant petals, participants could quickly and intuitively report a symptom profile shortly after each hypoglycaemic episode. These self reported episodes are linked to blinded CGM data, allowing for an integrated perspective that combines objective glucose readings with participants' lived experiences.

2.2 | Eligibility criteria and participants

Eligibility criteria for inclusion in this follow-up study required that participants had completed the Hypo-METRICS study within the previous 2 months, had access to a computer or smartphone with internet connectivity, and were willing and able to participate in an online survey. Participants included individuals with both T1D and insulin-treated T2D from 18 to 80 years.

2.3 | Consent and Ethical Approval

Participants who expressed interest in the questionnaire study received detailed information about its purpose and instructions for completing the online survey. Participation was voluntary, and individuals could withdraw at any time without providing a reason. The study received ethical approval from the relevant Ethics Committees at all participating hospitals and medical institutions within the European Union. In the United Kingdom, a favourable opinion was issued by the UK-wide Integrated Research Approval System (IRAS) on behalf of all participating UK sites. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and adhered to Good Clinical Practice (GCP) guidelines.

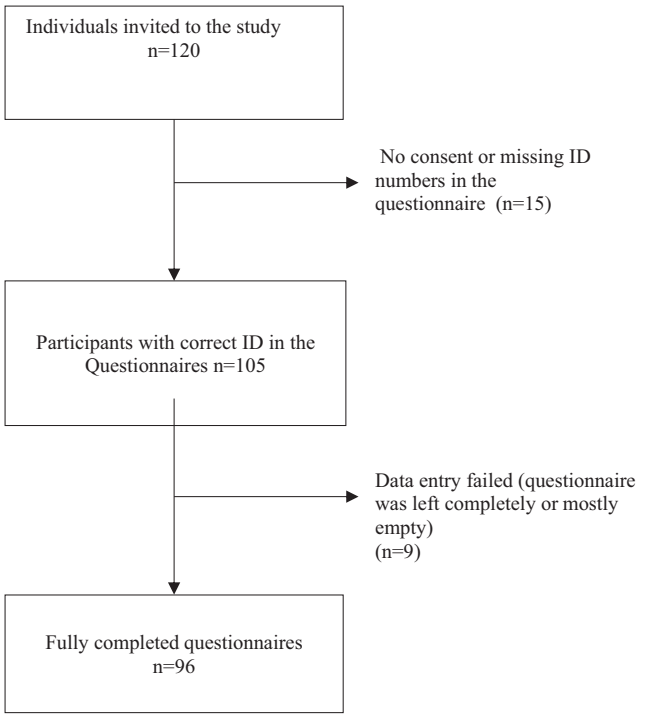

FIGURE 1 Study participation flow.

A flow chart illustrating participant flow throughout the study is presented in Figure 1.

2.4 | Study design and questionnaire description

After providing written informed consent, participants received an email with a personalized link to the online questionnaire, which was administered via the web-based platform Qualtrics (a web-based survey platform, headquartered in Provo, Utah, and Seattle, Washington, USA; https://www.qualtrics.com) and presented in the language of each participating country.

The questionnaire comprised of three sections. In section one, participants were asked to evaluate the original questions of the Hypo-METRICS App (Table S1). They were instructed to rate, on a scale of 1 to 10 (with 1 meaning completely disagree and 10 meaning completely agree), the ease of understanding the questions and the perceived relevance of each item in relation to how diabetes affected their daily lives.

In section two, participants were presented 19 statements related to the Hypo-METRICS app, each of which could be assigned to one of the following categories: engagement, content, functionality, perceived changes in diabetes self management or impact of the Covid-19 pandemic. For each statement, they indicated their level of agreement again on a scale from 1 to 10 (1 = completely

disagree, 10 = completely agree), to evaluate the app across these dimensions.

In both parts, a rating above 5 (or at or below 5 for negatively phrased items) was interpreted as indicating user satisfaction with the app, while a rating at or below 5 (or above 5 for negatively phrased items) was considered to reflect user dissatisfaction.

The final section comprised two numerical questions (concerning the number of questions in the check-ins) and two open-ended items which allowed participants to share general impressions and provide qualitative feedback on their experience with the app ('Do you think any of the questions or answers in the check-ins should be re-phrased? If yes, please describe which and why'. 'Do you think important questions relevant to your hypoglycaemia were missing in the check-ins? If yes, please describe'.).

App usage was also evaluated. It was calculated as the number of completed check-in sessions divided by the number of scheduled check-in sessions for each participant, expressed as a percentage. Scheduled check-ins included three notifications per day (morning, afternoon and evening) over the 10-week study period (i.e. up to 210 sessions). Days on which a participant withdrew from the study early or where the app was not installed were excluded from the denominator.

