Effectiveness of the MyDiaMate application in reducing diabetes distress in adults with type 1 diabetes : Study protocol of the multi-national, randomised-controlled MyREMEDY trial

Primary publication

Mohr, Theresa C.; De Wit, Maartje; Embaye, Jiska; u. a. (2025): Effectiveness of the MyDiaMate application in reducing diabetes distress in adults with type 1 diabetes : Study protocol of the multi-national, randomised-controlled MyREMEDY trial, in: Diabetic medicine : journal of Diabetes UK, Oxford: Wiley-Blackwell, Vol. 42, Nr. 1, e15442, pp. 1–9, doi: 10.1111/dme.15442.

Received: 26 June 2024 | Accepted: 16 September 2024

DOI: 10.1111/dme.15442

DIABETIC Medicine

STUDY PROTOCOLS

Effectiveness of the MyDiaMate application in reducing diabetes distress in adults with type 1 diabetes: Study protocol of the multi-national, randomised-controlled MyREMEDY trial

Theresa C. Mohr[1] | **Maartje de Wit**[1] | **Jiska Embaye**[1] | **Dominic Ehrmann**[2,3] | **Norbert Hermanns**[2,3,4] | **Gina Lehmann**[2] | **María Teresa Anarte Ortiz**[5,6] | **Laura Torreblanca Murillo**[5] | **Kirsty Winkley**[7] | **Alexandra Famiglietti**[7] | **Frans Pouwer**[1,8,9,10] | **Frank J. Snoek**[1]

[1]Department of Medical Psychology, Amsterdam UMC, Vrije Universiteit Amsterdam, Medical Psychology, Amsterdam Public Health, Amsterdam, The Netherlands

[2]FIDAM RDC—Research Institute Diabetes, Bad Mergentheim, Germany

[3]Department of Clinical Psychology and Psychotherapy, University of Bamberg, Bamberg, Germany

[4]Diabetes Clinic Mergentheim, Bad Mergentheim, Germany

[5]Departamento de Personalidad, Evaluación y Tratamiento Psicológico, Facultad de Psicología, Universidad de Málaga, Málaga, Spain

[6]Instituto de Investigación Biomedica de Málaga, Málaga, Spain

[7]Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care, King's College London, London, UK

[8]Department of Psychology, University of Southern Denmark, Odense, Denmark

[9]Steno Diabetes Center Odense, Odense, Denmark

[10]School of Psychology, Deakin University, Geelong, Victoria, Australia

Correspondence
Theresa C. Mohr, Department of Medical Psychology, Amsterdam UMC, Vrije Universiteit Amsterdam, Medical Psychology, Amsterdam Public Health, 1081 BT Amsterdam, The Netherlands.
Email: t.c.mohr@amsterdamumc.nl

Funding information
Breakthrough T1d

Abstract

Aims: Diabetes distress is common among people with type 1 diabetes (T1D), negatively affecting quality of life, self management, and diabetes outcomes. E-health-based interventions could be an effective and low-cost way to improve the psychological care for people with T1D experiencing diabetes distress. The MyREMEDY study aims to test the effectiveness of the online unguided self-help intervention MyDiaMate in decreasing diabetes distress in adults with T1D. MyDiaMate is based on Cognitive Behavioural Therapy and consists of eight modules, each focusing on a different aspect of living with T1D that is often experienced as burdensome (e.g. hypoglycaemia, fatigue).

Methods: The effectiveness of MyDiaMate will be tested through a randomised-controlled trial across four European countries (the Netherlands, Germany, Spain and the United Kingdom). Six hundred and sixty adults ($N = 165$ per

country) with T1D will be recruited and randomised with a balance of 2:1 into the intervention and care as usual groups. Intervention group members receive access to MyDiaMate for 6 months, care as usual group members receive access after 3 months for 3 months. Participants fill in questionnaires at 0 (baseline), 3 (effectiveness) and 6 months (follow-up). Primary outcome is diabetes distress at 3 months. Secondary outcomes are emotional well-being, psychological self-efficacy in relation to diabetes, social engagement, fatigue, and glycaemic outcomes. Moreover, logdata of MyDiaMate use is passively collected. Linear mixed model analyses will be used to test the effectiveness of MyDiaMate along with identifying which user subgroup benefits most from MyDiaMate use.
Trial Registration: Clinicaltrials.gov NCT06308549.

