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Using Artificial Intelligence-informed Experience-Based Co-Design (AI-EBCD) to create a virtual reality-based mindfulness application to reduce diabetes distress: protocol for a mixed-methods feasibility study

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ABSTRACT

Introduction People with type 2 diabetes can experience diabetes distress which can negatively affect health outcomes. Non-pharmacological interventions such as mindfulness can help address diabetes distress. However, face-to-face programmes can be constrained by cost, poor accessibility and lack of availability. Mobile apps for mindfulness may overcome these issues but evidence of their effectiveness is limited, and some have poor interface design with basic visualisations and feedback.

Methods and analysis Our study will explore using virtual reality (VR) as an immersive and interactive technology that could support mindfulness practice to help reduce diabetes distress. We will use a mixed-methods design to pilot a new co-design process called Artificial Intelligence-informed Experience-Based Co-Design. Phase 1 will identify and evaluate existing VR mindfulness apps, followed by interviews with mindfulness experts to gain their perspectives on practising mindfulness in virtual settings. This will be followed by a participatory design phase with a series of five co-design workshops where adults with type 2 diabetes will (1) discuss diabetes distress and learn about mindfulness, (2) evaluate commercially available VR mindfulness apps, (3) employ artistic methods to produce a personalised mindfulness experience, (4) create digital content for a virtual mindfulness experience via generative artificial intelligence tools and (5) prioritise key design features, functionality and content for a tailored VR mindfulness app. The final phase will focus on developing a bespoke VR mindfulness app and evaluating it with adults with type 2 diabetes using interviews, questionnaires and VR app analytics to determine if the new digital mental health intervention can help reduce diabetes distress and improve quality of life.

Ethics and dissemination We received ethical approval from The University of Manchester (2024-18262-32710 and 2024-21170-37093). Written informed consent will be obtained from all participants. Dissemination will include scientific publications and presentations, social media, knowledge translation events and educational resources for teaching students.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A new co-design methodology is being used that meaningfully involves people with type 2 diabetes in creating a virtual reality (VR) based mindfulness application to help reduce diabetes distress.
⇒ Co-create and evaluate a bespoke VR mindfulness app tailored to the needs of adults with type 2 diabetes.
⇒ An interdisciplinary and inclusive approach is being adopted with patient and public involvement to ensure the complexities of developing a digital mental health intervention are considered and an acceptable and feasible solution achieved.
⇒ Only a prototype VR mindfulness app will be developed due to time and funding constraints.

INTRODUCTION

Type 2 diabetes

Type 2 diabetes is a chronic metabolic disease that can cause microvascular and macrovascular changes in the body over time, leading to serious complications such as blindness, renal failure, ischaemic stroke and other cardiovascular diseases.[1] People with type 2 diabetes also need to undertake daily self-care which can include a range of activities such as eating a healthy diet, being physically active, monitoring blood glucose and taking glucose-lowering medication among others to reach optimal targets that prevent long-term complications from occurring.[2] However, the burden of self-management combined with concerns about the complications of diabetes

can lead to psychological issues such as diabetes distress.[3] There is also a substantial personal cost associated with type 2 diabetes which can cause additional distress to those with this chronic condition. In addition, there are significant direct and indirect healthcare costs associated with type 2 diabetes,[4] estimated to be $327 billion in the United States in 2017[5] and £10 billion in the United Kingdom (UK) annually[6] which does not include the costs of social care.

Diabetes distress encompasses the concerns people with diabetes have about managing their diabetes and preventing its known complications, along with anxieties about accessing healthcare services.[3 7] This distress can manifest as feelings of helplessness and shame particularly if living with overweight or obesity, worries about hypoglycaemic events, burnout from managing the various self-care tasks, as well as potential stigma from healthcare providers which can result in missed appointments.[8 9] This psychological issue occurs in approximately 36% of people with type 2 diabetes and can negatively affect health outcomes as it is linked to poor self-care, lower mood and increased risk of elevated HbA1c levels.[10–12] Diabetes distress also tends to occur more in women, younger people, non-white and ethnic minority populations and those with shorter diabetes duration.[8 10 12–14] With the global numbers of people with type 2 diabetes expected to rise to 642 million by 2040,[15] diabetes distress is a pressing issue.