2.5 | Statistical analysis

The analysis focused on descriptive statistics to summarize the collected data and provide an overview of participant demographics and key questionnaire responses. Given the scope of the study, advanced inferential statistics were not applied, as the aim was to provide a comprehensive description of the dataset rather than to test specific hypotheses.

3 | RESULTS

Out of the 120 questionnaires distributed to people that fulfilled the eligibility criteria, responses from 96 participants were considered valid and included in the analysis. Fifteen responses were excluded due to missing ID numbers; an additional nine responses were excluded because they contained insufficient data (the questionnaire was left completely or almost entirely empty). This resulted in an effective response rate of 80%.

The included 96 participants had a mean age of 57.2 ± 16.1 years. Thirty-eight (40%) were women, 29 (30%) lived with diabetes type 1 (T1D) and 67 (70%) with diabetes type 2 (T2D). Twenty-five participants (26%) were affected by impaired awareness of hypoglycaemia (IAH); 44% were retired and the mean app usage was 89.5% of the time ± 8.6%. For more details, see Table 1 (demographics).

TABLE 1 Participants' demographic characteristics.

Variable	Participants (N=96)
Age (years), mean (SD)	57.2 (±16.1)
Country	
Austria	15
Denmark	6
The Netherlands	38
United Kingdom	37
Women gender, *n* (%)	38 (40%)
Diabetes type, *n* (%)	
T1D (diabetes mellitus, type 1)	29 (30%)
T2D (diabetes mellitus, type 2)	67 (70%)
IAH (impaired awareness of hypoglycaemia/Gold score), *n* (%)	
Yes	25 (26%)
Highest level of education, *n* (%)	
Primary school	9 (9%)
Secondary High School	23 (24%)
College/Undergraduate	39 (40%)
Master/PhD/MBA	18 (19%)
Other	7 (7%)
Employment status, *n* (%)	
Full-time education	6 (6%)
Full-time employment	24 (25%)
Part-time employment	12 (13%)
Unemployed, but actively looking for work	3 (3%)
Unemployed, not actively looking for work	9 (9%)
Retired	42 (44%)

3.1 | The Hypo-METRICS app and participants' ratings on relevance and understandability

Participants were asked to rate each item from the Hypo-METRICS app's check-in section—completed three times per day—on understandability and perceived relevance to daily life with hypoglycaemia.

On the 1–10 scale assessing understandability, the items addressing sleep quality, general well-being/mood, fear of hypoglycaemia and hyperglycaemia, social interaction and self reporting of hypoglycaemic episodes showed mean ratings of 7.5 or higher. The item 'How

many hours did you miss from activities other than work today?' had a mean understandability rating of 5.7 among retired and unemployed participants and 6.3 among employed participants. For perceived relevance, the items on self reported hypoglycaemia, fear of hypoglycaemia and sleep quality showed mean scores of 7.0, 6.8 and 6.6, respectively. The items on fear of hyperglycaemia and general well-being/mood both had mean scores of 6.1. Work- and productivity-related items showed lower mean scores, with the item on hours missed averaging 4.0 among retired/unemployed participants and 5.0 among employed participants.

Regarding perceived relevance, the item 'self report of hypoglycaemia' had the highest mean score (7.0), followed by 'fear of hypoglycaemia' (6.8) and 'sleep quality' (6.6). 'Fear of hyperglycaemia' and 'general well-being/mood' both averaged 6.1. Work- and productivity-related questions had lower mean scores, with the question on hours missed averaging 4.0 among retired or unemployed participants and 5.0 among employed participants.

An overview of these results is shown in Figure 2, where orange bars represent ratings of '*The question is easy to understand*' and red bars represent '*The question is relevant to how hypoglycaemia affects me*'. A more detailed breakdown of individual item scores is available in the Table S1.

3.2 | Ratings on engagement, content, functionality, change in diabetes self management and impact of the Covid-19 pandemic

A summary of key findings is presented in Table 2.

Overall, participants reported high levels of usability and acceptability. Items related to functionality and content showed high mean ratings, especially those addressing ease of use and clarity of instructions. Motivation and engagement appeared to vary over time, as indicated by lower mean scores on items related to response fatigue or reduced interest. Participants did not report notable changes in diabetes self management, although some indicated greater awareness of hypoglycaemic symptoms and more frequent monitoring of glucose levels. Reports of increased confidence in insulin dose adjustments were

