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An open study to explore the acceptability, safety, and effects of a smartphone application for university students who self-harm.

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Abstract

Background: Many university students self-harm but few receive support. Smartphone apps have been identified as acceptable sources of support for students who self-harm, but the use of self-harm prevention apps is yet to be explored in this population.

Objective: This study sought to explore the acceptability, safety and effects of a specific app (BlueIce) for university students who self-harm.

Methods: This was an exploratory, mixed methods study with 15 university students attending university wellbeing services with self-harming thoughts and/or behaviours. BlueIce was offered alongside the face-to-face support provided by the wellbeing service. Self-harming thoughts and behaviours, coping self-efficacy, and symptoms of anxiety and depression were measured before and after using BlueIce for 6 weeks. Follow up interviews were also undertaken to explore how students perceived BlueIce in more in depth.

Results: Following app use, there were statistically significant reductions in symptoms of anxiety and depression. Participants found BlueIce to be acceptable, safe and helpful, and reported that they were more able to cope with difficult feelings and better understand their self-harm triggers following use of the app.

Conclusion: BlueIce was an acceptable, safe and helpful source of support for university students struggling with self-harm thoughts and/or behaviours. This builds on previous findings with adolescents and suggests that BlueIce could be a particularly acceptable and helpful resource for university students.

Strengths and limitations

- The first study to evaluate a self-help smartphone app with university students who self-harm
- Qualitative findings were evaluated using a pre-existing framework for evaluating engagement with digital interventions
- Semi-structured interviews provided rich feedback on how students perceived the app.
- Recruitment challenges meant a small sample size for the quantitative analyses.

Introduction

Self-harm among university students

Self-harm is particularly prevalent at universities, with university students being twice as likely to self-harm than their non-student peers [1]. This may result from the numerous challenges that students face while at university, associated with academic, financial, geographical and social stressors, which leave them more vulnerable to experiencing mental health difficulties [2]. It is estimated that around a quarter of students will self-harm while at university [3], however, self-harm often goes unreported due to the shame, stigma and misconceptions surrounding it [4, 5, 6, 7, 8, 9]. This means that prevalence rates are often underestimated and that very few students who self-harm ever seek or receive professional help [10, 11]. This suggests that alternative options for support should be explored.

In a qualitative study, 25 UK university students with lived experience were interviewed about their opinions on support available for self-harm [12]. This study found that whilst some students appreciated the benefits of human connection that came with professional support, several barriers to seeking help were identified [12]. These included long waiting lists for mental health services, not wanting to take up support when they believed others may need it more, worrying about receiving a negative response upon disclosing self-harm, and feeling embarrassed and ashamed of self-harming. This study also explored how students perceive digital interventions, and found that they were viewed positively. In particular, students valued the anonymity, accessibility and convenience they can offer. In addition, students reported that they felt less exposed and inhibited compared to speaking with someone face-to-face, and noted how they always have their phones on them so could access a smartphone-based digital intervention anytime and anywhere [12].

These findings have been corroborated elsewhere, with a survey of 479 college/university students showing that around three quarters had used or were using a digital mental health intervention, and high satisfaction rates were reported [13]. Interestingly, 91% of participants in this study indicated that they had experienced barriers to accessing mental health services. This further suggests that digital mental health interventions can bridge the gap between students and mental health support.

Research has also investigated the effectiveness of digital mental health interventions for university students. A systematic review found that digital interventions are effective in reducing symptoms of anxiety and depression, while also improving psychology wellbeing among students [14]. This was also found in a randomised controlled trial with UK university students, where use of a mental health app significantly improved anxiety and depression scores compared to a control group, and that these effects were sustained at follow up [15]. It therefore seems as though digital interventions can be both acceptable to university students and effective in improving their psychological wellbeing.

Given the difficulties students face in seeking professional support for self-harm, coupled with the perceived advantages of digital support, a smartphone application (app) seems like a valued option. However, despite these potential benefits, there is no research investigating the use of a smartphone app for students who self-harm specifically [16].

BlueIce

A self-harm prevention app (BlueIce) has been evaluated with adolescents aged 12-17. Use of BlueIce was associated with a reduction in symptoms of anxiety and depression, as well as a reduction in the frequency of self-harm behaviours [18]. Qualitative findings also supported the app being acceptable, helpful and safe to use [19]. Given the positive findings from this app with adolescents, preliminary work subsequently investigated whether it could also be of use to university students. Students were shown screenshots of the app while its functionality was explained to them, and they believed that it could help them manage their self-harm while also promoting positive mental wellbeing [17]. Students described how they believed BlueIce could provide relief in moments of distress by offering them distractions or outlets for their feelings, while also offering them longer term coping strategies to help manage their emotions.

Overall, it seems as though BlueIce is an effective and appealing intervention for self-harm that could also be beneficial to university students. However, while the perceived acceptability of BlueIce for university students has been initially explored, the potential effects of the app on the mental health of this group is unknown. This study aims to explore the effects and acceptability of BlueIce for university students with mental health problems and self-harming thoughts and behaviours attending university wellbeing services.

Methods

Design

This was an exploratory, open, mixed-methods study employing pre- and post-intervention questionnaires and follow-up interviews.

Patient and public involvement

This research was informed by participants' responses in a previous study [12] who gave guidance on how best to evaluate interventions for self-harm, meaning their expertise contributed to the choice of measures used here.

Recruitment

Participants were students at one UK University who were recruited via the university's mental health services. The wellbeing service at this university is comprised of trained counsellors, wellbeing advisors and mental health advisors. They offer various forms of mental health support to students experiencing mild mental health difficulties, or they are able to direct students to more appropriate external specialist support if required. Help available through the university includes talking therapy, counselling, workshops, support groups and self-help resources. Typically, support is available both virtually and in person on the university campus.

Wellbeing staff were informed about the study and the intervention by the researcher, and were asked to highlight the study to any students meeting the inclusion criteria stated below. Posters advertising the study were placed in the waiting room so students were also able to directly sign up for the study. Interested students were directed to an online information sheet with space to enter their email to receive more information about the study. They were then contacted by the researcher (BC) who discussed the study with them either over a call on Microsoft Teams or over email.

Students were eligible to participate if:

1) They were currently (within the past two months) experiencing self-harm thoughts or behaviours
2) They were receiving/due to receive counselling or wellbeing support from the university services
3) They were willing to participate
4) They owned a smartphone running iOS or Android.

There were no exclusion criteria, although all potential participants were discussed with the university wellbeing service team lead to confirm suitability. All students who were interested in taking part were deemed suitable by the wellbeing team lead.

Intervention

BlueIce (https://www.oxfordhealth.nhs.uk/blueice/) was co-produced with young people with lived experience of self-harm, alongside clinical staff and academics. It has therapeutic grounding in both cognitive behavioural therapy and dialectical behavioural therapy [20] and was developed in line with guidance from the Medical Research Council [21]. In terms of safety, the app is pin-protected and no data is shared outside of the app. BlueIce contains a mood diary, emergency contacts and mood lifting activities that the user can add to and personalise. The activities are informed by common reasons people self-harm and, again, have therapeutic underpinnings. They include photographs, music, physical activities, guided mindfulness recordings and breathing exercises, a thought diary, distress tolerance techniques, and phone numbers of people to contact when at risk of self-harming [20]. Please see appendix 1 for screenshots of the app.

Procedure

Data collection occurred between March 2021 and February 2022. Consent forms, baseline and post-use questionnaire data were collected using the Online Surveys software (https://www.onlinesurveys.ac.uk/). Post-use interviews for participants were conducted using Microsoft Teams and were recorded using the within-software capabilities. Once consent and baseline questionnaires were completed, participants were sent a text containing a unique link to download BlueIce. They were emailed a user guide (please see appendix 2) and a video demonstrating how to use the app. Participants were then free to use the app as they wished and were able to keep the app after the study ended. They attended treatment as usual with the university mental health services during the study but had no other contact with the research team until the follow-up questionnaires and interview six weeks later.

Measures

Self-Harm: To measure self-harm, the Alexian Brothers Urge to Self Injure Scale (ABUSI) [22] and the Ottawa Self-injury Inventory [23] were administered. The Ottawa self-injury Inventory includes a subscale about the addictive nature of self-harm, which was removed for the purposes of this study as it was deemed not to be necessary to address our research aims.

Anxiety: The Generalised Anxiety Disoder-7 (GAD-7) [24] is a brief measure that has shown good sensitivity at screening for anxiety disorders. Scores of 5 suggest mild anxiety, 10 suggest

moderate anxiety and 15 suggest severe anxiety. It has also been well validated for use with university students [25, 26, 27].

Depression: The Patient Health Questionnaire-9 (PHQ-9) [28] is commonly used, has strong psychometric properties and has previously been used in a sample of UK university students [28]. A score of 5-9 suggests mild depression, 10-14 moderate depression, 15-19 moderately severe depression, and a score of 20-27 suggests severe depression.

Coping: The Coping Self-efficacy scale [29] consists of three subscales: stopping unpleasant emotions and thoughts, using problem-focused coping, and seeking support from family and friends. The total maximum score is 260, with greater coping self-efficacy indicated by higher scores. This measure has good psychometric properties [29] and has previously been used with university students who self-harm [30].

Acceptability of BlueIce: Following the six-week intervention period, participants were asked to complete a questionnaire about the acceptability of BlueIce [18, 19]. This questionnaire was developed by the researchers and explores engagement with the app, experience of using the app, and any impact that the app has had. Please see appendix 3.

Interview Schedule

Semi-structured interviews were conducted following the trial period that explored participants' experiences of using BlueIce and any impact they perceived it to have had on their mental wellbeing. The interviews were semi-structured and lasted between 15 and 45 minutes (M = 24.6, SD = 10.34). The interview schedule was designed by BC and was informed by previous interview schedules used to determine the acceptability of BlueIce with adolescents [19] and university students [17]. This began with an open question 'what did you think about BlueIce', with prompt questions asking for feedback on specific elements of the app used if participants struggled to answer. Questions were also included that asked about any perceived impact of BlueIce and whether they believed BlueIce could be helpful for other university students.

Data analysis

Descriptive statistics were used to summarise the sample with regards to demographic characteristics, self-harm characteristics and anxiety and depression symptomatology. Paired samples t-tests were used to assess pre-post change on quantitative measures.

Follow up interviews were analysed using qualitative content analysis, to allow for both an exploration and quantification of the qualitative data. The transcripts were first transcribed verbatim by BC. All three coders (BC, KW, and EM) then read and re-read the transcripts until they had become immersed in the data. Three transcripts were picked at random for BC, KW and EM to code in order to develop a coding frame (please see appendix 4). No more than 10 key codes in the frame were aimed for, so as not to have more codes than transcripts, but ultimately 11 were settled on [31]. The rest of the transcripts were then independently coded in batches of two transcripts at a time, after which the three coders met to discuss and make any necessary adaptations to the coding frame. As there were more than two coders, Cronbach's alpha was used to measure inter-coder reliability, which suggested good agreement, $\alpha = .79$.

While the codes and the coding frame were developed inductively and independently, BC, KW and EM identified that the codes aligned with a pre-existing framework of engagement with digital interventions [32]. The codes were therefore organised relative to the categories within this framework during analysis (please see appendix 5). The framework is divided into intervention-specific factors ('suitability', 'usability' and 'acceptability') and person-specific factors ('motivation', 'capability' and 'opportunity'), with codes exemplifying each category and barriers and facilitators to each. To operationalise this framework within the context of our findings, BC, KW and EM developed definitions for each of these categories:

Intervention-specific factors
Suitability: The suitability (or not) of this intervention with this population specifically, i.e., whether it could be feasibly implemented in this population.

Usability: Factors affecting the overall experience of using the app (e.g. enjoyment, ease of use) either positively or negatively to determine whether the app is fit for purpose.

Acceptability: Specific factors or features of the intervention (relating to the content and purpose) that the target population liked or disliked, as well as more general, overall perception of the app as acceptable or not.

Person-specific factors
Motivation: Whether the target population had enough reason to want to use it or not, both initially and more long term, because of the perceived need for the app or its perceived impact/ helpfulness. This relates to more internal drive factors, such as the extent to which they wanted to use it.

Capability: Whether the individual was able to use it or not and the barriers to this. Whereas motivation relates to more personal factors, capability relates more to externally influencing factors, such as being too busy.

Opportunity: Factors which improved or reduced participants' opportunities to receive support (for mental health and/or self-harm) via the app, as well as opportunities that the app provides or does not provide.

Ethical considerations

This study received ethical approval from the University Research Ethics Approval Committee for Health [EP 20/21 015]. Participants were provided with an information sheet detailing the study, allowing them a chance to ask any questions before giving informed consent. They were informed that they could drop out of the study at any time and without giving a reason, and that they would be able to remove their data from the study prior to anonymisation. Participants were made aware that their participation would be confidential and that all responses would be anonymised. Participants received no financial compensation for taking part.

Results

Sample characteristics

15 participants completed the baseline and follow-up questionnaires, and 10 participants completed the follow up interviews. Participants were mostly white (13/15, 87%), undergraduate (14/15, 93%) females (14/15, 93%) in their first year of study (10/15, 67%). All participants had self-harmed in the last 2 months (8/15, 53%) or were having thoughts of self-harm (7/15, 47%). Participants' ages ranged from 18-26 (mean 19.87, SD 2.39). Please see Table 1 for full participant demographics.

Table 1
Demographic characteristics of the sample

Demographic (N = 15)		n (%)
Age	18-20	11 (73%)
	21-23	3 (20%)
	24+	1 (7%)
Gender Identity	Female	14 (93%)
	Male	0 (0%)
	Non-binary	1 (7%)
Year of Study	1	10 (67%)
	2	1 (7%)
	3	3 (20%)
	4	1 (7%)
Degree type	Undergraduate	14 (93%)
	Postgraduate	1 (7%)
Ethnicity	White	13 (87%)

	Asian/Asian British	1 (7%)
	Black/African/Caribbean/Black British	1 (7%)
Sexuality	Heterosexual	8 (53%)
	Bisexual	5 (33%)
	Prefer not to say	1 (7%)
	Pansexual	1 (7%)
Self-harm Status	Current self-harm[a]	8 (53%)
	Current thoughts of self-harm[a]	7 (47%)

[a] This is defined as being within the past two months

Anxiety, depression and coping

Scores of the GAD-7 suggested that anxiety symptomatology was high within the sample (mean 12.47, SD 4.42), with many participants (12/15, 80%) experiencing at least moderate anxiety. Similarly, all participants were experiencing symptoms of at least mild depression (mean 16.50, SD 5.17), with a third (5/15, 33%) experiencing severe depression. On average, participants in this study seemed mildly confident in their abilities to cope (mean 92.93, SD 33.37), although this is lower than has been found in other samples of students who self-harm (e.g., mean 140.25, SD 48.26 [30].

Self-harm

Questions regarding self-harm thoughts and behaviour did not specify a timeframe so that those who had not self-harmed within the last two months were still able to provide insight into what their self-harming behaviours were typically like. Within the two weeks prior to joining the study, most participants had thoughts of self-harming rarely or occasionally (9/15, 60%) and had self-harmed never or rarely (12/15, 80%). However, when they occurred, urges to self-harm were typically rated as strong (10/15, 67%). Participants were divided on how difficult they found it to resist harming themselves in the past week, with half saying they had not found it at all difficult or had found it mildly difficult (8/15, 53%), while four participants had found it very hard or had been unable to resist harming themselves (27%).

On average, participants were aged 15 (SD 2.42) when they first self-harmed, although ages ranged from 10-19. Nearly all participants had last self-harmed within the past two years (14/15, 93%), with one participant not having self-harmed since 2011. Around a quarter of participants

reported that they usually never tell anybody if /when they self-harm (4/15, 27%), while the most common sources of support sought were university counsellors (9/15, 60%) (this was expected given that participants were recruited through university wellbeing services) and friend(s) (8/15, 53%). Cutting was the most common method of self-harming among the sample (11/15, 73%). When self-harming, only one participant (1/15, 7%) reported never feeling relief afterwards, and relief typically either lasted between 1-30 minutes (8/15, 53%) or for hours (5/15, 33%). When self-harming, between 1-60 minutes typically elapsed between thinking about it and acting upon it (11/13, 73%). Techniques most used to distract themselves from self-harming were talking with someone (9/15, 60%), doing anything to keep their hands busy (8/15, 53%) and watching TV (8/15, 53%). On a scale of 0 – 4, participants were moderately motivated to stop self-harming (mean 2.93, SD .80) and felt moderately able to stop self-harming (mean 2.40, SD 1.12). The most common sources of treatment the sample had received were self-help (6/15, 40%) or university counselling (5/15, 33%). The function subscale within the Ottawa Self-injury Inventory determined that students typically self-harmed for internal emotion regulation (mean 12.69, SD 6.36), and were least likely to self-harm for sensation seeking (mean 1.36, SD 1.95).

Quantitative Results

Differences before and after treatment

After the trial period, participants scored significantly lower on symptoms of anxiety as assessed by the GAD7 (mean 10.00, SD 4.16), $t(14) = 2.26$, $P = .040$, $d = .58$, and on symptoms of depression assessed by the PHQ 9 (mean 12.47, SD 3.66), $t(13) = 5.50$, $P < .001$, $d = 1.47$. Scores on the ABUSI were lower following the trial period (mean 11.07, SD 1.48) compared to before the trial period (mean 13.13, SD 6.66) although this difference was not statistically significant $t(14) = 1.49$, $P = .16$, $d = .38$. Similarly, scores on the coping measure were not statistically significantly higher after the trial period, however, scores for the 'stop unpleasant thoughts and emotions' subscale were significantly higher (i.e. improved) on post-measures (mean 28.60, SD 15.32) than on pre-measures (mean 21.80, SD 10.27), $t(14) = -2.36$, $P = .033$, $d = .61$.

BlueIce Use

Over the six weeks, the median use of BlueIce was between six and 12 times (5/15, 33%), with 3/15 (20%) using it a couple of times a week, every day and at least once a day, respectively. Two participants did not use BlueIce at all (15%), because they forgot to. Of the 13 participants who used the app, 11 (73%) personalised BlueIce by adding their own ideas to different sections of the app. Just over a third (5/13, 39%) set reminders to use the app, but everyone used the mood diary to track their mood. The majority (11/13, 85%) chose to use BlueIce in distressing moments when they felt like harming themselves, and almost half said that it did stop some episodes of self-harm (6/11*, 55%). Over half said that they definitely would continue to use BlueIce (8/13, 62%) with only one person reporting that they would not (1/13, 8%). On a scale of 0-4, participants rated that they typically found BlueIce easy to use (mean 3.54, SD .52) and helpful (mean 2.47, SD 1.20), and that they would likely recommend to others (mean 2.73, SD 1.16). On the other hand, participants were less sure that they preferred BlueIce to face to face meetings (mean 1.38, SD 1.30). On a scale of 1-10, participants indicated that they had experienced small improvements in their self-harm (mean 4.31, SD 2.50) and mental health (mean 3.46, SD 2.73) since using BlueIce. Out of five, on average participants gave BlueIce 3.46 (SD 1.05) stars.

**two participants did not answer this question*

Qualitative results

Qualitative interviews were completed with 10 participants.

Intervention-specific factors

Suitability: *Facilitators*

Although BlueIce was originally designed for adolescents, most participants felt that it was appropriate for university students. One participant commented that being designed for a younger population may have been beneficial as the app was simple to use:

'I didn't think it was [designed for adolescents]. It didn't look that way, although, like, I did like how clean and simple it was. I think it stops it being almost, like, distracting, and I liked how clean it looked' [012]

Two participants (20%) felt that the app would be particularly suitable for students who are more introverted or isolated and who may struggle to seek professional support:

'Or maybe for a person even who is, like, really, you know, a shy person and not so really outgoing. And, you know, maybe doesn't want to talk to a therapist or something, For those people, maybe, you know, an app would be better option.' [016]

Finally, four participants (40%) discussed how the scope of BlueIce seemed to extend beyond self-harm, as *'to me it seems like the kind of thing that most people would probably find useful' [008].* Participants specified that it would also be suitable for students who are struggling more generally, for example with exam stress, anxiety, or frustration:

'*I think this could definitely be used by people who are dissociating or having other issues that aren't self-harm, like feeling really anxious for example, feeling really down, just not knowing what to do or feeling really overwhelmed, I think it could be used for a lot of different things' [006]*

Suitability: *Barriers*

Conversely, three participants (30%) also discussed how the intervention may not be suitable for everybody, as people have different experiences of self-harm and different needs from support:

'It seemed like a good app, but not so suited to the way I sort of deal with things… I sort of tried out some of the mood…what is it called? The… the ones where it's like methods of coping? I tried out some of those. And, I like, I just didn't find any of them sort of suited to me, like I've still not worked out any particular ways of dealing with it myself. So I think, like, yeah, I think it's good, just not for me.' [008]

This also exemplifies how there tended to be a recognition among participants that, even if BlueIce may not have been particularly suitable for them, they could see how it could be of value to others.

Usability: *Facilitators*
Participants typically found the app simple and easy to use. They appreciated it giving them prompts and guiding them through the app pages, as they noted how moments of distress can be overwhelming, making it difficult to organise thoughts independently:

'I really like the pages where you can answer questions and, like, the buttons because I hate, like, speaking. Like, in those moments I hate speaking. I hate like… I find it really hard sometimes, l can like, you know, write down my thoughts on, like, that page. But like, a lot of the time I just can't, like, I'm too overwhelmed or, like, I just, yeah, I don't know what I'm thinking, but having the questions or the little buttons like, I love that… because it just helps me so much be able to find what I need…So being given prompts, um, is really, yeah, I really, really like that.' [010]

The simplicity of the app design was highlighted by 7 participants, with references being made to it not being overwhelming with too many options. The aesthetics of the app were also praised by five participants (50%), who enjoyed the colour scheme, the icons, the inconspicuous nature of the app, the format, and the logo.

'Everything looks so happy on the phone. I mean, I like the color. The color is really good. The blue and white….And I think also, yeah, when I was doing it then, when the light is off in the night in bed, it had like this, I don't know, dreamy, calm effect of me, like a cloud or, I don't know, yeah, something like that. It does something to you, just the color and the design.'[016]

Four participants (40%) also felt that the app was private, and appreciated having the passcode so that nobody but them could access it. This helped users to feel more confident being open with the app, knowing that their thoughts and feelings would be kept secure.

'I would say the pin password that you set up, that you need to access the app, it was helpful and it create a sense of privacy and especially, I mean less so now because obviously I don't live at home, but there's part of me that likes the idea of, you know, say, if ever anyone was looking over my phone or trying to access my phone knowing that, you know, I wouldn't have to…you know, there'd be preventions, I won't have to feel like I was at risk of someone opening it up and seeing everything.' [013]

Finally, the option to set reminders to use the app was praised by 3 participants (30%), including one participant who did not use the app frequently, as they acknowledged that it would have helped them to engage more with the app if they had done so.

Usability: *Barriers*
While the majority of participants responded positively to the app design and content, one participant did not like the colours and would have preferred pastel colours that would have felt more soothing for them:

'Just generally thinking about the colour scheme (laughter) maybe more soothing colours, I know it's called BlueIce but maybe the calm of a slightly paler blue… I think a pastel kind of thing would be better' [003]

The other barriers to usability identified by one participant was that the music section within BlueIce did not link with Spotify, but only Apple Music or music saved on the user's phone, and that they were not able to select more than one photo at a time to upload to the 'good times' section.

Acceptability: *Facilitators*
Further to BlueIce being perceived as suitable and usable, participants also discussed how it was acceptable and safe to use. Four participants specifically discussed how they do not perceive any risks to BlueIce being widely used, as they *'really didn't see anything on the app that kind of made me feel any negative emotions or anything.' [016]*

One participant elaborated on how they were initially concerned that having an app for self-harm on their phone could be triggering and make them more likely to self-harm, but that they were glad that this was not the case:

'There was part of me that was a little bit nervous that having the app would make me focus more on self-harm and so therefore maybe, you know, like it would be in the forefront of my head because I'd be seeing the app on my phone everyday… but that didn't happen which was great, I think partly because the app itself is quite innocuous on my phone… it's not glaring at you that it's for self-harm.' [013]

Participants commented on the specific features within the app that they found helpful, for example the toolbox of mood lifting activities, as having these ideas suggested to them made it easier to find an alternative way of coping in the moment, rather than using self-harm, as the app helped them to remember other things they can do instead:

I think in the moment you can kind of, like, forget what you can do. I definitely always, like, don't know what to do, which means it [self-harm] becomes the only option, so just, like, being able to see in front of me that, like, there are things I can do to help, it just makes it easier.' [012]

Another benefit of the toolbox that was highlighted was the option to personalise it by adding the users own ideas to the different sections, as well as making notes of what they tried and whether it worked or not. Three participants (30%) discussed how this helped the app feel more tailored to them and to feel less impersonal.

Importantly, over half of participants (7/10, 70%) specifically mentioned the mood diary as being a positive feature of the app, as it meant that they were able to track how they had been feeling over previous days. Participants commented how this helped them to feel more aware of their mood and the reasons behind it:

'I like knowing what helps you, like if you need a break, what makes you, like, happy and like, looking back on times when you've been feeling, like, your best. But also knowing and understanding, like, when you're struggling, like, why that might be. I think just writing it down can definitely help' [012]

Further to helping users' to understand their moods and what mediates them, participants also discussed how the mood diary helped change their perspective, by helping them to acknowledge their good days as well as their bad:

'I also noticed something when I checked the calendar because, obviously I can see the color codes right, and I felt happy seeing, for example, three or four green ones instead of seeing like, you know, a red and orange and stuff like that. Yeah, I felt like this also had an impact on then how I felt when I saw it. You know, I was like, 'ohh actually I do have good days. My life is not only like, you know, so stressful and bad' because I can see all the green color.' [016]

Further to the mood diary helping users to be aware of their mood and improving their perspective, three participants (30%) also noted how it provided a useful outlet for them that offered some relief from their difficult emotions:

'I think it was great for kind of like, when I didn't feel well for just, putting like, you know, notes down about like, my emotions, what I'm feeling…I just noticed that, kind of, when I write things down when I'm not feeling well, I write it out, it's kind of like a little bit of relief as well' [016]

Acceptability: *Barriers*
Despite the mostly positive perception of the mood diary, one of the barriers to acceptability discussed by four participants was the mood diary being oversimplified. While some participants enjoyed the simplicity of the app, others felt that the spectrum of emotions available on the mood diary did not capture their range of experiences, and that the 'other' option was not sufficient:

'I guess sometimes the mood tracker, just because it only has emotions on one spectrum, so it's either just happy or sad. Even though there was an 'other' option, you could change the words but you couldn't change the colour of the, I dunno what you'd call it, but you can't change the colour of the thing' [001]

Another participant liked the idea of using a mood diary but found that, upon actually using it, that the reminders to track their mood made them more aware of it when they did not necessarily want to be:

'I've downloaded, like, other apps in the past to try and do this sort of mood tracker thing. I do quite like the idea of being able to see that, but then, when I actually did it…it, like, would just like, pop up in the middle of the day and it'd be like 'oh how am I feeling?'. And then I'd be like 'how am *I feeling?... well I'm not feeling terrible…' and I tend to sort of try and ignore that stuff generally when I can.' [017]*

Person-specific factors

Motivation*: Facilitators*

Further to the benefits and the impact of the mood diary, eight participants (80%) also discussed more general impacts of the app that maintained their motivation to engage with it. One participant mentioned how the app had had a positive impact on them as they were better able to manage their self-harm:

'I've definitely been struggling less… just being able to know that I could, like, track it somewhere, like, almost, like, put it in something, um, I thought was quite helpful. Just being able to almost like, confide in the app you know? It definitely stopped [self-harm] being such a regular occurrence' [012]

Six (60%) specified that they were motivated to engage with the app as they felt that it encouraged positive action that was beneficial for their wellbeing, *'it encourages me to do things that I know will help me, but I just normally can't be assed to do' [010].* Further to this, participants appreciated being made aware of numerous *'stress relieving techniques, and knowing there's like, more options out there, say like, I didn't want to do meditation one day, then I know I could find another one on there to help' [011].* In this way, the app proved to be a helpful resource for participants who used it to identify new strategies to help manage their emotions.

One specific way in which the app helped reduce urges to self-harm was in helping participants to regulate their emotions:

'I found it quite helpful…regulating my mood for the rest of the day, 'cause I found that once I acknowledged it on the app and could see that I'd, you know, acknowledged it and was aware of it, I kind of became less likely to, you know, snap at a family member, and stuff like that… Yeah, yeah 'cause like in the past, a lot of like, triggers for self-harm have been frustration related as opposed to kind of like, sadness related….and I imagine that if I hadn't necessarily had that outlet, I would have then become so frustrated I would have been tempted self-harm' [013]

Participants were also motivated to continue using the app as it helped to remind them of activities that they found joyful, and helped them to realise that these activities could be beneficial in managing self-harm as well as improving their wellbeing:

'I'd look at, like, the activity suggested and stuff like that and kind of… it would remind me that those things were things I wouldn't necessarily think to do, and that they would work. So I think like one of them was talking about, like going for walks and stuff, and it's like, I know I like walks and I know they distract me, but I never put two and two together and thought that maybe it would be good in that kind of scenario…The next day I went for a walk and kind of felt like absolutely amazing… But yeah, like, so I think that was again one of the other key things is that it made me kind of stop and take note of things that actually do help and make me associate them with, like, self-harm prevention rather than just them being like activities that I like to do…since getting it in the last six weeks, I've gone on quite a few walks that I may not have necessarily gone on if I hadn't thought like oh, hang on a minute, that's something that I could do and enjoy and that I could actually, like knew could have a positive effect on my mental health' [013]

Finally, continued use of the app was associated with learning strategies that work without necessarily having to have their phone on them:

'Even if I don't have my phone with me, I now have some of those ideas in my head 'cause once you use them, you know, once you've used the app for a bit, like, you can get - It it can help you just get into a routine of, like, when you start to feel a certain way and know what works, uhm, stuff like the ideas on the app and stuff, what works, what doesn't' [010]

This suggests that the app was beneficial in helping participants to develop and maintain longer term coping strategies that they could use instead of self-harming.

Motivation: *Barriers*
Despite this, four participants (40%) also discussed the difficulties they faced in being motivated enough to use the app. Reasons for this included forgetting to use it, low mood hindering their motivation, being stressed, having low energy, and not believing that anything could help..One participant emphasised that the lack of external encouragement to engage with the app would make it harder to be motivated, as *'you have to remember, you have to like, very much like do it for yourself' [017]*

Further, three participants (30%) felt that they did not need the app as they did not have urges to self-harm.

Capability*: Facilitators*
Participants felt that BlueIce being a smartphone app meant that it was particularly suitable for university students, who are *'kind of stereotypically always attached to their phone' [13],* so for whom it would be particularly accessible and convenient. References were also made to BlueIce being more *'private' [011]* than person-based support, like counseling, for example.

Opportunity*: Facilitators*
Nine participants (90%) perceived BlueIce to be subject to fewer barriers of access as other services or interventions are, allowing more individuals the opportunity to access support. Barriers to other services discussed include long waiting lists, difficult referral processes, fees, lack of personalisation, lack of out of hours support' and support being 'scattered' across resources.

'But obviously compared to things like therapy and stuff, you have it 24/7. So in that way it it's so much better than therapy because, you know therapy, you know I, I get like twice a week for like an hour each time' [010]

Six participants (60%) discussed how BlueIce could also serve as a useful adjunct for people who are in receipt of professional support, by allowing them a space to track their thoughts and feelings between sessions:

'This could be my diary for example and I can note it down. And then because we can forget stuff and I could forget something significant, and then when I have to therapy session we can talk

about everything and my feelings on that day, and I think it would support the counseling session.' [016]

Finally, one participant praised the opportunity to still be able to receive support without requiring any interaction:

'I think it might be quite helpful because, I know that there are times for me at least where if I'm not feeling great I don't like talking to people, but also, like, I don't exactly want to neglect my health either, so having that option to not have to talk to anyone but still sort of helping yourself in a way is really nice.' [001]

Opportunity*: Barrier*

Conversely, four participants (40%) also discussed how they do not perceive BlueIce as a replacement for professional support, as there are further opportunities for support that the app does not provide. Three participants (30%) noted how the lack of human interaction is a downside as they valued input from a mental health professional. One participant explained how this is important to them as they need firm direction in therapy in order to improve their wellbeing:

'What I have with my counselor now you know, sometimes he would say something and I'll be like… especially with me, with my personality and you know, not being able maybe to take help from other people, or not knowing what's best for myself, and then someone else telling me what to do… I'd already told him as well, 'you need to be a bit harsh with me'. I don't want anyone soft.' [016]

One participant commented on how they perceived the function of BlueIce to be more relative to in the moment distractions, whereas therapy is important for *'getting to the route of the problem, and I think that to get to the route of a problem it needs to be face to face, it needs to be individualised, and you wouldn't want a computer or something to go through that with you cos then it can get it wrong and that can have consequences and things' [003]*

Discussion

This exploratory study is the first to evaluate the acceptability, safety and preliminary effects of a smartphone app (BlueIce) for university students who self-harm. Overall, the app was found to be acceptable and safe, as well as effective in helping participants to manage their self-harm and promote behaviour beneficial to wellbeing. However, some limitations of the app were also noted, such as the motivation required to engage with it.

Comparison with prior work

Levels of anxiety and depression symptomatology within the sample were higher than have been found in clinical samples with similar age groups. For example, Bentley et al., (2021) found mean GAD-7 and PHQ-9 scores of 8.5 and 10.6 respectively, compared to 12.5 and 16.5 in the current sample. Interestingly, surveys of university students have found scores that are comparable to those found in non-student clinical populations; Akram et al (2020) reported a mean GAD-7 score of 9.3 and a PHQ-9 score of 10.1 based on a sample of 1,273 students. This

endorses findings that university students are at a significantly heightened risk of struggling with mental health difficulties [1, 33]. In the baseline measures all participants classed themselves as either having self-harmed within the past 2 months or as currently having thoughts of self-harm. Despite this, in the two weeks prior, very few had self-harmed or had thoughts of self-harming. This raises interesting questions regarding how individuals who self-harm perceive their self-harm status. Claréus et al [34] investigated this and identified that individuals typically perceive themselves as having stopped self-harming if they had done so few times within the past month or year. However, some participants still did identify as someone who self-harms despite not having self-harmed within the past year. Importantly, it was found that how individuals perceive their recovery is more important than the time that has elapsed since the last act of self-harm. This corroborates the importance of asking participants to self-identify their self-harm status, rather than presuming they no longer self-harm in accordance with a certain time frame.

The current sample scored lower on measures of coping self-efficacy than in other studies of university students who self-harm [30]. It is important to acknowledge the context in which this research occurred, as the trial period was within a national lockdown due to the COVID-19 pandemic, in which everyone was encouraged to stay at home to stop the spread of the virus. Contact with anyone outside of the household was restricted. Consequently, many institutions closed, including universities, and most interaction had to occur in online spaces instead. This meant that university students were no longer attending in-person lectures, and the participants in this study were no longer attending in-person counseling sessions. This context may explain participants' lower coping self-efficacy, as students may have had less access to resources that positively impacted their abilities to cope, such as social networks [35]. A survey of 576 students did indeed find that the pandemic negatively impacted students' mood and wellness [36], suggesting they may have been particularly vulnerable during this time.

Despite this sample comprising students who had all disclosed self-harm to a mental health professional, a quarter of participants in this study indicated that they usually do not tell anybody when they self-harm. This suggests that, even for this group who have disclosed self-harm to a mental health professional and volunteered for a research study regarding a self-harm intervention, discussing self-harm can still be challenging. Importantly, this sample seemed to struggle more with self-harm urges than self-harm behaviours, with 12 participants indicating that they had self-harmed either rarely or never within the past two weeks, but with two thirds indicating that their urges to self-harm were strong. This reinforces the importance of measuring self-harm urges as well as behaviours, as they can be predictive of future self-harm and can still be very distressing for the individual [37, 38]. Moreover, a questionnaire completed by 1,296 students found that self-harm thoughts alone are still able to allow the individual relief from difficult emotions [39].

Generally, there was a high level of engagement with the app with several participants using it frequently, adding personalised content to the app, tracking their mood, and using BlueIce in moments of distress. High levels of engagement with BlueIce have also been found in previous studies with adolescents [40]. Despite the app originally being designed with and for adolescents, this did not seem to deter university students from engaging with it and finding it beneficial. Participants in this study typically praised the simplicity of the app and enjoyed the design, although some found the mood diary too simple to capture their experiences; this split in opinion

replicates findings from the previous evaluation of the acceptability of BlueIce with university students [17]. Nonetheless, those who did benefit from the mood diary discussed how it helped them to manage their emotions by providing an outlet for them through which they could get some relief from their difficult feelings, as well as being able to identify triggers for different moods. This mirrors findings from another study with young adults who self-harm, who found mood tracking via a smartphone app beneficial in managing emotions and identifying triggers [41]. Participants in the current study also found it helpful being able to reflect on their mood in difficult moments, as well as more broadly in order to gain perspective and feel more optimistic by realising that they do have good days as well as bad. These qualitative findings resonate with the quantitative findings showing an increase in participants perceived self-efficacy in being able to stop unpleasant thoughts or emotions following the trial period, rated using the coping self-efficacy scale [29]. It may be that the techniques participants learnt to manage their emotions, promote positive wellbeing and to cope in alternative ways as opposed to self-harm, as discussed above, may have contributed to their heightened beliefs in their abilities to stop difficult thoughts and emotions.

Around half of the participants indicated that BlueIce had stopped them from harming themselves at certain points. While this is important, previous research with university students with lived experience of self-harm highlighted that relying on a reduction in self-harm behaviours is not necessarily the best way to measure the success of an intervention [42], preferring a more holistic and wider perspective that also considers their general wellbeing [43]. In particular, university students who self-harm have emphasised wanting self-harm interventions to help them to learn more adaptive coping strategies and to address their broader mental health difficulties that are 'triggers' for their self-harm [12]. 80% of participants in the interviews discussed some positive impact of the app, including helping them to develop longer term, alternative coping strategies, and encouraging action that was beneficial for their wellbeing. As mentioned, participants' perceived abilities to stop unpleasant thoughts and emotions also improved. Further, participants in this study believed that BlueIce could help students struggling with a range of mental health difficulties, as well as typical university stressors such as exams. Overall, this would suggest that BlueIce typically aligned with university students' favoured outcomes of interventions. However, one participant did specify that professional support is necessary for getting to the route of the issue behind their self-harm. This reinforces the heterogeneity surrounding preferences for support that has been found previously [12, 44, 45], emphasising the need to ensure university students are able to access a variety of resources and sources of support.

The function that BlueIce could provide was explored, with participants suggesting it could be a helpful adjunct to counseling that allowed users to log how they had been feeling in between sessions to relay back to their counselor. Participants also discussed finding it helpful in moments of distress by reminding them of techniques to manage their emotions or distract themselves, without the user having to search for techniques themselves. The longer-term impact was also discussed, with participants commenting on having a better understanding of their triggers and how to manage their emotions, without even having the app in front of them. This confirms the perception identified in a previous study investigating the acceptability of BlueIce with university students, where it was identified as a useful reminder of adaptive coping strategies in difficult moments, as well as a means of learning ways of processing emotions [17].

This also reflects findings with adolescents, who reported that BlueIce helped them to reframe difficult thoughts and provided a helpful distraction [19].

Limitations

Firstly, participants in this study all used the app alongside counseling provided by the university wellbeing services. As such, it is not possible to directly attribute the improvements in participants' wellbeing to either the counseling or the app. Similarly, participants were recruited from one university wellbeing service who had already sought help for their self-harm. These findings may not be representative of students attending other universities or those who self-harm but have not sought help. As BlueIce was found to be safe to use, future research should seek to assess the impact of implementing BlueIce more widely with students in the general university population.

Secondly, this was an exploratory open study with a small number of participants and as such data is limited and must be interpreted with caution. Future research would benefit from a larger scale study to determine the effectiveness of BlueIce in this population.

Finally, this research occurred during a period of national lockdown due to the COVID-19 pandemic. This could have affected our results which may be lacking temporal validity.

Conclusion

In summary, BlueIce proved to be a safe, acceptable and helpful tool for university students attending face-to-face mental health services. Following use, participants reported that they had developed more adaptive coping mechanisms, were better able to identify triggers for self-harm, and had fewer symptoms of depression and anxiety. This mirrors previous research into the use of BlueIce among university students, adding further credence to its benefits for this population.