Interventions that target diabetes distress directly such as psychoeducation can be effective in reducing emotional distress rather than relying on behavioural interventions that focus on changes in lifestyle or education programmes.[7 16] Mindfulness practice, derived from Buddhist meditation, is a type of contemplative practice that involves paying attention to present-moment experiences in a non-judgemental way.[17] Popular mindfulness-based interventions (MBIs) are Mindfulness-Based Stress Reduction[18] and Mindfulness-Based Cognitive Therapy.[19] There is robust evidence that MBIs are beneficial for people with physical and mental health conditions.[20–22] A systematic review of MBIs for people with type 1 and 2 diabetes showed that these were effective in improving psychological outcomes such as stress, anxiety, depression and distress among others, with mixed evidence of their impact on physiological outcomes such as HbA1c and blood pressure.[23] More recent reviews of mindfulness and acceptance-based approaches for those with type 1 and 2 diabetes also found small to moderate improvements in diabetes distress and quality of life.[24]

Mindfulness-based interventions

However, MBIs used with people with type 1 and 2 diabetes have been mainly face-to-face individual or group-based sessions that were facilitator led, with a handful using home-based practice.[25] An in-person approach can be limited by cost, poor accessibility and lack of availability,[25] with high rates of attrition and dropout over time.[26] Digital forms of MBIs such as online versions or mobile applications (apps) can provide convenient, inexpensive and accessible ways to access mindfulness programmes.[27] A review of mobile mindfulness apps found that Headspace, Smiling Mind, iMindfulness and Mindfulness Daily scored highest in terms of engagement, functionality, visual aesthetics, information quality and subjective quality.[28] However, the review findings stressed that most apps provided guided meditation only and not mindfulness practice, and there was limited evidence of their effectiveness in improving health outcomes. Furthermore, some mindfulness apps can have poor interface design with limited visualisations and feedback which could contribute to low adherence and dropout from these digital mental health programmes.[29–31]

Virtual reality (VR) is a technology where the user is fully immersed in computer-generated virtual environments using a VR headset. It is being used in many ways in healthcare such as mitigating anxiety and distress[32] or as a distraction therapy to help manage pain.[33 34] Some studies have examined VR apps for mindfulness. Navarro-Haro *et al*[35] recruited 44 mindfulness experts to examine dialectical behaviour therapy mindfulness skills training delivered via an Oculus Rift VR headset and reported significantly less sadness, anger and anxiety after the VR intervention. This provides preliminary evidence of the feasibility and acceptability of using VR to practice mindfulness based on expert clinical feedback. Reviews of VR-based mindfulness apps found some improvement in anxiety, depression and sleep, as VR offered more immersive, audio-visual environments but they also identified weak study designs and a lack of personalised experiences, as few VR mindfulness apps were co-designed with end users.[36 37] Furthermore, there are no scientific studies that explore the potential for reducing diabetes distress through VR-based mindfulness practice where the technology has been co-designed with people with diabetes.

Participatory design

The use of participatory approaches to develop health technologies with different end users is increasingly popular. Such approaches seek to improve how hardware and/or software is designed and functions and the impact this has on outcomes. By actively involving end users in designing a digital health tool, their needs and personal preferences can be considered and included in the final solution.[38 39] Such involvement may lead to better quality and more usable tools that could increase user engagement and improve health outcomes in the long term.[40 41] Co-design encompasses concept creation, prototyping and iterative user testing, incorporating a range of creative approaches such as think aloud methods, paper prototyping, scenarios and personas as well as more traditional research methods like interviews, focus groups and participant observation. Experience-based Co-Design (EBCD)[42 43] and the Centre for eHealth Research Roadmap among others[44] are examples of participatory frameworks that use several methods and staged approaches to help co-design health technologies.

