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Exploring digital cognitive behavioural therapy for insomnia in an early intervention in psychosis service – A study protocol for an initial feasibility study with process evaluation

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Abstract

Aim: Early psychosis may be a critical time at which clinical trajectories are still evolving, and sleep interventions hold promise to improve outcomes at this stage. Although cognitive behavioural therapy (CBT) for insomnia shows promise in psychosis, there has been limited evaluation of delivery within current care. This study aims to evaluate the feasibility and acceptability of providing fully-automated digital CBT for insomnia (CBT-I) within an early intervention in psychosis service.

Methods: We will conduct a single-arm feasibility trial within an early psychosis intervention service, and up to 40 individuals experiencing a first episode of psychosis and with evidence of insomnia can be enrolled (May 2021 – August 2022). Additional service user inclusion criteria are capacity to consent and access to a suitable technological device to access digital CBT. Participants will be offered access to a fully-automated digital CBT-I program (Sleepio) delivered using web and/or mobile app. The study comprises pre- and post- intervention questionnaire assessments and interviews with service users and staff to provide initial outcome signals.

Results: Quantitative questionnaire data will be analysed descriptively, alongside rates of eligibility, consent, uptake and completion. Qualitative data will be analysed using thematic analysis. Results will be used to develop a logic model describing feasibility and implementation.

Conclusions: From this study, we hope to better understand how to deliver digital CBT for insomnia within an early intervention in psychosis service. This study will help inform further research, including how best to support staff in using Sleepio, and inform the design of subsequent trials in this area.

KEYWORDS
digital CBT, early intervention services, first-episode psychosis, insomnia, sleep

1 | INTRODUCTION

Timely detection and treatment of early psychosis can significantly improve the clinical trajectory of those with psychosis. Indeed, addressing psychosis systematically across a population via early intervention is fundamental to basic healthcare, *c.f.* (McGorry & Mei, 2018). Early psychosis has been described as a critical period in the trajectory of psychotic disorders (Birchwood et al., 1998), and clinical staging models assume that interventions delivered early in the course of illness development will be more effective and less harmful (McGorry et al., 2008). This is supported by meta-analytic evidence which shows a pooled remission rate of 57.9%, and recovery rate of 37.9% from first-episode psychosis, outside of randomized controlled trials (Lally et al., 2017).

Outcomes at this stage may still be malleable, with a focus on early secondary prevention – that is, improving outcomes once illness has developed (McGorry et al., 2008). Benefits of early intervention services include reduced psychiatric hospitalization and relapse, improved total symptom severity, increased remission and recovery, better global functioning, greater involvement in school or work, and improved quality of life (Correll et al., 2018). Service users attending early psychosis services are perceived by staff to value support with functional and social recovery (White et al., 2015).

Sleep may be a modifiable factor, which could help promote recovery from psychosis. Sleep disturbances are common in early psychosis, with insomnia the most common at up to 50% prevalence (Reeve et al., 2018; Subramaniam et al., 2018). Insomnia disorder is linked to alterations in how individuals feel and function throughout the day, for example, (Delf & Beattie, 2022; Kyle et al., 2010), and the addition of sleep interventions to the early intervention repertoire could contribute towards improving outcomes, such as social recovery, at this stage. Indeed, cognitive therapies optimize and accelerate symptomatic and functional recovery (McGorry et al., 2008). Furthermore, sleep and emotions are closely linked – insomnia is known to predict the development of mood disorders (Hertenstein et al., 2019) – and emotion is important to early psychosis (Birchwood, 2003), which has been described as "a shattering life event" (page 373). In addition, sleep changes in schizophrenia occur as early as 6 weeks before relapse (Spaniel et al., 2018), rendering them a potentially useful early sign and treatment focus. Improving sleep may therefore be an important means of improving broader outcomes and wellbeing in early psychosis.