KEYWORDS
diabetes distress, e-health, self-help intervention, type 1 diabetes

1 | INTRODUCTION

The psychological burden of living with and self-managing Type 1 Diabetes (T1D) is well-recognised.[1] Up to 40% of people with T1D show elevated diabetes distress, defined as the negative affective experience caused by the demands of living with and self-managing the disease.[2] In turn, diabetes distress can also adversely impact self management and glycaemic outcomes in people with T1D.[3] There is a pressing need for psychological support in this population with a view on improving both mental and physical health. There have been few psychological intervention studies targeting diabetes distress in adults with (Type 1) diabetes. For those studies, such interventions appear to have a decreasing effect on diabetes distress.[4,5] However, the accessibility of such interventions is limited in many settings, often due to a lack of resources. Here, digital solutions or e-mental health interventions can be helpful.[6,7] E-mental health has become widespread, as the recent COVID-19 pandemic has accelerated the uptake and applicability of digital solutions for a range of mental health problems.[8,9] Therapist-guided online psychological interventions have been shown to be effective for the treatment of depression in people with diabetes and therefore have potential to be implemented in routine diabetes care.[10–13] In addition to this, (online) self-help programmes have been developed and found to be effective in reducing diabetes distress, depression and anxiety in people with diabetes with the advantage of a large reach at relatively low costs.[14] Such an approach would appear particularly salient for persons with diabetes experiencing difficulties in mentally coping with the disease, as indicated by elevated diabetes distress. This was the rationale for the development of MyDiaMate, a multi-modal, online self-help programme specifically tailored to the mental health needs of adults with T1D experiencing diabetes distress. MyDiaMate can be used on a mobile phone, tablet or computer and consists of multiple modules focused on diabetes in the context of everyday life, low mood, low energy, issues around hypoglycaemia, coping with the social environment and problems around eating. The application was pilot-tested for feasibility and acceptability.[15] Based on the positive results, a pilot implementation study was conducted in the Netherlands to determine uptake and user behaviours. During a period of 22 months, an updated version of MyDiaMate was freely offered to adults with T1D for download and use, showing widespread interest in using MyDiaMate.[16] The positive results regarding feasibility and user behaviour justify the conduct of an evaluation study analysing effectiveness. The present study named MyREMEDY (MYdiamate for REMission of Elevated diabetes Distress in tYpe 1 diabetes) aims to test the effectiveness of MyDiaMate in a two-arm randomised-controlled trial running in parallel across four European countries (the Netherlands, Germany, Spain and the United Kingdom). We have the following objectives:

Key points

- MyDiaMate is an online self-help application targeting diabetes distress in Type 1Diabetes.
- The randomised-controlled MyREMEDY trial investigates the effectiveness of MyDiaMate in reducing diabetes distress.
- The trial is executed in the Netherlands, Germany, the United Kingdom, and Spain.

1. To determine the effectiveness of MyDiaMate in terms of improvement of diabetes distress (primary outcome) at 3 months, relative to care as usual (CAU) in adults with elevated diabetes distress across four countries.
2. To determine changes in participants' self-reported emotional well-being, fatigue, psychological self-efficacy in relation to diabetes, social network and glycaemic outcomes at 3 months against CAU.
3. To explore differential effects, that is who profits most from MyDiaMate, based on the efficacy data, stratified for baseline user profiles (diabetes distress and/or low well-being, and/or fatigue) and usage of the app (as evidenced by log-data) in reducing diabetes distress.

2 | METHODS

2.1 | Design

A multi-national two-arm randomised-controlled trial will be conducted, coordinated by one centre per country (Amsterdam UMC, FIDAM RDC—Research Institute Diabetes, Universidad de Málaga, King's College London). All participants will complete a set of questionnaires at three time points via electronic person-reported outcome surveys built into the Castor EDC: At baseline after 3 months (efficacy measure) and after 6 months (follow-up). After the baseline assessment, we randomise individuals with a balance of 2:1 (Intervention:CAU) per country through Castor EDC in block sizes of 6, 9 and 12. The intervention group will receive access to MyDiaMate directly after randomisation for the duration of 6 months. The CAU group will receive access to MyDiaMate 3 months later, following the efficacy measurement. A full overview of the MyREMEDY study procedure is displayed in Figure 1. The MyREMEDY study procedure is fully digitalised, and participants do not have to travel for study contacts.

2.2 | Intervention

MyDiaMate aims to assist persons living with T1D in improving their mental health. It is web-based and can be used both on a personal computer, smartphone or tablet (Android or iOS). MyDiaMate runs on a secure, user-friendly eHealth platform (www.minddistrict.com) and does not require a referral or support from a health care professional. The programme is designed for people with T1D experiencing diabetes-related emotional distress. It is not meant to replace professional psychological help and does not provide any medical advice. The content and features of MyDiaMate have been developed iteratively, with input from people with T1D as well as health professionals throughout the development process.[15] It is grounded in principles of Cognitive Behavioural Therapy (CBT), building on diabetes-specific CBT interventions that has been shown to be acceptable, appreciated and effective in adults with T1D.[12,13,17–20]