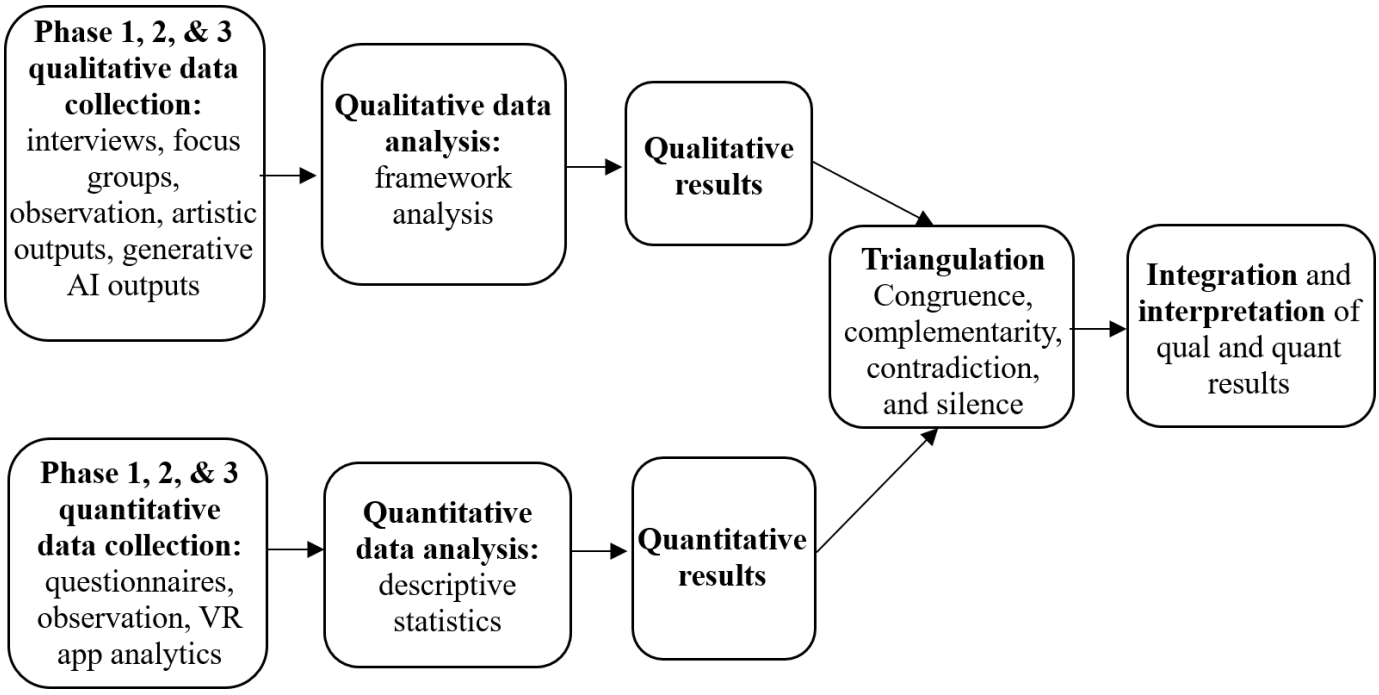

Figure 1 Three-phased mixed-methods study design. AI, artificial intelligence; VR, virtual reality.

However, new generative artificial intelligence (AI) tools, such as AI image, audio, music and video generators, emerged in 2023 and can create a range of digital media quickly via prompts from human users.[45] These represent a new way to co-design digital health interventions with end users that could lead to digital health tools that are faster, more affordable to create and potentially more cost-effective. To date, few scientific studies have integrated generative AI tools into the co-design process and used them with end users to help create a new digital health tool.

Hence, this study aims to:

1. Understand the virtual experiences (design features, functionality, content) people with type 2 diabetes would like from a VR mindfulness app.
2. Examine how acceptable and feasible a novel co-design process, incorporating generative AI tools, is when creating a VR mindfulness app with people with type 2 diabetes.
3. Explore the perspectives of people with type 2 diabetes towards a bespoke VR mindfulness app and its impact on diabetes distress and quality of life.

METHODS AND ANALYSIS

Study design

An interdisciplinary team of researchers with backgrounds in medical informatics, diabetes, nursing, nutrition, health psychology and sociology conceptualised and designed this research study. A three-phased mixed-methods approach will be used following the UK Medical Research Council guidelines on developing and testing complex interventions.[46] A concurrent triangulation approach will be adopted as quantitative and qualitative data will be collected in parallel, and two or more methods will be used to confirm, cross-validate or corroborate the research findings (figure 1). Two theoretical frameworks, Leventhal's *et al*[47] common-sense model of self-regulation, and the mechanisms of change identified in the Mental Health Experience Co-design framework,[48] will underpin the study. The Good Reporting of a Mixed Methods Study checklist will be used to report the study's findings.[49]

Phase 1: evidence synthesis and expert insights

In phase 1, a review of commercially available VR apps for mindfulness will be undertaken using a robust methodological approach[50] to determine the availability and quality of existing VR-based mindfulness tools. A systematic, scoping or narrative review would not be feasible due to the lack of scientific studies on these types of VR apps. The key design features/aesthetics, functionality and content/information of VR mindfulness apps will be extracted, and the quality of the VR apps independently evaluated using the Mobile App Rating Scale (MARS) to enable a rich understanding of existing VR-based mindfulness interventions.[51] The findings of the commercial health app review will inform interviews with mindfulness experts in February and March 2024. A purposive sample of mindfulness practitioners will be recruited through professional email networks and the British Association of Mindfulness-based Approaches (www.bamba.org.uk). They will be interviewed to identify key concepts and practices to include in a virtual mindfulness experience (table 1, online supplemental file 1). The timing, frequency and duration of a VR mindfulness intervention will also be discussed to gauge when, how often and for how long a person with type 2 diabetes should use a VR

