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RESEARCH ARTICLE



A novel smartphone-based intervention targeting sleep difficulties in individuals experiencing psychosis: A feasibility and acceptability evaluation

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Abstract

Objectives: Cognitive Behavioural Therapy (CBT) is an effective psychological intervention for sleep difficulties and has been used successfully in individuals with psychosis. However, access is restricted due to lack of resources and staff training. Delivering CBT for sleep problems using smartphone technology may facilitate wider access. This study aimed to evaluate the feasibility, acceptability and potential usefulness of a guided, smartphone-based CBT intervention targeting sleep disturbance for individuals with psychosis.

Design: Participants with psychosis spectrum diagnoses were recruited to a single-arm, uncontrolled study and engaged with the seven-module programme via smartphone app for six weeks with therapist support.

Method: Feasibility was assessed by rates of referral, recruitment and completion. Acceptability was assessed by app usage, a satisfaction questionnaire and qualitative analysis of participants' semi-structured interview. Pre- and postintervention assessment of sleep, psychotic experiences, mood, well-being and functioning was conducted. Mean change confidence intervals were calculated and reported as an indication of usefulness.

Results: Fourteen individuals consented to participation, and eleven completed the post-intervention assessment. On

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average, each participant engaged with 5.6 of 7 available modules. Qualitative feedback indicated the intervention was considered helpful and would be recommended to others. Suggested improvements to app design were provided by participants. Potential treatment benefits were observed for sleep difficulties, and all outcomes considered, except frequency of hallucinatory experiences.

Conclusions: It is feasible and acceptable to deliver therapist-guided CBT for sleep problems by smartphone app for individuals with psychosis. This method provides a low-intensity, accessible intervention, which could be offered more routinely. Further research to determine treatment efficacy is warranted.

KEYWORDS

cognitive behavioural therapy, digital intervention, insomnia, mHealth, psychosis

Practitioner points

- A therapist-guided, smartphone-based cognitive behavioural therapy intervention for sleep problems was acceptable to individuals with psychosis.
- Participants valued the convenience and helpfulness of the intervention, although recommended modifications to app design to improve engagement in future.
- The intervention could have a beneficial impact on sleep problems, mental health and global outcomes. Further research is warranted to determine efficacy.

BACKGROUND

Sleep disturbance and psychotic experiences commonly co-occur (Reeve et al., 2015; Waite et al., 2020). Self-reported sleep disturbance is highly prevalent amongst individuals with psychosis (Davies et al., 2017; Laskemoen et al., 2019; Reeve et al., 2019). In a UK cross-sectional study of over 1800 service users with non-affective psychosis, 50% met criteria for insomnia disorder and were interested in psychological support to improve sleep (Freeman, Taylor, et al., 2019). Furthermore, sleep disturbance has been suggested as both a causal and maintaining factor of psychotic experiences (Freeman, 2016; Waite et al., 2020).

Current UK guidelines recommend cognitive behavioural therapy for Insomnia (CBTi) as the first-line treatment for chronic insomnia in adults (National Institute for Health and Care Excellence (NICE), 2020). CBTi targets key cognitive and behavioural factors considered to maintain insomnia, such as arousal when attempting to sleep and learned sleep-preventing associations (Wilson et al., 2019). CBTi is effective (Mitchell et al., 2012; Morin et al., 2006; Taylor & Pruiksma, 2014) and cost-effective in comparison with pharmacotherapy or no treatment (Natsky et al., 2020).

Adapted CBTi is also effective for individuals with psychosis in reducing sleep disturbance (Chiu et al., 2018; Freeman et al., 2015; Hwang et al., 2019). However, face-to-face CBTi is resource intensive, requiring trained professionals to deliver six-to-eight sessions (Freeman et al., 2015). Reported access

for individuals experiencing psychosis is consequently low (Reeve et al., 2019). The use of technology may provide an important avenue for increasing access to such interventions.

Digital technology, such as internet platforms and smartphone apps, can offer flexible access to interventions, which may be crucial for individuals with a disrupted sleep cycle (Bucci, Morris, et al., 2018). Smartphone portability enables interventions to target mechanisms in real-life and real-time (also known as 'ecological momentary intervention'; Reininghaus et al., 2016). Rather than exclude users with low motivation, digital interventions can support such needs through brief, targeted intervention, referred to as 'digital micro interventions' (Baumel et al., 2020). Benefits to service providers include lower costs and reduced clinician contact (e.g. Ben-Zeev et al., 2021; Richards et al., 2020).

Digital interventions to deliver CBT for primary insomnia, such as SLEEPIO (Espie et al., 2012) and SHUT-I (Christensen et al., 2016; Ritterband et al., 2009), are well established. Effectiveness is comparable to that of in-person CBTi (Seyffert et al., 2016; Zachariae et al., 2016) and cost-effectiveness superior to individual or group CBTi, and pharmacotherapy (Darden et al., 2020). In non-clinical populations and in individuals with non-psychotic psychiatric conditions, digital CBTi can significantly improve not only insomnia, but also reduce paranoia, hallucinations and psychoticism (Freeman et al., 2017; Zetterqvist et al., 2021). No study investigating the use of digital CBT for sleep problems in individuals with psychosis has yet been published.