International guidelines uniformly recommend cognitive behavioural therapy (CBT) as the first-line treatment for insomnia (Edinger et al., 2021; Qaseem et al., 2016; Riemann et al., 2017) and CBT for insomnia (CBT-I) has been studied in psychosis. For example, the 'BEST' study (Freeman et al., 2013; Freeman et al., 2015); see also (Myers et al., 2011) recruited patients with persistent, distressing delusions or hallucinations in the context of non-affective psychosis who were above clinical threshold on the Insomnia Severity Index. In this pilot study, face-to-face CBT-I benefitted insomnia at 12 and 24 weeks. Effects on delusions and hallucinations were more variable, with benefits noted on fatigue, quality of life and psychological wellbeing. There were no adverse events considered linked to study treatment. Similar results have been reported in a non-randomized study, with inpatients, over 8 weeks (Hwang et al., 2019). Other studies have investigated sleep profiles and associated treatment response in psychosis (Hwang et al., 2019; Waters et al., 2020). More recently, another feasibility study has considered a bespoke app-based sleep intervention in psychosis, combined with therapeutic goal-setting in advance (Taylor et al., 2022). These authors found that of 60 referrals, 21 were assessed for eligibility, and 13 started the intervention. 78.57% (*n* = 11) of these participants had a first-episode psychosis. However, few studies have evaluated the potential of CBT-I within an early intervention service, and digital CBT has the added benefit of not requiring staff to be trained in CBT-I.

To our knowledge there is one (ongoing) feasibility study about sleep interventions in early psychosis, among those at ultra-high risk of psychosis (Waite et al., 2020) - the earliest potentially treatable stage of psychosis development (McGorry et al., 2008). That said, there are challenges associated with providing CBT-I in this population alongside facilitators (Chiu et al., 2016; Waite et al., 2016; Waite et al., 2018). Clinicians perceive barriers to treating sleep problems relate to patient-factors, service-related factors (including no perceived barriers), and other environmental factors (Rehman et al., 2017), see also (Barrett et al., 2020).

Digitally delivered CBT (dCBT) holds promise for the efficacious treatment of insomnia, with evidence of its effectiveness in a range of age groups and clinical populations (Soh et al., 2020). Of relevance to psychosis, a large randomized controlled trial of dCBT for insomnia demonstrated significant reductions in insomnia symptoms as well as paranoia and hallucinations in students compared to controls (Freeman et al., 2017). Improvements in sleep mediated reductions in both paranoia and hallucinations, which raises the possibility that sleep may be a prudent treatment target to improve broader symptoms of mental health conditions.

Digital interventions also permit the delivery of evidence-based interventions at scale, and this is of particular relevance to countries with national healthcare services (Espie, 2009). Combined with the remote delivery of sessions, such interventions are also well suited to implementation within a pandemic. Indeed, dCBT for insomnia can be feasibly integrated into current clinical services alongside usual care, and augment treatment outcomes (Stott et al., 2021).

However, the treatment of sleep disturbances in psychosis does not always follow best-practice guidelines (Barrett et al., 2020; Rehman et al., 2017; Riemann et al., 2017).

In a digital framework, based upon expectations, reach, fidelity and implementation were identified as important factors from the perspectives of services users, carers, and staff regarding early warning signs in psychosis (Allan et al., 2019). These authors found that for those with psychosis, digital interventions need to be user-friendly, with access to accurate data. Staff perceive facilitators to be youth and the clinical usefulness of data. Barriers, according to staff, relate to service user paranoia and lifestyles, as well as staff time and a lack of data context. Service users themselves have data privacy concerns, and concerns that the app will replace current services.

The usage of Sleepio may be aided by the age-group of early intervention services in Scotland, which are youth-focussed. This is hoped to engender feelings of empowerment and autonomy, and thus recovery (Leamy et al., 2011), with sleep interventions being valued. An added benefit, for the service, is that service users will be able to complete the intervention in their own time thus not adding to their work schedules, and dCBT-I is readily scalable. We, therefore, plan to investigate the feasibility of dCBT for insomnia within an Early Intervention in Psychosis (EIP) service using a mixed methods approach.

Within a population of people under the care of EIP services, we could anticipate feasibility and implementation challenges. Anticipated challenges include: factors impacting eligibility, factors impacting on uptake of offered interventions, poor adherence to the intervention, interactions between the course of mental ill-health and app use, and the impact of clinician and service user views of apps or sleep interventions. People attending mental health services are disproportionately affected by digital poverty and exclusion (Spanakis et al., 2021; Tobitt & Percival, 2019) and digital health innovations like Sleepio are known to increase the risk of health inequality for people experiencing severe mental ill-health (Spanakis et al., 2021). In the OASIS trial, many participants did not begin using the app and the rate of attrition from intervention was fairly high (Freeman et al., 2017). Conversely, although not published prior to the design of this study, (Gumley et al., 2022) demonstrated relatively low attrition from app use in this population, although retention of participants was poorer in the app group than treatment as usual. The presence of a sleep disorder is associated with more severe positive psychosis symptoms, cognitive disorganization, and affect (Reeve et al., 2018).

