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SafeSpace: what is the feasibility and acceptability of a codesigned virtual reality intervention, incorporating compassionate mind training, to support people undergoing cancer treatment in a clinical setting?

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ABSTRACT

Objectives The SafeSpace study codesigned and tested a virtual reality (VR) intervention, incorporating relaxation and compassionate mind training to determine acceptability/feasibility in an oncology setting and evaluate impact on physical/psychological well-being and quality of life.

Design A two-phase study. Phase I determined key characteristics using an experienced-based codesign approach. Phase II evaluated the intervention using various measures and qualitative interviews in a mixed methods approach. Descriptive statistics were used to analyse measures data and framework analysis to analyse interviews.

Setting A specialist cancer centre, UK.

Participants 11 in phase I and 21 in phase II. Participants were in cancer treatment, recovery or palliative care.

Primary and secondary outcome Primary outcome: acceptability of the intervention, assessed by >60% uptake of three sessions. Secondary outcomes: impact on psychological well-being using EQ-5D/QLQ-C30, Profile of Mood Scale, Warwick and Edinburgh Mental Well-being Scale, Depression and Anxiety Severity Scale 21, Self-Compassion Scale, Acceptance and Action Questionnaire and a locally developed questionnaire to capture self-compassion post use. Physiological impact was assessed by change in heart rate (HR)/HR variability and electrodermal activity (EDA).

Results Twenty participants (mean age=48.7 years; SD=16.87); 65% (n=13) completed three sessions. Mental well-being improved following each use and from baseline to after session 3 (VR 1—z=2.846, p≤0.01; VR 2—z=2.501, p≤0.01; VR 3—z=2.492, p≤0.01). There was statistically significant difference in mean scores for EDA at mid-session and post session compared with pre session (F (1.658, 4.973)=13.364, p<0.05). There was statistically significant reduction in stress levels from baseline to post session 3. Participants found the intervention acceptable and highlighted areas for development.

Conclusion The intervention is acceptable and feasible and has shown positive effects on mental well-being/stress in the oncology setting. Larger studies are needed to confirm findings.

Strengths and limitations of this study

- This is the first study in an oncology setting exploring use of virtual reality to deliver a psychological support intervention.
- Acceptability and feasibility were tested in the oncology setting. Within the evaluation phase, the potential impact of the intervention on psychological, physiological well-being and quality of life was assessed.
- This is a mixed methods study: intervention developed using an experience-based codesign approach working with people affected by cancer, alongside qualitative techniques to capture experience of intervention use.
- The intervention consisted of three short sessions per participant. As compassionate mind training is relatively new and has had very limited use in cancer care, participants only received a small dose. This may have limited the overall effect of the intervention.
- This was an acceptability and feasibility project so sample size was small which limits the inferences that can be drawn from this study.

BACKGROUND

The number of people living with cancer is expected to double to four million over the next 20 years.[1] Treatment involves surgery, radiotherapy, chemotherapy or other, alone or in combination. Many treatments have unpleasant side effects and consequently

people may not adhere to recommended regimens.[2] People affected by cancer (PABC) commonly experience poor psychological well-being and poor quality of life (QoL).[3–5] Some become isolated from friends/family or are unable to continue working, causing financial difficulties and further isolation.[2] At least one in four people—around 500 000 people in the UK—face poor health or disability after treatment.[1]

Virtual reality (VR)

VR is the computer-generated simulation of a three-dimensional (3D) image or environment that can be interacted with, or explored, in a way that seems real, by an individual using 3D glasses, a headset with integrated screen, or gloves with integrated sensors. Healthcare has seen a growth in technologies such as VR to provide support.[6] Recently, it has become more affordable and seen a dramatic improvement in user experience.[7] It has previously been used in various applications including pain management, multiple sclerosis[8–10] and treatment of psychological conditions, such as phobias and anxiety.[11–13] Within cancer care, VR has been used to manage pain, anxiety and symptom distress. However, current literature regarding its effectiveness is equivocal. In a review of 19 studies,[14] of those which reported on pain (n=6), half found that VR had a statistically significant positive effect in patients with cancer. This was substantiated by other work[15] which reported decreased pain and state anxiety levels post VR use by women with severe/chronic pain following breast cancer treatment. In contrast, a recent meta-analysis of cancer-related symptom management[16] showed the only statistically significant effect was reduced fatigue levels. Other studies[17 18] using VR reported positive results as a distraction technique during chemotherapy administration. These were small samples (n=16 and n=20, respectively) of women with breast cancer. Subsequent studies of larger, more diverse cohorts reported significant impact on reducing perception of time when receiving chemotherapy, validating the distractive nature of VR.[19 20]