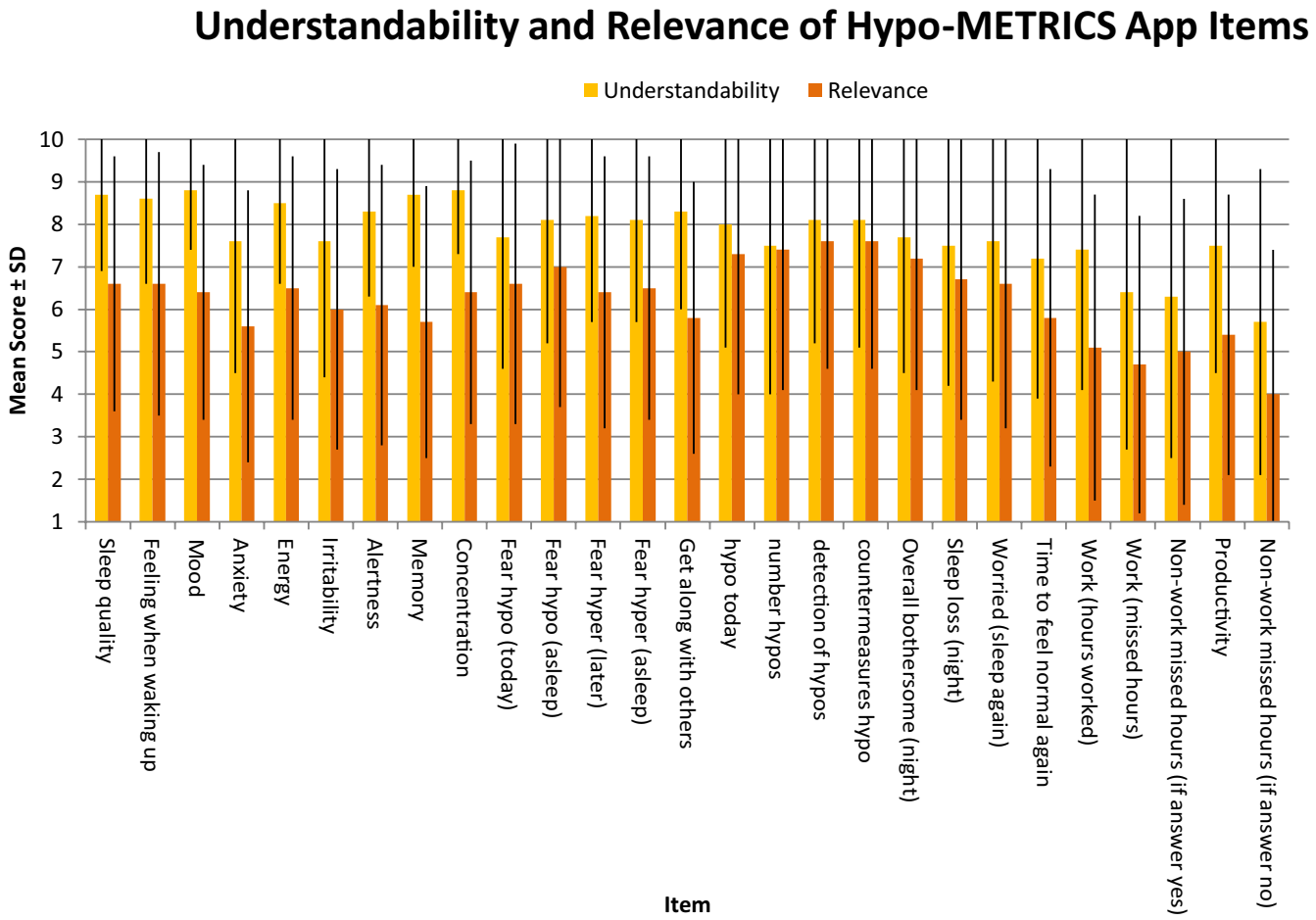

FIGURE 2 Understandability and relevance of Hypo-METRICS app items.

TABLE 2 Key usability and perceived changes in diabetes self management of the Hypo-METRICS app.

Dimensions	Item/question	Mean (SD)	Interpretation
Functionality	It was easy to use the check-ins	9.4 (2.2)	High user-friendliness
	Check-in reminders were helpful	8.1 (2.5)	Effective user guidance through reminders
Content	The instructions were easy to understand	8.7 (1.5)	High clarity and structure
	The time required was acceptable	8.7 (1.7)	Easily integrated into daily routine
Engagement	My responses became automated over time	6.1 (2.3)	Slight decline in engagement over time
	My motivation decreased as the study progressed	5.6 (3.4)	Suggests some repetitiveness in use
Perceived changes in diabetes self management	I checked my glucose levels more often	6.9 (3.0)	Increased reflection on glucose monitoring
	I have a better understanding of how hypoglycaemia affects me	7.2 (3.0)	Increased reflection on the personal impact of hypoglycaemia
Hypo-METRICS motif	The flower was easy to use	5.6 (3.4)	Some technical difficulties in using the flower (fat-finger error)

TABLE 3 Summary of participant feedback and suggestions for improvement ($N = 96$).