Low rates of mobile phone ownership in people with psychosis have previously impeded the development of digital interventions. However, research indicates rates are on the rise (Firth et al., 2016) and views on digital interventions are positive amongst individuals with psychosis (Berry et al., 2019; Gay et al., 2016). Digital technology has clear potential to support treatment of psychosis (Firth & Torous, 2015). For example, independence is facilitated through ongoing self-monitoring of symptoms (Palmier-Claus et al., 2012) and real-time access to self-management strategies (Bucci, Barrowclough, et al., 2018).

Attempts to use smartphone technology to intervene in sleep difficulties in individuals with psychosis have so far been limited. The FOCUS intervention offers sleep hygiene as one of five treatment components, but it showed no change in self-reported sleep difficulties (Ben-Zeev et al., 2014). Sleep hygiene education alone is consistently found to be less effective than CBT for sleep problems (Chung et al., 2018; Espie et al., 2019). An internet-based CBT intervention for psychosis by Westermann et al. (2020) included sleep difficulties as one of 11 symptom-orientated modules, finding non-significant improvements to insomnia.

Stand-alone, automated smartphone interventions offer a low-cost alternative to face-to-face care but may have limitations (Palmqvist et al., 2007; Spek et al., 2007). Disengagement and non-adherence are common (Baumel et al., 2019; Waller & Gilbody, 2009). Blended interventions, in which the technology is supported by therapist contact, provide a compromise (Torous, 2018). Through a sense of relatedness with the therapist, the blended approach may enhance motivation, increase confidence in the therapy and enable the client to feel supported (Doherty et al., 2012; Wilhelmsen et al., 2013). For individuals with psychosis, the inclusion of therapist contact in digital interventions appears beneficial (Killikelly et al., 2017).

Despite growing evidence of the feasibility and acceptability of smartphone interventions for individuals with psychosis, and the established evidence for digital CBT in the treatment of sleep problems, at present, no published study evaluates the use of digital CBTi for individuals with psychosis. This study addresses this by investigating the feasibility and acceptability of delivering CBT for sleep problems, adapted for individuals with psychosis, as a guided smartphone intervention. A secondary aim was to investigate the potential usefulness of the intervention.

METHOD

Ethics approval

This study was granted ethics approval by the National Health Service (NHS) Health Research Authority, Wales Research Ethics Committee 7 (Ref: 20/WA/0234).

Participants

Participants were referred by their South London NHS community care team or were currently under the care of a community team and had consented to contact for research purposes. Inclusion criteria were (i) a schizophrenia-spectrum condition diagnosis; (ii) age 16–65 years old; (iii) experiencing current sleep difficulties present for at least four weeks [score of 16 or over on the Sleep Condition Indicator (SCI; Espie et al. (2014))] and (iv) in a stable clinical condition (as assessed by the individual's clinical team). Participants were excluded from participation if they (i) were considered at high risk of sleep apnoea [indicated by Sleep Apnoea subscale of the SLEEP-50 (Spoormaker et al., 2005) with clinician judgment]; (ii) lacked capacity to give informed consent; (iii) were currently in receipt of other individual psychological therapy, or actively involved in another research study; (v) had a reading ability or command of English language inadequate for engaging with the app; and (vi) had a primary diagnosis of a learning disability, organic syndrome or alcohol or substance dependency considered likely to interfere with the intervention. Additionally, participants were required to either own an app-compatible smartphone or be willing to use a study-provided smartphone.

A sample size of 15 was considered adequate to meet the study aims, allowing for an expected dropout rate of 20% to achieve 12 completed cases (Julious, 2005). As this study was not intended to detect effects through inferential statistical tests, power analysis was not required (Leon et al., 2011).

Demographic measures

Participants self-reported their age, gender and ethnicity. The current diagnosis was retrieved from the individual's medical record and confirmed by a member of the clinical care team. Familiarity with and use of technology was assessed by eight questions used in previous research (Khurana et al., 2016; Sedgwick et al., 2021). Subscales of the SLEEP-50 (Spoormaker et al., 2005) were used to provide an indication of Insomnia, Circadian Rhythm Sleep Disorder and Nightmare Disorder at baseline (according to the Diagnostic and Statistical Manual of Mental Disorders 4th Edition (DSM-IV; American Psychiatric Association, 1994) criteria).

Primary outcomes

Feasibility

Feasibility of recruitment was assessed by the number of participants who (1) were referred, (2) were suitable, (3) attended the screening assessment, (4) were eligible, (5) consented and (6) completed follow-up.

Acceptability

Acceptability of the intervention was assessed by app engagement, an Experience Feedback Questionnaire and a semi-structured interview. Attendance at the sleep review meeting and engagement with three modules (i.e. four sessions, in line with Freeman et al. (2015)) was defined as the minimum therapeutic dose. A participant was considered to have engaged with a module if accessed within the pre-scheduled My Sleep Programme or accessed for at least 5 min within the self-initiated Resources Section (see Intervention Structure). A 'reminder' was considered engaged if the content was opened and interacted with by the participant (e.g. answering a question).

The Experience Feedback Questionnaire was developed for evaluation of acceptability of mHealth interventions for individuals with psychosis (Cella et al., 2018; Edwards et al., 2016). Participants are asked to rate on a 7-point Likert scale ('strongly disagree' to 'strongly agree') whether the app was (1)

disruptive to daily life, (2) disruptive to usual activities, (3) embarrassing to use, (4) easy to remember to use and (5) enjoyable to use. A score of 1–4 was considered acceptable for items one to three, and a score of 4–7 considered acceptable for items four and five, as recommended by Edwards et al. (2016).