MyDiaMate offers various features known to be critical for successful self-help and engagement, such as goal setting, self-assessments, psychoeducation with tips and tricks and links to resources (e.g. peer support), cognitive and behavioural strategies and exercises (including relaxation, mindfulness), patient videos (testimonials), mood and energy journalling and automated notifications. Modules are translated into the respective languages, with the same content and format across the four participating countries. The wording used in the programme is constructive and adapted to local customs (e.g. addressing the user formally or informally depending on local cultural norms). MyDiaMate allows for flexible use, where favourite pages can be bookmarked, and the user can stop and restart at any time and as often as wished. In the MyREMEDY study, MyDiaMate offers eight modules (Figure 2). The first module ('Diabetes in Balance') opens by default for all participants and is centred around common sources of diabetes distress, such as the disruptive impact of stress on blood glucose, worries about complications and coping with 'negative' results. After finishing 'Diabetes in Balance', the participant can choose to activate four short psychoeducational modules that focus on coping with hypoglycaemia and related concerns ('Hypos'), problems related to eating behaviour ('Food and Feelings'), stressful social interactions ('My Environment') and setting and following realistic goals ('My Goals'), in no particular order. The programme also offers two in-depth modules, called 'My Mood' and 'My Energy'. The first aims to improve emotional well-being and offers CBT-based techniques for helpful thinking, stress management and mood repair.[13] 'My Energy' is aimed at decreasing persistent fatigue and offers evidence-based strategies, including restoring sleep/wake rhythm and engaging in activity scheduling.[17] In our previous studies, MyDiaMate users presented with different profiles in terms of their specific concerns, level of emotional well-being and fatigue.[16] To help the participants decide on whether to follow the 'My Mood' and/or 'My Energy' module that take more reading time and practicing, we added a short assessment. At the start of 'Diabetes in Balance', participants fill in the Fatigue subscale of the Checklist Individual Strength (CIS) and the World Health Organisation-Five Well-Being Index (WHO-5).[21,22] If a participant scores <13 on the WHO-5 or ≥35 on the CIS fatigue subscale, the 'My Mood' or 'My Energy' module will be triggered

