 UK – Creative Impact Fund

## Tend VR MBCT – A Radical Solution to the Global Problem of Depression and Anxiety

The cost-effective and population-scalable VR solution for delivering mindfulness-based cognitive therapy (MBCT) to treat depression

# Final Report for CIRCE

## Tend-VR MBCT - A Radical Solution to the Global Problem of Depression and Anxiety

### **Summary**

The world is currently experiencing a global mental health crisis, with close to 600 million people around the world suffering from depression and/or anxiety (WHO, 2022). Academic research over the past 15 years has found MBCT (Mindfulness-Based Cognitive Therapy) to be one of the most effective treatments for anxiety and depression, and for preventing relapse (see e.g. Batink et al., 2013, Burgess et al. 2021, Kuyken et al. 2008, McCartney 2021, and Williams et al. 2007).

Tend-VR was created as a ground-breaking solution for many of the main issues currently surrounding mental health treatments generally - and MBCT in particular - such as cost, scalability, availability of trained practitioners and facilitators, desirability and effectiveness. In 2021, Tend-VR built the world's first virtual reality VR-based, self-guided MBCT course. The programme provides users with an 8-week course in MBCT whilst immersing them in a stunning and tranquil VR environment.

The funding we received from CIRCE has enabled us to provide both technical innovation by creating ultra realistic virtual environments that allow users to immerse themselves more profoundly and social innovation with the development of an effective and scalable MBCT course to treat depression and the validation of its utility.

The initial overall results from this CIRCE-funded study, with 45 participants, are very positive, with improvements in PHQ-9 (depression scores) and GAD-7 (anxiety scores) being shown by almost 70% of participants on the trial, with participants who had the highest (i.e. worse) PHQ-9 and GAD-7 scores showing the most dramatic improvements. In addition, 85% of participants would recommend Tend-VR MBCT to family and friends and 83% report their experience of Tend-VR as being positive. The feedback received throughout this study is instrumental for Tend-VR's next steps, including prioritisation of any key changes needed to improve the course and user experience, as well as going to market.

Our research and development activities for our CIRCE project have been hugely significant for us as a business. Improving our programme and the immersive nature of our environments is essential to ensure usability for participants, and providing evidence of the efficacy of both our method of delivery and the MBCT course itself is vital if we are to successfully commercialise our product — whether this is as an employee wellness tool for other businesses or provided for use via a health service.

### Journey:

In the process of developing and conducting our project for CIRCE, our journey was marked by some key milestones. The table that follows sets out those key milestones and their part of the journey, with an explanation about their significance.

<b>Milestone</b>	<b>Stage of the journey</b>	<b>Why this was important and what we learned</b>
Improvements to immersive environments	Immediately after the commission was awarded, before the participants were recruited	The user experience is vitally important to sustain engagement and provide a realistic environment. Completing the immersive environment improvements before the study commenced meant that we knew our participants were going to have the best possible VR experience.
Changes to the course and the level of interactivity, including re-recording voiceover	Immediately after the commission was awarded, before the participants were recruited	<p>Based on feedback from our academic advisor (Professor Gould from UCL) and principal investigator PI (Dr Bevan), we reworked some aspects of the course content and its interactivity to ensure it was as close as possible to the group version of the MBCT course, and appropriately adapted to the VR environment. This ensured equivalence to the standard MBCT programme, enabling comparisons to be made.</p> <p>The Tend-VR MBCT course is based on 40 sessions, broken down into eight weeks. We carefully analysed each week to consider how many interactive tasks there were, the average length of time between each interactive activity, as well as the length of each session. Week four was identified as being both the longest, least interactive and the most challenging in terms of content (since it deals with negative thinking).</p> <p>As a result we made a complete overhaul of week four, resulting in a much more user friendly experience that demands much less of participants in terms of time and attention.</p> <p>In addition, we made significant changes to the overall number and types of interactive activities available throughout the course to give participants more engagement with the environment in which they are. We added gamified elements such as fish that could be fed and that would grow and multiply as a result, plants that could be watered and grow, stones that could be skipped across the lake, and interactable wind chimes – amongst many others – all aimed at making the environment a relaxing and enjoyable space in which to learn MBCT. We found in our first study that gamified elements were consistently mentioned by participants in post-completion interviews as a significant contributor to user adherence.</p>
Conclusion of our main technical build	Immediately before participants were recruited	Achieving the Quality Assurance and Bug Fixing milestone was crucial for Tend, to ensure the software's reliability and efficacy. By identifying and rectifying bugs rapidly, we maximised the chances of a seamless user experience, vital for maintaining participant engagement and accurately assessing the VR MBCT's therapeutic impact. Our meticulous

		<p>approach underlines Tend's commitment to delivering clinically validated and effective mental health solutions.</p> <p>The current trial software was posted to the participants at the beginning of the trial, and since that time we have only had one bug reported with our software, in that when users have completed all 8 weeks, the menu freezes. We have since fixed the issue and successfully patched for users that want to start the course over again.</p> <p>The technical build process began with foundational improvements in functionality, which involved not only refining basic operations but also extending these enhancements to the intricacies of our VR environments. One key focus was rectifying technical challenges that were detrimentally impacting the frame-rate, a crucial element for ensuring a fluid virtual reality experience. We forensically analysed each shader, material, texture and object in the 3D world, attempted alternate pipeline builds (from Built In Render Pipeline to Universal Render Pipeline) and different graphics packages (Vulkan from OpenGL ES 3) before finalising our approach.</p>
<p>Designing study protocols and achieving ethics approval</p>	<p>Immediately before participants were recruited</p>	<p>Our principal investigator Dr Bevan developed our study protocol, with feedback from the team, our clinical partners and our academic adviser. It is an extensive document designed to give all participants and partners a thorough understanding of all processes involved in the study and vital aspects such as safeguards, data collection and protection, with the golden thread of participants' welfare running through it. The study protocol also ensures that all collaborators in the study agree to take the same approach, with a key focus on participant wellbeing and safeguarding.</p> <p>Procuring sign off on the study ethics by our clinical partners, The Retreat Clinics, was a big step for us, as it was a signal that all aspects of our study had been scrutinised and found to be of very low/negligible risk to participants and study collaborators.</p>
<p>Participant recruitment (see Innovation section for recruitment flowchart)</p>	<p>At the start of the study</p>	<p>Recruiting participants for a mental health trial poses several distinct challenges that we needed to overcome at the start of our journey. Key issues were:-</p> <ul style="list-style-type: none"> <li>● Stigma and privacy concerns surrounding mental health - to overcome this as much as possible we used careful wording and confidentiality clauses in all of our adverts and consent forms.</li> <li>● Participant characteristics – we needed to ensure that our participants had some level of depression and/or anxiety but were not severely depressed or anxious to safeguard their wellbeing. This meant we had to construct careful exclusion and inclusion criteria (see innovation section), some of which were included in the recruitment adverts, as well as standard and supportive emails to send to people who were not suitable for the study. We used an Expression of Interest Form, which</li> </ul>