Compassion-focused therapy (CFT)

Compassion can be defined as 'the sensitivity to suffering in self and others, with a deep commitment to try to relieve it'. CFT is an integrated, multimodal treatment approach that draws from sociology, psychology and neuroscience.[21] Central to CFT is compassionate mind training (CMT) which was originally developed for people who find self-warmth and self-acceptance difficult.[22 23] It teaches the skill and practice of training the mind, by inviting people to develop their own images of warmth through practices such as slow and deeper breathing, compassionate voice tones, imagery and facial expressions,[24] and helps people develop self-compassion.[22] CMT can be delivered on a one-to-one or group basis.[23 25] Studies examining other psychological interventions such as cognitive behavioural therapy in a cancer population have shown favourable effects;[26] however, this requires specialist training, supervision and certification needs,[27] and appropriate training can be complex and costly.[28 29] CMT can be self-administered and once learnt, can be recalled in multiple environments including at home.[21] CFT and CMT have been shown to reduce suffering and improve QoL in a range of health problems such as anxiety/depression, eating disorders, phobias and pain management[30–33] and are becoming more mainstream and acceptable.[34 35]

While effectiveness is equivocal, the application of VR within cancer as a distraction technique is accepted. However, its use to deliver psychological therapies, such as CMT, remains unexplored. Little is known about how these treatment approaches might be combined, whether there is any synergistic effect and if such an intervention is acceptable and feasible in the clinical environment.

Aim

To codesign a VR intervention, incorporating CMT, and assess its acceptability and feasibility to support people undergoing cancer treatment in a clinical setting.

Primary outcome: acceptability of the intervention, assessed by >60% uptake of three sessions

Secondary outcomes: impact on psychological well-being using EQ-5D/QLQ-C30, Profile of Mood Scale (POMS), Warwick and Edinburgh Mental Well-being Scale (WEMWBS), Depression and Anxiety Severity Scale 21 (DASS21), Self-Compassion Scale (SCS), Acceptance and Action Questionnaire (AAQII) and a locally developed questionnaire to capture self-compassion post use. Physiological impact was assessed by change in heart rate (HR)/HR variability (HRV) and electrodermal activity (EDA).

METHODS

This was a two-phased study using an experience-based codesign (EBCD) approach in phase I and mixed methods in phase II. Due to the originality of the intervention, not previously implemented in this setting and population, this research is deemed an acceptability and feasibility study. EBCD is a method of participatory research that embeds experience of service users and staff into service design.[36] Phase I: development of the intervention by codesigning and refining several continuously improved prototypes with PABC. Intervention delivery and evaluation model were also established (please see online supplemental flowchart 1 for EBCD process). Phase II: formal acceptability/feasibility and evaluation of the intervention, with PABC, using the range of psychological, physiological and QoL measures agreed in phase I, and further explored through qualitative feedback obtained during follow-up interviews. Data were triangulated to strengthen the credibility of the acceptability and feasibility findings[37] (please see online supplemental flowchart 2 for data triangulation process).

Sample

A convenience sample was used to recruit participants to both phases of the study. Two separate groups of participants were recruited to either phase; phase I participants were no longer in treatment or follow-up; phase II participants were either receiving treatment or were in treatment follow-up.

Instruments for psychological assessment

Demographic data collected included age, gender, diagnosis, cancer group, cancer stage and aim of treatment.