Table 1 Phases of Artificial Intelligence-informed Experience-Based Co-Design (AI-EBCD)

Aims	Activities
Phase 1: evidence synthesis and expert insights	
Evidence synthesis: Identify and evaluate commercially available VR-based mindfulness apps.	► Search and screen relevant VR-based mindfulness apps. ► Extract and analyse data. ► Assess the VR apps using the Mobile App Rating Scale.[59] ► Synthesis data to produce the review findings in February 2024.
Expert insights: Gather the perspectives of experts on VR for mindfulness practice and VR-based mindfulness apps.	► Semistructured interviews with mindfulness practitioners (n=10) in March 2024.
Phase 2: participatory design	
Co-design workshop 1: Support adults with type 2 diabetes (n=10) to discuss diabetes distress and the potential for mindfulness practice to help manage this.	► Focus group using emotional mapping to discuss diabetes distress in May 2024. ► Mindfulness training provided by an experienced mindfulness practitioner with video-recorded participant observation. ► Focus group to discuss mindfulness practice for managing diabetes distress.
Co-design workshop 2: Enable adults with type 2 diabetes (n=10) to evaluate existing VR-based mindfulness apps.	► Focus group to evaluate and discuss existing VR-based mindfulness apps in May 2024. ► Mobile App Rating Scale[59] and Mindful Attention Awareness Scale[60] will be completed to evaluate existing VR-based mindfulness apps identified in phase 1.
Co-design workshop 3: Support adults with type 2 diabetes (n=10) to create a personalised mindfulness experience.	► Artistic methods (eg, drawing, photo elicitation, textiles) will be used to create personalised mindfulness experiences, with video-recorded participant observation and photographs of artistic outputs taken. ► Focus group to discuss the artistic process and artistic outputs in June 2024.
Co-design workshop 4: Facilitate adults with type 2 diabetes (n=10) to create digital content for a virtual mindfulness experience.	► Think aloud interviews will be conducted in June 2024 to explore using generative AI tools to create digital content, with screenshots and downloads of the generative AI outputs recorded.
Co-design workshop 5: Assist adults with type 2 diabetes (n=10) to score and rank design features, functionality and content for a VR mindfulness app.	► Group prioritisation exercise following nominal group technique in June 2024 to identify key design features, functionality and content from the previous co-design workshops. ► Draft a software design document for a tailored VR mindfulness app based on the group prioritisation exercise.
Phase 3: VR app development and evaluation	
VR app development: Develop a prototype VR mindfulness app.	► Scaffold Unity app from July to September 2024. ► Deploy and test on Android devices. ► Document software development on GitHub.
VR app evaluation: Evaluate the prototype VR mindfulness app with adults with type 2 diabetes who experience diabetes distress (n=10).	► Diabetes Distress Scale[13 66 67] and the Diabetes-specific Quality of Life questionnaire[68 69] will be completed before and after VR app use in October and November 2024. ► Interviews in November 2024 to discuss participants' perspectives of using the new VR mindfulness app. ► User analytics from the VR mindfulness app.

AI, artificial intelligence; VR, virtual reality.

mindfulness app.[52 53] These insights will inform the participatory design process and ensure that a high-quality VR intervention is developed with people with type 2 diabetes that is tailored to their needs.

Phase 2: participatory design

EBCD will be used to support the participatory design process. EBCD enables end users to co-design products or services in partnership with healthcare professionals and researchers through observation, filmed interviews,

dialogue and creative methods.[54 55] EBCD will be adapted for this study, and artistic practices and generative AI tools will be integrated into the process. This is a new creative approach to enhance how digital health interventions are co-designed with patients, referred to as Artificial Intelligence-informed Experience-Based Co-Design (AI-EBCD). Additional creative methods such as a range of artistic practices will also be used to enhance the participatory design process.

Sampling and recruitment

A purposive sample of people with type 2 diabetes will be targeted to participate in a series of co-design workshops. They will be recruited using professional email networks, advertisements on social media and announcements via diabetes charities. The inclusion criteria will be adults, aged 18 years and older, who have been diagnosed with type 2 diabetes for more than 12 months and self-report prior experience of diabetes distress. The ability to read and write in English will also be a condition of participating in the study, as will owning an Android-based smartphone as the prototype VR mindfulness app in phase 3 will only be developed for Android-based mobile devices. Android is an open-source platform and can be faster and more flexible when developing apps than iOS, and has a larger global market share with more people using this platform than Apple products.[56] The exclusion criteria will be children and adolescents with type 2 diabetes, women with gestational diabetes, anyone who has non-diabetic hyperglycaemia or people with type 1 diabetes. Those who do not own a smartphone or only have an iPhone handset, along with those who are not fluent in the English language will be excluded. We will not conduct a formal sample size calculation as co-designing digital health interventions and evaluating them via user testing typically requires small samples due to the level of interaction and engagement required from participants and researchers at all stages of the process. Although a sample size of 40 is suggested when undertaking usability testing of eHealth applications,[57] this will not be feasible due to time and funding constraints.