Further research is indicated using robust methodologies and appropriately powered cohorts to investigate these effects further.

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Conflict of interests

Paul Stallard designed the BlueIce app but receives no financial gain from the app or from this research. The other authors declare that they have no conflicts of interest.

References

1. Swannell SV, Martin GE, Page A, et al. Prevalence of Nonsuicidal Self-Injury in Nonclinical Samples: Systematic Review, Meta-Analysis and Meta-Regression. *Suicide Life Threat Behav* 2014;44:273–303. https://doi.org/10.1111/sltb.12070

2. Taliaferro LA, Muehlenkamp JJ. Risk Factors Associated With Self-injurious Behavior Among a National Sample of Undergraduate College Students. *J Am Coll Health* 2015;63:40–8. https://doi.org/10.1080/07448481.2014.953166
3. Griffin K, Twynstra J, Gilliland JA, et al. Correlates of self-harm in university students: A cross-sectional study. *J Am Coll Health* 2021;0:1–8. https://doi.org/10.1080/07448481.2021.1909049
4. Chandler A. Narrating the self-injured body. *Med Humanit* 2014;40:111–6. https://doi.org/10.1136/medhum-2013-010488
5. Long M. 'We're not monsters … we're just really sad sometimes:' hidden self-injury, stigma and help-seeking. *Health Sociol Rev* 2018;27:89–103.
6. Sheehy K, Noureen A, Khaliq A, et al. An examination of the relationship between shame, guilt and self-harm: A systematic review and meta-analysis. *Clin Psychol Rev* 2019;73(101779). https://doi.org/10.1016/j.cpr.2019.101779
7. Simone AC, Hamza CA. Examining the disclosure of nonsuicidal self-injury to informal and formal sources: A review of the literature. *Clin Psychol Rev* 2020;82(101907). https://doi.org/10.1016/j.cpr.2020.101907
8. Simone AC, Hamza CA. A longitudinal examination of predictors of nonsuicidal self-injury disclosures among university students. *J Clin Psychol* 2021;1(18). https://doi.org/10.1002/jclp.23277
9. Staniland L, Hasking P, Boyes M, et al. Stigma and nonsuicidal self-injury: Application of a conceptual framework. *Stigma Health* 2021;6:312–23. https://doi.org/10.1037/sah0000257
10. Fitzgerald J, Curtis C. Non-suicidal self-injury in a New Zealand student population: Demographic and self-harm characteristics. *N Z J Psychol* 2017;46:156–63.
11. Whitlock J, Eckenrode J, Silverman D. Self-injurious Behaviors in a College Population. *Pediatrics* 2006;117:1939–48. https://doi.org/10.1542/peds.2005-2543 PMID: 16740834
12. Cliffe B, Stallard P. University students' experiences and perceptions of interventions for self-harm. *J Youth Stud* 2022;0:1–15. https://doi.org/10.1080/13676261.2022.2033187

13. Topooco N, Fowler LA, Fitzsimmons-Craft EE, et al. Digital interventions to address mental health needs in colleges: Perspectives of student stakeholders. *Internet Interventions.* 2022;28:100528. https://doi.org/10.1016/j.invent.2022.100528

14. Lattie EG, Adkins EC, Winquist N, et al. Digital Mental Health Interventions for Depression, Anxiety, and Enhancement of Psychological Well-Being Among College Students: Systematic Review. *J Med Internet Res* 2019 Jul;21(7). https://www.jmir.org/2019/7/e12869 https://doi.org/10.2196/12869

15. Ponzo S, Morelli D, Kawadler JM, et al. Efficacy of the Digital Therapeutic Mobile App BioBase to Reduce Stress and Improve Mental Well-Being Among University Students: Randomized Controlled Trial. *JMIR mHealth and uHealth* 2020 Apr;8:e17767. https://doi.org/10.2196/17767

16. Barnett P, Arundell LL, Saunders R, et al. The efficacy of psychological interventions for the prevention and treatment of mental health disorders in university students: A systematic review

and meta-analysis. *Journal of Affective Disorders.* 2021;280:381–406. https://doi.org/10.1016/j.jad.2020.10.060

17. Cliffe B, Stokes Z, Stallard P. The Acceptability of a Smartphone App (BlueIce) for University Students Who Self-harm. *Arch Suicide Res.* 2022;0:1–17. https://doi.org/10.1080/13811118.2021.2022552

18. Stallard P, Porter J, Grist R. A Smartphone App (BlueIce) for Young People Who Self-Harm: Open Phase 1 Pre-Post Trial. *JMIR MHealth UHealth* 2018;6:e32. https://doi.org/10.2196/mhealth.8917

19. Grist R, Porter J, Stallard P. Acceptability, Use, and Safety of a Mobile Phone App (BlueIce) for Young People Who Self-Harm: Qualitative Study of Service Users' Experience. *JMIR Ment Health* 2018 Feb;5(1). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5845106/ https://doi.org/10.2196/mental.8779

20. Stallard P, Porter J, Grist R. Safety, Acceptability, and Use of a Smartphone App, BlueIce, for Young People Who Self-Harm: Protocol for an Open Phase I Trial. *JMIR Res Protoc* 2016;5:e217. https://doi.org/10.2196/resprot.6525

21. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008 Sep;337. https://www.bmj.com/content/337/bmj.a1655 https://doi.org/10.1136/bmj.a1655

22. Washburn JJ, Juzwin KR, Styer DM, et al. Measuring the urge to self-injure: Preliminary data from a clinical sample. *Psychiatry Res* 2010;178:540–4. https://doi.org/10.1016/j.psychres.2010.05.018

23. Cloutier PF, Nixon MK. The Ottawa Self-Injury Inventory: A preliminary evaluation. Abstracts to the 12th International Congress European Society for Child and Adolescent Psychiatry. *European Child & Adolescent Psychiatry*. 2003;

24. Spitzer RL, Kroenke K, Williams JBW, et al. A Brief Measure for Assessing Generalized Anxiety Disorder: The GAD-7. *Arch Intern Med*. 2006;166:1092. https://doi.org/10.1001/archinte.166.10.1092

25. Bártolo A, Monteiro S, Pereira A. Factor structure and construct validity of the Generalized Anxiety Disorder 7-item (GAD-7) among Portuguese college students. *Cad Saúde Pública* 2017;33:e00212716. https://doi.org/10.1590/0102-311x00212716

26. Farrer LM, Gulliver A, Bennett K, et al. Demographic and psychosocial predictors of major depression and generalised anxiety disorder in Australian university students. *BMC Psychiatry* 2016;16:241. https://doi.org/10.1186/s12888-016-0961-z

27. Musiat P, Goldstone P, Tarrier N. Understanding the acceptability of e-mental health - attitudes and expectations towards computerised self-help treatments for mental health problems. *BMC Psychiatry* 2014;14:109. https://doi.org/10.1186/1471-244X-14-109

28. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9. *J Gen Intern Med*. 2001;16:606–13. https://doi.org/10.1046/j.1525-1497.2001.016009606.x

29. Chesney MA, Neilands TB, Chambers DB, et al. A validity and reliability study of the coping self-efficacy scale. *Br J Health Psychol* 2006;11:421–37. https://doi.org/10.1348/135910705X53155

30. Midkiff MF, Lindsey CR, Meadows EA, et al. The role of coping self-efficacy in emotion regulation and frequency of NSSI in young adult college students. *Cogent Psychol*. 2018;5:1520437. https://doi.org/10.1080/23311908.2018.1520437
31. O'Connor C, Joffe H. Intercoder Reliability in Qualitative Research: Debates and Practical Guidelines. *Int J Qual Methods* 2020;19:1609406919899220. https://doi.org/10.1177/1609406919899220
32. Liverpool S, Mota CP, Sales CMD, et al. Engaging Children and Young People in Digital Mental Health Interventions: Systematic Review of Modes of Delivery, Facilitators, and Barriers. *J Med Internet Res* 2020;22:e16317. https://doi.org/10.2196/16317
33. Stallman HM. Psychological distress in university students: A comparison with general population data. *Australian Psychologist* 2010;45:249–57. https://doi.org/10.1080/00050067.2010.482109

34. Claréus B, Hasking PA, Gray N, et al. Is ceasing self-injury enough? Differences in psychological health between people reporting behavioral cessation of non-suicidal self-injury and those who consider themselves to have stopped self-injuring. *J Clin Psychol* 2022;jclp.23409. https://doi.org/10.1002/jclp.23409

35. Sahu P. Closure of Universities Due to Coronavirus Disease 2019 (COVID-19): Impact on Education and Mental Health of Students and Academic Staff. *Cureus* 2020 Apr;12(4). https://www.cureus.com/articles/30110-closure-of-universities-due-to-coronavirus-disease-2019-covid-19-impact-on-education-and-mental-health-of-students-and-academic-staff https://doi.org/10.7759/cureus.7541

36. Copeland WE, McGinnis E, Bai Y, et al. Impact of COVID-19 Pandemic on College Student Mental Health and Wellness. *Journal of the American Academy of Child & Adolescent Psychiatry*. 2021;60:134-141.e2. https://doi.org/10.1016/j.jaac.2020.08.466

37. Burke TA, Ammerman BA, Hamilton JL, et al. Nonsuicidal self-injury scar concealment from the self and others. *Journal of Psychiatric Research*. 2020;130:313–20. https://doi.org/10.1016/j.jpsychires.2020.07.040

38. Miller M, Redley M, Wilkinson PO. A Qualitative Study of Understanding Reasons for Self-Harm in Adolescent Girls. *International Journal of Environmental Research and Public Health* 2021;18:3361. https://doi.org/10.3390/ijerph18073361

39. Martin J, Bureau JF, Cloutier P, et al. A Comparison of Invalidating Family Environment Characteristics Between University Students Engaging in Self-Injurious Thoughts & Actions and Non-Self-Injuring University Students. *J Youth Adolescence* 2011;40:1477–88. https://doi.org/10.1007/s10964-011-9643-9

40. Muscara F, Ng O, Crossley L, Lu S, et al. The feasibility of using smartphone apps to manage self-harm and suicidal acts in adolescents admitted to an inpatient mental health ward. *Digit Health* 2020 Nov;6. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7705813/ https://doi.org/10.1177/2055207620975315

41. Honary M, Bell B, Clinch S, et al. Shaping the Design of Smartphone-Based Interventions for Self-Harm. *Proceedings of the 2020 CHI Conference on Human Factors in Computing Systems* Honolulu HI USA: ACM; 2020:1–14. https://dl.acm.org/doi/10.1145/3313831.3376370

42. Owens C, Fox F, Redwood S, et al. Measuring outcomes in trials of interventions for people who self-harm: qualitative study of service users' views. *BJPsych Open* 2020 Mar;6(2). https://www.cambridge.org/core/journals/bjpsych-open/article/measuring-outcomes-in-trials-of-interventions-for-people-who-selfharm-qualitative-study-of-service-users-views/00B4C4A51CB7627AEBE960FAB87DCB04 https://doi.org/10.1192/bjo.2019.93

43. Knowles S, Sharma V, Fortune S, et al. Adapting a codesign process with young people to prioritize outcomes for a systematic review of interventions to prevent self-harm and suicide. *Health Expectations* 2022. https://onlinelibrary.wiley.com/doi/abs/10.1111/hex.13479 https://doi.org/10.1111/hex.13479

44. Carroll R, Metcalfe C, Gunnell D. Hospital Presenting Self-Harm and Risk of Fatal and Non-Fatal Repetition: Systematic Review and Meta-Analysis. *PLoS One* 2014 Feb;9(2). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3938547/ https://doi.org/10.1371/journal.pone.0089944

45. Hume M, Platt S. Appropriate interventions for the prevention and management of self-harm: a qualitative exploration of service-users' views. *BMC Public Health* 2007;7:9. https://doi.org/10.1186/1471-2458-7-9


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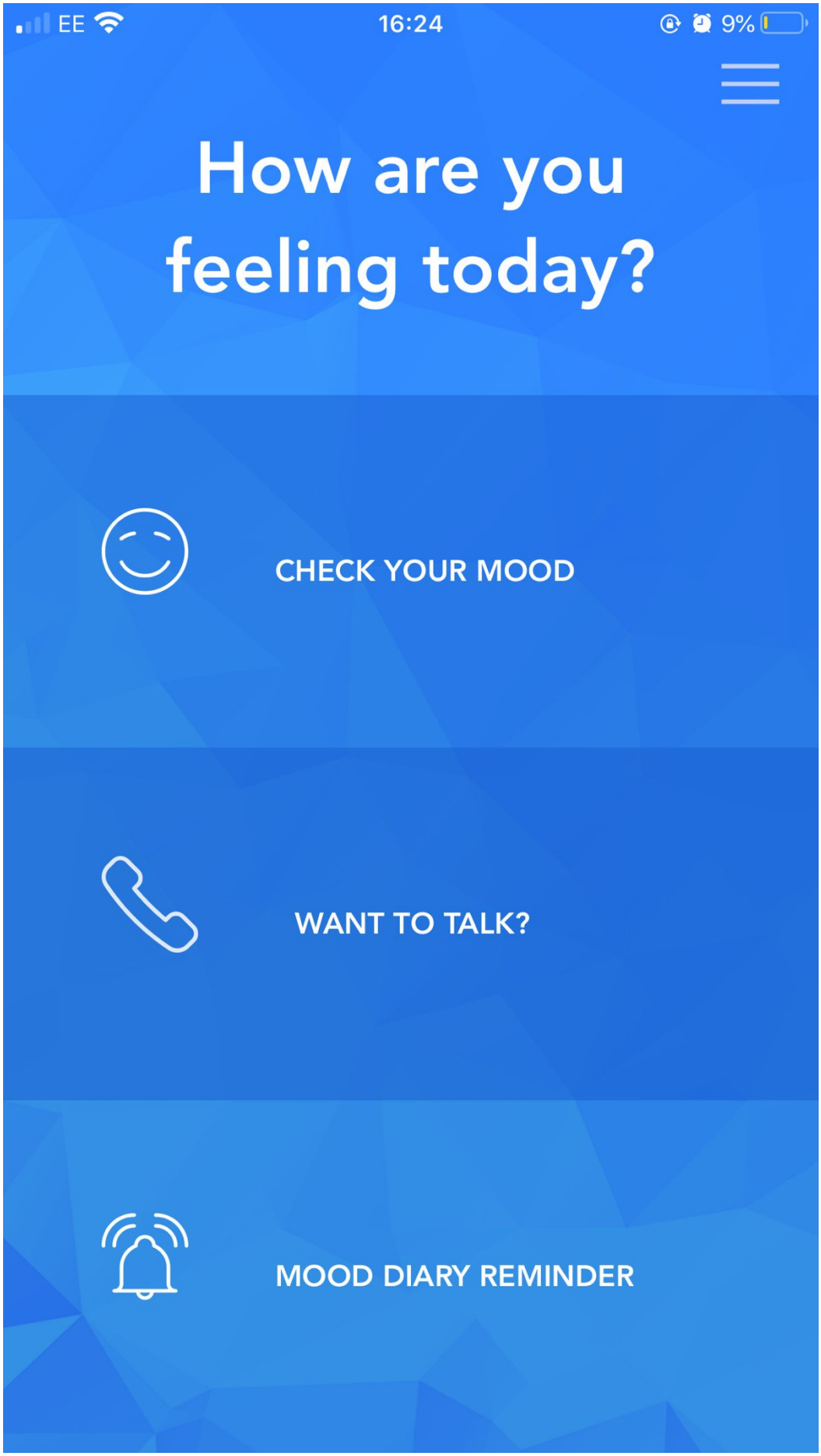
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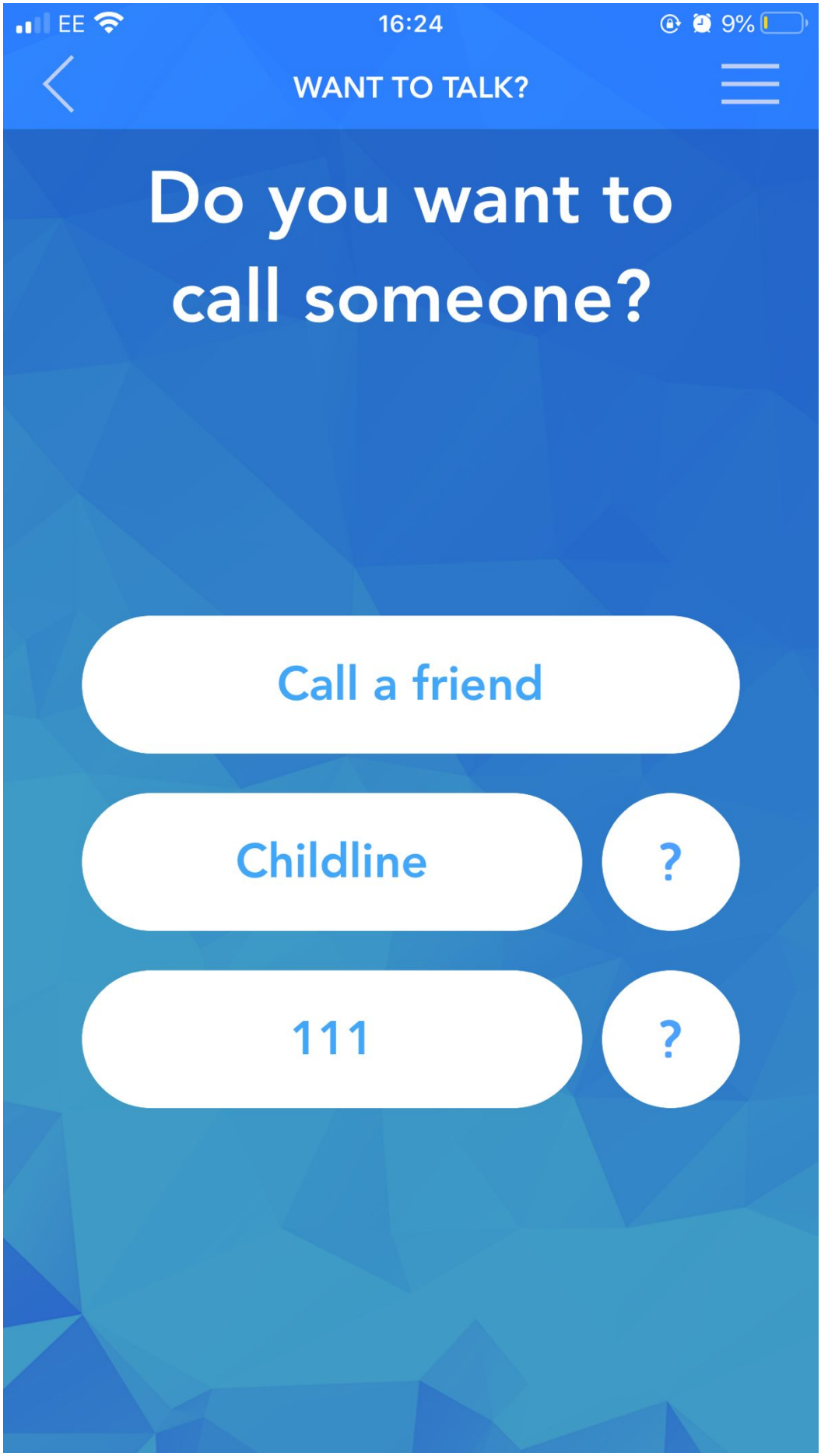
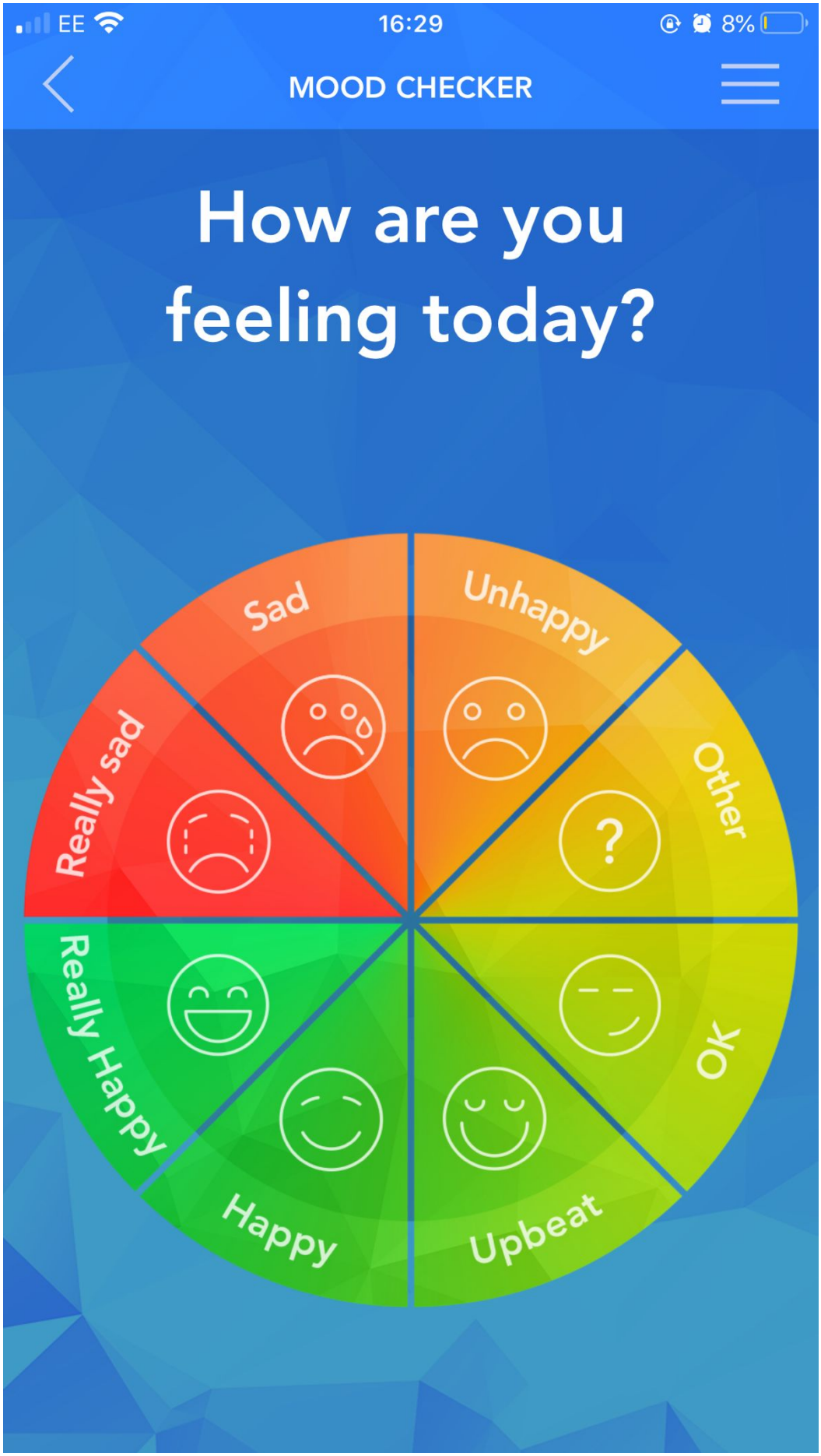
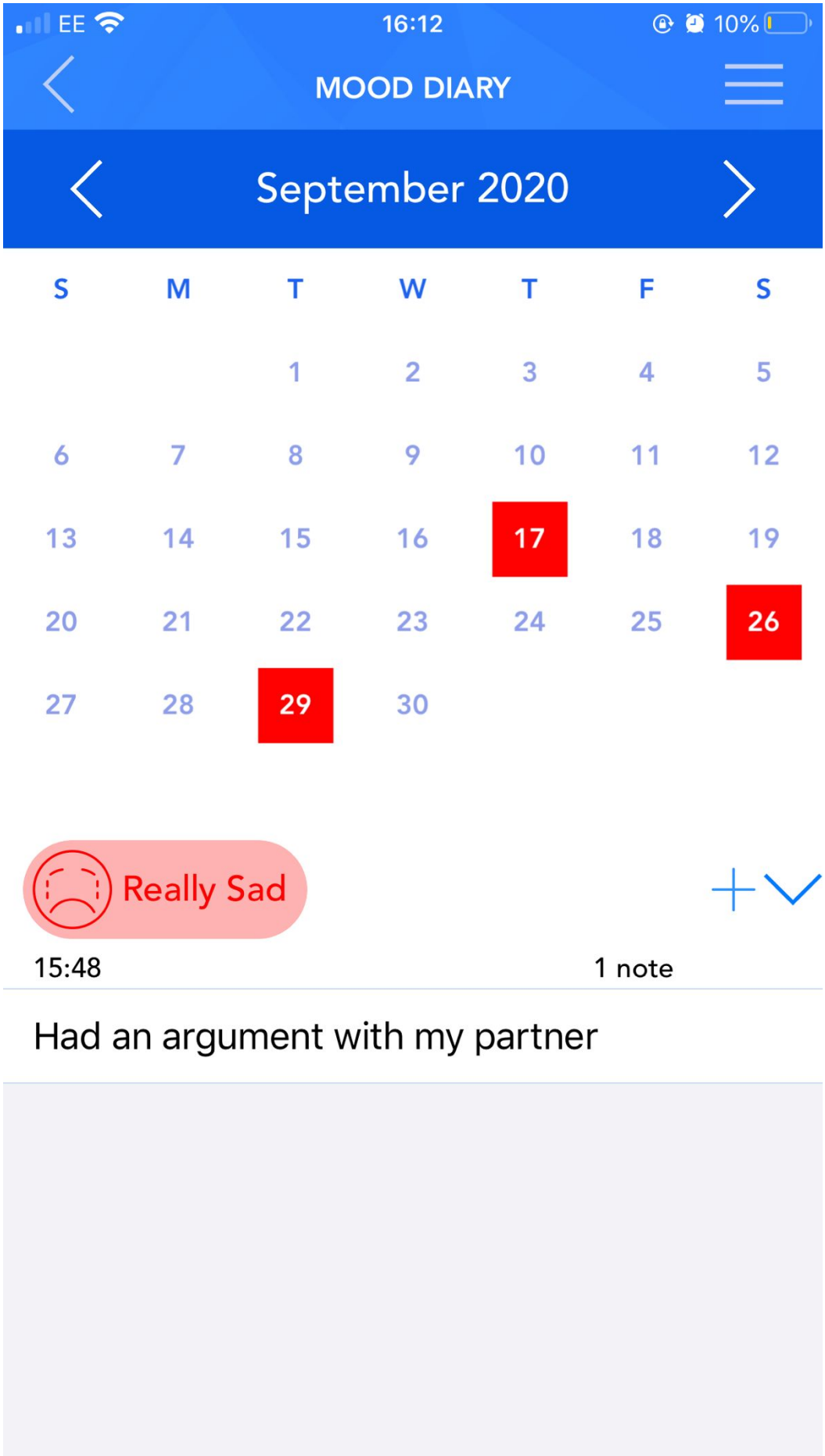
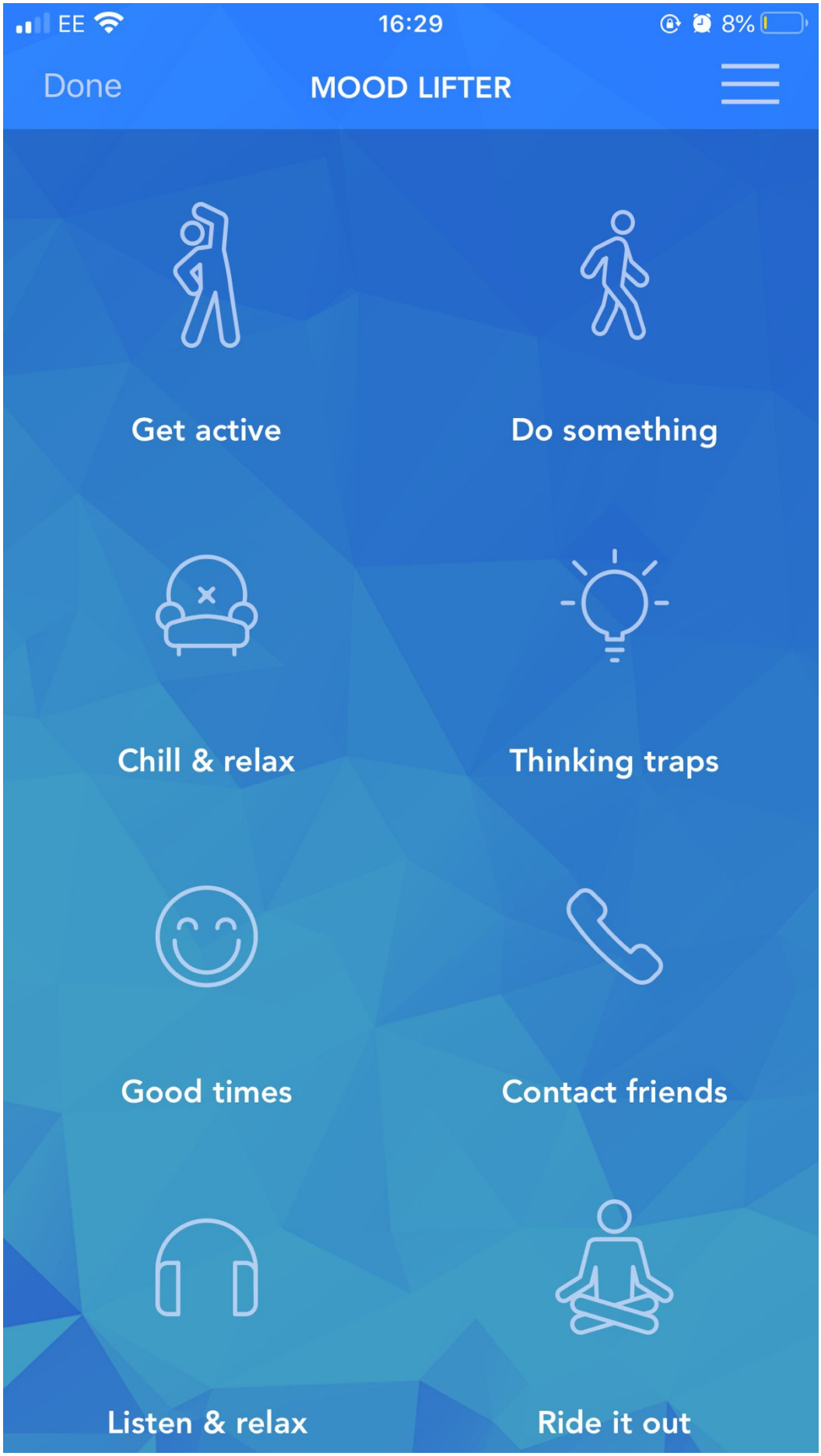
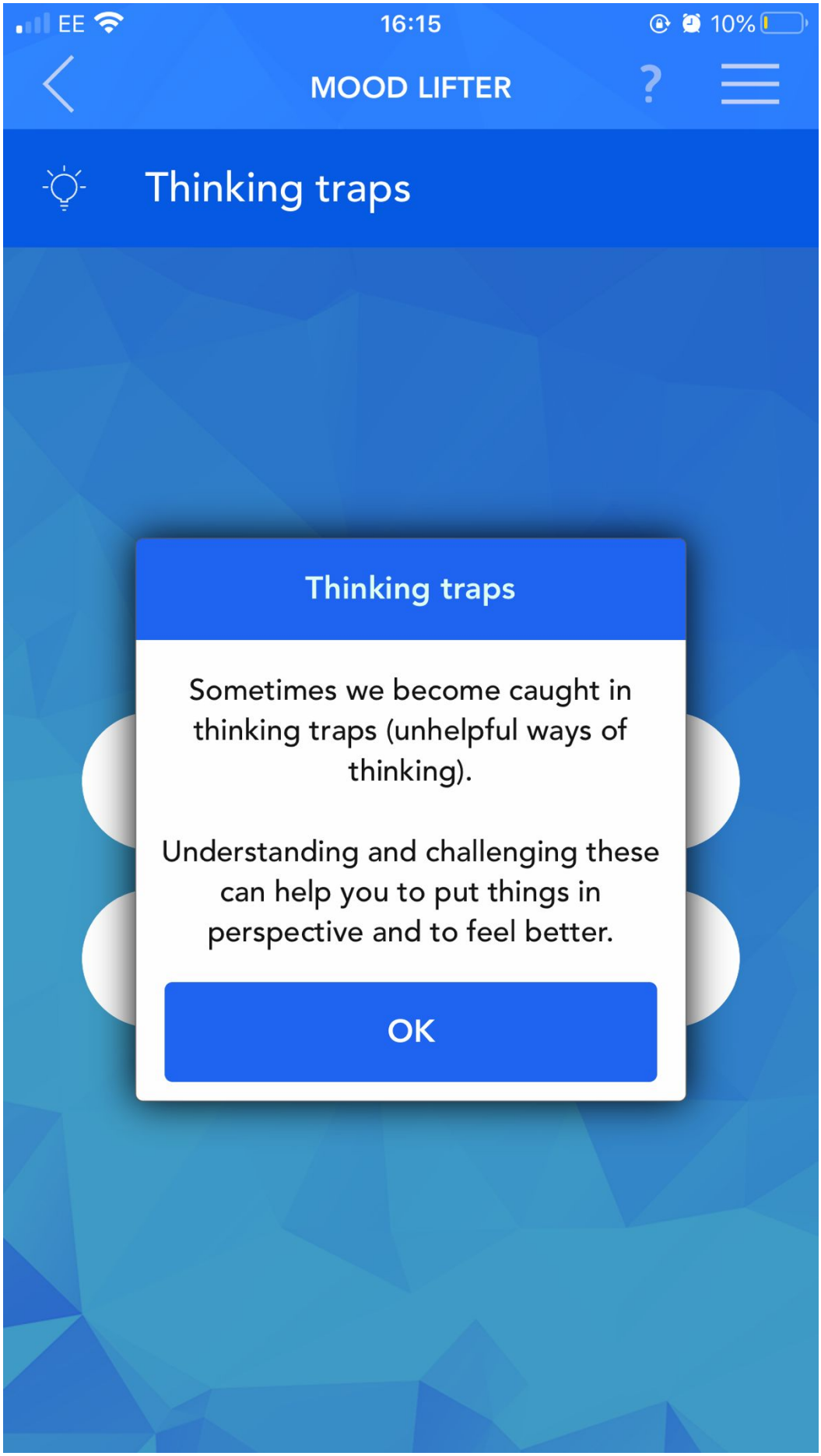
WANT TO TALK?
MOOD DIARY REMINDER

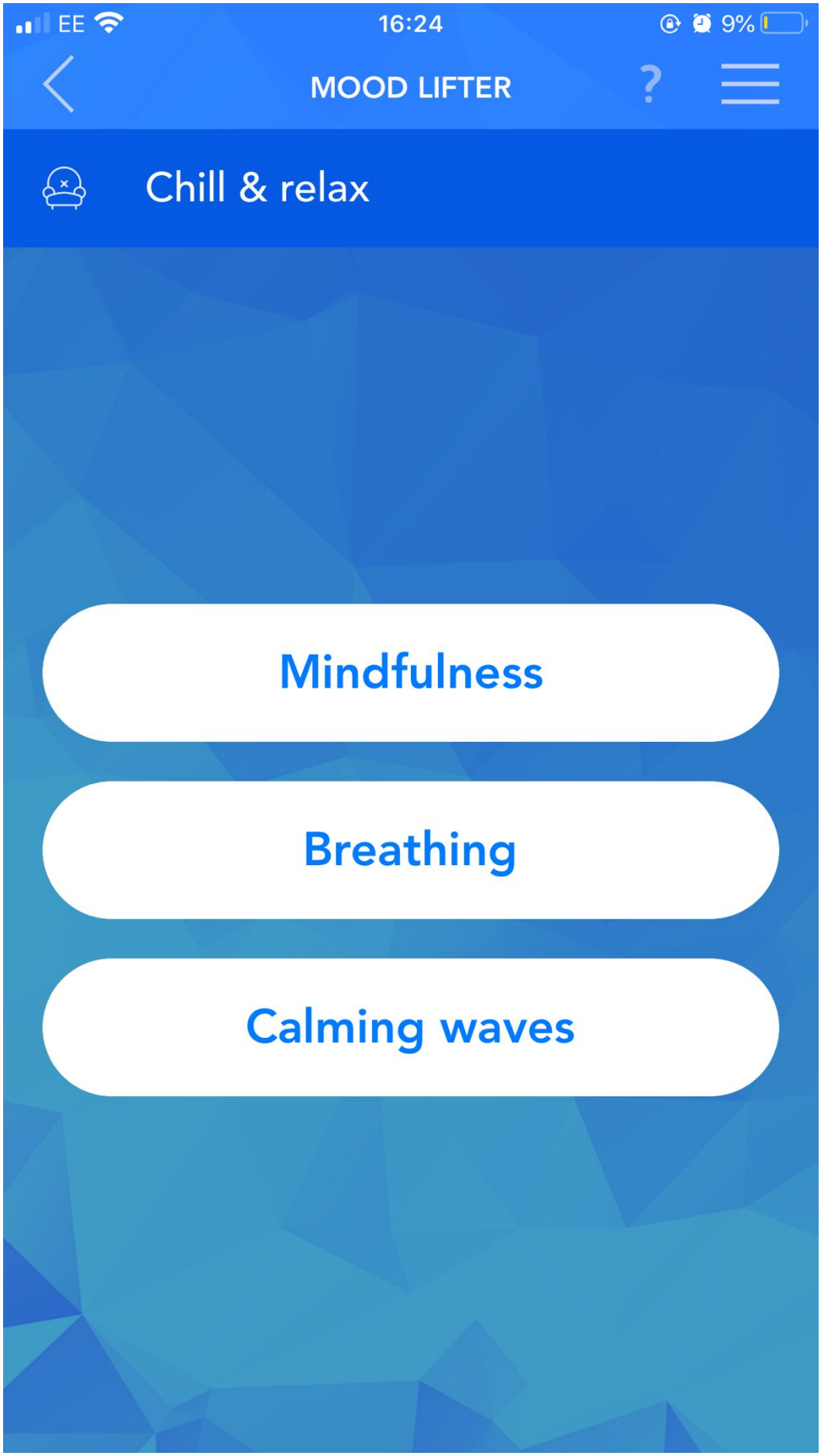

EE
16:24
9%
WANT TO TALK?
Do you want to call someone?
Call a friend
Childline
?
111
?