The POMS

The POMS[38] examines six mood subscales: tension–anxiety, depression, anger–hostility, vigour, fatigue and confusion. Total mood disturbance score is computed by adding the five negative subscale scores and subtracting the vigour score. Higher total mood score indicates greater degree of mood disturbance.[39] The POMS subscales and total score have demonstrated sound internal consistency reliability ($\alpha \geq 0.84$).[40]

The WEMWBS

The WEMWBS[41] is a 14-item scale of mental well-being covering subjective well-being and psychological functioning. It is scored by summing responses to each item on a 1–5 Likert Scale. The minimum scale score is 14 and maximum is 70. It has been validated in the UK in ages 16+ years.[42] A non-validated, adapted version, AWEMWBS, was used immediately after each intervention use. The WEMWBS asks participants to describe their experience over the last 2 weeks. The adapted version asks the participant to describe how they are feeling immediately after the intervention.

The AAQII

The AAQII is a seven-item measure of psychological inflexibility or experiential avoidance. Items are scored on a Likert Scale of 1 (never true) to 7 (always true) and are summed up. Higher scores equal greater levels of psychological inflexibility, with proven reliability and validity.[43]

The SCS

The SCS[44] is a 26-item instrument that measures self-compassion through three hypothesised dimensions with their negative counterparts: self-kindness versus self-judgement, common humanity versus isolation and mindfulness versus overidentification, according to a five-point scale (1=almost never; 5=almost always). Subscale scores are computed by calculating the mean of subscale item responses. To compute the total score, the self-kindness, common humanity and mindfulness are summed with reverse scores of the self-judgement, isolation and overidentification subscales. Higher scores indicate greater self-compassion. In the original version, the total score showed excellent internal consistency ($\alpha=0.92$) and so did the six subscales (range: 0.75–0.81).[45]

The DASS-21

The DASS-21[46] is a 21-item instrument that assesses depression, anxiety and stress. Each seven-item scale has four responses ranging from 0 (did not apply to me at all) to 3 (applied to me much/most of the time). A higher score indicates higher levels of depression, anxiety and stress. The DASS-21 has excellent internal consistency[47] and construct validity.[47 48]

The EQ5D-3L

The EQ5D[49] is designed to measure generic health outcome and comprises two parts: the EQ5D-3L self-classifier, a self-reported description of health problems according to five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and the EQ-VAS, a self-rated health status using a visual analogue scale to record perception of current overall health; the scale is graduated from 0 (the worst imaginable health state) to 100 (the best imaginable state). It has been shown to be reliable and valid in cancer populations.[50]

The QLQ-C30

The QLQ-C30[51] is used to measure general aspects of HRQOL in patients with cancer. EORTC QLQ-C30, V.3, incorporates five functional scales on physical, role, cognitive, emotional and social functioning, three symptom scales on fatigue, pain and nausea and vomiting, single items assessing dyspnoea, insomnia, loss of appetite, constipation and diarrhoea, one item assessing perceived financial impact and global health status/QoL Scale (Global QoL). Each item is scored in one of the four categories: (1) 'Not at all', (2) 'A little', (3) 'Quite a bit' and (4) 'Very much', with the exception of 'Global QoL'. It has been shown to be reliable and valid in cancer populations.[52–54]

Locally developed questionnaire

The locally developed questionnaire specifically targeted self-compassion after intervention use. It comprised 12 questions such as: 'To what extent did the virtual reality help you have insight into your current situation?' and 'To what extent did the virtual reality make you feel encouraged about the future?' Scored using a 7-item Likert Scale ranging from not at all (1) to very much (7), the tool had excellent internal consistency ($\alpha=9.44$);[55] a higher score indicated that the intervention had a more positive impact.

Physiological assessment

Physiological assessment was made using HR, HRV and EDA.[56]

Procedure

Potential participants were identified by clinical teams, and a diverse convenience sample undergoing a range of cancer treatments across tumour types from one specialist centre recruited. Inclusion criteria were: (1) having a diagnosis of cancer; (2) age over 18 years and (3)

ability to provide written consent. Exclusion criteria were people: (1) considered too unwell and (2) in whom use of VR is not recommended, for example, registered blind, motion sickness,[57] seizure disorder or known psychiatric conditions such as schizophrenia or personality disorder.[58] Exclusion criteria were assessed by medical records, self-report and in consultation with clinical staff. All procedures were in accordance with the Declaration of Helsinki (1964) and later amendments or comparable ethical standards. Procedure included two phases with two different groups of participants; phase I aimed to inform development of the intervention through a series of workshops with patients with previous experience of cancer and treatment. Phase II involved the application and evaluation of the intervention in the clinical setting with patients currently in treatment or follow-up, to assess acceptability and feasibility through intervention uptake and user experience. The study was reviewed by a statistician; phase I is purely qualitative. Phase II statistical considerations are referred to in the descriptive statistics section.