Co-design workshops

The first workshop, planned for May 2024, will focus on understanding diabetes distress and mindfulness. A focus group and emotional mapping techniques will be used with people with type 2 diabetes to elicit their lived experience of diabetes distress and the factors that affect this (online supplemental file 2). Participants will discuss their personal experiences of diabetes distress and then analyse these by plotting elements of their stories on emotional maps.[54] These maps will have a series of touchpoints or factors that contribute to diabetes distress displayed on the wall enabling participants to explore feelings associated with these touchpoints. Emotion words (positive and negative) drawn from participants' personal stories will be written on post-it notes and placed alongside the identified touchpoint to conclude the focus group. Then participants will receive education on mindfulness practice and learn several mindfulness techniques (eg, breathing, meditation, body scanning). They will also receive educational resources to continue practising mindfulness at home. Participants will be observed (observer-as-participant) both in person and through a filmed video recording to understand people's behaviours and gauge their physical, mental and emotional reactions to mindfulness as a concept and practice. Descriptive field notes will be taken detailing who is present and their actions and interactions in paraphrased statements, and analytic notes recorded to interpret what is being observed.[58] A discussion at the end of the workshop will elicit the perspectives of people with type 2 diabetes on mindfulness and its practice, and its potential to reduce diabetes distress. The collective reflections and observations captured throughout the workshop will be used to help identify the features (eg, design, functionality and content) for a VR mindfulness app for further discussion and prioritisation in workshop 5 and to inform an evaluation of the co-design process and its outputs.

The second co-design workshop, planned for May 2024, will centre on evaluating existing VR mindfulness apps. Participants will be trained to use VR headsets (ie, Meta Quest 2 and Google Cardboard) and given instructions on how to navigate a selection of VR mindfulness apps. Meta Quest VR headsets and Android smartphones will be pre-loaded with the top-rated VR mindfulness apps identified in phase 1. People with type 2 diabetes will spend 10–15 minutes using each VR app to experience different virtual environments that could enhance mindfulness, after which they will complete the MARS[59] and Mindful Attention Awareness Scale.[60] These will help determine the person's perspective on the quality of each VR app (design features, functionality and content) and how well they think it could support mindfulness practice. To avoid simulation or cybersickness (eg, nausea, dizziness) that some people experience from being immersed in a VR experience for too long,[61] a 10–15 minute break between using each VR app will be encouraged. A discussion at the end of the workshop will elicit the perspectives of people with type 2 diabetes on the design features, functionality and content that they liked and disliked in the VR mindfulness apps. These group reflections along with the objective measures will be used to inform further discussion and prioritisation of key app features in workshop 5.

The third co-design workshop, planned for June 2024, will use artistic practices for example, drawing, photo elicitation and textiles with people with type 2 diabetes to support them to create a personalised mindfulness experience.[62] Each participant will be provided with a range of artistic resources and given 60–90 minutes to design creative outputs related to a mindfulness environment they would like to experience. Participants will be observed and filmed throughout the workshop to capture how they interact with the artistic materials, the type of creative process they employ and their physical, mental and emotional reaction to using arts-based

practices to create a personalised mindfulness experience. To conclude the workshop, participants will share their final artistic output and the rationale for it with the group to facilitate discussion on arts-based approaches to inform the design of a digital health intervention. Photographs of all the artistic outputs will also be taken. The collective reflections, observations and images captured throughout the workshop will be used to help identify the features (eg, design, functionality and content) of a VR mindfulness app for further discussion and prioritisation in workshop 5 and to inform an evaluation of the co-design process and its outputs.