		<p>included PHQ-9 (measuring depression) and GAD-7 (measuring anxiety) questionnaires as well as other detailed questions to ensure the potential participants were suitable.</p> <ul style="list-style-type: none"> <li>Fully informed consent and safeguarding - conducting mental health trials ethically is paramount, especially when dealing with vulnerable populations. Ensuring participants are fully informed about the trial and obtaining their informed consent were essential steps in our journey. The guidelines included detailed documentation and rigorous data handling procedures to ensure participant safety.</li> </ul>
Fulfilment and trial initiation	Commencement of trial, after participants had given fully informed consent	<p>Sending out headsets at the start of October was hugely significant for us, as it signalled the end of the main technical build. Our latest version of the app was uploaded to the headsets, meaning that any future updates would have to be downloaded by participants by connecting to their WiFi.</p> <p>Preparation of all the headsets and ensuring their readiness was a complicated process. We downloaded our MBCT course to each Meta Quest 2 headset individually, meticulously ensuring that every device was loaded with the necessary content. Then, we carefully packed each headset for immediate usage, with the necessary printed information, and readied the headsets for dispatch, as shown in image 1 below. This step proved much more time-consuming than anticipated. Reflecting on this step, we are contemplating outsourcing this activity in the future.</p>
Supporting participants & collecting outcomes measures	Throughout the trial, from the point at which participants received the headsets until the final session	<p>Receiving feedback from participants as they started to progress through the MBCT course was an important part of our journey. We developed a protocol for dealing with support queries and logging comments. All the feedback we received has proved extremely valuable for helping us refine our course and how we deliver it.</p> <p>In November, we asked participants to complete a mid-point online questionnaire to assess their PHQ-9 depression and GAD-7 anxiety scores and to see if they wanted to share any thoughts on the course so far. Through this process we gained valuable insights into the general progress of all the participants, and it has been extremely gratifying to see so many positive written responses regarding the impact the course has already had for many of the participants (see comments from participants in the Impact section and the summary).</p>
Initiating European collaborations and translations	Once the study was underway	<p>Another aim for this CIRCE-funded project was to find ways to assist as many individuals globally who face depression and anxiety as possible, many of whom may face an additional challenge understanding English. Thus, we decided that we could make positive progress towards this with our CIRCE project by taking steps to translate our 8-week MBCT course into a few other European languages, such as Romanian, German, and Spanish. In addition, our CIRCE</p>

		project provided us with an important opportunity to begin to extend our work into Europe by starting to make connections with academics and institutions in various EU countries in preparation for exploring further studies and funding opportunities.
Trial end processes and logistics	Once the participants' involvement in the study has been completed	<p>The completion of our trial is a multi-layered phase encompassing several key elements:</p> <ul style="list-style-type: none"> <li>• The return of VR headsets by participants signifies the practical end of their involvement and allows for an evaluation of the logistics involved in deploying VR technology in a clinical setting. This step is essential for understanding the feasibility of large-scale implementation of such interventions.</li> <li>• Outcome measures - these responses provide the quantitative data necessary for assessing the intervention's effectiveness in treating depression and anxiety. This step is crucial for establishing a solid foundation for the clinical validity of our VR-based treatment.</li> <li>• Qualitative feedback gathered through exit interviews and surveys offer insights into the participants' experiences and perceptions. This feedback is integral to understanding the subjective impact of the intervention and identifying areas for improvement.</li> </ul>

**Image 1: Preparing the Meta Quest 2 headsets for our participants (a) & after headsets were prepared for shipment (b)**



**Innovation:**

This VR adaptation of MBCT also addresses major accessibility issues. Traditional MBCT, being a face-to-face therapy, often limits access due to geographical and time constraints, cost and lack of availability of trained practitioners. The VR version, however, breaks these barriers, enabling users to access the programme from any location, at any time and without the need for a practitioner, thereby expanding the reach and impact of MBCT. This increased accessibility is a crucial advancement in mental health care, where access to quality treatment can often be limited.

In addition, the use of VR technology for delivering MBCT is an innovative shift in clinical practice. It represents a fusion of traditional therapeutic methods with cutting-edge technology, opening up new possibilities for treatment delivery. This integration not only enhances the appeal and engagement of the therapy but also has the potential to increase its effectiveness by providing a more engaging and personalised therapeutic experience. Image 2 provides an example of the very high quality, realistic virtual world Tend created.

Importantly, Tend’s VR version of MBCT is rooted in evidence-based practice. Our commitment to maintaining the therapeutic integrity and efficacy of traditional MBCT, while adapting it to a VR format, is critical. Through rigorous testing and research, we ensure that the VR version upholds the standards of traditional MBCT, thus maintaining its credibility and effectiveness in the mental health field.

To create this innovative approach, we faced several distinct challenges and had to expand and build our team to address all the areas required to move this idea from the concept stage to a viable product ready to go to market.

**Image 2: An example of the Tend virtual world**



<b>Technological innovations</b>		
Innovation	Success factors	Challenges
Development of the technical requirements needed to build the virtual reality environment that best delivers an effective MBCT course without practitioner input.	Our technical team worked efficiently and intelligently to create the most optimal, realistic and efficient VR environment for the 8-week MBCT course to ensure that the environments were sensitive to the subjective qualities required for effective learning, as well as to encourage adherence to the course. See Image 2 above.	We had to ensure that we could make iterative improvements to the entire system rather than to individual sections of the app. We found it necessary to think through how to implement a new technological aspect into our software by incorporating a new user interface (UI) system.