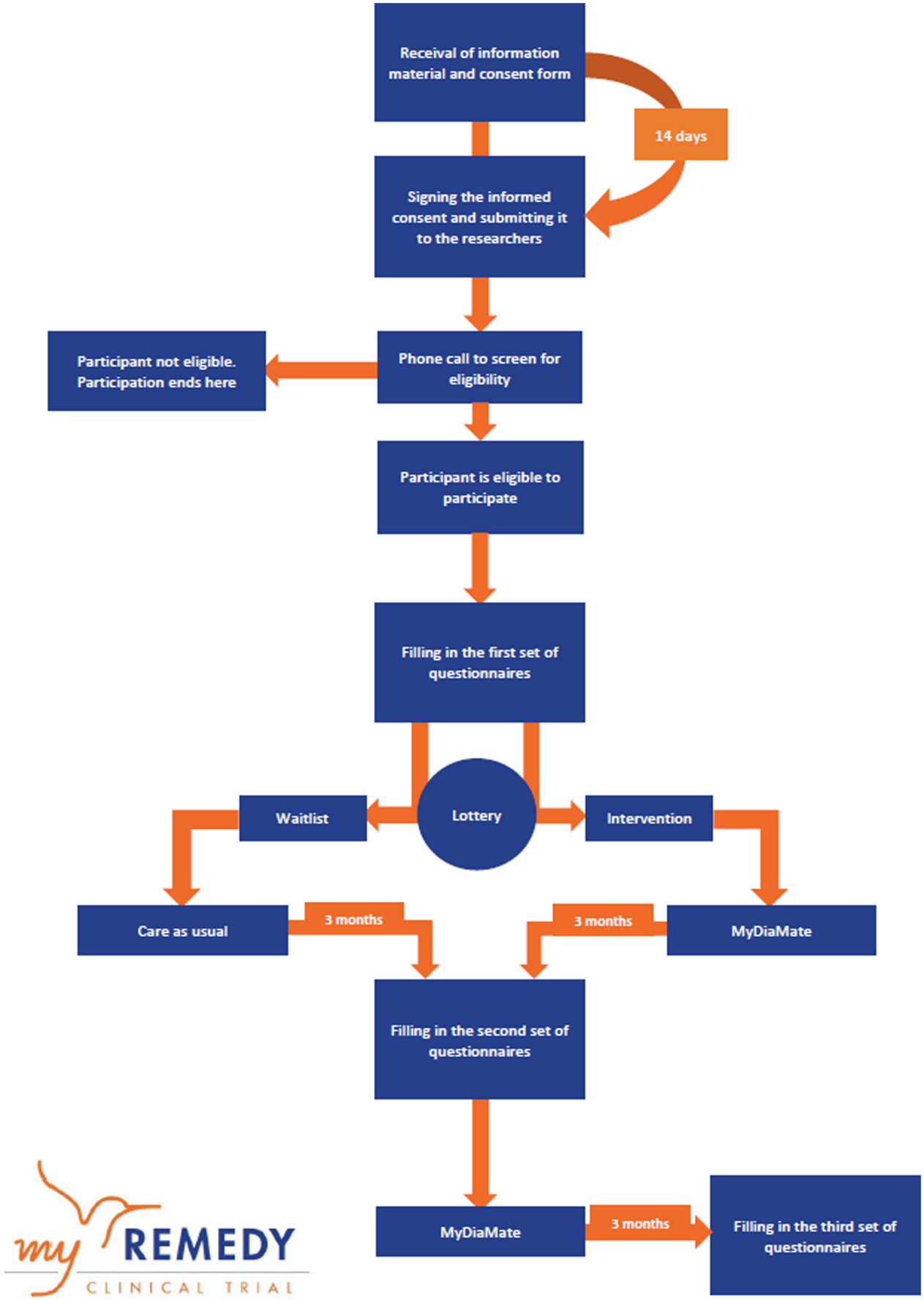

FIGURE 1 Flowchart of the MyREMEDY study procedure.

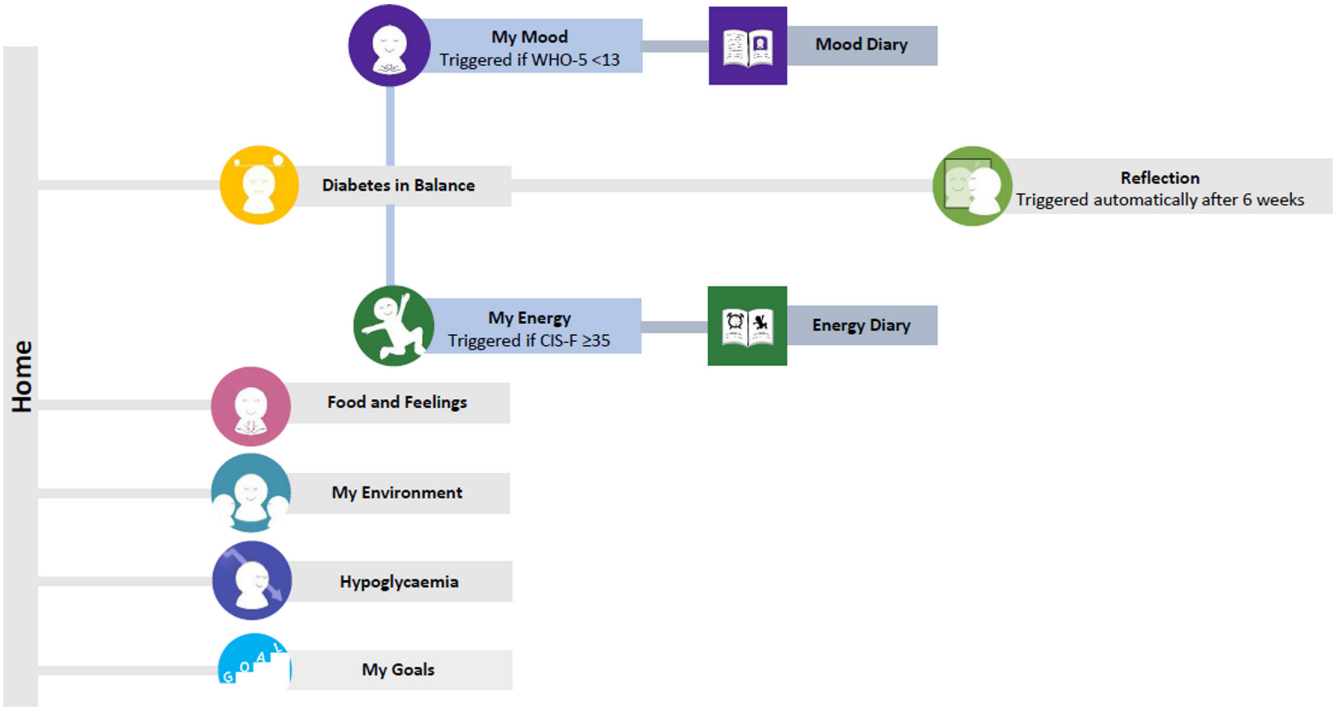

FIGURE 2 Overview of the MyDiaMate modules.

and appear on the homepage after 1 week. In case both scores cross the established cut-off scores, both modules will be triggered sequentially: 'My Mood' after 1 week and 'My Energy' a week later, to avoid overload. The mood and energy diaries are linked to their respective modules and can be accessed by the participant if so wished. Halfway through the 3-months of MyDiaMate use, a 'Reflection' module will appear on their homepage. Here, participants are encouraged to think about their learnings and (re-)visit modules if they feel like they have not made sufficient progress.