Themes	Description	No. of Comments	Suggestion for improvement
Preferred frequency of check-ins	Satisfaction with three daily check-ins	53	N/A.
Vagueness of questions about missed work or other activities	These questions were more difficult to understand, particularly for retired/unemployed participants	19	Provide an explanation for why these questions are included
Repetition of questions	Participants reported repetitive content, which led to boredom and careless responding	11	Vary the questions weekly
Time burden during frequent hypoglycaemic episodes	Frequent hypoglycaemia made completing check-ins burdensome, especially at night/in the morning. Therefore, not all episodes were reported	7	For multiple hypos in one night, only record the times of episodes and complete the questions only once, with optional notes if needed
Hypo-METRICS flower: engaging but occasionally difficult	The flower was generally seen as quick and engaging, but some users found it challenging to use (fat-finger error)	6	Enlarge petals to prevent accidental double-clicks, especially for users with thick fingers

uncommon. Responses to two COVID-19-related items suggested that the pandemic had little influence on participation or hypoglycaemia management.

The full set of item-level results, including all 19 statements with corresponding means and standard deviations, is available in the Table S2.

3.3 | Participant feedback and suggestions for improvement

Qualitative feedback provided in free-text fields revealed several areas for potential improvement. Although these suggestions were not implemented within the current study, they provide guidance for future refinement. Issues mentioned by ≥10% of participants were considered common, while less frequent comments were noted if they indicated substantial burden or subgroup-specific challenges (Table 3).

4 | DISCUSSION

The results of this evaluation indicate that the Hypo-METRICS app was well received by participants, who reported high levels of usability, clarity and content relevance.

Regarding clarity, only one out of the 29 items received notable criticism from participants. The question 'How many hours did you miss from activities other than work today for any reason?', which was included to capture aspects of the macroeconomic impact of diabetes,

was perceived as unclear and confusing—particularly by participants not undergoing paid work (retired and unemployed persons; see also results section). One participant noted:

> 'What do you mean with "did you miss from other activities than work for any reason today?" If I missed my guitar lesson because I was looking after my grandchildren, what does my answer "1 hour" tell you?'

A more precise formulation of this question, along with a brief explanation of its purpose, might have improved the clarity of the item and participants' understanding.

Responses regarding the relevance of the questions as to the effect of hypoglycaemia in their daily lives showed that the more the question was directly linked to the hypoglycaemic episode or to fear of this episode, the more relevant it was considered to be. Questions about mood or work could also be attributed to causes other than hypoglycaemia and were therefore rated lower.

Participants were generally satisfied with both the content and functionality of the app, and the Hypo-METRICS motif, used for instant reporting of symptoms of hypoglycaemia, was generally perceived as practical and visually engaging, but some participants noted usability issues. For individuals with thick and clumsy fingers, the main issue was technical: they found it difficult to tap a single petal without accidentally selecting two at once. In contrast, other participants more often noted that not all of their hypoglycaemia symptoms were represented by the available petals.

Maintaining consistent engagement over time seems to have presented a challenge for some, the reason being repetitive questions and automated answers, resulting in a decrease in motivation over the course of the study. This problem has also been described in similar studies.[20,21] Enhancement of motivation should be addressed for future app use, possibly by targeted incentives or AI solutions that could add a bit of variety to the questions.

The results suggested that engaging with the app over a 10-week period made people think more about the impacts of their hypoglycaemic episodes and made them remember checking their glucose values more frequently; however, this did not amount to notable changes in diabetes self management.

Further analyses are being conducted to assess potential changes in HbA1c, patient-reported outcomes and rates of hypoglycaemia over the 10-week study, with results to be published in a forthcoming paper.

Most of the existing research on the impact of hypoglycaemia on daily life has focused on severe episodes requiring third-party assistance.[22] For example, a recent, large real-world survey conducted across North America found that despite widespread use of modern diabetes technology, 44% of participants experienced at least one severe hypoglycaemic episode over the course of a year. The majority (70%) were managed at home by family or friends, highlighting the on-going prevalence of hypoglycaemia and the broad impact of severe episodes—not only on individuals but also on their immediate social environment.[23] Our study has focused more on milder forms of hypoglycaemia, which occur far more frequently, can nevertheless substantially impair daily functioning, and have so far received only very limited attention in the literature.[2,10] One of the examples showing that even milder forms of PRH can disrupt daily life is Søholm et al.,[10] who demonstrated that PRH episodes were followed by significant impairments in energy, mood, cognitive functioning and sleep, alongside heightened negative affect and fear.