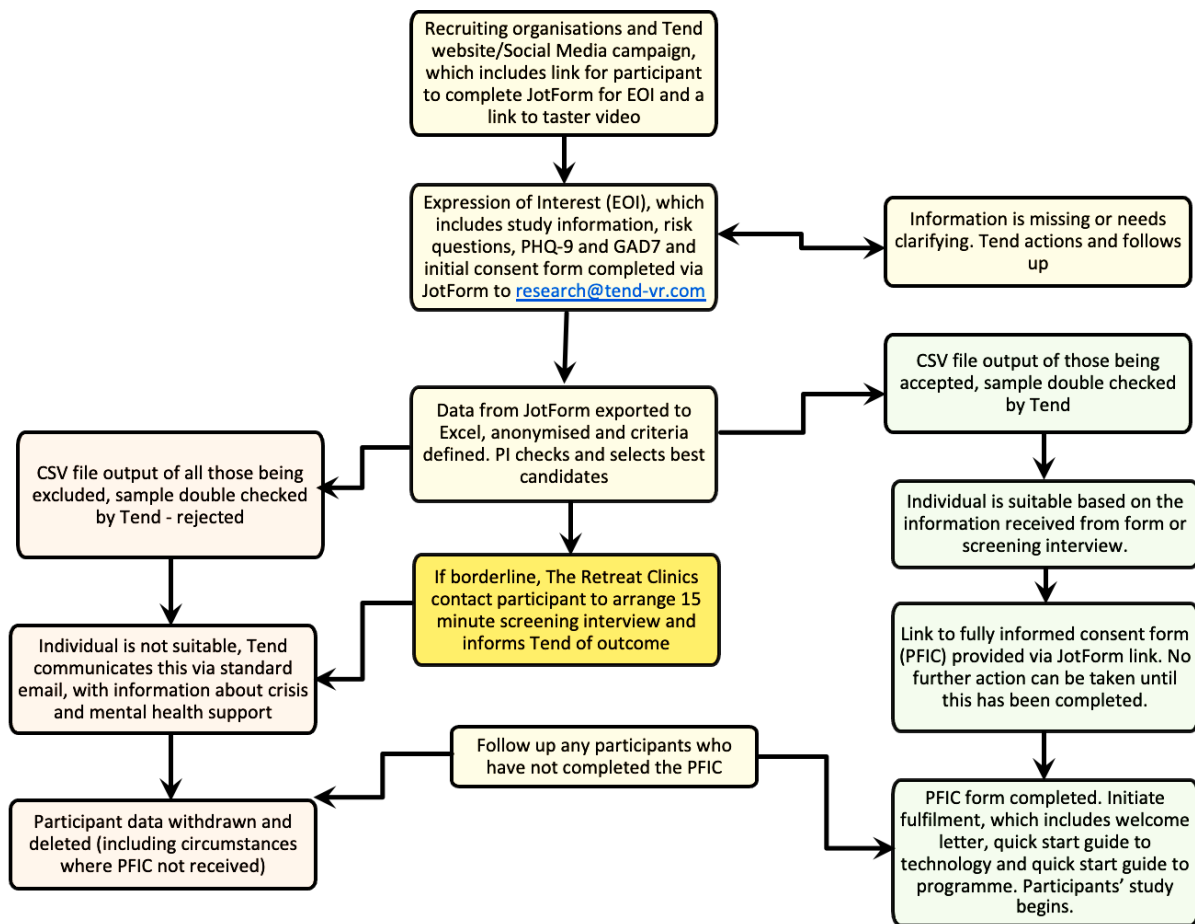
<b>Mental health and wellbeing innovations</b>		
Innovation	Success factors	Challenges
Creation of a virtual-reality, practitioner-independent version of mindfulness-based cognitive therapy (VR MBCT).	This pioneering step of transposing MBCT into a VR format represents a significant leap forward for addressing many of the problems currently facing most countries trying to find better (and more feasible) ways to address the ever-growing mental health crisis, as well as for providing for individuals suffering with depression and/or anxiety an easily accessible, rapid and effective treatment. It also adds an immersive dimension to MBCT that appears to enhance its efficacy and engagement levels. Unlike traditional settings, VR allows users to experience mindfulness practices in a fully immersive and controlled environment. This can be particularly beneficial for individuals dealing with anxiety and depression, as it provides a safe space to practise mindfulness and cognitive strategies without the overwhelming stimuli of the real world.	The transformation to what is usually a group-based, practitioner-delivered mental health intervention into a self-led, VR immersive environment methodology was challenging. It has taken many years of trial and error, the input of large numbers of experts and proof of concept trials has been challenging. Trying to ensure the skills development central to the success of MBCT translates into a VR world that can be self-driven has not been simple, but our trials thus far show how successful it has been.



<b>Participant-focused innovations</b>		
<b>Innovation</b>	<b>Success factors</b>	<b>Challenges</b>
Use of expert feedback to assure excellence in course content	We received feedback and guidance from our academic advisor Professor Becky Gould (UCL), who has considerable expertise in MBCT and a particular interest in virtual reality, as well as from our principal investigator Dr Kim Bevan OBE, who has over 20 years of experience delivering mental health services.	Ensuring practitioners and experts were satisfied with the virtual course was essential but it did mean many iterations and significant re-recording for some elements of the course to ensure it was consistent with the non-virtual course.
Ethics and participant welfare as a golden thread	Dr Bevan's significant expertise in governance, safeguarding, information security and regulatory frameworks made her ideally placed to guide us on these aspects of our trial design.	Navigating these challenges required a careful and empathetic approach, balancing the need for a robust and representative sample while considering the unique ethical and practical considerations of mental health research.
Recruitment methods and general study methodology	<p>After successfully navigating the development of the VR MBCT course, we started the recruitment process using social media platforms. We created an explanatory video (see <a href="#">Tend VR 2023 Study - YouTube</a>) and announced the exciting news on LinkedIn, resulting in almost 10k views and nearly 100 reposts of our initial post.</p> <p>Each potential participant was asked to complete an online form for the Expression of Interest (EOI), the link for which was provided in the recruitment advert. We also received assistance with spreading the word regarding our recruitment from various partners and groups in our network, most notably New Horizons, a mental health charity in Wales, which we had identified as a critical region of great need but limited resources regarding the mental health profile in that part of the UK.</p>	We expected that recruiting sufficient numbers of participants to fulfil the demands of the study methodology would be challenging and take a great deal of effort and networking. This did turn out to be the case but recruitment happened faster than we initially expected, with 45 suitable participants, who met the inclusion criteria, being recruited for the CIRCE study within 4 weeks of the first advert being published.