2.3 | Participants and recruitment

Adults (age ≥18 years) who received the diagnosis T1D from a physician at least 6 months before study participation are eligible if they have a mean score ≥2 on the 2-item Diabetes Distress Scale (DDS-2), representing clinically meaningful diabetes distress,[23] and have access to the Internet on a smartphone or tablet/laptop/pc for the entirety of the study duration. Exclusion criteria include: having been diagnosed with a psychiatric disorder (e.g. depressive disorder, anxiety disorder, schizophrenia, bipolar disorder, dementia, post-traumatic stress disorder and personality disorder) in the past 6 months for which the person is under psychological/psychiatric treatment, suicidality, having started a treatment with psychotropic medication in the past 3 months, illiteracy, cognitive impairment, vision and/or hearing problems that would hamper using MyDiaMate and (only applicable to the Netherlands) prior use of MyDiaMate. Participants will be recruited via the local study websites, social media, diabetes organisations, study participant databases and outpatient clinics across each country.

2.4 | Procedures

Adults who are interested in participating in the MyREMEDY study can contact the researchers via email or by filling in a contact form on the local research websites and receive the information letter and consent form via email or post. Candidates have 14 days to read the information letter, ask questions and send the signed consent form back to the local research assistant. After having received the signed informed consent form, the local research assistant schedules a phone call or online meeting with the candidate, during which the inclusion and exclusion criteria are screened. If eligible, participants receive the invitation to fill in the baseline measurement. If the candidate is not eligible or fails to fill in the baseline assessment within 14 days (a necessary condition for randomisation), they can no longer participate in the MyREMEDY study and will be replaced. After the baseline measurement, participants are randomised directly. Those in the intervention group receive access to

MyDiaMate immediately. Three months after randomisation, participants receive the invitation to complete the second (efficacy) measurement. After completing the second measurement, the participants in the CAU group also gain access to MyDiaMate. Another 3 months later, all participants receive an invitation to the third and last (follow-up) measurement. With this, access to MyDiaMate is revoked and the MyREMEDY study ends for the participant. Participants in the intervention group who have not accessed MyDiaMate receive a reminder 7 days after account creation from the research assistant. Participants who have voluntarily dropped out or withdrew from the study for any reason at any point after having filled in the baseline assessment will not be replaced; however, the data collected up to this point will be utilised in analyses. Participants receive a reimbursement of 10€/10£ for each completed questionnaire.

2.5 | Assessments

The following variables are assessed: Socio-demographic (only at baseline) and clinical (e.g. comorbidities, usage of health care) characteristics, and at all three measurement points: diabetes-related distress, emotional well-being, psychological self-efficacy in relation to diabetes, social engagement, fatigue and glycaemic outcomes. Moreover, we also passively collect the logdata of MyDiaMate use.

2.5.1 | Main outcome

2.5.1.1 | *Diabetes-related distress*

The Problem Areas in Diabetes (PAID) questionnaire measures diabetes-specific psychosocial adjustment in 20 items measured on a 5-point scale.[24] A higher total score (range 0–100) translates to more diabetes distress.

2.5.2 | Secondary outcomes

2.5.2.1 | *Emotional well-being*

The World Health Organization—Five Well-Being Index (WHO-5) self report measure assesses current mental well-being in five positively formulated items measured on a 6-point Likert scale.[22] A higher total score (range 0–100) represents higher emotional well-being.

2.5.2.2 | *Psychological self-efficacy in relation to diabetes*

The 8-item short form of the Diabetes Empowerment Scale (DES-SF) assesses psychological self-efficacy in relation to diabetes on a 5-point scale.[25,26] A higher mean score (range 1–5) represents stronger psychological self-efficacy in relation to diabetes.

2.5.2.3 | *Social engagement*

The 6-item abbreviated Lubben Social Network Scale (LSNS-6) measures social networks and social support on a 6-point scale.[27] A higher sum score (range 0–30) represents more social engagement.

2.5.2.4 | *Fatigue*

We use the 8-item Fatigue Severity subscale of the Checklist Individual Strength (CIS) to assess fatigue on a 7-point scale.[21] Positively framed items will be recoded, so that a higher sum score (range−56) represents stronger fatigue.

2.5.2.5 | *Glycaemic outcomes*

At all three measurement points, participants self report clinical and glycaemic metrics, if known or possible. The metrics in question are: way of administering insulin, presence (yes/no) and nature of complications, presence (yes/no) and nature of comorbidities, number of events of severe hypoglycaemia and ketoacidosis, most recent HbA1c (measured in both mmol/mol and %) and, if the participant makes use of Continuous Glucose Monitoring: Average glucose, upper and lower personal limit of the target range and the time above, below and within that target range across the past 14 days.