The semi-structured interview focused on the participant's experience of the app, barriers to engagement and their perception of the impact of the intervention (see Supporting Information for interview schedule). Interviews were conducted by the main researcher at the follow-up assessment appointment.

Secondary outcomes

Sleep quality and insomnia severity were assessed using the Pittsburgh Sleep Quality Index (PSQI; Buysse et al. (1989)) and the Insomnia Severity Index (ISI; Bastien et al. (2001)) respectively. Psychotic experiences were assessed using the Revised Green et al. Paranoid Thoughts Scale (R-GPTS; Freeman, Loe, et al. (2019)) and the Specific Psychotic Experiences Questionnaire (Hallucinations subscale; SPEQ-H; Ronald et al. (2014)). Affective symptoms, well-being and functioning were assessed respectively using the Depression, Anxiety and Stress Scale-21-item version (DASS-21; Henry and Crawford (2005)), Warwick-Edinburgh Mental Well-being Scale (WEMWBS; Tennant et al. (2007)) and Work and Social Adjustment Scale (WSAS; Mundt et al. (2002)). All outcome measures have been used in previous psychosis research (for example, see Freeman et al., 2015; Freeman, Leo, et al., 2019; Freeman, Taylor, et al., 2019; Jolley et al., 2015; Reeve, Nickless, et al., 2018; Sheaves et al., 2019).

Intervention

Intervention content

The smartphone app intervention draws on CBTi techniques, adapted for individuals with psychosis (Freeman et al., 2015; Waite et al., 2016). See Table 1, for a summary of key strategies.

In line with guidance by Waite et al. (2016), formal sleep restriction was omitted from this intervention, due to the potential to increase psychotic experiences (Reeve, Emsley, et al., 2018; Waters et al., 2018). A modified approach to sleep restriction was included, intending to increase sleep efficiency by gradually limiting time spent in bed to a goal window. For example, a participant waking at 12.00 PM due to delayed sleep onset would be encouraged to gradually compress the sleep window by setting an alarm progressively closer to their goal awakening time.

Although many individuals with psychosis experience distressing nightmares, the core therapeutic technique, Imagery Rehearsal Therapy, is recommended to be accompanied by careful risk monitoring for individuals with psychosis (Sheaves et al., 2019). Consequently, and in contrast to the protocol specified by Waite et al. (2016), the intervention was not included in the present digital programme.

Intervention structure

The app was delivered using an existing external survey platform ('ExpiWell'). The intervention consisted of a system-initiated, pre-scheduled programme ('My Sleep Programme') and a user-initiated, access-any-time 'Resources Section'. My Sleep Programme consisted of six core weekly modules, and one further participant-chosen module ('Managing Worry' or 'Coping with Voices'). Each required up to 30 min to complete. New content was delivered in the form of 'surveys', to which participants were alerted with a home screen notification. The intervention was interactive and conversational; utilising a range of question-response styles to actively involve the user, with supportive feedback provided. Content was tailored to participant responses using branching logic, as shown in Figure 1. This format has similarly been used in other app-based interventions designed for individuals with psychosis

Week	Format	Module name	Module type	Key CBT principles and techniques included
0	Therapist supported	Sleep Review Meeting	N/a	Assessment Formulation Goal setting
1	Self-help	Understanding Our Sleep	Core	Sleep psychoeducation
	Self-help	Preparing for Good Sleep	Core	Sleep hygiene techniques
2	Self-help	Bed is for Sleeping (Part 1)	Core	Stimulus control: ¼ hour rule Wind-down routine
3	Self-help	Bed is for Sleeping (Part 2)	Core	Stimulus control problem solving Rise-up routine
4	Self-help	Increasing Daytime Activity	Core	Activity scheduling
5 (a)	Self-help	Managing Night-time Worry	Option	Setting a Worry Period Using a Worry Tree Problem solving skills
5 (b)	Self-help	Coping with Voices	Option	Voices psychoeducation Coping Strategies
6	Self-help	Putting it all together	Core	Relapse prevention
All	Self-help	Relaxation and Mindfulness	Additional resource	Audio-guided relaxation and mindfulness exercises

TABLE 1 Summary of intervention module components

Abbreviation: CBT, cognitive behavioural therapy.

(Ben-Zeev et al., 2013; Bucci, Lewis, et al., 2018; Depp et al., 2019). The Resources Section (see Figure S1 for example display) enabled participants to re-access module summaries, and access audio-guided relaxation and mindfulness exercises.

Brief, daily, targeted reminders provided a real-world, real-time intervention to support implementation of changes. To support adherence for service users with motivational difficulties, reminders required no more than 5 min to complete and had a specific interventional focus (i.e. a 'Digital Micro Intervention'; Baumel et al. (2020)). For further details and examples of reminder content, see Table S1.

A service user with lived experience of psychosis, as well as four non-clinical individuals, was consulted with regard to intervention language, format and content, and to test functionality. Recommended changes were implemented during the app development process.