Patient and public involvement (PPI)

PPI was sought, and we recruited two representatives to be the members of the study team who further informed the research question and study processes. Both had personal experience of cancer and treatment and previous experience of PPI work as part of a research study. By nature, the EBCD method involved patients in the intervention and evaluation design. The evaluation measures used were selected in collaboration with the patient participants who attended the evaluation workshop and their burden considered. PPI representatives were not directly involved in participant recruitment. A lay summary of results will be shared with participants via email.

RESULTS/FINDINGS

Phase I: intervention development

Eleven participants in total took part, please see online supplemental table 1. Five workshops, conducted over 6 months, were facilitated by a research team including experts in VR and CMT, using an EBCD approach. All were digitally recorded and, along with observations collected by two researchers, transcribed and analysed using thematic analysis.

Initial design workshop

Seven participants took part, which started with individuals telling their story, challenges along their pathway and what was important to include. Participants were able to try a range of equipment and experiences in a VR demonstration. They were encouraged to share, critique and propose ideas, using the design studio method.[59] Analysis of data identified a number of 'touch points', these being what was emotionally most important to participants, which were used to inform the first iteration of the intervention.

User-testing workshops

Three user-testing workshops took place in which three/four participants each were invited to try the subsequently developed prototype; a total of 11 participants took part in one or more. Participants were asked about their experience particularly focusing on quality and content of the intervention. Further 'touch points' informed the design of the next iteration, which was refined until the codesign team was satisfied that it had been developed to acceptable quality.

Findings from phase I

Over the course of the user-testing workshops, the intervention became more refined and focused on detail within, such as recognition of what constitutes a 'safe space', voice quality (eg, pace/tone) and guidance versus instruction. The themes that emerged which underpinned design of the final specification included: (1) being given permission to 'step out' of current situation; (2) importance of voice; (3) need for sign-posting/on-boarding information; (4) being able to explore and (5) being guided versus being instructed. The final iteration consisted of three short sessions of VR/CMT. VR 1 allowed participants to get used to being in a VR environment. VR 2 introduced a soothing breathing exercise, and VR 3 introduced a CMT self-compassion exercise. CMT language developed progressively with each use. A choice of three environments was given: a beach as a 360° video, and animated mountain and forest scenes. Professional voiceover actors provided a choice of female or male audio (table 1). It was agreed that the intervention should be offered at any stage of treatment and acknowledged that three sessions may not be sufficient to administer a meaningful 'dose' of CMT but would be enough to generate preliminary data.

Evaluation workshop

A final workshop was held with five participants, who had taken part in either design or testing, to establish an evaluation model. A range of demographic, psychological and physiological measures were reviewed and agreed to be

Table 1 Final intervention content

All sessions approximately 10 min long		
VR1	VR2	VR3
Choice of male or female voice	Choice of male or female voice	Choice of male or female voice
Choice of a VR beach, mountain or forest scene	Choice of a VR beach, mountain or forest scene	Choice of a VR beach, mountain or forest scene
Adapting to wearing VR headset and being in a VR environment	Simple soothing/breathing exercise, introduction to CMT	Simple CMT exercise

CMT, compassionate mind training; VR, virtual reality.

Table 2 Schedule for study procedure

Measure		Baseline	Pre each intervention	Post each intervention
Name/age/gender/dx/tx	Demographic information	X		
EQ-5D	HRQoL	X	X	
QLQ-C30	HRQoL	X		X
Acceptance and Action Questionnaire II	Psychological flexibility	X		
Depression and Anxiety Severity Scale 21	Anxiety/depression/stress	X		X
Profile of Mood Scale	Mood	X	X	X
Warwick and Edinburgh Mental Well-being Scale (WEMWBS)	Mental well-being	X	X	
Self-compassion Scale	Self-compassion	X		X
Adapted WEMWBS	Mental well-being immediate timepoint			X
Locally developed questionnaire	Self-compassion			X
Heart rate (HR)/HR variation/electrodermal activity	Physiological	Monitored continuously before, during and after intervention		

collected at baseline and pre and post each intervention use (see table 2). The final intervention was delivered on a head-mounted, stand-alone device; this was considered inexpensive and practical.