	<p>Of the participants recruited, a proportion were of low socioeconomic status, mainly drawn from the Welsh Valleys population. According to the <a href="#">Public Health Network Cymru (2023)</a>, Wales has the highest sickness absence rate of any UK region (Wales 2.8% vs UK average of 2.2%), the majority of which is attributed to mental health issues. Moreover, the Welsh Valleys area generally underperforms as a whole across a range of economic indicators, with subsequent impacts on mental health. <a href="#">Mind Cymru's report 'Too Long to Wait' (2021)</a> suggests that people in Wales, despite great need, struggle to access mental health support, face a lack of choice and wait too long, sometimes more than two years. Working with people in the Welsh Valleys through the CIRCE study enabled exploration of the effectiveness of VR-based MBCT for this population and possibly offer potential solutions to some of the issues facing the Welsh Government's mental health strategies.</p>	
<p>Inclusion and exclusion criteria as an aid to recruitment of suitable candidates</p>	<p>Inclusion and exclusion criteria were evaluated using the EOI responses and a screening interview if needed. For a score of 19 on the PHQ-9 and/or a score of 15 on the GAD-7 at recruitment stage, a phone call and screening interview with a clinical professional from The Retreat Clinics could be arranged to determine whether the person could be included in the study. Scores above 19 on the PHQ-9 were not included in the study.</p>	<p>We expected that we'd need to screen a large number of participants to ensure we recruited the numbers we needed. However, during recruitment we realised that we did not need to screen any participants because sufficient numbers of people expressed an interest for us to apply our strict cut-off criteria without needing to consider scorers on the borderline of acceptability. However, for future, larger studies we are aware that screening may be necessary.</p>

**Figure 1: Recruitment process flowchart**



Partnerships		
Innovation	Success factors	Challenges
Clinical partnership with a well-established therapy providers - The Retreat Clinics	The Retreat Clinics and Tend-VR worked very closely together to create a safe trial and ensure the safety and wellbeing of participants.	The turnaround time for the joint development of the documentation and procedures necessary for good clinical governance was challenging but worthwhile.
University College London	Professor Gould worked closely with the PI for Tend to jointly produce the study protocol, ensuring academic rigour in addition to sound clinical governance.	Securing a suitable academic partner was challenging. We were seeking a high profile academic who also had training in MBCT and a clinical background, which we knew was a lot to ask. However, Professor Gould and UCL were the perfect fit.

## The study details

### 1. Objectives

For our trial, our primary objective was to investigate the question “How feasible and acceptable is a VR-based MBCT course for people experiencing self-reported symptoms of anxiety and depression?” We defined feasibility as the number of participants who are retained to completion of the programme and who complete the outcomes measures. Acceptability was defined as the level of engagement, sustainability and satisfaction experienced by participants, which is measured by the questionnaires, as well as the end-of-study interviews for a subset of participants. We chose to collect PHQ-9 depression scores and GAD-7 anxiety scores at pre-study, mid-study and end-of-study time points; SMQ Mindfulness scores and WEMWBS Mental Well-being scores at pre-study and end-of-study time points, and perform post-study interviews with a randomised selection of participants.

Our secondary objectives were to:

- Use outcome measures to evaluate and monitor the effectiveness of the VR-based MBCT programme via analysis of user data from headsets and outcomes from end of study interviews, as well as the variables to be considered, at timepoints before, during and post-study.
- Clarify key study design parameters for a future RCT via analysis of user data from headsets and outcomes from end of study interviews, as well as the variables to be considered at before, during and post-study timepoints.
- Monitor the engagement, sustainability, experiences and retention levels of participants via analysis of user data from headsets and outcomes from end of study interviews at before, during and post-study timepoints.

### 2. Methodology

Core aspects of traditional MBCT practice were selected using a combination of literature review, technical capability testing and the outcomes from the proof-of-concept study to provide a full VR-based MBCT programme. The programme can be 8-12 weeks in duration (depending on the participant), with approximately 8 hours of direct teaching via the VR headset. The use of the VR headset was distributed over 5-7 days per week for approximately 20 minutes per session, depending on the engagement of the user. Users were also encouraged to practise the skills they developed as they went through the programme outside of the use of the VR headset. All data collection will be completed by 31<sup>st</sup> January 2024, including the post-study interviews and surveys.

Within the programme structure, key elements of MBCT practice such as breath work, body scans and awareness of automatic thinking were maintained. In addition, practical and game-like elements were introduced to make the most of the VR environment and increase the likelihood of sustained engagement and interest. In live (traditional nonVR) MBCT, participants are frequently asked to use their imagination to picture aspects such as bringing awareness to an object, which some people find very difficult. Within the VR environment this is helped and supported by imagery and practical exercises.

We chose to take a mixed methods approach combining quantitative outcome scales with qualitative interview at the end of the programme to review participants' engagement with the VR headset specifically. This method allows for comparison of outcomes measures for indication of efficacy whilst also allowing exploration of users' experiences with the VR platform and future factors for comparative research.

The VR headsets (Meta Quest 2) were delivered by post to the homes of participants in the study, meaning that the study was not carried out in a homogenous "laboratory-like" setting, but does reflect how the headsets will be used in real-life situations.

## **2.1. Participation**

The VR-based MBCT programme is 8 weeks in duration; however, participants were engaged in the study for approximately 12-16 weeks, including pre-study screening measures, initiation and post-course follow up, which involved gathering outcome measures, interview and survey data. The actual number of weeks participants engaged depended on the individual, influenced by a number of factors including motivation, life events during the trial and ease of use of the headsets. Data were collected predominantly via anonymised and GDPR compliant online forms.

## **2.2. Screening and initial risk evaluation**

The EOI form asked for a wide range of information from each potential participant, including risk questions and an initial consent form. Each participant needed to satisfy all of the inclusion and exclusion criteria. If any risk was indicated, then a screening interview could be carried out by The Retreat Clinics, to determine whether to reject the candidate participant. In practice, these interviews were not required because sufficient numbers of people expressed an interest allowing the PI to recruit only those participants who were not scoring on the borderline of acceptability.

Potential participants deemed not to fit the study criteria via the EOI form were informed via email in a sensitive and appropriate manner, including signposting to mental health and crisis support sources and resources.

By contrast, potential participants who met all the criteria and who were not considered to be at risk were accepted onto the trial. They were sent a link to an online version of the detailed Participant Fully Informed Consent Form (PFIC) and were sent the full Participant Information Pack via email. Both of these are available on request.

## **2.3. Fully informed consent**

The Participant Information Pack (PIP) and the Participant Fully Informed Consent Form (PFIC) provided participants with all the information they required in order to make a fully informed consent. Participants were also offered an option to contact either Tend-VR for any clarification or The Retreat Clinics for any more clinically-based queries. In addition to the electronic sources of information, participants received support materials within the posted headset box, such as an onboarding letter to welcome the participants, a notebook and pen and a contact sheet providing key contact details for members of Tend-VR and The Retreat Clinics.