Sleep review meeting

Prior to the digital intervention, participants met with the research therapist, a Trainee Clinical Psychologist in the final year of training, for up to 1 h, to collaboratively review sleep diaries completed for one week prior, and identify key problem areas (e.g. sleep onset latency and wake time after onset). Participants were supported to establish sleep-related SMART (Specific, Measurable, Achievable, Relevant and Time-Bound) goals. The therapist highlighted intervention content pertinent to the individual's difficulties and supported the participant to choose between the two optional modules ('Managing Worry' or 'Coping with Voices').

Procedure

Eligible participants gave informed written consent and completed baseline assessment questionnaires electronically, with the support of a researcher by phone or video call. Participants were supported to register to the ExpiWell app on their smartphone. They then completed a Core Consensus Sleep Diary (Carney



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FIGURE 1 Example of intervention branching logic to deliver tailored responses

et al., 2012) through the app daily for seven days. After seven days, the sleep review meeting with the research therapist was conducted. Participants engaged with the automated app for six weeks. Participants were offered up to 30 min of therapist contact weekly. Therapist contact included 'technical', 'use' and 'clinical' support (Schueller et al., 2017), to overcome any barriers related to engagement, understanding and implementation of strategies as required. Following the intervention, participants were asked to complete a further seven days of sleep diaries, before participating in the follow-up assessment and feedback interview. Participants were compensated f_{10} for each research assessment and interview completed.

Analysis

Descriptive statistics are reported as frequency n (%) for categorical variables and mean (standard deviation) for continuous variables. Mean change scores between baseline and post-intervention, with 95% confidence intervals (CIs), were calculated. This level of CI was chosen to ensure high confidence in the direction of change (Lee et al., 2014). Effect size estimates are reported using Cohen's d (mean difference between groups divided by pooled standard deviation). As the primary objective of the study was to assess feasibility and acceptability, p values are not reported, in line with recommendations on pilot studies (Lancaster et al., 2004). Quantitative analyses were conducted using SPSS 26. A thematic analysis (Braun & Clarke, 2006) was conducted by the lead author (KT) to explore patterns within the qualitative interview data, using Nvivo software.

RESULTS

Missing data

One baseline PSQI data point was missing and was prorated using the participant's mean score for that scale.

Participants

Fourteen participants were recruited for the study. Baseline demographic and clinical characteristics are provided in Table 2. Participants were aged between 22 and 57 years.

Familiarity with technology

Almost all participants (n = 13, 92.86%) currently owned a smartphone; one was temporarily borrowing a device from a friend; none required a study smartphone. All had internet access available at home; 10 (71.43%) had access to Wi-Fi. All participants reported using the internet daily, most commonly on their smartphone (n = 11, 78.57%). Most participants (n = 13, 92.86%) reported at least moderate familiarity and confidence with the use of touch screen devices, one was neither familiar nor confident.

Primary outcomes: feasibility and acceptability

Feasibility of recruitment

Recruitment and retention to the study are shown in Figure 2. Three participants were lost to follow-up: one was uncontactable after baseline to begin the intervention; two initiated use but were uncontactable

TABLE 2 Baseline demographic and clinical characteristics of the sample

Sociodemographic characteristic	<i>п</i> (%) ^а
Age in years, mean (SD)	35.57 (10.88)
Gender	
Male	9 (64.29%)
Female	5 (35.71%)
Ethnicity	
Black/African/Caribbean/Black British	6 (42.86%)
White	3 (21.43%)
Any other ethnic group	1 (7.14%)
Asian/Asian British	2 (14.29%)
Mixed/Multiple Ethnic Groups	2 (14.29%)
Mental health service type	
Early intervention service	11 (78.57%)
Adult community mental health team	3 (21.43%)
Diagnosis	
First episode of psychosis	11 (78.57%)
Schizophrenia	2 (14.29%)
Schizoaffective disorder	1 (7.14%)
SLEEP-50	
Insomnia	11 (78.6%)
Circadian rhythm disorder	6 (42.9%)
Nightmares	3 (21.4%)

Abbreviation: SD, standard deviation.

^aData are reported as n (%) unless otherwise stated. N = 14.

for follow-up (one discontinued use after a technical issue caused disruption, and one was admitted to hospital for surgery during participation). The rate of treatment retention was therefore 78.6%.

Adherence to the intervention

Of the two optional modules, the most selected was Managing Worry (n = 11; 84.6%). The mean number of modules engaged with was 5.6 (SD = 1.8): all engaged with at least two modules, 12 met criteria for the minimum therapeutic dose (sleep review meeting and at least three modules), seven engaged with all seven modules. Engagement declined over time: all participants (n = 13; 100%) engaged with the week one modules, reducing to 61.5% (n = 8) by week six. On average, participants engaged with 13.7 (34.3%; SD = 10.4) of the 40 reminders. Responses to reminders similarly declined over time, starting at a mean of 44.6% (SD = 33.8%) completed in week one, reducing to 29.5% (SD = 36.7%) at week six. All accessed the self-initiated 'Resources Section' at least six times (Median = 15.0, IQR = 37.5). Two participants accessed the resource section over 100 times. Inclusive of the initial sleep review meeting, each participant received between 60 to 171 min of clinician time throughout the intervention (M = 107.1, SD = 32.8). See Table S2 for full details of app usage.