These factors are is likely to impact on engagement and adherence throughout the study timelines. App usage may also affect mental health symptomatology – increased paranoia is one possible outcome of digital intervention for those affected by psychosis (Eisner et al., 2019). For this reason, it was important for us both to gather data on service user views and questionnaire data on pre/post symptomatology. Previous work has demonstrated the likely impacts of both service user and clinician views on sleep (Rehman et al., 2017; Waite et al., 2020) as well as digital interventions (Allan et al., 2019). Clinician beliefs about service user engagement are known to impact on whether psychological interventions are offered to people affected by psychosis (Kingdon & Kirschen, 2006). The EMPOWER implementation study demonstrated that beliefs about digital intervention act as important mediators in implementation (Allan et al., 2019), see also (Palmier-Claus et al., 2013).

The feasibility-related research questions that this project therefore aims to address are:

1. What is the rate of ineligibility and why?
2. What is the rate of consent into the study?
3. Can we characterize participant sleep disorder?
4. Do participants complete Sleepio initial assessment?
5. Do participants enter daily and weekly data?
6. How many sessions do participants complete?
7. What is the rate of attrition from intervention?
8. Do participants complete post-intervention assessment?
9. What do clinicians identify as facilitators and barriers to app use?
10. What do service users identify as facilitators and barriers to app use?

2 | METHODS

2.1 | Service description and participants

The study is situated within a local early intervention in psychosis service based in Glasgow, Scotland. The 'Esteem' service includes ∼250 service users, with ∼150 new users per year. At present, Greater Glasgow and Clyde are the only health board in Scotland to have an EIP service, although this is beginning to change with recent moves to propagate these services by the Scottish Government (HIS, 2021).

The service covers a population of approximately 1.14 million people (NHSGGC, 2021). Individuals can be referred if they are likely to be experiencing a first episode psychosis, and are aged 16–35. It is typically a 2-year service, based upon secondary prevention and fidelity to early intervention in psychosis models, including assertive outreach. It is a multidisciplinary team consisting of 16 community psychiatric nurses, five clinical psychologists, five professional services staff, four consultant psychiatrists, four occupational therapists, three support workers, two peer support workers, two assistant psychologists, and a team lead. Nurses and occupational therapists act as an individuals' 'keyworker'.

Potential service user participants will be referred to the study following a dialogue with their keyworker and will be included if they meet eligibility criteria and provide written informed consent. Up to 40 service user participants will be recruited. As a mixed-methods study focused on the feasibility of implementation, formal sample size calculation would not be appropriate. This service user sample size number was decided based upon practical considerations including the recruitment timeframe and service size.

Service users will be included if they have: (1) capacity to consent, (2) access to technology supported by the app (web and iOS) and (3) evidence of sleep disturbance on the brief 2-item Sleep Condition Indicator defined by a score <3 (Luik et al., 2019). Exclusion criteria are (1) moderate to severe learning disability, (2) acute psychosis (recent crisis contact or hospitalization), (3) incapacity to provide informed consent, (4) insufficient English to access intervention, (5) organic impairment, and (6) no access to a device, which can be used for Sleepio intervention.

In addition to service users, up to 10 staff participants will also be recruited, and invited to complete pre- and post- intervention interviews. Staff participants will be serving as an individuals' keyworker in the service. Keyworkers will be provided with an information sheet, which clarifies their role as clinicians-and potentially as research participants (in semi-structured interviews) via email and letter. Information sheets will also be available in staff areas of the service buildings.

The study has approval from the West of Scotland Research Ethics Service (ID 21-WS-0010) and NHS Greater Glasgow and Clyde (ID GN21MH015) and is registered on ClinicalTrials.gov (NCT05050201).