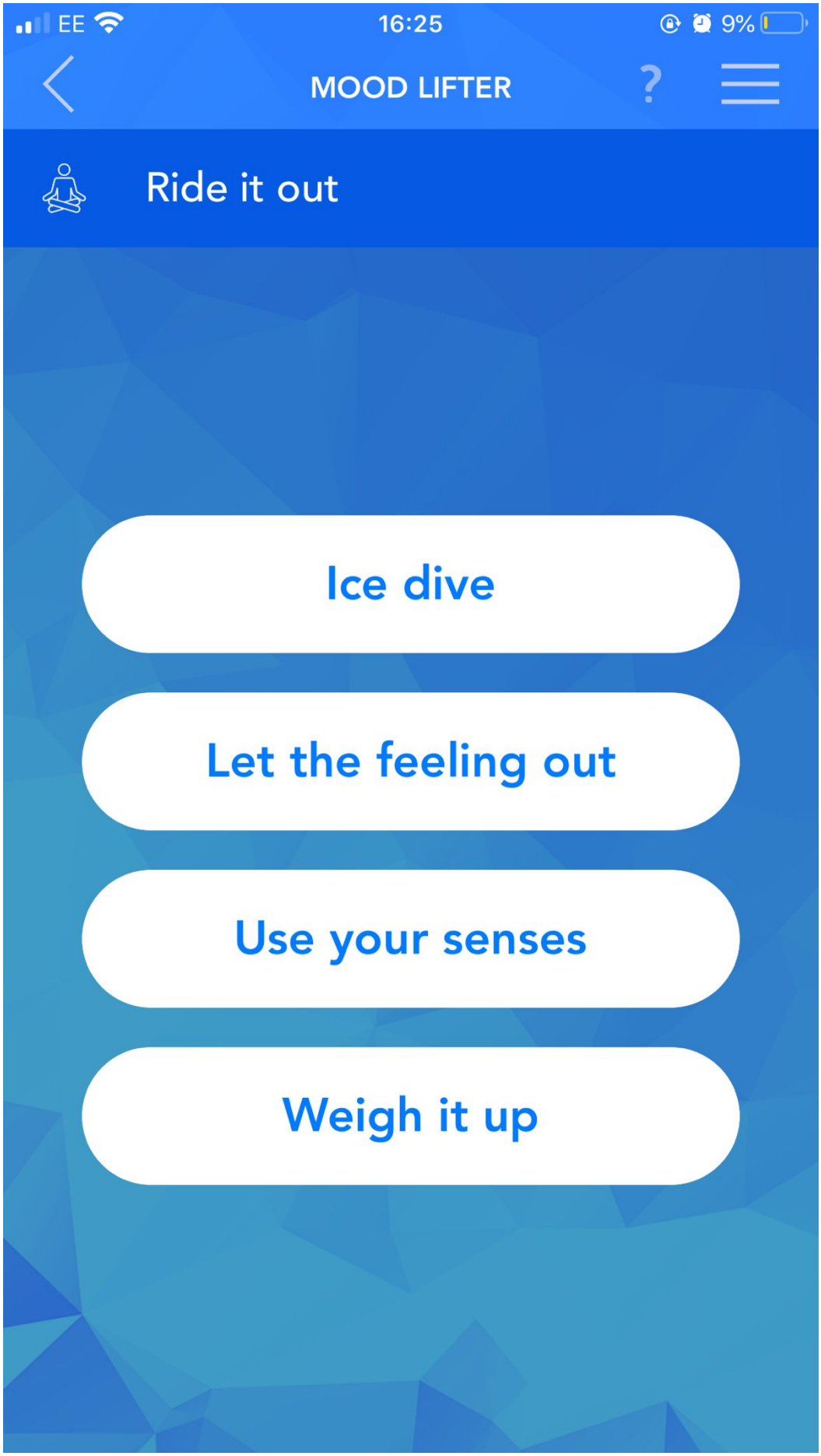

EE
16:29
8%
MOOD CHECKER
How are you feeling today?
Sad
Unhappy
Really sad
Other
?
Really Happy
OK
Happy
Upbeat

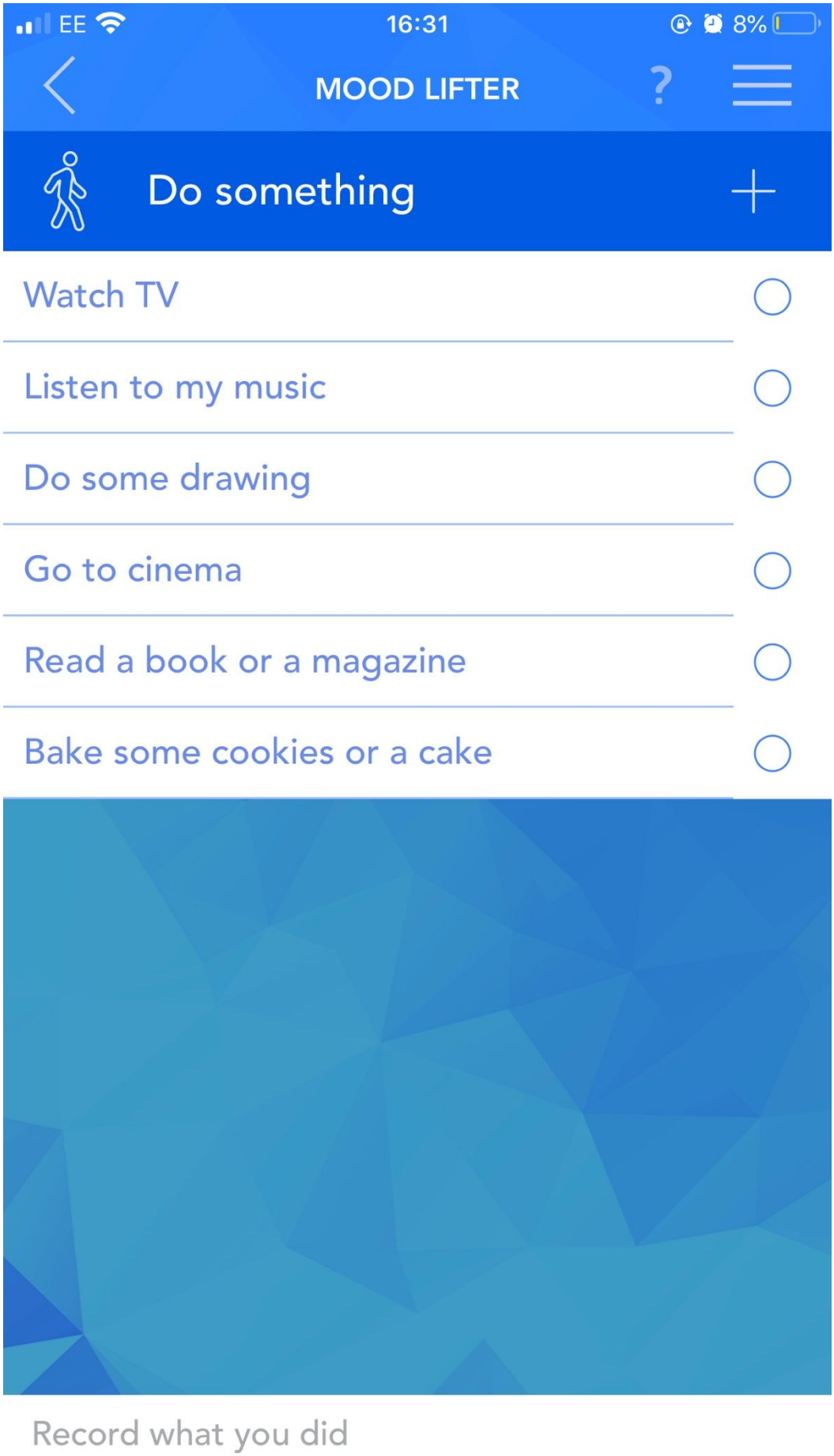

EE
16:12
10%
MOOD DIARY
September 2020
S M T W T F S
1 2 3 4 5
6 7 8 9 10 11 12
13 14 15 16 17 18 19
20 21 22 23 24 25 26
27 28 29 30
Really Sad
15:48
1 note
Had an argument with my partner

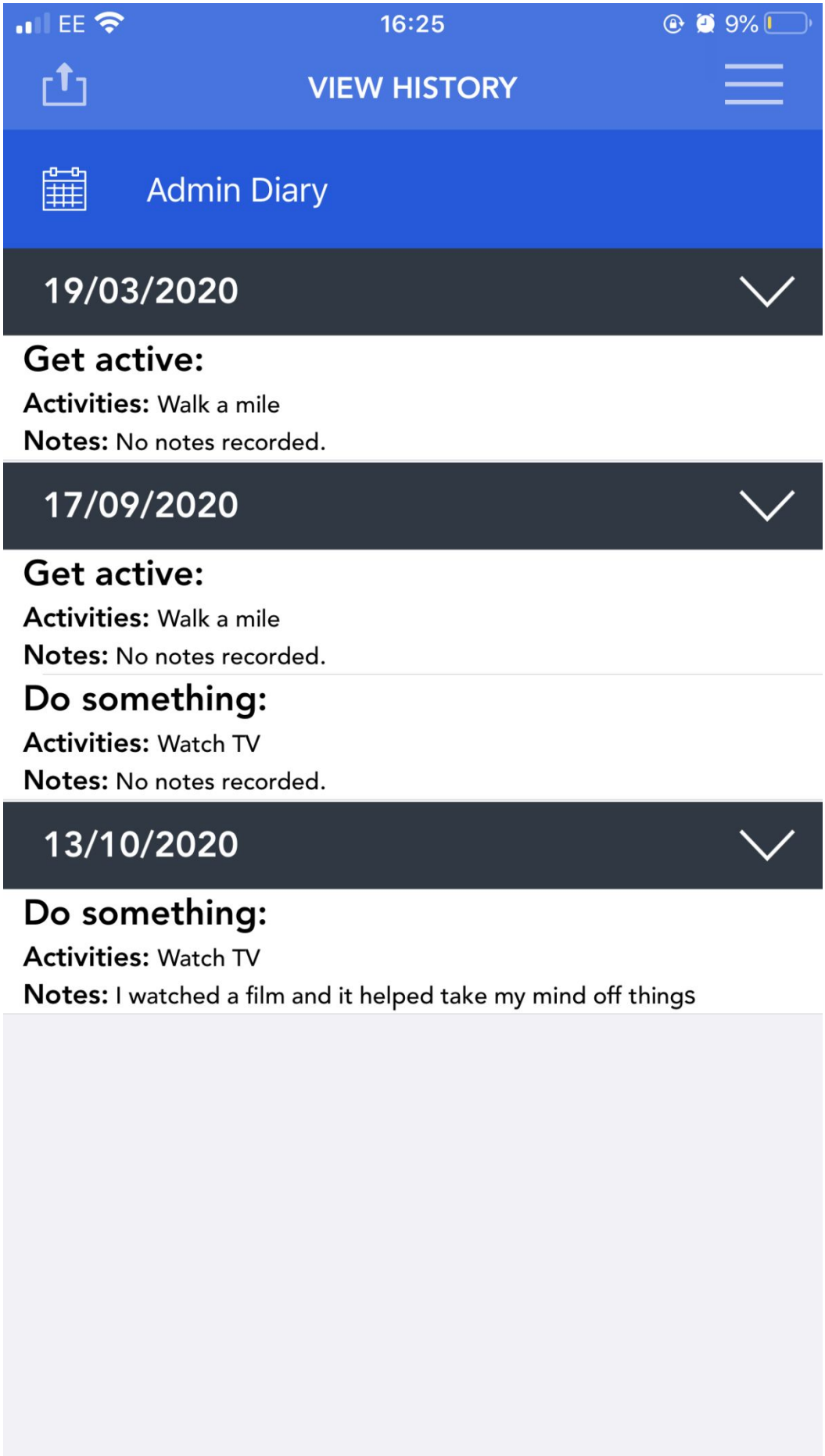

EE
16:29
8%
Done
MOOD LIFTER
Get active
Do something
Chill & relax
Thinking traps
Good times
Contact friends
Listen & relax
Ride it out


EE
16:15
10%
MOOD LIFTER
Thinking traps
Thinking traps
Sometimes we become caught in thinking traps (unhelpful ways of thinking).
Understanding and challenging these can help you to put things in perspective and to feel better.
OK


EE
16:24
9%
MOOD LIFTER
Chill & relax
Mindfulness
Breathing
Calming waves


EE
16:25
9%
MOOD LIFTER
Ride it out
Ice dive
Let the feeling out
Use your senses
Weigh it up


EE
16:31
8%
MOOD LIFTER
Do something
Watch TV
Listen to my music
Do some drawing
Go to cinema
Read a book or a magazine
Bake some cookies or a cake
Record what you did


EE
16:25
9%
VIEW HISTORY
Admin Diary
19/03/2020
Get active:
Activities: Walk a mile
Notes: No notes recorded.
17/09/2020
Get active:
Activities: Walk a mile
Notes: No notes recorded.
Do something:
Activities: Watch TV
Notes: No notes recorded.
13/10/2020
Do something:
Activities: Watch TV
Notes: I watched a film and it helped take my mind off things

BlueIce User Guide

Login

Set your log in PIN number to a number you will remember. You will be asked for your PIN each time you log on.

If you forget your PIN it can be reset by pressing the reset button. Unfortunately you will lose any notes or items your have saved.

How are you feeling today?

This is the home page where you can check your mood, talk to helplines or friends, or set your mood diary reminder. You can return to the Home page by tapping the top left menu and selecting home.

Mood checker

This is the mood wheel – tap the mood that best describes how you are feeling. You can add a note to explain why you are feeling like this.

Mood diary

This is a record of the moods you have entered. You will see a calendar and if you select a day you can see all the moods and notes you entered for that day.

Mood lifter

This is a toolbox of ideas to help you manage your emotions.

Add notes

Wherever you see 'record what you did' or 'type your notes here' tap the screen and a box will appear for you to add your notes. Your saved notes will appear in view history.

Add items

Wherever you see this button you can add your own items. You can do this in most of the mood lifter sections and in the Mood Diary.

Delete items

You can delete any items that you have added .

Apple/iOS: swipe left, tap delete

Android: Hold your finger on the item for two seconds. A box will appear and you can click edit, delete or cancel.

View history

Tap on the menu button and click view history. Here you can view your notes and all the things you entered that you tried to do on each day.

Privacy

All data you enter is stored on your phone. It is not transmitted or saved any where else unless you chose to download or send a copy

Download your entries

Tap the top right icon on this page to send a copy of the entries you have made to an email address.

Information

When you see this button you can tap it to find out more information. .

Set up mood diary reminder

On the Home screen you can set two reminders to record your mood each day. Set the time and click OK.

You can delete reminders by:

Apple/iOS: tap to open timer and select delete.

Android: hold your finger on the reminder time for 2/3 seconds and select the option to delete.

Exiting BlueIce

Open the top left menu and select logout.

Feedback

To send feedback to the BlueIce team open the top left menu and tap the feedback button.

This will create an email to the BlueIce team..

BlueIce is designed to be used alongside face to face work with a mental health worker.

If BlueIce isn't helping you then discuss this with your mental health worker.

The effectiveness and acceptability of a smartphone app (BlueIce) for university students experiencing self-harm thoughts/behaviours.

Experience of using BlueIce Questionnaire

1. Roughly how many times did you use BlueIce over the past 6 weeks?

☐ Once or twice

☐ Up to 5 times

☐ 6-12 times (up to once per week)

☐ Couple of times per week

☐ More often (please specify)

2. Did you personalise (i.e. add you own ideas to) the following sections of the mood lifter?

☐ Get Active (physical activities)

☐ Do something (get busy)

☐ Good times (photos)

☐ Listen and relax (music)

☐ Thinking traps (download your head)

☐ Contact friends (add 2/3 friends)

☐ Ride it out (soothing toolbox)

3. What sections of BlueIce did you use the most?

4. Did you set reminders to complete the mood diary?

☐ Yes

☐ No

5. Did you use the mood checker section to record your mood?

☐ Yes

☐ No

If NO – were there any reasons why?

_____

If YES – how often did you use it and was it helpful?

_____

6. Did you use BlueIce when you were distressed and felt like harming yourself?

☐ Yes

☐ No

If No – Were there any reasons why you didn't use BlueIce (e.g. didn't need to, forgot, didn't think it would help). ***Got to Question 9***

If Yes – Over the past 12 weeks how many times did you use BlueIce when you were thinking of harming yourself?

☐ Once or twice

☐ Up to 5 times

☐ 6-12 times (up to once per week)

☐ Couple of times per week

☐ More often (please specify)

7. Did BlueIce ever stop you from harming yourself?

☐ Yes

☐ No

If no, why do you think it didn't stop you from harming yourself?

If Yes, how many times did it stop you from harming yourself?

☐ Once or twice

☐ Up to 5 times

☐ 6-12 times (up to once per week)

☐ Couple of times per week

☐ More often (please specify)

8. Which sections of BlueIce helped you most when you were thinking of harming yourself?

9. Were there times when you self-harmed that you didn't use BlueIce

☐ **Yes**

☐ **No**

If Yes

- What stopped you from using BlueIce (no phone, forgot, feelings too intense)?

10. Were there any parts of BlueIce you found unhelpful, didn't like or didn't use?

11. Please read the statement below and indicate the extent to which you agree or disagree.

	Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree
BlueIce was easy to use					
BlueIce was helpful					
I prefer BlueIce to face to face meetings					
I would recommend BlueIce to other students					

12. Choose a number between 1-10 to show how much your self-harm has improved after using BlueIce?

1	2	3	4	5	6	7	8	9	10

No improvement Much improvement

13. Choose a number between 1-10 to show how much your mental health has improved after using BlueIce?

1	2	3	4	5	6	7	8	9	10

No improvement Much improvement

14. How many stars would you give BlueIce?
    - *
    - **
    - ***
    - ****
    - *****

15. Is life different for you now after using BlueIce and, if so, how is it different?

16. Will you continue to use BlueIce?

☐ Yes
☐ No
☐ Not sure

Umbrella code	Definition	Examples
User friendly (or not)	This code encapsulates the general design of BlueIce (i.e. the logo, the colours) as well as being user friendly (i.e. simple, not overwhelming, easy to use). Can also include more general design features e.g. passcode & privacy etc.	'Everything looks so happy on the phone. I mean, I like the color. The color is really good. The blue and white'
Engagement	Participants discussing their engagement (or lack of) with BlueIce, or motivation being a barrier to engage with it / the activities within it. Can also include references to not having the time to use it, or forgetting to use it because they need to be motivated to take those steps to engage. Different to heterogeneity because that's more acknowledging differences.	'for the things with the activity ones, I don't know, umm… for me, it's hard to engage in stuff like that.' 'I was just lacking the motivation, especially when I'm feeling low '
Further support required	References to the app lacking an element of interaction, whether it be generally with another human or with a clinician specifically. Can also include general references to BlueIce not being enough and needing more support. Can also include references to it not being 'enough', i.e. it is missing components e.g. psychoeducation or further explanations, not taking enough into account.	'I think I would need someone there with me and be like, OK, do this and that now really taking me, yeah, through all the steps'
Adjunct to therapy	Participants mentioning that BlueIce could work well alongside / in conjunction with therapy, or it being a useful first step to help get students to seek therapy/ realise they need therapy etc. NOT saying it wouldn't work without therapy and that it has to be alongside therapy.	'if it's if the therapist then says like, you know, homework wise or something, I'll always like have a diary. This could be my diary for example and I can note it down. And then because we can forget stuff and I could forget something significant, and then when I have to therapy session we can talk about everything and my feelings on that day and I think it would support yeah the counselling session.'
Positive impact	Positive comments about the mood diary helping students to track their mood, or alter their perspective on how they've been feeling. Also references to the app providing	'I write things down when I'm not feeling well, I write it out, it's kind of like a little bit of relief as well'

	them an outlet / providing relief from negative emotions/emotion regulation, allowing them to vent etc. Also talking about awareness of current mood.	
Unhelpful	Negative comments about the mood diary / app relating to the red days being unhelpful, not needing to track their mood, or the moods not capturing their emotional ranges.	
Safe	Participants saying that BlueIce is safe to use, it not having risks associated with it or it being helpful for students generally.	'Ohh no, no risks, no cause it's still like free to use the app whenever and I really didn't see anything on the app that kind of made me feel any negative emotions or anything.'
Heterogeneity	Any references to the individual experience of self-harm or of interventions, including comments about 'personally…' or 'others may be different…', acknowledging the importance of not providing a one size fits all approach.	'what works for me might not work for another person' 'I know that some people that would give it a chance, and I think it would be very, you know, helpful for them.'
Target populations	Participants saying that BlueIce could be helpful for specific groups of people, i.e., based on their self-harm (e.g. low level or 'new' to SH), mental health status (e.g. people with specific diagnoses like ADHD or dissociation) or demographics (e.g. age, students).	'Or maybe for a person even who is like really, you know, a shy person and not so really outgoing. And, you know, maybe doesn't want to talk to therapist or something for those people, maybe, you know, an app would be better option.'
Barriers to other interventions	Discussion of barriers to other services **but** only if this relates to BlueIce somehow, e.g., it would help to overcome these barriers like not having a waiting list or something. Include other digital interventions in this as well (helplines, websites, face to face). Accessible also relates to the ease of access of BlueIce both in the first instance (i.e. not having to join a wait list etc) and also in the moment (i.e. out and about). Includes references to it being on a phone which is easily accessed.	'also for the university, I know there's a long list waiting list for people to get therapy and stuff' 'because obviously it's an app and we are all just you know on our phones at the moment, phone is like, what would life be without the phone'

Toolbox	References to it being a helpful toolbox (e.g. everything in one place). Also comments on the extent of personalisation available of the toolbox, i.e. whether it's enough or not enough. Negative comments specifically about the suggestions in the mood lifter (e.g. going to the cinema or whatever)	'it's not really personalized as well you know like obviously it's just like a general thing'

Categories	Codes	Barrier	Facilitator
Intervention Specific factors			
Suitability		Heterogeneity	Target populations
Usability		Not user friendly	User friendly
Acceptability			Safe
		Unhelpful	
		Toolbox	Personalisation options
Person Specific Factors			
Motivation		Engagement barriers	
			Positive impact
Capability		Motivation	
Opportunity		Further support required	
			Barriers to other support
			Adjunct to therapy

BMJ Open

Is a smartphone application (BlueIce) acceptable and safe for university students who self-harm: an open study

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Primary Subject Heading:	Mental health
Secondary Subject Heading:	Public health, Qualitative research
Keywords:	MENTAL HEALTH, Suicide & self-harm < PSYCHIATRY, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS

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Is a smartphone application (BlueIce) acceptable and safe for university students who self-harm: an open study

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Abstract

Background: Many university students self-harm but few receive support. Smartphone apps have been identified as acceptable sources of support for students who self-harm, but the use of self-harm prevention apps is yet to be explored in this population.

Objective: This study sought to explore the acceptability and safety of a specific app (BlueIce) for university students who self-harm.

Methods: This was an exploratory, mixed methods study with 15 university students attending university wellbeing services with self-harming thoughts and/or behaviours. BlueIce was offered alongside the face-to-face support provided by the wellbeing service. Self-harming thoughts and behaviours, coping self-efficacy, and symptoms of anxiety and depression were measured before and after using BlueIce for 6 weeks. Follow up interviews were also undertaken to explore how students perceived BlueIce in more in depth.

Results: Following app use, there were statistically significant reductions in symptoms of anxiety (baseline M 12.47, SD 4.42; follow-up M 10, SD 4.16) $t(14) = 2.26$, $P = .040$, $d = .58$ and depression (baseline M 16.5, SD 5.17, follow-up M 12.27, SD 3.66) $t(13) = 5.50$, $P < .001$, $d = 1.47$. Qualitative findings showed participants found BlueIce to be acceptable, safe and helpful, and reported that they were more able to cope with difficult feelings and better understand their self-harm triggers following use of the app.

Conclusion: BlueIce was an acceptable, safe and helpful source of support for university students struggling with self-harm thoughts and/or behaviours. This builds on previous findings with adolescents and suggests that BlueIce could be a particularly acceptable and helpful resource for university students.

Strengths and limitations

- The first study to evaluate a self-help smartphone app with university students who self-harm
- Qualitative findings were evaluated using a pre-existing framework for evaluating engagement with digital interventions
- Semi-structured interviews provided rich feedback on how students perceived the app.
- Recruitment challenges meant a small sample size for the quantitative analyses.
- Students were only recruited from one university.

Introduction

Self-harm among university students

Self-harm, defined broadly in the current study as any intentional act of harm or injury directed towards the self irrespective of motivation [1] is particularly prevalent at universities, with a systematic review finding university students to be twice as likely to self-harm than their non-student peers [2]. In this review, studies measured self-harm on a range of scales, including lifetime, past four weeks, six months, 12 months and 3 years. The higher prevalence o fself-harm amongst students may result from the numerous challenges that they face while at university, associated with academic, financial, geographical and social stressors, which leave them more vulnerable to experiencing mental health difficulties [3]. A Canadian study estimated that around a quarter of students will self-harm while at university [4], however, self-harm often goes unreported due to the shame, stigma and misconceptions surrounding it that leaves many students unable to discuss their self-harm [5, 6, 7, 8, 9, 10]. This means that prevalence rates are often underestimated and that very few students who self-harm ever seek or receive professional help [11, 12]. This suggests that alternative options for support should be explored so that students who do not yet feel ready or able to discuss self-harm can still access other forms of support.

In a qualitative study, 25 United Kingdom (UK) university students with lived experience were interviewed about their opinions on support available for self-harm [13]. This study found that whilst some students appreciated the benefits of human connection that came with professional support, several barriers to seeking help were identified [13]. These included long waiting lists for mental health services, not wanting to take up support when they believed others may need it more, worrying about receiving a negative response upon disclosing self-harm, and feeling embarrassed and ashamed of self-harming. This study also explored how students perceive digital interventions, and found that they were viewed positively. In particular, students valued the anonymity, accessibility and convenience they can offer. In addition, students reported that they felt less exposed and inhibited compared to speaking with someone face-to-face, and noted how they always have their phones on them so could access a smartphone-based digital intervention anytime and anywhere [13].

These findings have been corroborated in the USA, with a survey of 479 college/university students showing that around three quarters had used or were using a digital mental health intervention, and high satisfaction rates were reported [14]. Interestingly, 91% of participants in this study indicated that they had experienced barriers to accessing mental health services. This further suggests that digital mental health interventions can bridge the gap between students and mental health support.

Research has also investigated the effectiveness of digital mental health interventions for university students. A systematic review found that digital interventions are effective in reducing symptoms of anxiety and depression, while also improving psychology wellbeing among students [15]. This was also found in a randomised controlled trial with UK university students, where use of a mental health app significantly improved anxiety and depression scores compared to a control group, and that these effects were sustained at follow up [16]. It therefore seems as

though digital interventions can be both acceptable to university students and effective in improving their psychological wellbeing.

Given the difficulties students face in seeking professional support for self-harm, coupled with the perceived advantages of digital support, a smartphone application (app) seems like a valued option. However, despite these potential benefits, no prior research has been conducted where university students have used and evaluated a smartphone app specifically developed to help manage self-harm [17].

BlueIce

A self-harm prevention app (BlueIce) has been evaluated with UK adolescents aged 12-17. Use of BlueIce was associated with a reduction in symptoms of anxiety and depression, as well as a reduction in the frequency of self-harm behaviours [18]. Qualitative findings also supported the app being acceptable, helpful and safe to use [19]. Given the positive findings from this app with adolescents (up to the age of 18 years), preliminary work subsequently investigated whether it could be acceptable to UK university students. In interviews, students were shown screenshots of the app while its functionality was explained to them. Feedback was positive with university students believing that BlueIce could help them manage their self-harm while also promoting positive mental wellbeing [20]. Students described how they believed BlueIce could provide relief in moments of distress by offering them distractions or outlets for their feelings, while also offering them longer term coping strategies to help manage their emotions.

Overall, it seems as though BlueIce is an effective and appealing intervention for self-harm that could also be beneficial to university students. However, while the perceived acceptability of BlueIce for university students has been initially explored, this is yet to be corroborated by students actually using the app.This study aims to build on previous work by exploring the acceptability and safety of BlueIce for university students using the app alongside attending university wellbeing services.

Methods

Design

This was an exploratory, open, mixed-methods study employing pre- and post-intervention questionnaires and follow-up interviews.

Patient and public involvement

This research was informed by participants' responses in a previous study [13] who gave guidance on how best to evaluate interventions for self-harm, meaning their expertise contributed to the choice of measures used here.

Recruitment

Participants were students at one UK University who were recruited via the university's mental health services. This sample was chosen to ensure that students had support in place should the app not be helpful, whilst being able to explore the safety of using the app in this population. The wellbeing service at this university is comprised of trained counsellors, wellbeing advisors and mental health advisors. They offer various forms of mental health support to students

experiencing mild mental health difficulties, or they are able to direct students to more appropriate external specialist support if required. Help available through the university includes talking therapy, counselling, workshops, support groups and self-help resources. Typically, support is available both virtually and in person on the university campus.

Wellbeing staff were informed about the study and the intervention by the researcher, and were asked to highlight the study to any students meeting the inclusion criteria stated below. Posters advertising the study were placed in the waiting room so students were also able to directly sign up for the study. Interested students were directed to an online information sheet with space to enter their email to receive more information about the study. They were then contacted by the researcher (BC) who discussed the study with them either over a call on Microsoft Teams or over email.

Students were eligible to participate if:

1) They were currently (within the past two months) experiencing self-harm thoughts or behaviours
2) They were receiving/due to receive counselling or wellbeing support from the university services
3) They were willing to participate
4) They owned a smartphone running iOS or Android.

Current self-harm was defined as within the past two months in line with the definition used within the K-SADS [21]. This was deemed appropriate to account for the often sporadic and spontaneous nature of self-harm. There were no exclusion criteria, including no specific exclusion criteria for participants who may have been at risk of suicide.. Given the broad definition of self-harm used in this study, differentiations were not made between suicidal or non-suicidal self-harm, meaning some participants in this study may have been experiencing suicidal thoughts. Clinical judgement was used on an individual case basis, as all potential participants were discussed with the university wellbeing service team lead to confirm suitability. All students who were interested in taking part were deemed suitable by the wellbeing team lead.

An information power approach was taken to determine the adequacy of the sample size for the qualitative analysis. Given the narrow aim of the study, the specificity of the experiences of the sample, the previous findings regarding the acceptability of BlueIce, and the in-depth dialogue within the interviews, a smaller sample of 10 participants was appropriate to address the research aims [22]. A further 5 participants completed the quantitative questionnaire but did not want to take part in an interview.

Intervention

BlueIce (https://www.oxfordhealth.nhs.uk/blueice/) was co-produced with young people with lived experience of self-harm, alongside clinical staff and academics. It has therapeutic grounding in both cognitive behavioural therapy and dialectical behavioural therapy [23] and was developed in line with guidance from the Medical Research Council [24]. In terms of safety, the app is pin-protected and no data is shared outside of the app. BlueIce contains a mood diary, emergency contacts and mood lifting activities that the user can add to and personalise. The

activities are informed by common reasons people self-harm and, again, have therapeutic underpinnings. They include photographs, music, physical activities, guided mindfulness recordings and breathing exercises, a thought diary, distress tolerance techniques, and phone numbers of people to contact when at risk of self-harming [23]. Currently, BlueIce is freely available on a prescription basis within participating child and adolescent mental health services, with the aim of becoming freely available to download via common app stores once the outcomes have been established. Please see appendix 1 for screenshots of the app.

Procedure

Data collection occurred between March 2021 and February 2022. Consent forms, baseline and post-use questionnaire data were collected using the Online Surveys software (https://www.onlinesurveys.ac.uk/). Post-use interviews for participants were conducted using Microsoft Teams and were recorded using the within-software capabilities. Once consent and baseline questionnaires were completed, participants were sent a text containing a unique link to download BlueIce. They were emailed a user guide (please see appendix 2) and a video demonstrating how to use the app. Participants were then free to use the app as they wished and were able to keep the app after the study ended. They attended treatment as usual with the university mental health services during the study but had no other contact with the research team until the follow-up questionnaires and interview six weeks later.

Measures

Self-Harm: To measure self-harm, the Alexian Brothers Urge to Self Injure Scale (ABUSI) [25] and the Ottawa Self-injury Inventory [26] were administered. The Ottawa self-injury Inventory includes a subscale about the addictive nature of self-harm, which was removed for the purposes of this study as it was deemed not to be necessary to address our research aims. These measures were chosen to capture both self-harm urges and behaviours, as there is evidence to suggest that thoughts of self-harm can still provide affect regulation [27] . Moreover, it has been found that even students who do not currently self-harm can still struggle significantly with urges to [13].

Anxiety: The Generalised Anxiety Disoder-7 (GAD-7) [28] is a brief measure that has shown good sensitivity at screening for anxiety disorders. Scores of 5 suggest mild anxiety, 10 suggest moderate anxiety and 15 suggest severe anxiety. It has also been well validated for use with university students [29, 30, 31].

Depression: The Patient Health Questionnaire-9 (PHQ-9) [32] is commonly used, has strong psychometric properties and has previously been used in a sample of UK university students [32]. A score of 5-9 suggests mild depression, 10-14 moderate depression, 15-19 moderately severe depression, and a score of 20-27 suggests severe depression.

Coping: The Coping Self-efficacy scale [33] consists of three subscales: stopping unpleasant emotions and thoughts, using problem-focused coping, and seeking support from family and friends. The total maximum score is 260, with greater coping self-efficacy indicated by higher scores. This measure has good psychometric properties [33] and has previously been used with university students who self-harm [34].

Acceptability of BlueIce: Following the six-week intervention period, participants were asked to complete a questionnaire about the acceptability of BlueIce [18, 19]. This questionnaire was developed by the researchers and explores engagement with the app, experience of using the app, and any impact that the app has had. Please see appendix 3.

Interview Schedule

Semi-structured interviews were conducted following the trial period that explored participants' experiences of using BlueIce and any impact they perceived it to have had on their mental wellbeing. The interviews were semi-structured and lasted between 15 and 45 minutes (M = 24.6, SD = 10.34). The interview schedule was designed by BC and was informed by previous interview schedules used to determine the acceptability of BlueIce with adolescents [19] and university students [20] (please see appendix 4). This began with an open question 'what did you think about BlueIce', with prompt questions asking for feedback on specific elements of the app used if participants struggled to answer. Questions were also included that asked about any perceived impact of BlueIce and whether they believed BlueIce could be helpful for other university students.

Data analysis

Descriptive statistics were used to summarise the sample with regards to demographic characteristics, self-harm characteristics and anxiety and depression symptomatology. Paired samples t-tests were used to assess pre-post change on quantitative measures.

Follow up interviews were analysed using qualitative content analysis [35] , to allow for both an exploration and quantification of the qualitative data. The transcripts were first transcribed verbatim by BC. All three coders (BC, KW, and EM) then read and re-read the transcripts until they had become immersed in the data. Three transcripts were picked at random for BC, KW and EM to code in order to develop a coding frame (please see appendix 5). No more than 10 key codes in the frame were aimed for, so as not to have more codes than transcripts, but ultimately 11 were settled on [36]. The rest of the transcripts were then independently coded in batches of two transcripts at a time, after which the three coders met to discuss and make any necessary adaptations to the coding frame. As there were more than two coders, Cronbach's alpha was used to measure inter-coder reliability, which suggested good agreement, $\alpha = .79$ [37].

While the codes and the coding frame were developed inductively and independently, BC, KW and EM identified that the codes aligned with a pre-existing framework of engagement with digital interventions [38]. The codes were therefore organised relative to the categories within this framework during analysis (please see appendix 6). The framework is divided into intervention-specific factors ('suitability', 'usability' and 'acceptability') and person-specific factors ('motivation', 'capability' and 'opportunity'), with codes exemplifying each category and barriers and facilitators to each. To operationalise this framework within the context of our findings, BC, KW and EM developed definitions for each of these categories:

Intervention-specific factors

Suitability: The suitability (or not) of this intervention with this population specifically, i.e., whether it could be feasibly implemented in this population.

Usability: Factors affecting the overall experience of using the app (e.g. enjoyment, ease of use) either positively or negatively to determine whether the app is fit for purpose.

Acceptability: Specific factors or features of the intervention (relating to the content and purpose) that the target population liked or disliked, as well as more general, overall perception of the app as acceptable or not.

Person-specific factors

Motivation: Whether the target population had enough reason to want to use it or not, both initially and more long term, because of the perceived need for the app or its perceived impact/ helpfulness. This relates to more internal drive factors, such as the extent to which they wanted to use it.

Capability: Whether the individual was able to use it or not and the barriers to this. Whereas motivation relates to more personal factors, capability relates more to externally influencing factors, such as being too busy.

Opportunity: Factors which improved or reduced participants' opportunities to receive support (for mental health and/or self-harm) via the app, as well as opportunities that the app provides or does not provide.

Ethical considerations

This study received ethical approval from the University Research Ethics Approval Committee for Health [EP 20/21 015]. Participants were provided with an information sheet detailing the study, allowing them a chance to ask any questions before giving informed consent. They were informed that they could drop out of the study at any time and without giving a reason, and that they would be able to remove their data from the study prior to anonymisation. Participants were made aware that their participation would be confidential and that all responses would be anonymised. Participants received no financial compensation for taking part.

Results

Sample characteristics

15 participants completed the baseline and follow-up questionnaires, and 10 participants completed the follow up interviews. Participants were mostly white (13/15, 87%), undergraduate (14/15, 93%) females (14/15, 93%) in their first year of study (10/15, 67%). All participants had self-harmed in the last 2 months (8/15, 53%) or were having thoughts of self-harm (7/15, 47%). Participants' ages ranged from 18-26 (mean 19.87, SD 2.39). Please see Table 1 for full participant demographics.

Table 1
Demographic characteristics of the sample

Demographic (N = 15)		n (%)
Age	18-20	11 (73%)
	21-23	3 (20%)
	24+	1 (7%)
Gender Identity	Female	14 (93%)
	Male	0 (0%)
	Non-binary	1 (7%)
Year of Study	1	10 (67%)
	2	1 (7%)
	3	3 (20%)
	4	1 (7%)
Degree type	Undergraduate	14 (93%)
	Postgraduate	1 (7%)
Ethnicity	White	13 (87%)
	Asian/Asian British	1 (7%)
	Black/African/Caribbean/Black British	1 (7%)
Sexuality	Heterosexual	8 (53%)
	Bisexual	5 (33%)

	Prefer not to say	1 (7%)
	Pansexual	1 (7%)
Self-harm Status	Current self-harm[a]	8 (53%)
	Current thoughts of self-harm[a]	7 (47%)

[a] This is defined as being within the past two months

Anxiety, depression and coping

Scores of the GAD-7 suggested that anxiety symptomatology was high within the sample (mean 12.47, SD 4.42), with many participants (12/15, 80%) experiencing at least moderate anxiety. Similarly, all participants were experiencing symptoms of at least mild depression (mean 16.50, SD 5.17), with a third (5/15, 33%) experiencing severe depression. On average, participants in this study seemed mildly confident in their abilities to cope (mean 92.93, SD 33.37), although this is lower than has been found in other samples of students who self-harm (e.g., mean 140.25, SD 48.26 [30].

Self-harm

Questions regarding the prevalence of self-harm thoughts and behaviour did not specify a timeframe that they had to have occurred within so that those who had not self-harmed within the last two months were still able to provide insight into what their self-harming behaviours were typically like. Within the two weeks prior to joining the study, most participants had thoughts of self-harming rarely or occasionally (9/15, 60%) and had self-harmed never or rarely (12/15, 80%). However, when they occurred, urges to self-harm were typically rated as strong (10/15, 67%). Participants were divided on how difficult they found it to resist harming themselves in the past week, with half saying they had not found it at all difficult or had found it mildly difficult (8/15, 53%), while four participants had found it very hard or had been unable to resist harming themselves (27%).

On average, participants were aged 15 (SD 2.42) when they first self-harmed, although ages ranged from 10-19. Nearly all participants had last self-harmed within the past two years (14/15, 93%), with one participant not having self-harmed since 2011. Around a quarter of participants reported that they usually never tell anybody if /when they self-harm (4/15, 27%), while the most common sources of support sought were university counsellors (9/15, 60%) (this was expected given that participants were recruited through university wellbeing services) and friend(s) (8/15, 53%). Cutting was the most common method of self-harming among the sample (11/15, 73%), followed by hitting (6/15, 40%), scratching (5/15, 33%), interfering with wound healing (5/15, 33%) and banging head (4/15, 27%).When self-harming, only one participant (1/15, 7%) reported never feeling relief afterwards, and relief typically either lasted between 1-30 minutes (8/15, 53%) or for hours (5/15, 33%). When self-harming, between 1-60 minutes typically elapsed between thinking about it and acting upon it (11/13, 73%). Techniques most used to

distract themselves from self-harming were talking with someone (9/15, 60%), doing anything to keep their hands busy (8/15, 53%) and watching TV (8/15, 53%). On a scale of 0 – 4, participants were moderately motivated to stop self-harming (mean 2.93, SD .80) and felt moderately able to stop self-harming (mean 2.40, SD 1.12). The most common sources of treatment the sample had received were self-help (6/15, 40%) or university counselling (5/15, 33%). The function subscale within the Ottawa Self-injury Inventory determined that students typically self-harmed for internal emotion regulation (mean 12.69, SD 6.36), and were least likely to self-harm for sensation seeking (mean 1.36, SD 1.95). Only one participant (7%) had visited a doctor for their self-harm, and two participants (13%) had made a previous suicide attempt.

Quantitative Results

Differences before and after treatment

After the trial period, participants scored significantly lower on symptoms of anxiety as assessed by the GAD7 (mean 10.00, SD 4.16), $t(14) = 2.26$, $P = .040$, $d = .58$, and on symptoms of depression assessed by the PHQ 9 (mean 12.47, SD 3.66), $t(13) = 5.50$, $P < .001$, $d = 1.47$. Scores on the ABUSI were lower following the trial period (mean 11.07, SD 1.48) compared to before the trial period (mean 13.13, SD 6.66) although this difference was not statistically significant $t(14) = 1.49$, $P = .16$, $d = .38$. Similarly, scores on the coping measure were not statistically significantly higher after the trial period, however, scores for the 'stop unpleasant thoughts and emotions' subscale were significantly higher (i.e. improved) on post-measures (mean 28.60, SD 15.32) than on pre-measures (mean 21.80, SD 10.27), $t(14) = -2.36$, $P = .033$, $d = .61$. No scores on any measures were worse following the intervention period, and no adverse events were reported by wellbeing staff or participants.