Experience feedback questionnaire

Acceptability criteria were not met for two participants regarding disruption to lives (18.2% rated 5 'Somewhat agree' to 7 'Strongly agree', M = 2.36, SD = 1.57) and for one individual in terms of

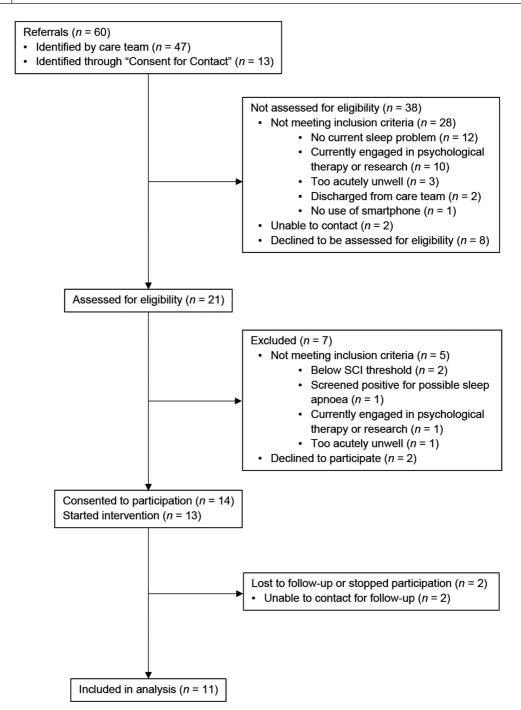


FIGURE 2 Participant flow diagram

disruption to usual daily activities (n = 1, 9.1% rated 5 – 7, M = 2.27, SD = 1.56). The intervention was acceptable to all participants in terms of embarrassment of use (n = 11, 100.0% rated 1 'Strongly disagree' to 4 'Neither agree nor disagree', M = 1.64, SD = 0.92). Most participants considered the app enjoyable to use, with nine meeting acceptability criteria (81.8% rated 4 'Neither agree nor disagree' to 7 'Strongly agree', M = 5.09, SD = 1.51). However, only two-thirds met acceptability criteria in terms

of ease of remembering to use (n = 7, 63.6% rated 4 - 7, M = 4.09, SD = 2.17). For a full breakdown of participant responses, see Table S3.

Semi-structured interview

Ten participants provided qualitative feedback on their experience. Themes developed from the data are summarised below, with relevant quotes presented in Table 3.

Experience of sleep prior to participation

Participants described sleep prior to the intervention as too short, erratic, delayed in onset, and disturbed by frequent awakenings (Table 3, quote 1). Some reported sleeping mostly during the daytime and avoiding sleep due to worries and vivid nightmares (quote 2). Participants connected the COVID-19 pandemic restrictions and their poor sleep, in impacting routine and ability to utilise strategies (quote 3):

Usefulness of the intervention

All reported improved sleep due to participation (Table 3, quotes 4 and 5). Changes described included a reduced time to fall asleep, waking for shorter periods during the night, a longer sleep duration or a more regular sleeping pattern. Four participants noted continued difficulties after participating, such as occasional nights of poor sleep and nightmares. The intervention was described as helpful, and all participants commented on learning new strategies. Several participants reported a beneficial impact beyond sleep, on daytime functioning, mood, well-being and social interactions (quote 6). When asked specifically, all denied experiencing any negative impact on well-being as a consequence of participation. All participants were encouraging of others to use the intervention if experiencing similar difficulties with sleep (quote 7).

Advantages of intervention format

The most common positive feedback was related to convenience: participants reported finding it easy to fit using the app into their schedule and were positive about the availability and flexibility of accessing the app (Table 3, quote 8). Five participants described the app content as straightforward and user-friendly (quote 9). Daily reminders were highlighted as useful for remembering to engage and implement strategies. Three participants perceived the app format to be motivating and facilitating self-efficacy in intervening with sleep problems (quote 10). Access to therapist support was considered advantageous, due to having someone check in on progress (quote 11). Furthermore, one participant reported preference for reduced therapist contact, in comparison with traditional methods (quote 12).

Barriers to use and suggested improvements

Several participants reported technical issues, such as difficulties accessing the app, due to temporary lack of internet access, or loss of a phone. A software update caused temporary access issues for several participants. The consequent lack of access to content and strategies was noted as problematic for one participant (Table 3, quote 13). Five participants reported glitches in the app that interfered with user experience (e.g. content getting stuck or displaying as incomplete after completion).

Difficulty with app navigation was reported by some participants as a negative, and recommendations were given to modify the layout and appearance to improve efficiency of access (quotes 14 and 15). The quantity of written content was perceived to be too much by several participants, and greater variety in content delivery was desired (e.g. images, audio and video). Gamification, such as a rewardbased point system, was recommended by four participants (quote 16).