2.5.2.6 | *MyDiaMate usage*

Minddistrict automatically collects and saves intervention usage data (=logdata) that will be exported at two points in time: After the first 3 months (efficacy measure) and at the end of the 6 months (follow-up measure). In line with the MyDiaMate pilot, we will investigate the frequency of opening and completing modules respectively, module completion time, and answers given to self-reflection questions within modules.[15,16]

2.6 | Sample Size

We can expect an effect size of 0.3 as this is in line with results from meta-analytic reviews on psychological interventions for diabetes.[4,28] To be able to detect a small to moderate effect size of 0.3 (Cohen's d) on the Problem Areas in Diabetes questionnaire, our main outcome measure, a total sample of $N = 528$ is needed. The calculations in G*Power took into account: Baseline assessment as covariate, 2:1 randomised groups, a power of 0.90 and a two-sided alpha of 0.05. Anticipating an attrition rate of 20% at 3 months, we aim to recruit $N = 660$ participants, which is $N = 165$ in each country.

2.7 | Analysis plan

Data collected from Germany, Spain and the United Kingdom will be transferred to Amsterdam UMC (the Netherlands) and analysed centrally at the end of the study (estimated Autumn 2025). We have no reason to expect that the effects of the intervention will differ between the participating countries; however, we will check this assumption. Data will therefore be pooled and analysed together based on the intention-to-treat population. Intention-to-treat is defined as every person who completed the baseline assessment, irrespective of completion of the study. We will make use of the most up-to-date version of IBM SPSS Statistics and RStudio to analyse the data. Socio-demographic and clinical characteristics will be extracted from the baseline questionnaire in order to describe the sample. In line with our primary objective, we will build linear mixed-effects models predicting the PAID score from the interaction of group membership with time. If relevant baseline differences between groups occur, the analysis will be adjusted accordingly. In case of substantial violation of the normal distribution, analyses will be adjusted. As for the first of the secondary objectives, we will build linear mixed-effects models in order to predict the WHO-5, CIS fatigue subscale, DES-SF and LSNS-6 scores as well as glycaemic outcomes from the interaction between group membership and time. If relevant baseline differences between groups occur, the analysis will be adjusted accordingly. In case of substantial violation of the normal distribution, analyses will be adjusted. Lastly, we will explore differential effects by moderation analysis, looking into which subgroup of MyDiaMate users benefits the most from the programme. Data that will be analysed includes, but is not limited to, MyDiaMate usage (logdata), socio-demographic and clinical characteristics, mental health (i.e. baseline scores on the PAID, WHO-5, CIS fatigue subscale, DES-SF and LSNS-6) and glycaemic metrics (e.g. HbA1C, time in range). Sensitivity analyses with the per-protocol population will be conducted. Per-protocol is defined as participants who completed the baseline and the 3-month assessment and for participants of the intervention group who opened MyDiaMate at least once. Linear mixed-effects models are robust to missing data; therefore, no further missing data treatment will be applied. All analyses will be performed with an alpha of 0.05. Correction for multiple testing will be applied in line with the data's distributions.

3 | DISCUSSION

A significant proportion of people with T1D experience mental health problems and only a minority has access to psychological support.[2,3] E-health interventions can help to bridge this gap, at least for those with mildly to moderately severe distress. In MyREMEDY, we investigate the effectiveness of the web-based self-help programme MyDiaMate, in adults with elevated diabetes-related distress across four European countries: The Netherlands, Germany, the United Kingdom and Spain. The programme is suited for people with T1D without psychiatric co-morbidity who may not be eligible for professional psychological treatment or unwilling to seek professional support because they prefer to solve their problems on their own or with the help of family peers. MyDiaMate may also be useful as a way of lowering diabetes distress for adults on a waitlist or for persons with T1D who have previously received professional treatment and strive to maintain their acquired coping skills and mental resilience. This multi-national study will add to the literature regarding the effectiveness of online, low-intensity, unguided diabetes-specific psychological support in adults with T1D. Based on our pilot studies, we do not expect problems recruiting eligible persons with T1D.[15,16] From previous research into unguided mental health self-help applications, we can expect modest effect sizes when used as intended.[29] Importantly, this study will most likely provide insights to help better understand the differential effects of MyDiaMate, taking individual characteristics into account. This should stimulate further improvements of the self-help intervention, both in terms of personalisation of content and features, as well as stimulating user engagement. The long-term goal is to make MyDiaMate widely available and adapt the programme for more specific and individual mental health concerns, along with other target audiences, such as non-western populations, people with type 2 diabetes, youth and parents of minors with T1D.

FUNDING INFORMATION

The MyREMEDY clinical trial is funded by the Breakthrough T1d. Participant inclusion started in spring 2024, and data collection is planned to finish by autumn 2025. We aim to present trial results at scientific conferences and publish in peer-reviewed scientific journals and sources widely available to people with T1D, such as magazines.