BlueIce Use

Over the six weeks, the median use of BlueIce was between six and 12 times (5/15, 33%), with 3/15 (20%) using it a couple of times a week, every day and at least once a day, respectively. Two participants did not use BlueIce at all (15%), because they forgot to. Of the 13 participants who used the app, 11 (73%) personalised BlueIce by adding their own ideas to different sections of the app. Just over a third (5/13, 39%) set reminders to use the app, but everyone used the mood diary to track their mood. The majority (11/13, 85%) chose to use BlueIce in distressing moments when they felt like harming themselves, and almost half said that it did stop some episodes of self-harm (6/11*, 55%). Over half said that they definitely would continue to use BlueIce (8/13, 62%) with only one person reporting that they would not (1/13, 8%). On a scale of 0-4, participants rated that they typically found BlueIce easy to use (mean 3.54, SD .52) and helpful (mean 2.47, SD 1.20), and that they would likely recommend to others (mean 2.73, SD 1.16). On the other hand, participants were less sure that they preferred BlueIce to face to face meetings (mean 1.38, SD 1.30). On a scale of 1-10, participants indicated that they had experienced small improvements in their self-harm (mean 4.31, SD 2.50) and mental health (mean 3.46, SD 2.73) since using BlueIce. Out of five, on average participants gave BlueIce 3.46 (SD 1.05) stars.

**two participants did not answer this question*

Qualitative results

Qualitative interviews were completed with 10 participants.

Intervention-specific factors

Suitability: *Facilitators*

Although BlueIce was originally designed for adolescents, most participants felt that it was appropriate for university students. One participant commented that being designed for a younger population may have been beneficial as the app was simple to use:

'I didn't think it was [designed for adolescents]. It didn't look that way, although, like, I did like how clean and simple it was. I think it stops it being almost, like, distracting, and I liked how clean it looked' [012]

Two participants (20%) felt that the app would be particularly suitable for students who are more introverted or isolated and who may struggle to seek professional support:

'Or maybe for a person even who is, like, really, you know, a shy person and not so really outgoing. And, you know, maybe doesn't want to talk to a therapist or something, For those people, maybe, you know, an app would be better option.' [016]

Finally, four participants (40%) discussed how the scope of BlueIce seemed to extend beyond self-harm, as *'to me it seems like the kind of thing that most people would probably find useful' [008]*. Participants specified that it would also be suitable for students who are struggling more generally, for example with exam stress, anxiety, or frustration:

'*I think this could definitely be used by people who are dissociating or having other issues that aren't self-harm, like feeling really anxious for example, feeling really down, just not knowing what to do or feeling really overwhelmed, I think it could be used for a lot of different things' [006]*

Suitability: *Barriers*

Conversely, three participants (30%) also discussed how the intervention may not be suitable for everybody, as people have different experiences of self-harm and different needs from support:

'It seemed like a good app, but not so suited to the way I sort of deal with things… I sort of tried out some of the mood…what is it called? The… the ones where it's like methods of coping? I tried out some of those. And, I like, I just didn't find any of them sort of suited to me, like I've still not worked out any particular ways of dealing with it myself. So I think, like, yeah, I think it's good, just not for me.' [008]

This also exemplifies how there tended to be a recognition among participants that, even if BlueIce may not have been particularly suitable for them, they could see how it could be of value to others.

Usability: *Facilitators*
Participants typically found the app simple and easy to use. They appreciated it giving them prompts and guiding them through the app pages, as they noted how moments of distress can be overwhelming, making it difficult to organise thoughts independently:

'I really like the pages where you can answer questions and, like, the buttons because I hate, like, speaking. Like, in those moments I hate speaking. I hate like… I find it really hard sometimes, l can like, you know, write down my thoughts on, like, that page. But like, a lot of the time I just can't, like, I'm too overwhelmed or, like, I just, yeah, I don't know what I'm thinking, but having the questions or the little buttons like, I love that… because it just helps me so much be able to find what I need…So being given prompts, um, is really, yeah, I really, really like that.' [010]

The simplicity of the app design was highlighted by 7 participants, with references being made to it not being overwhelming with too many options. The aesthetics of the app were also praised by five participants (50%), who enjoyed the colour scheme, the icons, the inconspicuous nature of the app, the format, and the logo.

'Everything looks so happy on the phone. I mean, I like the color. The color is really good. The blue and white….And I think also, yeah, when I was doing it then, when the light is off in the night in bed, it had like this, I don't know, dreamy, calm effect of me, like a cloud or, I don't know, yeah, something like that. It does something to you, just the color and the design.'[016]

Four participants (40%) also felt that the app was private, and appreciated having the passcode so that nobody but them could access it. This helped users to feel more confident being open with the app, knowing that their thoughts and feelings would be kept secure.

'I would say the pin password that you set up, that you need to access the app, it was helpful and it create a sense of privacy and especially, I mean less so now because obviously I don't live at home, but there's part of me that likes the idea of, you know, say, if ever anyone was looking over my phone or trying to access my phone knowing that, you know, I wouldn't have to…you know, there'd be preventions, I won't have to feel like I was at risk of someone opening it up and seeing everything.' [013]

Finally, the option to set reminders to use the app was praised by 3 participants (30%), including one participant who did not use the app frequently, as they acknowledged that it would have helped them to engage more with the app if they had done so.

Usability: *Barriers*
While the majority of participants responded positively to the app design and content, one participant did not like the colours and would have preferred pastel colours that would have felt more soothing for them:

'Just generally thinking about the colour scheme (laughter) maybe more soothing colours, I know it's called BlueIce but maybe the calm of a slightly paler blue… I think a pastel kind of thing would be better' [003]

The other barriers to usability identified by one participant was that the music section within BlueIce did not link with Spotify, but only Apple Music or music saved on the user's phone, and that they were not able to select more than one photo at a time to upload to the 'good times' section.

Acceptability: *Facilitators*
Further to BlueIce being perceived as suitable and usable, participants also discussed how it was acceptable and safe to use. Four participants specifically discussed how they do not perceive any risks to BlueIce being widely used, as they *'really didn't see anything on the app that kind of made me feel any negative emotions or anything.' [016]*

One participant elaborated on how they were initially concerned that having an app for self-harm on their phone could be triggering and make them more likely to self-harm, but that they were glad that this was not the case:

'There was part of me that was a little bit nervous that having the app would make me focus more on self-harm and so therefore maybe, you know, like it would be in the forefront of my head because I'd be seeing the app on my phone everyday… but that didn't happen which was great, I think partly because the app itself is quite innocuous on my phone… it's not glaring at you that it's for self-harm.' [013]

Participants commented on the specific features within the app that they found helpful, for example the toolbox of mood lifting activities, as having these ideas suggested to them made it easier to find an alternative way of coping in the moment, rather than using self-harm, as the app helped them to remember other things they can do instead:

I think in the moment you can kind of, like, forget what you can do. I definitely always, like, don't know what to do, which means it [self-harm] becomes the only option, so just, like, being able to see in front of me that, like, there are things I can do to help, it just makes it easier.' [012]

Another benefit of the toolbox that was highlighted was the option to personalise it by adding the users own ideas to the different sections, as well as making notes of what they tried and whether it worked or not. Three participants (30%) discussed how this helped the app feel more tailored to them and to feel less impersonal.

Importantly, over half of participants (7/10, 70%) specifically mentioned the mood diary as being a positive feature of the app, as it meant that they were able to track how they had been feeling over previous days. Participants commented how this helped them to feel more aware of their mood and the reasons behind it:

'I like knowing what helps you, like if you need a break, what makes you, like, happy and like, looking back on times when you've been feeling, like, your best. But also knowing and understanding, like, when you're struggling, like, why that might be. I think just writing it down can definitely help' [012]

Further to helping users' to understand their moods and what mediates them, participants also discussed how the mood diary helped change their perspective, by helping them to acknowledge their good days as well as their bad:

'I also noticed something when I checked the calendar because, obviously I can see the color codes right, and I felt happy seeing, for example, three or four green ones instead of seeing like, you know, a red and orange and stuff like that. Yeah, I felt like this also had an impact on then how I felt when I saw it. You know, I was like, 'ohh actually I do have good days. My life is not only like, you know, so stressful and bad' because I can see all the green color.' [016]

Further to the mood diary helping users to be aware of their mood and improving their perspective, three participants (30%) also noted how it provided a useful outlet for them that offered some relief from their difficult emotions:

'I think it was great for kind of like, when I didn't feel well for just, putting like, you know, notes down about like, my emotions, what I'm feeling…I just noticed that, kind of, when I write things down when I'm not feeling well, I write it out, it's kind of like a little bit of relief as well' [016]

Acceptability: *Barriers*
Despite the mostly positive perception of the mood diary, one of the barriers to acceptability discussed by four participants was the mood diary being oversimplified. While some participants enjoyed the simplicity of the app, others felt that the spectrum of emotions available on the mood diary did not capture their range of experiences, and that the 'other' option was not sufficient:

'I guess sometimes the mood tracker, just because it only has emotions on one spectrum, so it's either just happy or sad. Even though there was an 'other' option, you could change the words but you couldn't change the colour of the, I dunno what you'd call it, but you can't change the colour of the thing' [001]

Another participant liked the idea of using a mood diary but found that, upon actually using it, that the reminders to track their mood made them more aware of it when they did not necessarily want to be:

'I've downloaded, like, other apps in the past to try and do this sort of mood tracker thing. I do quite like the idea of being able to see that, but then, when I actually did it…it, like, would just like, pop up in the middle of the day and it'd be like 'oh how am I feeling?'. And then I'd be like 'how am *I feeling?... well I'm not feeling terrible…' and I tend to sort of try and ignore that stuff generally when I can.' [017]*

Person-specific factors

Motivation*: Facilitators*
Further to the benefits and the impact of the mood diary, eight participants (80%) also discussed more general impacts of the app that maintained their motivation to engage with it. One participant mentioned how the app had had a positive impact on them as they were better able to manage their self-harm:

'I've definitely been struggling less… just being able to know that I could, like, track it somewhere, like, almost, like, put it in something, um, I thought was quite helpful. Just being able to almost like, confide in the app you know? It definitely stopped [self-harm] being such a regular occurrence' [012]

Six (60%) specified that they were motivated to engage with the app as they felt that it encouraged positive action that was beneficial for their wellbeing, *'it encourages me to do things that I know will help me, but I just normally can't be assed to do' [010].* Further to this, participants appreciated being made aware of numerous *'stress relieving techniques, and knowing there's like, more options out there, say like, I didn't want to do meditation one day, then I know I could find another one on there to help' [011].* In this way, the app proved to be a helpful resource for participants who used it to identify new strategies to help manage their emotions.

One specific way in which the app helped reduce urges to self-harm was in helping participants to regulate their emotions:

'I found it quite helpful…regulating my mood for the rest of the day, 'cause I found that once I acknowledged it on the app and could see that I'd, you know, acknowledged it and was aware of it, I kind of became less likely to, you know, snap at a family member, and stuff like that… Yeah, yeah 'cause like in the past, a lot of like, triggers for self-harm have been frustration related as opposed to kind of like, sadness related….and I imagine that if I hadn't necessarily had that outlet, I would have then become so frustrated I would have been tempted self-harm' [013]

Participants were also motivated to continue using the app as it helped to remind them of activities that they found joyful, and helped them to realise that these activities could be beneficial in managing self-harm as well as improving their wellbeing:

'I'd look at, like, the activity suggested and stuff like that and kind of… it would remind me that those things were things I wouldn't necessarily think to do, and that they would work. So I think like one of them was talking about, like going for walks and stuff, and it's like, I know I like walks and I know they distract me, but I never put two and two together and thought that maybe it would be good in that kind of scenario…The next day I went for a walk and kind of felt like absolutely amazing… But yeah, like, so I think that was again one of the other key things is that it made me kind of stop and take note of things that actually do help and make me associate them with, like, self-harm prevention rather than just them being like activities that I like to do…since getting it in the last six weeks, I've gone on quite a few walks that I may not have necessarily gone on if I hadn't thought like oh, hang on a minute, that's something that I could do and enjoy and that I could actually, like knew could have a positive effect on my mental health' [013]

Finally, continued use of the app was associated with learning strategies that work without necessarily having to have their phone on them:

'Even if I don't have my phone with me, I now have some of those ideas in my head 'cause once you use them, you know, once you've used the app for a bit, like, you can get - It it can help you

just get into a routine of, like, when you start to feel a certain way and know what works, uhm, stuff like the ideas on the app and stuff, what works, what doesn't' [010]

This suggests that the app was beneficial in helping participants to develop and maintain longer term coping strategies that they could use instead of self-harming.

Motivation: *Barriers*
Despite this, four participants (40%) also discussed the difficulties they faced in being motivated enough to use the app. Reasons for this included forgetting to use it, low mood hindering their motivation, being stressed, having low energy, and not believing that anything could help..One participant emphasised that the lack of external encouragement to engage with the app would make it harder to be motivated, as *'you have to remember, you have to like, very much like do it for yourself' [017]*

Further, three participants (30%) felt that they did not need the app as they did not have urges to self-harm.

Capability*: Facilitators*
Participants felt that BlueIce being a smartphone app meant that it was particularly suitable for university students, who are *'kind of stereotypically always attached to their phone' [13],* so for whom it would be particularly accessible and convenient. References were also made to BlueIce being more *'private' [011]* than person-based support, like counseling, for example.

Opportunity*: Facilitators*
Nine participants (90%) perceived BlueIce to be subject to fewer barriers of access as other services or interventions are, allowing more individuals the opportunity to access support. Barriers to other services discussed include long waiting lists, difficult referral processes, fees, lack of personalisation, lack of out of hours support' and support being 'scattered' across resources.

'But obviously compared to things like therapy and stuff, you have it 24/7. So in that way it it's so much better than therapy because, you know therapy, you know I, I get like twice a week for like an hour each time' [010]

Six participants (60%) discussed how BlueIce could also serve as a useful adjunct for people who are in receipt of professional support, by allowing them a space to track their thoughts and feelings between sessions:

'This could be my diary for example and I can note it down. And then because we can forget stuff and I could forget something significant, and then when I have to therapy session we can talk about everything and my feelings on that day, and I think it would support the counseling session.' [016]

Finally, one participant praised the opportunity to still be able to receive support without requiring any interaction:

'I think it might be quite helpful because, I know that there are times for me at least where if I'm not feeling great I don't like talking to people, but also, like, I don't exactly want to neglect my health either, so having that option to not have to talk to anyone but still sort of helping yourself in a way is really nice.' [001]

Opportunity: *Barrier*
Conversely, four participants (40%) also discussed how they do not perceive BlueIce as a replacement for professional support, as there are further opportunities for support that the app does not provide. Three participants (30%) noted how the lack of human interaction is a downside as they valued input from a mental health professional. One participant explained how this is important to them as they need firm direction in therapy in order to improve their wellbeing:

'What I have with my counselor now you know, sometimes he would say something and I'll be like… especially with me, with my personality and you know, not being able maybe to take help from other people, or not knowing what's best for myself, and then someone else telling me what to do… I'd already told him as well, 'you need to be a bit harsh with me'. I don't want anyone soft.' [016]

One participant commented on how they perceived the function of BlueIce to be more relative to in the moment distractions, whereas therapy is important for *'getting to the route of the problem, and I think that to get to the route of a problem it needs to be face to face, it needs to be individualised, and you wouldn't want a computer or something to go through that with you cos then it can get it wrong and that can have consequences and things' [003]*

Discussion

This exploratory study is the first to evaluate the acceptability and safety of a smartphone app (BlueIce) for university students who self-harm. Overall, the app was found to be acceptable and safe, as well helpful for participants to manage their self-harm and promote behaviour beneficial to wellbeing. Safety was determined quantitatively, with no scores on wellbeing measures deteriorating over the period, and qualitatively, with participants reporting that BlueIce was safe to use and presented no risks to students. Similarly, no adverse events were reported by participants or wellbeing staff. However, some limitations of the app were also noted, such as the motivation required to engage with it.

Comparison with prior work

Levels of anxiety and depression symptomatology within the sample were higher than have been found in clinical samples with similar age groups. For example, Bentley et al [39] found mean GAD-7 and PHQ-9 scores of 8.5 and 10.6 respectively, compared to 12.5 and 16.5 in the current sample. Interestingly, surveys of university students have found scores that are comparable to those found in non-student clinical populations; Akram et al [40] reported a mean GAD-7 score of 9.3 and a PHQ-9 score of 10.1 based on a sample of 1,273 students. This endorses findings that university students are at a significantly heightened risk of struggling with mental health difficulties [2, 41]. In the baseline measures all participants classed themselves as either having self-harmed within the past 2 months or as currently having thoughts of self-harm. Despite this,

in the two weeks prior, very few had self-harmed or had thoughts of self-harming. This raises interesting questions regarding how individuals who self-harm perceive their self-harm status. Claréus et al [42] investigated this and identified that individuals typically perceive themselves as having stopped self-harming if they had done so few times within the past month or year. However, some participants still did identify as someone who self-harms despite not having self-harmed within the past year. Importantly, it was found that how individuals perceive their recovery is more important than the time that has elapsed since the last act of self-harm. This corroborates the importance of asking participants to self-identify their self-harm status, rather than presuming they no longer self-harm in accordance with a certain time frame.

The current sample scored lower on measures of coping self-efficacy at baseline than in other studies of university students who self-harm [34]. It is important to acknowledge the context in which this research occurred, as the trial period was within a national lockdown due to the COVID-19 pandemic, in which everyone was encouraged to stay at home to stop the spread of the virus. Contact with anyone outside of the household was restricted. Consequently, many institutions closed, including universities, and most interaction had to occur in online spaces instead. This meant that university students were no longer attending in-person lectures, and the participants in this study were no longer attending in-person counseling sessions. This context may explain participants' lower coping self-efficacy, as students may have had less access to resources that positively impacted their abilities to cope, such as social networks [43]. A survey of 576 students did indeed find that the pandemic negatively impacted students' mood and wellness [44], suggesting they may have been particularly vulnerable during this time.

Despite this sample comprising students who had all disclosed self-harm to a mental health professional, a quarter of participants in this study indicated that they usually do not tell anybody when they self-harm. This suggests that, even for this group who have disclosed self-harm to a mental health professional and volunteered for a research study regarding a self-harm intervention, discussing self-harm can still be challenging. Importantly, this sample seemed to struggle more with self-harm urges than self-harm behaviours, with 12 participants indicating that they had self-harmed either rarely or never within the past two weeks, but with two thirds indicating that their urges to self-harm were strong. This reinforces the importance of measuring self-harm urges as well as behaviours, as they can be predictive of future self-harm and can still be very distressing for the individual [45, 46]. Moreover, a questionnaire completed by 1,296 students found that self-harm thoughts alone are still able to allow the individual relief from difficult emotions [47].

Generally, there was a high level of engagement with the app with several participants using it frequently, adding personalised content to the app, tracking their mood, and using BlueIce in moments of distress. High levels of engagement with BlueIce have also been found in previous studies with adolescents [48]. Despite the app originally being designed with and for adolescents, this did not seem to deter university students from engaging with it and finding it beneficial. Participants in this study typically praised the simplicity of the app and enjoyed the design, although some found the mood diary too simple to capture their experiences; this split in opinion replicates findings from the previous evaluation of the acceptability of BlueIce with university students [20]. Nonetheless, those who did benefit from the mood diary discussed how it helped them to manage their emotions by providing an outlet for them through which they could get

some relief from their difficult feelings, as well as being able to identify triggers for different moods. This mirrors findings from another study with young adults who self-harm, who found mood tracking via a smartphone app beneficial in managing emotions and identifying triggers [49]. Participants in the current study also found it helpful being able to reflect on their mood in difficult moments, as well as more broadly in order to gain perspective and feel more optimistic by realising that they do have good days as well as bad. These qualitative findings resonate with the quantitative findings showing an increase in participants perceived self-efficacy in being able to stop unpleasant thoughts or emotions following the trial period, rated using the coping self-efficacy scale [33]. It may be that the techniques participants learnt to manage their emotions, promote positive wellbeing and to cope in alternative ways as opposed to self-harm, as discussed above, may have contributed to their heightened beliefs in their abilities to stop difficult thoughts and emotions.

Around half of the participants indicated that BlueIce had stopped them from harming themselves at certain points. While this is important, previous research with university students with lived experience of self-harm highlighted that relying on a reduction in self-harm behaviours is not necessarily the best way to measure the success of an intervention [50], preferring a more holistic and wider perspective that also considers their general wellbeing [51]. In particular, university students who self-harm have emphasised wanting self-harm interventions to help them to learn more adaptive coping strategies and to address their broader mental health difficulties that are 'triggers' for their self-harm [13]. 80% of participants in the interviews discussed some positive impact of the app, including helping them to develop longer term, alternative coping strategies, and encouraging action that was beneficial for their wellbeing. As mentioned, participants' perceived abilities to stop unpleasant thoughts and emotions also improved. Further, participants in this study believed that BlueIce could help students struggling with a range of mental health difficulties, as well as typical university stressors such as exams. Overall, this would suggest that BlueIce typically aligned with university students' favoured outcomes of interventions. However, one participant did specify that professional support is necessary for getting to the route of the issue behind their self-harm. This reinforces the heterogeneity surrounding preferences for support that has been found previously [13, 52, 53], emphasising the need to ensure university students are able to access a variety of resources and sources of support.

The function that BlueIce could provide was explored, with participants suggesting it could be a helpful adjunct to counseling that allowed users to log how they had been feeling in between sessions to relay back to their counselor. Participants also discussed finding it helpful in moments of distress by reminding them of techniques to manage their emotions or distract themselves, without the user having to search for techniques themselves. The longer-term impact was also discussed, with participants commenting on having a better understanding of their triggers and how to manage their emotions, without even having the app in front of them. This confirms the perception identified in a previous study investigating the acceptability of BlueIce with university students, where it was identified as a useful reminder of adaptive coping strategies in difficult moments, as well as a means of learning ways of processing emotions [20]. This also reflects findings with adolescents, who reported that BlueIce helped them to reframe difficult thoughts and provided a helpful distraction [19]. This suggests that BlueIce could be a useful tool that is scalable, able to offer 'out of hours' support, can help students cope in difficult

moments, and reach more students who may be struggling with self-harm and feel unable to directly ask for help. Research into self-harm interventions in university settings is very limited, for example Nawaz et al [54] found only two studies meeting this criteria, neither of which were found to be effective in reducing self-harm. More research is needed to establish the effectiveness of BlueIce, nevertheless, the current study identifies it as a valuable and acceptable tool for students.

Limitations

Firstly, participants in this study all used the app alongside counseling provided by the university wellbeing services. As such, it is not possible to directly attribute the improvements in participants' wellbeing to either the counseling or the app. Similarly, participants were recruited from one university wellbeing service who had already sought help for their self-harm. These findings may not be representative of students attending other universities or those who self-harm but have not sought help. Similarly, the sample were demographically homogenous so these results may not generalise to students from other genders or ethnicities for example. As BlueIce was found to be safe to use, future research should seek to assess the impact of implementing BlueIce more widely with students in the general university population.

Secondly, this was an exploratory open study with a small number of participants and as such data is limited and must be interpreted with caution. Challenges to recruitment were experienced including problems accessing students during the university summer break and the COVID-19 pandemic when students were not physically present on campus. In addition, to maximise student safety, we recruited participants through the University wellbeing services but this meant that we had no direct access to possible participants. Steps were taken to try and mitigate these challenges, such as drafting email templates and eligibility checklists to reduce staff burden, but recruitment remained limited. Consequently, future research would benefit from a larger scale study to determine the effectiveness of BlueIce in this population.

Finally, this research occurred during a period of national lockdown due to the COVID-19 pandemic. This could have affected our results which may be lacking temporal validity.

Conclusion

In summary, BlueIce proved to be a safe, acceptable and helpful tool for university students attending face-to-face mental health services. Following use, participants reported that they had developed more adaptive coping mechanisms, were better able to identify triggers for self-harm, and had fewer symptoms of depression and anxiety. This mirrors previous research into the use of BlueIce among university students, adding further credence to its benefits for this population.

Further research is indicated using robust methodologies and appropriately powered cohorts to investigate these findings further.

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Competing interests

Paul Stallard designed the BlueIce app but receives no financial gain from the app or from this research. The other authors declare that they have no conflicts of interest.

Contributorship statement

All authors contributed to the draft of this manuscript. Bethany Cliffe completed data collection. Bethany Cliffe, Emma Moore and Kathryn Whittle completed qualitative data analysis. Bethany Cliffe completed quantitative data analysis. Paul Stallard provided supervision.

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Data sharing

Consent was not received from participants to make data publicly available.

References

1. NICE. Self-Harm [Internet]. 2013 Jun. (Quality Standard). Available from: https://www.nice.org.uk/guidance/qs34/resources/selfharm-2098606243525
2. Swannell SV, Martin GE, Page A, et al. Prevalence of Nonsuicidal Self-Injury in Nonclinical Samples: Systematic Review, Meta-Analysis and Meta-Regression. *Suicide Life Threat Behav* 2014;44:273–303. https://doi.org/10.1111/sltb.12070
3. Taliaferro LA, Muehlenkamp JJ. Risk Factors Associated With Self-injurious Behavior Among a National Sample of Undergraduate College Students. *J Am Coll Health* 2015;63:40–8. https://doi.org/10.1080/07448481.2014.953166
4. Griffin K, Twynstra J, Gilliland JA, et al. Correlates of self-harm in university students: A cross-sectional study. *J Am Coll Health* 2021;0:1–8. https://doi.org/10.1080/07448481.2021.1909049
5. Chandler A. Narrating the self-injured body. *Med Humanit* 2014;40:111–6. https://doi.org/10.1136/medhum-2013-010488
6. Long M. 'We're not monsters … we're just really sad sometimes:' hidden self-injury, stigma and help-seeking. *Health Sociol Rev* 2018;27:89–103.
7. Sheehy K, Noureen A, Khaliq A, et al. An examination of the relationship between shame, guilt and self-harm: A systematic review and meta-analysis. *Clin Psychol Rev* 2019;73(101779). https://doi.org/10.1016/j.cpr.2019.101779
8. Simone AC, Hamza CA. Examining the disclosure of nonsuicidal self-injury to informal and formal sources: A review of the literature. *Clin Psychol Rev* 2020;82(101907). https://doi.org/10.1016/j.cpr.2020.101907
9. Simone AC, Hamza CA. A longitudinal examination of predictors of nonsuicidal self-injury disclosures among university students. *J Clin Psychol* 2021;1(18). https://doi.org/10.1002/jclp.23277
10. Staniland L, Hasking P, Boyes M, et al. Stigma and nonsuicidal self-injury: Application of a conceptual framework. *Stigma Health* 2021;6:312–23. https://doi.org/10.1037/sah0000257
11. Fitzgerald J, Curtis C. Non-suicidal self-injury in a New Zealand student population: Demographic and self-harm characteristics. *N Z J Psychol* 2017;46:156–63.

12. Whitlock J, Eckenrode J, Silverman D. Self-injurious Behaviors in a College Population. *Pediatrics* 2006;117:1939–48. https://doi.org/10.1542/peds.2005-2543 PMID: 16740834
13. Cliffe B, Stallard P. University students' experiences and perceptions of interventions for self-harm. *J Youth Stud* 2022;0:1–15. https://doi.org/10.1080/13676261.2022.2033187
14. Topooco N, Fowler LA, Fitzsimmons-Craft EE, et al. Digital interventions to address mental health needs in colleges: Perspectives of student stakeholders. *Internet Interventions.* 2022;28:100528. https://doi.org/10.1016/j.invent.2022.100528
15. Lattie EG, Adkins EC, Winquist N, et al. Digital Mental Health Interventions for Depression, Anxiety, and Enhancement of Psychological Well-Being Among College Students: Systematic Review. *J Med Internet Res* 2019 Jul;21(7). https://www.jmir.org/2019/7/e12869 https://doi.org/10.2196/12869

16. Ponzo S, Morelli D, Kawadler JM, et al. Efficacy of the Digital Therapeutic Mobile App BioBase to Reduce Stress and Improve Mental Well-Being Among University Students: Randomized Controlled Trial. *JMIR mHealth and uHealth* 2020 Apr;8:e17767. https://doi.org/10.2196/17767
17. Barnett P, Arundell LL, Saunders R, et al. The efficacy of psychological interventions for the prevention and treatment of mental health disorders in university students: A systematic review and meta-analysis. *Journal of Affective Disorders.* 2021;280:381–406. https://doi.org/10.1016/j.jad.2020.10.060
18. Stallard P, Porter J, Grist R. A Smartphone App (BlueIce) for Young People Who Self-Harm: Open Phase 1 Pre-Post Trial. *JMIR MHealth UHealth* 2018;6:e32. https://doi.org/10.2196/mhealth.8917
19. Grist R, Porter J, Stallard P. Acceptability, Use, and Safety of a Mobile Phone App (BlueIce) for Young People Who Self-Harm: Qualitative Study of Service Users' Experience. *JMIR Ment Health* 2018 Feb;5(1). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5845106/ https://doi.org/10.2196/mental.8779
20. Cliffe B, Stokes Z, Stallard P. The Acceptability of a Smartphone App (BlueIce) for University Students Who Self-harm. *Arch Suicide Res.* 2022;0:1–17. https://doi.org/10.1080/13811118.2021.2022552
21. Kaufman J, Birmaher B, Brent D, Rao U, Flynn C, Moreci P, et al. Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version (K-SADS-PL): Initial Reliability and Validity Data. Journal of the American Academy of Child & Adolescent Psychiatry. 1997 Jul 1;36(7):980–8.
22. Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided by Information Power. Qual Health Res. 2016 Nov 1;26(13):1753–60.
23. Stallard P, Porter J, Grist R. Safety, Acceptability, and Use of a Smartphone App, BlueIce, for Young People Who Self-Harm: Protocol for an Open Phase I Trial. *JMIR Res Protoc* 2016;5:e217. https://doi.org/10.2196/resprot.6525
24. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008 Sep;337. https://www.bmj.com/content/337/bmj.a1655 https://doi.org/10.1136/bmj.a1655
25. Washburn JJ, Juzwin KR, Styer DM, et al. Measuring the urge to self-injure: Preliminary data from a clinical sample. *Psychiatry Res* 2010;178:540–4. https://doi.org/10.1016/j.psychres.2010.05.018

26. Cloutier PF, Nixon MK. The Ottawa Self-Injury Inventory: A preliminary evaluation. Abstracts to the 12th International Congress European Society for Child and Adolescent Psychiatry. *European Child & Adolescent Psychiatry*. 2003;
27. Martin J, Bureau JF, Cloutier P, Lafontaine MF. A Comparison of Invalidating Family Environment Characteristics Between University Students Engaging in Self-Injurious Thoughts & Actions and Non-Self-Injuring University Students. J Youth Adolescence. 2011 Nov 1;40(11):1477–88.
28. Spitzer RL, Kroenke K, Williams JBW, et al. A Brief Measure for Assessing Generalized Anxiety Disorder: The GAD-7. *Arch Intern Med*. 2006;166:1092. https://doi.org/10.1001/archinte.166.10.1092
29. Bártolo A, Monteiro S, Pereira A. Factor structure and construct validity of the Generalized Anxiety Disorder 7-item (GAD-7) among Portuguese college students. *Cad Saúde Pública* 2017;33:e00212716. https://doi.org/10.1590/0102-311x00212716
30. Farrer LM, Gulliver A, Bennett K, et al. Demographic and psychosocial predictors of major depression and generalised anxiety disorder in Australian university students. *BMC Psychiatry* 2016;16:241. https://doi.org/10.1186/s12888-016-0961-z
31. Musiat P, Goldstone P, Tarrier N. Understanding the acceptability of e-mental health - attitudes and expectations towards computerised self-help treatments for mental health problems. *BMC Psychiatry* 2014;14:109. https://doi.org/10.1186/1471-244X-14-109
32. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9. *J Gen Intern Med*. 2001;16:606–13. https://doi.org/10.1046/j.1525-1497.2001.016009606.x
33. Chesney MA, Neilands TB, Chambers DB, et al. A validity and reliability study of the coping self-efficacy scale. *Br J Health Psychol* 2006;11:421–37. https://doi.org/10.1348/135910705X53155
34. Midkiff MF, Lindsey CR, Meadows EA, et al. The role of coping self-efficacy in emotion regulation and frequency of NSSI in young adult college students. *Cogent Psychol*. 2018;5:1520437. https://doi.org/10.1080/23311908.2018.1520437
35. Elo S, Kyngäs H. The qualitative content analysis process. Journal of Advanced Nursing. 2008;62(1):107–15.
36. O'Connor C, Joffe H. Intercoder Reliability in Qualitative Research: Debates and Practical Guidelines. *Int J Qual Methods* 2020;19:1609406919899220. https://doi.org/10.1177/1609406919899220
37. Gliem JA, Gliem RR. Calculating, Interpreting, And Reporting Cronbach's Alpha Reliability Coefficient For Likert-Type Scales. 2003 [cited 2023 Jul 7]; Available from: https://scholarworks.iupui.edu/handle/1805/344
38. Liverpool S, Mota CP, Sales CMD, et al. Engaging Children and Young People in Digital Mental Health Interventions: Systematic Review of Modes of Delivery, Facilitators, and Barriers. *J Med Internet Res* 2020;22:e16317. https://doi.org/10.2196/16317
39. Bentley KH, Sakurai H, Lowman KL, Rines-Toth L, McKowen J, Pedrelli P, et al. Validation of brief screening measures for depression and anxiety in young people with substance use disorders. Journal of Affective Disorders. 2021 Mar 1;282:1021–9.
40. Akram U, Ypsilanti A, Gardani M, Irvine K, Allen S, Akram A, et al. Prevalence and psychiatric correlates of suicidal ideation in UK university students. Journal of Affective Disorders. 2020 Jul 1;272:191–7.

41. Stallman HM. Psychological distress in university students: A comparison with general population data. *Australian Psychologist* 2010;45:249–57. https://doi.org/10.1080/00050067.2010.482109
42. Claréus B, Hasking PA, Gray N, et al. Is ceasing self-injury enough? Differences in psychological health between people reporting behavioral cessation of non-suicidal self-injury and those who consider themselves to have stopped self-injuring. *J Clin Psychol* 2022;jclp.23409. https://doi.org/10.1002/jclp.23409
43. Sahu P. Closure of Universities Due to Coronavirus Disease 2019 (COVID-19): Impact on Education and Mental Health of Students and Academic Staff. *Cureus* 2020 Apr;12(4). https://www.cureus.com/articles/30110-closure-of-universities-due-to-coronavirus-disease-2019-covid-19-impact-on-education-and-mental-health-of-students-and-academic-staff https://doi.org/10.7759/cureus.7541
44. Copeland WE, McGinnis E, Bai Y, et al. Impact of COVID-19 Pandemic on College Student Mental Health and Wellness. *Journal of the American Academy of Child & Adolescent Psychiatry*. 2021;60:134-141.e2. https://doi.org/10.1016/j.jaac.2020.08.466
45. Burke TA, Ammerman BA, Hamilton JL, et al. Nonsuicidal self-injury scar concealment from the self and others. *Journal of Psychiatric Research*. 2020;130:313–20. https://doi.org/10.1016/j.jpsychires.2020.07.040
46. Miller M, Redley M, Wilkinson PO. A Qualitative Study of Understanding Reasons for Self-Harm in Adolescent Girls. *International Journal of Environmental Research and Public Health* 2021;18:3361. https://doi.org/10.3390/ijerph18073361
47. Martin J, Bureau JF, Cloutier P, et al. A Comparison of Invalidating Family Environment Characteristics Between University Students Engaging in Self-Injurious Thoughts & Actions and Non-Self-Injuring University Students. *J Youth Adolescence* 2011;40:1477–88. https://doi.org/10.1007/s10964-011-9643-9
48. Muscara F, Ng O, Crossley L, Lu S, et al. The feasibility of using smartphone apps to manage self-harm and suicidal acts in adolescents admitted to an inpatient mental health ward. *Digit Health* 2020 Nov;6. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7705813/ https://doi.org/10.1177/2055207620975315
49. Honary M, Bell B, Clinch S, et al. Shaping the Design of Smartphone-Based Interventions for Self-Harm. *Proceedings of the 2020 CHI Conference on Human Factors in Computing Systems* Honolulu HI USA: ACM; 2020:1–14. https://dl.acm.org/doi/10.1145/3313831.3376370
50. Owens C, Fox F, Redwood S, et al. Measuring outcomes in trials of interventions for people who self-harm: qualitative study of service users' views. *BJPsych Open* 2020 Mar;6(2). https://www.cambridge.org/core/journals/bjpsych-open/article/measuring-outcomes-in-trials-of-interventions-for-people-who-selfharm-qualitative-study-of-service-users-views/00B4C4A51CB7627AEBE960FAB87DCB04 https://doi.org/10.1192/bjo.2019.93
51. Knowles S, Sharma V, Fortune S, et al. Adapting a codesign process with young people to prioritize outcomes for a systematic review of interventions to prevent self-harm and suicide. *Health Expectations* 2022. https://onlinelibrary.wiley.com/doi/abs/10.1111/hex.13479 https://doi.org/10.1111/hex.13479
52. Carroll R, Metcalfe C, Gunnell D. Hospital Presenting Self-Harm and Risk of Fatal and Non-Fatal Repetition: Systematic Review and Meta-Analysis. *PLoS One* 2014 Feb;9(2). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3938547/ https://doi.org/10.1371/journal.pone.0089944

53. Hume M, Platt S. Appropriate interventions for the prevention and management of self-harm: a qualitative exploration of service-users' views. *BMC Public Health* 2007;7:9. https://doi.org/10.1186/1471-2458-7-9
54. Nawaz RF, Anderson JK, Colville L, Fraser-Andrews C, Ford TJ. Review: Interventions to prevent or manage self-harm among students in educational settings – a systematic review. Child and Adolescent Mental Health [Internet]. [cited 2023 Mar 3];n/a(n/a). Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/camh.12634