2.2 | Intervention

Digital CBT for insomnia will be delivered using Sleepio (Big Health Ltd.; www.sleepio.com). It is structured around 6 sessions each lasting approximately 15–20 min, which deliver evidence-based cognitive (e.g., cognitive restructuring, paradoxical intention, positive imagery, putting the day to rest), behavioural (e.g., stimulus control, sleep restriction and relaxation), and educational (e.g., sleep hygiene) techniques. Content is delivered by an animated avatar and is personalized based on responses to an initial sleep survey and daily sleep diaries completed throughout the programme. The 8-item SCI (Espie et al., 2014) is embedded within the app prior to each session. To date, Sleepio has been tested in 12 randomized controlled trials (Barnes et al., 2017; Bostock et al., 2016; Cheng et al., 2019; Denis et al., 2017; Espie et al., 2012; Espie et al., 2019; Felder et al., 2020; Freeman et al., 2017; Kalmbach et al., 2020; Kyle et al., 2020; McGrath et al., 2017; Pillai et al., 2015), showing benefits to sleep and broader mental health including symptoms of paranoia and hallucinations (Freeman et al., 2017).

The intervention will be offered in tandem with treatment as usual, which comprises components of early intervention, including individual-centred assessments, low-dose, slow-increment antipsychotic medication and multifamily group psychoeducation (Addington et al., 2013). Adverse events and effects will not be monitored, and are not a research question, however any which emerge will be reported.

2.3 | Procedures

Service user participants will be asked to provide consent for their details to be passed onto the research team by their keyworker, via a generic study-specific email account, hosted by the NHS. Referrals will be generated via a variety of mechanisms. Evolving strategies include regular email reminders to staff and presentations at the multidisciplinary team meetings, journal club presentations, as well as enquiries to the research team about potential suitability by email and phone call. An information leaflet has also been circulated.

Service user participants will be invited to take part in optional interviews at baseline, and at 10 weeks from consent, alongside the questionnaire assessments, which are completed via interview online or face-to-face, depending on preference. There is also a mid-point check-in. Data collection is facilitated by online platforms, although this can be conducted face-to-face.

Staff are invited to take part in pre-intervention interviews at the start of the study, and will be invited to take part in post-intervention interviews towards the end of the study timeline.

Qualitative data is anticipated to be collected via MS Teams, which will be recorded and transcribed.

Data collection commenced May 2021 and is currently due to cease by late 2022.

2.4 | Measures

The key feasibility outcomes are rates of eligibility, consent, uptake of the intervention and completion of all 6 sessions of dCBT-I. This study will include measures of insomnia symptoms, mood, symptoms related to psychosis, and anxiety related to COVID-19. As this research explicitly focuses on feasibility and implementation, we will not analyse any change in these measures across time. However, these may provide outcome signals.

The two-item Sleep Condition Indicator (SCI-2) is a brief measure used to ascertain the presence of insomnia (Espie et al., 2014; Luik et al., 2019). It asks respondents to rate the extent to which poor sleep has troubled them, and the number of nights per week a sleep problem is experienced, both over the past month. Items are scored 0–4, with scores 0–2 indicative of insomnia. This measure is used as an inclusion criterion.

Insomnia severity will be assessed using the Insomnia Severity Index, or ISI (Bastien et al., 2001), which evaluates the night-time and daytime symptoms of insomnia disorder across 7 items. Items are scored 0–4, and it has been validated as a treatment-related measure of change.

The depression, anxiety, and stress scale, 21 item version is used to measure mood (Henry & Crawford, 2005). Items include "I found it hard to wind down", "I felt I was close to panic", and "I felt down-hearted and blue". Each subscale comprises seven items, scored over the past week from 0–3. It is taken as a dimensional measure of these constructs.

The revised Green et al. Paranoid Thoughts Scale (Freeman et al., 2021; Green et al., 2008) was used to assess feelings of paranoia over the past month, with items scored from 0–4. Items are rated over the past month in two parts, A (eight items) and B (10 items). Items include "I often heard people referring to me" (Part A) and "Certain individuals have had it in for me" (Part B).

The Specific Psychotic Experiences Questionnaire (SPEQ) – Hallucinations (Bell et al., 2005; Ronald et al., 2013) is used to assess hallucinations over the past month. Nine items are scored from "Not at all" to "Daily", and include questions as to how often you, for example, "See things that other people cannot?" or "Hear voices commenting on what you're thinking or doing?"