CONFLICT OF INTEREST STATEMENT

The researchers declare that there is no conflict of interest related to the MyREMEDY study.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

ETHICS STATEMENT

The trial follows the declaration of Helsinki and good clinical practices and has already received ethical approval in three out of the four countries.

ORCID

Theresa C. Mohr https://orcid.org/0009-0000-7454-5239
Maartje de Wit https://orcid.org/0000-0001-6029-5101
Jiska Embaye https://orcid.org/0009-0007-6966-1615
Dominic Ehrmann https://orcid.org/0000-0002-5794-5596
Norbert Hermanns https://orcid.org/0000-0002-2903-2677
Gina Lehmann https://orcid.org/0000-0002-1830-6484
María Teresa Anarte Ortiz https://orcid.org/0000-0002-3730-4644
Laura Torreblanca Murillo https://orcid.org/0000-0002-9760-0920
Kirsty Winkley https://orcid.org/0000-0002-1725-6040
Alexandra Famiglietti https://orcid.org/0009-0009-6840-016X
Frans Pouwer https://orcid.org/0000-0002-8172-9818
Frank J. Snoek https://orcid.org/0000-0001-9563-6762

REFERENCES

1. Van Duinkerken E, Snoek FJ, De Wit M. The cognitive and psychological effects of living with type 1 diabetes: a narrative review. *Diabet Med*. 2019;37(4):555-563. doi:10.1111/dme.14216
2. Skinner T, Joensen LE, Parkin T. Twenty-five years of diabetes distress research. *Diabet Med*. 2019;37(3):393-400. doi:10.1111/dme.14157
3. Ducat L, Philipson LH, Anderson BJ. The mental health comorbidities of diabetes. *JAMA*. 2014;312(7):691-692. doi:10.1001/jama.2014.8040
4. Schmidt CB, Van Loon BJP, Vergouwen ACM, Snoek FJ, Honig A. Systematic review and meta-analysis of psychological interventions in people with diabetes and elevated diabetes-distress. *Diabet Med*. 2018;35(9):1157-1172. doi:10.1111/dme.13709
5. Jenkinson E, Knoop I, Hudson JL, Moss-Morris R, Hackett RA. The effectiveness of cognitive behavioural therapy and third-wave cognitive behavioural interventions on diabetes-related distress: a systematic review and meta-analysis. *Diabet Med*. 2022;39(11):e14948. doi:10.1111/dme.14948
6. Andersson G. Internet-delivered psychological treatments. *Annu Rev Clin Psychol*. 2016;12(1):157-179. doi:10.1146/annurev-clinpsy-021815-093006
7. Torous J, Bucci S, Bell I, et al. The growing field of digital psychiatry: current evidence and the future of apps, social media, chatbots, and virtual reality. *World Psychiatry*. 2021;20(3):318-335. doi:10.1002/wps.20883
8. Andersson G, Titov N, Dear BF, Rozental A, Carlbring P. Internet-delivered psychological treatments: from innovation to implementation. *World Psychiatry/World Psychiatry*. 2019;18(1):20-28. doi:10.1002/wps.20610
9. De Witte NAJ, Carlbring P, Etzelmueller A, et al. Online consultations in mental healthcare during the COVID-19 outbreak: an international survey study on professionals' motivations and perceived barriers. *Internet Interv*. 2021;25:100405. doi:10.1016/j.invent.2021.100405
10. Carreira M, De Adana MSR, Pinzón JL, Anarte-Ortiz MT. Internet-based cognitive-behavioral therapy is effective in reducing depressive symptomatology in type 1 diabetes: results of a randomized controlled trial. *Front Clin Diabetes and Healthc*. 2023;4:1-10. doi:10.3389/fcdhc.2023.1209236
11. Newby JM, Robins L, Wilhelm K, et al. Web-based cognitive behavior therapy for depression in people with diabetes mellitus: a randomized controlled trial. *J Med Internet Res*. 2017;19(5):e157. doi:10.2196/jmir.7274
12. Nobis S, Lehr D, Ebert DD, et al. Efficacy of a web-based intervention with mobile phone support in treating depressive symptoms in adults with type 1 and type 2 diabetes: a randomized controlled trial. *Diabetes Care*. 2015;38(5):776-783. doi:10.2337/dc14-1728
13. Van Bastelaar KMP, Pouwer F, Cuijpers P, Riper H, Twisk JWR, Snoek FJ. Is a severe clinical profile an effect modifier in a web-based depression treatment for adults with type 1 or type 2 diabetes? Secondary analyses from a randomized controlled trial. *J Med Internet Res*. 2012;14(1):e2. doi:10.2196/jmir.1657
14. Wicaksana AL, Apriliyasari RW, Tsai P. Effect of self-help interventions on psychological, glycemic, and behavioral outcomes in patients with diabetes: a meta-analysis of randomized controlled trials. *Int J Nurs Stud*. 2024;149:104626. doi:10.1016/j.ijnurstu.2023.104626
15. Muijs LT, De Wit M, Knoop H, Snoek FJ. Feasibility and user experience of the unguided web-based self-help app 'MyDiaMate' aimed to prevent and reduce psychological distress and fatigue in adults with diabetes. *Internet Interv*. 2021;25:100414. doi:10.1016/j.invent.2021.100414
16. Embaye J, De Wit M, Snoek FJ. A self-guided web-based app (MyDiaMate) for enhancing mental health in adults with type 1 diabetes: insights from a real-world study in The Netherlands. *JMIR Diabetes*. 2024;9:e52923. doi:10.2196/52923
17. Menting J, Tack CJ, Van Bon AC, et al. Web-based cognitive behavioural therapy blended with face-to-face sessions for chronic fatigue in type 1 diabetes: a multicentre randomised controlled trial. *The Lancet Diabetes & Endocrinology*. 2017;5(6):448-456. doi:10.1016/s2213-8587(17)30098-0
18. Rondags SMPA, De Wit M, Twisk JWR, Snoek FJ. Effectiveness of HypoAware, a brief partly web-based psychoeducational intervention for adults with type 1 and insulin-treated type 2 diabetes and problematic hypoglycemia: a cluster randomized controlled trial. *Diabetes Care*. 2016;39(12):2190-2196. doi:10.2337/dc16-1614
19. Snoek FJ, Pouwer F, Welch G, Polonsky WH. Diabetes-related emotional distress in Dutch and U.S. diabetic patients: cross-cultural validity of the problem areas in diabetes scale. *Diabetes Care*. 2000;23(9):1305-1309. doi:10.2337/diacare.23.9.1305
20. Van Son J, NyklíČek I, Pop VJM, et al. The effects of a mindfulness-based intervention on emotional distress, quality of life, and HbA1c in outpatients with diabetes (DiaMind). *Diabetes Care*. 2013;36(4):823-830. doi:10.2337/dc12-1477
21. Vercoulen JHMM, Swanink CMA, Fennis JFM, Galama JMD, Van Der Meer JWM, Bleijenberg G. Dimensional assessment of