The fourth co-design workshop, planned for June 2024, will support people with type 2 diabetes to use several generative AI tools such as image, video, audio and music generators to create digital content they would like in a virtual mindfulness experience. These AI tools require simple text-based prompts from users to create a range of digital media, for example, audio, images, video and music.[45] Participants will be educated about the ethical and socio-legal issues associated with generative AI tools such as algorithmic bias and copyright concerns. The digital content from the generative AI tools will not be used directly to develop a VR mindfulness app but represents a novel co-design technique to support people to express their creativity and personal preferences using different forms of digital media. Think aloud (cognitive) interviews will be employed as each participant interacts with the generative AI tools to explore the usability of the digital tool, their thoughts on how well it works and the digital media it is able to create.[63] A detailed protocol of tasks to complete will be developed for each generative AI tool to facilitate the think aloud process, and participants will also be given space and time to use these novel platforms in more ad-hoc and imaginative ways (online supplemental file 3). Screenshots or downloads of the outputs of the generative AI tools will also be captured to help inform the design of a VR mindfulness app in workshop 5.

The fifth and final workshop, planned for June 2024, will be a prioritisation exercise to identify key VR app features, followed by an in-depth collective reflection on the entire co-design process. For the prioritisation exercise, individual and group scoring and ranking of key design features, functionality and content that people with type 2 diabetes would like in a VR mindfulness app will take place to conclude the participatory design process. Nominal group technique (NGT) will be used to facilitate group consensus on the design of the VR mindfulness app.[64] In this approach, equal representation is important, ensuring that one individual does not dominate the process, nor dominant group members impose their opinions and views on more reticent participants. Therefore, NGT can lessen the impact of unhelpful group dynamics and encourage participation from all group members, regardless of their personal characteristics, beliefs or values. The results of previous co-design workshops will be shared with participants and discussed in a facilitator-led virtual focus group which will be recorded. An emotion mapping exercise will help participants highlight key elements they would like in a virtual mindfulness app.[65] The facilitator will present the design features, functionality and content, and participants will be asked to score each touchpoint (key element in a virtual mindfulness app) from 0 to 10 to indicate their preference to exclude (score 0) or include (score 10) it, resulting in a visualisation of all the negative and positive points. The facilitator will combine all the scores to narrow participant feedback to a shortlist of touchpoints (ie, design features, functionality and content). A final round of scoring will take place to rank the top most popular touchpoints. Group discussion using a 'round robin' technique will be used to resolve disagreements and approve the final list which will be incorporated in a software design specification document for a VR mindfulness app. Then emotion mapping will be used to explore the five co-design workshops where each will be reflected on with participants who will be asked to share their experiences (both positive and negative) of the approaches used and outputs generated. This will help assess the acceptability and feasibility of the new AI-EBCD process in co-designing a digital health tool with end users.

Phase 3: VR app development and evaluation

The design specification document produced at the end of phase 2 will be used to develop a VR mindfulness app that is tailored to the needs of people with type 2 diabetes. An agile software development methodology incorporating user testing between July and September 2024 will be employed to refine and finalise the design, functionality and content of the VR mindfulness app. People with type 2 diabetes who participated in phase 2 will be provided with VR headsets to evaluate the new VR mindfulness app. Recommendations on the timing, duration and frequency of VR app use will be provided to participants based on phase 1 results. For example, using the VR mindfulness app 3–4 times per week for 8 weeks, for 15 minutes per session could be recommended. This will enable people with type 2 diabetes to be immersed in an audiovisual and interactive experience to practice mindfulness to help reduce diabetes distress and improve quality of life.

Participants will be asked to complete the Diabetes Distress Scale (DDS)[13 66 67] and the Diabetes-specific Quality of Life Scale (DSQoLS)[68 69] before and after using the new VR mindfulness app in October and November 2024. These are psychometrically reliable and valid instruments. The DDS was standardised primarily with adults with type 2 diabetes.[9] It was developed to identify key sources of diabetes distress and contains 17 items, each rated on a 6-point Likert scale, from 'not a problem' to 'a serious problem'. The scale yields a total diabetes distress score, plus scores for four subscales: emotional burden, regimen distress, physician distress and interpersonal distress. The DSQoLS comprises 64 items ranging from individual treatment goals (10 items), satisfaction

with treatment success (10 items) and diabetes-related distress (44 items).

User analytics from the VR mindfulness app such as the date/time a user launches the app, which VR mindfulness experiences they select and how long they spend in these will also be downloaded at the end of the evaluation period in November 2024. This will help us determine when, how often and for how long it was used by each participant, giving us an indication of adherence to and attrition from the digital mental health intervention. Finally, semistructured interviews will be conducted at the end of the app evaluation period in November 2024 to explore the perspectives of people with type 2 diabetes on the usability of the VR mindfulness app and its impact on diabetes distress and quality of life (online supplemental file 4). This will help them reflect on their experiences of using the VR mindfulness app and its design features, functionality and content. These qualitative and quantitative insights will help refine and finalise the app design to ensure that a prototype digital mental health intervention is available for people with type 2 diabetes.