EE
16:12
10%
Please enter your PIN
C
1
2
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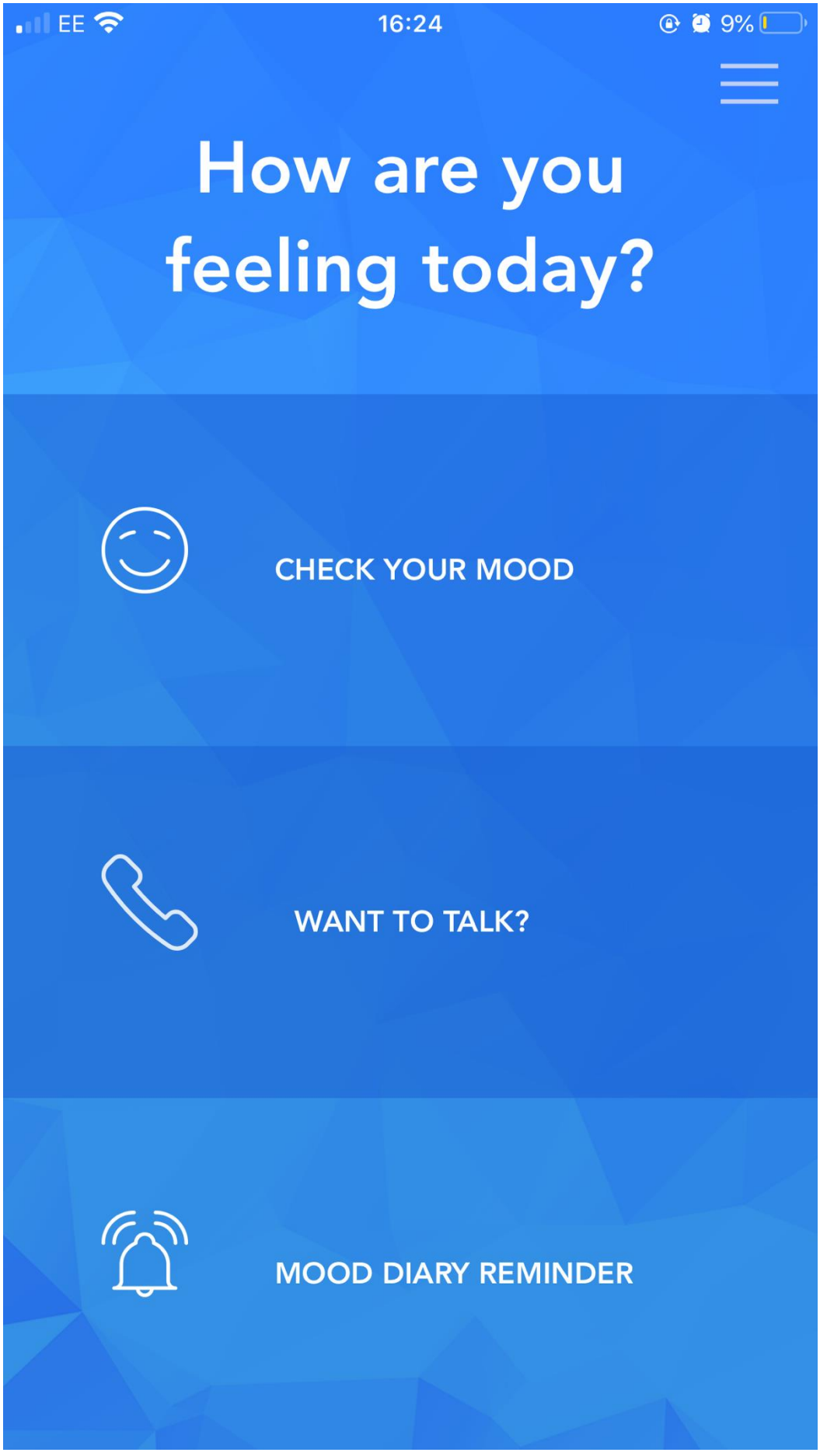
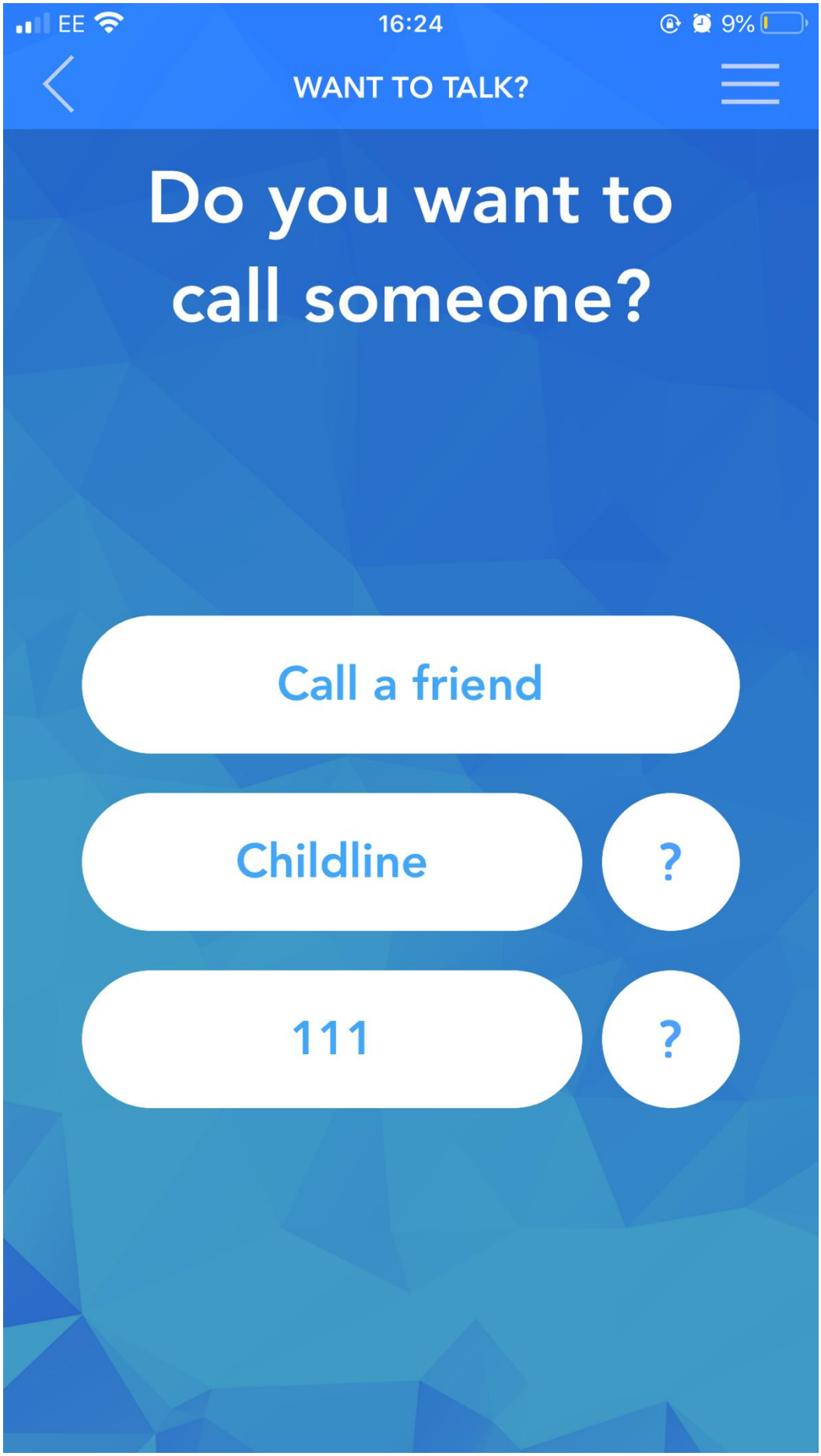
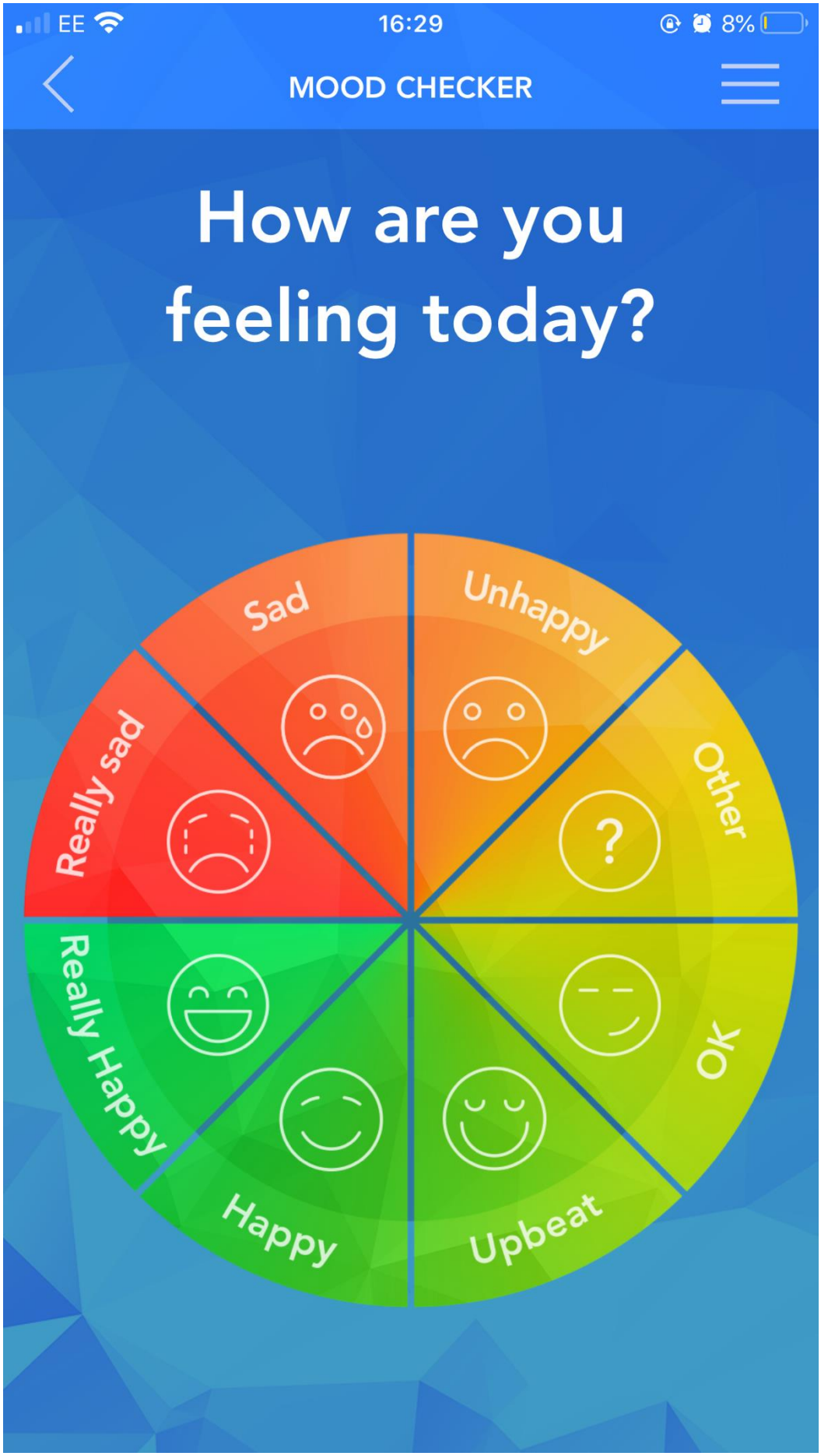
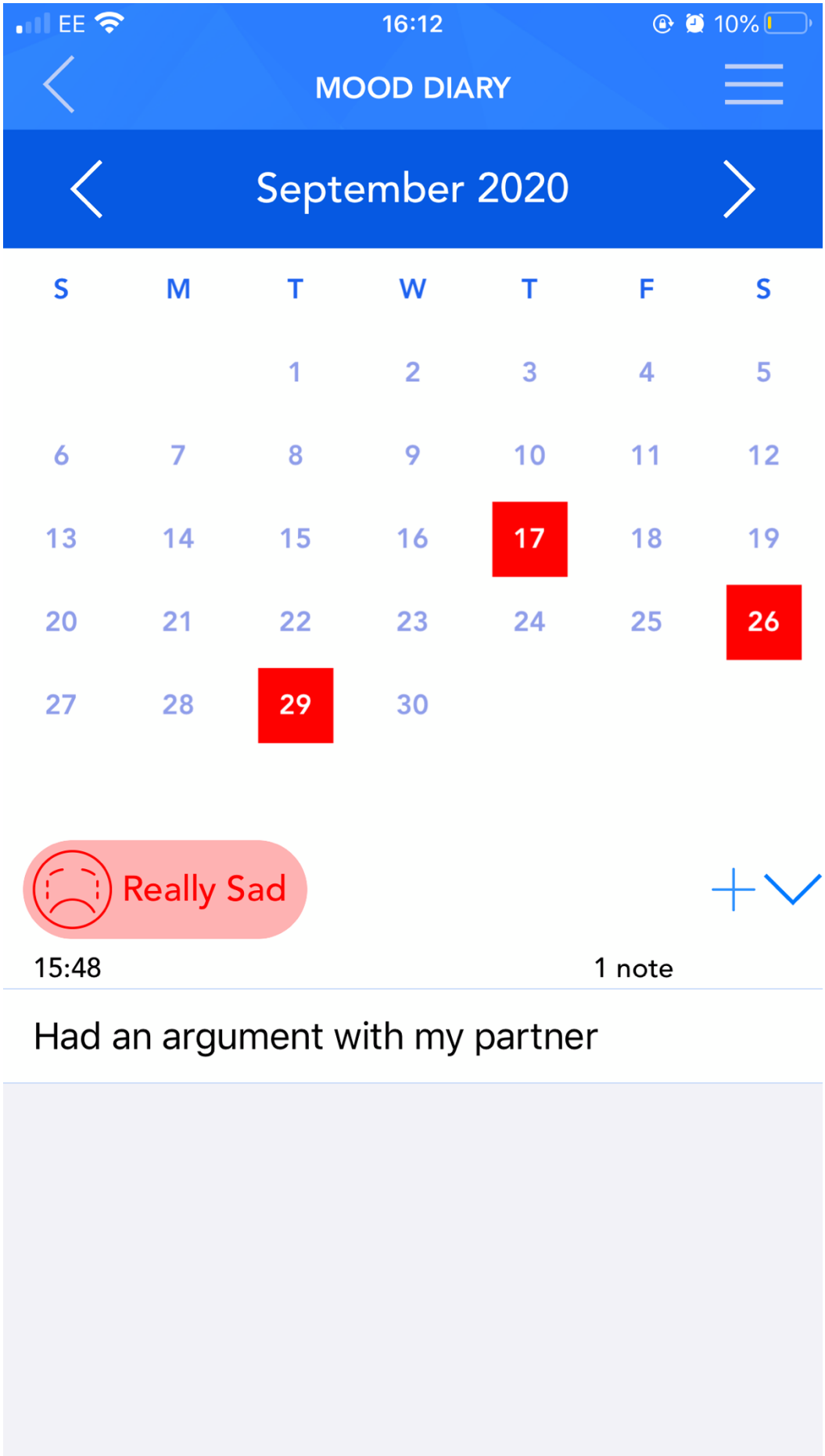
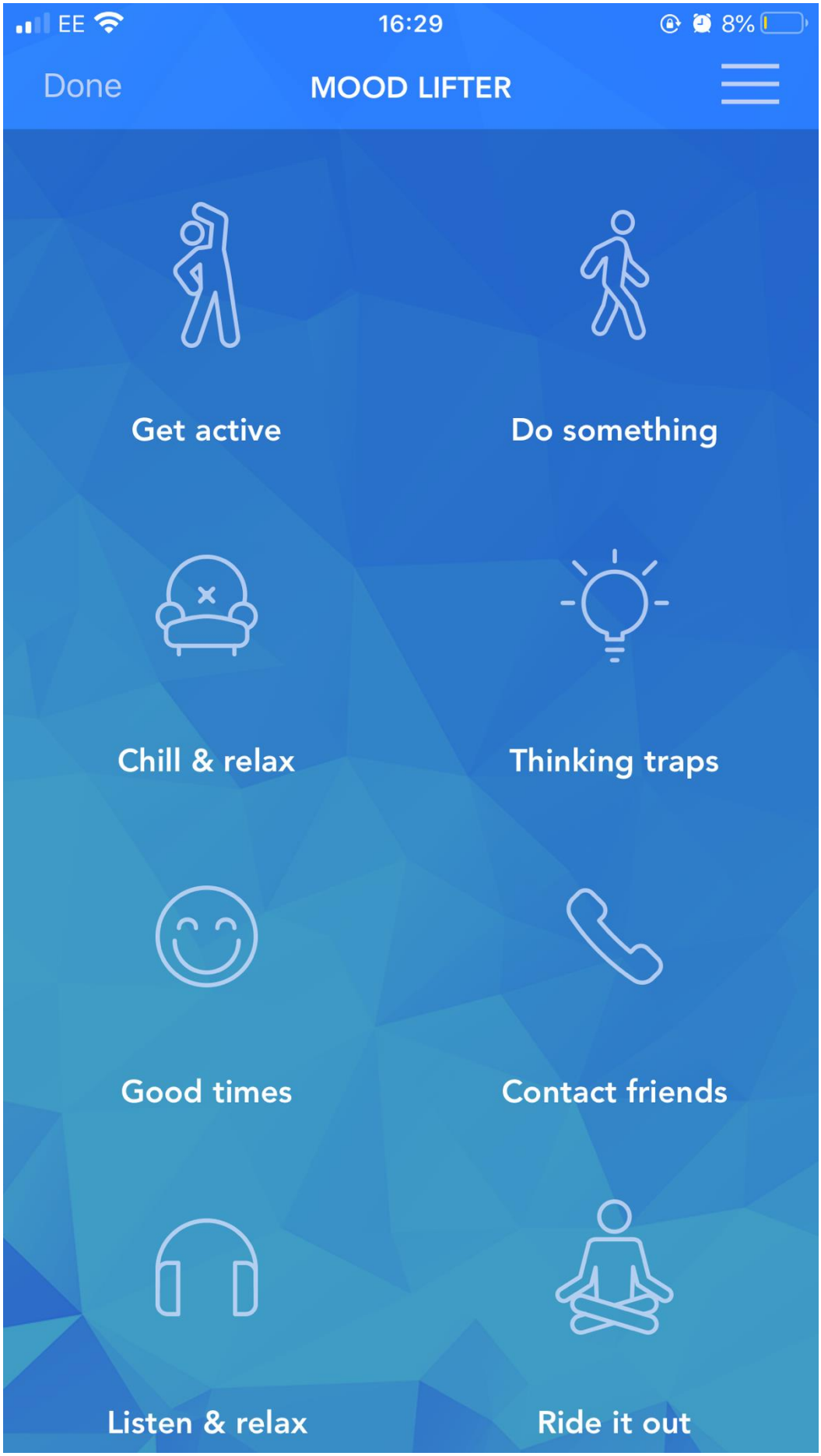
4
5
6
7
8
9
Reset
0
Enter

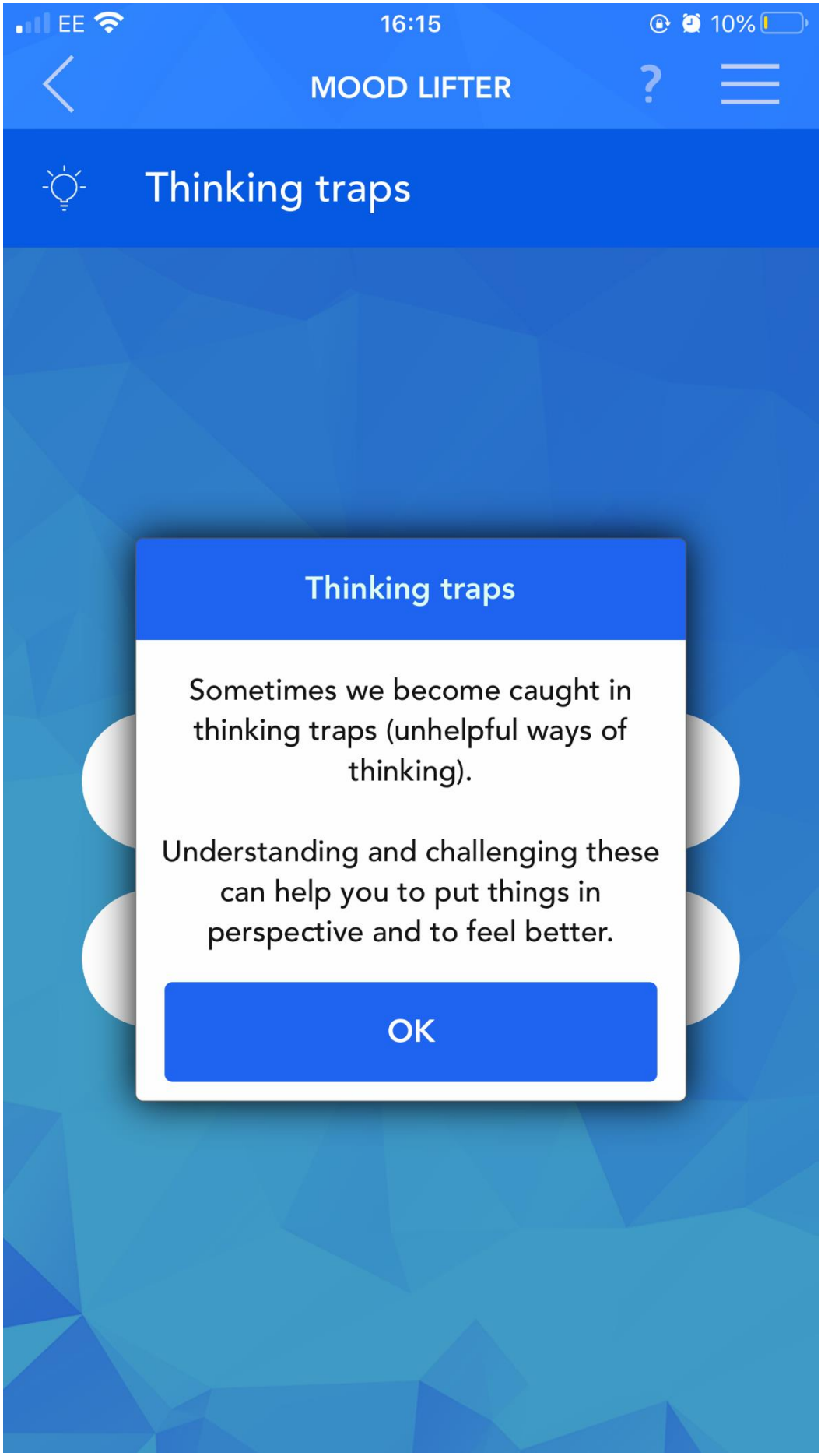

EE
16:24
9%
How are you feeling today?
CHECK YOUR MOOD
WANT TO TALK?
MOOD DIARY REMINDER

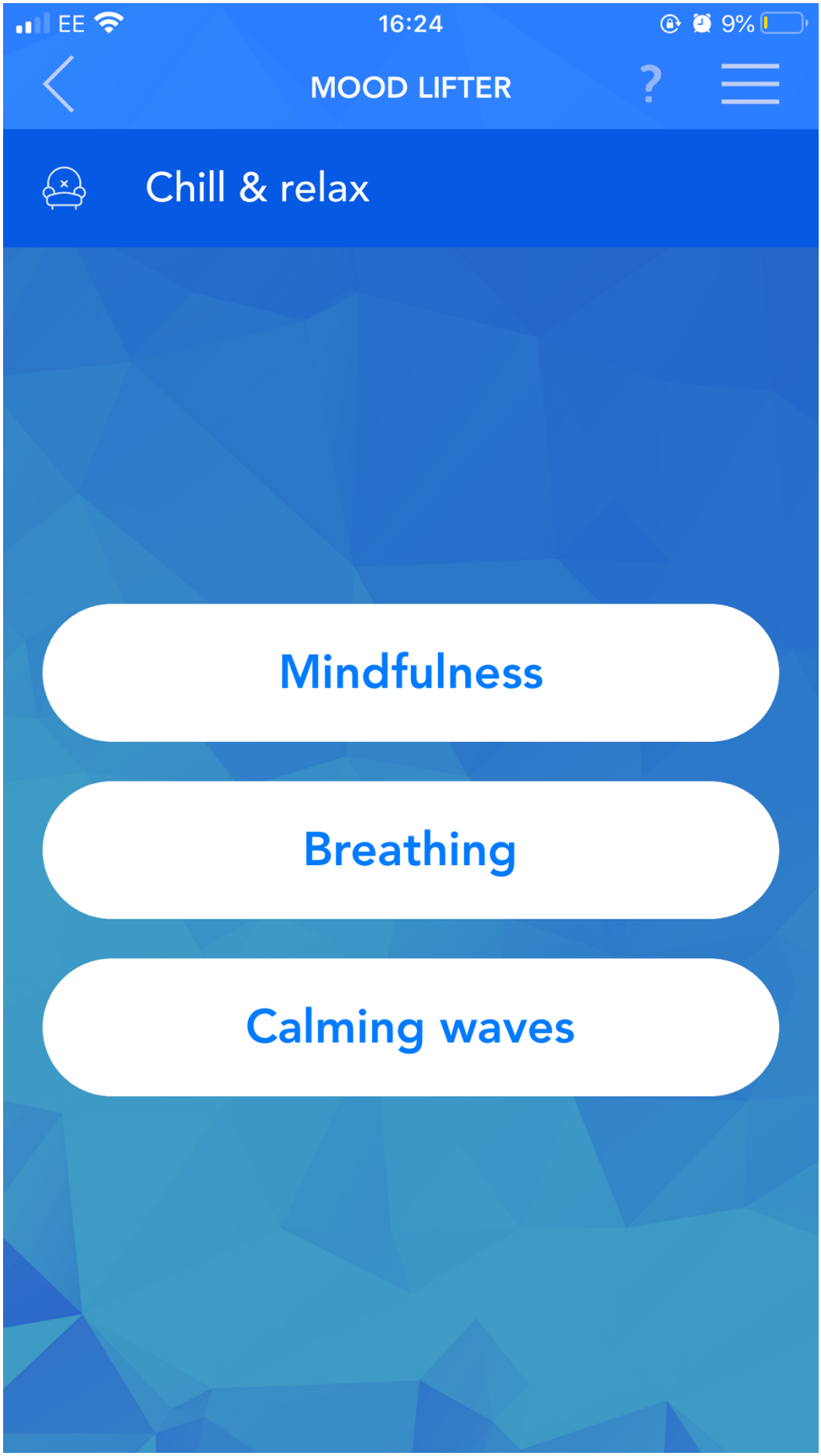

EE
16:24
9%
WANT TO TALK?
Do you want to call someone?
Call a friend
Childline
?
111
?

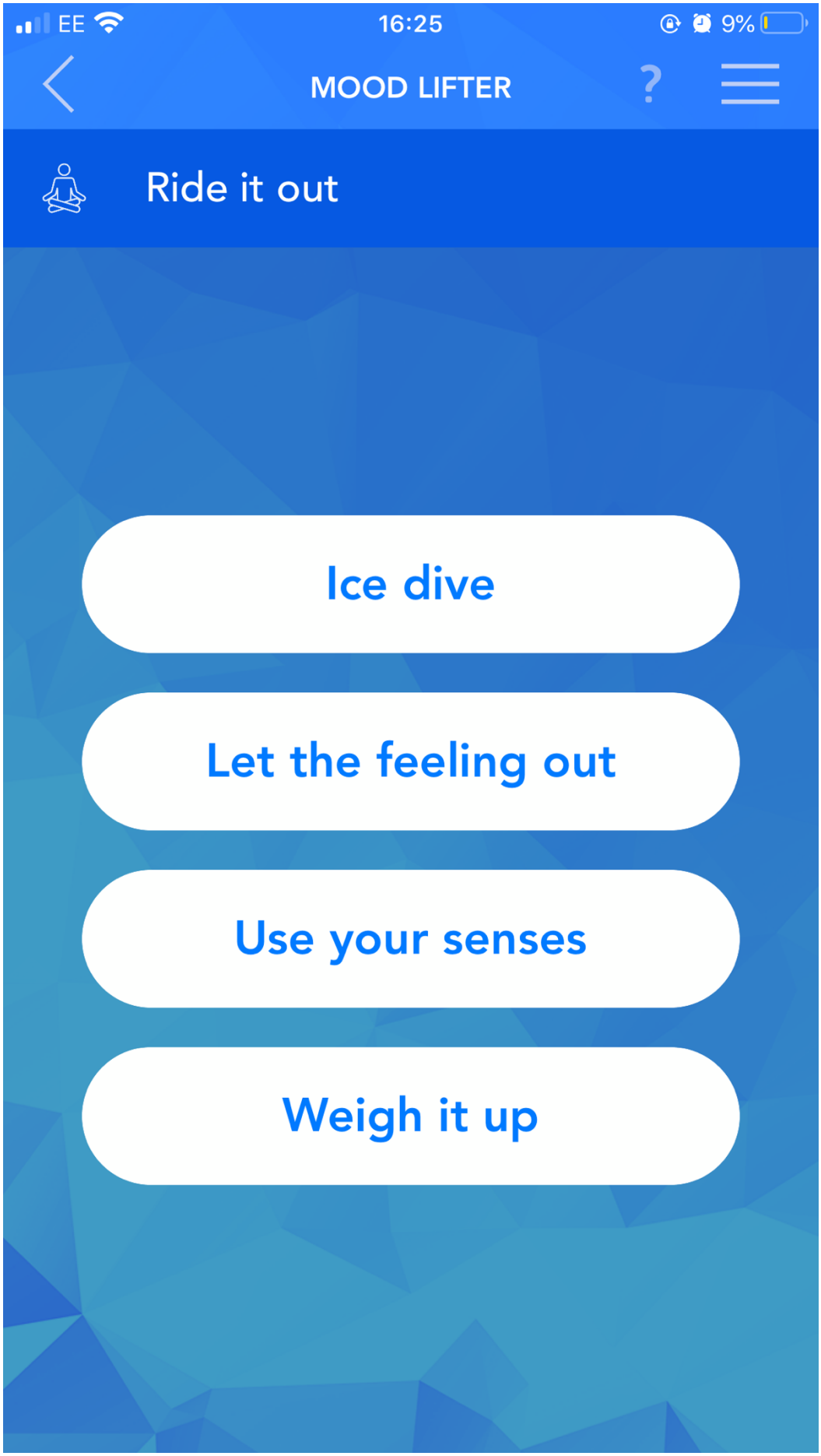

EE
16:29
8%
MOOD CHECKER
How are you feeling today?
Sad
Unhappy
Really sad
Other
?
Really Happy
OK
Happy
Upbeat

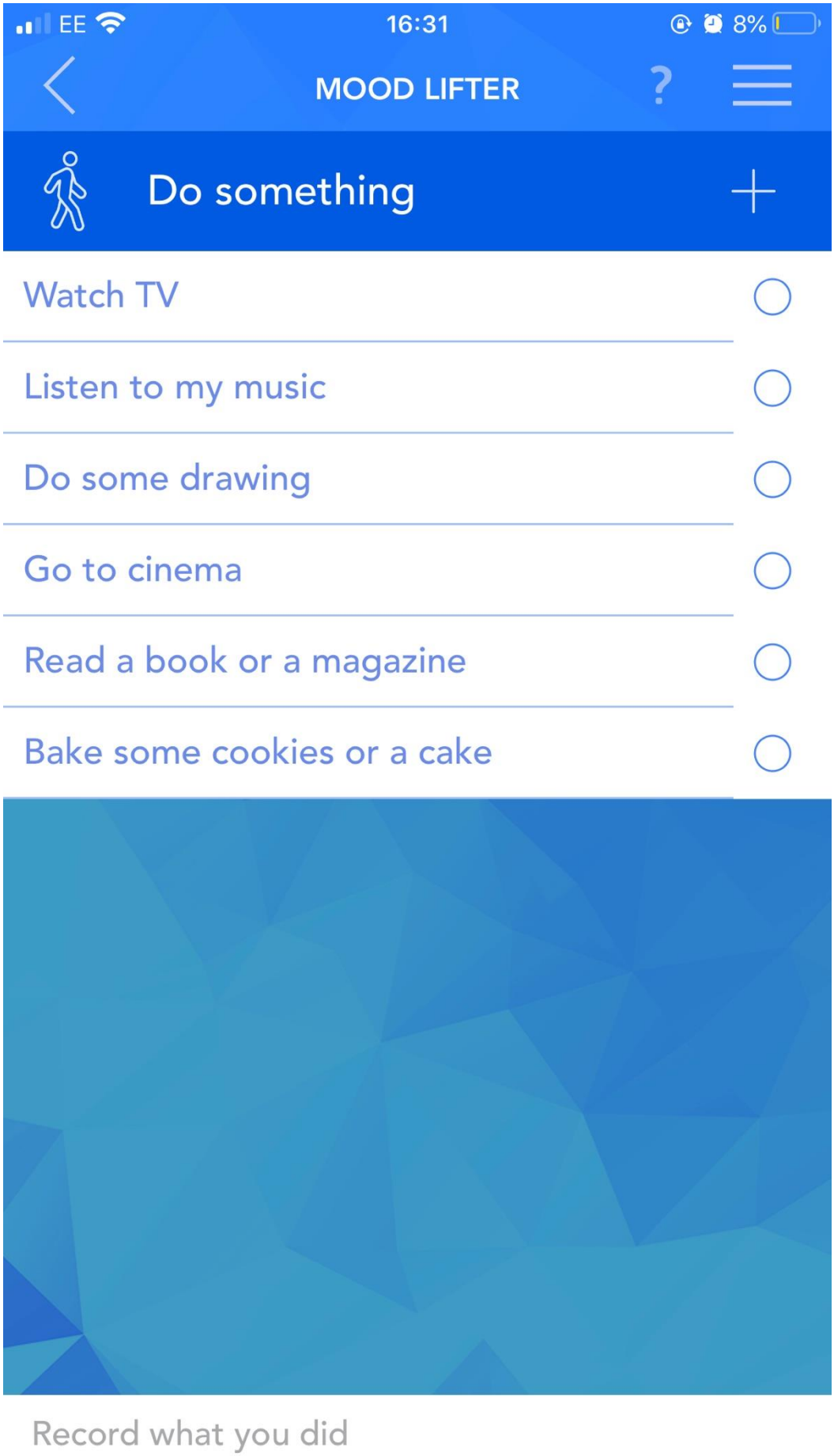

EE
16:12
10%
MOOD DIARY
September 2020
S M T W T F S
1 2 3 4 5
6 7 8 9 10 11 12
13 14 15 16 17 18 19
20 21 22 23 24 25 26
27 28 29 30
Really Sad
15:48
1 note
Had an argument with my partner

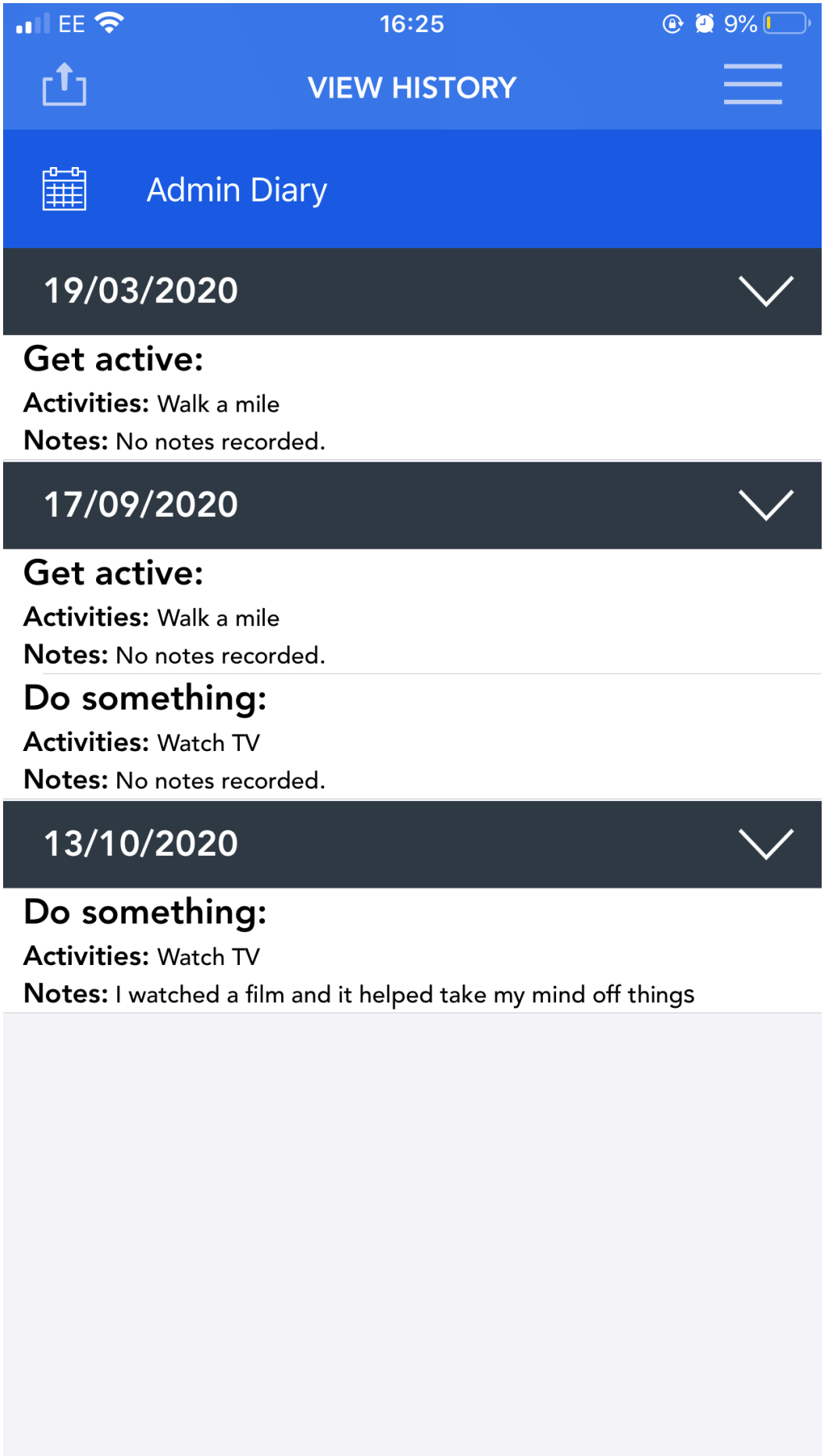

EE
16:29
8%
Done
MOOD LIFTER
Get active
Do something
Chill & relax
Thinking traps
Good times
Contact friends
Listen & relax
Ride it out


EE
16:15
10%
MOOD LIFTER
Thinking traps
Thinking traps
Sometimes we become caught in thinking traps (unhelpful ways of thinking).
Understanding and challenging these can help you to put things in perspective and to feel better.
OK


EE
16:24
9%
MOOD LIFTER
Chill & relax
Mindfulness
Breathing
Calming waves


EE
16:25
9%
MOOD LIFTER
Ride it out
Ice dive
Let the feeling out
Use your senses
Weigh it up


EE
16:31
8%
MOOD LIFTER
Do something
Watch TV
Listen to my music
Do some drawing
Go to cinema
Read a book or a magazine
Bake some cookies or a cake
Record what you did


EE
16:25
9%
VIEW HISTORY
Admin Diary
19/03/2020
Get active:
Activities: Walk a mile
Notes: No notes recorded.
17/09/2020
Get active:
Activities: Walk a mile
Notes: No notes recorded.
Do something:
Activities: Watch TV
Notes: No notes recorded.
13/10/2020
Do something:
Activities: Watch TV
Notes: I watched a film and it helped take my mind off things

BlueIce User Guide

Login

Set your log in PIN number to a number you will remember. You will be asked for your PIN each time you log on.

If you forget your PIN it can be reset by pressing the reset button. Unfortunately you will lose any notes or items your have saved.

How are you feeling today?

This is the home page where you can check your mood, talk to helplines or friends, or set your mood diary reminder. You can return to the Home page by tapping the top  left menu and selecting home.

Mood checker

This is the mood wheel – tap the mood that best describes how you are feeling. You can  add a note to explain why you are feeling like this.

Mood diary

This is a record of the moods you have entered. You will see a calendar and if you select a day you can see all the moods and notes you entered for that day.

Mood lifter

This is a toolbox of ideas to help you manage your emotions.

Add notes

Wherever you see 'record what you did' or 'type your notes here' tap the screen and a box will appear for you to add your notes. Your saved notes will appear in view history.

 Add items

Wherever you see this button you can add your own items. You can do this in most of the mood lifter sections and in the Mood Diary.

Delete items

You can delete any items that you have added .

Apple/iOS: swipe left, tap delete

Android: Hold your finger on the item for two seconds. A box will appear and you can click edit, delete or cancel.

 View history

Tap on the menu button and click view history. Here you can view your notes and all the things you entered that you tried to do on each day.

Privacy

All data you enter is stored on your phone. It is not transmitted or saved any where else unless you chose to download or send a copy

 Download your entries

Tap the top right icon on this page to send a copy of the entries you have made to an email address.

 Information

When you see this button you can tap it to find out more information. .

Set up mood diary reminder

On the Home screen you can set two reminders to record your mood each day. Set the time and click OK.

You can delete reminders by:

Apple/iOS: tap to open timer and select delete.

Android: hold your finger on the reminder time for 2/3 seconds and select the option to delete.

Exiting BlueIce

Open the top left menu  and select logout.

Feedback

To send feedback to the BlueIce team open the top left menu  and tap the feedback button.

This will create an email to the BlueIce team..

BlueIce is designed to be used alongside face to face work with a mental health worker.

If BlueIce isn't helping you then discuss this with your mental health worker.

The effectiveness and acceptability of a smartphone app (BlueIce) for university students experiencing self-harm thoughts/behaviours.

Experience of using BlueIce Questionnaire

1. Roughly how many times did you use BlueIce over the past 6 weeks?

☐ Once or twice

☐ Up to 5 times

☐ 6-12 times (up to once per week)

☐ Couple of times per week

☐ More often (please specify)

2. Did you personalise (i.e. add you own ideas to) the following sections of the mood lifter?

☐ Get Active (physical activities)

☐ Do something (get busy)

☐ Good times (photos)

☐ Listen and relax (music)

☐ Thinking traps (download your head)

☐ Contact friends (add 2/3 friends)

☐ Ride it out (soothing toolbox)

3. What sections of BlueIce did you use the most?

4. Did you set reminders to complete the mood diary?

☐ Yes

☐ No

5. Did you use the mood checker section to record your mood?

☐ Yes

☐ No

If NO – were there any reasons why?

_____

If YES – how often did you use it and was it helpful?

_____

6. Did you use BlueIce when you were distressed and felt like harming yourself?

☐ Yes

☐ No

If No – Were there any reasons why you didn't use BlueIce (e.g. didn't need to, forgot, didn't think it would help). ***Got to Question 9***

If Yes – Over the past 12 weeks how many times did you use BlueIce when you were thinking of harming yourself?