chronic fatigue syndrome. *J Psychosom Res*. 1994;38(5):383-392. doi:10.1016/0022-3999(94)90099-x

22. Topp CW, Østergaard SD, Søndergaard S, Bech P. The WHO-5 well-being index: a systematic review of the literature. *Psychother Psychosom*. 2015;84(3):167-176. doi:10.1159/000376585
23. Fisher L, Glasgow RE, Mullan JT, Skaff MM, Polonsky WH. Development of a brief diabetes distress screening instrument. *Ann Fam Med*. 2008;6(3):246-252. doi:10.1370/afm.842
24. Polonsky WH, Anderson BJ, Lohrer PA, et al. Assessment of diabetes-related distress. *Diabetes Care*. 1995;18(6):754-760. doi:10.2337/diacare.18.6.754
25. Anderson RM, Fitzgerald JT, Gruppen LD, Funnell MM, Oh MS. The diabetes empowerment scale-short form (DES-SF). *Diabetes Care*. 2003;26(5):1641-1642. doi:10.2337/diacare.26.5.1641-a
26. Anderson RM, Funnell MM, Fitzgerald JT, Marrero DG. The diabetes empowerment scale: a measure of psychosocial self-efficacy. *Diabetes Care*. 2000;23(6):739-743. doi:10.2337/diacare.23.6.739
27. Lubben JE, Blozik E, Gillmann G, et al. Performance of an abbreviated version of the Lubben social network scale among three European community-dwelling older adult populations. *Gerontologist*. 2006;46(4):503-513. doi:10.1093/geront/46.4.503
28. Sturt J, Dennick K, Hessler D, Hunter BM, Oliver J, Fisher L. Effective interventions for reducing diabetes distress: systematic review and meta-analysis. *Int Diabetes Nurs*. 2015;12(2):40-55. doi:10.1179/2057332415y.0000000004
29. Baumeister H, Reichler L, Munzinger M, Lin JH. The impact of guidance on internet-based mental health interventions—a systematic review. *Internet Interv*. 2014;1(4):205-215. doi:10.1016/j.invent.2014.08.003

How to cite this article: Mohr TC, de Wit M, Embaye J, et al. Effectiveness of the MyDiaMate application in reducing diabetes distress in adults with type 1 diabetes: Study protocol of the multinational, randomised-controlled MyREMEDY trial. *Diabet Med*. 2025;42:e15442. doi:10.1111/dme.15442