Phase II: evaluation/acceptability of intervention

The final intervention was evaluated and tested for acceptability/feasibility. A further 21 people were recruited. Four study visits were organised, coinciding with planned appointments, spaced at least a week apart. At initial visit, written consent was obtained and demographic data were collected. Participants completed the baseline set of questionnaires relating to psychological state and QoL. The study then proceeded as per table 2. Telephone interviews were conducted once the participant had completed intervention use.

Quantitative

Summary measures for participant characteristics, VR use data variables and questionnaire scores were presented as means and SD for continuous (approximate), normally distributed variables and frequencies. Categorical variables were reported as percentages. Shapiro-Wilk test was used to confirm normal distribution of continuous summary scales (all p values >0.05). Friedman's test for repeated measures was performed to assess whether there was a statistically significant difference in scores between baseline, VR1, VR2 and VR3. Wilcoxon signed ranks test was used to compare baseline and VR3 session scores. Analysis of variance (ANOVA) was performed to assess changes in EDA, HR and HRV within each session. All p values were two-sided throughout; significance was set at the 5% level. IBM SPSS V.25 was used to analyse the data. Missing data were addressed (see online supplemental table 2).

Participants

Overall, 7 males and 14 females consented to take part. One participant was subsequently lost to follow-up. Mean age was 48.7 years (SD=16.87; range: 22–77). Mean time elapsed since diagnosis was 37.08 months (SD=45.00; range: 2–149). Overall, 16 participants (80%) were in active treatment. They had various tumour types with gynaecological cancer being most common (N=4; 20%) (see table 3).

Acceptability/feasibility data

In total, 49 sessions of VR were delivered and completed. Acceptability of the intervention was deemed satisfactory as >60% (N=13; 65%) of participants completed all three sessions. This was agreed by discussion with the statistician, based on evidence which reported attrition levels between 16.9% and 26.0%[60] and reporting dropout rates

Table 3 Tumour types

Tumour type	N	%
Lower Gastrointestinal	2	10
Haematological	1	5
Gynaecological	4	20
Head and neck	3	15
Breast	3	15
Genitourinary	3	15
Other	4	20

Table 4 Acceptability and feasibility data

	VR1		VR2		VR3	
	n	%	n	%	n	%
No. that took part in VR	20	100	16	80	13	65
No. that did not take part in VR			4	20	7	35
Reasons for not completing VR						
Insufficient time			1	25	3	43
Deterioration in condition					1	14
Discontinuation of treatment at site			1	25	1	14
Adverse effect from VR					1	14
Unknown			2	50	1	14
Voice						
Male	12	60	8	50	6	46
Female	8	40	8	50	7	54
Chosen VR environment						
Beach	12	60	5	31	8	61
Mountain	6	30	8	50	5	39
Forest	2	10	3	19	0	0
Private room						
Yes	11	55	9	56	8	61
No	9	45	7	44	5	39
Did the participant change the environment while using VR?						
Yes	2	10	0	0	1	8
No	18	90	16	100	12	92
Did the participant experience external noise?						
Yes	9	45	6	37.5	5	38
No	11	55	10	62.5	8	62
Total time in VR (min)						
Mean	10.8		10.44		10.00	
SD	1.852		2.502		1.633	
Range	7–15		7–16		8–14	
Did the participant experience any problems with the equipment?						
No	12		13		12	
Yes	8		3		1	
Minor	5		0		1	
Additional intervention	2		3		0	
Unresolvable	1		0		0	
Did the participant experience an adverse event?						
Yes	1	5	2	12.5	0	0
No	19	95	14	87.5	13	100

VR, virtual reality.

of up to 41.4%.[61] In addition, dropout rates were reportedly lower among studies that did not include some form of between-session intervention which was the case in the current study.[60] Thus, 60% was deemed a safe option for acceptability purposes and further agreed within the evaluation workshop.

Reasons for not completing and further details are displayed in table 4.