The welfare of the participant was the golden thread running through the study and all of the organisations and individuals involved were required to read and approve our study protocol.

## 2.4. Baseline measures

To establish their starting point in terms of mental health and wellbeing, participants were asked to complete two pre-acceptance measures, two further measures once accepted and one qualitative interview was available if risk was indicated:-

- PHQ-9 – this is the Patient Health Questionnaire-9, a multipurpose instrument for screening, diagnosing, monitoring and measuring the severity of depression.
- GAD-7 – this is the Generalised Anxiety Disorder 7 questionnaire, used as a screening tool and severity measure for generalised anxiety disorder.
- WEMWBS – this is the Warwick-Edinburgh Mental Wellbeing Scale which measures mental wellbeing in the general population using a 14-item scale.
- SMQ – this is the Southampton Mindfulness Questionnaire, The Southampton Mindfulness questionnaire (SMQ) is a 16-item scale, one of the available instruments to assess mindfulness and has been described as particularly suited for clinical populations. The 16 items are scored on a 7-point Likert scale, worded 'strongly disagree' (0) to 'strongly agree' (6), yielding a total range of 0–96. Eight items are framed positively, eight negatively. It was used in this study to measure any increases in mindfulness that occur by the end of the study.
- Screening interview: This was to be used only if there were any risks identified pre-acceptance, when the participant has completed the PHQ-9 and the GAD-7, or if any of the initial information received from the participant suggests risk. This was not necessary for reasons outlined above.

## 2.5. Participants' welfare and monitoring

**Mid-study:** Participants were sent a link to an online form to complete the PHQ-9 and the GAD-7 to check on progress. These measures were scored and evaluated by Tend's PI Dr Kim Bevan, and any participants showing signs of a significant decrease in their mental health were given a follow-up phone call by The Retreat Clinics to check in with the participant and signpost them to further sources of support. In total, four participants were followed up by The Retreat Clinics. All these participants were interviewed and deemed to not be at risk and all wished to continue with the study, stating that the VR MBCT was proving to be helpful to them.

**During the study:** Each week participants were asked to complete a handwritten journal for reflection (included in the headset pack) that they could share back with the study team should they wish to do so.

**End of study:** We are in the process of collecting the final outcomes data and will analyse this as soon as we have collected it from all participants who have completed (or almost completed) the course. The bulk of the intervention element of the course occurs in the first 4-5 weeks, which means that all participants who have reached that stage will be considered as having completed the study.

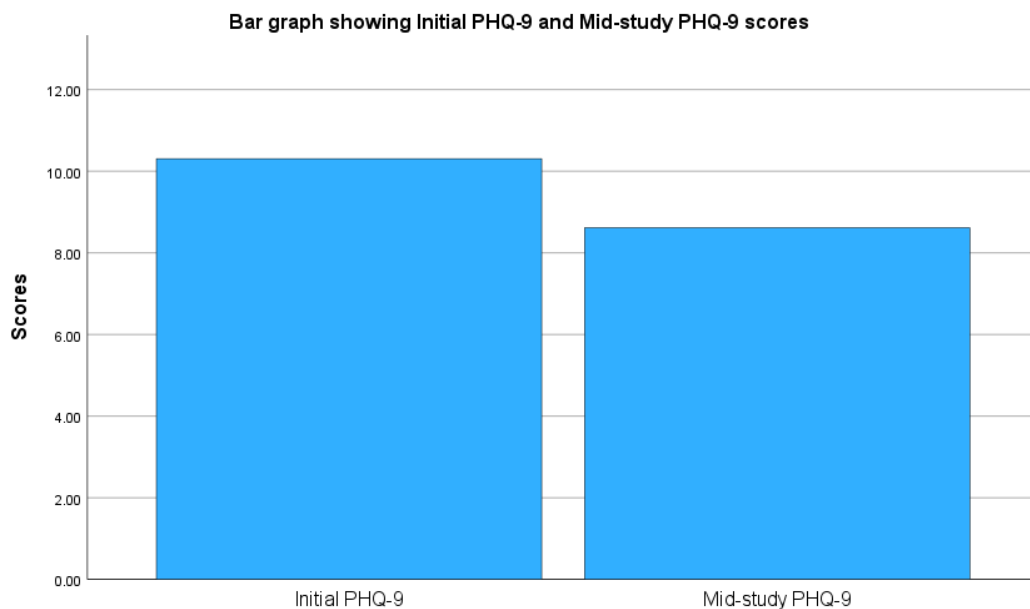
### 3. Impact

During the course of our CIRCE-funded research, we have confirmed and improved on earlier findings from Tend-VR's previous study that our MBCT VR course has the potential to provide a rapid and scalable treatment for the many people suffering from depression and anxiety. It significantly reduces the need for a facilitating practitioner (a major current bottleneck), as well as providing a non drug-based alternative to treatments for depression and anxiety. Initial outcomes in relation to our secondary objectives suggest it is an effective and appropriate intervention for people with mild to moderate depression and/or anxiety.