☐ Once or twice

☐ Up to 5 times

☐ 6-12 times (up to once per week)

☐ Couple of times per week

☐ More often (please specify)

7. Did BlueIce ever stop you from harming yourself?

☐ Yes

☐ No

If no, why do you think it didn't stop you from harming yourself?

If Yes, how many times did it stop you from harming yourself?

☐ Once or twice

☐ Up to 5 times

☐ 6-12 times (up to once per week)

☐ Couple of times per week

☐ More often (please specify)

8. Which sections of BlueIce helped you most when you were thinking of harming yourself?

9. Were there times when you self-harmed that you didn't use BlueIce

☐ **Yes**

☐ **No**

If Yes

- What stopped you from using BlueIce (no phone, forgot, feelings too intense)?

10. Were there any parts of BlueIce you found unhelpful, didn't like or didn't use?

11. Please read the statement below and indicate the extent to which you agree or disagree.

	Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree
BlueIce was easy to use					
BlueIce was helpful					
I prefer BlueIce to face to face meetings					
I would recommend BlueIce to other students					

12. Choose a number between 1-10 to show how much your self-harm has improved after using BlueIce?

1	2	3	4	5	6	7	8	9	10

No improvement Much improvement

13. Choose a number between 1-10 to show how much your mental health has improved after using BlueIce?

1	2	3	4	5	6	7	8	9	10

No improvement Much improvement

14. How many stars would you give BlueIce?
    - *
    - **
    - ***
    - ****
    - *****

15. Is life different for you now after using BlueIce and, if so, how is it different?

16. Will you continue to use BlueIce?

☐ Yes
☐ No
☐ Not sure

Experience of BlueIce Interview

1. What did you think about using BlueIce?
   Example prompt questions:
   - What did you think about the mood diary?
   - What did you think about the different techniques suggested?
   - Did you like the way it looked / was laid out?
   - Was it easy/hard to use?
   - Did you personalise BlueIce at all?
   - How does using BlueIce compare to other types of support for self-harm?

2. Do you think BlueIce has helped you to manage your self-harm / improve your wellbeing?
   Example prompt questions:
   - What techniques did you try that helped/didn't help?
   - What impact did BlueIce have on your self-harm/mood?
   - What bits specifically do you think helped / didn't help?
   - Do you think using BlueIce helped you learn or practice alternative coping strategies?

3. Why do you think BlueIce helped / didn't help you manage your self-harm and wellbeing?
   Example prompt questions:
   - How does it compare to other types of support you've had?
   - Were there any barriers to using BlueIce?
   - Do you think it's just BlueIce that isn't helpful for you, or smartphone apps in general?

4. Do you think BlueIce could be helpful for other university students?
   Example prompt questions:
   - Do you think students would use BlueIce?
   - What would the disadvantages and advantages be for other students using BlueIce?
   - Do you think if a student was struggling to ask for formal support, they may benefit from using BlueIce?

5. Is there anything else you would like to say about BlueIce or about this study, that hasn't yet been covered in the questionnaires or in this interview?

Umbrella code	Definition	Examples
User friendly (or not)	This code encapsulates the general design of BlueIce (i.e. the logo, the colours) as well as being user friendly (i.e. simple, not overwhelming, easy to use). Can also include more general design features e.g. passcode & privacy etc.	'Everything looks so happy on the phone. I mean, I like the color. The color is really good. The blue and white'
Engagement	Participants discussing their engagement (or lack of) with BlueIce, or motivation being a barrier to engage with it / the activities within it. Can also include references to not having the time to use it, or forgetting to use it because they need to be motivated to take those steps to engage. Different to heterogeneity because that's more acknowledging differences.	'for the things with the activity ones, I don't know, umm… for me, it's hard to engage in stuff like that.' 'I was just lacking the motivation, especially when I'm feeling low '
Further support required	References to the app lacking an element of interaction, whether it be generally with another human or with a clinician specifically. Can also include general references to BlueIce not being enough and needing more support. Can also include references to it not being 'enough', i.e. it is missing components e.g. psychoeducation or further explanations, not taking enough into account.	'I think I would need someone there with me and be like, OK, do this and that now really taking me, yeah, through all the steps'
Adjunct to therapy	Participants mentioning that BlueIce could work well alongside / in conjunction with therapy, or it being a useful first step to help get students to seek therapy/ realise they need therapy etc. NOT saying it wouldn't work without therapy and that it has to be alongside therapy.	'if it's if the therapist then says like, you know, homework wise or something, I'll always like have a diary. This could be my diary for example and I can note it down. And then because we can forget stuff and I could forget something significant, and then when I have to therapy session we can talk about everything and my feelings on that day and I think it would support yeah the counselling session.'
Positive impact	Positive comments about the mood diary helping students to track their mood, or alter their perspective on how they've been feeling. Also references to the app providing	'I write things down when I'm not feeling well, I write it out, it's kind of like a little bit of relief as well'

	them an outlet / providing relief from negative emotions/emotion regulation, allowing them to vent etc. Also talking about awareness of current mood.	
Unhelpful	Negative comments about the mood diary / app relating to the red days being unhelpful, not needing to track their mood, or the moods not capturing their emotional ranges.	
Safe	Participants saying that BlueIce is safe to use, it not having risks associated with it or it being helpful for students generally.	'Ohh no, no risks, no cause it's still like free to use the app whenever and I really didn't see anything on the app that kind of made me feel any negative emotions or anything.'
Heterogeneity	Any references to the individual experience of self-harm or of interventions, including comments about 'personally…' or 'others may be different…', acknowledging the importance of not providing a one size fits all approach.	'what works for me might not work for another person' 'I know that some people that would give it a chance, and I think it would be very, you know, helpful for them.'
Target populations	Participants saying that BlueIce could be helpful for specific groups of people, i.e., based on their self-harm (e.g. low level or 'new' to SH), mental health status (e.g. people with specific diagnoses like ADHD or dissociation) or demographics (e.g. age, students).	'Or maybe for a person even who is like really, you know, a shy person and not so really outgoing. And, you know, maybe doesn't want to talk to therapist or something for those people, maybe, you know, an app would be better option.'
Barriers to other interventions	Discussion of barriers to other services **but** only if this relates to BlueIce somehow, e.g., it would help to overcome these barriers like not having a waiting list or something. Include other digital interventions in this as well (helplines, websites, face to face). Accessible also relates to the ease of access of BlueIce both in the first instance (i.e. not having to join a wait list etc) and also in the moment (i.e. out and about). Includes references to it being on a phone which is easily accessed.	'also for the university, I know there's a long list waiting list for people to get therapy and stuff' 'because obviously it's an app and we are all just you know on our phones at the moment, phone is like, what would life be without the phone'

Toolbox	References to it being a helpful toolbox (e.g. everything in one place). Also comments on the extent of personalisation available of the toolbox, i.e. whether it's enough or not enough. Negative comments specifically about the suggestions in the mood lifter (e.g. going to the cinema or whatever)	'it's not really personalized as well you know like obviously it's just like a general thing'

Categories	Codes	Barrier	Facilitator
Intervention Specific factors			
Suitability		Heterogeneity	Target populations
Usability		Not user friendly	User friendly
Acceptability			Safe
		Unhelpful	
		Toolbox	Personalisation options
Person Specific Factors			
Motivation		Engagement barriers	
			Positive impact
Capability		Motivation	
Opportunity		Further support required	
			Barriers to other support
			Adjunct to therapy

Table 2

CONSORT checklist of information to include when reporting a pilot trial

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Title and abstract			
1a	Identification as a randomised trial in the title	Identification as a pilot or feasibility randomised trial in the title	1
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives:			
2a	Scientific background and explanation of rationale	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	4
Methods			
Trial design:			
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of pilot trial design (such as parallel, factorial) including allocation ratio	4
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants:			
4a	Eligibility criteria for participants		5
4b	Settings and locations where the data were collected		5
4c		How participants were identified and consented	5

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Interventions:			
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered		6
Outcomes:			
6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	6,7
6b	Any changes to trial outcomes after the trial commenced, with reasons	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
6c		If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size:			
7a	How sample size was determined	Rationale for numbers in the pilot trial	5,6
7b	When applicable, explanation of any interim analyses and stopping guidelines		N/A
Randomisation:			N/A
Sequence generation:			
8a	Method used to generate the random allocation sequence		N/A
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism:			
9	Mechanism used to implement the random allocation sequence (such as		N/A

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
	sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		
Implementation:			
10	Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions		N/A
Blinding:			
11a	If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how		N/A
11b	If relevant, description of the similarity of interventions		
Analytical methods:			
12a	Statistical methods used to compare groups for primary and secondary outcomes	Methods used to address each pilot trial objective whether qualitative or quantitative	7,8
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	N/A
Results			
Participant flow (a diagram is strongly recommended):			
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	6
13b	For each group, losses and exclusions after randomisation, together with reasons		N/A

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Recruitment:			
14a	Dates defining the periods of recruitment and follow-up		6
14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	N/A
Baseline data:			
15	A table showing baseline demographic and clinical characteristics for each group		9, 10
Numbers analysed:			
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	10,11
Outcomes and estimation:			
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	10,11
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	N/A
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms:			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		N/A
19a		If relevant, other important unintended consequences	N/A

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Discussion			
Limitations:			
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	21
Generalisability:			
21	Generalisability (external validity, applicability) of the trial findings	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	21
Interpretation:			
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	18,19
22a		Implications for progression from pilot to future definitive trial, including any proposed amendments	21
Other information			
Registration:			
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry	N/A
Protocol:			
24	Where the full trial protocol can be accessed, if available	Where the pilot trial protocol can be accessed, if available	N/A
Funding:			
25	Sources of funding and other support (such as supply of drugs), role of funders		N/A
26		Ethical approval or approval by research review committee, confirmed with reference number	8

BMJ Open

Is a smartphone application (BlueIce) acceptable and safe for university students who self-harm: an open study

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Is a smartphone application (BlueIce) acceptable and safe for university students who self-harm: an open study

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Abstract

Background: Many university students self-harm but few receive support. Smartphone apps have been identified as acceptable sources of support for students who self-harm, but the use of self-harm prevention apps is yet to be explored in this population.

Objective: This study sought to explore the acceptability and safety of a specific app (BlueIce) for university students who self-harm.

Methods: This was an exploratory, mixed methods study with 15 university students attending university wellbeing services with self-harming thoughts and/or behaviours. BlueIce was offered alongside the face-to-face support provided by the wellbeing service. Self-harming thoughts and behaviours, coping self-efficacy, and symptoms of anxiety and depression were measured before and after using BlueIce for 6 weeks. Follow up interviews were also undertaken to explore how students perceived BlueIce in more in depth.

Results: Following app use, there were statistically significant reductions in symptoms of anxiety (baseline M 12.47, SD 4.42; follow-up M 10, SD 4.16) $t(14) = 2.26$, $P = .040$, $d = .58$ and depression (baseline M 16.5, SD 5.17, follow-up M 12.27, SD 3.66) $t(13) = 5.50$, $P < .001$, $d = 1.47$. Qualitative findings showed participants found BlueIce to be acceptable, safe and helpful, and reported that they were more able to cope with difficult feelings and better understand their self-harm triggers following use of the app.

Conclusion: BlueIce was an acceptable, safe and helpful source of support for university students struggling with self-harm thoughts and/or behaviours. This builds on previous findings with adolescents and suggests that BlueIce could be a particularly acceptable and helpful resource for university students.

Strengths and limitations

- The first study to evaluate a self-help smartphone app with university students who self-harm
- Qualitative findings were evaluated using a pre-existing framework for evaluating engagement with digital interventions
- Semi-structured interviews provided rich feedback on how students perceived the app.
- Recruitment challenges meant a small sample size for the quantitative analyses.
- Students were only recruited from one university.

Introduction

Self-harm among university students

Self-harm, defined broadly in the current study as any intentional act of harm or injury directed towards the self irrespective of motivation [1] is particularly prevalent at universities, with a worldwide systematic review finding university students to be twice as likely to self-harm than their non-student peers [2]. In this review, studies measured self-harm on a range of scales, including lifetime, past four weeks, six months, 12 months and 3 years. The higher prevalence of self-harm amongst students may result from the numerous challenges that they face while at university, associated with academic, financial, geographical and social stressors, which leave them more vulnerable to experiencing mental health difficulties [3]. A Canadian study estimated that around a quarter of students will self-harm while at university [4], however, self-harm often goes unreported due to the shame, stigma and misconceptions surrounding it that leaves many students unable to discuss their self-harm [5, 6, 7, 8, 9, 10]. This means that prevalence rates are often underestimated and that very few students who self-harm ever seek or receive professional help [11, 12]. This suggests that alternative options for support should be explored so that students who do not yet feel ready or able to discuss self-harm can still access other forms of support.

In a qualitative study, 25 United Kingdom (UK) university students with lived experience were interviewed about their opinions on support available for self-harm [13]. This study found that whilst some students appreciated the benefits of human connection that came with professional support, several barriers to seeking help were identified [13]. These included long waiting lists for mental health services, not wanting to take up support when they believed others may need it more, worrying about receiving a negative response upon disclosing self-harm, and feeling embarrassed and ashamed of self-harming. This study also explored how students perceive digital interventions, and found that they were viewed positively. In particular, students valued the anonymity, accessibility and convenience they can offer. In addition, students reported that they felt less exposed and inhibited compared to speaking with someone face-to-face, and noted how they always have their phones on them so could access a smartphone-based digital intervention anytime and anywhere [13].

These findings have been corroborated in the USA, with a survey of 479 college/university students showing that around three quarters had used or were using a digital mental health intervention, and high satisfaction rates were reported [14]. Interestingly, 91% of participants in this study indicated that they had experienced barriers to accessing mental health services. This further suggests that digital mental health interventions can bridge the gap between students and mental health support.

Research has also investigated the effectiveness of digital mental health interventions for university students. A systematic review found that digital interventions are effective in reducing symptoms of anxiety and depression, while also improving psychology wellbeing among students [15]. This was also found in a randomised controlled trial with UK university students, where use of a mental health app significantly improved anxiety and depression scores compared to a control group, and that these effects were sustained at follow up [16]. It therefore seems as

though digital interventions can be both acceptable to university students and effective in improving their psychological wellbeing.

Given the difficulties students face in seeking professional support for self-harm, coupled with the perceived advantages of digital support, a smartphone application (app) seems like a valued option. Wider research has also suggested that digital interventions for self-harm can be helpful and produce positive outcomes for other [17]. However, despite these potential benefits, no prior research has been conducted where university students have used and evaluated a smartphone app specifically developed to help manage self-harm [18].

BlueIce

A self-harm prevention app (BlueIce) has been evaluated with 44 UK adolescents aged 12-17 attending child and adolescent mental health services. Use of BlueIce was associated with a reduction in symptoms of anxiety and depression, as well as a reduction in the frequency of self-harm behaviours [19]. Qualitative findings also supported the app being acceptable, helpful and safe to use [20]. Given the positive findings from this app with adolescents (up to the age of 18 years), preliminary work subsequently investigated whether it could be acceptable to UK university students. In qualitative interviews, 25 students were shown screenshots of the app while its functionality was explained to them and they were asked to provide initial feedback on the concept of the app and its perceived suitability for university students. Feedback was positive with university students believing that BlueIce could help them manage their self-harm while also promoting positive mental wellbeing [21]. Students described how they believed BlueIce could provide relief in moments of distress by offering them distractions or outlets for their feelings, while also offering them longer term coping strategies to help manage their emotions.

Overall, it seems as though BlueIce is an effective and appealing intervention for self-harm that could also be beneficial to university students. However, while the perceived acceptability of BlueIce for university students has been initially explored in qualitative interviews, this is yet to be corroborated by students actually using the app. This study aims to build on previous work by exploring the acceptability and safety of BlueIce for university students using the app alongside attending university wellbeing services.

Methods

Design

This was an exploratory, open, mixed-methods study employing pre- and post-intervention questionnaires and follow-up interviews.

Patient and public involvement

This research was informed by participants' responses in a previous study [13] who gave guidance on how best to evaluate interventions for self-harm, meaning their expertise contributed to the choice of measures used here.

Recruitment

Participants were students at one UK University (there were no restrictions around year of study or degree type) who were recruited via the university's mental health services. This sample was

chosen to ensure that students had support in place should the app not be helpful, whilst being able to explore the safety of using the app in this population. The wellbeing service at this university is comprised of trained counsellors, wellbeing advisors and mental health advisors. They offer various forms of mental health support to students experiencing mild mental health difficulties, or they are able to direct students to more appropriate external specialist support if required. Help available through the university includes talking therapy, counselling, workshops, support groups and self-help resources. Typically, support is available both virtually and in person on the university campus.

Wellbeing staff were informed about the study and the intervention by the researcher, and were asked to highlight the study to any students meeting the inclusion criteria stated below. Posters advertising the study were placed in the waiting room so students were also able to directly sign up for the study. Interested students were directed to an online information sheet with space to enter their email to receive more information about the study. They were then contacted by the researcher (BC) who discussed the study with them either over a call on Microsoft Teams or over email.

Students were eligible to participate if:

1) They were currently (within the past two months) experiencing self-harm thoughts or behaviours
2) They were receiving/due to receive counselling or wellbeing support from the university services
3) They were willing to participate
4) They owned a smartphone running iOS or Android.

Current self-harm was defined as within the past two months in line with the definition used within the K-SADS [22]. This was deemed appropriate to account for the often sporadic and spontaneous nature of self-harm. There were no exclusion criteria, including no specific exclusion criteria for participants who may have been at risk of suicide. Given the broad definition of self-harm used in this study, differentiations were not made between suicidal or non-suicidal self-harm, meaning some participants in this study may have been experiencing suicidal thoughts. A broad definition was used to capture a range of self-harm experiences, due to the heterogeneous nature of self-harm. Clinical judgement was used on an individual case basis, as all potential participants were discussed with the university wellbeing service team lead to confirm suitability. All students who were interested in taking part were deemed suitable by the wellbeing team lead.

An information power approach was taken to determine the adequacy of the sample size for the qualitative analysis. This dictates that the sample size required is dictated by the richness of the interview data, whereby if participants provide thorough and in-depth responses, fewer participants are required to address the research question. Given the narrow aim of the study, the specificity of the experiences of the sample, the previous findings regarding the acceptability of BlueIce, and the in-depth dialogue within the interviews, a smaller sample of 10 participants was appropriate to address the research aims [23]. A further 5 participants completed the quantitative questionnaire but did not want to take part in an interview.

Intervention

BlueIce (https://www.oxfordhealth.nhs.uk/blueice/) was co-produced with young people with lived experience of self-harm, alongside clinical staff and academics. It has therapeutic grounding in both cognitive behavioural therapy and dialectical behavioural therapy [24] and was developed in line with guidance from the Medical Research Council [25]. In terms of safety, the app is pin-protected and no data is shared outside of the app. BlueIce contains a mood diary, emergency contacts and mood lifting activities that the user can add to and personalise. The activities are informed by common reasons people self-harm and, again, have therapeutic underpinnings. They include photographs, music, physical activities, guided mindfulness recordings and breathing exercises, a thought diary, distress tolerance techniques, and phone numbers of people to contact when at risk of self-harming [24]. Currently, BlueIce is freely available on a prescription basis (i.e., a mental health professional can 'prescribe' it to young people to use for free using a single-use access code) within participating child and adolescent mental health services, with the aim of becoming freely available to download via common app stores once the outcomes have been established. Please see appendix 1 for screenshots of the app.

Procedure

Data collection occurred between March 2021 and February 2022. Consent forms, baseline and post-use questionnaire data were collected using the Online Surveys software (https://www.onlinesurveys.ac.uk/). Post-use interviews for participants were conducted using Microsoft Teams and were recorded using the within-software capabilities. Once consent and baseline questionnaires were completed, participants were sent a text containing a unique link to download BlueIce. They were emailed a user guide (please see appendix 2) and a video demonstrating how to use the app. Participants were then free to use the app as they wished and were able to keep the app after the study ended. They attended treatment as usual with the university mental health services during the study but had no other contact with the research team until the follow-up questionnaires and interview six weeks later. No renumeration was provided to participants.

Measures

Self-Harm: To measure self-harm, the Alexian Brothers Urge to Self Injure Scale (ABUSI) [26] and the Ottawa Self-injury Inventory [27] were administered. The Ottawa self-injury Inventory includes a subscale about the addictive nature of self-harm, which was removed for the purposes of this study as it was deemed not to be necessary to address our research aims. These measures were chosen to capture both self-harm urges and behaviours, as there is evidence to suggest that thoughts of self-harm can still provide affect regulation [28] . Moreover, it has been found that even students who do not currently self-harm can still struggle significantly with urges to [13].

Anxiety: The Generalised Anxiety Disoder-7 (GAD-7) [29] is a brief measure that has shown good sensitivity at screening for anxiety disorders. Scores of 5 suggest mild anxiety, 10 suggest moderate anxiety and 15 suggest severe anxiety. It has also been well validated for use with university students [30, 31, 32].

Depression: The Patient Health Questionnaire-9 (PHQ-9) [33] is commonly used, has strong psychometric properties and has previously been used in a sample of UK university students

[33]. A score of 5-9 suggests mild depression, 10-14 moderate depression, 15-19 moderately severe depression, and a score of 20-27 suggests severe depression.

Coping: The Coping Self-efficacy scale [34] consists of three subscales: stopping unpleasant emotions and thoughts, using problem-focused coping, and seeking support from family and friends. The total maximum score is 260, with greater coping self-efficacy indicated by higher scores. This measure has good psychometric properties [34] and has previously been used with university students who self-harm [35].

Acceptability of BlueIce: Following the six-week intervention period, participants were asked to complete a questionnaire about the acceptability of BlueIce [19, 20]. This questionnaire was developed by the researchers and explores engagement with the app, experience of using the app, and any impact that the app has had. Please see appendix 3.

Interview Schedule

Semi-structured interviews were conducted following the trial period that explored participants' experiences of using BlueIce and any impact they perceived it to have had on their mental wellbeing. The interviews were semi-structured and lasted between 15 and 45 minutes (M = 24.6, SD = 10.34). The interview schedule was designed by BC and was informed by previous interview schedules used to determine the acceptability of BlueIce with adolescents [20] and university students [21] (please see appendix 4). This began with an open question 'what did you think about BlueIce', with prompt questions asking for feedback on specific elements of the app used if participants struggled to answer. Questions were also included that asked about any perceived impact of BlueIce and whether they believed BlueIce could be helpful for other university students.

Data analysis

Descriptive statistics were used to summarise the sample with regards to demographic characteristics, self-harm characteristics and anxiety and depression symptomatology. Paired samples t-tests were used to assess pre-post change on quantitative measures.

Follow up interviews were analysed using qualitative content analysis [36], to allow for both an exploration and quantification of the qualitative data. The transcripts were first transcribed verbatim by BC. All three coders (BC, KW, and EM) then read and re-read the transcripts until they had become immersed in the data. Three transcripts were picked at random for BC, KW and EM to code in order to develop a coding frame (please see appendix 5). No more than 10 key codes in the frame were aimed for, so as not to have more codes than transcripts, but ultimately 11 were settled on [37]. The rest of the transcripts were then independently coded in batches of two transcripts at a time, after which the three coders met to discuss and make any necessary adaptations to the coding frame. As there were more than two coders, Cronbach's alpha was used to measure inter-coder reliability, which suggested good agreement, $\alpha = .79$ [38].

While the codes and the coding frame were developed inductively and independently, BC, KW and EM identified that the codes aligned with a pre-existing framework of engagement with digital interventions [39]. The codes were therefore organised relative to the categories within this framework during analysis (please see appendix 6). The framework is divided into

intervention-specific factors ('suitability', 'usability' and 'acceptability') and person-specific factors ('motivation', 'capability' and 'opportunity'), with codes exemplifying each category and barriers and facilitators to each. To operationalise this framework within the context of our findings, BC, KW and EM developed definitions for each of these categories:

Intervention-specific factors
Suitability: The suitability (or not) of this intervention with this population specifically, i.e., whether it could be feasibly implemented in this population.

Usability: Factors affecting the overall experience of using the app (e.g. enjoyment, ease of use) either positively or negatively to determine whether the app is fit for purpose.

Acceptability: Specific factors or features of the intervention (relating to the content and purpose) that the target population liked or disliked, as well as more general, overall perception of the app as acceptable or not.

Person-specific factors
Motivation: Whether the target population had enough reason to want to use it or not, both initially and more long term, because of the perceived need for the app or its perceived impact/ helpfulness. This relates to more internal drive factors, such as the extent to which they wanted to use it.

Capability: Whether the individual was able to use it or not and the barriers to this. Whereas motivation relates to more personal factors, capability relates more to externally influencing factors, such as being too busy.

Opportunity: Factors which improved or reduced participants' opportunities to receive support (for mental health and/or self-harm) via the app, as well as opportunities that the app provides or does not provide.

Ethical considerations

This study received ethical approval from the University Research Ethics Approval Committee for Health [EP 20/21 015]. Participants were provided with an information sheet detailing the study, allowing them a chance to ask any questions before giving informed consent. They were informed that they could drop out of the study at any time and without giving a reason, and that they would be able to remove their data from the study prior to anonymisation. Participants were made aware that their participation would be confidential and that all responses would be anonymised. Participants received no financial compensation for taking part.

Results

Sample characteristics

15 participants completed the baseline and follow-up questionnaires, and 10 participants completed the follow up interviews. Participants were mostly white (13/15, 87%), undergraduate (14/15, 93%) females (14/15, 93%) in their first year of study (10/15, 67%). All participants had

self-harmed in the last 2 months (8/15, 53%) or were having thoughts of self-harm (7/15, 47%). Participants' ages ranged from 18-26 (mean 19.87, SD 2.39). Please see Table 1 for full participant demographics.

Table 1
Demographic characteristics of the sample

Demographic (N = 15)		n (%)
Age	18-20	11 (73%)
	21-23	3 (20%)
	24+	1 (7%)
Gender Identity	Female	14 (93%)
	Male	0 (0%)
	Non-binary	1 (7%)
Year of Study	1	10 (67%)
	2	1 (7%)
	3	3 (20%)
	4	1 (7%)
Degree type	Undergraduate	14 (93%)
	Postgraduate	1 (7%)
Ethnicity	White	13 (87%)
	Asian/Asian British	1 (7%)

	Black/African/Caribbean/Black British	1 (7%)
Sexuality	Heterosexual	8 (53%)
	Bisexual	5 (33%)
	Prefer not to say	1 (7%)
	Pansexual	1 (7%)
Self-harm Status	Current self-harm[a]	8 (53%)
	Current thoughts of self-harm[a]	7 (47%)

[a] This is defined as being within the past two months

Anxiety, depression and coping

Scores of the GAD-7 suggested that anxiety symptomatology was high within the sample (mean 12.47, SD 4.42), with many participants (12/15, 80%) experiencing at least moderate anxiety. Similarly, all participants were experiencing symptoms of at least mild depression (mean 16.50, SD 5.17), with a third (5/15, 33%) experiencing severe depression. On average, participants in this study seemed mildly confident in their abilities to cope (mean 92.93, SD 33.37), although this is lower than has been found in other samples of students who self-harm (e.g., mean 140.25, SD 48.26 [30].

Self-harm

Questions regarding the prevalence of self-harm thoughts and behaviour did not specify a timeframe that they had to have occurred within so that those who had not self-harmed within the last two months were still able to provide insight into what their self-harming behaviours were typically like. Within the two weeks prior to joining the study, most participants had thoughts of self-harming rarely or occasionally (9/15, 60%) and had self-harmed never or rarely (12/15, 80%). However, when they occurred, urges to self-harm were typically rated as strong (10/15, 67%). Participants were divided on how difficult they found it to resist harming themselves in the past week, with half saying they had not found it at all difficult or had found it mildly difficult (8/15, 53%), while four participants had found it very hard or had been unable to resist harming themselves (27%).

On average, participants were aged 15 (SD 2.42) when they first self-harmed, although ages ranged from 10-19. Nearly all participants had last self-harmed within the past two years (14/15, 93%), with one participant not having self-harmed since 2011. Around a quarter of participants reported that they usually never tell anybody if /when they self-harm (4/15, 27%), while the most

common sources of support sought were university counsellors (9/15, 60%) (this was expected given that participants were recruited through university wellbeing services) and friend(s) (8/15, 53%). Cutting was the most common method of self-harming among the sample (11/15, 73%), followed by hitting (6/15, 40%), scratching (5/15, 33%), interfering with wound healing (5/15, 33%) and banging head (4/15, 27%).When self-harming, only one participant (1/15, 7%) reported never feeling relief afterwards, and relief typically either lasted between 1-30 minutes (8/15, 53%) or for hours (5/15, 33%). When self-harming, between 1-60 minutes typically elapsed between thinking about it and acting upon it (11/13, 73%). Techniques most used to distract themselves from self-harming were talking with someone (9/15, 60%), doing anything to keep their hands busy (8/15, 53%) and watching TV (8/15, 53%). On a scale of 0 – 4, participants were moderately motivated to stop self-harming (mean 2.93, SD .80) and felt moderately able to stop self-harming (mean 2.40, SD 1.12). The most common sources of treatment the sample had received were self-help (6/15, 40%) or university counselling (5/15, 33%). The function subscale within the Ottawa Self-injury Inventory determined that students typically self-harmed for internal emotion regulation (mean 12.69, SD 6.36), and were least likely to self-harm for sensation seeking (mean 1.36, SD 1.95). Only one participant (7%) had visited a doctor for their self-harm, and two participants (13%) had made a previous suicide attempt.

Quantitative Results

Differences before and after treatment

After the trial period, participants scored significantly lower on symptoms of anxiety as assessed by the GAD7 (mean 10.00, SD 4.16), $t(14) = 2.26$, $P = .040$, $d = .58$, and on symptoms of depression assessed by the PHQ 9 (mean 12.47, SD 3.66), $t(13) = 5.50$, $P < .001$, $d = 1.47$. Scores on the ABUSI were lower following the trial period (mean 11.07, SD 1.48) compared to before the trial period (mean 13.13, SD 6.66) although this difference was not statistically significant $t(14) = 1.49$, $P = .16$, $d = .38$. Similarly, scores on the coping measure were not statistically significantly higher after the trial period, however, scores for the 'stop unpleasant thoughts and emotions' subscale were significantly higher (i.e. improved) on post-measures (mean 28.60, SD 15.32) than on pre-measures (mean 21.80, SD 10.27), $t(14) = -2.36$, $P = .033$, $d = .61$. No scores on any measures were worse following the intervention period, and no adverse events were reported by wellbeing staff or participants.

BlueIce Use

Over the six weeks, the median use of BlueIce was between six and 12 times (5/15, 33%), with 3/15 (20%) using it a couple of times a week, every day and at least once a day, respectively. Two participants did not use BlueIce at all (15%), because they forgot to. Of the 13 participants who used the app, 11 (73%) personalised BlueIce by adding their own ideas to different sections of the app. Just over a third (5/13, 39%) set reminders to use the app, but everyone used the mood diary to track their mood. The majority (11/13, 85%) chose to use BlueIce in distressing moments when they felt like harming themselves, and almost half said that it did stop some episodes of self-harm (6/11*, 55%). Over half said that they definitely would continue to use BlueIce (8/13, 62%) with only one person reporting that they would not (1/13, 8%). On a scale of 0-4, participants rated that they typically found BlueIce easy to use (mean 3.54, SD .52) and helpful (mean 2.47, SD 1.20), and that they would likely recommend to others (mean 2.73, SD

1.16). On the other hand, participants were less sure that they preferred BlueIce to face to face meetings (mean 1.38, SD 1.30). On a scale of 1-10, participants indicated that they had experienced small improvements in their self-harm (mean 4.31, SD 2.50) and mental health (mean 3.46, SD 2.73) since using BlueIce. Out of five, on average participants gave BlueIce 3.46 (SD 1.05) stars.

**two participants did not answer this question*

Qualitative results

Qualitative interviews were completed with 10 participants.

Intervention-specific factors

Suitability: *Facilitators*

Although BlueIce was originally designed for adolescents, most participants felt that it was appropriate for university students. One participant commented that being designed for a younger population may have been beneficial as the app was simple to use:

'I didn't think it was [designed for adolescents]. It didn't look that way, although, like, I did like how clean and simple it was. I think it stops it being almost, like, distracting, and I liked how clean it looked' [012]

Two participants (20%) felt that the app would be particularly suitable for students who are more introverted or isolated and who may struggle to seek professional support:

'Or maybe for a person even who is, like, really, you know, a shy person and not so really outgoing. And, you know, maybe doesn't want to talk to a therapist or something, For those people, maybe, you know, an app would be better option.' [016]

Finally, four participants (40%) discussed how the scope of BlueIce seemed to extend beyond self-harm, as *'to me it seems like the kind of thing that most people would probably find useful' [008].* Participants specified that it would also be suitable for students who are struggling more generally, for example with exam stress, anxiety, or frustration:

'*I think this could definitely be used by people who are dissociating or having other issues that aren't self-harm, like feeling really anxious for example, feeling really down, just not knowing what to do or feeling really overwhelmed, I think it could be used for a lot of different things' [006]*

Suitability: *Barriers*

Conversely, three participants (30%) also discussed how the intervention may not be suitable for everybody, as people have different experiences of self-harm and different needs from support:

'It seemed like a good app, but not so suited to the way I sort of deal with things… I sort of tried out some of the mood…what is it called? The… the ones where it's like methods of coping? I

tried out some of those. And, I like, I just didn't find any of them sort of suited to me, like I've still not worked out any particular ways of dealing with it myself. So I think, like, yeah, I think it's good, just not for me.' [008]

This also exemplifies how there tended to be a recognition among participants that, even if BlueIce may not have been particularly suitable for them, they could see how it could be of value to others.

Usability: *Facilitators*
Participants typically found the app simple and easy to use. They appreciated it giving them prompts and guiding them through the app pages, as they noted how moments of distress can be overwhelming, making it difficult to organise thoughts independently:

'I really like the pages where you can answer questions and, like, the buttons because I hate, like, speaking. Like, in those moments I hate speaking. I hate like… I find it really hard sometimes, l can like, you know, write down my thoughts on, like, that page. But like, a lot of the time I just can't, like, I'm too overwhelmed or, like, I just, yeah, I don't know what I'm thinking, but having the questions or the little buttons like, I love that… because it just helps me so much be able to find what I need…So being given prompts, um, is really, yeah, I really, really like that.' [010]

The simplicity of the app design was highlighted by 7 participants, with references being made to it not being overwhelming with too many options. The aesthetics of the app were also praised by five participants (50%), who enjoyed the colour scheme, the icons, the inconspicuous nature of the app, the format, and the logo.

'Everything looks so happy on the phone. I mean, I like the color. The color is really good. The blue and white….And I think also, yeah, when I was doing it then, when the light is off in the night in bed, it had like this, I don't know, dreamy, calm effect of me, like a cloud or, I don't know, yeah, something like that. It does something to you, just the color and the design.'[016]

Four participants (40%) also felt that the app was private, and appreciated having the passcode so that nobody but them could access it. This helped users to feel more confident being open with the app, knowing that their thoughts and feelings would be kept secure.

'I would say the pin password that you set up, that you need to access the app, it was helpful and it create a sense of privacy and especially, I mean less so now because obviously I don't live at home, but there's part of me that likes the idea of, you know, say, if ever anyone was looking over my phone or trying to access my phone knowing that, you know, I wouldn't have to…you know, there'd be preventions, I won't have to feel like I was at risk of someone opening it up and seeing everything.' [013]

Finally, the option to set reminders to use the app was praised by 3 participants (30%), including one participant who did not use the app frequently, as they acknowledged that it would have helped them to engage more with the app if they had done so.

Usability: *Barriers*
While the majority of participants responded positively to the app design and content, one participant did not like the colours and would have preferred pastel colours that would have felt more soothing for them:

'Just generally thinking about the colour scheme (laughter) maybe more soothing colours, I know it's called BlueIce but maybe the calm of a slightly paler blue… I think a pastel kind of thing would be better' [003]

The other barriers to usability identified by one participant was that the music section within BlueIce did not link with Spotify, but only Apple Music or music saved on the user's phone, and that they were not able to select more than one photo at a time to upload to the 'good times' section.

Acceptability: *Facilitators*
Further to BlueIce being perceived as suitable and usable, participants also discussed how it was acceptable and safe to use. Four participants specifically discussed how they do not perceive any risks to BlueIce being widely used, as they *'really didn't see anything on the app that kind of made me feel any negative emotions or anything.' [016]*

One participant elaborated on how they were initially concerned that having an app for self-harm on their phone could be triggering and make them more likely to self-harm, but that they were glad that this was not the case:

'There was part of me that was a little bit nervous that having the app would make me focus more on self-harm and so therefore maybe, you know, like it would be in the forefront of my head because I'd be seeing the app on my phone everyday… but that didn't happen which was great, I think partly because the app itself is quite innocuous on my phone… it's not glaring at you that it's for self-harm.' [013]

Participants commented on the specific features within the app that they found helpful, for example the toolbox of mood lifting activities, as having these ideas suggested to them made it easier to find an alternative way of coping in the moment, rather than using self-harm, as the app helped them to remember other things they can do instead:

I think in the moment you can kind of, like, forget what you can do. I definitely always, like, don't know what to do, which means it [self-harm] becomes the only option, so just, like, being able to see in front of me that, like, there are things I can do to help, it just makes it easier.' [012]

Another benefit of the toolbox that was highlighted was the option to personalise it by adding the users own ideas to the different sections, as well as making notes of what they tried and whether it worked or not. Three participants (30%) discussed how this helped the app feel more tailored to them and to feel less impersonal.

Importantly, over half of participants (7/10, 70%) specifically mentioned the mood diary as being a positive feature of the app, as it meant that they were able to track how they had been

feeling over previous days. Participants commented how this helped them to feel more aware of their mood and the reasons behind it:

'I like knowing what helps you, like if you need a break, what makes you, like, happy and like, looking back on times when you've been feeling, like, your best. But also knowing and understanding, like, when you're struggling, like, why that might be. I think just writing it down can definitely help' [012]

Further to helping users' to understand their moods and what mediates them, participants also discussed how the mood diary helped change their perspective, by helping them to acknowledge their good days as well as their bad:

'I also noticed something when I checked the calendar because, obviously I can see the color codes right, and I felt happy seeing, for example, three or four green ones instead of seeing like, you know, a red and orange and stuff like that. Yeah, I felt like this also had an impact on then how I felt when I saw it. You know, I was like, 'ohh actually I do have good days. My life is not only like, you know, so stressful and bad' because I can see all the green color.' [016]

Further to the mood diary helping users to be aware of their mood and improving their perspective, three participants (30%) also noted how it provided a useful outlet for them that offered some relief from their difficult emotions:

'I think it was great for kind of like, when I didn't feel well for just, putting like, you know, notes down about like, my emotions, what I'm feeling…I just noticed that, kind of, when I write things down when I'm not feeling well, I write it out, it's kind of like a little bit of relief as well' [016]

Acceptability: *Barriers*
Despite the mostly positive perception of the mood diary, one of the barriers to acceptability discussed by four participants was the mood diary being oversimplified. While some participants enjoyed the simplicity of the app, others felt that the spectrum of emotions available on the mood diary did not capture their range of experiences, and that the 'other' option was not sufficient:

'I guess sometimes the mood tracker, just because it only has emotions on one spectrum, so it's either just happy or sad. Even though there was an 'other' option, you could change the words but you couldn't change the colour of the, I dunno what you'd call it, but you can't change the colour of the thing' [001]

Another participant liked the idea of using a mood diary but found that, upon actually using it, that the reminders to track their mood made them more aware of it when they did not necessarily want to be:

'I've downloaded, like, other apps in the past to try and do this sort of mood tracker thing. I do quite like the idea of being able to see that, but then, when I actually did it…it, like, would just like, pop up in the middle of the day and it'd be like 'oh how am I feeling?'. And then I'd be like 'how am *I feeling?... well I'm not feeling terrible…' and I tend to sort of try and ignore that stuff generally when I can.' [017]*

Person-specific factors

Motivation: *Facilitators*

Further to the benefits and the impact of the mood diary, eight participants (80%) also discussed more general impacts of the app that maintained their motivation to engage with it. One participant mentioned how the app had had a positive impact on them as they were better able to manage their self-harm:

'I've definitely been struggling less… just being able to know that I could, like, track it somewhere, like, almost, like, put it in something, um, I thought was quite helpful. Just being able to almost like, confide in the app you know? It definitely stopped [self-harm] being such a regular occurrence' [012]

Six (60%) specified that they were motivated to engage with the app as they felt that it encouraged positive action that was beneficial for their wellbeing, *'it encourages me to do things that I know will help me, but I just normally can't be assed to do' [010]*. Further to this, participants appreciated being made aware of numerous *'stress relieving techniques, and knowing there's like, more options out there, say like, I didn't want to do meditation one day, then I know I could find another one on there to help' [011]*. In this way, the app proved to be a helpful resource for participants who used it to identify new strategies to help manage their emotions.