Some thought the duration of the intervention was not long enough for implementation of strategies and change to occur. Increased user control was sought, such as the ability to personalise scheduling of alerts, and greater flexibility in pacing (quote 17). Participants indicated that increased interactivity and therapist guidance could have been beneficial. In-app communication was recommended, to facilitate more immediate problem resolution and support strategy implementation (quote 18). For some

Theme	Quote	Participant (gender)	Quotation
Experience of sleep prior	1	5 (male)	All over the place. Like very messed up in terms of sleep patterns and the sleeping routine so it would be Kind of me going to sleep around I think four, five in the morning, um And then getting out really late, like one or two in the afternoon
	2	2 (female)	I dreaded going to sleep because I don't know. I just found it easier to just stay up worrying than to get to sleep
	3	6 (female)	I think part of it is the lockdown though as well, I think. Because I'm not doing my usual things in the day
Usefulness of the intervention	4	1 (female)	I think that my sleep has improved. If I'm gonna be honest and grade it like you know, in percentage wise I'll say it increased by it's been better by, I'd say, 40%
	5	7 (male)	There wasn't like a set routine for sleep until I learned about how a routine could help through the app
	6	4 (male)	I can tell the impact in my everyday life in helping take care of the girls. Yeah, I mean in my everyday interaction with people, sleep is It plays a major role, so it's been really good, yeah
	7	10 (male)	Yeah, and just see how it goes. It certainly like it's never going to do any harm like it's not going to You knon, I would say that it's definitely worth trying. Yeah, it's been beneficial for me, so And I'm sceptical about this kind of stuff
Advantages of the intervention	8	1 (female)	The advantage of using the app was it, it's there any time of the today, you can refer to it. It's like a little notebook you know with exercises and information, just like a little book, you can carry and just refer to it
	9	9 (male)	'cause, you like praise the reader with the like 'well done you've achieved Like Module 2', whatever they had, like a well-done sticker, [] it's not like rocket science, so it's kind of user-friendly type of thing
	10	2 (female)	And it almost, like, each day you kind of want to do better than the last time. So, say I went to bed later, you kind of like consciously want to go to bed earlier and maybe wake up earlier just to see if you can sort of Change the narrative
	11	7 (male)	The fact that there's an app, and there's someone like [trial therapist] to like, keep me in tack or like keep checking up on my progress. I think those, those elements made the experience better for me
	12	10 (male)	some people don't like talking to people like, you know, sometimes you don't want to talk to people about stuff you might just prefer to deal with an app

TABLE 3 Example quotations to represent themes developed from qualitative feedback

TABLE 3 (Continued)

Theme	Quote	Participant (gender)	Quotation
Barriers to use and suggested improvements	13	6 (female)	So yeah, because I'm, I'm not a technical person at all [], that's the only downside of it is if it doesn't work okay, then it, it has quite an impact
	14	3 (male)	Just the amount of work you had to do to get a quick reminder of what you wanna do [] you'd have to go through quite a hit just to get to the section that you want
	15	10 (male)	You know colour the backgrounds or something so that you could, I don't know, just make it easy to navigate and find your way around it and understand what you've done, and what you haven't
	16	5 (male)	So, I think changing the format to like a scoring system. Where at the end of, you know, the session you, you'd have a total score. [] I don't know Your brain is kind of wired to see like [] if you see a score, it just [] encourages you to like, do it even more
	17	6 (female)	it's quite a lot in a short time. And I feel like for me, it would have been better to do one thing and do it for a few weeks and then add something on
	18	4 (male)	"if it's a recording of [therapist] tutoring, or [therapist] walking through the steps, I see that more interactive. Because [] I see somebody there trying to tell me what to do. I mean it will make more meaning in that sense'
	19	3 (male)	But it's also a lot to keep doing everyday There's a lot to the app
	20	7 (male)	It's like when you're in school, you have homework you never want to do your homework, but it has to be done. So, I felt like that about this, like it's just something that has to be done, so I placed high importance on it
	21	10 (male)	it would bave been better if I wasn't moving house. Like, if I'd done it at a more stable time in my life, [] well, I would bave been able to put things into place it straight away, as soon as you learn them, rather than having to think, 'oh, yeah well, I'll do this, but I can't do this until I've moved into a new place or'
Adverse experiences	22	2 (female)	Maybe if I had a particularly bad night, that I just didn't want to Keep a record of that if you will
	23	10 (male)	Apart from being a little bit anxious about not filling it in properly, but I mean, that's me that's nothing to do with the app, I shouldn't worry about things like that, but I do

participants, the amount of time and effort required to complete modules was off-putting, with a preference for 'shorter chunks' of information (quote 19). However, participants also acknowledged that time and effort were necessary to experience benefits (quote 20).

Factors outside of the app impacted engagement and implementation for some, including daily routine, work and mood. One participant reported accommodation changes, which prevented them utilising strategies as consistently as intended (quote 21).

Outcome	Baseline (<i>n</i> = 11), Mean (<i>SD</i>)	Follow-up (<i>n</i> = 11), Mean (<i>SD</i>)	Mean change (95% CI)	Effect size estimate d
Insomnia severity (ISI)	18.45 (4.99)	12.91 (5.75)	5.55 (2.64, 8.45)	1.02
Sleep Quality (PSQI)	13.00 (3.97)	9.73 (3.95)	3.27 (0.91, 5.64)	0.83
Ideas of reference (R-GPTS)	11.45 (10.14)	7.09 (7.62)	4.36 (1.25, 7.48)	0.49
Ideas of persecution (R-GPTS)	15.45 (14.17)	12.18 (13.90)	3.27 (-0.52, 7.06)	0.23
Hallucinations (SPEQ-H)	10.64 (11.05)	10.27 (11.44)	0.36 (-3.58, 4.31)	0.03
Depression (DASS-21)	19.82 (13.58)	14.18 (13.43)	5.64 (3.49, 7.79)	0.42
Anxiety (DASS-21)	10.36 (8.85)	7.64 (6.31)	2.73 (-0.89, 6.35)	0.35
Stress (DASS-21)	18.55 (10.28)	16.00 (10.81)	2.55 (-0.46, 5.56)	0.24
Emotional well-being (WEMWBS)	40.18 (12.05)	43.36 (12.52)	-3.18 (-6.24, -0.12)	0.26
Adjustment (WSAS)	23.18 (11.37)	20.18 (11.19)	3.00 (-0.32, 6.32)	0.27