Patients are in a unique position to contribute indispensable information to healthcare quality, as they are the only individuals who experience the whole episode of care from start to finish. Consequently, the systematic assessment of patient experiences and outcomes through Patient-Reported Experience Measures and Patient-Reported Outcomes Measures is essential in any quality improvement enterprise.[24]

Another important feature of our study is EMA, which is in line with a growing body of research highlighting the value of EMA in clinical studies of diabetes. Some of these report that for both persons with type 1 and type 2 diabetes, using diabetes apps was positively associated with self care behaviour and might support changes in lifestyle and glucose monitoring.[25,26] Other studies highlight the potential of EMA-based app designs to capture meaningful, real-time patient experiences that may remain undetected through conventional assessment methods. For example, one study[27] found that EMA-derived diabetes distress was more closely associated with glycaemic outcomes than traditional questionnaires. Another recent study[28] combined EMA with continuous glucose monitoring and ambulatory cognitive testing to demonstrate that nocturnal hypoglycaemia was linked to impaired next-day cognitive performance. These findings, along with our own results, underscore the value of EMA in capturing real-world data on symptoms, behaviours and glucose dynamics with high temporal resolution and reduced recall bias.

4.1 | Limitations

Our study is not without limitations. Participants were selected from the Hypo-METRICS study and needed to be capable of using a smartphone and completing an

online questionnaire. These criteria may have introduced a certain degree of selection bias. As the questions in this analysis were specifically developed to evaluate selected aspects of the Hypo-METRICS app, they have not been validated against standardized app evaluation tools, which may limit the validity and generalizability of our findings. Another limitation relates to the satisfaction threshold: Because no validated or widely accepted cut-off exists for defining (dis)satisfaction on this specific scale, we used a straightforward midpoint-based threshold (5 out of 10) to distinguish between lower and higher satisfaction levels.

4.2 | Core strength of the Hypo-METRICS app and future opportunities

The Hypo-METRICS app is unique in that it aims to report hypoglycaemic episodes and symptoms by the participant, notably, in real time, thereby reducing one of the big problems of questionnaires filled out long after the episode of hypoglycaemia has occurred—namely, recall bias, which tends to lead to an underestimation of the number of experienced episodes. Our findings align with other evaluations of the Hypo-METRICS app, focused on qualitative reporting[18] and completion rates across user demographics.[29] User satisfaction is crucial, as a positive reception of the app by participants would make it possible to serve as a supplementary tool to CGM and glucose meters in diabetes research in order to reveal those cases where sensor-detected episodes of hypoglycaemia do not align with patient-reported symptoms. These cases are not rare: As Divilly et al.[17] demonstrated, more than 60% of all hypoglycaemic episodes measured in Hypo-METRICS by continuous glucose monitoring (CGM) were asymptomatic, and over 40% of the episodes reported by participants occurred at glucose levels above 70 mg/dL, thus not being captured by CGM sensors. Also, Søholm et al. reported on the importance of person-reported hypoglycaemia (PRH), as he showed that it significantly impacted various aspects of daily functioning, whereas sensor-detected hypoglycaemia (SDH) alone had minimal or no discernible impact.[10]

5 | CONCLUSION

The study findings demonstrate that the Hypo-METRICS app was well received by participants, who found it user-friendly and easy to integrate into their daily routines. Built on the principles of EMA, the app enables real-time documentation of hypoglycaemic episodes and reduces recall bias inherent in traditional assessment methods. Given these unique strengths, the app has the potential to become an essential instrument for researchers aiming to capture the real-world burden and impact of hypoglycaemia.

AUTHOR CONTRIBUTIONS

Conceptualization: MC, US, JM, MB, FP and SAA; Methodology: MC, US, EJA, NA and BG; Investigation: MC, NA, PD, NZ, US and SC; Formal analysis: MC, EJA, PC and UPB; Data curation: MC, NA, BG and NZ; Visualization: MC, MB and FP; Writing—original draft: MC; Writing—review and editing: all authors; Supervision: SAA, RJMC, SH, JM, UPB, ME, JBB and PC; Resources: MC; Project administration: MC and US; Funding acquisition: BG.

AFFILIATIONS

[1]Division of Endocrinology and Diabetology, Department of Internal Medicine, Medical University of Graz, Graz, Austria
[2]Department of Psychology, University of Southern Denmark, Odense, Denmark
[3]School of Psychology, Institute for Health Transformation, Deakin University, Geelong, Victoria, Australia
[4]The Australian Centre for Behavioural Research in Diabetes, Diabetes Victoria, Carlton, Victoria, Australia
[5]Steno Diabetes Center Odense (SDCO), Odense, Denmark
[6]Department of Health and Caring Sciences, Western Norway University of Applied Sciences, Bergen, Norway
[7]Department of Internal Medicine of Radboud University Medical Centre, Nijmegen, The Netherlands
[8]Department of Internal Medicine, Maastricht University Medical Center, Maastricht, The Netherlands
[9]CARIM Cardiovascular Research Institute Maastricht, Maastricht University, Maastricht, The Netherlands
[10]Montpellier University Hospital, Montpellier, France
[11]Institute of Metabolic Science and Department of Medicine, University of Cambridge, Cambridge, UK
[12]Level 4, Institute of Metabolic Science, Addenbrooke's Hospital, Cambridge, UK
[13]Department of Endocrinology and Nephrology, Copenhagen University Hospital—North Zealand, Hillerød, Denmark
[14]Department of Endocrinology and Nephrology, Copenhagen University Hospital, Hillerød, Denmark
[15]School of Medicine, Ninewells Hospital, University of Dundee, Dundee, UK
[16]Division of Clinical Medicine, School of Medicine and Public Health, University of Sheffield, Sheffield, UK
[17]Academic Directorate of Diabetes and Endocrinology, Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, UK
[18]Department of Diabetes, Faculty of Life Sciences and Medicine, King's College London, London, UK
[19]St. Vincent's University Hospital, Dublin, University College Dublin, Dublin 4, Ireland
[20]Diabetes Research Centre, University of Leicester, Leicester, UK
[21]Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care, King's College London, London, UK
[22]Department of Medical Psychology, Radboud University Medical Center, Nijmegen, The Netherlands