One specific way in which the app helped reduce urges to self-harm was in helping participants to regulate their emotions:

'I found it quite helpful…regulating my mood for the rest of the day, 'cause I found that once I acknowledged it on the app and could see that I'd, you know, acknowledged it and was aware of it, I kind of became less likely to, you know, snap at a family member, and stuff like that… Yeah, yeah 'cause like in the past, a lot of like, triggers for self-harm have been frustration related as opposed to kind of like, sadness related….and I imagine that if I hadn't necessarily had that outlet, I would have then become so frustrated I would have been tempted self-harm' [013]

Participants were also motivated to continue using the app as it helped to remind them of activities that they found joyful, and helped them to realise that these activities could be beneficial in managing self-harm as well as improving their wellbeing:

'I'd look at, like, the activity suggested and stuff like that and kind of… it would remind me that those things were things I wouldn't necessarily think to do, and that they would work. So I think like one of them was talking about, like going for walks and stuff, and it's like, I know I like walks and I know they distract me, but I never put two and two together and thought that maybe it would be good in that kind of scenario…The next day I went for a walk and kind of felt like absolutely amazing… But yeah, like, so I think that was again one of the other key things is that it made me kind of stop and take note of things that actually do help and make me associate them with, like, self-harm prevention rather than just them being like activities that I like to do…since getting it in the last six weeks, I've gone on quite a few walks that I may not have necessarily gone on if I hadn't thought like oh, hang on a minute, that's something that I could do and enjoy and that I could actually, like knew could have a positive effect on my mental health' [013]

Finally, continued use of the app was associated with learning strategies that work without necessarily having to have their phone on them:

'Even if I don't have my phone with me, I now have some of those ideas in my head 'cause once you use them, you know, once you've used the app for a bit, like, you can get - It it can help you just get into a routine of, like, when you start to feel a certain way and know what works, uhm, stuff like the ideas on the app and stuff, what works, what doesn't' [010]

This suggests that the app was beneficial in helping participants to develop and maintain longer term coping strategies that they could use instead of self-harming.

Motivation: *Barriers*
Despite this, four participants (40%) also discussed the difficulties they faced in being motivated enough to use the app. Reasons for this included forgetting to use it, low mood hindering their motivation, being stressed, having low energy, and not believing that anything could help..One participant emphasised that the lack of external encouragement to engage with the app would make it harder to be motivated, as *'you have to remember, you have to like, very much like do it for yourself' [017]*

Further, three participants (30%) felt that they did not need the app as they did not have urges to self-harm.

Capability*: Facilitators*
Participants felt that BlueIce being a smartphone app meant that it was particularly suitable for university students, who are *'kind of stereotypically always attached to their phone' [13],* so for whom it would be particularly accessible and convenient. References were also made to BlueIce being more *'private' [011]* than person-based support, like counseling, for example.

Opportunity*: Facilitators*
Nine participants (90%) perceived BlueIce to be subject to fewer barriers of access as other services or interventions are, allowing more individuals the opportunity to access support. Barriers to other services discussed include long waiting lists, difficult referral processes, fees, lack of personalisation, lack of out of hours support' and support being 'scattered' across resources.

'But obviously compared to things like therapy and stuff, you have it 24/7. So in that way it it's so much better than therapy because, you know therapy, you know I, I get like twice a week for like an hour each time' [010]

Six participants (60%) discussed how BlueIce could also serve as a useful adjunct for people who are in receipt of professional support, by allowing them a space to track their thoughts and feelings between sessions:

'This could be my diary for example and I can note it down. And then because we can forget stuff and I could forget something significant, and then when I have to therapy session we can talk

about everything and my feelings on that day, and I think it would support the counseling session.' [016]

Finally, one participant praised the opportunity to still be able to receive support without requiring any interaction:

'I think it might be quite helpful because, I know that there are times for me at least where if I'm not feeling great I don't like talking to people, but also, like, I don't exactly want to neglect my health either, so having that option to not have to talk to anyone but still sort of helping yourself in a way is really nice.' [001]

Opportunity: *Barrier*

Conversely, four participants (40%) also discussed how they do not perceive BlueIce as a replacement for professional support, as there are further opportunities for support that the app does not provide. Three participants (30%) noted how the lack of human interaction is a downside as they valued input from a mental health professional. One participant explained how this is important to them as they need firm direction in therapy in order to improve their wellbeing:

'What I have with my counselor now you know, sometimes he would say something and I'll be like… especially with me, with my personality and you know, not being able maybe to take help from other people, or not knowing what's best for myself, and then someone else telling me what to do… I'd already told him as well, 'you need to be a bit harsh with me'. I don't want anyone soft.' [016]

One participant commented on how they perceived the function of BlueIce to be more relative to in the moment distractions, whereas therapy is important for *'getting to the route of the problem, and I think that to get to the route of a problem it needs to be face to face, it needs to be individualised, and you wouldn't want a computer or something to go through that with you cos then it can get it wrong and that can have consequences and things' [003]*

Discussion

This exploratory study is the first to evaluate the acceptability and safety of a smartphone app (BlueIce) for university students who self-harm. Overall, the app was found to be acceptable and safe, as well helpful for participants to manage their self-harm and promote behaviour beneficial to wellbeing. Safety was determined quantitatively, with no scores on wellbeing measures deteriorating over the period, and qualitatively, with participants reporting that BlueIce was safe to use and presented no risks to students. Similarly, no adverse events were reported by participants or wellbeing staff. However, some limitations of the app were also noted, such as the motivation required to engage with it.

Comparison with prior work

Levels of anxiety and depression symptomatology within the sample were higher than have been found in clinical samples with similar age groups. For example, Bentley et al [40] found mean GAD-7 and PHQ-9 scores of 8.5 and 10.6 respectively, compared to 12.5 and 16.5 in the current

sample. Interestingly, surveys of university students have found scores that are comparable to those found in non-student clinical populations; Akram et al [41] reported a mean GAD-7 score of 9.3 and a PHQ-9 score of 10.1 based on a sample of 1,273 students. This endorses findings that university students are at a significantly heightened risk of struggling with mental health difficulties [2, 42]. In the baseline measures all participants classed themselves as either having self-harmed within the past 2 months or as currently having thoughts of self-harm. Despite this, in the two weeks prior, very few had self-harmed or had thoughts of self-harming. This raises interesting questions regarding how individuals who self-harm perceive their self-harm status. Claréus et al [43] investigated this and identified that individuals typically perceive themselves as having stopped self-harming if they had done so few times within the past month or year. However, some participants still did identify as someone who self-harms despite not having self-harmed within the past year. Importantly, it was found that how individuals perceive their recovery is more important than the time that has elapsed since the last act of self-harm. This corroborates the importance of asking participants to self-identify their self-harm status, rather than presuming they no longer self-harm in accordance with a certain time frame.

The current sample scored lower on measures of coping self-efficacy at baseline than in other studies of university students who self-harm [35]. It is important to acknowledge the context in which this research occurred, as the trial period was within a national lockdown due to the COVID-19 pandemic, in which everyone was encouraged to stay at home to stop the spread of the virus. Contact with anyone outside of the household was restricted. Consequently, many institutions closed, including universities, and most interaction had to occur in online spaces instead. This meant that university students were no longer attending in-person lectures, and the participants in this study were no longer attending in-person counseling sessions. This context may explain participants' lower coping self-efficacy, as students may have had less access to resources that positively impacted their abilities to cope, such as social networks [44]. A survey of 576 students did indeed find that the pandemic negatively impacted students' mood and wellness [45], suggesting they may have been particularly vulnerable during this time.

Despite this sample comprising students who had all disclosed self-harm to a mental health professional, a quarter of participants in this study indicated that they usually do not tell anybody when they self-harm. This suggests that, even for this group who have disclosed self-harm to a mental health professional and volunteered for a research study regarding a self-harm intervention, discussing self-harm can still be challenging. Importantly, this sample seemed to struggle more with self-harm urges than self-harm behaviours, with 12 participants indicating that they had self-harmed either rarely or never within the past two weeks, but with two thirds indicating that their urges to self-harm were strong. This reinforces the importance of measuring self-harm urges as well as behaviours, as they can be predictive of future self-harm and can still be very distressing for the individual [46, 47]. Moreover, a questionnaire completed by 1,296 students found that self-harm thoughts alone are still able to allow the individual relief from difficult emotions [48].

Generally, there was a high level of engagement with the app with several participants using it frequently, adding personalised content to the app, tracking their mood, and using BlueIce in moments of distress. High levels of engagement with BlueIce have also been found in previous studies with adolescents [49]. Despite the app originally being designed with and for adolescents,

this did not seem to deter university students from engaging with it and finding it beneficial. Participants in this study typically praised the simplicity of the app and enjoyed the design, although some found the mood diary too simple to capture their experiences; this split in opinion replicates findings from the previous evaluation of the acceptability of BlueIce with university students [21]. Nonetheless, those who did benefit from the mood diary discussed how it helped them to manage their emotions by providing an outlet for them through which they could get some relief from their difficult feelings, as well as being able to identify triggers for different moods. This mirrors findings from another study with young adults who self-harm, who found mood tracking via a smartphone app beneficial in managing emotions and identifying triggers [50]. Participants in the current study also found it helpful being able to reflect on their mood in difficult moments, as well as more broadly in order to gain perspective and feel more optimistic by realising that they do have good days as well as bad. These qualitative findings resonate with the quantitative findings showing an increase in participants perceived self-efficacy in being able to stop unpleasant thoughts or emotions following the trial period, rated using the coping self-efficacy scale [34]. It may be that the techniques participants learnt to manage their emotions, promote positive wellbeing and to cope in alternative ways as opposed to self-harm, as discussed above, may have contributed to their heightened beliefs in their abilities to stop difficult thoughts and emotions.

Around half of the participants indicated that BlueIce had stopped them from harming themselves at certain points. While this is important, previous research with university students with lived experience of self-harm highlighted that relying on a reduction in self-harm behaviours is not necessarily the best way to measure the success of an intervention [51], preferring a more holistic and wider perspective that also considers their general wellbeing [52]. In particular, university students who self-harm have emphasised wanting self-harm interventions to help them to learn more adaptive coping strategies and to address their broader mental health difficulties that are 'triggers' for their self-harm [13]. 80% of participants in the interviews discussed some positive impact of the app, including helping them to develop longer term, alternative coping strategies, and encouraging action that was beneficial for their wellbeing. As mentioned, participants' perceived abilities to stop unpleasant thoughts and emotions also improved. Further, participants in this study believed that BlueIce could help students struggling with a range of mental health difficulties, as well as typical university stressors such as exams. Overall, this would suggest that BlueIce typically aligned with university students' favoured outcomes of interventions. However, one participant did specify that professional support is necessary for getting to the route of the issue behind their self-harm. This reinforces the heterogeneity surrounding preferences for support that has been found previously [13, 53, 54], emphasising the need to ensure university students are able to access a variety of resources and sources of support.

The function that BlueIce could provide was explored, with participants suggesting it could be a helpful adjunct to counseling that allowed users to log how they had been feeling in between sessions to relay back to their counselor. Participants also discussed finding it helpful in moments of distress by reminding them of techniques to manage their emotions or distract themselves, without the user having to search for techniques themselves. The longer-term impact was also discussed, with participants commenting on having a better understanding of their triggers and how to manage their emotions, without even having the app in front of them. This

confirms the perception identified in a previous study investigating the acceptability of BlueIce with university students, where it was identified as a useful reminder of adaptive coping strategies in difficult moments, as well as a means of learning ways of processing emotions [21]. This also reflects findings with adolescents, who reported that BlueIce helped them to reframe difficult thoughts and provided a helpful distraction [20]. This suggests that BlueIce could be a useful tool that is scalable, able to offer 'out of hours' support, can help students cope in difficult moments, and reach more students who may be struggling with self-harm and feel unable to directly ask for help. Research into self-harm interventions in university settings is very limited, for example Nawaz et al [55] found only two studies meeting this criteria, neither of which were found to be effective in reducing self-harm. More research is needed to establish the effectiveness of BlueIce, nevertheless, the current study identifies it as a valuable and acceptable tool for students.

Limitations

Firstly, participants in this study all used the app alongside counseling provided by the university wellbeing services. As such, it is not possible to directly attribute the improvements in participants' wellbeing to either the counseling or the app. Similarly, participants were recruited from one university wellbeing service who had already sought help for their self-harm. These findings may not be representative of students attending other universities or those who self-harm but have not sought help. Similarly, the sample were demographically homogenous so these results may not generalise to students from other genders or ethnicities for example. As BlueIce was found to be safe to use, future research should seek to assess the impact of implementing BlueIce more widely with students in the general university population.

Secondly, this was an exploratory open study with a small number of participants and as such data is limited and must be interpreted with caution. Challenges to recruitment were experienced including problems accessing students during the university summer break and the COVID-19 pandemic when students were not physically present on campus. In addition, to maximise student safety, we recruited participants through the University wellbeing services but this meant that we had no direct access to possible participants. Steps were taken to try and mitigate these challenges, such as drafting email templates and eligibility checklists to reduce staff burden, but recruitment remained limited. Consequently, future research would benefit from a larger scale study to determine the effectiveness of BlueIce in this population.

Finally, this research occurred during a period of national lockdown due to the COVID-19 pandemic. This could have affected our results which may be lacking temporal validity.

Conclusion

In summary, BlueIce proved to be a safe, acceptable and helpful tool for university students attending face-to-face mental health services. Following use, participants reported that they had developed more adaptive coping mechanisms, were better able to identify triggers for self-harm, and had fewer symptoms of depression and anxiety. This mirrors previous research into the use of BlueIce among university students, adding further credence to its benefits for this population.

Further research is indicated using robust methodologies and appropriately powered cohorts to investigate these findings further.

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Competing interests

Paul Stallard designed the BlueIce app but receives no financial gain from the app or from this research. The other authors declare that they have no conflicts of interest.

Contributorship statement

All authors contributed to the draft of this manuscript. Bethany Cliffe completed data collection. Bethany Cliffe, Emma Moore and Kathryn Whittle completed qualitative data analysis. Bethany Cliffe completed quantitative data analysis. Paul Stallard provided supervision.

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Data sharing

Consent was not received from participants to make data publicly available.

References

1. NICE. Self-Harm [Internet]. 2013 Jun. (Quality Standard). Available from: https://www.nice.org.uk/guidance/qs34/resources/selfharm-2098606243525
2. Swannell SV, Martin GE, Page A, et al. Prevalence of Nonsuicidal Self-Injury in Nonclinical Samples: Systematic Review, Meta-Analysis and Meta-Regression. *Suicide Life Threat Behav* 2014;44:273–303. https://doi.org/10.1111/sltb.12070
3. Taliaferro LA, Muehlenkamp JJ. Risk Factors Associated With Self-injurious Behavior Among a National Sample of Undergraduate College Students. *J Am Coll Health* 2015;63:40–8. https://doi.org/10.1080/07448481.2014.953166
4. Griffin K, Twynstra J, Gilliland JA, et al. Correlates of self-harm in university students: A cross-sectional study. *J Am Coll Health* 2021;0:1–8. https://doi.org/10.1080/07448481.2021.1909049
5. Chandler A. Narrating the self-injured body. *Med Humanit* 2014;40:111–6. https://doi.org/10.1136/medhum-2013-010488
6. Long M. 'We're not monsters … we're just really sad sometimes:' hidden self-injury, stigma and help-seeking. *Health Sociol Rev* 2018;27:89–103.
7. Sheehy K, Noureen A, Khaliq A, et al. An examination of the relationship between shame, guilt and self-harm: A systematic review and meta-analysis. *Clin Psychol Rev* 2019;73(101779). https://doi.org/10.1016/j.cpr.2019.101779
8. Simone AC, Hamza CA. Examining the disclosure of nonsuicidal self-injury to informal and formal sources: A review of the literature. *Clin Psychol Rev* 2020;82(101907). https://doi.org/10.1016/j.cpr.2020.101907

9. Simone AC, Hamza CA. A longitudinal examination of predictors of nonsuicidal self-injury disclosures among university students. *J Clin Psychol* 2021;1(18). https://doi.org/10.1002/jclp.23277
10. Staniland L, Hasking P, Boyes M, et al. Stigma and nonsuicidal self-injury: Application of a conceptual framework. *Stigma Health* 2021;6:312–23. https://doi.org/10.1037/sah0000257
11. Fitzgerald J, Curtis C. Non-suicidal self-injury in a New Zealand student population: Demographic and self-harm characteristics. *N Z J Psychol* 2017;46:156–63.
12. Whitlock J, Eckenrode J, Silverman D. Self-injurious Behaviors in a College Population. *Pediatrics* 2006;117:1939–48. https://doi.org/10.1542/peds.2005-2543 PMID: 16740834
13. Cliffe B, Stallard P. University students' experiences and perceptions of interventions for self-harm. *J Youth Stud* 2022;0:1–15. https://doi.org/10.1080/13676261.2022.2033187
14. Topooco N, Fowler LA, Fitzsimmons-Craft EE, et al. Digital interventions to address mental health needs in colleges: Perspectives of student stakeholders. *Internet Interventions.* 2022;28:100528. https://doi.org/10.1016/j.invent.2022.100528
15. Lattie EG, Adkins EC, Winquist N, et al. Digital Mental Health Interventions for Depression, Anxiety, and Enhancement of Psychological Well-Being Among College Students: Systematic Review. *J Med Internet Res* 2019 Jul;21(7). https://www.jmir.org/2019/7/e12869 https://doi.org/10.2196/12869

16. Ponzo S, Morelli D, Kawadler JM, et al. Efficacy of the Digital Therapeutic Mobile App BioBase to Reduce Stress and Improve Mental Well-Being Among University Students: Randomized Controlled Trial. *JMIR mHealth and uHealth* 2020 Apr;8:e17767. https://doi.org/10.2196/17767
17. 1. Cliffe B, Tingley J, Greenhalgh I, Stallard P. mHealth Interventions for Self-Harm: Scoping Review. Journal of Medical Internet Research. 2021 Apr 30;23(4):e25140.
18. Barnett P, Arundell LL, Saunders R, et al. The efficacy of psychological interventions for the prevention and treatment of mental health disorders in university students: A systematic review and meta-analysis. *Journal of Affective Disorders.* 2021;280:381–406. https://doi.org/10.1016/j.jad.2020.10.060
19. Stallard P, Porter J, Grist R. A Smartphone App (BlueIce) for Young People Who Self-Harm: Open Phase 1 Pre-Post Trial. *JMIR MHealth UHealth* 2018;6:e32. https://doi.org/10.2196/mhealth.8917
20. Grist R, Porter J, Stallard P. Acceptability, Use, and Safety of a Mobile Phone App (BlueIce) for Young People Who Self-Harm: Qualitative Study of Service Users' Experience. *JMIR Ment Health* 2018 Feb;5(1). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5845106/ https://doi.org/10.2196/mental.8779
21. Cliffe B, Stokes Z, Stallard P. The Acceptability of a Smartphone App (BlueIce) for University Students Who Self-harm. *Arch Suicide Res.* 2022;0:1–17. https://doi.org/10.1080/13811118.2021.2022552
22. Kaufman J, Birmaher B, Brent D, Rao U, Flynn C, Moreci P, et al. Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version (K-SADS-PL): Initial Reliability and Validity Data. Journal of the American Academy of Child & Adolescent Psychiatry. 1997 Jul 1;36(7):980–8.
23. Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided by Information Power. Qual Health Res. 2016 Nov 1;26(13):1753–60.

24. Stallard P, Porter J, Grist R. Safety, Acceptability, and Use of a Smartphone App, BlueIce, for Young People Who Self-Harm: Protocol for an Open Phase I Trial. *JMIR Res Protoc* 2016;5:e217. https://doi.org/10.2196/resprot.6525
25. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008 Sep;337. https://www.bmj.com/content/337/bmj.a1655 https://doi.org/10.1136/bmj.a1655
26. Washburn JJ, Juzwin KR, Styer DM, et al. Measuring the urge to self-injure: Preliminary data from a clinical sample. *Psychiatry Res* 2010;178:540–4. https://doi.org/10.1016/j.psychres.2010.05.018
27. Cloutier PF, Nixon MK. The Ottawa Self-Injury Inventory: A preliminary evaluation. Abstracts to the 12th International Congress European Society for Child and Adolescent Psychiatry. *European Child & Adolescent Psychiatry*. 2003;
28. Martin J, Bureau JF, Cloutier P, Lafontaine MF. A Comparison of Invalidating Family Environment Characteristics Between University Students Engaging in Self-Injurious Thoughts & Actions and Non-Self-Injuring University Students. J Youth Adolescence. 2011 Nov 1;40(11):1477–88.
29. Spitzer RL, Kroenke K, Williams JBW, et al. A Brief Measure for Assessing Generalized Anxiety Disorder: The GAD-7. *Arch Intern Med*. 2006;166:1092. https://doi.org/10.1001/archinte.166.10.1092
30. Bártolo A, Monteiro S, Pereira A. Factor structure and construct validity of the Generalized Anxiety Disorder 7-item (GAD-7) among Portuguese college students. *Cad Saúde Pública* 2017;33:e00212716. https://doi.org/10.1590/0102-311x00212716
31. Farrer LM, Gulliver A, Bennett K, et al. Demographic and psychosocial predictors of major depression and generalised anxiety disorder in Australian university students. *BMC Psychiatry* 2016;16:241. https://doi.org/10.1186/s12888-016-0961-z
32. Musiat P, Goldstone P, Tarrier N. Understanding the acceptability of e-mental health - attitudes and expectations towards computerised self-help treatments for mental health problems. *BMC Psychiatry* 2014;14:109. https://doi.org/10.1186/1471-244X-14-109
33. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9. *J Gen Intern Med*. 2001;16:606–13. https://doi.org/10.1046/j.1525-1497.2001.016009606.x
34. Chesney MA, Neilands TB, Chambers DB, et al. A validity and reliability study of the coping self-efficacy scale. *Br J Health Psychol* 2006;11:421–37. https://doi.org/10.1348/135910705X53155
35. Midkiff MF, Lindsey CR, Meadows EA, et al. The role of coping self-efficacy in emotion regulation and frequency of NSSI in young adult college students. *Cogent Psychol*. 2018;5:1520437. https://doi.org/10.1080/23311908.2018.1520437
36. Elo S, Kyngäs H. The qualitative content analysis process. Journal of Advanced Nursing. 2008;62(1):107–15.
37. O'Connor C, Joffe H. Intercoder Reliability in Qualitative Research: Debates and Practical Guidelines. *Int J Qual Methods* 2020;19:1609406919899220. https://doi.org/10.1177/1609406919899220
38. Gliem JA, Gliem RR. Calculating, Interpreting, And Reporting Cronbach's Alpha Reliability Coefficient For Likert-Type Scales. 2003 [cited 2023 Jul 7]; Available from: https://scholarworks.iupui.edu/handle/1805/344

39. Liverpool S, Mota CP, Sales CMD, et al. Engaging Children and Young People in Digital Mental Health Interventions: Systematic Review of Modes of Delivery, Facilitators, and Barriers. *J Med Internet Res* 2020;22:e16317. https://doi.org/10.2196/16317
40. Bentley KH, Sakurai H, Lowman KL, Rines-Toth L, McKowen J, Pedrelli P, et al. Validation of brief screening measures for depression and anxiety in young people with substance use disorders. Journal of Affective Disorders. 2021 Mar 1;282:1021–9.
41. Akram U, Ypsilanti A, Gardani M, Irvine K, Allen S, Akram A, et al. Prevalence and psychiatric correlates of suicidal ideation in UK university students. Journal of Affective Disorders. 2020 Jul 1;272:191–7.
42. Stallman HM. Psychological distress in university students: A comparison with general population data. *Australian Psychologist* 2010;45:249–57. https://doi.org/10.1080/00050067.2010.482109
43. Claréus B, Hasking PA, Gray N, et al. Is ceasing self-injury enough? Differences in psychological health between people reporting behavioral cessation of non-suicidal self-injury and those who consider themselves to have stopped self-injuring. *J Clin Psychol* 2022;jclp.23409. https://doi.org/10.1002/jclp.23409
44. Sahu P. Closure of Universities Due to Coronavirus Disease 2019 (COVID-19): Impact on Education and Mental Health of Students and Academic Staff. *Cureus* 2020 Apr;12(4). https://www.cureus.com/articles/30110-closure-of-universities-due-to-coronavirus-disease-2019-covid-19-impact-on-education-and-mental-health-of-students-and-academic-staff https://doi.org/10.7759/cureus.7541
45. Copeland WE, McGinnis E, Bai Y, et al. Impact of COVID-19 Pandemic on College Student Mental Health and Wellness. *Journal of the American Academy of Child & Adolescent Psychiatry*. 2021;60:134-141.e2. https://doi.org/10.1016/j.jaac.2020.08.466
46. Burke TA, Ammerman BA, Hamilton JL, et al. Nonsuicidal self-injury scar concealment from the self and others. *Journal of Psychiatric Research*. 2020;130:313–20. https://doi.org/10.1016/j.jpsychires.2020.07.040
47. Miller M, Redley M, Wilkinson PO. A Qualitative Study of Understanding Reasons for Self-Harm in Adolescent Girls. *International Journal of Environmental Research and Public Health* 2021;18:3361. https://doi.org/10.3390/ijerph18073361
48. Martin J, Bureau JF, Cloutier P, et al. A Comparison of Invalidating Family Environment Characteristics Between University Students Engaging in Self-Injurious Thoughts & Actions and Non-Self-Injuring University Students. *J Youth Adolescence* 2011;40:1477–88. https://doi.org/10.1007/s10964-011-9643-9
49. Muscara F, Ng O, Crossley L, Lu S, et al. The feasibility of using smartphone apps to manage self-harm and suicidal acts in adolescents admitted to an inpatient mental health ward. *Digit Health* 2020 Nov;6. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7705813/ https://doi.org/10.1177/2055207620975315
50. Honary M, Bell B, Clinch S, et al. Shaping the Design of Smartphone-Based Interventions for Self-Harm. *Proceedings of the 2020 CHI Conference on Human Factors in Computing Systems* Honolulu HI USA: ACM; 2020:1–14. https://dl.acm.org/doi/10.1145/3313831.3376370
51. Owens C, Fox F, Redwood S, et al. Measuring outcomes in trials of interventions for people who self-harm: qualitative study of service users' views. *BJPsych Open* 2020 Mar;6(2). https://www.cambridge.org/core/journals/bjpsych-open/article/measuring-outcomes-in-trials-of-interventions-for-people-who-selfharm-qualitative-study-of-service-users-views/00B4C4A51CB7627AEBE960FAB87DCB04 https://doi.org/10.1192/bjo.2019.93

52. Knowles S, Sharma V, Fortune S, et al. Adapting a codesign process with young people to prioritize outcomes for a systematic review of interventions to prevent self-harm and suicide. *Health Expectations* 2022. https://onlinelibrary.wiley.com/doi/abs/10.1111/hex.13479 https://doi.org/10.1111/hex.13479
53. Carroll R, Metcalfe C, Gunnell D. Hospital Presenting Self-Harm and Risk of Fatal and Non-Fatal Repetition: Systematic Review and Meta-Analysis. *PLoS One* 2014 Feb;9(2). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3938547/ https://doi.org/10.1371/journal.pone.0089944
54. Hume M, Platt S. Appropriate interventions for the prevention and management of self-harm: a qualitative exploration of service-users' views. *BMC Public Health* 2007;7:9. https://doi.org/10.1186/1471-2458-7-9
55. Nawaz RF, Anderson JK, Colville L, Fraser-Andrews C, Ford TJ. Review: Interventions to prevent or manage self-harm among students in educational settings – a systematic review. Child and Adolescent Mental Health [Internet]. [cited 2023 Mar 3];n/a(n/a). Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/camh.12634


EE
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Please enter your PIN
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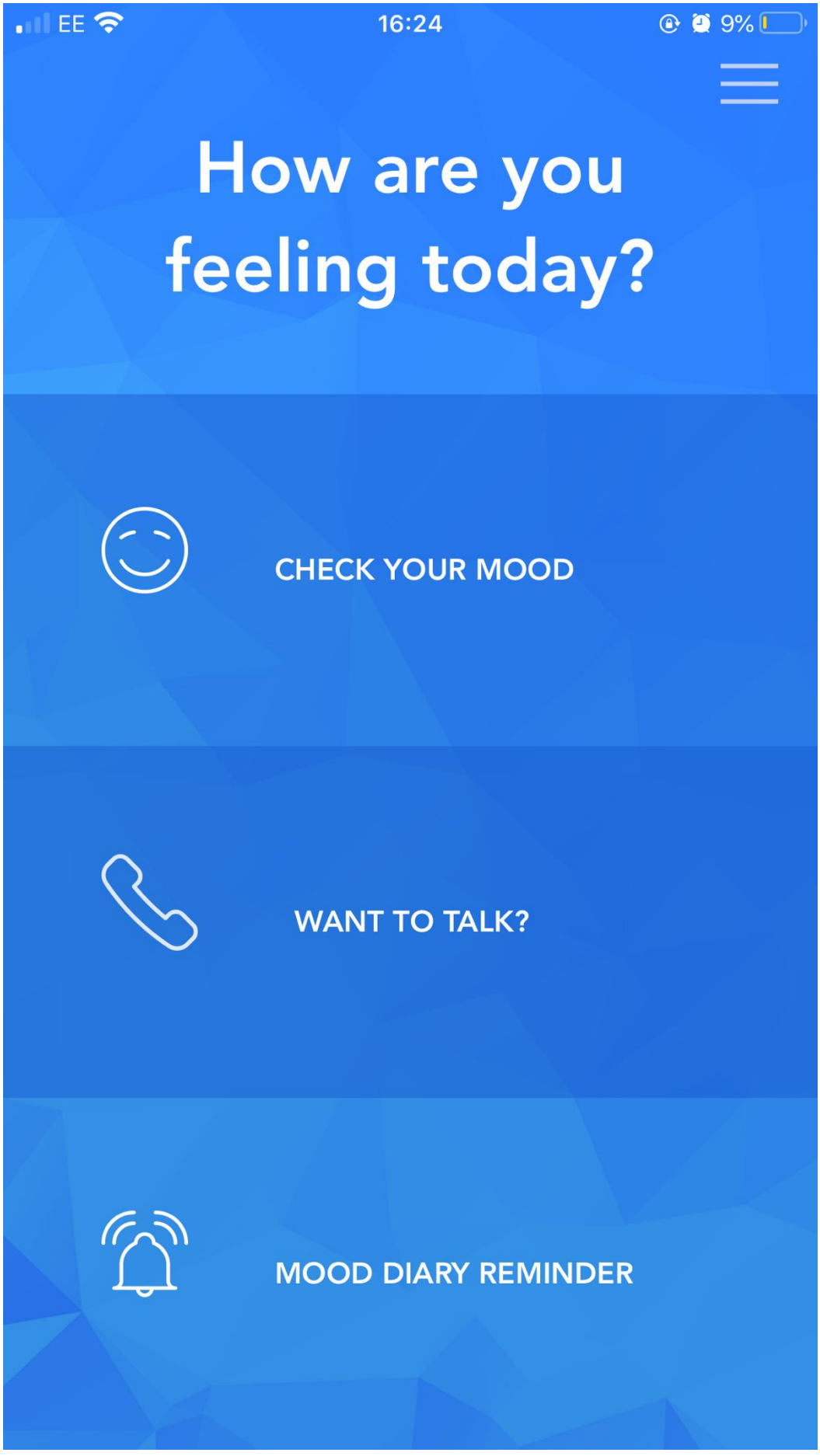
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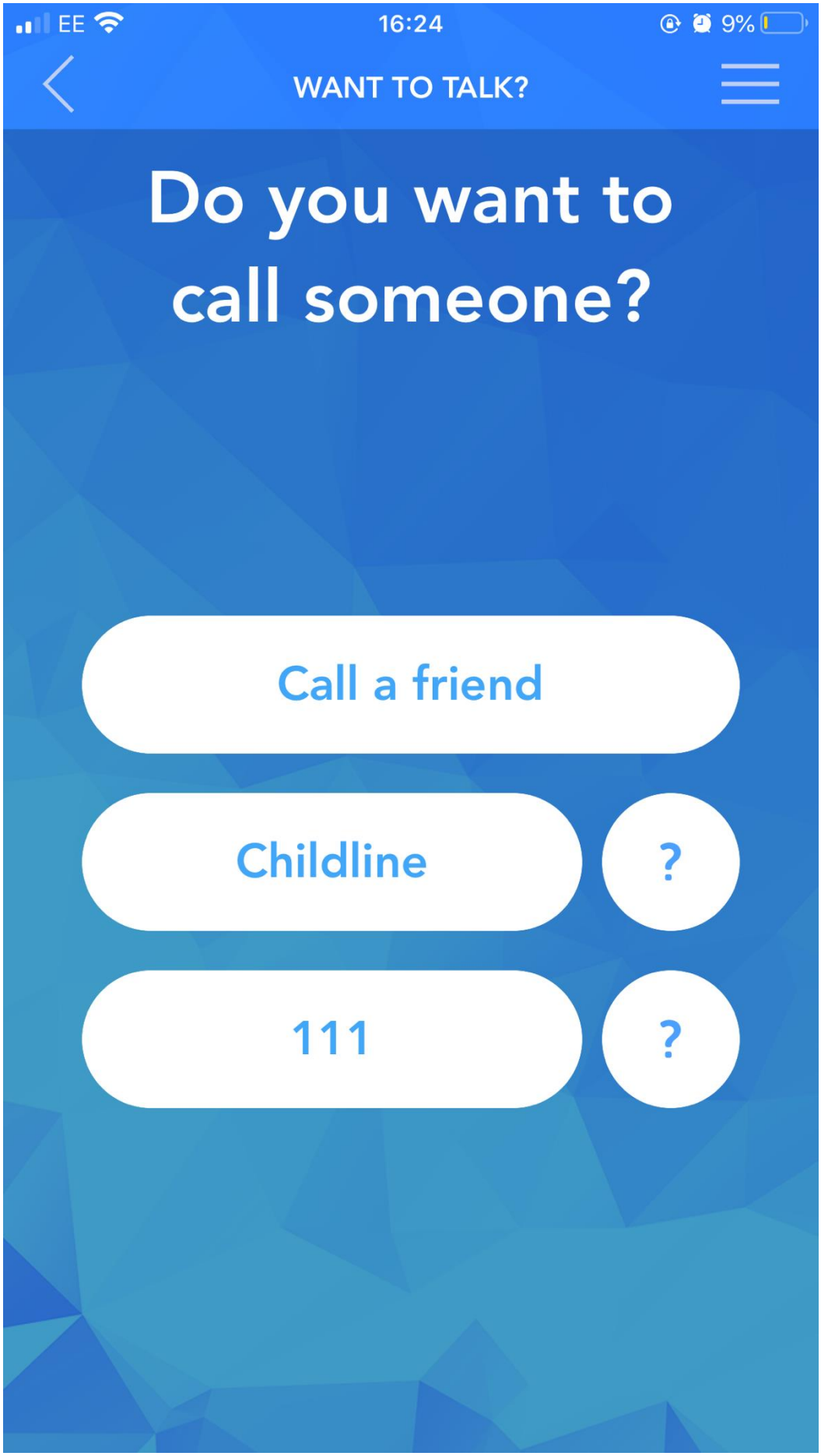
How are you feeling today?
CHECK YOUR MOOD
WANT TO TALK?
MOOD DIARY REMINDER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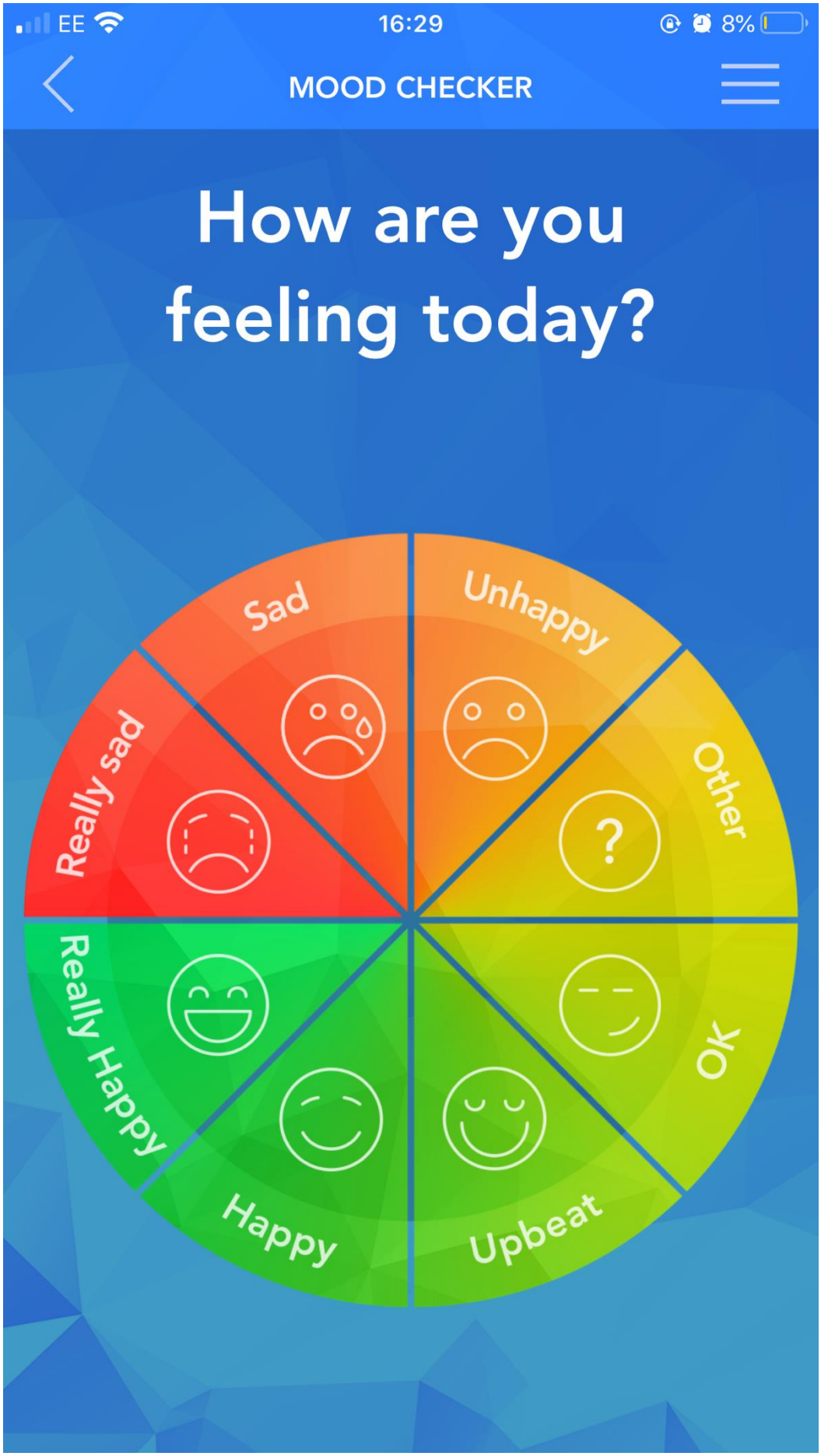
WANT TO TALK?
Do you want to call someone?
Call a friend
Childline
?
111
?