Adverse events (AEs)

Three minor AEs were recorded by two participants who experienced mild nausea and dizziness while using the

intervention. In both, this resolved spontaneously. The third was in one of the same participants but occurred 48 hours after completing VR2. They reported nausea and dizziness for 48 hours resolving with bed rest. Considering this, they were advised not to undergo the third session.

Descriptive statistics

Descriptive statistics were computed for all questionnaire scores within respective domains and are presented as frequencies and standard deviations (see online supplemental table 3). Friedman and Wilcoxon signed ranks tests were performed to compare potential changes in variables between baseline and VR1, VR2 and VR3 sessions. Missing data for each variable are shown in online supplemental table 4. Two-sided 95% CIs for the exact percentage can be calculated with maximum±23% with a sample size of 20. The proposed sample size of 20 was chosen during the EBCD process mainly for pragmatic reasons and was determined by available resources. A sample size of between 24 and 50 has previously been recommended for pilot and feasibility studies.[62]

Multivariate analyses

Quality of life

There were no statistically significant changes in QoL in either the EQ5D-3L or the QLQ-C30 responses (see online supplemental table 5).

Psychological measures

Total mood scores (POMS) were compared pre- and post-intervention. There was a statistically significant increase in total scores after the first session (VR 1) (z=−2.136, p=0.03) suggesting there was an improvement in mood. There was improvement in scores post second session (VR2) but this was not statistically significant (see online supplemental table 6). Mental well-being (WEMWBS) scores showed statistically significant changes from pre- to post-VR session (VR 1—z=−2.846, p≤0.01; VR 2—z=−2.501, p≤0.01; VR 3—z=−2.492, p≤0.01). There was a consistent beneficial effect maintained throughout all sessions and a statistically significant increase in WEMWBS scores from baseline to VR 3 (x^2=12.905, df=3, p=0.005) (see online supplemental tables 5 and 6).

There was a statistically significant reduction in stress levels as measured by the DASS21 from baseline to post session 3 (z=−2.138, p=0.03) (see online supplemental table 6). While there was a positive and beneficial trend from baseline to post session 3 (VR3) in most of the sub scores, none reached statistical significance (see online supplemental tables 5 and 6).

Physiological measures

ANOVA was conducted to compare EDA, HR and HRV within each session. A decrease in mean EDA for each of the three sessions was recorded, dropping from pre-intervention level and maintained following removal of headset; this was significant for the first session. Using ANOVA with repeated measures and a Greenhouse-Geisser correction, mean scores for EDA were statistically significantly different at mid-session and post-session compared with pre-session levels (F(1.658, 4.973)=13.364, p<0.05). Similarly, the only statistically significant change in HR was in the second session with a decrease from pre-session to mid-session followed by a return to pre-session levels at post-session (F(1.424, 4.271)=13.364, p<0.05) (see online supplemental table 6A,B). No change was observed in HRV.

Table 5 Demographic information of interview participants

Age	Gender	Diagnosis
Mean=55.5 years	Female: n=6, 55%	Urology: n=3, 27.3%
Range: 24–77 years	Male: n=5, 45%	Gynaecology: n=3, 27.3%
		Sarcoma: n=2, 18.1%
		Bowel: n=1, 9.1%
		Lung: n=1, 9.1%
		Other: n=1, 9.1%

Qualitative findings

As an acceptability/feasibility study, qualitative feedback was sought to support quantitative results and gather the reality of the intervention use in a real-world setting.[63] Participants were invited to a semi-structured telephone interview to acquire a deeper understanding of their experience; 11 participants consented. Demographic data are shown in table 5. Interviews were audio recorded and transcribed. Feedback was also given following each individual use of the intervention; this was summarised and recorded manually by the researcher and analysed alongside interview data using framework analysis.[64] The framework was informed by analysis of the first two transcripts which were coded independently by three researchers and themes discussed and agreed. The subsequent interview transcripts and participant comments were analysed using the agreed framework. Three themes emerged: (1) practical issues; (2) immersion and (3) impact of intervention.

Practical issues

Participants reported equipment as comfortable and relatively straightforward to use. Clear guidance was considered important, and a designated room suggested for the future.