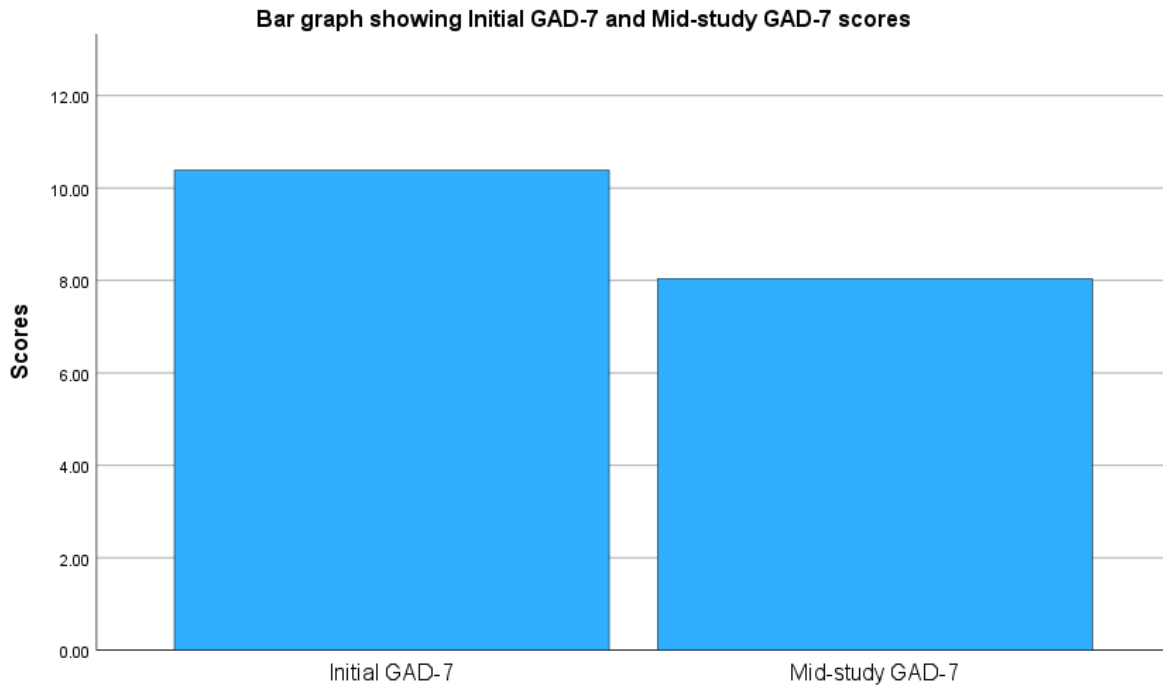
Tend-VR's MBCT course can be completed at home at whatever time is convenient to the user, and at a lower cost than traditional MBCT courses. Most importantly, our VR MBCT course equips users with new tools and strategies for navigating life more effectively, all in a calming virtual environment. The support from CIRCE has been vital, enabling us to make a significant impact on the mental health of trial participants and providing a rich source of feedback to help direct our improvement and further develop the course, its delivery and the underlying technology. We are confident that this is just the initial step in revolutionising the treatment of depression and anxiety through VR.

#### 3.1. Quantitative data

We gathered data from our participants at the start and mid-way through the study. Findings indicate that there has been a decrease in both PHQ-9 depression (see graph 1) and GAD-7 anxiety (see graph 2) scores. These results mirror those from our initial pilot study, and we are expecting similar significant reductions in both PHQ-9 and GAD-7 in the final scores, as well as improvement in wellbeing and mindfulness skills as measured by the WEMWBS and SMQ.



Graph 1: Bar graph showing a reduction in **mean** PHQ-9 depression scores (n=26 - responses as of Dec 6, 2023)



Graph 2: Bar graph showing a reduction in **mean** GAD-7 anxiety scores

Overall, at the midpoint of the study:-

- Improvements in PHQ-9 and GAD-7 were shown by almost 70% of participants on the trial, with participants who had the highest PHQ-9 and GAD-7 scores showing the most dramatic improvements
- When asked the question 'How likely is it that you would recommend Tend VR MBCT to friends and family, on a scale of 1-5' 85% of people would recommend Tend to friends and family
- When asked the question 'How positive has your experience been of using Tend VR MBCT on a scale of 1-5?' 83% of participants had a positive experience of Tend VR MBCT.

### 3.2. Qualitative data

Quantitative data is highly valuable in demonstrating trends, but is limited in the sense that it provides information as a snapshot at different timepoints, e.g. of how a person is feeling on that particular day. Qualitative data provides a richer source of information about how participants experience the intervention. This is demonstrated by (unsolicited) feedback received from a participant in our 2021-22 pilot study. They wanted to express how Tend-VR had helped them overcome depression, gain valuable tools to manage anxiety levels and how repeating the course multiple times helped them to positively transform their life. Receiving such feedback had a positive impact on the whole team and underlines the importance of the collection of qualitative data from our participants. We have already received very positive feedback from our participants in the CIRCE study, when collecting mid-point measures and at other points over the last few months:



## Comments from participants

*I am very much enjoying using Tend. I really think I will miss it at the end of the course. It feels very different to sitting doing an online course, or reading a book.. or even being with a therapist in person. I have found being immersed in, what feels like, your own little private retreat an actual treat, and I look forward to my sessions. I am currently waiting on ADHD diagnosis and am finding that having something to look at or interact with during the sessions (such as the ball for breathing, or the mannequin for the body scan) a real help to keep me focused. I do struggle to with the body scan without it! I have tried audio-only mindfulness apps and really struggled to sit and listen to them without drifting off or getting bored. I was busy this past week and found it difficult to find the time to do Tend daily. I noticed a difference in how I felt that week and I feel that doing Tend regularly long term could be the key for some people (especially me!). I have been trying to remember to do the exercises outside of Tend also, which I am finding easier, having practised within the VR first. I would recommend Tend to anyone and everyone I meet if I could!"*

*People have said that I'm really different now. One of my friends said 'you're so different, you're more open' I feel like I've got myself back a little bit*

*...really been enjoying the sessions. I found myself feeling very relaxed while in the VR and also afterwards and I feel like my mood has improved.*

*I'm really enjoying the experience and actually find that I would want to continue to use this on an on-going basis...*

*I felt really anxious one day so went home and did about 40 minutes on Tend. It really helped centre my thoughts and I was able to approach the situation in a calm and centred manner.*

*...really enjoying the sessions and finding myself looking forward to them now!*

*the software is really immersive and it makes meditation possible for me who often struggle to relax.*

*...I just wanted to send a short email to say how much I am loving the Tend course so far! I've just finished week 6, and I have really been noticing a difference in my anxiety levels, self-awareness and confidence in dealing with more difficult situations, as well as giving myself more grace and understanding on the days when I don't manage things so well. I'm really really grateful to have had the opportunity to join the Tend study, and I just wanted to let you all know that, at least for me, this has been a very positive experience so far.*

*I think this is \*absolutely brilliant\* and wish I could spend all day feeding the fish.*

*I'm really enjoying the whole virtual experience. I've tried many different versions of mindfulness and CBT over the years and this has been the most positive by far. I love the immersive aspect which really helps me to focus and escape from all my everyday stuff and am definitely feeling the benefit. I love being able to transport myself to this beautiful place to watch sunsets, rainstorms and just to sit by the lake or by the roaring fire. I don't want it to end! Many thanks for the opportunity to experience this fantastic study.*

We will be asking all individuals who have taken the time to give us their positive feedback if they would be willing to become involved with Tend-VR as advocates of our MBCT course and to serve as an Expert by Experience for us in current and future projects. Initial exploration of this with some participants suggest the response to this would be very positive.

### **3.3. Impact through social media**

With our LinkedIn post and video during the recruitment phase, we were able to provide an insight into trial participation and we achieved nearly 10k views and 100 reposts. As a testament to this, we had more than double the number of applicants compared to eventual participants, which meant that it was not necessary to recruit and screen applicants who did not meet our strict criteria for the study.