Data analysis

All qualitative data from the mindfulness experts in phase 1 (eg, interviews), the co-design workshops in phase 2 (eg, filmed and in-person observations, interviews, focus groups, artistic and generative AI outputs) and the end user evaluation in phase 3 (eg, interviews) will be analysed using the framework approach.[70] The phase 3 results will be underpinned by Leventhal's common-sense model of self-regulation[47] and the eight mechanisms of change (ie, recognition, dialogue, cooperation, accountability, mobilisation, enactment, creativity and alignment) from the Mental Health Experience Co-design framework.[48] Following an inductive approach, the data will be coded and categorised into overarching themes and subthemes until data saturation occurs and any negative or deviant data explored to enhance internal validation. This will enable a rich understanding of (1) participants' perspectives on the design, functionality and content for a VR mindfulness app, (2) the acceptability and feasibility of the new AI-EBCD process and (3) whether this novel digital intervention can help reduce diabetes distress and improve quality of life. A deductive method will then be adopted, and the themes and subthemes from the phase 3 results mapped to the key concepts in the common-sense model of self-regulation or the mechanisms of change in co-design where appropriate, to build new conceptual frameworks detailing how a VR mindfulness app can support self-care in people with type 2 diabetes and the acceptability and feasibility of the new AI-EBCD process. This will enable the voices and stories of people with type 2 diabetes to be gathered, analysed and synthesised into meaningful narratives that constructively explain how to co-design VR technology with people with diabetes to enhance diabetes care and outcomes. N-Vivo QSR V.12.0 will be used to support this analytical process.

All quantitative data from the co-design workshops in phase 2 (eg, observations, MARS and the Mindful Attention Awareness Scale) and from end user evaluations in phase 3 (eg, Diabetes Distress Scale, the Diabetes-specific Quality of Life Scale and user analytics from the VR app) will be analysed using descriptive statistics (eg, mean, SD) and results displayed in contingency tables. Simple regression modelling may also be performed to evidence changes regarding diabetes distress and quality of life before and after the digital mental health intervention. SPSS will be used to support this analytical process.

The results of the qualitative and quantitative analyses will be compared and contrasted to identify where the findings converge or agree, where they complement each other, where differences or contradictions occur or where 'silence' (themes arise in one dataset but not the other) emerges in what people with type 2 diabetes would like in a VR mindfulness app (ie, design, functionality, content), the acceptability and feasibility of the AI-EBCD process and how the new digital intervention could influence diabetes distress and quality of life. This will result in a convergence coding matrix to present the results from each component of the study and any meta-themes that arise from the different analyses to demonstrate the value of integrating the results of qualitative and quantitative analyses.[71] A mixed-methods matrix will also be developed where individual cases are the sole focus of analysis. Participant responses to questionnaires will be compared with their interview and focus group transcripts, observational notes and creative outputs with data on each case summarised and displayed in a matrix. This will facilitate detailed individual and cross-case analyses and the identification of any negative cases[72] helping to enhance the richness of the findings of the mixed-methods study.

Rigour and reflexivity

Research rigour will be enhanced throughout the study via several approaches to ensure that the findings represent the views of people with type 2 diabetes.[73]

- *Credibility*: Informal peer debriefing will take place periodically where the research process and interpretation of transcripts, field notes from observation, interviews and focus groups, and artistic and generative AI outputs will be discussed with experienced research colleagues. These conversations will be useful in considering personal perspectives and beliefs that could have influenced the chosen approach and results, to minimise researcher bias. Due to the limited timeframe and resources for the study, respondent validation will not be undertaken but a reflexive diary will be kept helping mitigate any potential researcher bias.
- *Dependability*: Clear descriptions will be provided of all methods including approaches to data collection and analysis and decisions taken at each stage. This detailed protocol outlining how the study will be carried out has been drawn up and will be adhered to when undertaking all aspects of the study. The

scientific review of commercially available VR mindfulness apps will be registered on open access platforms such as PROSPERO or OSF to ensure transparency and consistency in the methods used. This will enable other researchers to follow the same process and arrive at similar findings. The robustness of the analysis process will be enhanced through a series of coding clinics with senior researchers, who will check samples of analytical coding.