> …putting the headset on isn't really a problem … we're all going to have to get used to some kind of virtual reality at some point … hadn't tried it before but it was very interesting. 012

The importance of tailoring to the individual was highlighted.

> I find breathing exercises really frustrating … I have tumours in my lungs, the amount I can inhale, the amount of time I can hold for is less than for other

people. So, someone will say hold it this many beeps and then you can't … you feel like you failed at it and you check out… 019

IMMERSION

This relates to quality of VR imagery, ability to explore and impact of voices used in the audio. Lack of quality was seen as negatively impacting immersion and improvement suggested for the future with a preference for 'real' environments rather than animated.

> The beach was definitely more…realistic, you felt more sort of immersed in … compared with the other two. 026

While there was positive reaction to the professional voices, some participants described becoming disengaged.

> …I had the final session with the lady [voice], and she was excellent … it was very believable. She really did explain it, she was really part of it, and all that. Whereas, I felt with him [male voice], more like that he was reading a script. 027

Not all participants liked the compassion therapy aspect of the intervention.

> …the compassionate mind therapy, I couldn't see the point of at all … you are in a compassion rich environment … Nurses, the Doctors, friends and family… the last thing you … need is another dose of compassion… 027

There was a mixed reaction to external noise; some found it detracted from the quality of experience but others found it reassuring as it gave awareness of what was going on around them.

> …the noise cancelling was pretty good but I did still hear, if I focused properly, the pump beeping if something went wrong … it was sort of the right balance between not being completely disconnected if something happened. I think, anymore and I would have felt too isolated. 026

Impact of intervention

The intervention was seen as having immediate and lasting effects, with some recognising the ability to replicate the 'safe space' for themselves.

> The breathing techniques, I started to employ when I was having a scan even though the scan was very short. I thought that was quite useful for that. I hadn't really thought of that before but I found it actually quite calming. 017

For others, the impact was short lived but still considered useful.

> I don't think it will have a lasting impact…It definitely made the rest of the day easier … But the next day, the day after, I didn't still have that same sense of calm, it was just kind of immediately after… 019

Participants' past experience of non-medical support measures emerged as relevant to receptiveness and engagement with the overall VR/CMT experience.

> But I've also been on some of these yoga type things where you just try and relax and get into the mood and all that kind of thing…I thought it was quite useful for that…the talking was the same. 012

Participants also gave valuable feedback regarding the research process and informing a larger study, with particular reference to burden of questionnaires.

> I think some of them were a little bit repetitive, I though the one with all the options about being angry, sad … went on for ages. I don't think that really needs to be that long. 017

Qualitative findings supported the quantitative results and indicated that the intervention was acceptable and had a beneficial effect on mental well-being, anxiety and stress (see online supplemental table 7 for an example of data synthesis).

DISCUSSION

The aim of the study was to codesign a low-cost VR intervention enabling rapid access to safe, calm and soothing environments accompanied by quality controlled and guided CMT exercises and assess acceptability/feasibility in an oncology setting. The intervention was found to be acceptable with nearly two-thirds of participants completing three sessions, meeting the defined endpoint. This was supported by findings from interview data, confirming participants were positive, and supporting need for such interventions to help PABC deal with the psychological impact of cancer/treatment. This is consistent with wider literature in which new technologies were also found to be favourable, in their case, regardless of age, background or gender.[17 65] Also consistent, it was found to be acceptable and safe to use across several settings including inpatient, outpatient and day care.[17–19 65–67] While a positive trend was observed in some psychological domains, the overall effectiveness of the intervention remains unclear.

The final version of the intervention consisted of three short, separate sessions of VR/CMT. It is difficult to determine whether VR or CMT had more effect as arguably patients only received a relatively small dose of CMT. This was substantiated in interview findings which highlighted that most participants were unaware of any progression and/or did not relate to the CMT exercises. Participants thought the intervention should be longer, and incorporate more sessions, to have lasting effect. Other research in people having chemotherapy[20] argues that VR may not be effective for all as those with greater symptom distress had more accurate perception of time, suggesting they

were not able to block out negative external cues. In order to effect significant change on individual levels of self-compassion, more and longer sessions may be required.[68] A future multiarm randomised controlled trial (RCT) may explore which aspect (VR/CMT/both) has most, if any, effect. Acceptability and feasibility data also showed the beach scene to be the most popular and the forest scene the least. This is echoed in other work that cites a tree environment as gloomy[69] and highlights the importance of choice.