### **3.4. Impact of work internally on our team**

Our team consists of dedicated individuals from various fields and backgrounds, including technology, scientific research and the creative industry. For many in the team, undertaking this project alongside our other business activities has highlighted the enormous physical and mental demands on startup teams, and thus the importance of taking time to maintain our health even when there appears to be limited time to do so. We are fortunate that our innovation aids mental health, and so our team members have ready access to a tool to support them in this regard.

The primary motivator for our team is the profound impact observed in trial participants, many of whom experience considerable improvements in their mental health. As evidenced in the pilot study, some individuals perceive their interaction with Tend-VR as transformative, with spontaneous testimonies from participants affirming this impact. The capability to effect substantial positive change in individuals' lives serves as a significant inspiration. Amidst the challenges and stresses inherent in executing a multifaceted project like Tend, remembering the positive impact on participants is a significant boost to morale.

Upon securing funding, our team, initially comprising a modest number of team members with many working freelance or part-time, recognised the need to rapidly adapt to capitalise on this exceptional chance, mindful of the complex and time-intensive nature of organising and conducting clinical trials. Subsequently, we augmented our team with freelance specialists possessing extensive experience in their respective fields, thus maintaining lower operational costs. Additionally, we opted to forego a physical office to further reduce expenses.

The plus sides of this model were that we could run a company that was lean and with great flexibility. The downside is that it is harder to manage the multiple complex components and logistics at crunch times. CIRCE invited us to help run a BarCamp at the San Sebastián summer gathering related to this theme, which we took full advantage of to explore different models for start up team structures. We found that preparing for that session proved rich food for thought and led to our revising our view of how to grow our productivity and efficiency without incurring huge costs (which we dubbed 'the Octopus model').

The BarCamp encouraged others to take a similar creative journey by asking them to draw their current organisational structures and to draw their ideal team arrangement. Many insights

were generated, as well as the joy that often accompanies free-form creative efforts in the midst of solution-focused, time-pressured startup minds.

## **4. Extending our reach to the rest of Europe**

We have initiated conversations with various academics across Europe, with two main researchers showing high interest in future collaborations, including Dr Maria Ruzafa Martinez from the University of Murcia in Spain and Dr Pawel Holas from the University of Warsaw in Poland. To ensure the accessibility of our content, we believe that it is crucial for Tend to be available in languages other than English. We have, therefore, commenced the translation drafts of our script into Romanian, German and Spanish.

## **5. Learning**

Through unwavering dedication and long hours from the whole team, we were able to successfully optimise and deploy Tend-VR's 8-week MBCT course to 45 volunteer participants across the UK and to prepare ourselves for the pre-launch phase. We learned a great deal along the way, including how we might optimise our processes in the future.

### **5.1. Technical/Development phase**

We faced a number of challenges in the process of building the latest iteration of Tend-VR MBCT and readying it for trial. The biggest challenge was that the version of the platform prepared for the pilot study required considerable work from the development team to rewrite a large amount of the core code – this is common for early iterations of software so as to improve them holistically.

We encountered various other technical issues, including unexpected rendering issues and the necessity for computers to be completely reinstalled. The decision to incorporate new plugins toward the project's end resulted in significant complications.

Additionally, in the first few weeks of the trial, we faced issues with one of our external suppliers, responsible for the dashboard which displays the Tend App for users to click on for launching the programme. This was extremely frustrating, as we were reliant on a third party to fix it, which underscored the fact that there are certain aspects of the project that will be out of our control in terms of issues with the headset itself or non-Tend software. In future we will likely use the now available Meta MDM (mobile device management) software which should be more reliable.

### **5.2. Trial launch**

As we reached the end of the development phase and sent out headsets to our trial participants, we performed a 'cold debrief' with our team where we asked team members to give their impressions of how well our project pathway went and what we could learn from it. This important process highlighted three key issues:

- We realised that we had let the technical timeline for development of the product drive the overall project timeline. This underlined the need for a better project management system,

which would aim at estimating appropriate timings for tasks, helping to guide each team member towards successfully completing their goals.

- We acknowledged how demanding the fulfilment process was in terms of sending out headsets. Each headset required an upload of the software, testing and setup (a very significant time drain, which often presented technical problems), packaging with all the necessary printed information and arranging pickup and tracking by the delivery company. This was a huge amount of work and success was achieved only with unwavering dedication and late nights from team members. Our learning from this is the necessity of outsourcing this activity for future trials and sales. Now that we are revisiting this part of the business, we are actively exploring different models for headset deployment and different payment models.
- During our discussion, we also identified that different members of the team respond differently to work pressures such as deadlines and unforeseen problems, so this has forced us to consider how we want to deal with this as a company in the mental health arena. As a result, we realised looking after team mental health was just as important as for our users, so we've made a start on drafting a company charter which has mental health support at its core.

### **5.3. Recruitment**

As mentioned previously, we encountered challenges when extending trial invitations to individuals who met our stringent eligibility criteria. Specifically, we found that individuals who were presently engaged in therapeutic interventions or exhibited more pronounced symptoms of anxiety and depression, as determined through the PHQ-9 and GAD-7 assessments integrated into our Expression of Interest questionnaire, were excluded from participation. Despite our initial pool of over 50 eligible participants, we faced the issue of some participants failing to return their Fully Informed Consent Form (PFIC) in a timely manner. Consequently, these individuals were omitted from the study, resulting in the distribution of VR headsets to 45 participants.

This experience has highlighted the critical importance of allocating an extended duration to the recruitment phase in future trials. It became evident that providing additional time is imperative for several reasons. Firstly, it enables us to recruit participants who align more closely with our specified parameters for the study. Secondly, it allows sufficient time for the procurement of their informed consent, ensuring that all participants are fully aware of the study's details and implications before committing. Lastly, and equally importantly, it ensures that our recruitment efforts result in an ample surplus of participants. This surplus is vital as it accommodates those individuals who may not promptly communicate their consent to participate or encounter unforeseen delays in the consent process.

In conclusion, our experience has illuminated the necessity of an extended recruitment phase in our future trials. This proactive approach not only enhances the quality and inclusivity of our research but also safeguards against any potential setbacks arising from delays in participant consent.