The Fear of COVID-19 Scale (Ahorsu et al., 2020) will used to assess pandemic-related fears. Seven items are rated in terms of "strongly disagree" to "strongly agree", on a five-point Likert scale. Items include, for example, "I am most afraid of coronavirus-19", and "I cannot sleep because I am worrying about getting coronavirus-19".

3 | ANALYSES

The key feasibility parameters are rates of eligibility, uptake, consent and completion. Eligibility will provide important information about access; acceptability will be inferred from the other outcomes. Quantitative data from this feasibility study will be analysed descriptively, in terms of the median, mean, quartiles and range. No significance testing will be performed. Qualitative data will be analysed based

upon the six stages of thematic analysis (Braun & Clarke, 2006), underpinned by socio-ecological models.

One core principle of this approach relates to the inter-relations of multiple dimensions which can impact upon a range of health outcomes (Stokols, 1996). A further core principle relates to the importance of individual characteristics in interaction with the environment (Stokols, 1996). In addition, a variety of concepts from systems theory are also adopted alongside inter-dependencies of dimensions, and social ecological models are interdisciplinary (Stokols, 1996). Given the complexities inherent in psychosis and NHS services, this framework appears to be particularly useful. An advantage of a social ecological framework is that it can help mitigate conceptual blind-spots in analysis through its consideration of multiple levels of analysis (Stokols, 1996).

We also plan to conduct a process evaluation of lessons learned during this study, and adaptations made. This may relate to how clinicians approach research studies (Jenkinson et al., 2014), as well as engagement strategies (Yu et al., 2020). Data from staff and service user interviews will also be analysed qualitatively, and a process evaluation conducted, for example, (Skivington et al., 2021). Lastly, we intend to summarize study results and process data in a logic model (Moore et al., 2015) describing the feasibility and implementation of Sleepio in this context.

4 | DISCUSSION

Sleep interventions, namely CBT hold promise to improve outcomes and recovery in first-episode psychosis but are not widely accessible. Fully-automated dCBT, however, can provide access to evidence-based insomnia treatments at scale, but it is unknown to what extent such an intervention can be delivered within an EIP service. There is a currently a gap in knowledge about how to implement evidence-based treatments for insomnia with a first-episode psychosis sample in early intervention services.

Potential design limitations include the (lack of) provision of study mobile phones. This was explicitly considered in study design. We chose not to provide devices in this feasibility study as NHS services would not ultimately be able to offer this outside a research context. We therefore felt that capturing exclusion through digital poverty would be more ecologically valid. Although this may lead to digital exclusion, we note a similar recent study which found 92.86% ($n = 13$) currently owned a smartphone and all had home internet access (Taylor et al., 2022). Any reasons for non-participation in the current study will be logged, including lack of device. Future research may also wish to consider the potential benefits of sleep interventions on other outcomes beyond those addressed in this feasibility study, such as on functional domains.

The implementation of sleep and circadian interventions and associated behavioural change has recently been raised as a major challenge (Harvey, 2022). The OASIS study found that 50% or participants withdrew from assessments, and uptake of the Sleepio intervention was relatively low, with 50% accessing at least two sessions (Freeman et al., 2017). Early results from this study suggest a need to pragmatically tailor communications to potential participants' preferences, and future studies may wish to include peer-support for insomnia treatments, *c.f.* (Gumley et al., 2020).

Through this work, we hope to better understand how the key feasibility and implementation parameters are evidenced with a first-episode psychosis sample, and service, with a process evaluation to assess service user and staff perspectives as factors in feasibility and implementation. Therefore, this study may provide context on how best to implement a fully-automated dCBT intervention within existing clinical services for this population. Future research may additionally wish to measure and analyse change in sleep and mental health symptoms through dCBT-I intervention and/or consider the potential benefits of sleep intervention on social or functional domains in early psychosis.

CONFLICT OF INTEREST

Alasdair L. Henry is employed by Big Health Ltd., the developers of Sleepio, receives a salary from the company and is a shareholder. Jeanette Waxmonsky is employed by Big Health Inc. and receives a salary from the company.

DATA AVAILABILITY STATEMENT

Not available.

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