Throughout both phases, participants expressed that they liked being able to step out of their situation into a 'safe space', and some positively described reimagining the VR environment when they felt stressed. This happened quickly; for some, it was after the first session. Consistent with other work,[19 20] participants reported time passed quickly while using the intervention suggesting distractive qualities which may be helpful during lengthy or perceived unpleasant procedures. 'Presence' within the context of VR has been defined as the 'sense of being there' or as the 'feeling of being in a world that exists outside the self' and causes the user to suspend disbelief and believe they are in the virtual environment, reacting as if they are in the real world.[70] This varied between participants, as the quality of imagery and content of audio were reported by some as detracting from the immersive experience. It is generally acknowledged that presence is dependent on either the characteristics of the user or the media employed[71] and relates to willingness to suspend disbelief. Our findings support this; those who had engaged with psychological therapies previously reported they were less concerned with the quality of imagery. Arguably, this study engaged an unusual convenience sample with a mean time since diagnosis of 3 years, of which 80% were still in treatment who potentially may have been more exposed to such therapies over time. Moving forward, using tools to evaluate the degree of presence, such as the Presence Questionnaire,[72] and perhaps time perception may be valuable.

A key challenge is identifying who might benefit most from VR, alongside who is not appropriate, to ensure safety. Research[17–19] has highlighted benefits in chemotherapy populations in particular, with reduction of fatigue, anxiety, symptom distress and perception of time. Contrary to this, in our study, both participants who experienced AEs were undergoing chemotherapy. However, effects were mild and could not definitively be attributed to the intervention. For one, the effect was so mild that it was not mentioned at the time, and the other was disappointed not to continue, seeing the benefit of the VR experience outweighing the effect of the AE. Clinical guidance surrounding patient monitoring during use is recommended.

Interesting findings in terms of secondary aims emerged, in particular, improvements in mental wellbeing and stress. Surprisingly and consistent with other research,[73] we did not see a statistically significant reduction in anxiety levels as reported in other VR studies in this setting.[15 18] This needs to be treated with caution as this could be due to use of different measures. Standardisation may help to make future findings more generalisable/comparable.

A strength is the mixed methods approach whereby qualitative techniques were employed to capture experience of the intervention and strengthen the rigour of the acceptability and feasibility process.[37] The majority of studies used tools to capture symptom change[15 20 67] with only one[74] using open-ended questions in their methodology. Further commonalities included issues surrounding appropriate usage space and the negative effect of external noise. Developing the intervention for home use may improve quality and impact of experience.

The study has several limitations. The sample size was small (n=21) and the study is potentially underpowered, with a high attrition rate. However, this number of participants was deemed appropriate by the EBCD group (who developed the evaluation model) and local statisticians, to assess the intervention for acceptability, and included a diverse mix of demographics and tumour/treatment type. The small sample did not allow for adjustment of confounding variables in the quantitative analysis so that any notable differences in baseline characteristics or response to the intervention in the study population could be identified. It is acknowledged that a larger sample would be needed moving forward. Reasons for attrition are noted and may provide intelligence for any future pilot or larger study. Furthermore, even though the EBCD group designed the evaluation model and chose measures, interview data highlighted that the quantity were burdensome and repetitive. Consequently, participants described being unable to give full attention and findings may not be a true reflection of feelings. Two non-validated tools were used to capture mental wellbeing and participant self-compassion and as such may lack consistency and sensitivity.

CONCLUSION

A VR/CMT intervention is acceptable to PABC and is recognised as offering a novel approach to addressing unmet psychological needs at various stages of the cancer pathway. While feasible/safe to deliver in the oncology setting, developing a flexible approach in which users can access the intervention independently, for example, in their own homes, may increase uptake/impact and allow more autonomy. Future research should focus on conducting larger scale RCTs in which length or frequency of VR and amount of CMT given would be increased, alongside a bigger sample and a control to increase generalisability of findings. Careful consideration is required when selecting evaluative measures.

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