ACKNOWLEDGEMENTS

We thank all participants for their time and contributions, the members of the HypoRESOLVE consortium and everyone involved in developing the Hypo-METRICS app, including the HypoRESOLVE Patient Advisory Committee, for their valuable support and guidance. For the purpose of open access, the authors have applied a Creative Commons Attribution (CC BY) licence to any Author Accepted Manuscript version arising from this submission. Open Access funding provided by Medizinische Universitat Graz/KEMÖ.

FUNDING INFORMATION

This Project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 777460. JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA and T1DExchange, JDRF, IDF, HCT. This paper reflects the authors' view and the JU is not responsible for any use that may be made of the information it contains.

CONFLICT OF INTEREST STATEMENT

All authors are members of the HypoRESOLVE consortium; their institutions received EU Horizon 2020 funding (grant No. 777460). JKM: advisory board member for Abbott Diabetes Care, Becton-Dickinson/embecta, Biomea Fusion, Boehringer Ingelheim, Eli Lilly, Medtronic, Novo Nordisk, Roche Diabetes Care, Pharmasens, Prediktor SA, Sanofi, Viatris; speaker honoraria from Abbott Diabetes Care, AstraZeneca, Becton-Dickinson/embecta, Eli Lilly, Dexcom, Medtronic, Medtrust, Menarini, Novo Nordisk, Roche Diabetes Care, Sanofi, Servier, Viatris, Ypsomed; shareholder of decide Clinical Software GmbH and elyte Diagnostics GmbH. SAA: consultation fees from NIH (CLEAR study); advisory board membership and consulting fees from Vertex (with travel reimbursement and honoraria); and Chair of the Diabetes UK Steering Committee for the islet cell antibody registry. BG: member of the Data Safety Monitoring Board for the DARE study. ME: received institutional payments for clinical trial work from Abbott Diabetes Care, Novo Nordisk, ITB Medical and Lexicon; research funding from Novo Nordisk; personal speaker fees from Abbott Diabetes Care, Novo Nordisk and Eli Lilly; conference travel support from Sanofi; advisory board roles with Pila Pharma, Zucara, vTv Therapeutics, Medtronic, Sanofi and Vertex; Trustee of Diabetes UK (honorary). UPB: received payments or honoraria for lectures from Abbott, Novo Nordisk and Tandem; expert testimony and travel support from Novo Nordisk; and equipment or services from Novo Nordisk. FP: received unrestricted research grants from Novo Nordisk and Eli Lilly (industry partners in the Hypo-RESOLVE consortium). PC: received research funding, consulting fees and honoraria from Abbott Diabetes, Dexcom, Sanofi, Insulet, Ypsomed, Roche and Medtronic, and consulting fees from Vertex. SH: reports EU HypoRESOLVE MMI support (institution), research funding from Dexcom (institution), honoraria from Medtronic and Novo Nordisk (institution), and advisory board participation for Eli Lilly (institution). JMB: received a one-time lecture fee from Boehringer Ingelheim and travel support (flight and hotel) for EASD 2024 from AstraZeneca. NA: reports EU funding via institution. RM: reports Innovative Medicines Initiative 2 funding (institution), honoraria from Sanofi (personal) and serves as a non-executive member of the NHS Tayside Health Board. US is a former employee of Novo Nordisk Denmark. PD reports consulting fees from Dexcom, honoraria from Novo Nordisk and Grunenthal and travel support from Novo Nordisk. All other authors report no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author, Prof. Dr. Julia K. Mader, upon reasonable request.