#### **5.4. Trial communications**

In the course of our research and development efforts, we have identified a notable challenge pertaining to our capacity to issue personalised and timely communications to participants during the data collection phase. This encompasses a range of interactions, such as inquiring about their experiences with the VR headset or addressing periods of inactivity, for example, if a participant has not engaged with the headset for a duration of two weeks. The emergence of this challenge has led us to critically evaluate and explore potential strategies for enhancing our engagement with participants and users. Our objective is to cultivate a consistent and effective usage of the virtual reality headset, thereby maximising the therapeutic benefits of the MBCT 8-week course.

A particularly promising approach that we are currently deliberating involves the creation of a bespoke mobile application. This application would be readily available for download on participants' smartphones. The primary function of this app would be to foster better adherence to the therapeutic regimen. It would serve as a virtual companion to the participants, offering comprehensive guidance on how to optimally utilise the course materials and the VR headset. Moreover, the app would feature a system of tailored reminders and notifications, designed to motivate and remind users to regularly engage with the MBCT course. These reminders could be customised according to the individual's usage patterns and preferences, thereby providing a more personalised and user-centric experience.

In essence, this mobile application would not only act as a tool for instruction and reminders but also as a means of maintaining a continuous and interactive connection between the user and the therapeutic program. By leveraging the convenience and ubiquity of smartphones, we aim to bridge any gaps in communication and engagement, thus ensuring that participants remain actively involved and committed to their mental health journey through the MBCT 8-week course. This approach aligns with our broader mission of employing innovative and accessible technology to enhance mental health care and ensure that effective treatment options are available to a wider population.

#### **5.5. Learning to inform the future beyond our CIRCE study**

Delivering our research project with CIRCE, with highly limited resources, both in terms of staff and finance, is a challenge that resonates deeply with the typical startup experience. It requires high-performing team members coordinating on difficult tasks to complete novel tasks in short timeframes and with minimal resources.

This challenge was further amplified as we endeavoured to sign up our first clients (a critical milestone for any emerging business), crafted our go to market strategy, developed minimum service level requirements essential for attracting and retaining clients, engaged investors and stakeholders, all whilst simultaneously delivering a clinically and therapeutically useful innovative digital health product in a trial for 45 people.

Exploring collaborative opportunities with established organisations also took up significant resources and managing these relationships alongside internal projects and external commitments adds another layer of complexity to our operations.

Learning how to prioritise tasks is an ongoing challenge in this dynamic environment. In a startup, every task seems critical, and the ability to discern which tasks will drive the most value is a skill that develops over time. It involves understanding the interplay between various business functions and recognising the impact of each task on our overall objectives.

These challenges are emblematic of the startup journey. They require a blend of strategic foresight, operational agility, and the ability to continuously learn and adapt. Each task, whether it's market strategy development, business planning, sales pipeline cultivation, or investor or partnership management, plays a crucial role in propelling our business forward. Navigating these challenges successfully is key to establishing a strong foundation for long-term success in the dynamic and competitive landscape of startups. However, the complexity of tasks, constant context switching and workload does not come without costs for core team members, with our mental health often being somewhat degraded by the process. We have considered adding a new module within Tend-VR MBCT targeted specifically at entrepreneurs from what we have learned on this journey.

## **5.6. Linking back to CIRCE**

With the constant support and encouragement from the CIRCE team, we successfully developed an 8-week VR MBCT course, deployed it, and delivered a trial to 45 participants. We would like to use this opportunity to thank profusely the team at CIRCE. We have never worked with such a kind, thoughtful, generous, helpful and knowledgeable group in this context before and are extraordinarily grateful for their time, expertise and commitment.

Attending CIRCE events was a crucial aspect in our journey to foster creative ideas and emphasised the significance of a collaborative model. We now have a true appreciation of the learning opportunities that can be gained from interactions between diverse groups. The variety of people attending, in terms of both their inherent diversity and their professional focus has generated some truly excellent ideas that we would not have come up with on our own.

We had the privilege of connecting with incredible individuals. For example, in September at the Fellow and Fund Convention in Berlin, the ideas from Natasha and Manik in particular concerning distribution models were very thought-provoking, and these have radically changed how we think about our core business model. In addition, we had some extremely insightful discussions with our mentors Alissa and Richy, which prompted us to look again at what we want to achieve with pre-order agreements/waitlists. Our team spans across the globe, with members contributing from the UK, Italy and the US. We consider this multi-cultural environment a key strength, enabling us to find innovative and creative solutions. Leveraging this strength, we are aiming to establish a resilient network across Europe and explore partnership opportunities in mainland Europe.

In conclusion, our journey with the CIRCE team has been nothing short of transformative. We extend our heartfelt thanks to the remarkable individuals at CIRCE for their unwavering support, kindness, and expertise throughout our collaboration. Their contributions have been invaluable in the successful development and deployment of our 8-week VR MBCT course, helping over 45 participants through a difficult time in their lives. Many of those lives will be irrevocably changed for the better, and we would like to thank CIRCE on their behalf for making that possible.

## **5.7. How insights speak to cultural and creative industries and made a creative impact**

Tend's work demonstrates how technological innovation, particularly the integration of Virtual Reality (VR) with Mindfulness-Based Cognitive Therapy (MBCT), has the potential to revolutionise audience engagement strategies in the cultural and creative industries. By employing VR to deliver MBCT, a technique traditionally limited to therapeutic settings, Tend demonstrates the potential of virtual environments to reach and engage audiences in unprecedented ways. This approach presents a compelling model for cultural industries to explore.

Moreover, Tend's integration of MBCT with VR technology underscores the synergistic relationship between art, science and technology. This convergence can lead to the creation of experiences in the cultural and creative industries that are not only aesthetically appealing but also grounded in scientific principles. Such a blend enhances the educational and experiential quality of creative content, making it both informative and emotionally resonant. It represents a new frontier in content development, where the aesthetic value of art combines with the empirical rigour of science to produce more impactful and meaningful experiences.

Additionally, the expected reductions in clinical depression and anxiety scores observed in Tend's study with CIRCE emphasise the importance of data-driven approaches in both mental health treatment and creative content development. In creative industries, leveraging data and research findings can lead to more informed and impactful content creation. This approach allows for content that is tailored to the diverse needs and preferences of audiences, ensuring that creative outputs are not only artistically valid but also resonate deeply on a personal and emotional level with their audience. This data-driven methodology in content creation could serve as a beacon for cultural and creative industries, guiding them towards more empathetic, inclusive, and effective audience engagement.



Image 3: Individual enjoying Tend during the CIRCE event in Berlin beginning of December 2023



Image 4: Sharing our innovation with the CIRCE group during the Berlin event beginning of December 2023 - a significant highlight during our time with CIRCE.



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