EE
16:29
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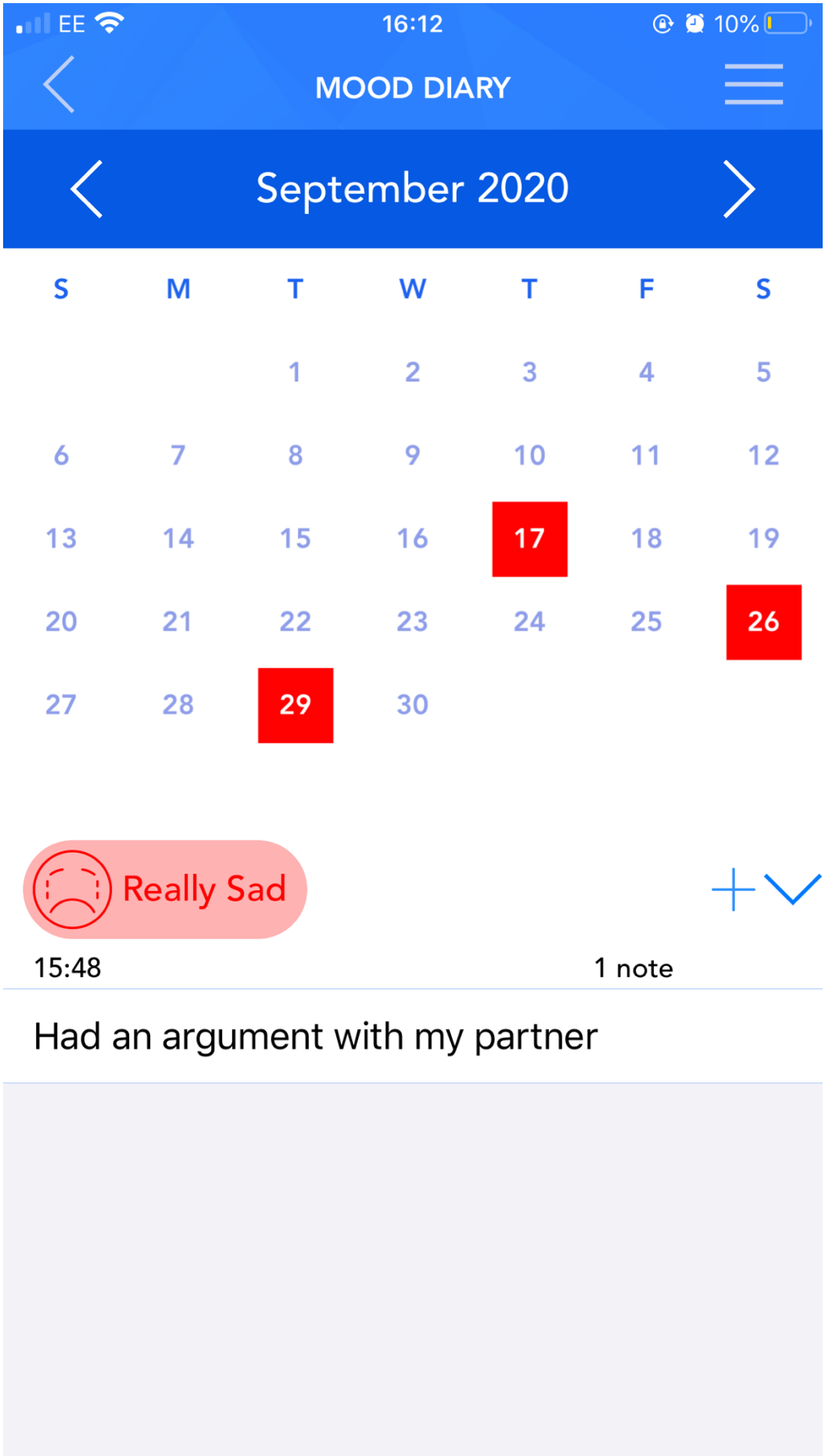
MOOD CHECKER
How are you feeling today?
Sad
Unhappy
Really sad
Other
?
Really Happy
OK
Happy
Upbeat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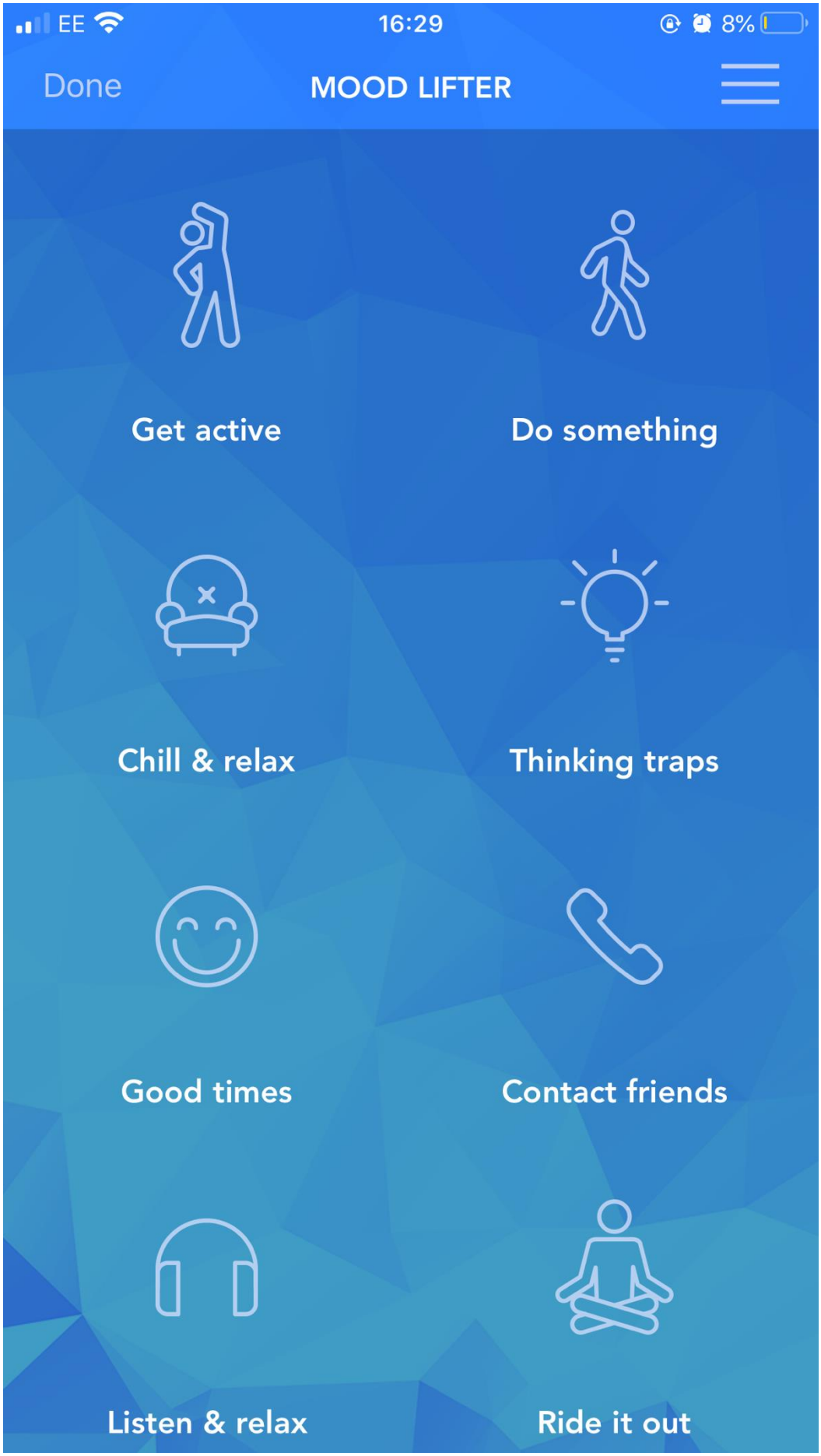
MOOD DIARY
September 2020
S M T W T F S
1 2 3 4 5
6 7 8 9 10 11 12
13 14 15 16 17 18 19
20 21 22 23 24 25 26
27 28 29 30
Really Sad
15:48
1 note
Had an argument with my partner


EE
16:29
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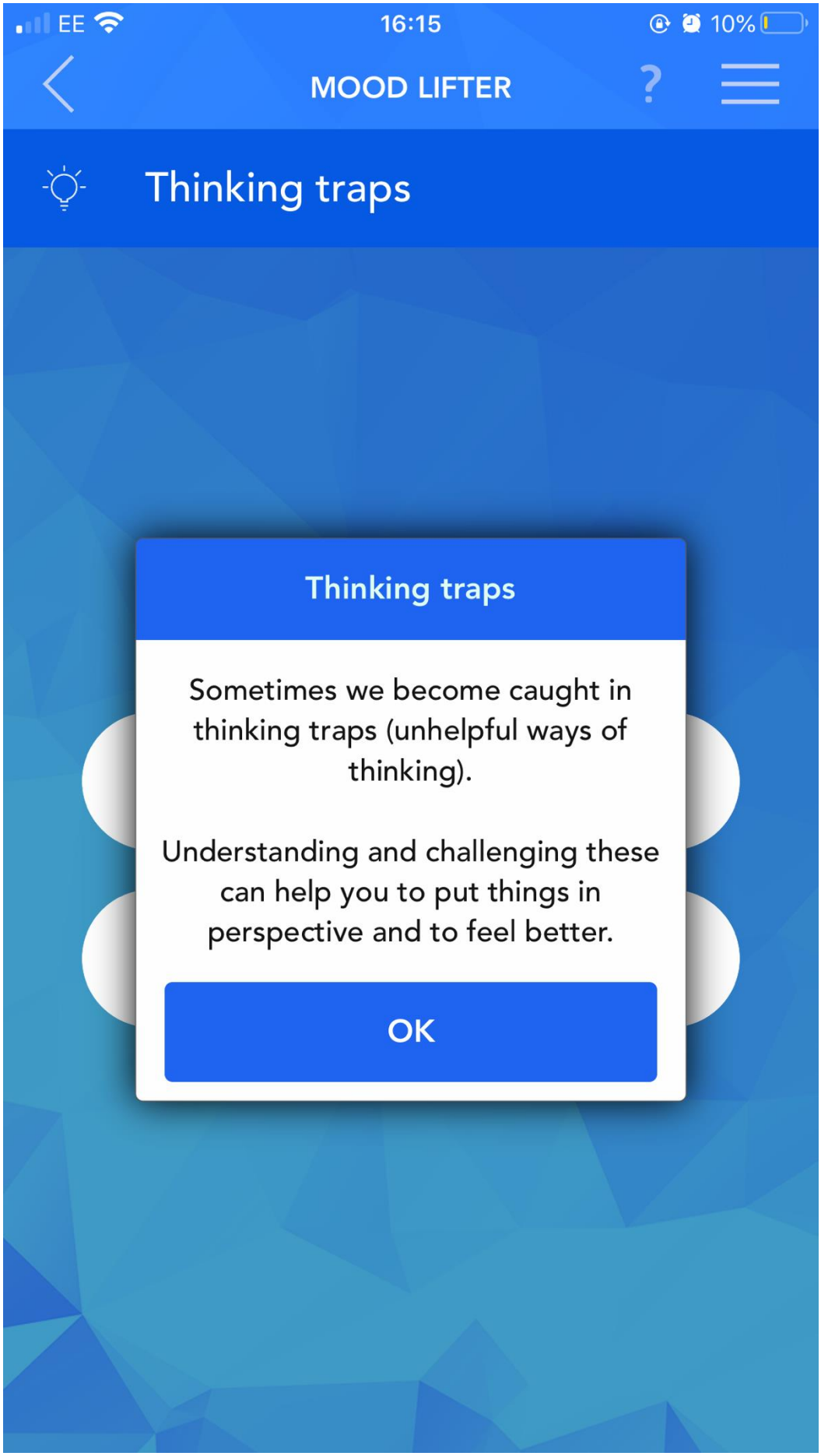
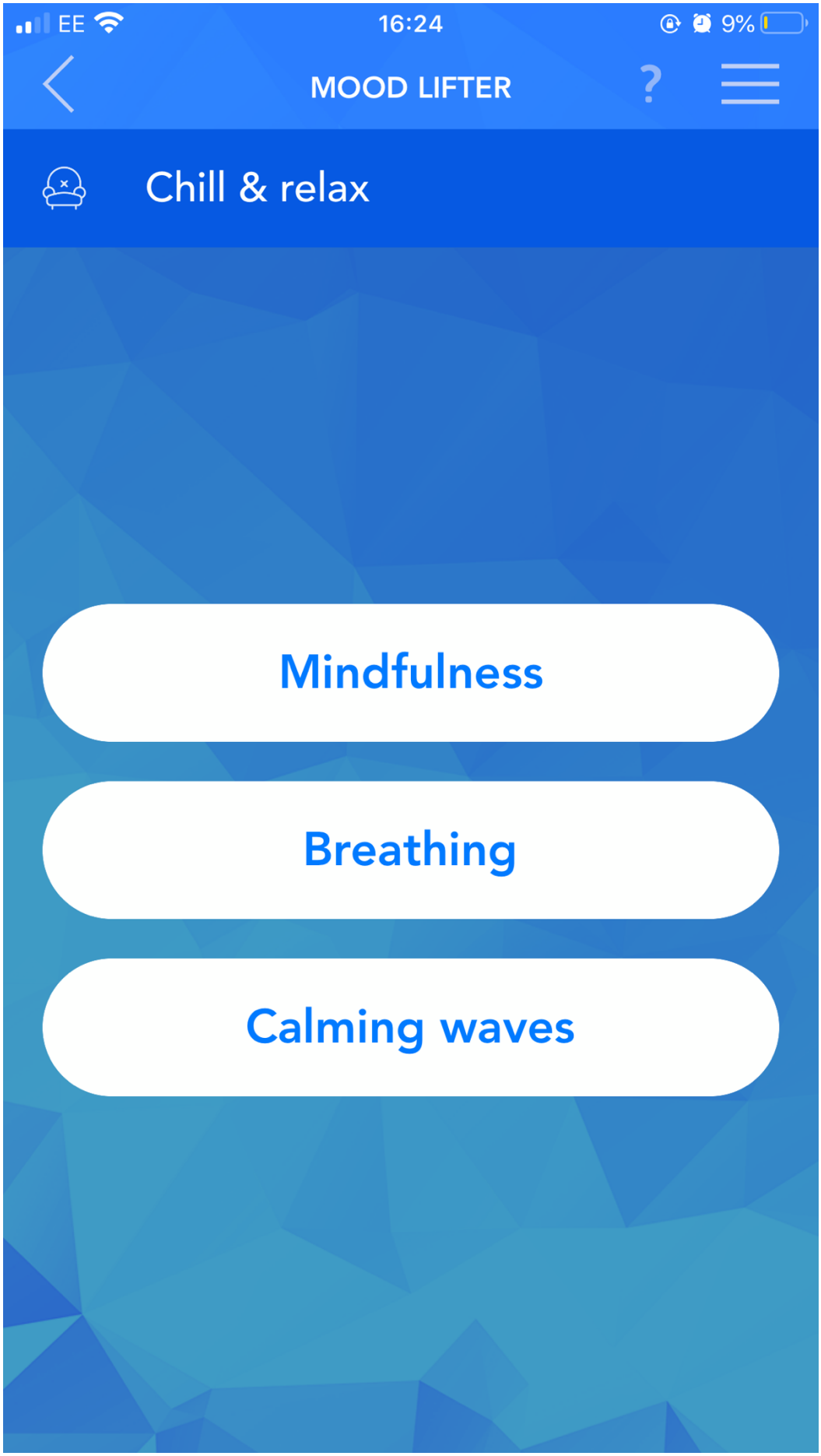
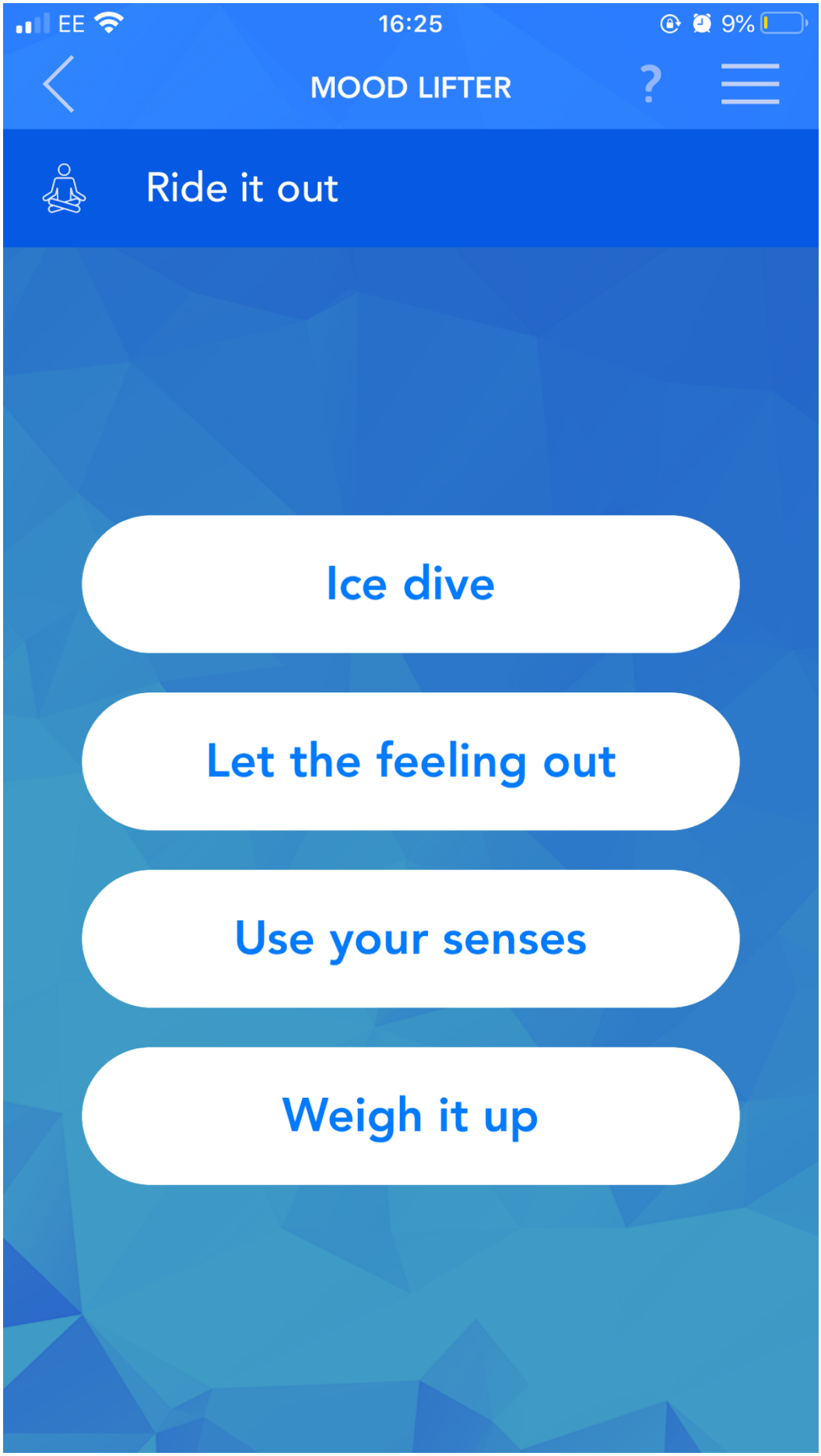
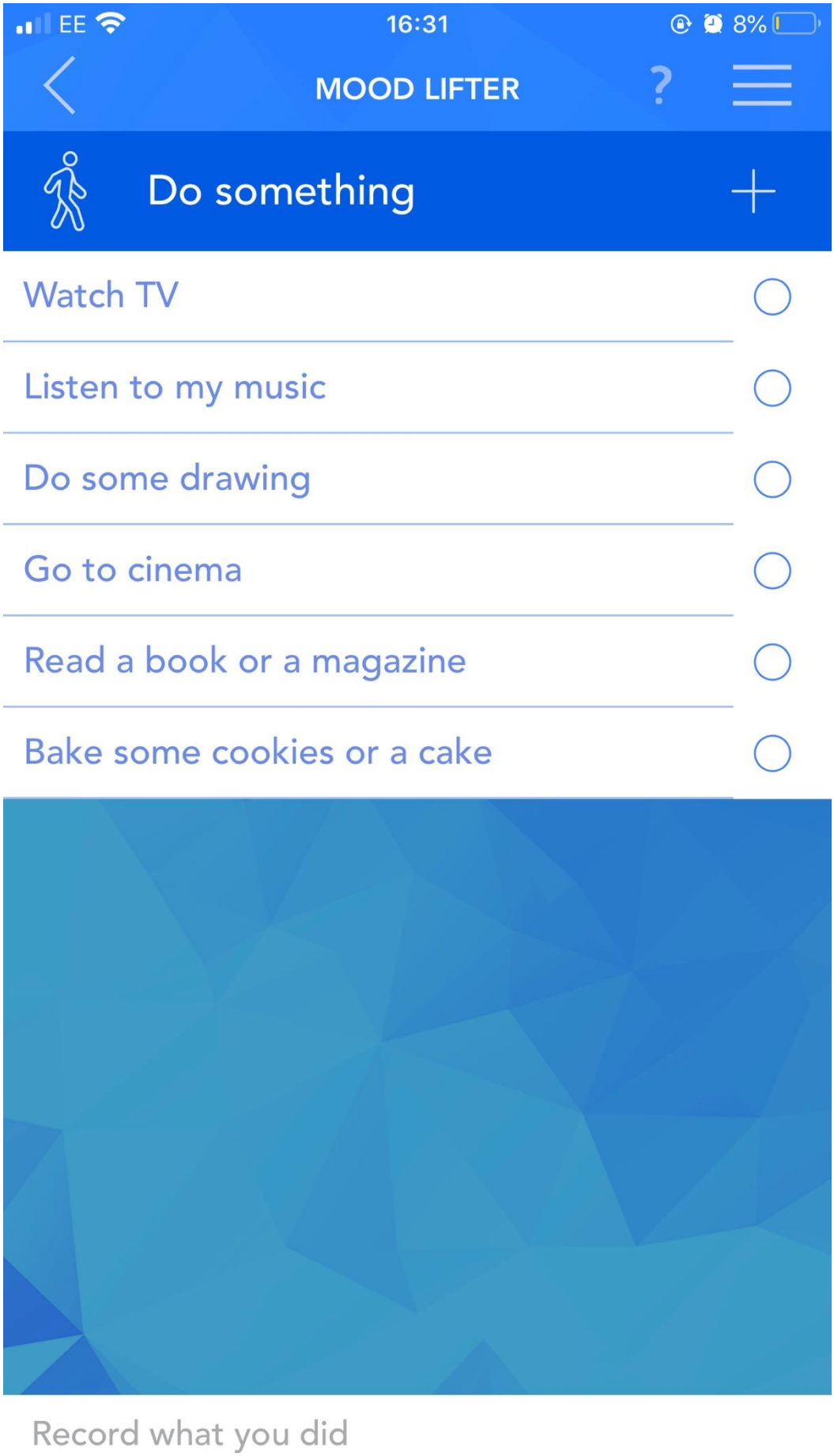
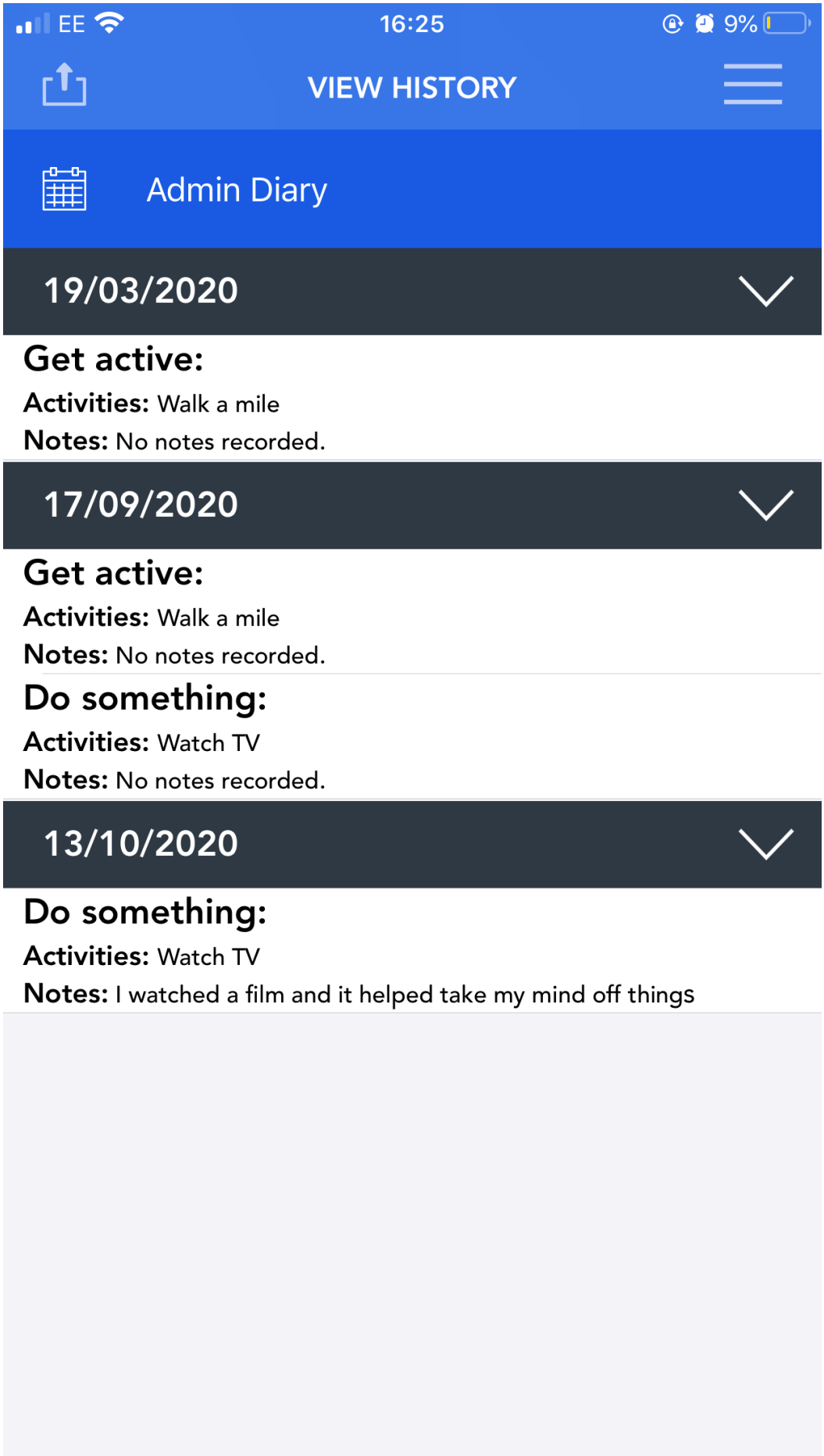
Done
MOOD LIFTER
Get active
Do something
Chill & relax
Thinking traps
Good times
Contact friends
Listen & relax
Ride it out


EE
16:15
10%
MOOD LIFTER
Thinking traps
Thinking traps
Sometimes we become caught in thinking traps (unhelpful ways of thinking).
Understanding and challenging these can help you to put things in perspective and to feel better.
OK


EE
16:24
9%
MOOD LIFTER
Chill & relax
Mindfulness
Breathing
Calming waves


EE
16:25
9%
MOOD LIFTER
Ride it out
Ice dive
Let the feeling out
Use your senses
Weigh it up


EE
16:31
8%
MOOD LIFTER
Do something
Watch TV
Listen to my music
Do some drawing
Go to cinema
Read a book or a magazine
Bake some cookies or a cake
Record what you did


EE
16:25
9%
VIEW HISTORY
Admin Diary
19/03/2020
Get active:
Activities: Walk a mile
Notes: No notes recorded.
17/09/2020
Get active:
Activities: Walk a mile
Notes: No notes recorded.
Do something:
Activities: Watch TV
Notes: No notes recorded.
13/10/2020
Do something:
Activities: Watch TV
Notes: I watched a film and it helped take my mind off things

BlueIce User Guide

Login

Set your log in PIN number to a number you will remember. You will be asked for your PIN each time you log on.

If you forget your PIN it can be reset by pressing the reset button. Unfortunately you will lose any notes or items your have saved.

How are you feeling today?

This is the home page where you can check your mood, talk to helplines or friends, or set your mood diary reminder. You can return to the Home page by tapping the top  left menu and selecting home.

Mood checker

This is the mood wheel – tap the mood that best describes how you are feeling. You can  add a note to explain why you are feeling like this.

Mood diary

This is a record of the moods you have entered. You will see a calendar and if you select a day you can see all the moods and notes you entered for that day.

Mood lifter

This is a toolbox of ideas to help you manage your emotions.

Add notes

Wherever you see 'record what you did' or 'type your notes here' tap the screen and a box will appear for you to add your notes. Your saved notes will appear in view history.

 Add items

Wherever you see this button you can add your own items. You can do this in most of the mood lifter sections and in the Mood Diary.

Delete items

You can delete any items that you have added .

Apple/iOS: swipe left, tap delete

Android: Hold your finger on the item for two seconds. A box will appear and you can click edit, delete or cancel.

 View history

Tap on the menu button and click view history. Here you can view your notes and all the things you entered that you tried to do on each day.

Privacy

All data you enter is stored on your phone. It is not transmitted or saved any where else unless you chose to download or send a copy

 Download your entries

Tap the top right icon on this page to send a copy of the entries you have made to an email address.

 Information

When you see this button you can tap it to find out more information. .

Set up mood diary reminder

On the Home screen you can set two reminders to record your mood each day. Set the time and click OK.

You can delete reminders by:

Apple/iOS: tap to open timer and select delete.

Android: hold your finger on the reminder time for 2/3 seconds and select the option to delete.

Exiting BlueIce

Open the top left menu  and select logout.

Feedback

To send feedback to the BlueIce team open the top left menu  and tap the feedback button.

This will create an email to the BlueIce team..

BlueIce is designed to be used alongside face to face work with a mental health worker.

If BlueIce isn't helping you then discuss this with your mental health worker.

The effectiveness and acceptability of a smartphone app (BlueIce) for university students experiencing self-harm thoughts/behaviours.

Experience of using BlueIce Questionnaire

1. Roughly how many times did you use BlueIce over the past 6 weeks?

☐ Once or twice

☐ Up to 5 times

☐ 6-12 times (up to once per week)

☐ Couple of times per week

☐ More often (please specify)

2. Did you personalise (i.e. add you own ideas to) the following sections of the mood lifter?

☐ Get Active (physical activities)

☐ Do something (get busy)

☐ Good times (photos)

☐ Listen and relax (music)

☐ Thinking traps (download your head)

☐ Contact friends (add 2/3 friends)

☐ Ride it out (soothing toolbox)

3. What sections of BlueIce did you use the most?

4. Did you set reminders to complete the mood diary?

☐ Yes

☐ No

5. Did you use the mood checker section to record your mood?

☐ Yes

☐ No

If NO – were there any reasons why?

_____

If YES – how often did you use it and was it helpful?

_____

6. Did you use BlueIce when you were distressed and felt like harming yourself?

☐ Yes

☐ No

If No – Were there any reasons why you didn't use BlueIce (e.g. didn't need to, forgot, didn't think it would help). ***Got to Question 9***

If Yes – Over the past 12 weeks how many times did you use BlueIce when you were thinking of harming yourself?

☐ Once or twice

☐ Up to 5 times

☐ 6-12 times (up to once per week)

☐ Couple of times per week

☐ More often (please specify)

7. Did BlueIce ever stop you from harming yourself?

☐ Yes

☐ No

If no, why do you think it didn't stop you from harming yourself?

If Yes, how many times did it stop you from harming yourself?

☐ Once or twice

☐ Up to 5 times

☐ 6-12 times (up to once per week)

☐ Couple of times per week

☐ More often (please specify)

8. Which sections of BlueIce helped you most when you were thinking of harming yourself?

9. Were there times when you self-harmed that you didn't use BlueIce

☐ **Yes**

☐ **No**

If Yes

- What stopped you from using BlueIce (no phone, forgot, feelings too intense)?

10. Were there any parts of BlueIce you found unhelpful, didn't like or didn't use?

11. Please read the statement below and indicate the extent to which you agree or disagree.

	Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree
BlueIce was easy to use					
BlueIce was helpful					
I prefer BlueIce to face to face meetings					
I would recommend BlueIce to other students					

12. Choose a number between 1-10 to show how much your self-harm has improved after using BlueIce?

1	2	3	4	5	6	7	8	9	10

No improvement Much improvement

13. Choose a number between 1-10 to show how much your mental health has improved after using BlueIce?

1	2	3	4	5	6	7	8	9	10

No improvement Much improvement

14. How many stars would you give BlueIce?
    - *
    - **
    - ***
    - ****
    - *****

15. Is life different for you now after using BlueIce and, if so, how is it different?

16. Will you continue to use BlueIce?

☐ Yes
☐ No
☐ Not sure

Experience of BlueIce Interview

1. What did you think about using BlueIce?
   Example prompt questions:
   - What did you think about the mood diary?
   - What did you think about the different techniques suggested?
   - Did you like the way it looked / was laid out?
   - Was it easy/hard to use?
   - Did you personalise BlueIce at all?
   - How does using BlueIce compare to other types of support for self-harm?

2. Do you think BlueIce has helped you to manage your self-harm / improve your wellbeing?
   Example prompt questions:
   - What techniques did you try that helped/didn't help?
   - What impact did BlueIce have on your self-harm/mood?
   - What bits specifically do you think helped / didn't help?
   - Do you think using BlueIce helped you learn or practice alternative coping strategies?

3. Why do you think BlueIce helped / didn't help you manage your self-harm and wellbeing?
   Example prompt questions:
   - How does it compare to other types of support you've had?
   - Were there any barriers to using BlueIce?
   - Do you think it's just BlueIce that isn't helpful for you, or smartphone apps in general?

4. Do you think BlueIce could be helpful for other university students?
   Example prompt questions:
   - Do you think students would use BlueIce?
   - What would the disadvantages and advantages be for other students using BlueIce?
   - Do you think if a student was struggling to ask for formal support, they may benefit from using BlueIce?

5. Is there anything else you would like to say about BlueIce or about this study, that hasn't yet been covered in the questionnaires or in this interview?

Umbrella code	Definition	Examples
User friendly (or not)	This code encapsulates the general design of BlueIce (i.e. the logo, the colours) as well as being user friendly (i.e. simple, not overwhelming, easy to use). Can also include more general design features e.g. passcode & privacy etc.	'Everything looks so happy on the phone. I mean, I like the color. The color is really good. The blue and white'
Engagement	Participants discussing their engagement (or lack of) with BlueIce, or motivation being a barrier to engage with it / the activities within it. Can also include references to not having the time to use it, or forgetting to use it because they need to be motivated to take those steps to engage. Different to heterogeneity because that's more acknowledging differences.	'for the things with the activity ones, I don't know, umm… for me, it's hard to engage in stuff like that.' 'I was just lacking the motivation, especially when I'm feeling low '
Further support required	References to the app lacking an element of interaction, whether it be generally with another human or with a clinician specifically. Can also include general references to BlueIce not being enough and needing more support. Can also include references to it not being 'enough', i.e. it is missing components e.g. psychoeducation or further explanations, not taking enough into account.	'I think I would need someone there with me and be like, OK, do this and that now really taking me, yeah, through all the steps'
Adjunct to therapy	Participants mentioning that BlueIce could work well alongside / in conjunction with therapy, or it being a useful first step to help get students to seek therapy/ realise they need therapy etc. NOT saying it wouldn't work without therapy and that it has to be alongside therapy.	'if it's if the therapist then says like, you know, homework wise or something, I'll always like have a diary. This could be my diary for example and I can note it down. And then because we can forget stuff and I could forget something significant, and then when I have to therapy session we can talk about everything and my feelings on that day and I think it would support yeah the counselling session.'
Positive impact	Positive comments about the mood diary helping students to track their mood, or alter their perspective on how they've been feeling. Also references to the app providing	'I write things down when I'm not feeling well, I write it out, it's kind of like a little bit of relief as well'

	them an outlet / providing relief from negative emotions/emotion regulation, allowing them to vent etc. Also talking about awareness of current mood.	
Unhelpful	Negative comments about the mood diary / app relating to the red days being unhelpful, not needing to track their mood, or the moods not capturing their emotional ranges.	
Safe	Participants saying that BlueIce is safe to use, it not having risks associated with it or it being helpful for students generally.	'Ohh no, no risks, no cause it's still like free to use the app whenever and I really didn't see anything on the app that kind of made me feel any negative emotions or anything.'
Heterogeneity	Any references to the individual experience of self-harm or of interventions, including comments about 'personally…' or 'others may be different…', acknowledging the importance of not providing a one size fits all approach.	'what works for me might not work for another person' 'I know that some people that would give it a chance, and I think it would be very, you know, helpful for them.'
Target populations	Participants saying that BlueIce could be helpful for specific groups of people, i.e., based on their self-harm (e.g. low level or 'new' to SH), mental health status (e.g. people with specific diagnoses like ADHD or dissociation) or demographics (e.g. age, students).	'Or maybe for a person even who is like really, you know, a shy person and not so really outgoing. And, you know, maybe doesn't want to talk to therapist or something for those people, maybe, you know, an app would be better option.'
Barriers to other interventions	Discussion of barriers to other services **but** only if this relates to BlueIce somehow, e.g., it would help to overcome these barriers like not having a waiting list or something. Include other digital interventions in this as well (helplines, websites, face to face). Accessible also relates to the ease of access of BlueIce both in the first instance (i.e. not having to join a wait list etc) and also in the moment (i.e. out and about). Includes references to it being on a phone which is easily accessed.	'also for the university, I know there's a long list waiting list for people to get therapy and stuff' 'because obviously it's an app and we are all just you know on our phones at the moment, phone is like, what would life be without the phone'

Toolbox	References to it being a helpful toolbox (e.g. everything in one place). Also comments on the extent of personalisation available of the toolbox, i.e. whether it's enough or not enough. Negative comments specifically about the suggestions in the mood lifter (e.g. going to the cinema or whatever)	'it's not really personalized as well you know like obviously it's just like a general thing'

Categories	Codes	Barrier	Facilitator
Intervention Specific factors			
Suitability		Heterogeneity	Target populations
Usability		Not user friendly	User friendly
Acceptability			Safe
		Unhelpful	
		Toolbox	Personalisation options
Person Specific Factors			
Motivation		Engagement barriers	
			Positive impact
Capability		Motivation	
Opportunity		Further support required	
			Barriers to other support
			Adjunct to therapy

Table 2

CONSORT checklist of information to include when reporting a pilot trial

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Title and abstract			
1a	Identification as a randomised trial in the title	Identification as a pilot or feasibility randomised trial in the title	1
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives:			
2a	Scientific background and explanation of rationale	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	4
Methods			
Trial design:			
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of pilot trial design (such as parallel, factorial) including allocation ratio	4
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants:			
4a	Eligibility criteria for participants		5
4b	Settings and locations where the data were collected		5
4c		How participants were identified and consented	5

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Interventions:			
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered		6
Outcomes:			
6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	6,7
6b	Any changes to trial outcomes after the trial commenced, with reasons	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
6c		If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size:			
7a	How sample size was determined	Rationale for numbers in the pilot trial	5,6
7b	When applicable, explanation of any interim analyses and stopping guidelines		N/A
Randomisation:			N/A
Sequence generation:			
8a	Method used to generate the random allocation sequence		N/A
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism:			
9	Mechanism used to implement the random allocation sequence (such as		N/A

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
	sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		
Implementation:			
10	Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions		N/A
Blinding:			
11a	If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how		N/A
11b	If relevant, description of the similarity of interventions		
Analytical methods:			
12a	Statistical methods used to compare groups for primary and secondary outcomes	Methods used to address each pilot trial objective whether qualitative or quantitative	7,8
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	N/A
Results			
Participant flow (a diagram is strongly recommended):			
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	6
13b	For each group, losses and exclusions after randomisation, together with reasons		N/A

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Recruitment:			
14a	Dates defining the periods of recruitment and follow-up		6
14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	N/A
Baseline data:			
15	A table showing baseline demographic and clinical characteristics for each group		9, 10
Numbers analysed:			
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	10,11
Outcomes and estimation:			
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	10,11
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	N/A
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms:			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		N/A
19a		If relevant, other important unintended consequences	N/A

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Discussion			
Limitations:			
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	21
Generalisability:			
21	Generalisability (external validity, applicability) of the trial findings	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	21
Interpretation:			
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	18,19
22a		Implications for progression from pilot to future definitive trial, including any proposed amendments	21
Other information			
Registration:			
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry	N/A
Protocol:			
24	Where the full trial protocol can be accessed, if available	Where the pilot trial protocol can be accessed, if available	N/A
Funding:			
25	Sources of funding and other support (such as supply of drugs), role of funders		N/A
26		Ethical approval or approval by research review committee, confirmed with reference number	8