ORCID

Monika Cigler https://orcid.org/0000-0001-5827-7991
Uffe Søholm https://orcid.org/0000-0003-0848-9421
Melanie Broadley https://orcid.org/0000-0003-4408-6304
François Pouwer https://orcid.org/0000-0002-8172-9818
Evertine J. Abbink https://orcid.org/0009-0006-5424-3704
Namam Ali https://orcid.org/0000-0003-4302-7820
Bastiaan E. de Galan https://orcid.org/0000-0002-1255-7741
Eric Renard https://orcid.org/0000-0002-3407-7263
Mark Evans https://orcid.org/0000-0001-8122-8987
Julie Maria Bøggild Brøsen https://orcid.org/0000-0001-7361-4407
Ulrik Pedersen-Bjergaard https://orcid.org/0000-0003-0588-4880
Rory J. Mc Crimmon https://orcid.org/0000-0002-3957-1981
Simon Heller https://orcid.org/0000-0002-2425-9565
Sharon Caunt https://orcid.org/0000-0003-1479-8861
Stephanie A. Amiel https://orcid.org/0000-0003-2686-5531

Patrick Divilly https://orcid.org/0000-0001-6916-3164
Natalie Zaremba https://orcid.org/0000-0002-1720-1621
Pratik Choudhary https://orcid.org/0000-0001-7635-4735
Julia K. Mader https://orcid.org/0000-0001-7854-4233

REFERENCES

1. Sherr JL, Laffel LM, Liu J, et al. Severe hypoglycemia and impaired awareness of hypoglycemia persist in people with type 1 diabetes despite use of diabetes technology: results from a cross-sectional survey. *Diabetes Care*. 2024;47(6):941-947. doi:10.2337/dc23-1765
2. Chatwin H, Broadley M, Speight J, et al. The impact of hypoglycemia on quality of life outcomes among adults with type 1 diabetes: a systematic review. *Diabetes Res Clin Pract*. 2021;174:108752. doi:10.1016/j.diabres.2021.108752
3. Beck RW, Bergenstal RM, Riddlesworth TD, et al. Validation of time in range as an outcome measure for diabetes clinical trials. *Diabetes Care*. 2019;42(3):400-405. doi:10.2337/dc18-1444
4. Lind M, Polonsky W, Hirsch IB, et al. Design and methods of a randomized trial of continuous glucose monitoring in persons with type 1 diabetes with impaired glycemic control treated with multiple daily insulin injections (GOLD study). *J Diabetes Sci Technol*. 2016;10(3):754-761. doi:10.1177/1932296816642578
5. Beck RW, Riddlesworth T, Ruedy K, et al. Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using insulin injections. *JAMA*. 2017;317(4):371-378. doi:10.1001/jama.2016.19975
6. Aleppo G, Ruedy KJ, Riddlesworth TD, et al. REPLACE-BG: a randomized trial comparing continuous glucose monitoring with and without routine blood glucose monitoring in adults with well-controlled type 1 diabetes. *Diabetes Care*. 2017;40(4):538-545. doi:10.2337/dc16-2482
7. Martin CT, Criego AB, Carlson AL, Bergenstal RM. Advanced technology in the management of diabetes: which comes first—continuous glucose monitor or insulin pump? *Curr Diab Rep*. 2019;19(8):50. doi:10.1007/s11892-019-1177-7
8. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. Flash glucose-sensing technology as a replacement for blood glucose monitoring for the management of insulin-treated type 2 diabetes: a multicenter, open-label randomized controlled trial. *Diabetes Ther*. 2017;8(1):55-73. doi:10.1007/s13300-016-0223-6
9. Perrin N, Bodicoat DH, Davies MJ, Robertson N, Snoek FJ, Khunti K. Effectiveness of psychoeducational interventions for the treatment of diabetes-specific emotional distress and glycaemic control in people with type 2 diabetes: a systematic review and meta-analysis. *Prim Care Diabetes*. 2019;13(6):556-567. doi:10.1016/j.pcd.2019.04.001 PMID:31040069.
10. Søholm U, Broadley M, Zaremba N, et al. The impact of hypoglycemia on daily functioning among adults with diabetes: a prospective observational study using the hypo-METRICS app. *Diabetologia*. 2024;67(10):2160-2174. doi:10.1007/s00125-024-06233-1
11. Blome C, Augustin M. Measuring change in quality of life: bias in prospective and retrospective evaluation. *Value Health*. 2015;18(1):110-115. doi:10.1016/j.jval.2014.10.007
12. Brod M, Christensen T, Thomsen TL, Bushnell DM. Impact of nocturnal hypoglycemic events on diabetes management, sleep quality, and next-day function: results from a four-country survey. *J Med Econ*. 2012;15(1):77-86. doi:10.3111/13696998.2011.623709
13. Speight J, Reaney MD, Barnard KD. Not all roads lead to Rome—a review of quality of life measurement in adults with diabetes. *Diabet Med*. 2009;26(4):315-327. doi:10.1111/j.1464-5491.2009.02792.x
14. Søholm U, Broadley M, Zaremba N, et al. Investigating the day-to-day impact of hypoglycemia in adults with type 1 or type 2 diabetes: design and validation protocol of the hypo-METRICS application. *BMJ Open*. 2022;12(2):e051651. doi:10.1136/bmjopen-2021-051651
15. Divilly P, Zaremba N, Mahmoudi Z, et al. Hypo-METRICS: hypoglycemia-MEasurement, ThResholds and ImpaCtS—a multi-country clinical study to define the optimal threshold and duration of sensor-detected hypoglycemia that impact the experience of hypoglycemia, quality of life and health economic outcomes: the study protocol. *Diabet Med*. 2022;39(9):e14892. doi:10.1111/dme.14892
16. de Galan BE, McCrimmon RJ, Ibberson M, et al. Hypo-RESOLVE consortium. Reducing the burden of hypoglycemia in people with diabetes through increased understanding: design of the hypoglycemia REdefining SOLutions for better liVEs (hypo-RESOLVE) project. *Diabet Med*. 2020;37(6):1066-1073. doi:10.1111/dme.14240
17. Divilly P, Martine-Edith G, Zaremba N, et al. Relationship between sensor-detected hypoglycemia and patient-reported hypoglycemia in people with type 1 and insulin-treated type 2 diabetes: the hypo-METRICS study. *Diabetes Care*. 2024;47(10):1769-1777. doi:10.2337/dc23-2332
18. Søholm U, Zaremba N, Broadley M, et al. Assessing the content validity, acceptability, and feasibility of the hypo-METRICS app: survey and interview study. *JMIR Diabetes*. 2023;8:e42100. doi:10.2196/42100
19. UMotif. UMotif announces first new validated innovation in eCOA/ePRO since paper instruments were deployed on smartphones. 2022 Accessed July 29, 2025. https://umotif.com/news/umotif-announces-first-new-validated-innovation-in-ecoa-epro-since-paper-instruments-were-deployed-on-smartphones/
20. Woldaregay AZ, Issom DZ, Henriksen A, et al. Motivational factors for user engagement with mHealth apps. *Stud Health Technol Inform*. 2018;249:151-157. PMID:29866972.
21. Mustafa AS, Ali N, Dhillon JS, Alkawsi G, Baashar Y. User engagement and abandonment of mHealth: a cross-sectional survey. *Healthcare (Basel)*. 2022;10(2):221. doi:10.3390/healthcare10020221
22. Pathak RD, Schroeder EB, Seaquist ER, et al. Severe hypoglycemia requiring medical intervention in a large cohort of adults with diabetes receiving care in U.S. integrated health care delivery systems: 2005–2011. *Diabetes Care*. 2016;39(3):363-370. doi:10.2337/dc15-0858
23. Ratzki-Leewing A, Black JE, Kahkoska AR, et al. Severe (level 3) hypoglycemia occurrence in a real-world cohort of adults with type 1 or 2 diabetes mellitus (iNPHORM, United States). *Diabetes Obes Metab*. 2023;25(12):3736-3747. doi:10.1111/dom.15268