TABLE 4 Pre- and post-intervention scores for efficacy outcome measures, for non-dropouts

Abbreviations: CI, confidence interval; *d*, Cohen's *d*; DASS-21, Depression, Anxiety and Stress Scale—21-item version (each subscale score ranges from 0 to 21, higher scores indicate more severe symptoms); ISI, Insomnia Severity Index (scores range from 0 to 28, higher scores indicate more severe insomnia symptoms); PSQI, Pittsburgh Sleep Quality Index (scores range from 0 to 21, higher scores indicate worse sleep quality); R-GPTS, Revised Green et al., Paranoid Thoughts Scale (Reference scores range from 0-32, Persecution scores range from 0 to 40, higher scores indicate more severe symptoms); *SD*, standard deviation; SPEQ-H, Specific Psychotic Experiences Questionnaire—Hallucinations subscale (scores range from 0 to 45, higher scores indicate better well-being); WEAWBS, Warwick-Edinburgh Mental Well-being Scale (scores range from 1 to 25, higher scores indicate better well-being); WSAS, Work and Social Adjustment Scale (scores range from 0 to 45, higher scores indicate more severe difficulties).

Adverse experiences

A minority of participants reported finding aspects of the content difficult to engage with. One participant reported preferring to avoid documenting a bad night of sleep (Table 3, quote 22). Another found the Managing Worry module challenging due to thinking through current, ongoing life stressors. One participant reported anxiety about accuracy of module completion (quote 23).

Secondary outcomes

Mean scores for secondary outcome measures at baseline and follow-up, as well as effect size estimates for change over time, are presented in Table 4. At baseline, all participants scored above cut-off for sleep disturbance (PSQI) and insomnia disorder (ISI). At follow-up, all continued to score above cut-off for sleep disturbance (PSQI); however, five (45.5% of completed follow-ups) no longer scored above cut-off for insomnia disorder (ISI). Participants experienced an overall treatment benefit for sleep disturbance, insomnia, ideas of reference, depression and well-being (95% confidence intervals (CIs) for change scores do not overlap zero). The effects were in the direction of improvement for ideas of persecution, anxiety, stress and functioning; however, the CIs do cross zero for these outcomes. No effect was observed for hallucination frequency.

DISCUSSION

This study aimed to assess the feasibility and acceptability of a novel smartphone-based CBT intervention for sleep difficulties for individuals with psychosis and to assess the potential clinical utility of the intervention.

Feasibility

Despite increased pressure on clinical teams during the global COVID-19 pandemic, the rate of recruitment (approximately 15 referrals/3.5 recruited per month) was in line with, or higher than, previous research into sleep interventions for individuals with psychosis (e.g. Freeman et al., 2015; Sheaves et al., 2019), and studies of digital interventions for individuals with psychosis (e.g. Bell et al., 2020; Lim et al., 2020). Suitable individuals infrequently declined to be screened (13%), and recruitment uptake was good (88%). Study attrition was in line with the anticipated level (21%), and comparable rates have been observed in previous research (e.g. Bucci, Barrowclough, et al., 2018; Ludwig et al., 2020; Moritz et al., 2016). Two participants dropped out due to reasons unrelated to the intervention; therefore, retention may be anticipated to be higher in future studies. This study's research procedures therefore appear feasible.

Acceptability

Participant feedback indicated acceptability and highlighted the value of convenience and flexibility. Practical barriers to accessing face-to-face therapy (e.g. scheduling conflicts, transportation, childcare; Harvey & Gumport, 2015) may therefore be overcome by this approach. Dissatisfaction was typically related to modifiable elements of the app, alteration of which could further increase acceptability.

Engagement with intervention modules was good: 85% of those who consented to participate received the minimum therapeutic dose. Reminder engagement was lower, although unsurprising as participants were encouraged to prioritise module completion. Despite this, qualitative feedback indicated usefulness of the reminders, a function not possible in traditional face-to-face delivery. All participants engaged with the user-initiated 'Relaxation & Mindfulness' module, which appeared to translate well as an ecological momentary intervention in this format. Engagement declined over time, a pattern commonly observed in digital intervention studies (Ben-Zeev et al., 2014). A possible solution is an 'adaptive treatment strategy' in which potential engagement failures are identified, and the intervention adapted to involve more intensive therapeutic contact (Forsell et al., 2019).

An average of 107 min of clinician time was required per participant, and this is a substantial reduction compared with face-to-face approaches, which have typically involved between 240 and 480 min of therapist contact (Freeman et al., 2015; Myers et al., 2011). This is a promising indication that the intervention could be made more widely available than traditional CBTi. Frequency and duration of clinician contact were participant-led, to offer patient choice and flexibility (Stawarz et al., 2020). However, feedback indicated preference for additional guidance; therefore, regular, pre-scheduled contact may be a more optimal method for future interventions (Shim et al., 2017). Additionally, pre-recorded video therapist guidance (Ben-Zeev et al., 2018) could be embedded within the intervention to increase accessibility and engagement.