- *Confirmability*: The research teams' perspectives on this topic will be clearly stated, and the rationale for the scientific review, underpinning theory and methodology approach evidenced and published. The strengths and limitations of the research study will also be highlighted, so it is clear where there are gaps in data and its analysis, and how this influenced the result. Video and audio-recordings will be listened to and compared against transcripts to ensure they correspond with one another. The triangulation of results will be feasible due to the variety of participants (mindfulness practitioners and people with type 2 diabetes), approaches (multiple types of primary data collection and analyses) and researchers (nursing, nutrition, health psychology, medical informatics, sociology, patient and public involvement and engagement representative) contributing to the research study. Therefore, the diversity of the data and the chain of evidence collected will help support the findings, which will be verified against those of the scientific review to ensure that the results are robust and valid.
- *Transferability*: To increase the applicability of the study's findings to other areas, it is important to describe the context in as much detail as possible. Therefore, the theoretical and methodological approaches are described, and the choices made at each stage of the research process will be documented. In addition, qualitative quotes for themes and subthemes will be provided in published articles to support the findings. Furthermore, a clear overview of the VRUnwind study and its setting within the UK will also be given, as this richness will enable readers to understand the context and limitations inherent in the results and make the best judgement on how transferable they are to other areas.

Patient and public involvement

A patient and public involvement engagement representative is involved in this research study, attends research team meetings and reviews key documentation. They will be involved in all three phases of the study by informing planning and decision-making and supporting data collection and analysis as a lay researcher. They will also participate in dissemination events and ensure that the findings are summarised and shared in an accessible and inclusive way. The co-design of the digital mental health intervention (AI-EBCD approach) also involves potential end users in all workshops and in the evaluation of the VR mindfulness app.

ETHICS AND DISSEMINATION

Ethical approval was obtained from The University of Manchester research ethics committee in January 2024 for phases 1 and 2 of the study (ref: 2024-18262-32710), and in August 2024 for phase 3 of the study (ref: 2024-21170-37093). Written informed consent will be obtained from all participants. The study will employ a number of dissemination channels to reach academic, clinical, patient, public and policy audiences nationally and internationally. Multimedia content will be curated and posted on social media platforms to share the results with a range of online communities. Scientific peer-reviewed publications will be produced, and the study's results presented at national and international conferences. The findings will also be delivered at local face-to-face/virtual seminars to reach clinicians and researchers, and integrated into teaching programmes at the collaborating universities to ensure students training to become healthcare professionals learn about the importance of co-designing interventions and how technology can support self-care of a chronic disease.

DISCUSSION

The VRUnwind study was designed by an interdisciplinary team with the aim to co-design a VR-based mindfulness application with people with type 2 diabetes to help reduce diabetes distress and improve quality of life. The VR app aims to support the self-management of diabetes distress and may not be prescribed by a healthcare professional but accessed by an individual with diabetes. A strength of this study is its mixed-methods approach, combining quantitative and qualitative data collection and analysis in each phase to understand how a new co-design process incorporating generative AI can help create a VR mindfulness app for people with type 2 diabetes, and the impact this VR app has on their diabetes distress and quality of life. The authors hope that the study helps to address some of the challenges people with type 2 diabetes face in managing diabetes distress every day, and that the bespoke VR mindfulness app can reduce the negative effects that this psychological issue has on the management of type 2 diabetes and the health outcomes of people with type 2 diabetes. There are some limitations that may affect the conduct and results of the study such as difficulties recruiting a diverse population of adults with type 2 diabetes to participate in the co-design workshop and VR app evaluation. The stigma some people with this chronic disease experience,[74] time constraints[75] and a lack of trust in those conducting clinical research[76] may make recruitment challenging, leading to a smaller sample size which might reduce the robustness of the study's results. In order to overcome this problem, a range of recruitment channels will be used such as professional networks, social media and local community groups, and accessible and engaging recruitment materials will be designed to attract participants, with clear and robust participant information sheets and consent forms provided, and a

financial incentive offered for participating in the study. Another limitation may be the digital literacy skills of people with type 2 diabetes which if low could affect how well they take part in the co-design workshops,[77 78] particularly those involving the VR headsets and hand controllers, and the online generative AI tools. Furthermore, generative AI tools can generate digital content that is unexpected or biased which may frustrate users.[79] To address this, we will provide training on how to use the VR equipment and generative AI tools at the beginning of the workshops as well as highlight their limitations and risks and provide hands-on support to participants throughout to ensure that they can participate fully in the co-design process. Furthermore, the design requirements of each individual participant may not be feasible to incorporate into a prototype VR mindfulness app due to time and funding constraints. We will use NGT in the last co-design workshop to prioritise the most important design features for development and apply for further funding to create a more immersive and interactive VR mindfulness app if the results of this initial pilot study prove promising. Finally, this study will be conducted in the UK which is a more digitally advanced country compared with other regions of the world. Hence, the results may not be generalisable to countries where socio-economic and geo-political contexts and hence diabetes care and the use of digital mental health interventions are very different.

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