24. Mainz J, Kristensen S, Roe D. The power of the patient's voice in the modern health care system. *Int J Qual Health Care*. 2022;34(Suppl 1):ii1-ii2. doi:10.1093/intqhc/mzac001
25. Kebede MM, Pischke CR. Popular diabetes apps and the impact of diabetes app use on self-care behaviour: a survey among the digital community of persons with diabetes on social media. *Front Endocrinol (Lausanne)*. 2019;10:135. doi:10.3389/fendo.2019.00135
26. Kebede MM, Schuett C, Pischke CR. The role of continuous glucose monitoring, diabetes smartphone applications, and self-care behavior in glycemic control: results of a multi-national online survey. *J Clin Med*. 2019;8(1):109. doi:10.3390/jcm8010109
27. Ehrmann D, Schmitt A, Priesterroth L, Kulzer B, Haak T, Hermanns N. Time with diabetes distress and glycemia-specific distress: new patient-reported outcome measures for the psychosocial burden of diabetes using ecological momentary assessment in an observational study. *Diabetes Care*. 2022;45:1522-1531. doi:10.2337/dc21-2339
28. Zuniga-Kennedy M, Wang OH, Fonseca LM, et al. Nocturnal hypoglycemia is associated with next day cognitive performance in adults with type 1 diabetes: pilot data from the GluCog study. *Clin Neuropsychol*. 2024;38(7):1627-1646. doi:10.1080/13854046.2024.2315749
29. Zaremba N, Martine-Edith G, Divilly P, et al. Associations of clinical, psychological, and sociodemographic characteristics and ecological momentary assessment completion in the 10-week hypo-METRICS study: hypoglycemia measurements, thresholds and impacts. *Diabet Med*. 2024;41(8):e15345. doi:10.1111/dme.15345

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Cigler M, Søholm U, Broadley M, et al. User evaluation of the Hypo-METRICS app: A tool for real-time symptom reporting of hypoglycaemia. *Diabet Med*. 2025;00:e70185. doi:10.1111/dme.70185