Potential usefulness

Improvement in sleep difficulties from baseline to post-treatment was indicated both quantitatively and qualitatively within participant feedback. Caution is taken in discussion of clinical effects, as this study was not sufficiently powered.

Similar to that observed in primary insomnia (Lancee et al., 2013), mean change in ISI scores indicated a smaller reduction in insomnia than in individual face-to-face CBTi for individuals with psychosis (Freeman et al., 2015; Myers et al., 2011). However, improvements in the current study were equivalent to that of group CBTi for individuals with psychosis (Hwang et al., 2019), and in line with at least 'slight improvement' (>4.65 points) in a clinical sample of individuals with primary insomnia (Morin et al., 2011). At post-treatment, while almost half of participants no longer met screening criteria for insomnia disorder, many continued to experience difficulties above clinical threshold. Smartphone-based delivery of CBT for sleep problems may therefore provide a low-intensity alternative to face-to-face. If these results were confirmed by appropriately designed efficacy studies, 'low-intensity' psychological interventions (e.g. digital interventions and group workshops) could be offered to service users first, and stepped-up to 'high-intensity' interventions (e.g. face-to-face sessions) where difficulties persist.

Improvements were also observed in mental health outcomes, including paranoid thoughts, depression, anxiety and stress, and global outcomes of psychological well-being and functioning. Anxiety and depression may mediate the relationship between sleep disturbance and psychotic experiences (Reeve et al., 2015). As such, as demonstrated in this study, effective intervention in sleep difficulties may have a broad impact on individuals with psychosis and should be prioritised.

Study limitations and future directions

Clear limitations to this study include the small sample size, uncontrolled design and unblinded assessments. Post-treatment effects must therefore be interpreted as estimates, and efficacy should be confirmed in future in an appropriately powered randomised controlled trial. Such investigation would facilitate accurate comparison of effects with existing interventions, such as traditional face-to-face delivery of CBTi.

This study involved a small number of participants, although represented a range of sociodemographic characteristics. Most participants experienced early difficulties with psychosis and were under the care of an Early Intervention in Psychosis Service. Most were familiar and confident in the use of technology. This limits the generalisability of the study's findings. Future evaluation of the intervention should seek to broaden the sample further to individuals with chronic difficulties who may be under the care of other community mental health services. Were the sample to represent a wider range of technological competence, additional training may need to be incorporated, and could be done so through in-app video guidance (Hoffman et al., 2020). However, the one participant who did not feel confident prior to use found the current intervention easy to use. Individuals were included who self-reported symptoms of insomnia; no diagnostic clinical assessment was conducted. Identification of specific sleep disorders with clinical assessment in future research may help to specify who this intervention is most helpful for.

One clinician administered assessments, provided therapeutic intervention support and conducted the semi-structured interview. This may have influenced outcomes and qualitative feedback provided. Furthermore, qualitative feedback indicated some participants experienced offers of therapeutic contact as a check-in regarding engagement for research purposes, rather than clinical support to facilitate intervention implementation. This may have reduced utilisation of therapist support.

Limitations of the user interface, technical glitches and a lack of user control were noted as detrimental to user experience. Future interventions would likely require ongoing provision of technical support for users. The current intervention was delivered through an externally hosted platform, ExpiWell. This platform had many well-suited features: compatibility with a range of smartphone devices; rolling schedule of content delivery; capacity for branching logic to tailor content; and a web platform for the therapist to access individual responses. Technology is rapidly developing. As such, digital interventions frequently become outdated quicker than they are evaluated and implemented (Mohr et al., 2017). The use of an externally hosted platform provides benefits to app maintenance and longevity, such as app updates to ensure compatibility with software requirements.

One optional module (i.e. Coping with Voices or Managing Worry) was selected by participants according to the relevance to their sleep disturbance. However, these difficulties commonly cooccur, and several participants indicated both modules were equally relevant to them. Future interventions may benefit from availability of all modules to all participants, with additional therapist guidance to structure an individualised programme. Due to the dynamic nature of such difficulties, an increased duration of availability of the app could also enable users to re-access content when most needed. Similarly, increased availability of the in-app sleep diary throughout the intervention would facilitate self-monitoring of progress and may be a beneficial in future developments. In a fully powered trial, such modifications could also facilitate analysis of mechanisms of change within the intervention. This study took place during the COVID-19 pandemic. Participants noted a specific impact of lockdown restrictions on their sleep and routine, as well as their ability to fully implement intervention strategies. Others reported benefits to participating, due to otherwise limited daily activities. COVID-19 restrictions may have therefore impacted the study findings, but it is unclear in which direction.

CONCLUDING REMARKS AND IMPLICATIONS

This digital intervention demonstrated promising potential for reducing sleep difficulties in people with psychosis, making intervention access more equitable and increasing access to otherwise scarce psychological therapy.

CONFLICTS OF INTEREST

All authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

Kathryn M. Taylor: Conceptualization; Formal analysis; Investigation; Methodology; Project administration; Visualization; Writing – original draft; Writing – review & editing. Jonathan Bradley: Conceptualization; Methodology; Supervision; Writing – review & editing. Matteo Cella: Conceptualization; Methodology; Resources; Supervision; Writing – review & editing.

DATA AVAILABILITY STATEMENT

Research data are not shared due to ethical restrictions.

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